

The interplay between law and technology, or the RoboLaw project in context

Erica Palmerini

1. The RoboLaw project, an ongoing research

The RoboLaw project – whose full title is *Regulating Emerging Robotic Technologies in Europe: Robotics Facing Law and Ethics* – intends to investigate the ways in which emerging technologies in the field of bio-robotics have a bearing on the national and European legal systems, challenging traditional legal categories and qualifications, posing risks to fundamental rights and freedoms that have to be considered, and more generally demanding a regulatory ground on which they can be developed and eventually launched.¹

Building on the perception of a pressing need for a legal framework to accompany the development of robotic technologies, the aim of the research is to outline a comprehensive analysis of the current state-of-the-art of regulation pertaining to robotics in different legal systems, in order to understand whether new regulation is needed or whether the problems posed by robotic technologies can be handled within the framework of existing laws.

Robotics is a wide and multi-faceted domain, which crosses boundaries between disciplines and encompasses biotechnology, nanotechnology, and neuro-technology. The ambition to achieve a thorough overview of the legal implications of robotics therefore

¹ The project is funded within the 7th FP (Grant Agreement n. 289092), began in March 2012 and will last for 24 months. The research is carried out by a consortium of four partners from various institutions and with different backgrounds and expertise: the Dirpolis Institute and the Biorobotics Institute of the Scuola Superiore Sant'Anna in Pisa, the Tilburg Institute for Law, Technology and Society (TILTI) of Tilburg University, the School of Systems Engineering of the University of Reading, and the Department of Philosophy of Humboldt University of Berlin.

requires a complex approach and demands that a multifarious conceptual apparatus be put in place. Moving from a structural and functional description of different types of robotic technologies and the potential scenarios in which they can be deployed, an in-progress roadmap entails to set out a taxonomy connecting robotic applications with the various human capabilities that may be affected (both in terms of enhancement or augmentation and in terms of recovery or assistance). Through this taxonomy, we can clarify the legal relevance of the technologies being considered, in terms of the influence upon categories such as legal capacity and competence; the ways they impinge on interests such as identity, privacy, health and bodily integrity, and on the concepts, underlying these values, of autonomy and responsibility; and the impact they otherwise have on different areas of the law, such as tort law or insurance law.

Among a broader spectrum of sophisticated technologies, some examples immediately convey their profound inferences with anthropological, philosophical and legal conceptions, and taken as case in point of the innovation raised by concrete social demands, appear as paradigmatic hypothesis to be illustrated.

Brain-Computer Interfaces (BCIs) use biometric brain signals (deriving from the variation in metabolic or electric activities in some parts of the brain) to create forms of 'alternative communication' for people who cannot speak or move any parts of their body (including their eyes), and suffer from pathologies that do not affect their self-awareness. The main legal issue with regard to BCIs is whether and to what extent the will expressed by the individual through these biomedical 'media' could be considered legally relevant and valid without there being a need to activate legal instruments of guardianship. This application also requires to define criteria in order to assess if a patient is competent (and therefore eligible for this mechanism to be used to express his will and give his informed consent) or not; and to provide ways for controlling and verifying the correspondence between the mental activity picked up by the machine and the person's actual will (through, for instance, feed-back from the patient). Other concerns are the protection of privacy in operations of 'mind-reading' and guarantees of *habeas mentem* against neuro-technological incursions into the intimate sphere of the person. In this respect, the possibility of *opting out* from the connection with the BCI

should be included, and the decisions that are communicated, including a decision to stop using the device, should be respected.²

Mechatronic and biomedical prostheses assist individuals who suffer from motor disabilities, while bionic implants such as retinal or cochlear implants permit blind or deaf people to regain vision or hearing. But the potential uses of these technologies go well beyond the restoration of impaired functions, permitting either new functions to be added or ordinary levels of performance to be exceeded. Bionic implants may in fact also be used in healthy individuals, to expand or strengthen their capacities such as their muscle power, sight or hearing. We encounter here the category of cyborgs – enhanced human beings who are equipped with robotic technologies or who are biomedically enhanced. Changing one's body through technology begins to be conceptualized as a right, an open possibility that becomes part of the right “to freely construct one's identity using all the socially available opportunities” and thus widens the scope of fundamental human rights.³ The connection with disability law also demands special attention;⁴ one problem, for instance, is to what extent the use of cybernetic devices is compatible with the enjoyment of the benefices of legislation against disabilities. The prospect of human enhancement, finally, entails a complex web of evaluations on various levels, achievable only by combining the scientific appraisal of the technical aspects of the phenomenon with a philosophical reflection on the impact of the technology on the identity and liberty of the person, and a legal and ethical reflection upon its consistency with the concept of human dignity.

