RoboLaw

Grant Agreement number: 289092

Project acronym: RoboLaw

Project title: Regulating Emerging Robotic Technologies in Europe: Robotics facing Law and Ethics

Funding scheme: Collaborative project (CP), FP7-SiS-Challenge 1-3: Regulating emerging scientific and technological developments

Project website address: www.robolaw.eu

D6.2

Guidelines on Regulating Robotics

Delivery date: 22/09/2014

Start date of project: 01/03/2012 Duration: 27 months

Organisation name of lead contractor for this deliverable: SSSA

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Version: Final

Project co-funded by the European Commission within the Seventh Framework Programme (2007-2013)		
Dissemination Level		
PU	Public	**X**
PP	Restricted to other programme participants (including the Commission Service)	
RE	Restricted to a group specified by the consortium (including the Commission Service)	
CO	Confidential, only for members of the consortium (including the Commission Service)	

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Introduction

1. Aim of this report.

The aim of this report is to offer an in depth analysis of the ethical and legal issues raised by robotic applications and to provide the European and national regulators with guidelines to deal with them.

The RoboLaw project was devoted 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 could be developed and eventually launched. After a comprehensive analysis of the current state-of-the-art of regulation pertaining to robotics in different legal systems has been carried out throughout the research, the present document tries to respond to the question whether new regulation is needed or the problems posed by robotic technologies can be handled within the framework of existing laws.

2. Methodology.

The report has been prepared through a combination of desk research, empirical research and expert consultation. Desk research was carried out through an extensive analysis of the existing literature in the domains of robotics and roboethics, Science and Technology Studies and Philosophy of Technology, and of the relevant law. According to the ELSI approach, aimed at analyzing the ethical, legal and social issues raised by robotic applications in view of their consideration in public policy deliberations, the theoretical and conceptual exercise has been accompanied by an investigation on empirical data, collected through surveys targeted at the general public and aimed at understanding the perception of robotics in society. Expert consultation was attained through different methods, like questionnaires, multi-stakeholders' workshops, qualitative interviews, active involvement in drafting the state-of-the-art of the technologies being examined, contributions of the members of the External Advisory Board and the Supporting External Networks (a-b).

3. Overview of the report.

Chapter one provides an introduction to the relationship between regulation and robotics, by clarifying where the need for a legal appraisal and intervention comes from and explaining how the RoboLaw project has corresponded to it. The paths explored and the lines of investigation undertaken in the project are here synthesized, in order to highlight the driving themes that cross-cut the entire research. Since robotics is a wide domain, and robotic technologies differ from one another, a case-by-case approach was adopted and four diverse technological applications have been examined in depth in the following chapters. While chapter 2 deals with autonomous vehicles issue, chapter 3 (surgical robots), 4 (prosthetics) and 5 (care robots) examine robotic applications that are destined to be deployed in the healthcare sector, and contribute to cluster applications, that qualify for a homogeneous and distinctive treatment. Each of these chapters is structured in four parts: an introduction to the topic; a technological overview of the state-of-the-art pertaining to the technology examined; an ethical analysis; and a legal analysis, that ends with recommendations for policy makers. The Conclusions highlight the research's main proposals and try to generalize its findings to other type of emerging technologies.

1. The roadmap towards the "Guidelines on regulating robotics"*

* This chapter has been written with contributions by: Erica Palmerini (§§ 1-2.2.1; 4.1-6; 7.1); Pericle Salvini (§§ 3, 7); Bert-Jaap Koops (§§ 4, 4.1); Antonio Carnevale (§ 4.1).

1. Robotics and regulation.

The investigation on the interplay between robotics and regulation moves from a request for a legal framework that can accompany the developments of robotics. The request is coming from the very actors that operate in this sector, at the experimental and at the industrial level, who cannot properly appraise the risks and duties entwined in their work until a clear analysis of this interplay has been made. The research has explored both the formal and the substantial aspects of the binomial robotics and regulation. On the one hand, it has focused on the different legal tools that can be employed in order to regulate technology in general, and robotic technologies in particular; on the other hand, the contents of the extant relevant legislation have been examined, with the aim of verifying whether they can already provide a systematic legal framework or other forms of regulation are needed, notwithstanding the adaptability and flexibility of the available rules.

1.1. Why regulation?

As an early overview of the RoboLaw project appeared in 2012 on *The Economist* has put it, 'Overly rigid regulations might stifle innovation, but a lack of legal clarity leaves device-makers, doctors, patients and insurers in the dark' (*The Economist*, September 1st 2012). The article focuses mainly on human bionic systems, that is on an array of technologies (going from bionic prostheses to exoskeletons to body implants to brain-computer interfaces), that will allow to restore lost bodily functions and eventually overcome different types of disabilities, whose deployment, though, poses more general concerns with regard to the impact on the accepted notions of human nature, identity, normalcy, disability, and the correspondent legal effects and protection.

Similar statements can be found when the technologies at stake are autonomous vehicles (Piesing, 18 February 2013), software robots deployed in modern finance (Lin, 2012-2013), care robots or other robotic technologies meant to be used in the healthcare setting. A transparent regulatory environment is seen as a key element for the development of a robotics and autonomous systems market, where products and services can be incubated and deployed (UK Robotics and Autonomous Systems Special Interest Group (RAS-SIG), 2014: 7). A widely spread perception reveals the concern that premature and obtrusive legislation might hamper scientific advancement and prevent potential advantages from happening, burden competitiveness or cause economic or other inefficiencies. At the same time, somehow paradoxically, it is accepted that the lack of a reliable and secure legal environment may equally hinder technological innovation. Therefore the propensity to avoid excessive regulation clashes with an opposite urge to fill in a legal gap that affects legal certainty and causes people to act in an ambiguous environment where rights and responsibilities cannot be clearly acknowledged or predicted. 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, and calls for a regulatory framework which supports safe and value-consistent scientific advancement.

This plea for regulation only rarely assumes the shape of a moratorium or a definitive ban on further development of a given technology. An appeal to outlaw the development, production

and use of a certain robotic application has been voiced in the realm of military robotics, with regard to fully autonomous weapons like battlefield robots or military drones.[1]

More often, there is genuine request from researchers and industries for a legal and ethical governance to which they can fine-tune their strategies and plans about innovative robotic applications. 'Laws and regulations will be crucial to the way that markets for robots develop', a Special Report "Robots. Immigrants from the future", featured in *The Economist* earlier this year (March 29th 2014: 16), has pointed out. The ambition of the European Union to promote innovation in the internal market and foster competitiveness makes robotics a strategic sector, to which the European institutions are devoting considerable attention. At the same time research and industrial production in the domain of robotics have to grow in accordance with the complementary objective, which is enshrined in the European order, to establish itself as an area of freedom, security and justice.

The competing goals of protecting consumers and more generally end-users from harm and fostering innovation have therefore to become embedded in the regulatory endeavour and in the innovation process itself. In this respect, the most proactive regulatory system seems to have to combine multiple tools and constructs: legal rules, technical norms and standards, codes of conducts and good practices. These can guarantee certainty, flexibility, accuracy and context-based interpretation.

A problem often underlined when confronting the relationship between technology and regulation is the law slow pace, in the sense that technological innovation outrun the ability of the regulator to intervene early enough at the emergence of a new product. The problem of regulatory connection (Brownsword & Goodwin, 2012: 63 ff., 371 ff.) 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.

On the other hand, a 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. In this time frame, the RoboLaw project has tried to work, even if some of the issues at stake may not be fully mature, in order to avoid that technologies develop in a totally unregulated environment, where they influence users' behaviour, generate needs, trigger a market demand, and end up imposing with the force of the fact. Even anticipating future risks of activities that are in constant evolution, an ethical and legal framework needs to be carefully conceived in order to craft the appropriate rules when required, and provide the research and production processes with ethical and legal values to which to conform when designing innovative products.

[1] Human Rights Watch, Losing Humanity: The Case Against Killer Robots, November 19, 2012. A report prepared together with Harvard Law School's International Human Rights Clinic (IHRC), calls for an international treaty that would prohibit the development, production, and use of fully autonomous weapons, and also on individual nations to pass laws and adopt policies as important measures to be taken at the domestic level.

2. The RoboLaw project and the "Guidelines on regulating robotics" in the framework of Responsible Research and Innovation (RRI)

The research on robotics and regulation has been undertaken with a constant point of reference to the EU policies on Responsible Research and Innovation (RRI).[2] The main concerns and meanings that are entrenched in this formula have been respected and applied both from a methodological and a substantial point of view. On the one side, an interdisciplinary approach has been a constant feature of the study from its inception. It was attained by integrating various disciplines and competences in the project's structure and team. The diverse expertise of the researchers involved in the consortium (lawyers, philosophers, S&T studies experts, engineers) have led to a constant interaction aimed at exchanging information, opinions and perspectives in order for the suggested rules to be sound from a technical point of view, informed by an appraisal of the ethical issues at stake, and compliant with a general frame of reference that was derived from common fundamental values and more specific principles of the applicable law. Throughout the two-year research, multiple stakeholders were involved in the research process with the goal to include all possible relevant perspectives, including that of operators in the robotic industry and market, potential or actual users (e.g. person with disabilities, surgeons, care associations), insurers, society at large (see Di Carlo & Salvini, 2014). Dissemination activities throughout the project were carried out also with the aim of getting inputs and views from the public, as a way of ensuring public participation and integrating social views into the policy-making and regulatory processes (see Salvini, 2014a, 2014b).

Moreover, an ethical appraisal of various robotic technologies in their potential scenarios of deployment has been carried out as a core research exercise within the project. Any legal evaluation should, in fact, take into account the problems that the former perspective sheds light on, so that it can inform the fashion in which new rules are tailored or the existing ones are to be interpreted. In other words, ethics of technology and of robotics in particular was not considered an autonomous exercise and deferred to experts of the field. Rather, it was seen as an integral part of the analysis leading to distinctive features of the proposed solutions. A methodology to perform the ethical analysis was drafted (Bisol, Carnevale & Lucivero, 2013) and then applied to the technologies we considered more deeply as a case in point (*infra*, § 2.1). The External Advisory Board[3] also commented extensively on the analyses of technologies from the various disciplinary standpoints of its components. However, it especially focused on the use of the applied ethics conceptual apparatus in the evaluation carried out.

On the normative side, the prospect of regulating robotics has had as points of reference the two requirements of ethical acceptability and orientation towards societal needs that identify the pillars of the concept of RRI. Not only do robotic products and applications have to comply with the core values embraced in the European context by the constitutional traditions of Member States

[2] See, lately, European Commission (2013). *Options for Strengthening Responsible Research and Innovation*. Luxembourg: Publications Office of the European Union. Also, R. von Schomberg (2011). *Towards Responsible Research and Innovation in the Information and Communication Technologies and Security*. Brussels: Directorate General for Research and Innovation, European Commission.

[3] The External Advisory Board (EAB) is a scientific advisory board established in order to support the RoboLaw research activities and it expresses advises on the Deliverables elaborated by the consortium. The members of EAB are: Prof. Francesco Donato Busnelli; Prof. José M. Galván Casas; Prof. Martha J. Farah; Prof. Stefano Rodotà; Prof. Maxim Stamenov.

and positively affirmed by the Charter on fundamental rights, but particular attention, and possibly a peculiar legal status in some respects, should also be given to those that respond to societal needs, therefore contribute to achieve normative goals such as equality of opportunities, justice, solidarity and to improve the quality of life of the European citizens, especially the more deprived and vulnerable. The Capability Approach (*infra*, § 4.1) also provides an important normative framework in this respect.

The input for regulating advancements in robotics coming from the researchers and the industries that operate in this sector is driven by concerns regarding safety, risks and liability. While taking into account these factors, which can act as barriers to innovation and development, the project's roadmap has included other aspects that we deem should be an essential part of any attempt to contribute to the governance of science and technology. Issues of justice, solidarity, protection of fundamental rights, non discrimination and prevention of exclusion have been regarded as critical for the regulatory assessment of robotic technologies.

2.1 The ethical analysis embedded in the legal analysis

In view of the RoboLaw project's main goal that consists in tackling the regulatory challenges posed by emerging robotic technologies and drafting recommendations for the European Commission, a thorough and systematic ethical analysis of said technologies was also undertaken. This investigation was necessary in order to identify the challenges at stake and provide the subsequent legal analysis with conceptual tools able to portray both the values and the ethical drawbacks pinpointed in the current theoretical debate.

In order to conduct ethical analyses for different types of robotic technologies in a coherent and comparable fashion, a methodology was drafted, that defines the type of ethical analysis that is more appropriate in the light of the final objective of the research, and how it should be conducted (Bisol, Carnevale & Lucivero, 2013). The method that has been described and adopted not only allows to situate the specific analyses against the backdrop of the current approach to ethical reasoning, but also tries to capture the issues that are more closely linked to the purpose of the RoboLaw' project, and identify the guiding principles brought forward by the roboethics literature.

One of the features of the chosen approach that permits to meet the RRI model is the inclusion of both the public debate on robotics and the academic literature, since they highlight different aspects and perspectives. Furthermore, a broad range of stakeholders were involved in the discussion concerning new technologies and their normative assumptions and positions were discerned, with the purpose of improving the process of governance of robotics by establishing the conditions for participation and democratic deliberation. Besides supporting a participatory method in the reconstruction of the issues at stake, a techno-ethic approach reveals values and human interests that robotic technologies may contribute to advance and uses them as guiding principle for the legal part of the regulatory endeavor. At the same time it provides institutions with the capacity to appraise the risks purported by robotic technologies, which have to be taken into account in responsible decision-making about the technologies in question.

2.2 Science, technology, and regulation intertwined.

Any proposal for regulation of robotic technologies has to ground on the extant debate on the interplay between law, science and technology. The attention devoted to the contents of the law to be adopted could not avoid to confront the debate on the kind(s) of regulation that is better suited for this task. A constant line of investigation throughout the research has focused on this relationship and addressed the multiple ways in which the regulator can tackle such an evolving object like technological development (D2.1, 2012; Palmerini & Stradella, 2013).

Since the recognition that the dichotomy between science as a fact-finding domain and law as the realm of the "ought-to-be" no longer represents the reality, the mutual acknowledgment of the respective boundaries of science and policy has been replaced by a "co-production" regime (Jasanoff, 1990). 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" (Tallacchini, 2002: 339 f.), within which contributions from both actors complement each other and reciprocally elicit and legitimise its contents.

New regulatory forms and an array of legal tools that can be deployed in order to capture this complex connection have been thoroughly analyzed in order to identify the sources of law at stake in the perspective of regulating technological development.

The key elements to be taken into account in this endeavor are the transnational nature of technological innovation and its shifting and sometimes abruptly transforming nature; the technicalities inherent in the regulation process of such phenomena and the need to resort, to some extent, to technical delegation (Zei, 2013); the need to adhere to a set of fundamental principles shared at the European level (see § 4.1; Koops *et al.*, 2014).

These elements converge in order to indicate that a general frame of principles agreed at the European level would better serve the purpose of fostering innovation in the robotic domain in Europe, and giving the correspondent market an important push in terms of competitiveness with external markets. This framework should attain a twofold objective: on the one hand, it should contribute to identify the main goals and achievements expected by advancements in robotic research and industrial applications; on the other hand, it should serve to settle on a nucleus of core fundamental rights and freedoms that developments in the robotic field may infringe and that, on the contrary, have to be regarded as intangible.

2.2.1 Robotics and regulation by design

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) and a regulatory tool, by incorporating regulation and legal compliance into the technology itself. The concept of techno-regulation and propositions such as "code as law" and "normative technology" (Yeung & Koops, 2008) highlight the fact that technologies can play a regulatory role. Norms can be directly incorporated into technology in the sense that a command and the compliance to it are imbued in the technology itself. For instance, "privacy by design" – which means that data protection safeguards are built into products and services from the earliest stage of development – is deemed to become an essential principle in EU data protection regulation.[4] As robots have to function in complex social environments, an increasing body of research and literature is investigating the utility and the feasibility of implementing in the machines an entire set of ethical and legal requirements, so that they behave according to social and legal rules. A study accomplished within the project has shown that robots compliance to a given normative framework is extremely difficult to realize from a technical point of view, and can also be questioned under several other aspects,

[4] 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.

but is nonetheless important 'to move from a focus on the regulation of human beings to a focus on the regulation of robots behavior through design' (Lucivero & Leenes, 2014).

3. What is a robot?

In order to propose a regulatory framework for robotics, it has been necessary to provide an explication of the term "robot" that could constitute the basis for the ethical and legal analysis. As a matter of fact, the term "robot" can mean different things to different people, since there is no agreement on its meaning neither among professional users (i.e. roboticists) nor among laypeople.