² For an introduction to the legal implications of BCIs see e.g. F.G. Pizzetti, 'Libertà di autodeterminazione e protezione del malato nel “Brain-Computer interfacing”: un nuovo ruolo per l'amministrazione di sostegno?', (2011) *Rivista critica di diritto privato* 31-59; for an ethical and philosophical appraisal, see F. Lucivero and G. Tamburrini, 'Ethical monitoring of brain-machine interfaces. A note on personal identity and autonomy', (2008) 22 *Artificial Intelligence & Society* 449-460; G. Tamburrini, 'Brain to Computer Communication: Ethical Perspectives on Interaction Models', (2009) 2 *Neuroethics* 137-149.

³ S. Rodotà, 'Of machines and men: the road to identity. Scenes for a discussion', in M. Hildebrandt and A. Rouvroy (eds), *Law, Human Agency and Autonomic Computing. The Philosophy of Law Meets the Philosophy of Technology* (Oxford-New York: Routledge, 2011), 179-198, at 180.

⁴ C.R. Bockman, 'Cybernetic-Enhancement Technology and the Future of Disability Law', (2010) 95 *Iowa Law Review* 1315-1340.

Implantable devices are being designed which can be used to track an individual who is in need of constant surveillance and care, like someone with dementia or a minor with a mental disability. In this case the body is modified in its very physicality in order that it can be directly monitored, and it ends up being transformed into a networked entity, configured to receive and transmit signals permanently. As opposed to the dimension of “appropriation”, where the technology becomes an integral part of the body according to the person’s choice and allows him to construct his identity freely (which is what occurs in the two cases previously mentioned), here we come across an “expropriation”, where a person’s body is altered in order to enable its external control.⁵ The interests potentially affected by this type of technological application are privacy, dignity, physical integrity, identity. The fact that such technologies may be implanted without consent in small children or people with diminished legal competence is also a sensitive issue; an intervention on a person who cannot consent can be carried out only if it is in her best interests, and mainly for health reasons, whereas the implanting of a tracking device does not necessarily satisfy this requirement. Nevertheless, limited or even exceptional cases in which the purpose pursued through a tracking implant prevails over the risk of harm could be identified, provided that the implant into the body is reversible – an essential pre-condition that ensures that the individual can maintain governance over his own body.⁶

At the frontiers of the current scientific landscape, autonomous assistive robotic technologies, and particularly companion robots endowed with a certain degree of ‘sentience’, which are able to perform a multitude of assisting roles but are especially devoted to the care of elderly and disabled people, are in the process of being devised. Extant legal systems are not well equipped to deal with next generation robots that exhibit autonomous behaviour in human-inhabited environments. Several legal problems may arise with the advent of this new class of machines, starting from their standing as subjects, capable of entering

⁵ Rodotà, n 3 above, 180. See also European Group on Ethics in Science and New Technologies, *Opinion on the ethical aspects of ICT implants in the human body* (16 March 2005, Opinion N° 20) (Luxembourg: Office for Official Publications of the European Communities, 2005).

⁶ Rodotà, n 3 above, 195.

into basic transactions, performing legal acts, and being accountable for the damage caused to their users and to third parties;⁷ to entrusting robots with a financial basis, raised from producers and users alike and collected before the machine is put into public use in order to make it liable for obligations;⁸ to the introduction of forms of compulsory third party insurance such as is required for motor vehicles; to the governance of the personal data that will be processed by domestic robots, thus involving the field of privacy and data protection.⁹

The final product of this multifaceted investigation is intended to be a set of policy recommendations defining guidelines and suggestions on the regulation of emerging robotic technologies. This body of principles, addressed to the European policy makers, should develop a specific European approach to the topic, consistent with core European values.

2. Identifying the key issues in the ‘law and technology’ debate

This ambitious goal places the research against a background that in recent years has become a meaningful setting for the task of regulating technological development, albeit from a specific and limited perspective.

The interplay between science and the law¹⁰ has rapidly taken on the features of a precise and bounded research topic for lawyers, almost

⁷ E. Stradella *et al.*, ‘Subjectivity of Autonomous Agents. Some Philosophical and Legal Remarks’, in O. Boissier, G. Bonnet and C. Tessier (eds), *Rights and Duties of Autonomous Agents*, Proceedings of the 1st Workshop on Rights and Duties of Autonomous Agents (Montpellier, 28 August 2012), in conjunction with the 20th European Conference on Artificial Intelligence (ECAI 2012), 24-31, available at <<http://ceur-ws.org/Vol-885>>.

⁸ See the document drafted within the framework of the European project euRobotics by C. Leroux *et al.*, *Suggestions for a green paper on legal issues in robotics* (draft version 31 December 2012).

⁹ R. Calo, ‘Robots and Privacy’, in P. Lin, K. Abney and G. Bekey (eds), *Robot Ethics: The Ethical and Social Implications of Robotics* (Cambridge, MA: MIT Press, 2012), 187-201.

¹⁰ The complex relationship between law, science and technology is discussed in an extensive body of literature. See, for instance and without claiming to be exhaustive, S. Jasanoff, *Science at the Bar. Law, Science, and Technology in America* (Cambridge, MA: Harvard University Press, 1995); S. Goldberg, *Culture Clash. Law and Science in America*

turning into an autonomous branch of legal theory. There is a growing body of literature investigating how legal analysis and the regulatory endeavour are changing in the light of technological developments.¹¹ Analyses of the modalities of this interchange do not always converge, but they normally agree that the rule of law has to be reaffirmed against any technocratic drift, in order to avoid technological advances undermining human rights and democratic values. Another reason for concern, consequent on the conceptual autonomy acquired by this field of inquiry, is the potential dissociation from the more general and comprehensive environment delineated by a common set of overarching principles that are shared by contemporary (European at least) legal systems, and the risk of fragmenting and applying them according to the context.¹²

If we reduce the coordinates informing the debate to some essential, albeit deeply interrelated, issues, these points can be disentangled and discussed autonomously in the following sections. We will thus examine: the demise of an approach to science and technology, on the one hand, and to the law, on the other hand, that treats them as separate and non-communicating systems, upheld by different rules and methods; the impact of the complex characteristics of the subject that is to be regulated on the modalities of regulation, and the metamorphosis it impresses on traditional lawmaking procedures; the possibility of identifying common patterns according

(New York: New York University Press, 1994); A. Andronico and B. Montanaro (eds), *Scienza e normatività. Profili etici, giuridici e politico sociali*, Proceedings of the XXIV National Conference of the Italian Society of Philosophy of Law (Catania-Ragusa, 23-25 September 2004) (Napoli: Scriptaweb, 2006); M.A. Hermitte (ed.), *La liberté de la recherche et ses limites. Approches juridiques* (Paris: Romillat, 2001); G. Comandé and G. Ponzanelli (eds), *Scienza e diritto nel prisma del diritto comparato* (Torino: Giappichelli, 2004).

¹¹ See e.g. A.J. Cockfield, 'Towards a Law and Technology Theory', (2004) 30 *Manitoba Law Journal* 383-415; A.J. Cockfield and J. Pridmore, 'A Synthetic Theory of Law and Technology', (2007) 8 *Minnesota Journal of Law, Science & Technology* 475-513; B.J. Koops, 'Ten Dimensions of Technology Regulation - Finding Your Bearings in the Research Space of an Emerging Discipline', in M. Goodwin, B.J. Koops and R. Leenes (eds), *Dimensions of Technology Regulation* (Nijmegen: Wolf Legal Publishers, 2010), 309-324, and *Id.*, *infra*. For an updated and rich overview of this field of legal inquiry, see R. Brownsword and M. Goodwin, *Law and the Technologies of the Twenty-First Century. Texts and Materials* (Cambridge-New York: Cambridge University Press, 2012).

¹² S. Rodotà, *infra*, points out this risk in the concluding words of his essay. From a rather different perspective, Santosuosso, *infra*, is also sceptical about the need for a general theory of 'law & tech'.

to which technology regulation should occur, and that are valid notwithstanding the specific nature of each technology that is being addressed.

3. Law and technology: a two-way discourse?

An ultimate dichotomy – science as a fact-finding domain and law as the realm of the ‘ought-to-be’ – has been undermined; a plain assumption, that the fact-finding dimension is independent from the normative dimension and, logically and chronologically, occurs before the making of normative judgments, has been deconstructed;¹³ likewise, the idea that technology is neutral. A clear-cut edge between the two fields of action has faded away and the mutual acknowledgment of the each one’s own boundaries has been replaced by a “co-production” regime, where science and policy are reciprocally interrelated.¹⁴ The law is more and more involved in regulating scientific activities, products and results; at the same time legal intervention is often grounded on expert knowledge and scientific notions and concepts penetrate legal categories. The “double bind” between law and science truly produces a “hybrid knowledge” in which contributions from both actors complement each other and reciprocally elicit and legitimise its contents.¹⁵

More precisely, science and technology are no longer simply a target of regulation, but have become both a regulatory actor (through risk assessment/risk governance for instance)¹⁶ and a regulatory tool, by incorporating regulation and legal compliance into the technology itself.