Virtual robots, softbots, nanorobots, biorobotics, bionics, androids, humanoids, cyborgs, drones, exoskeletons are just some of the terms currently used to designate a robot, or some aspects of it, in scientific and popular languages. If, on the one hand, the number of "things" that are becoming "robotics" is increasing due to the trend toward the convergence of science and technologies as well as due to an indiscriminate use of the term robot in popular and academic language, on the other hand, it becomes increasingly difficult to point out the elements that make robots unique with respect to other "things". The words of Joseph Engelberger, one of the fathers of robotics, are emblematic of the difficulties in defining a robot: 'I can't define a robot, but I know one when I see one' (Engelberger, 1989).

It is worth noting that far from solving the issue here, in the next paragraphs we will describe how the variety of meanings associated to the word "robot" has been addressed within the RoboLaw project.

According to the most widespread understanding, a robot is an *autonomous machine able to perform human actions*. Three complementary attributes emerge from such a definition of robot: They concern: 1) *physical nature*: it is believed that a robot is unique since it can displace itself in the environment and carry out actions in the physical world. Such a distinctive capability is based on the assumption that a robot must possess a physical body. Indeed, robots are usually referred to as machines;[5] 2) *autonomy*: in robotics it means the capability of carrying out an action on its own, namely, without human intervention. Autonomy is usually assumed to be a key factor in qualifying a thing as a "robot" or as "robotic". In fact, in almost all dictionaries definitions, including authoritative sources such as the International Standard Organisation (ISO 13482), there is always a reference to autonomy.[6] Finally, 3) *human likeness*: the similarity to human beings. The idea that a robot should be humanoid in its appearance and behaviour is deeply rooted in the imaginary of people as a result of the effects of popular culture and our tendency to anthropomorphism. However, the design of human morphological and behavioural features may have functional motivations: indeed, the human form and behavior are evidently the best models for solving the problems related to the interactions of the robot with the environment and human beings (Breazeal, 2004). It should be pointed out here that with the advent of service robotics neither can users be exclusively identified with trained operators, but the category encompasses potentially anyone, nor is it possible to assume that robots operate in industrial environments only, since applications may span from the sitting room to the inside of a human body. Although human-

[5] According to the dictionary a robot is 'a machine capable of carrying out a complex series of actions automatically, especially one programmable by a computer' (OED, 2014).

[6] See definition of robot given in fn 5.

likeness is still pursued by many roboticists (e.g. Honda Asimov), the number of robots which do not have a human-like design, such as drones or surgical robots, is increasing.

An alternative way to make sense of the word robot, less subjective with respect to the one described above, would be to look at a robot main components. Indeed, there is a widespread consensus among practitioners in describing a robot as consisting of four main elements: sensors, actuators, controllers and power supply. However, the drawback of such an approach is that given the large diffusion of sensors, actuators and micro-controllers in almost all technological products, too many devices could qualify as robots. Indeed, even a computer connected to a printer should be considered as a robot, since it possesses all of the above components. The problem is that many roboticists would not agree (Bekey, Lin & Abney, 2011).

In the framework of the RoboLaw project, instead of attempting to elaborate a new definition of robot, we devised a taxonomy of robotics, which, by classifying the main features of robots, allowed us to make sense of the plurality of uses and applications (Salvini, 2013). The taxonomy consists of six categories or classes, which have been identified by taking into account the most recurring features appearing in definitions of robots:[7]

1) *Use* or *task*. It refers to the specific purpose or application for which the robot is designed. Indeed, the etymology of the word (from Czech *robota*, meaning "forced labour")[8] implies that robots are meant to carry out a job or service. Potentially robots can be used for 'any application that can be thought of' (Murphy, 2000: 16). Conventionally, applications are divided into tow macro categories: service and industrial applications.

2) The *environment* is the outside of the robot, the space where the robot will carry out its actions. Within this category it is possible to make a macro distinction between physical and non-physical environments. In this way, it is possible to bring together robots that operate on space, air, land, water and the human body (or other biological environments) and those working in cyberspace, such as softbot.

3) *Nature* refers to the way in which a robot manifests itself or exists. Within this category it is possible to distinguish between two main sub-categories determined by the type of embodiment: embodied and disembodied robots. Machines, hybrid bionic systems and biological robots belong to the former sub-class, while software or virtual agents belongs to the latter. In this way, it was possible to avoid discriminating robots by the material they are made of, and therefore enlarge the definition to comprehend software agents (also know as virtual robots or softbots), artificial biological robots, such as nanorobots (Dong, Subramanian & Nelson, 2007) and finally, hybrid-bionic systems, which are made of biological and mechatronic components (e.g. limb prosthesis).

4) *Human-robot interaction* (HRI). This category takes into account the relationship between robots and human beings. It is a varied category including modes of interaction, interfaces, roles, and proximity between humans and robots.

5) *Autonomy* specifies a robot degree of independence from an outside human supervisor in the execution of a task in a natural environment (i.e. out of a laboratory). Within this category different levels of autonomy can be included: full autonomy, semi-autonomy and tele-operation. In this way it was possible to consider as robots both autonomous vehicles, such as the Google car (see *infra*, Ch. 2) and the da Vinci (see *infra*, Ch. 3), a tele-operated system used for robotic assisted surgery.

The categories identified in the taxonomy have mainly hermeneutic and analytical values, since they help us to make sense of the variety of existing applications and provide us with a

[7] For an overview of the most recurring aspects in robot definitions see Salvini, 2013, Table 1, p. 20 f.

[8] OED, 2014.

coherent method for bringing together apparently heterogeneous applications. As a matter of fact, in line with the RoboLaw consortium decision to favour inclusion rather than exclusion, by turning some of the most common features of robots into general categories common to all kinds of robots, it was possible to turn differences into similarities. Within each category a wide range of possibilities (including opposite options) may coexist. For instance, in the category "autonomy" there might be fully autonomous devices as well as fully tele-operated ones; likewise, in the category "nature" it is possible to have robots embodied in a physical or virtual "body". Of all categories, the task or the robot intended purpose can be considered as the most fundamental one, since it subsumes all the others. Accordingly, as it will be explained in § 7.1, four case studies have been selected by considering their application domain: healthcare (i.e. robotic assisted surgery, prosthetics, and care) and logistics (i.e. self-driving cars).

Finally and to sum up, the taxonomy points out the peculiarity of each robot, which cannot be discussed in isolation from its task, operative environment, nature, human-robot interaction and level of autonomy. Moreover, until the day in which robots will be able to auto replicate, their teleology will always be derived from human beings. This means that notwithstanding the possibilities offered by technological advancements in artificial learning, intelligence, consciousness, and sentience, the human being will be always the ultimate responsible for the robot design and use.

4. Mapping robolaw

In order to be able to develop guidelines and recommendations for regulating emerging robotic applications, it is important to first analyze the current regulatory landscape: which existing norms apply to various robotic applications, and where can possible regulatory gaps or inadequacies be discerned that require regulatory intervention? An important initial step in the roadmap towards developing guidelines for regulating robotics has therefore been to map the existing regulatory landscape. In order to map this landscape in a systematic way, the project has first devised a methodology for analyzing existing regulatory provisions, which enables knowing what to map and how to structure and color the map (Koops *et al.*, 2012).

The developed methodology consists of two parts. The first part (Koops *et al.*, 2012: 9-17) presents concepts and distinctions relevant for identifying and describing norms. It identifies, first, *where* to find norms, not only in law but also in "soft law", i.e. standards, and social norms, looking at potentially relevant jurisdictions and possible legal areas and application areas that regulate different types of robotics. Second, it identifies the *type and status* of norms in the hierarchy of norms, ranging from fundamental, inalienable rights to non-binding self-regulatory rules, which have different forms, levels of bindingness, and origins, also depending on the legal tradition. Third, it identifies the *context and purpose* of the norms, as the existence and gist of norms is related to the stage of technological development, the level(s) and types of risk involved, and the purpose that the norms aim to achieve in their context.

After having identified and briefly described norms, an inventory of robotics regulation can use the *second part* of the methodology (Koops *et al.*, 2012: 18-22) to provide a more-in-depth analysis of the regulatory field. This part zooms in on the identified norms, by providing concepts and distinctions that can be used to classify and compare them. Potentially, relevant aspects for classifying norms are the regulatory pitch, range, tilt, and connectivity; whether and to what extent the norms involve fundamental legal concepts and values; and which (possibly hidden) constraints and perspectives (e.g., cultural or linguistic frames or cultures) underlie the norms. Norms can

subsequently be compared through the method of comparative legal research, which should take into account all different "formants" composing the legal system of different jurisdictions. A recommended approach is to ask questions and describe cases of regulatory relevance, related to different developments in robotics, and to analyse how different legal systems address these questions and cases (Koops *et al.*, 2012: 22).

The methodology and comparative approach has subsequently been used by the project team to map the existing regulation applying to various robotics applications (Leenes (ed.), 2012). The analysis focused on those areas of law that are most likely to have a general bearing on the broad field of robotics. Five common legal themes[9] can be identified as having the broadest bearing on robotics regulation: 1) health, safety, consumer, and environmental regulation; 2) liability (including product liability and liability in certain sectors); 3) intellectual property rights (both to the robot itself and to works created by the robot); 4) privacy and data protection; and 5) capacity to perform legal transactions, e.g., whether intelligent agents can enter into contracts.

1) An extensive set of EU-based *health and safety requirements* is relevant for robots and robotic technologies. The requirements aim at protecting workers in factories against the dangers of (heavy) machinery and equipment. For industrial robots, specific regulation (for instance ISO standard 10218) has been developed. In contrast to industrial robots, which are applied in a controlled and well-structured environment, service robots are applied in less structured environments for a wide range of tasks, often by people with no specific training. As robotic applications move from structured, professional environments of industry into hospitals, homes, shops, and the street, a new wave of regulation will have to be developed to cope with the specific health and safety issues that emerge in these new environments. Differences in safety risks and levels of user training will affect the nature of safety requirements and hence the design of the robots. Another relevant finding is that there is a complex interplay between different regulations, which involve different regimes for different stages of robots' lifecycle, ranging from regulation of hazardous substances and product safety requirements to rules on disposal of waste equipment. Depending on their type, they fall under general regimes of consumer goods and product safety but also potentially under product-specific regimes, such as toys or cars. This complex interplay merits further study for determining which sets of legal requirements obtain for which types of robots and robotic devices, in order to see whether gaps in legal protection or conflicting rules exist for certain specific robotic applications (Leenes, 2012: 31-60).

2) Robots cannot be held *liable* themselves for acts or omissions that cause damage to third parties under existing legal regimes. However, manufacturers, owners or users of robotic technologies may be held responsible for damage caused by robots, if the cause of the robot's behaviour can be traced back to them and if they could have foreseen and avoided the robot's behaviour under rules of fault liability. Moreover, they can be held strictly liable for acts or omission of the robot, for example, if the robot can be qualified as a dangerous object or if it falls under product liability rules. However, it is hard to provide evidence of the link between human behaviour and damage caused by robotic technologies, particularly in cases where a person cannot distinctly control the actions of a robot. The damage may also be the result of a multitude of factors, given the complexity of robots' functioning and their interaction with unpredictable environmental factors. This makes the liability risks difficult to estimate, which can lead to legal uncertainty that

[9] Another key common theme, namely fundamental rights protection, has been singled out for separate treatment, since it is an overarching theme that affects all aspects of robotics regulation – see *infra*, § 4.1.

may have to be addressed by the legislature. The law should strike a careful balance between the conflicting interests of manufacturers, users, and third parties, and between risk regulation and stimulation of innovation (Leenes, 2012: 61-134; see also *infra*, § 5).

3) Robotics inventions and products can be protected by *intellectual property rights* (IPR), such as patents and trademarks and copyright. There are no legal provisions that specifically apply to robotics, but existing legal regimes and doctrines can relatively clearly be applied to robotics. Nevertheless, there may be public-policy reasons to extend or reduce the protection afforded by IPRs, and further research is needed to determine whether the current application of IPRs sufficiently meets the needs of the robotic industry and society at large. A second IPR-related question is whether robots themselves are capable of producing copyrightable works. The UK has dedicated legislation with a positive stance to computer-generated or robot-generated works (although it is debated how this should be applied exactly), whereas other countries lack such legislation and seem to deny the possibility of such protection. This is an area where the law as it stands does not come up with clear answers. Issues that need clarification in legal research and practice are, for example, what exactly is a computer-generated work, who is the initial rights holder of such a work, and how the criterion of an "own intellectual creation" can be applied to computer-generated works (Leenes, 2012: 135-158).

4) Many robots will contain information technology and many of those are likely to process sensor data. When these data concern individuals, the processing of these data by robots is subject to *data protection regulation*, involving requirements relating to, among other things, transparency, security, and lawful and fair processing. The data controller (this will often be the owner) has to comply with the data protection requirements. The emerging field of privacy by design can prove useful in making and keeping robots data protection-compliant. Some legal requirements can be implemented in the robot's software and interface, such as data security through data encryption and data access control. Requirements such as informed consent can be implemented in system design, for example through interaction with users via displays and input devices. Designing in data protection is not only relevant for compliance purposes, but it can also improve social acceptance. However, there are significant differences in data protection frameworks between the EU and other jurisdictions, which could make it difficult for manufacturers catering for the international market to design in specific data protection rules (Leenes, 2012: 159-188).

5) Software agents are becoming more intelligent and capable of taking over tasks traditionally done by humans. Also physical robots, such as companion and care robots will become more sophisticated and may have to be equipped with a capability of rendering basic services beyond pure material care, such as assistance in purchasing food, drugs, newspapers, or bus tickets. For such applications, it could be useful if robots would have the *capacity to perform legal transactions*. Robots currently do not have legal personality; in the current legal frameworks, they can only act as "mere tools", so the legal responsibility for robot actions rests with their human "master". Theoretically, however, it is possible to attribute legal personality to robots by changing the law. Basic requirements for granting legal personality to non-human entities, such as corporations, are that they are registered and have property. Registration requirements could in principle be extended to robots (including requirements on how robots can prove their registered identity); the capability of owning property is less easy to create, although legal constructions could be devised to accommodate this. Another issue to resolve if robots were to be granted legal personality is how disputes can be resolved in which the robot is a party; how can they be represented in court? (Leenes, 2012: 189-227)

The map of existing regulation pertaining to robotics applications demonstrates that robot-specific regulation does not exist in most fields. The map of the regulatory landscape consists primarily of a broad description of legal areas in general, in which relevant elements and doctrines of the respective fields need to be applied to concrete forms of robotics. This often involves considerable interpretation and an assessment of the rationale underlying existing legal provisions, to determine whether, how, and to what extent specific forms of robotics are regulated in different legal domains. As such an assessment often also contains a normative element – judging whether and how specific forms of robotics *should* be regulated – it is helpful to take recourse to a shared normative framework that can guide the evaluation of the regulatory implications of robotics. Hence, a second major element of the roadmap towards guidelines for regulating robotics involves an analysis of the role of fundamental rights and liberties in the European context.

4.1 The protection of fundamental rights and liberties in the European research and market sphere

Technological advances, together with the economic power of companies and research institutions, are often held responsible for producing knowledge and industrial applications without any concern for the exposure at risk of democratic values and human rights. On the contrary, the concern for the protection of fundamental rights potentially undermined by technological developments has recently become a characteristic feature of European science-making.

The objective of undertaking a comprehensive analysis of regulation needs with regard to robotic technologies does not take place in a void: a theoretical framework and a tissue of rules to which many robotic products and applications can be fine-tuned already exist, as the first phase of the research has tried to highlight in a systematic way. But, in this respect, the most general legal and ethical environment to be taken into account is given by a common set of overarching principles that are shared in the contemporary European legal order.

Human rights are in fact an essential apparatus to deploy in order to promote and guarantee responsible advances in science and technology. The protection of fundamental rights has played different roles throughout the study: it has provided a background on which to test the desirability of different robotic applications; it has contributed to design the safeguards that have to be observed in order for future developments to be consistent with values we hold dear; it has directed the analysis on the human capabilities that are affected by robots and therefore are potentially relevant for the regulatory effort undertaken by the RoboLaw project; finally, it has offered a constitutional legal basis on which specific rules for certain robotic applications can be grounded and justified.