¹³ B. Wynne *et al.*, *Taking European Knowledge Society Seriously*, Report of the Expert Group on Science and Governance to the Science, Economy and Society Directorate, Directorate-General for Research, European Commission (Luxembourg: Office for Official Publications of the European Communities, 2007).

¹⁴ S. Jasanoff, *The Fifth Branch. Science Advisers as Policymakers* (Cambridge, MA: Harvard University Press, 1990); M. Tallacchini, ‘La costruzione giuridica della scienza come co-produzione tra scienza e diritto’, (2002) XVIII *Politeia* 126-137.

¹⁵ M. Tallacchini, ‘La costruzione giuridica dei rischi e la partecipazione del pubblico alle decisioni *science-based*’, in Comandé and Ponzanelli (eds), n 10 above, 339-355, at 339 f.

¹⁶ But for a critical view of a technocratic approach to risk management see A. Arcuri, *infra*.

In regulating science, the law does not just receive content, supposedly merely descriptive, produced outside its domain, and give it prescriptive quality; on the contrary, it exerts critical choices over objectively uncertain scientific judgments and not value-neutral knowledge. At the same time, the legislator is bound to pass on to technical bodies and expert organizations the task of the minute regulation of sectors whose complexity and constant evolution fall outside its statutory capability.

The concept of techno-regulation and propositions such as ‘code as law’ and ‘normative technology’,¹⁷ which have appeared in the literature, highlight a clearly different perspective. Technologies play a regulatory role, at times in a very indirect manner in the sense that they operate as auxiliary tools for better achieving a legal objective (like DNA profiling for criminal law); at other times as a non-normative regulatory device, in which a command (and compliance to it) are imbued in the technology itself (think of filters preventing the access by minors to certain websites, or biometric keys for entering a room). “Privacy by design” – that is “data protection safeguards built into products and services from the earliest stage of development” – is meant to become an essential principle in EU data protection regulation.¹⁸ In the future, the concept of code as law might even assume disquieting features, as in the, perhaps trite, example of genetic manipulation intended to delete genes predisposing a person to unsocial or criminal behaviour. In this respect, concerns about the use of technology as a regulatory tool have emerged, and the causes for concern grow with the increasing tendency to rely on technology as a

¹⁷ Besides the seminal work of L. Lessig, *Code and Other Laws of the Cyberspace* (New-York: Basic Books, 1999) and its second edition *Code: version 2.0* (New-York: Basic Books, 2006), see K. Yeung, ‘Towards an Understanding of Regulation By Design’, in R. Brownsword and K. Yeung (eds), *Regulating Technologies* (Oxford: Hart, 2008), 79 ff; B.-J. Koops, ‘Criteria for Normative Technology: The Acceptability of ‘Code as law’ in Light of Democratic and Constitutional Values’, *ibidem*, 157 ff; more recently, the Symposium *Technology: Transforming the Regulatory Endeavour* (Berkeley, 3 March 2011) and the proceedings published in (2011) 26 *Berkeley Technology Law Journal* 1315.

¹⁸ See Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *Safeguarding Privacy in a Connected World. A European Data Protection Framework for the 21st Century*, COM/2012/09; and the Proposal for a Regulation of the European Parliament and of the Council *on the protection of individuals with regard to the processing of personal data and on the free movement of such data* (General Data Protection Regulation), COM(2012) 11 final, Brussels, 25 January 2012.

replacement for other forms of regulation, as it proves to be the most effective (because it basically excludes the option of non-compliance). Moreover, while technologies employed in order to back the rules and promote conformity do not impact on our concept of law and its normative quality, technologies whose function is to assure a certain conduct challenge this assumption, indicating a shift from a “traditional legal order to a technologically managed order”,¹⁹ that might corrode the sense of moral commitment we have towards norms protecting the interests of others and cause us “to lose the spirit of legality”.²⁰

Reverting to the question mark in the title to this section, whether it is possible to remove it depends on the ability to strike the right balance between technology as a regulatory opportunity that should be seized, and technology as a regulatory temptation, that ends up marginalizing other forms of regulation and threatens values such as autonomy and human dignity.