Exploring fundamental rights as a "a touchstone for regulation" implies both to tackle the question whether fundamental rights are menaced by new technical opportunities purported by robotics, and whether, on the contrary, an efficient and proactive protection of fundamental rights and liberties proclaimed at the European level requires to foster innovation in robotics also by means of especially designed legal rules or inventive interpretation. Many rights recognized at the national and supranational level are certainly affected by developments in robotics; a (provisional) catalogue of these rights and the ways in which they can be altered or transformed or made effective through different types of robotic technologies have been enumerated (Koops *et al.*, 2013). The resulting question whether there are legal gaps in legal protection of fundamental rights due to new forms of aggression brought about by robotics has been addressed (Gasson & Koops, 2013); subsequently, the need to establish new fundamental rights or to enlarge the scope of the existing

ones in the light of novel risks of infringement has been confronted (Koops *et al.*, 2013). A third step was to investigate whether and to what extent the constitutional framework could point to developments in robotics that would better fulfil fundamental values and ensure the rights' implementation, so to impress a beneficial direction both to the legal and the scientific endeavour. The values that appear relevant in this respect are equality, solidarity, and justice and, within the value-based structure assumed by the European Charter of Fundamental Rights, the principle of non-discrimination (art. 21), the rights of the elderly (art. 25) and the integration of persons with disabilities (art. 26), the right to healthcare (art. 35), and to consumer protection (art. 38). Robotics products that are developed for applications in the healthcare context; care and companion robot used for the assistance of the elderly, to help them live an independent life and be socially active; advanced prostheses, orthoses and exoskeletons that can improve the quality of life of persons with various types of disabilities: these applications have been given a special attention in the present research, in consideration of their correspondence to qualified social needs and the ability to meet and accomplish core values.

These social needs and core values are intrinsically related to the notion of human flourishing, which 'treats each person as an end and as a source of agency and worth in her own right' (Nussbaum, 2000: 69). To foster human flourishing, the Capability Approach as developed by Martha Nussbaum and Amartya Sen provides a productive framework, emphasizing that human well-being depends on 'what people are actually able to do and to be' (Nussbaum, 2000: 5) rather than looking at abstract categories of average human beings' well-being. This approach provides a perspective of how humans are empowered to do something, which is a useful perspective to apply in the European regulatory framework that is built on human rights and fundamental freedoms (Lucivero *et al.*, 2013: 5).

The Capability Approach includes the environment of humans as an important factor in understanding human capabilities. The key role that technology plays in humans' environment has been further elucidated in philosophy of technology and Science and Technology Studies.

The relationship the human being entertains with technology has already in many ways changed our bodies and our perceptions of what is outside and what is inside it, leading in different ways both to an extension of capabilities beyond human reach and to an inclusion of things and devices into the body itself. An approach based on the impact of robotics on human capabilities has also been adopted because it is relevant in the perspective of regulation: in fact 'current legal rules may not be well-aligned with human capabilities that did not exist or that were substantially different, at the time they were drafted' (Lucivero *et al.*, 2013: 8). As technologies modulate what we value and how much we value it, an understanding of the relationships between technologies and human capabilities sheds further light on the interaction between these technologies and our moral standards and values, making the technological dimension at least as important as the biological and social dimensions of human capabilities (Lucivero *et al.*, 2013: 5). It is important to realize that technologies do not only afford new or enhanced capabilities, but may also lead to the loss of existing capabilities through a variety of means (examples of this type are discussed in Lucivero *et al.*, 2013: 30 f.). This dual character of technology's impact on human capabilities has to be always considered in ethical and regulatory analyses of robotics.

The ethical approach entrenched in the Capability Approach, which also has legal implications, allows us to highlight the ways in which technology-related changes in our values can be assessed: we can distinguish between those developments that contribute positively to intrinsically valuable human capabilities, and those developments that contribute negatively to these capabilities or that only impact on capabilities that do not have the intrinsic "dignity" of

contributing to human flourishing. Such an assessment will inevitably touch upon the principles and values that are affirmed in our constitutional protection of fundamental rights. Based on this perspective, we can determine which technology developments should be changed through regulatory efforts, or should receive a lower prioritization in policies aimed at technological innovation, if those technology developments only tend 'to expand undesirable, trivial or instrumental capabilities' (Oosterlaken, 2012: 5).

Furthermore, this approach gives us the opportunity to rethink philosophically and anthropologically the theme of disability as part of a revisited human condition. Disabled individuals cannot be protected until we understand that disability is not a mere pathology, but a universal perspective of life. Disability is an expression of the human condition, which cannot be conceptualized merely as a deficiency or human minus. Conversely, disability has shown us that everyone can become disabled, because humans are naturally and culturally vulnerable. For this reason, we build societies and create technologies to overcome these difficulties of life, but in so doing we become culturally vulnerable because social life requires to be increasingly supported by technological implementations (Carnevale & Bonino, 2013).

Bearing in mind that some robotic applications, namely those intended to help the elderly and the disabled, foster fundamental values, the analysis has focused also on the ways to provide the right incentives for their development, which we deem desirable. This specific perspective has led for instance to propose special rules in the context of liability for damages deriving from the use of prostheses, in order both to shield the producer from excessive liability (thus providing correct incentives for expanding research and the market for such technologies), and to compensate the victims (Bertolini, 2013; see also, *infra*, Ch. 4, § 4.2). The same rationale can apply to surgical and care robots (see, respectively, Ch. 3, § 4.7; and Ch. 5, § 3), and, to some extent, to automated cars (see Ch. 2, § 4.2).

Given this background, special attention has been given throughout the research to the possibility of introducing robotics in healthcare (see *infra*, § 7.1). This field should be considered strategic for European intervention in response to the challenges of increasing the quality of healthcare, and offering better treatment to the patients in terms of early diagnostic and effective treatment of diseases; reducing the costs associated with modern medicine; supporting disabled people with technologies that overcome their motor or sensor impairment; and confronting the problems brought about by demographic change, with population ageing, increasing demand for healthcare, decreasing availability of care providers, excessive burdens for family carers.

5. Risks and responsibilities.

The problem of damages occurred due to robots' action and the associated issue of liability are generally considered the most pressing questions by researchers, manufacturers and other stakeholders (Bekey, Lin & Abney, 2011). *The Economist Special Report* cited above stressed precisely the fact that 'manufacturers' technical ability to produce robots that can help in the home might easily outrun their capacity to deal with the resulting liability issues, especially if the robots operate in the homes of elderly people with cognitive difficulties' (p. 16). The reasons underlying this assumption can only be sketched.

First of all, it is necessary to take into account the increasing complexity of technological products and systems. This aspect is not distinctive of robotics, but robots contribute further to it,

reducing the scope for human control and oversight (von Schomberg, 2008: 333). In the setting of complex robotic systems, roles of many different individuals overlap and are tied one to another; the overall process of building and making a robot operational involves multiple actors that sometimes contribute to a segment and have not control, or even understanding, over the entire device and its functioning (Wallach, 2011: 194). The difficulties in ascertaining responsibility for accidents in complex systems ask for rules that allow compensation of damages, but also spread its costs among the multiple actors, that, intervening at different stages in the production and distribution process, may be called to bear the consequences according to innovative schemes.

Another variable often indicated as making liability for a robot's action a special case is the increasing autonomy that these machines display and their learning capacity, that render difficult to assess responsibility. Autonomy, at different degrees and extents, is a characteristic feature of robots, that has to be implemented in machines, if we want them to be able to operate in complex environments, where they will encounter influences that their designers could not anticipate, and will receive new inputs that can impact on their behaviour in an unpredictable way. The assumption that 'anything a robot does is the result of programming, and hence the machine can do only what it is intentionally programmed to do' is deemed to be 'a quaint oversimplification' (Bekey, Lin & Abney, 2011). Furthermore, complex systems may display 'emergent behaviours' (Arkin, 1998), i.e., modes of behaviour which were not predicted by the designer but which arise as a result of unexpected interactions among the components of the system or with the operating environment. This unpredictability of behaviour would challenge the principle underlying most common rules on liability for damages, that is the control that the person deemed to be responsible can exert over the action of the damaging agent. The conclusion is that the traditional ways of responsibility ascription, based on negligence or deriving from failing to take proper care, are not compatible with increasing unpredictable machines, because nobody has enough control over the machine action (Matthias, 2004).

A third element to be taken into account while discussing the issue of robots and liability is the great variety of potential uses and contexts in which the consumers can decide to deploy robots, that designers and engineers will not be able to envision in order to adopt the necessary safeguards (Asaro, 2007: 2). Moreover consumers could interfere with robots as long as their software system works on an open platform, that would be open to third party innovation that a manufacturer could not anticipate (Calo, 2011).

Several analyses share this view on the special features that robotic systems exhibit and invite to address this responsibility gap, but then part when try to envisage possible solutions in terms of legal remedies. The main responses provided by the scholars can be clustered into three groups.

A first proposal is to limit liability, as a way both to boost innovation in the robotic industry, by reducing the fears of liability-related costs, and to exclude that producers have to bear responsibility for risks that could not be avoided notwithstanding the care in informing and designing the products. The 'compromise between the need to foster innovation and the need to incentivize safety' would have precedents in the immunity of gun manufacturers from what people do with their guns, on the assumption that robots can be put to multiple uses not all of which can be predicted and warned against by producers, or in the immunity enjoyed by web providers. A "selective immunity" for open robotic platforms manufacturers would avoid disincentives to open robotics while preserving incentives for safety (Calo, 2011: 131 ff.).

A second solution resorts to the creation of legal personhood for robots in order to make them responsible for any damage they may have caused (Leroux *et al.*, 2012). The proposal comes from the observation that robots are being programmed to show increasing adaptive and learning capabilities, and can therefore react unpredictably to the inputs they receive from the environment. In these cases, the attribution of liability to the robot's owner could still apply, based on existing models such as the vicarious liability for injuries caused by animals, or the parental responsibility for damages produced by minors. But another scheme is explored, because, ultimately, 'it seems that producer, programmer, owner and user are assuming the role of "external controller" of an entity that seems to be capable of expressing embryonic but growing levels of autonomy and subjectivity' (*Ibid.*: 57). Building on the reasoning about the forms of responsibility arising from a robot's action, a more general discourse on robots' legal subjectivity is made (*Ibid.*: 58 ff.). "Electronic personhood" is considered a plausible approach for embodied robots (or software agents) that display a certain degree of autonomy and interact with people. Robots would have to be registered and equipped with an asset in order to be able to compensate for damages or fulfil obligations. Different choices could be made regarding how this financial basis should be composed and funded.

A third solution is by increasing the owner' responsibility. This idea rests on the assumption that the party aggrieved by the robot would encounter many difficulties were he/she to prove the negligence of the owner and/or the causality, due to the complexity and the lack of transparency of highly sophisticated machines to the ordinary citizens. The reason to apply a strict liability instead of a negligence standard would stem from the fact that the owner is a beneficiary of technology and can obtain additional advantages in introducing robots into his organization. Many national liability rules enforce this paradigm for damages brought about by a thing or a person that is included in the organization of work or that is owned by the tortfeasor. The reinforced owner's accountability would be accompanied, in this proposal, by a liability cap limiting the amount of damages the same person could be called to compensate and also by some forms of insurance, that often supplement the model of strict liability, and could make the system more feasible and sustainable while innovation progresses (Decker, 2014).

On the background of this discussion on liability for robot related damages, an emerging field of inquiry, known as machine ethics, introduces another variable to the debate. Machine ethics studies propose of installing the ability for moral reasoning in the autonomous systems, in order for them to be able to confront unexpected situations and react appropriately to unanticipated inputs (Wallach, 2011; Bekey, Lin & Abney, 2011). This result should be attained by equipping robots with a code of conduct that enables them to take moral decision, and this can be done according to two main technical methods, top-down and bottom-up (Wallach & Allen, 2009). The prospect of intelligent robots has to be taken into account in the choice of the optimal private law remedy to deal with robot-caused injuries, but it is not a stand-alone solution, that would settle every possible conflict. Even if this approach should become technically feasible, it would not strike out the problem of ascription of liability for damages; these could be reduced, but nevertheless occur and therefore the need to solve the issue remains.

6. Robotics and human enhancement technologies

Piercing into the debate on human enhancement has been a natural outcome of the research on prosthetics and more generally body implants, since said technologies not only can restore lost or impaired functions, but can also improve and strengthen them to a degree otherwise not

attainable by human beings. Robotics qualifies in fact as one of the most powerful means to achieve the enhancement of the human being - although probably not the most controversial one, partly because it does not introduce changes in the human nature that can be passed on to the offspring.

The subject of human enhancement, being extremely broad and rich, cannot easily be captured in an adequate way. This happen because it is widespread throughout diverse disciplines that confront it from their peculiar angle; it is very fragmented since multiple perspectives open up, depending on the technical mean used to achieve enhancement or the kind of function it impacts on. "Genetic" and "pharmacological", "cognitive" and "physical", "moral" or "mood" enhancement pose different problems, and a provisional conclusion has been offered exactly in the following terms: 'each kind of enhancement will need to be treated on its own, weighing the benefits of the technology against the costs it may impose, as well as the costs of regulation' (Greely, 2005). However, said possibilities can also be explored within a more general theoretical framework where the same set of questions about human enhancement as such has to be posed. Another reason that explains the difficulties in offering a comprehensive account of the debate is that it grounds on concepts and assumptions that are not fully defined and continue to be discussed among scholars, engendering further complexities to be dealt with. Moreover, the debate is developing not only on a theoretical level, but it has invested political institutions that have commissioned reports and studies on the topic, which proves to be a prominent aspect of the current bioethical scenario (BMA, 2007; Danish Council of Ethics, 2011; President's Council on Bioethics, 2003; Nordmann, 2004). A theoretical analysis was therefore needed in order to uncover the philosophical and ethical aspects involved and to clarify the constraints that apply to the phenomenon from a legal point of view. The investigation that has taken place in the context of the RoboLaw project draws also from other European research projects whose focus is precisely on the subject of human enhancement in general (see ENHANCE and EPOCH – Ethics in Public Policy Making: The Case of Human Enhancement, G.A. n. 266660), or on neuro-enhancement (see NERRI – Neuro-Enhancement: Responsible Research and Innovation, G.A. n. 321464).

A general introduction to the topic has been developed in a report (Battaglia & Carnevale, 2013), that was meant to analyze the phenomenon, to illustrate the evolution of the debate, and to question it philosophically. Observing a proliferation of definitions that over the years have been given of human enhancement, and therefore a conceptual and terminological vagueness which actually persists, this report is an attempt to clarify the terms of the debate. Furthermore it parts from the mere representation of polarized positions often found in accounts of human enhancement, and also from the perspective of single fields of knowledge, and tries to attain a comprehensive framework as well as to encourage a normative approach that deals with threats, challenges and opportunities.

In order to map further the debate on human enhancement and provide an examination from different disciplinary perspectives (law, ethics, technology assessment, philosophy of technology), a workshop has gathered a mixed group of researchers (D5.2 Neuro-Technological Interventions: Therapy or Enhancement?) and following this meeting a book has been published (Lucivero & Vedder, 2013). Both initiatives aimed at challenging some basic assumptions deep-rooted in the discussion, like the distinction between therapy and enhancement often intended as a boundary-marking line. In reality this binomial cannot function properly because it is blurred in itself, reposing, as it does, on concepts of normalcy and disability, health and illness, human functioning and human capacities that are culture-based and normative notions, change over time, and can hardly be defined and distinguished in a clear-cut and uncontroversial fashion. At the same time, this alternative still permeates the debate and cannot be dismissed if only because for pragmatic reasons: it serves to decide, for instance, whether an intervention should be paid for by a

health system or insurance company or not (Coenen, Schuijff & Smits, 2011: 523). An open and multidisciplinary discussion has further revealed, on the other hand, that common threads and shared beliefs can be found in the positions commonly considered in radical contrast (Battaglia & Carnevale, 2014).

Despite the plurality of approaches and definitions, it is worth to start reflecting on the subject in general and more specifically on the kind of enhancement purported by robotic technologies. This study can have a prospective relevance in order to define a common European approach. It has been noted that human biological enhancement can be seen as a competitive advantage and this adds to the complexity of regulating human enhancement. Transnational regulation would be necessary, in order to avoid that restrictive regulation or a ban in one country is weakened by a more permissive legislation in competing countries (Greely, 2005; Coenen, Schuijff & Smits, 2011; see also, *infra*, Ch. 4, § 4.3.4). A policy to be identified at the European level would reduce this type of risk and ensure consistency with the constitutional common framework and with the precautionary principle as broadly embraced in European science society. Human enhancement may in fact have an impact on the free flow of goods between the Member states, but also affect the structure of society and values such as distributive justice, solidarity and dignity. Moreover, safety issues and respect for individual autonomy are also at stake, as well as problems of coercion or, more subtly, indirect coercion; the protection of vulnerable groups and the principle of non discrimination equally play a significant role in the debate around human enhancement, being at the same time relevant objectives of the European institutions' activities. Given the experimental nature of most enhancing technologies, the duty to comply with actual regulation for medical research is also a problem to be afforded within the, equivocal but to some extent inevitable, alternative between therapy and enhancement. Pragmatic reasons, as mentioned above, also underpin this distinction, and policy guidance could support national decisions both at the state and at the professional self-regulation level about appropriate registration of interventions in health institutions, and help hospital committees to decide on a case-by-case basis. All these themes make the policy and regulatory interest of the European Union both desirable and appropriate with respect to its competencies and goals (Ruud ter Meulen, 2013; Coenen, Schuijff & Smits, 2011).

7. The need for an analytical approach and selection of case studies

Given the great number of potential applications of robotics, and the extreme variety of the features they exhibit, an analytical approach had to be adopted, in order to carry out an investigation that could be at the same time exhaustive and precise, but also could give room for further generalization.

In fact, the RoboLaw project did not start with a pre-defined set of applications to analyse, but it had a more general (and ambitious) objective, that is, the regulation of emerging robotic technologies. However, given the reason just provided above, concerning the impossibility to deal with robotics as a homogenous field, because of the peculiarities of each application, it was decided to adopt a case-by-case approach.[10]

[10] The focus is on applications of robots rather than single technologies for mainly two evident reasons: the impossibility to isolate a technology or system from its context of use including the operative

It is now necessary to clarify why, out of hundreds of possible applications, the RoboLaw consortium decided to focus on four specific cases, namely: self-driving vehicles, surgical robots, robotic prostheses, and care robots.

The method used for identifying the applications and justifying their selection derives mainly from practical qualitative and quantitative reasons. First of all, as to the quality, that is, to the type of applications selected, the choice was mainly dictated by the availability of engineering and legal expertise within the RoboLaw consortium. In other words, aware of the importance of relaying on a deep understanding of the working of the technologies (i.e. hardware and software), as well as of the legal and ethical implications, it was decided to restrict the choice only to the applications for which the RoboLaw consortium possessed both substantial engineering as well as legal knowledge.[11]

As a result, the adoption of this criterion can explain the exclusion of some ethically and legally relevant application. Among the most remarkable missing case is, for instance, military robotics, which is due to the lack of expertise in international military law within the consortium. Similarly, the lack of applications involving drones and underwater robots, although they are relevant research areas at UoR and SSSA, respectively, is due to the absence of expertise in their specific regulatory frameworks, i.e. law of aerial space and maritime law.

Secondly, as far as the quantity of the cases is concerned, the short life span of the project (i.e. 27 months) and the structure of the workplan, with less than 12 months dedicated to the ethical and legal analysis, restricted the choice to a very limited number of cases.

Although the cases selected are neither exhaustive (the absence of softbots, drones, nanorobots and military applications is illustrative), nor exemplary with respect to the ethical and legal implications raised by robots, nevertheless, they offer a wide range of topics (identified in the categories of the taxonomy discussed above, see § 3) which are shared by many robots.

With regards task, the four case studies selected can be to distinguished into two major application domains: healthcare (i.e. prostheses, care and robotic assisted surgery) and logistics (i.e. self-driving cars), which can be further sub-divided into more specific tasks: on the one hand surgery, prosthetics, and assistance, and, on the other, mobility. Three different types of operative environments can be identified, both public and private: public roads (for self-driving cars), domestic settings (for care robots), and the human body (for prostheses and robotic assisted surgery). As far as the robot nature is concerned, all the cases selected belong to the category of "embodied" robots; however, it is possible to further distinguish between machines (i.e. robotic assisted surgery, care robots, and self-driving cars) and hybrid-bionic systems (i.e. prostheses, active orthoses and exoskeletons). Finally, concerning the category human-robot interaction, the cases offer several kinds of relations between robots and human beings: from functional substitution or augmentation of human capabilities and anatomical connection with the human

environment and the users and the impossibility to focus on a single technology since the majority of technologies do not work in isolation but rather as components of technological systems. For instance, a relevant feature such as autonomy consists of the integration of different hardware and software technologies, like sensors for perceptual capabilities and controllers for data processing. Among all technologies robotics is definitely one of the most multidisciplinary.

[11] An overview of the research activities carried out at SSSA and UoR is provided in Salvini & Shah (2013).

body (i.e. prostheses, orthoses and exoskeletons), instrumental relation with professional operators (i.e. robotic assisted surgery), to emotional attachment and social interaction with non professional users (i.e. care robots).

In order to assess whether or not the choice of the case studies was reflected by the perception of the public opinion, an online survey was devised and published on the RoboLaw website.[12] The survey was aimed at identifying the most relevant applications of robots according to a four-items triage[13] consisting of: novelty, imminence, social pervasiveness and utility. Given the limited number of responses, the survey has negligible statistical value. However, the results confirmed the appropriateness of the choice made with respect to the criteria of the triage. Indeed, out the 10 applications proposed (surgical robots, self-driving cars, nanorobots, surveillance drones, companion robots, software agents, sexual robots, telepresence robots, industrial robots and robotic prosthesis), the four cases selected scored the highest values with respect to each item of the triage.[14]

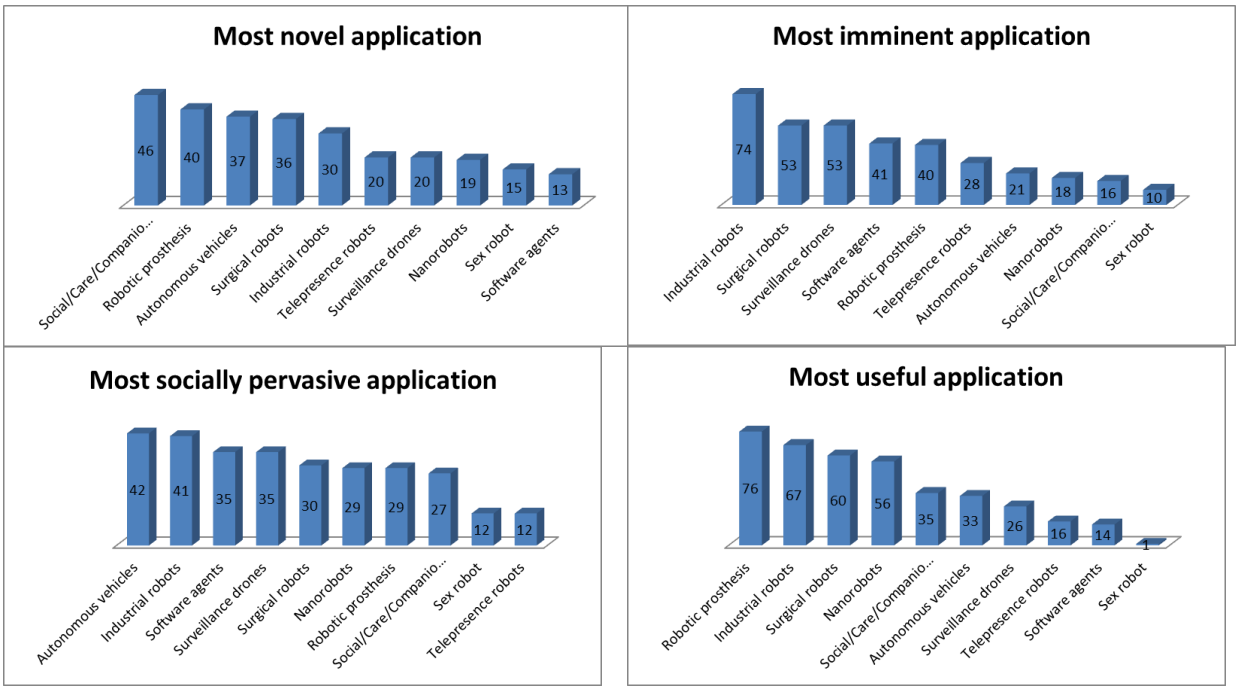

Figure 1 Results of the online survey

[12] The RoboLaw survey is still accessible at: https://docs.google.com/forms/d/1Mhbi2H7XAk5CHfA448SQ2NK0jbgS_p3_0jtqz0xCpBM/viewform

[13] The triage consists of assessing the relevance of a topic by drawing on three or more parameters. In the EU funded project EthicBots (http://ethicbots.na.infn.it/), the triage was used to identify ethically sensitive technologies by means of three parameters: imminence, novelty, and social pervasiveness. The triage depends heavily on the level of expertise of the respondents (i.e. expert vs. layperson). The RoboLaw consortium decided that the triage was too subjective and required too many different competences to be considered as a viable method for the selection of the case studies.

[14] There is just a minor exception concerning imminence, which will be explained later.

With respect to novelty, care robots are considered the most novel application. It is worth pointing out here that novelty measured the degree of newness of the ethical and legal implications brought about by a specific robot application and not the novelty of the application. It is possible to explain such a result by taking into account the outcomes of the Special Eurobarometer survey on public attitudes towards robots (Special Eurobarometer 382, 2012). According to the European survey, which involved more than 20.000 people, among the most relevant worries towards robots is the fear that they may increase social isolation and reduce human contact, in particular in applications targeted at disabled, elderly people and children. Therefore, it seems plausible to assume that, according to the public perception, the potential effects caused by the replacement of human beings with robots in tasks involving human "warm" qualities (i.e. emotional attachment to robots) should be deemed as newest with respect to, for instance, jobs reduction or liability issues, which have been around at least since the Industrial Revolution. It is remarkable that in the first four positions there are the applications selected, namely: care robots (46%), robotic prostheses (40%), autonomous vehicles (37%) and surgical robots (36%).

Autonomous vehicles or self-driving cars resulted to be the most socially pervasive application. In the RoboLaw survey, social pervasiveness measured the level of potential diffusion of a product or service among people (i.e. users and non users). The score received by self-driving cars can be explicated first of all by considering either the fact that cars are already one of the most widespread technological applications and that self driving capabilities could further increase a car usability, by making driving easier and by potentially granting accessibility to currently excluded categories of users (e.g. blind or people affected by quadriplegia). Secondly, the result can be explicated also by taking into account the popularity of self-driving cars among the public opinion, which is due to the extensive coverage received by media (i.e. Google Car) and by the diffusion of automation functionalities in many existing cars (e.g. ABS, autonomous parking system, speed control).

As far as imminence is concerned, in the first position are industrial robots. This result is no surprise if one considers that imminence measured the level of maturity or market readiness of a robot application. Indeed, manufacturing robots has a long history (perhaps the oldest) in robotics applications. The first robot to be deployed in a factory was UNIMATE, in 1962 (Nof, 1999). Nowadays, industrial applications continue to be the most relevant field in the robotic market (IFR, 2014). What may be surprising is that the public perception correctly identified surgical robots as the second most imminent robotic application. Indeed, robots like the da Vinci by Intuitive Surgical Inc. are currently in use in many hospitals worldwide. It seems also correct the position of drones in the third place, which massive usage has been largely demonstrated, especially in military operations. On the contrary, less accurate seems the score received by software agents (in the fourth position), which are currently in use in many web-applications. Such a result can be explained by taking into account both the persistent resistance in considering softbots as robots and their scarce popularity with respect to hardware applications.

Finally, as far as usefulness is concerned, it measures the level of utility of a robot application. In the first position are robotic prostheses, followed by industrial robots and surgical robots. The primacy of medical or health related applications is evidently explained by acknowledging the high social value of these applications.

7.1 A special case for robotics in healthcare.

Three out of the four technologies selected for an in-depth analysis are characterized for their context of application, that of healthcare, and for the underlying function of ensuring better

quality and efficiency in the delivery of medical treatment and care. Robotized surgery (Ch. 3) has been introduced in order to perform operations with more precision, to reach sites into the patient's body without open surgery but with the same accuracy in vision and action, and to gain in terms of time for recovery. Advanced prosthetics, orthoses and exoskeletons (Ch. 4) are meant to improve the quality of life of disabled people by restoring or supporting lost or compromised functions, such as mobility or the ability to grasp objects, more generally all the tasks that a non disabled person is able to perform. Care robots (Ch. 5) also are to be employed for the assistance and care of elderly and disabled people, performing several different functions: from telepresence and monitoring safety, to assisting in daily activities (ex. in fetching objects, reminding of taking drugs, connecting to family or healthcare professionals), to facilitating or correcting the movements.

The technologies examined (and others that have not been included, such as devices for diagnosis, rehabilitation or therapy) define a cluster of applications of robotics that for several different reasons fits very well with the project basic aim and rationale. All of them are triggered by policy tendencies and social phenomena observed in this sector, which efforts in robotics research are trying to correspond to: improvement of the quality of medical treatments (through high precision surgery), attempts to increase independence and social inclusion of vulnerable persons, like the elderly and persons with disabilities, population ageing and demographic change, with expected shortage of (informal and professional) caregivers. These challenges fall quite well within the bundle of competences and sectors of intervention of the European Union: the protection of health and the right of access to healthcare represent fundamental principles established in the Charter of fundamental rights (art. 35), while art. 152 of the EU Treaty identifies the promotion of public health as a core area for the EU action. Therefore the improvement of medical products and procedures, and of safety and efficiency in healthcare delivery are suitable objectives of EU policies to be accomplished also by means of technological progress, particularly in robotics. The free flow of goods in the EU market might also be compromised by different regulations in different countries; in the sector of medicines, the Directive 2001/20/EC on clinical trials has addressed the same problem, providing a common framework that ensures the free marketability of the final products in all MS.

At the same time robotics for healthcare is a domain that more than others requires regulatory intervention and where legislation promoting innovation is called for. A report that was elaborated within the e-Health activities of the European Commission, DG Information Society, in its key policy recommendations, advocates for the inclusion of two 'horizontal lines' on ethical and legal issues in any program devoted to the development of this emerging field (R4H. Robotics for healthcare, 2008: 8). Moreover, it identifies legal issues as one of the most relevant points to focus on in the 'innovation trajectory' (*Ibid.*: 27) and comes to the conclusion that 'it is of crucial importance to solve' them, being otherwise 'major obstacles' to innovation in this field (*Ibid.*: 30). This importance of the legal questions depends on several factors, including the unsuitability of the actual trial procedures, conceived mainly for testing medicines, to experiment medical robotic devices. In the healthcare setting, the added vulnerability of patients and other people with health needs and the close interaction that is required in order to respond to them, entail to comply with stricter standards than in robotics application for human use in general. And the (at least partial) autonomy of robots deployed in care tasks increases the risks of unforeseen behavior, that cannot be properly controlled by an impaired user or in emergency situation. Data protection and data security in the healthcare scenario also figure as relevant concerns to be taken into account while designing a safe environment for robots actions, considering the enormous potential for collecting and storing data – and sensitive data in this case – that robotic technologies display.

In conclusion, a bundle of demographic, social, technological, economic and political factors that orientates the development of this sector makes it also a special case to be analyzed from a legal perspective, and one that qualifies as an effective context of implementation of the policy action of the European Union.

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2. Self-Driving Cars*

* This chapter has been written with contributions by: Huma Shah and Kevin Warwick (§§ 2.1-2.3); Federica Lucivero (§§3.1-3.4); Maurice Schellekens (2.1-2.3; 4.1-4.4).

1 Introduction

How would a traffic warden issue a penalty notice for a motor offence to a robot car – a car without a human driver? Legal expert Bryant Walker Smith warns: 'Rapid progress means self-driving cars are in the fast lane to consumer reality. Is the law up to speed too?' (*New Scientist*, 2012).

Automated driving is a technology that is catching the public imagination with various prototypes driving on European, U.S. and Japanese roads. First signs of the direction of technological development are becoming clear. Now is the time to address the ethical and legal challenges that technology imposes on society. It is not too early: the direction of technological development is slowly becoming clear. And it is not too late: the technology has not matured and only limited functionalities such as adaptive cruise control and automated parking are currently available in the market.

At the moment, the EU invests heavily in R&D, infrastructures and the regulatory environment in order to promote intelligent cars and automated systems. In this respect, the following initiatives can be mentioned: Mobility as one area of the DAFE, various ICT for Transport calls, iMobility forums looking at regulatory aspects, and various SMART support actions. This interest is mirrored in the US with the DARPA challenges for example.

In the regulatory field, much work still has to be done. There is some academic work on legal challenges, but not much on ethical challenges. This case highlights what work still needs to be done and indicates in some instances which directions regulatory developments could take.