4. The clashing features of techno-regulation

If we tried to sketch the key features of the regulatory enterprise faced with modern techno-science, we would come across multiple antitheses, revealing a double-edged dimension entwined in the plea for regulation. The very origin of these opposing trends resides in an ambiguous attitude towards the governance of science-centred issues, where there is no clear-cut answer even to the basic question of whether technology should or should not be regulated and to what extent the law needs to follow and adjust to technological change.

The nature of technology itself is at odds with long-term legal framing: on the one hand, its developments are unpredictable and therefore are not easily met by law reform; on the other hand, premature and obtrusive legislation might hamper them and prevent potential advantages from happening. Underpinning this tendency to the containment of lawmaking around scientific research and its applications is the fear of creating impediments for scientists, of

¹⁹ R. Brownsword, ‘Lost in Translation: Legality, Regulatory Margins, and Technological Management’, (2011) 26 *Berkeley Technology Law Journal* 1321-1365, at 1323 f.

²⁰ *Ibidem*, 1364.

burdening competitiveness or of causing economic or other inefficiencies. But, paradoxically, the propensity to avoid excessive regulation clashes with an opposite urge to fill in a legal gap that may itself hinder technological innovation, depriving it of a reliable and secure legal environment where the efficient conception and spread of its results can take place.

Over this assessment, the view that intervention is necessary, even in a situation where all implications cannot be fully anticipated or may be misjudged, ultimately tends to prevail, notwithstanding the scientific indeterminacy, in order to protect interests effectively against risks which are still unknown. This finding might even lead to a ban or the imposition of a moratorium on certain applications, or to creating disincentives for research, but it definitely calls for a regulatory framework which supports safe and value-consistent scientific advancement.

The debate then moves forward to consider the desired traits for techno-regulation. The mutual exchange between the formerly separate enclaves of technology and law especially affects the contents of regulation, but this interplay also has an impact on the kind of legal sources at stake, their order and status, their capacity to adapt to an intrinsically dynamic matter, the procedure through which they should be adopted, their substantive quality. All these characteristics polarize around opposite, thus symmetric, points, plastically showing the tensions, and indeed the complexity, intertwined in the discussion over the prospect of regulating science and technology.

4.1. *Fast-moving technology and lengthy lawmaking*

Law-making is a slow process, while technology changes rapidly. This distance between technological innovation and legal change may affect legal certainty and cause people to act in an ambiguous environment where rights and responsibilities cannot be clearly acknowledged or predicted. Moreover the development and diffusion of (unregulated) technology influences users' behaviour, generates needs, triggers a market demand, and ends up imposing itself with the force of the fact. On the other hand, the temporal gap between the emergence of a technology and the subsequent regulation allows more time for analysis and permits policy decisions and their implementation to be better informed. The law's slow pace, in this respect, is not

necessarily a weakness to warn against, but could prove to be a wise suspension of judgment, waiting for the issues at stake to mature.

In order to accommodate these opposing tendencies, any regulation should retain both flexibility and responsiveness, or even anticipation of the future risks of activities that are in constant evolution. The problem of regulatory connection²¹ in fact exists not only when a new technology is emerging and regulators have to face the challenge of “getting connected”, but also when the technology is in some way established and widespread, because it simply keeps moving and being transformed. And “staying connected” to technologies that evolve again has a bearing on the normative framework that has to adjust to the intrinsically mutant quality of its object.²²

In order to take into account this shifting quality of the matter to be regulated and keep the regulation connected to a dynamic reality, regulators can resort to various techniques: the introduction of sunset rules, which are subject to revision after a predetermined period of time;²³ “intelligent (anticipatory) drafting” and “purposive interpretation”;²⁴ technological neutrality, which presents however several shortcomings and proves not to be always effective against regulatory disconnection.²⁵ On a different track, in order for regulation to evolve with technology and in consideration of the constraints of a ‘hard law’ approach, legal systems are steered towards adopting “prospective and homeostatic” instruments, capable of adapting themselves to a changing landscape, which cannot be managed through statutory law.²⁶

²¹ The concept of ‘regulatory connection’ and its three phases – ‘getting connected’, ‘staying connected’ and ‘dealing with disconnection’ – are explained and thoroughly discussed in Brownsword and Goodwin, n 11 above, 63 ff, 371 ff.