In the first section of this report, we explain and define automated cars. In the second section, the different categories of automated driving that are commonly discerned will be explained. It will appear that a development path is foreseen in which a human driver will receive ever more automated assistance in their driving task and in which her role is slowly changing into that of a supervisor for the automated systems on board. Eventually, this may lead to a situation in which the human driver is taken out of the loop altogether. At that point, automated driving will have become autonomous driving. Given that autonomous driving is something for the somewhat more distant future, this case will pay ample attention to the intermediate stages of development. A separate, but linked, development is that of cooperative driving, for example platooning. The case analysis in this report will be restricted to the civilian use of automated cars. Military use, which partially involves other issues, is not addressed. The third section will make an inventory of outstanding ethical issues and value conflicts that need to be taken into account at this stage of technological development. The fourth section will address legal challenges and focus particularly on the issue of the chilling effects of liability law: could liability rules that are too strict impede innovation in the field?

2 Technological Overview

2.1 Definition and categorization

In the Robolaw project as a whole, a broad definition of robotics is used so as to encompass any interesting technologies. For the purpose of this deliverable, an automated car is characterized as having the capabilities of sensing, planning and acting. In this way automated cars are distinguished from the currently available technologies of driver assistance (such as cruise control). The State of Nevada interprets 'the term "autonomous vehicle" to exclude a vehicle enabled with a safety system or driver assistance system, including, without limitation, a system to provide electronic blind spot assistance, crash avoidance, emergency braking, parking assistance, adaptive cruise control, lane keep assistance, lane departure warnings and traffic jam and queuing assistance, unless the vehicle is also enabled with artificial intelligence and technology that allows the vehicle to carry out all the mechanical operations of driving without the active control or continuous monitoring of a natural person'. This definition is somewhat narrower than the one we envisage. It appears to exclude all technologies that function autonomously, but require the driver to monitor the functioning of the system continuously and to be able to intervene immediately. With these systems the human driver is apparently fully responsible. And in this respect they exhibit no legally relevant difference to human driven cars.

2.2 Overview of what is available on the market or as a research prototype

Technologies available on the market are functionalities that are built into existing human driven cars. They are usually marketed as functionalities that increase the comfort of the driver. Typical examples are adaptive cruise control, park assist and lane keeping. Adaptive cruise control attunes the speed of the car to that of the car driving in front of it. Park assist can parallel park a car without intervention of the driver. Lane keeping warns the driver when the car wanders out of the lane he is driving in. Common to these technologies is that they address only specific situations. Also, the driver is in full control and can intervene at any moment.

There are many prototypes being tested that drive (almost) completely autonomously. Many car manufacturers test automated vehicles, as do some non-car-manufacturers, such as Google. Google has a fleet of circa 10 automated vehicles. They are normal cars with additional equipment – such as a light radar and lasers – built into them. The software that controls the vehicle is called Google Chauffeur. Nevada and California have amended their legislation to allow these prototypes on their streets. Legally, a human is required to be in the driver's seat. In May 2014, Google presented its first autonomous car that they built entirely by themselves. This car has no steering wheel or pedals. It can drive around with a maximum speed of 25 Mph.

The AutoNOMOS Group at Free University of Berlin developed two prototypes that drive in the streets of Berlin. The specific goal this group chose for itself was to develop a self-driving car that can handle urban environments. Additional features tested on the prototype called 'Spirit-of-Berlin' include remote control through an iPhone or iPad, an eye-tracking system and a Brain-Computer-Interface.

2.3 Main technological challenges

Impressive demonstrations of automated cars driving on public roads are regularly reported in news media. Furthermore, some technologies are already on the market, such as adaptive cruise control, lane keeping and automated parking. This may give the impression that the technology is nearly market-ready. However, when probing deeper into the state-of-the-art it becomes clear that the demonstrations take place under favourable conditions (e.g. driving on a highway). The technologies available on in the market concern specific tasks only. The surrounding conditions under which these specific tasks are performed are relatively stable. In fact, there are still many technical challenges ahead on the road towards fully automated cars. According to experts, the following technical challenges exist:

- 'there are technical challenges, such as the speed of response from the sensors, their sensitivity to low-light conditions, and their capability to identify the essential information and avoid interference'.
- 'Google calls this the dog-food stage: not quite fit for human consumption. 'The risk is too high', Thrun says. 'You would never accept it.' The car has trouble in the rain, for instance, when its lasers bounce off shiny surfaces. (The first drops call forth a small icon of a cloud onscreen and a voice warning that auto-drive will soon disengage.) It can't tell wet concrete from dry or fresh asphalt from firm. It can't hear a traffic cop's whistle or follow hand signals.'

2.4 Future perspectives (in the middle term)

Classification of the technology development path: The German BASt-project group identified three degrees of automation: partial-, high- and full automation (Gasser, 2012). Partial automation means automation that controls the longitudinal and transverse direction of the car, but the driver has to be ready to take over control instantly at any moment. High automation refers to that type of automation where the longitudinal and transverse direction of the car are controlled by the system, which knows its own limitations and can detect, well in advance, situations it is unable to cope with. In such situations the system will ask the human driver to resume control well ahead of time. While the car is driving robotically, the driver can turn his attention away from driving the car and to something else. Full automation is the same as high automation except that, in addition, the system brings the car in a safe state if the driver fails to resume control once she is asked to do so. This means, for example, that the system is able to park the car on the hard shoulder if it foresees that it will be overcharged and the human driver does not react.

Car manufacturers have predicted when automated cars are expected to enter the market. Most predictions project a date somewhere around 2020. At the Robolaw stakeholder meeting, the attending representation of a car manufacturer indicated that fully automated cars will not be market-ready for another 10 years.

2.5 The environment in which a robotic car operates

The modern idea of a driverless car is made real by the technologies available to enable it to maneuver around existing environments (motorways, dual/single carriageways, primary and minor bypass routes, high streets and residential roads) rather than building special arteries keeping the robot car away from human drivers. The future driverless car, a "super computer on wheels", will incorporate crash avoidance onboard sensors, stored maps, inter-vehicle communication devices. It will always know where on the road it is as it looks around (Hodson,

2013). And it will have 'the potential to adapt to existing infrastructure rather than requiring it to alter for them' (KCRA News, 2013; Smith, 2012). It can also have lasers, small cameras to 'take the strain' of remembering regular journeys (Oxford University, 2013), such as driving children to school.

The likely development is that the intelligence is packed into the robotic car itself and not so much into the road infrastructure.[1] Governments do not have the financial resources to equip their roads with capability for guidance of robotic cars. The road network is too elaborate for that. This, however, does not mean that a robotic car will be able to learn about its environment only through its own sensors. It will have some help from outside other than through capabilities built into the road. Examples are navigation systems relying on satellites and communication between cars. An example of the latter development is the Car-to-X project.[2]

2.6 Reasons for automated cars

One of the main expected benefits of automated cars is a reduction in car accidents by eliminating human error that causes accidents. At the same time, autonomic technology introduces new sources of errors. Humans design automated cars. So, even if they stop driving them, some risk of accident due to design flaws, overlooked features or unintended consequences of designs remains. The technical challenge is to overcome these risks and reduce them to acceptable levels. What society considers to be an acceptable level of safety remains elusive for the moment. A combination of experience with automated cars and public discussion could bring more clarity on what is an acceptable level of safety.

Another important reason for developing automated cars is the assistance they could provide for those with mobility issues, such as ageing humans. As an example, the solution provided by Japan's ROPIT (robot personal intelligent transport system) single-passenger robot car (Poulteny, 2013) may be mentioned.

3. Ethical Analysis

Research institutes and businesses are currently investing in the development of automated cars, while governments need to deal with new challenges that this technology introduces into the current system. In order to better understand the nature of these challenges, a closer look at current discussions concerning automated cars is needed. Why are automated cars considered beneficial for societies by institutions, manufacturers, and the public? What are the arguments against automated driving put forward by opponents? Addressing these questions is a way to describe the ethical controversies and debates about the (un)desirability of these technologies. This is a first step in order to explore the expected value conflicts that policy-makers will need to take into account and balance off when regulating these technologies. The objective of the following ethical analysis is to offer such an overview.

[1] Erico Guizzo, How Google's Self-Driving Car Works, IEEE Spectrum 18 November 2011. Available at: http://spectrum.ieee.org/automaton/robotics/artificial-intelligence/how-google-self-driving-car-works .

[2] Press Information BMW, 21 October 2011. When cars talk to each other. Car-to-x – the communication platform of the future. Available at: https://www.press.bmwgroup.com/global/startpage.html .

Based on the methodology for ethical analysis of robotic technologies outlined in RoboLaw D5.6 (Bisol *et al.*, 2013), in § 3.1, the "normative" expectations and "value statements" concerning the benefits and disadvantages of automated cars are reviewed, following a literature review of existing discussions on this topic. Benefits and disadvantages of automated cars are not only debated issues, but they can also be inferred to by exploring the values that are inscribed in design choices as well as in socio-technical practices. This will be the scope of § 3.2. Based on this analysis of values in design choices and social configurations, § 3.3 maps some critical issues, pointing towards ethical conflicts and open disputes that need to be taken into account at this stage of technological development when relevant decisions are made. Finally, in the conclusion (§ 3.4) some lessons for policy makers are drawn.

3.1 Promises and threats of automated cars

The societal desirability of automated driving is fiercely debated among stakeholders. Proponents champion the numerous ways in which automated cars will benefit society, while opponents ponder on their unwanted side effects and disadvantages. In either case, societal and moral values are employed. Mapping these values in current debates is crucial in order to address the question of the "goodness" of automated cars and the ethical issues they may arise.

On May 19th 2010, the European Commission launched the Digital Agenda for Europe, a flagship initiative within Europe 2020, a 10-year strategy for the advancement of the EU economy.[3] This initiative assumes that digital technologies can help societies and policy makers to address several challenges. Mobility is one of the areas of application of the digital agenda: 'Human error is involved in 95% of all traffic accidents on Europe's roads, in which more than 30 000 people are killed and 1.5 million injured every year. Road transport also burns one quarter of the European Union's overall energy consumption, with one fifth of the EU's CO2 emissions caused by road vehicles. eSafety "smart" technologies, based on the powers of computers and telecoms, can make a major difference to these figures.'[4]

Highly automated cars are expected to increase traffic safety by reducing accidents due to human errors, such as the driver's distraction or reduced vigilance. Furthermore, the promise of intelligent cars and infrastructures is to reduce fuel consumption and optimize driving styles while reducing traffic congestion. The values of "safety" of drivers and road users and "sustainability" (as reduction of pollutants) seem to justify European investments in research on automated vehicles: 'Intelligent Transports Systems (ITS) make transport more efficient, faster, easier and reliable. The focus is on smart solutions to integrate passenger and freight flows across transport modes and provide sustainable solutions to infrastructure bottlenecks affecting roads, railways, sky, sea and waterways.' (COM, 2010 p.34)

The value of safety is connected here to what could be referred to as the value of "assistance" to the user: by reducing human factor related accidents, the automation of driving functions allows the driver to reduce vigilance and be more relaxed while driving. Furthermore, the value of sustainability is not only promoted because of the efficiency of the system and the resulting reduction of emission, but also by some social practices enabled by automated cars. This aspect is clearly highlighted by Sebastian Thrun, former researcher in Artificial Intelligence at Stanford and head of the Stanford team who developed Stanley – the winning robot in the 2005 DARPA Grand

[3] See http://ec.europa.eu/europe2020/index_en.htm.

[4] Retrieved on April 3rd 2014 from http://ec.europa.eu/digital-agenda/en/about-mobility.

Challenge – and currently employed at Google. According to Thrun, automated cars have a huge potential in car sharing with important consequences for the environment: 'What if we could, on the click of a button, order a rental car straight to us. And once at our destination, we wasted no time looking for a parking; instead we just let the car drive away to pick up its next customer. Such a vision could drastically reduce the number of cars needed, and also free up important other resources, such as space consumed by parked cars. Perhaps in the future, most of us share cars, enabled through robotic technology' (Thrun 2010, 105).

Automated cars are expected to increase traffic **safety** by reducing accidents, to improve traffic **efficiency** by smartly distributing traffic among lanes, to be **sustainable** by reducing emissions of pollutants. Another aspect that emerges from an exploratory review of the media discussion is the potential role of automated cars to increase **accessibility** to transportation for the elderly or people with disabilities that do not allow them to drive.[5] This aspect emerges in particular in one of Google's demonstrations of self-driving cars with a blind person in the driver's seat[6] as well as in the attention of United Spinal, one of the major stakeholders in the US disability community, for Google's research on automated car.[7] Safety, sustainability, efficiency, and accessibility constitute the broad range of values used in technology promoters' and policy discourses on automated cars.

As it always happens in debates about new technologies, not everyone agrees with enthusiastic views about the societal benefits of technological innovations. Several voices in popular magazines, blogs and forums have raised scepticism about the desirability of automated cars for society. In a post published on *The Atlantic* philosopher Patrick Lin raises the issue of the "trolley paradox". Imagine, he says, that train conductors are in a situation in which they have to decide whether to deviate the train and kill one person or maintain the direction and kill five persons on the track (Lin, 2013). In this "no win scenario", whatever decision the conductor will make, the result will be not good. In complicated cases, making a "good" decision requires to take into account a broad range of issues: a machine guided by an algorithm that aims to reduce damages to people or objects may not be able to identify and account for these issues. Lin argues that an ethics of numbers is not enough and in some cases is not desirable. According to Lin, a computer program does not have the capability to make life-threatening decisions which require moral judgment. In a no-win scenario, for example, in which one of the cars potentially involved in an accident carries children the moral judgement of the driver may opt for a decision that may be less cost-efficient (hitting two cars or injuring more persons) in order to protect a sensitive category. Automated systems are unable to engage in moral judgments as such. In fact, moral judgments require several moral skills that transcend the rational calculus between positive and negative effects and are therefore a human capacity. Furthermore, as Lin argues elsewhere[8] crash avoidance algorithms can be biased in the way they formalize the right behaviour in a specific context. Lin's conclusion is that automated cars should not go unsupervised and they always

[5] See http://www.disabled-world.com/disability/transport/autonomous-vehicles.php. Retrieved on May 29, 2014.

[6] http://www.disabilitynow.org.uk/article/self-driving-lets-car-take-strain. Retrieved on May 29, 2014.

[7] See http://www.unitedspinal.org/united-spinal-works-with-google-on-self-driving-car/. Retrieved on May 29, 2014.

[8] P. Lin, The robot car of tomorrow may just be programmed to hit you, May 6, 2014. Retrieved on May 29, 2014 from: http://cyberlaw.stanford.edu/publications/robot-car-tomorrow-may-just-be-programmed-hit-you.

require a human who is ready to make difficult decisions. It is important to remark that Lin does not conclude that automated cars should be banned because of the level of risk they imply. The argument that he brings forward does not condemn automated cars due to their inability to prevent certain no win scenarios, which may also occur in fully manual systems. Instead, his argument is that automated systems are not able to engage in moral judgments that are required for deliberation in these difficult situations. The moral judgment of the human supervisor is, therefore, necessary in order to make morally sound decisions in extreme situations.

A different position is taken by the supporters of machine intelligence who argue for the possibility of artificial moral agents. Noah Goodall (2014) acknowledges the inevitability of crashs both in automated and human controlled systems. If injury cannot be avoided, the system will have to decide the best way to crash. This is a complicated matter: if a car has to decide whether to collide with a motorbike driver wearing a helmet or one who is not wearing a helmet, would it be fair for it to crash into the first one in order to reduce the harm? Is it fair to penalize the driver who is complying with the law in order to protect the one who is not? Contrary to Lin, Goodall embraces an approach to machine ethics that explores the possibilities of building artificial moral agents (AMAs), that do not necessarily emulate human cognitive faculties but still function satisfactorily in morally significant situations (Allen *et al.*, 2005). Goodall grants computers and automated systems the capability to detect conditions accurately and to compute the most desirable and morally sound outcome. In the case of ethical decisions, according to Goodall, existing deontological and consequentialist approaches cannot be processed by automated systems. In fact, abstract rule-based approaches (for example, Asimov's laws that prescribe how a robot *should* behave) do not always determine a unique course of action and consequentialist approaches that quantify harm and damages do not always consider other relevant moral criteria (e.g. fairness and equality). He therefore suggests the use of an artificial intelligence approach, where automated systems increasingly learn from human behaviour through a neural network system. This solution still presents some problems. For example, one could argue that each individual holds a diverse range of moral stances that make them act differently in the same situation. How can one justify one moral model in a car vis-a-vis another (Gopnik, 2014)? A recurrent point in the literature and media[9] is that robots can follow the letter of the law, but they cannot interpret it. Therefore, automated cars may be designed to respect traffic codes. But they will not be able to make important decisions that may require the bending or infringement of the law. As pointed out in the British Royal Academy of Engineering, 'autonomous systems require people to give up some of their own choice and agency' (Royal Academy of Engineering, 2009: 3) and the extent to which this is desirable is debated.