²² For a vivid description of the worthless effort conventional law would spend in pursuit of technology see M. Kirby, ‘New Frontiers: Regulating Technology by Law and Code’, in Brownsword and Yeung, n 17 above, 367 ff.

²³ Rodotà, *infra*. For a critical appraisal, see D. Fenouillet, ‘La nécessité d’une réglementation législative spécifique’, in B. Feuillet-Le Mintier (ed.), *Normativité et biomédecine* (Paris: Economica, 2003), 102 f.

²⁴ Brownsword and Goodwin, n 11 above, 405 ff, 409 ff. But see also, for an illuminating example of smart regulation, M. Passaro, *infra*.

²⁵ C. Reed, ‘Taking Sides on Technology Neutrality?’, (2007) 4 *SCRIPTed* 263. See also, for an illustrative example, D’Ostuni and Marini Balestra, *infra*, § 8.

²⁶ S. Rodotà, ‘Diritto, scienza, tecnologia: modelli e scelte di regolamentazione’, in Comandé and Ponzanelli, n 10 above, 397-412, at 409.

4.2. *Soft law v hard law*

'Soft law' alternatives seem the most suitable governance approach, as they have looser procedures and are compatible with the process of internal adjustment through technical delegation to independent bodies which are enabled to register variations, assess the need for amendments and implement those amendments (§ 4.3).

Soft law devices are not only deemed essential in order for the law to comply with the dynamism inherent in the activity to be regulated and to cope with the uncertainties encountered; they also appear to be the favourite tools for rapidly filling regulatory gaps as new technologies are introduced, while safeguarding essential interests like human dignity, health, and the environment.

In addition, they have a better chance of remaining consistent with diverse cultures and moral viewpoints. The desirable traits of regulation in sensitive and contentious areas are in fact conciseness and economy; legislation, in particular, should be expressed in very general terms and limited to essential elements putting forward basic rights and obligations. A 'light' binding framework would have the advantage of not imposing on pluralistic communities, leaving it to procedures and standards set at a lower level to guarantee that a (few) over-arching principles are not compromised.

But the support for a wide range of flexible measures, for fewer formal or mandatory mechanisms, and for instruments that are not legally binding does not easily comply with the perceived need for a general frame of reference, possibly agreed on at an international level, on which technological advance should be grounded and which provides legal certainty to the actors involved. The latitude embraced by soft law instruments (in terms both of the extension of their influence beyond national borders and of the general character of the principles affirmed) allows convergence over no more than the elementary content of regulation, which is insufficient for governing complexity. The objective of extensive harmonization pursued by means of cross-boundary 'soft' regimes, depending on the voluntary compliance of multiple classes of agents, will often fail to be implemented and enforced.

4.3. Technical delegation and the public/private dichotomy

Technical delegation is a legal tool that is often used to handle complex scientific matters, to keep pace with their evolutionary change and to maintain a light quality to traditional legislation in fields characterized by a strong technological dimension. The need to resort to technical delegation to deal with science-centred issues results in a very distinctive feature of techno-regulation, its private substantial nature. Technology itself has been identified as a crucial factor in the growth of private transnational regulation.²⁷ Combining formal law and technical standards, as a feasible approach to techno-regulation, requires the private sector to be included in the legal order and raises problems of democratic control and legitimacy.

Technical and safety norms and standards have increasingly become a tool for regulation in many sectors; formulated by administrative agencies, non-governmental agencies, technical standard-setting bodies and professional associations, they exert a decisive influence on notions such as negligence, risk, and eventually on the allocation of liability, fuelling the so-called regulatory compliance defence. International standards, for instance, are essentially developed by international non-governmental organizations (the ISO, for instance),²⁸ in collaboration with their national members and the economic stakeholders in the member countries. Standardization is voluntary and is not legally binding unless national governments decide to incorporate the standards into their domestic legislation.

Legal norms that integrate technical norms are the product of expert knowledge; conceptualized as bridging a gap between science and regulation, they can no longer escape criticism of their legitimacy on the basis that science and technology are neutral. Moreover, technical norms that are crystallized into fixed precepts cannot react and adapt to change promptly, so their very function is challenged and they may lose their effectiveness.

By contrast, the devolution of technical rule-making to independent agencies or standard-setting bodies ensures the continuous adaptation

²⁷ F. Cafaggi, 'New Foundations of Transnational Private Regulation', (2011) 38 *Journal of Law and Society* 20-49, at 28 f, and *infra*.