In opposition to the previously discussed potential benefits for disabled and elderly users, some issues have been raised about the potential exclusion of non-users. Intelligent cars require intelligent infrastructures, which may not be suitable anymore for current vehicles (see Royal Academy of Engineering, 2009: 6-7). Furthermore, the increasing standard of safety may become the rule in few years time when cars that are perfectly functioning today will be considered old-fashioned and unsafe (Marcus, 2012). Thus, if it is true that automated cars enable the unskilled (people who can't drive), the disabled or elderly persons to sit behind the wheel (Hill, 2012), self-driving cars can make the driving experience more accessible for some users and less for other users who resist, for financial, esthetical or other reasons, to adopt the new system. To what extent

[9] See also Marcus, 2012.

the value of accessibility will indeed be actualized in concrete or produce new inequalities is still debated.[10]

3.2 Uncovering values in user-vehicle interaction

So far we have seen how normativity and values can be articulated in discourses about automated cars. Policy makers, technology developers, ethicists and journalists mobilize different values and arguments to justify or criticize the societal desirability and "goodness"[11] of these technologies. Values, however, are not only mobilized in discourses and expectations. They can also be elicited in design choices and in the social practices of automated driving, where they often remain implicit. As highlighted in previous deliverables of this project (Lucivero *et al.*, 2013; Lucivero & Leenes, 2014; Bisol, Carnevale & Lucivero, 2013), technological design is not simply dictated by functional choices, but also inspired or guided by what designers' value or think will be valued by society and users (Friedman *et al.*, 2003). This is also the case for automated cars. When engineers and manufacturers make design choices, they take into account that the automated car must be "safe", "efficient", "sustainable", and "user friendly". These values are translated into specific material functionalities and specifications (see van der Poel, 2009). One example of this concerns the difference in design for offering information to the human driver/supervisor about the car's status. Human-machine interaction is a very crucial topic in the automated car research and development. In fact, automated car developers acknowledge that automated cars put the human driver in a very unusual situation where their role shifts from "manual controller" to "supervisor" (Hoogendoorn *et al.*, 2014). This requires an adaptation of driving behaviour, which is important to monitor, in order to predict possible unexpected consequences due to drivers' lack of awareness or vigilance.[12] The figure below (Figure 2, Figure 3 and Figure 4) (from Schijndel-de Nooij *et al.*, 2011), shows the different ways in which manufacturers and projects (BMW, Daimler and HaveIt) have addressed the issue of Human-Machine Interfaces (HMIs). They all want to find a balance between keeping the driver aware of the process and avoiding an overload of information that would make the experience of driving unpleasant and stressful (for some drivers). However, technical specifications and functionalities differ and ultimately provide a different experience for the driver.

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[10] It is interesting that a broader body of academic literature focuses on unmanned vehicles for military purposes (Asaro, 2008, Sparrow, 2007, Borenstein, 2008, among others). Sharkey (2012) argues that the distance from the battlefield and analogy between the experience of guiding a drone at a distance and a computer game may reduce soldiers capabilities to "feel" the enemy and being in danger with consequences such as causing unnecessary or non-proportional harm. Other ethical analyses on the topic present some positive accounts of automation. According to Ron Arkin's ethical assessment of military robots (Georgia Institute of Technology), human behaviour on the battlefield rarely promotes warfare core values (such as loyalty, duty, respect, integrity, etc.). On the contrary, soldiers often infringe upon these values. In this sense, automated vehicles can act in a more ethical way, not only because they are more efficient, but also because they do not have emotions that emerge in stressful situations. Hence, they can behave more respectfully towards the enemy and report infractions (Arkin, 2007). Coeckelbergh (2013) explains that, in the case of drones, the remote control does not necessarily create an epistemic/moral distance of the human controller from the battlefield. In fact, powerful cameras in unmanned (air) vehicles allow the controller to have an even closer experience of the battlefield.

[11] For the use of the concept of "goodness" as a criterion to guide ethical analysis see Willems and Pols (2010).

[12] See also EU projects working on "human factors" in automated driving: http://adaptation-itn.eu and https://sites.google.com/site/itnhfauto/.

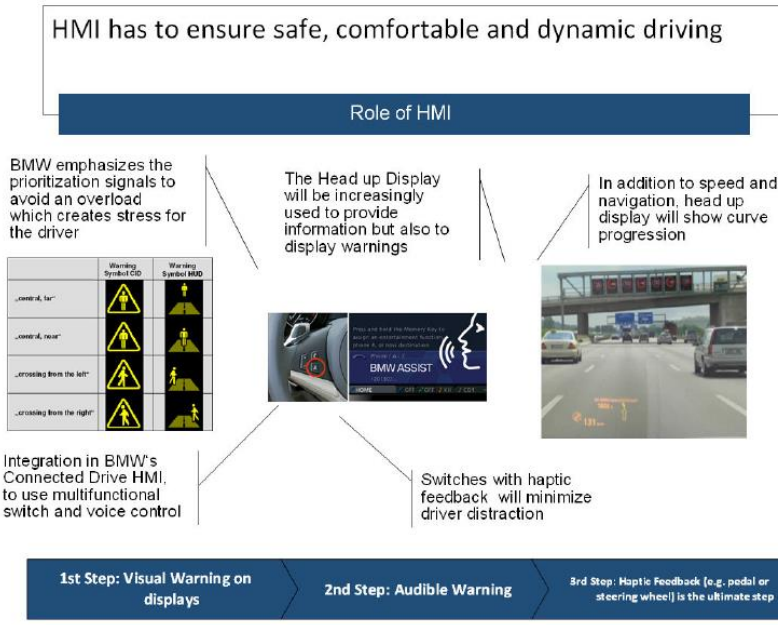

Figure 2 BMW examples of Human Machine Interfaces (Schijndel-de Nooij *et al.*, 2011)

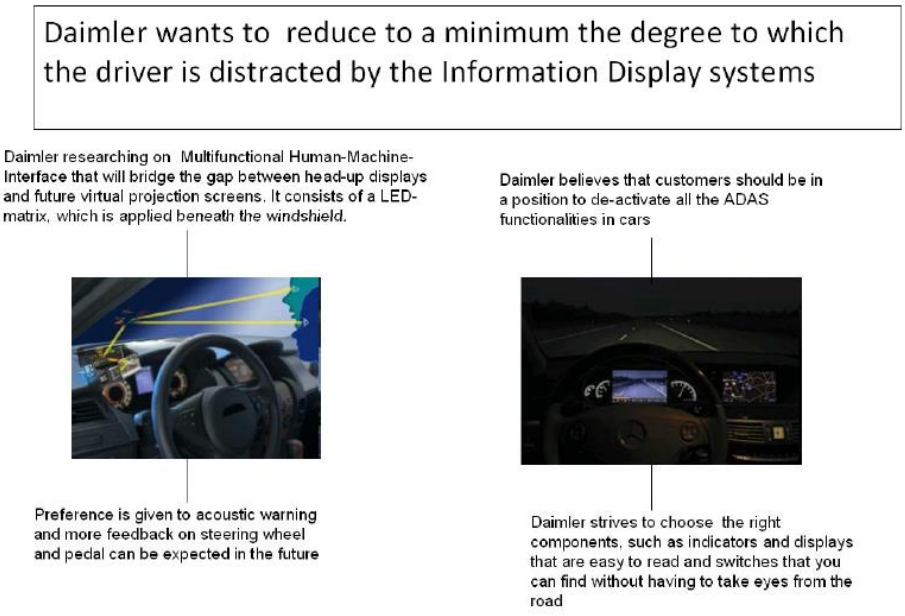

Figure 3 Daimler examples of Human Machine Interfaces (Schijndel-de Nooij *et al.*, 2011)

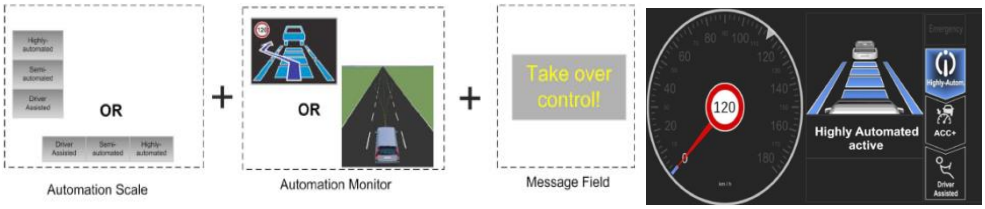

Figure 4 HAVEit display elements (Schijndel-de Nooij *et al.*, 2011)

The choice of the HMIs is important. After all, the way in which information is available to the driver determines whether they will feel in control and behave in the car, deciding to delegate decisions to the system or taking over. For empirical studies testing and predicting drivers' behaviour,[13] it is crucial to take into account the way the HMIs "mediate" human actions and interactions.[14] The philosophy of technology helps here. If we apply the table developed in RoboLaw D4.3 (Lucivero *et al.*, 2013), based on Ihde (1990) and Verbeek (2005)'s types of human-technology relationship, to the case of the automatic cars, different types of relationships can be singled out depending on the automated function and the level of user's adaptation. According to the post-phenomenological perspective, technologies have a role in the way we access the world. In the case of automated cars three types Verbeek's distinction between "pragmatic" and "hermeneutic" mediation as well as Don Ihde's "background relation" seem appropriate to describe the way these objects and their design relate to the users' way of interacting with the world.

- The most obvious relationship that can be expected is "**pragmatic mediation**", in which the user's agency is mediated by the technology. In fact, robotic cars redistribute roles and responsibilities among actors. Drivers delegate some driving and control responsibilities to the car. For example, in the case of automated speed control, the automated car system establishes the speed the car should have on a road. This system removes the human driver from the responsibility of adapting the driving speed in keeping with the existing regulation. In this context, the usual distinctions between the sphere of responsibility of the driver and the manufacturer are blurred and new questions arise. For example, if the car owner receives a speed ticket, who should be responsible for this misdemeanour? Is it the manufacturer, or the infrastructure company, the satellite system or the driver who is still supposed to supervise the system and check whether it obeys road signs? Exploring the forms of this pragmatic mediation in empirical and philosophical studies can help designing both better interfaces and more appropriate regulations. In fact, an exploration of how certain interfaces mediate drivers' actions and their awareness of their roles and responsibilities is a first step to understand whether drivers' perception is correct under the current framework and will lead to a desirable behaviour. This type of analysis can help designers to adapt interfaces in order to mediate drivers' actions differently. It can also help regulators to adapt existing frameworks to this new car-driver hybrid.

[13] The expected behaviour of the driver is difficult to predict and requires empirical studies that should address "average drivers" rather than "expert researchers".

[14] The concept of technological "mediation" is described in RoboLaw D4.3. It refers to the way in which technologies affect human perceptions and actions with consequences for allocation of moral responsibilities among actors (Verbeek, 2005).

- Automated cars can also be expected to enter into a "**hermeneutic mediation**" with the users. In fact, they are likely to mediate the user's perception and understanding of the world. Take as an example the images above, showing different types of HMIs. Different displays offer different types of information, including images of the road and other cars' positions, as well as speed and angles. The system could also specify when a situation requires the driver to take control. This "augmented" reality in the car offers additional information about the road situation which corresponds to a portion of the external word from the driver's perspective. Depending on how this information is provided and visualized, the driver will have a different perception of the danger in one situation or the other drivers' behaviour in another. Such a mediated perception of the road could be crucial in determining the drivers' sense of peril and responsibility as well as their subsequent behaviour. In some cases, for example, it may be beneficial to turn the mediated experience into a simulation of a direct experience. For example, empirical studies could show that it may be beneficial to turn warning signals closer to the everyday experience of the corresponding dangers in terms of perception, cognition and action strategies that are supposed to be executed. For example, the danger of collision may be signalled by the sound of very fast approaching object. Such a stimulus would command the user's entire attention and trigger an immediate and appropriate reaction if it is associated with one class of possible dangers. The desirable type of hermeneutic mediation should be incorporated into the design of human-machine interfaces in order to explore how they alter the users' perception of the outside world and the meanings and representations connected to them.

- When automated cars will be a component of accepted driving practices, they will not be seen or perceived by the driver as a technological mediation with the world. This is the case, for example, when it comes to our heating or electrical systems. Once they are set up, we do not continuously check whether they work properly. In these cases, the technology disappears as far as the user is concerned. It remains in the "**background**" and it only brings itself to the attention of the user when it malfunctions. In this situation, the driver of an automated car could get used to the technology and trust it without exerting any control. A car, however, is not a fridge, and if the system "breaks" and becomes visible in a life-threatening situation, the road or car users can be in serious danger. Therefore, designers and regulators may want to reduce at least this type of relationship between the users and the automated system, by not allowing the user to "forget" about the system and continuously demanding attention or control. This can be done by technical means, by continuously reminding the driver to control the road or by sending sound signals (see as an example the BMW HMIs system). It can also be done by regulatory means, i.e. by according to automated car users the status of drivers. This would, for example, obligate them to pay attention to the road and would require them to hold a driving licence.

The issue here is that the levels of automation and the type of technical specifications (as for example HMIs) create types of human-technology relationships that influence the users' understanding and agency in the world. Human factors in automated driving are determined by the interaction between values and assumptions inscribed in the design and the values, worldviews and beliefs held by the user. This value analysis is crucial in research on human factors and therefore need further study.

Moral values manifest not only in the technical design. They are also materialising in social practices of living and interacting (or even regulating). These practices with technologies are

intrinsically normative (Willelm & Pols, 2010) and the articulation of positions, norms and values – in short, the description of the internal normativity, or intra-normativity, to these practices (Pols, 2013) – is crucial in order to understand what is valued in that practice and what normative conflicts arise with the introduction of a new technology.[15] What is the intra-normativity in driving practices? What is important for drivers? And how do automated cars promote or counteract these values? Driving is a practice that is shaped by cultural and social norms and values. These norms and values can be elicited in drivers' attitudes, practices, ideas (e.g. perceptions of car types, driver characteristics) as well as in the way commercials depict driving experiences and behaviours. Age and gender differences, too, play a crucial role in driving experiences and perceptions (Redshaw, 2008): 'Technology is often heralded as the solution to reducing road death and injury rates, increasingly removing the human factor from the equation. However the values and social norms underlying the current dominant form of mobility cannot be ignored in confronting mobility issues into the future' (*Ibid*.: 154).

Values and social norms are extremely diverse if we consider the different actors who are involved in driving practices: 'In current understandings of mobility the driver or operator of a motor vehicle is seen as the one in control, and the passenger merely subject to that control. An agent of mobility however is not just a driver or operator of a motor vehicle, but is at times a pedestrian, a passenger, and possibly a cyclist. The boundaries between driver and car have become increasingly blurred with new technologies but remain significantly distinguished in cultural terms' (*Ibid.*: 154).

This diversity is even more obvious if we consider the interests and ideas of "good" for the stakeholders and major players in the field of smart mobility (see Figure 5 from the SMART 64 report: 87).

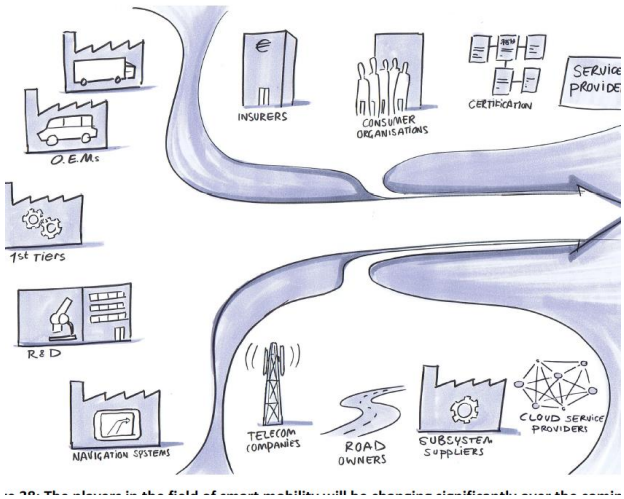

Figure 5 players in the field of smart mobility (Schijndel-de Nooij *et al.*, 2011)

Assessing the ethical issues raised by automated cars requires us, therefore, to elicit values and normative frameworks put forward by different stakeholders and players. Furthermore, the

[15] The concept of "intra-normativity" in social practices is based on an "empirical ethics" approach (Pols 2013) and is introduced in D5.6.

new practice of automated driving should be explored further in order to determine what people value and behave when engaging in driving automated vehicles.

3.3 Mapping critical issues

Automated cars are not good or bad per se. Instead, they "switch on" several ethical issues[16] such as safety (in the sense of protection of life and protection of the environment), surveillance and privacy (data protection, ownership of data, confidentiality), freedom (autonomy, mobility, personality), and justice (accessibility). These values are mobilized by players in the field of automated cars as justifications of their social desirability and by sceptical voices as a motivation of their criticism (see § 3.1). Furthermore, these ideas of "goodness" and normative views about societal benefits are encoded in design choices and enacted in stakeholders' practices (see § 3.2). It is crucial to note that not only some of the values are opposed to others in the discussions between proponents and opponents. Also, some of the values mobilized by proponents are conflicting with others.

Safety VS comfort (of not having to drive)

As explained above, safety is a key value for proponents of automated cars. The ideal of a "safe system" is encoded into technical choices about functionalities and technical specifications of the car. User-friendliness is another important value, since the human controller needs to be able to supervise the system in an easy and accessible way. User-friendliness, however, is also justified in terms of the aesthetics of the driving experience. Manufacturers want drivers to enjoy the driving experience allowing them to focus their attention also on other activities.[17] The importance of the value of comfort and the possibility of multi-tasking is also illustrated by Google's efforts of lobbying in Nevada state to support a bill that would allow occupants to be distracted while sitting behind the wheel and would not fine them for sending text messages (Ackerman, 2011; Markoff, 2011). Texting or being distracted allows automated car users to fully enjoy the "automated driving" experience that does not require their full attention. This is not always in line with the value of safety.[18]

Safety VS freedom

As discussed above, safety in driving practices is promoted by automated cars, thanks to the design of specific functionalities. A classic example concerns the possibility of imposing speed limits in a vehicle's design. Intelligent Speed Adaptation Systems have been tested in real environments as an enhancer of road safety (Oei & Polak, 2002). This form of "techno-regulation" (van den Berg & Leenes, 2013) allows us to steer human behaviour according to some lawful regulation by designing technologies that enable only certain actions. This type of regulation has been criticised

[16] See the criticality map in RoboLaw D5.6.

[17] As an example, see VOLVO's commercial for self-driving at https://www.youtube.com/watch?v=uDB6fFflTVA.

[18] A different type of issue concerns the pleasure derived from manually driving which is jeopardized by the very essence of automated cars. Manufacturers will indeed have to evaluate the importance that drivers attribute to the driving experience in order to ensure that there is, in fact, a demand for automated cars.

as being based on a "big brother" view.[19] The criticisms about the risks of state or private companies' surveillance of drivers' behaviour as well as the paternalistic approach that reduces drivers' freedom for the social benefit show that not everyone agrees about the priority of the value of safety over other values. Safety concerns therefore clash with the value of freedom as well as with the value of protecting your behaviour against other people's gaze (privacy).

Accessibility VS equality

Automated cars offer an opportunity for disabled people to be mobile and have access to places that can only be reached via car. Furthermore, it enables them to independently control a vehicle. This is emblematic in the case of the visually impaired person "driving" the Google car, as featured in one of Google's car trials (Hill, 2012). As mentioned above, automation promotes accessibility and equal opportunities for disabled people. If we look at automated cars from the perspective of the International Classification of Functionalities, Disability and Health (WHO 2001, see also RoboLaw D4.3), we can say that they contribute to enhance "activity and participation capabilities" such as: mobility, interpersonal interactions and relationships (by allowing people to get together but also to talk more in a car), major life areas (education, work employment and economic life which are related to mobility). At the same time, however, we could ask from the perspective of Sen and Nussbaum's "capability approach" (Nussbaum, 2000) whether disabled people do, indeed, have the freedom and opportunity to actualize these functionings – if, in a word, they have the capability to act in a certain way, in this case access places and being independently mobile. Such freedom depends on technical conditions (e.g. full automation), on the regulatory environment (e.g. existing regulation on need for a supervisor of the system who is able to take full control), on the geographical (e.g. presence of infrastructures that allow fully automated vehicles to safely circulate) and on financial conditions (e.g. affordable prices for automated cars). Under these conditions, not only are the capabilities of disabled people not promoted. We might also ask to what extent these technologies broaden the divide between the able-bodied and the disabled as well as between the poor and the rich, raising, therefore issues of equality.[20]

Efficiency VS privacy

Efficiency is an important value in the discourses about and the design of automated cars. This value is intended as a weighted balance of reduced (monetary and environmental) costs of fuel consumption, decreased road usage, increased road users' safety, improved traffic management and flow (reduced congestion). The efficiency in automated systems is highly improved through platooning or lane specific control (Hoogendoorn, 2013; Schijndel-de Nooij *et al.*, 2011). In fact, these smart systems that presuppose a communication between different vehicles and the highway infrastructure allow to control the behaviour of different vehicles in the most efficient way in terms of a balance of traffic management, fuel savings and safety. Vehicle to vehicle (V2V) communication and vehicle to infrastructure communication (V2I) both determine the speed limit on a given road, for example, or establish whether the car ahead is breaking or changing lane. These forms of communication are based on an exchange of information and data. The issue here is to establish the extent to which personal data is transmitted or could eventually be retrieved by public authorities (see Sanfeliu *et al.*, 2010). Whether or not this is the case, concerns about drivers' privacy could

[19] "UK fights EU bid to introduce speed limit devices: European road safety rules would force cars to fit systems that would automatically apply brakes to keep to speed limits". *The Guardian*. Press Association. September 1, 2013.

[20] On the issue of robotics and equality see Pirni & Lucivero (2013).

arise if this data would be accessible and ascribable to a single individual. Efficiency and privacy would seem to be clashing.

This list of conflicting values suggests that some of the issues above should be taken seriously into account at this stage of technological development in order to avoid clashes later. In discourses about automated cars, the societal importance of the value of safety is pointed out. Safety is of course important, but what emerges from the reflections above is that safety is not the only value at stake: comfort, freedom, equality, privacy are also brought forward in practices and debates about automated vehicles. The aesthetics of driving and comfort, freedom, privacy, equality are important values as well and in some cases societies and individuals may want to give them priority under certain conditions. For example, if a basic amount of safety is guaranteed, individuals may prefer to use their mobile phone while driving. Decisions that involve design, regulation, policy and use of automated cars will most likely engage stakeholders in a negotiation among these values. Manufacturers for example will have to weigh the safety of the vehicle against the comfort of driving, in order to make their products marketable. Regulators may decide to give up some safety that would result from a complete monitoring of the road traffic in order to protect the drivers' right to privacy and protect their personal data.

3.4 Policy considerations

The ethical analysis of automated cars offers a number of conclusions and recommendations for policy makers:

- Beside issues of safety and reliability testing, regulations and challenges concerning the human factor, it is important to look at how automated cars affect and/or interact with social norms and moral values. This is undermined so far.

- Ethical issues of automation go beyond "no win scenarios" presented in the literature. Which values are given priority in the design of these cars? What are the tradeoffs between, say, safety, efficiency and comfort? An analysis of values at stake is needed at this stage of technological development in order to make informed choices on preferable designs and policies.

- In the study of "human factors", empirical studies should also engage in qualitative descriptions of how automated driving mediates the users' understanding of and agency in the world. This is important for example in order to design systems in which responsibilities and roles are optimally distributed among human actors and technologies.

- Several critical issues have been highlighted: safety vs comfort, safety vs freedom, efficiency vs privacy and accessibility vs equality. These issues show that some values are competing within the very discourses of promoters of automated cars and should be addressed well in advance in order to avoid the polarization of the ethical debate in the future.

These conclusions suggest that an attention to the values at stake needs to accompany current attempts to design appropriate policies, technologies and regulations. For each issue and context, the relevant and conflicting values will need to be elicited and acknowledged. This can be done in different contexts including the developmental process involving the technology as well as at the policy and regulatory level. This attention to values is important in order to guarantee that

different social and moral concerns are explicitly addressed and choices are justified, avoiding to paint the entire situation with the same "safety" colour and only implicitly dealing with the other issues.

Technology and society shape accepted morals as well as existing regulation based on this normative background. Existing laws against reckless driving that require drivers to be attentive and vigilant, for example, are grounded on the value of "safety" for road users. However, new technologies change our perspectives on what is safe. Automated cars' proponents suggest that it is safer to have the system in charge because it is safer than humans. In order to make policy decisions concerning automated cars it is therefore important to analyse the moral values in transport policies and existing legislation, to reflect on how automated driving systems promote and counteract these values in their design and to give them a different meaning.

4 Legal Analysis

4.1 Introduction

The legal analysis will concentrate on one pressing issue: the liability of manufacturers for defective – in the sense of unsafe – automated cars and the influence this type of liability has on innovation in the field of automated cars. In particular, the question is asked whether liability rules may slow down innovation and how this could be addressed. The analysis presents a vision on this topic. This vision helps the discussion about further development of regulation in the field and makes clear which research is still needed.

The liability of the manufacturer is not the only legal issue that automated cars raise. Hereinafter other issues will shortly be mentioned. These other issues may, to a smaller or larger extent, influence the main question addressed here.

The following 'other' areas in which regulation may be required can be mentioned:

- The EC rules for type approval or at least the technical standards by which the type approval is decided need to be adapted to accommodate automated cars.[21] Authorities are struggling to define the technical requirements that an automated car must meet. The Dutch Rijksdienst voor het Wegverkeer foresees a gradual growth path in which components of an automated system are certified individually. This step-by-step approach will, in the long run, lead to a full certification for automated cars.[22]
- The rules for periodic technical inspections (such as the British MoT, the German TuV and AU and the Dutch APK) or at least the technical standards on whose basis these inspections take place may need to be adapted.[23] These rules are currently

[21] See Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers and of systems, components and separate technical units intended for such vehicles.

[22] Based on oral statements of a senior representative of RDW.

[23] Directive 2009/40/EC of the European Parliament and of the Council of 6 May 2009 on roadworthiness tests for motor vehicles and their trailers.

under revision in the so-called roadworthiness package.[24] Automated cars are not addressed in this revision.

- Rules about driver's licenses may need to be scrutinized. Are the current examinations adequate to prepare drivers for automated cars? What kind of license, if any, is needed for automated cars? Should all users of driverless cars be able to and have a licence to drive, or can they be novices?
- Technical standards for roads may require attention. The regulatory needs in this field are probably limited, given the technical direction automated driving takes: intelligence is built into the car rather than in the road.
- For the foreseeable future there will be a need for automated cars to rely on the human driver to resume control. Additional research in HMI is needed to discover the best ways in which human and car could interact. A regulatory need arises in that it may be necessary to ensure a certain extent of uniformity in these HMI, so that drivers using cars from different manufacturers do not get confused. Possibly, standardisation in this field is needed.
- Privacy issues may have to be dealt with. If all intelligence for automated driving is built into the car the privacy questions will be very limited (e.g. access of police or other government to data logged by the car). As we saw in the section about the state-of-the-art some form of communication between the car and the outside world is likely to take place. Examples are exchanges of data with navigation providers or exchanges with other cars on the road. Where exchanges of data take place privacy issues become more sensitive since these exchanged data may relate to identifiable persons such as the drivers and/or users of automated cars and perhaps other road users that the sensors of the car detect.[25]
- Upon the advent of automated cars, traffic rules may need to be adapted. An oft-mentioned example is art. 8 Vienna Convention that requires a vehicle to have a driver.[26] Another example is Google who are striving to change the laws forbidding a driver to use a mobile phone while driving; this is a prohibition that may be superfluous and unnecessarily restrictive when highly and fully automated cars are used.

4.2 A Legal definition

Four US states have enacted legislation that defines autonomous vehicles. The definitions can be found in the annex. In the table below, the core elements of the definitions have been reproduced. Below the table, an analysis of the definitions is undertaken.

[24] http://europa.eu/rapid/press-release_MEMO-12-555_en.htm

[25] Compare Article 29 Working Party, Working document on data protection and privacy implications in eCall initiative, 1609/06/EN, WP 125, 26 September 2006 and Opinion of the European Data Protection Supervisor on the Communication from the Commission on an Action Plan for the Deployment of Intelligent Transport Systems in Europe and the accompanying proposal for a Directive of the European Parliament and of the Council laying down the framework for the deployment of Intelligent Transport Systems in the field of road transport and for interfaces with other transport modes (2010/C 47/02), OJ C 47/6, 25 February 2010.

[26] Convention on Road Traffic, Vienna, November 8, 1968, 1042 U.N.T.S. 17.

TABLE 1 Analysis of the definitions

	Nevada	***California***	***Michigan***	***Florida***
Means	vehicle is also enabled with artificial intelligence and technology that	vehicle equipped with technology that	a motor vehicle on which automated technology has been installed, either by a manufacturer of automated technology or an upfitter that	Any vehicle equipped with autonomous technology
Purpose of the means	allows the vehicle to carry out all the mechanical operations of driving	has the capability of operating or driving the vehicle	enables the motor vehicle to be operated	that has the capability to drive the vehicle on which the technology is installed
Way of operating the means	without the active control or continuous monitoring of a natural person	without the active physical control or monitoring of a natural person	without any control or monitoring by a human operator	without the active control or monitoring by a human operator

The definitions have roughly the same structure. They describe the means of autonomous driving, the purpose of the means and the way in which the means are operated. Furthermore, the definitions of Nevada, Michigan and Florida mention many examples of technologies belonging to the category of partial automation as being excluded from the definition. These lists have not been included in the table above.

In the description of the means the Californian definition is the most succinct. The definition of Nevada mentions artificial intelligence and is therewith rather specific. It is not completely clear why artificial intelligence is mentioned. Perhaps, it is meant to exclude a conventional car with a brick on the accelerator from the definition. The definitions of Michigan and Florida both contain the word “automated” or “autonomous”. This makes their definitions recursive.

The description of the purpose of the means also differs between states. The Nevada definition does not appear to be completely sharp. By speaking of ‘carrying out all the mechanical operations of driving, the element of control is not clearly expressed: the technology controls the driving behaviour of the vehicle. The definition in Michigan uses the passive form (to be operated) thus leaving some doubt as to who is operating the vehicle: man or machine? Elsewhere in the definition a human operator is mentioned, hence it is probably meant that a human is operating the vehicle in the sense of using the vehicle. This use of the word ‘operating’ is a little confusing. The definitions of California and Florida are sharper in that they state that the technology drives the vehicle.

The way in which the means are operated also differs between states. All definitions state that control or monitoring by a natural person in one form or another is lacking. The definition in Michigan is the strictest. It does not allow any control or monitoring by a human operator. Maybe this is a bit too stringent. Automated cars with high automation (as in the BASt categorization) could be excluded from this definition. The other definitions speak of active (physical) control or (continuous) monitoring. This could be interpreted as leaving room for high automation. The natural person is not actively controlling the vehicle, but can – well in advance – be summoned to take control if the vehicle foresees a situation that it may not master. All partially automated cars are excluded from the definitions. As stated above, this is underlined in that the definitions of Nevada, Michigan and Florida mention many examples of these technologies as being excluded.

Based on the analysis above, the following definition appears to be the best combination of elements.

A vehicle enabled with artificial intelligence and technology that have the capability of operating or driving the vehicle without the active control or monitoring of a natural person.

4.2 Liability Law

This section explains the different functions of liability law and summarises the most relevant types of liability. For the latter, reference is made to deliverable D3.1 (Leenes, 2012) where appropriate.

Function and types

Liability law is about accidents. Accidents are costly. Liability law answers the question whether the costs of accidents are borne by the victim or whether those costs can be transferred to another actor, typically somebody who is in one way or another (co)responsible for the occurrence of the damage. In doing so liability law has two direct goals or functions. On the one hand, liability law tries to minimalize the occurrence and the cost of accidents. This breaks up in two sub-functions of liability law. It should provide an incentive for the "responsible" person to take adequate measures to prevent the occurrence of damage. It should provide for corrective measures when a responsible person falls short of taking adequate measures and another suffers damages as a consequence. On the other hand, liability law protects the victim by providing compensation. This is especially important if the victim cannot bear those costs very well. Examples of the latter may be situations in which the victim is a natural person and the costs are related to injury.