²⁸ A very accurate description of the standardization process managed by the ISO group on robotics is given by G. Virk, *infra*.

of norms, but raises doubts about their legitimacy, certainty and accessibility.²⁹

Private regulatory bodies will have to comply with the rule of law and promote inclusiveness and participation, but whether they will be able to embrace social and constitutional values (as opposed to self interest) and give them priority in their regulatory activities can be disputed. More radically, whether the normative settlement of highly sensitive and potentially risky activities should be delegated to the technical dimension remains questionable.

Similarly, an externalization from the participatory dimension imbued in democratic settings also affects ethical discourse. Ethics has become a matter of expertise devolved to (more or less institutionalized) expert committees. Called to purport ethical decisions, they are invested with a function that would be better served by organs representing all citizens.³⁰

Open criticism of rules made by experts without democratic legitimacy underlies a (tentative) change of paradigm in the European approach to the regulation of science: the principles of transparency, accountability, public participation and consultation are now considered central features, especially when techno-science is oriented toward social implementations that require political and public choices to be made.³¹ This blurring of boundaries between regulators and regulatees presents a double meaning: techno-regulation needs to include the views of regulatees in order to encompass social values, other than sheer risk-assessment and cost-benefit analysis, in its responses; but this inclusive attitude also reverberates, in a sort of virtuous cycle, on the goals of technology acceptance³² and on the effectiveness of regulation.³³

²⁹ A. Zei, *Tecnica e diritto tra pubblico e privato* (Milano: Giuffrè, 2008) and *infra*, L. Montanari, 'I poteri normativi degli organismi tecnico-scientifici', in Comandé and Ponzanelli, n 10 above, 445-478.

³⁰ Wynne, n 13 above, 47 ff.

³¹ A. Stirling, *From 'science and society' to 'science in society': towards a framework for 'co-operative research'*, Report of a European Commission Workshop (24-25 November 2005), Brussels, February 2006.

³² A. Vedder, *infra*, points to the need for inclusive design and inclusive regulation of emerging technologies, taking into account the views of professionals and consumers who are meant to be their primary users, in order to attain a good level of technology acceptance.

³³ An example of productive interaction between the EC level, national regulatory authorities and all interested parties in the communication technologies sector, opening

4.4. *Global technology v local law*

Technology is global, while law, being most often the product of nation states, pertains to their geographic territories; municipal law, therefore, is deemed to be ineffective in regulating such a cross-boundary phenomenon. The transnational character of technological activities again disqualifies conventional forms of legislation in favour of far-reaching legal tools and encourages supranational solutions to be found.

In this respect, some lessons may be drawn from what is happening in the bioethics domain: due to the exercise of free movement rights by European citizens, the proximity of states with diverse regulatory approaches to biomedicine may undermine the efficacy of the law and progressively de-legitimize restrictive positions.³⁴ It follows that harmonization of the law on bioethical matters at the supranational level seems necessary (although it is not clear whether this should be the result of activity by the European Union, which at the moment lacks the competence to intervene, or a goal pursued by the Parliaments of the EU Member States, forced into action by the inefficacy of restrictive rules applied in jurisdictions which are close to others with more liberal legislation). It is doubtful, however, that true harmonization can occur, due to the differences in the cultural traditions and the ethical choices of Member States, and also to the fact that judicial or legislative activity at the EU level does not appear to be well equipped to penetrate in depth the controversial questions posed by biomedicine.

In regulating scientific and technological advances a single international regulatory approach may in fact face local resistance; some thresholds might have to be recognized and accepted at the international level, in order to accommodate national perspectives on sensitive issues which touch on the values and cultural viewpoints of particular communities. It is worth noting that this precautionary and careful approach could be challenged by the prospect of regulation

up “a sort of European laboratory for the development of regulation, where ... the best practices can be selected by consensus”, is illustrated by D’Ostuni and Marini Balestra, *infra*, § 5.

³⁴ So-called ‘biomedical tourism’ – recourse, for instance, to reproductive technologies or to assistance for euthanasia abroad – occurs when restrictive regulations coexist and compete with more liberal models.

through ‘code’ and architecture,³⁵ which has another drawback in exactly its inability to take into account national borders as value-marking boundaries.³⁶

5. Techno-regulation(s): in the singular or in the plural?

A methodological issue almost immediately arises when one starts to confront the problem of techno-regulation – the question of outlining a general approach³⁷ that remains valid regardless of the particular technology being considered. The applicability of the same set of measures and strategies across diverse regulatory fields might, in fact, be difficult or even impossible as techno-regulation is deemed to be sector-specific. Not only this, but the differences between technologies also lie in their stage of advancement (from experimental research, to design, testing, launch and permeation into society);³⁸ the degree of controversy surrounding them or, on the contrary, their wide acceptance; the risks that they pose, and therefore the urgency with which regulation should intervene; the intrinsic characteristics of a specific technology that make it unique for the purpose of regulation.³⁹

Shortcomings in the principle of technological neutrality have shown that identical rules are not appropriate for every application, highlighting a communicability problem even within the same kind of

³⁵ “It is in this sense that ‘Code’ and architecture may challenge the previous assumption that, within its own borders, each nation state is entitled, and able, to enforce its own laws, reflecting its own values”: Kirby, n 22 above.

³⁶ According to the idea of “fundamental boundaries” proposed by J.H.H. Weiler, ‘Human Rights, Constitutionalism and Integration: Iconography and Fetishism’, (2001) 3 *International Law FORUM du droit international* 227-238.

³⁷ Cockfield, n 11 above, 386 ff, stigmatizes the compartmental approach which studies biotechnology, information technology, new media, etc., as distinct legal topics, that partly fall within the existing categories of intellectual property law, antitrust and competition law, and cyberlaw, while not attempting “to develop a broader theory” of law and technology intended as “one more tool within a scholar’s methodological toolbox”.

³⁸ The “temporal development cycle of technology” is taken into consideration in the taxonomy provided by Koops, *infra*.

³⁹ To some extent, this is the case with agri-food technologies, as underlined by E. Sirsi, *infra*.

technology. On the other hand, in communication technologies, the phenomenon of convergence “made technology-specific regulation obsolete and created a need for transversal rules applicable to all analogous communications services, networks, and devices”.⁴⁰ In more general terms, regulation is forever in danger of becoming obsolete not only if it is too specific, but also if it is too general to control specific developments, although this problem can be controlled by devolution to the technical dimension.

This remains the basic issue and may require an analytic rather than a synthetic approach in the sense that diverse types of technology need different regulatory regimes to suit their specificities and these can only to a limited extent be built over past regulatory actions.

Nonetheless, it is worth looking for invariants in the normative discourse around technological development in order to identify and emphasise a common thread, defined by concerns about the protection of important values such as human dignity, health, identity, data protection, and the environment. Safeguarding fundamental rights can thus represent an anchoring point and a substantive reason underlying all efforts for the construction of a shared normative stance with regards to technological advance, in line with the approach taken by the European community: “la volontà costante di integrare scienza e valori rappresenta il tratto più caratteristico dell’identità epistemica europea, la peculiare cifra della politica e del diritto della scienza in Europa”.⁴¹

A still incomplete, but firm, conclusion that technologies, being primarily at the service of man, should remain consistent with fundamental human rights and dignity seems to be well represented by the De Chirico’s painting that appears on the cover of this book: where, from a compound backdrop of gears and geometrical shapes suggesting the amorphous and disordered power of technology, stands out neatly, in the foreground, the man’s figure.

⁴⁰ M. D’Ostuni and F. Marini Balestra, *infra*, § 2.

⁴¹ “The constant will of integrating science and values represents the most characteristic trait of the European epistemic identity, the peculiar cipher of the policy and the law of science in Europe”: M. Tallacchini, ‘Politiche della Scienza contemporanea: le origini’, in S. Rodotà and M. Tallacchini (eds), *Ambito e fonti del biodiritto* (Milano: Giuffrè, 2010), in *Trattato di biodiritto* directed by S. Rodotà and P. Zatti, 53-77, at 71.

These preliminary remarks are intended to serve as an outline to the themes developed by the authors in the following chapters; at the same time they resume and continue some reflections introduced on the occasion of a workshop on *Regulating Technological Development at the Intersection of Science and Law*, held at the Scuola Superiore Sant'Anna on 21 and 22 June 2012, where the same authors have participated, offering extremely valuable insights. None of these initiatives would have been possible without the constant support of the Scuola Sant'Anna RoboLaw group – Elettra Stradella, Antonio Carnevale, Andrea Bertolini, Angela Di Carlo, Federico Azzarri, Luca Nocco, Vincenzo Casamassima, Alberto Pirni, Pericle Salvini and Serena Tarantino – to whom I want to express my gratitude. I hope that we shall have as productive a collaboration in the important commitment that will accompany us during the coming year.