When applying liability law decisions have to be made: How much money, time and effort should a potentially liable actor have spent on preventive measures? How can an equilibrium between the accessibility and the adequacy of compensation for the victim and the burden for the liable party be found? Given the decisions to be made, there is a need for a method to judge them. Roughly speaking, there are two approaches. The one is a utilitarian approach. It may, for example, ask whether decisions are efficient. An example is the famous formula of judge Learned Hand for judging the adequacy of preventive measures. According to this formula preventive measures should be taken if and when they have a value less than the expected damage that would occur if the preventive measures are not taken. The expected damage can be calculated by multiplying the amount of the damage with the probability that the damage will occur. The other approach is duty based. The extent of the preventive measures or the damages to be paid are determined in accordance with legal duties.

The legal systems under consideration have a number of types of liability that are potentially relevant. Hereinafter the different types of liability are shortly described as are the main criteria for liability.

Product liability is strongly harmonised.[27] Under these rules, a producer is liable for damage caused by a defect in his product. A product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including: (a) the presentation of the product; (b) the use to which it could reasonably be expected that the product would be put; (c) the time when the product was put into circulation.

Liability of the holder of a vehicle differs amongst jurisdictions. In Germany, for example, the so-called Halterhaftung is laid down in art. 7(1) StVG. It makes the holder of a motor vehicle liable for damages that follow from the death or injury of a person or damage to an object that occurs in the operation ('Betrieb') of the motor vehicle.

Liability of the driver also differs amongst jurisdictions. In Germany for example, it is laid down in § 18 StVG. The driver is liable under the same conditions as the holder of the vehicle. An important difference is that the driver can escape liability, if he proves that the damage is not caused by his fault. Below, more jurisdictions will be discussed.

Standard of liability

This deliverable deals with the question whether liability law constitutes a disincentive for manufacturers in the sense that they do not bring certain automated technologies to the market or introduce them later out of fear for the consequences that accidents with these technologies may have in terms of liability. So when discussing the standard of liability, the focus is on product liability since this directly affects the manufacturer and the production decisions he makes. Liability of the driver or the holder of the vehicle is of no direct concern to the manufacturer. In the section 'Function and Types', we saw that the standard for product liability is 'the safety a person is entitled to expect'.[28] It is not a subjective standard.[29] The directive indicates that when applying the standard all circumstances need to be taken into account, including: (a) the presentation of the product; (b) the use to which it could reasonably be expected the product would be put; (c) the time when the product was put into circulation. However, these circumstances do not appear to be very conducive to limiting the liability of the manufacturer (and thus limiting any chilling effects liability law may have). Why? When selling an automated car in the market, the marketing department of the manufacturer will praise the vehicle. So the presentation of the product will necessarily be controlled by other considerations than limiting a possible liability. The second circumstance is also not very helpful: the use to which it could reasonably be expected the product would be put. In case law, it has been determined that the manufacturer must take into account that the user of a product will not always take all precautions.[30] These circumstances exacerbate the chilling effect of liability rather than take it away. Are there other circumstances that can limit the liability? The formulation

[27] Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, OJ L 210, 07/08/1985, 29-33.

[28] See art. 6(1) Directive 85/374/EC.

[29] In the recitals to the directive, it is stated somewhat differently: the safety that the public at large is entitled to expect. This formulation expresses more clearly that it is an objective standard.

[30] HR 2 februari 1973, NJ 1973, 315, nt HB.

of the standard makes clear that absolute safety in the sense that the product will never cause damage is not always demanded. The public is not always entitled to expect this. Cars are a good example. A good luxury car pulls up in about 35 metres from 100 km/h. If the braking distance was smaller, a number of accidents would probably be avoided. But at present, it would be unreasonable to state that a car with such a braking distance is unsafe. For products the public is accustomed with, it is easier to see what level of safety a person may expect, even if that level falls short of absolute safety. The question is how the standard could be filled in with respect to a product that the public is not accustomed with, such as automated cars. Which degree of safety could a person expect? Since there is no experience with automated cars, an analogy with a product we have no experience with needs to be found. An obvious candidate for such a product is a human-driven car. It functions in the same environment as an automated car, it performs the same function as an automated car and apart from control aspects it is identical to an automated car. So how would the standard be filled in when taking the human driven car as an analogy? It is reasonable to assume that society does not want to make a rearward step in safety when admitting automated cars to the street. So, loosely formulated, the public at large is entitled to expect the automated car to be as safe as a human driven car. A difficulty in applying this criterion in this 'loosely formulated' form is that although a human driven car may be an adequate analogue for an automated car they are not the same. It may be expected that some accidents can be prevented with the use of automated cars. Examples are accidents caused by tiredness, or intoxication of a human driver. However, automated cars may also introduce new causes of accidents, such as accidents caused by the physical limitations of their sensors. Another problem may be that there is not one human driver that is equal to another human driver. So to whom should you compare the automated car? These problems can be overcome or at least diminished through a reformulated concretisation of the standard.

The concretisation "as safe as a human driven car" could be made more precise in the following ways:

1. The automated car should statistically be safer than human drivers, or

2. The automated car should be safer than the best human driver.

The first formulation is less strict than the second one. It does not mean that no accident will happen that a good human driver could have avoided. It merely means that automated cars statistically cause less (in number and in severity) accidents than cars driven by humans. In practical terms, the first formulation acts as a minimum standard. It is unlikely that automated cars not meeting this standard would be acceptable to the European public. As said before, the European public is probably not willing to make a rearward step in safety.

The second formulation means that an automated car is at least as good as the best human driver. This does not mean that no accidents will happen with automated cars. It only means that, if an accident happens, the best human driver could not have avoided it either. The practical significance of this is that once the technology for automated driving has reached this stage, nobody can reasonably object to the introduction of automated cars on safety grounds.

4.3 Liability and Innovation

Liability and innovation are not isolated from each other but influence each other. On the one hand, liability law may influence the decision of manufacturers to produce certain products. If the liability risks are deemed too high, manufacturers may delay the introduction of automated cars until technology allows a higher level of safety. Liability law may also have an effect on the trust

that the public has in certain products. On the other hand, in determining liability the effects on innovation may be taken into account. A producer can, for example, escape product liability if he shows that the state of scientific and technical knowledge at the time when he put the product into circulation was not unable to detect the defect. In this section, the effects of liability law on innovation in automated cars will be studied. It is found that certain adverse effects are to be expected and a way of dampening these effects is proposed.

The effect of liability on innovation

Automated cars take over some or perhaps all functions that a traditional human driver now performs when driving a car. As we saw before, this can take two forms. With partially automated cars the human driver is still the driver of the car. His function changes, however. He is not the person who actually operates the controls of the car. Rather, he becomes the person supervising the technology, ready to intervene at any moment. With highly and fully automated cars the human user becomes at least part of the time a mere passenger in the car. The car drives itself. In the latter case, it is clear that the responsibility for adequate control of the car has shifted from the human user to the machine. As a corollary, if it goes wrong and accidents happen caused by inadequate control of the car, it becomes very unlikely that the accident is attributable to a fault of the human user. It becomes more likely that the accident is attributable to the manufacturer of the car. So in highly and fully automated cars it appears that manufacturers run a higher risk of being held liable than in human driven cars. What about partially automated cars? Here, the human driver has the final responsibility, much like in traditional cars that are operated by the human driver only. So, superficially, a manufacturer does not seem to run a higher risk of being held liable. But is that so? Operating a car is not the same as supervising the automated systems of a car. Operating the controls of a car requires active involvement of the human driver. The active involvement makes it easier for humans to concentrate and to keep concentrating. Supervising a system on the other hand is to a large extent passive and involves the risk that the human driver gets distracted from his task. If this proves to be true, manufacturers may have a responsibility in designing partial automation in such a way that this risk is minimised. This responsibility – if it is not taken on adequately – may translate into a higher liability risk compared to human operated cars. In conclusion, all forms of automation may lead to higher liability risks for manufacturers. This is particularly the case with higher and fully automated cars.

Car manufacturers are well aware of this heightened liability risk.[31] They are also aware that accidents with automated cars will attract much attention from the press. Negative comments in the press may damage the reputation of the manufacturer. In the presence of horrible pictures of a crashed automated car, it is difficult to defend oneself and the ensuing public discussion may be governed more by emotion than by rational argument. In the literature, it is contended that these "market forces" make product liability law superfluous.[32] This however only applies when regulation on safety is strong. However, below in the section about 'framework conditions' we will see that certification authorities are struggling to determine the technical requirements that an automated car must meet in order for it to be roadworthy. Hence, strong administrative laws on safety are not to be expected in the short run and this leaves society to a larger extent reliant on product liability law.

[31] Some authors do not see a large risk of a chilling effect of liability in Europe (van der Heijden, 2001, 320-321).

[32] Poilinsky and Shavell, 2009.

A heightened liability risk (in the sense explained above) and the prospect of damage to the reputation, make manufacturers delay the introduction of automated technologies, using the extra time to make the technology a little bit safer. One could say that such a delay is not a bad thing. The automated cars entering the road will be safer than it would have been the case had they been introduced to the market earlier. But could it be that the introduction is delayed for too long? In fact, this argument can be made. To understand this, different stages in the development of the safety of automated cars need to be discerned.

The state-of the art in safety can be described by comparing it with the safety that existing human driven cars offer. A first stage is the stage at which automated cars are statistically at least as safe as human driven cars. In this stage it is not the case that no accidents will happen that a good human driver could have avoided. It merely means that, statistically, automated cars cause fewer accidents than cars driven by humans (both in number and in severity). A more advanced stage in safety is reached when automated cars are at least as good as the best human driver. This does obviously not mean that no accidents with automated cars will happen. But the accidents that do happen would also have happened had the car been driven by a human, even if this human was the best driver that humanity has, as yet, produced. If the latter stage in safety is reached, manufacturers will feel comfortable to introduce automated technologies to the market. In fact, in this stage nobody could reasonably object to the introduction of automated technology on safety grounds.

Rationally, it makes sense for society to introduce automated cars as soon as they are statistically safer than human drivers.[33] The number of accidents will drop. However, manufacturers will be very hesitant about bringing a car that only meets this threshold to the market. It may cause accidents that a human driver may have been able to avoid. Arguing that automated cars are statistically safer against the backdrop of a recent accident involving an automated car where a human could have avoided the accident is an uphill battle. This is the type of publicity that car manufacturers can very well do without.

Also, from a liability perspective such an accident may be risky. As we saw above, the standard for product liability is the safety that a person is entitled to expect. This is an open norm that needs to be filled in for automated cars. What safety could anybody (not just the user, but also other participants in the traffic) expect? Since there is no experience with automated cars an analogy with a product with which experience does exist needs to be found. An obvious candidate for such a product is a human-driven car. It functions in the same environment as an automated car, it performs the same function as an automated car and apart from control aspects it is identical to an automated car. So what could be the standard to apply when taking the human driven car as an analogy? The minimum standard is that an automated car should meet is that it is statistically at least as safe as non-automated car. The problem with this standard is that it is rather abstract. It is also difficult to ascertain whether a car meets this standard. This can be checked only through statistics that are built on large scale use. Therefore, it cannot be excluded that in legal practice a standard will be pushed forward that is easier to apply in an individual liability case. Such a standard could be that an automated car should be at least as good as an average or good human driver. With respect to concrete accidents, the simple question to be asked would be: would an average/ good human driver have been able to prevent this accident? The problem with such a non-

[33] Rationality is obviously not the only perspective by which the introduction of automated cars to the road may be judged. The ethical part of this deliverable addresses these other aspects. A societal discussion about the moment and conditions for introduction is needed.

statistical, human-based standard is that an automated car is different from a human being and fails in different respects than a human does. So it is very difficult to meet such a standard for makers of automated cars.[34] Moreover, the standard has a simple argumentative appeal. How could one defend automated cars that are "worse" than good human drivers? Car manufacturers are all too conscious of such a stringent criterion becoming the standard and the implication it could have for them.

The safety a person is entitled to expect also depends on the presentation of the product (art. 6(1) (a) Product Liability Directive).[35] In the marketing of automated cars, the benefits and new uses of cars will probably be stressed. This will push the expectation with regard to safety that the automated car offers up. The justified expectations of the safety can be lowered by attaching disclaimers to the product. However, disclaimers cannot be used to lower the safety expectations of the public arbitrarily. The Dutch Supreme Court found: 'For the answer to the question whether a warning can be considered to be an adequate measure for protection against a certain risk, it is of decisive relevance whether it can be expected that this warning will result in acts or omissions that avoid this risk.'[36] This was not decided in a case about product liability (but of liability of the manager of an airport decided under general Dutch tort law), but in the literature this finding is thought to be applicable to product liability as well.[37] In other words, if it can be expected that people will ignore a disclaimer, then the disclaimer does not take away the defectiveness of the product. Disclaimers that are too artificial will not work. This presents society with an anomalous situation. If automated cars are statistically safer than human driven cars, society has good reason to allow automated cars to the road. However, for fear of liability or bad press, manufacturers do not want to run the risk to introduce automated cars until they meet a higher standard, such as: no accidents happen that a good (or the best) human driver could have prevented.[38] So there is a delay in the introduction of automated cars that is purely down to liability law and fear for negative publicity.[39] We call this the chilling effect of liability law (Calabresi & Bobbit, 1978).

One proviso needs to be made at this point. In this text we look at safety only, other conditions relevant for the moment of introduction to the market are considered 'ceteris paribus'. These other conditions were not researched here and could very well pull the moment of introduction forward (such as competition between car manufacturers) or push the moment of introduction further into the future (e.g. motorists not feeling comfortable with automated vehicles).

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[34] A variant on Turing's imitation could test whether manufacturers have reached this stage and give scientific corroboration of the finding.

[35] Council Directive of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, 85/374/EEC, OJ L 210, 7.8.1985, 29.

[36] Unofficial translation of the Dutch text: 'Voor het antwoord op de vraag of een waarschuwing kan worden beschouwd als een afdoende maatregel met het oog op bescherming tegen een bepaald gevaar, is van doorslaggevende betekenis of te verwachten valt dat deze waarschuwing zal leiden tot een handelen of nalaten waardoor dit gevaar wordt vermeden. Source: HR 28 mei 2004, NJ 2005, 105 (Jetblast).

[37] Pape, 2009.

[38] See report of the stakeholder meeting of 29 October 2013 in Munich.

[39] For U.S, law see Fagnant & Kockelman, 2013, 12.

How to dampen chilling effects?

The foregoing raises the question how the chilling effect of liability law can be dampened without compromising the functions of liability law (as described above).

Assumptions and framework conditions

We make a number of assumptions: 1. Automated cars will only be introduced to the market if they are statistically safer than cars driven by humans. 2. It is in the motor insurers' interest that the number and severity of accidents is reduced. In addition we hold on to a number of framework conditions: the two functions of liability law stay in place and liability for accidents with automated cars should not reduce the usability of these cars to certain territories within the EU. These assumptions and framework conditions are elaborated below.

Assumption 1: Automated cars are statistically safer than cars driven by humans.

Why is it reasonable to make this assumption? Above we saw that society is most probably not willing to make a rearward step in safety with the introduction of automated cars. Manufacturers do not want to make such a step either. But what assurances can we have that the cars are not introduced on the road before they reach this level of safety? In the solution sketched below, manufacturers are not shielded from liability altogether. If a manufacturer nonetheless makes a rearward step in safety, the incentive and corrective function of liability law are still in place. Hence, there is a good reason to expect that manufacturers only introduce "safe" automated cars to the road. Where this is not the case, it is expected that corrective action on the basis of liability law can be taken.

That being said, it is not immediately clear what it means for automated cars to be statistically safer than cars driven by humans. A first indication that this is the case is that insurers pay out less in compensation for accidents involving automated cars per kilometre driven in such a car (than for accidents with purely human driven cars). Such a financial indicator may point either to a reduced number of accidents or to a reduced severity of accidents. However, it is possible that a lower total amount in compensation is the consequence of fewer but more severe accidents. It is also possible that it is the consequence of many more but less severe accidents. "Society" may have its views on how to assess such situations. More severe accidents may be deemed unacceptable even if their number is very low and the total amount of damages drops. It may also be that the amount paid in compensation is not an adequate indicator of the severity of an accident. In such cases, the financial indicator needs to be corrected. This once again stresses the importance of a public discussion about the admission of automated cars to the road and the implications this has. In conclusion, we assume that a reduction in the "per kilometre" payout by insurers should be the minimum result of the introduction of automated cars. Perhaps public discussion about the moment of introduction will require more (such as less severe accidents leading to permanent invalidity). It is up to society to decide which level and type of safety it deems acceptable.

Assumption 2: Insurers have an interest in accident reduction.

For a reduction of the chilling effect that product liability has on manufacturers, it will prove relevant that insurers have an interest in reducing the number and severity of accidents. However, insurance companies may not be interested in a reduction of accidents under all circumstances. The position insurers take may depend on many factors.

One such factor may be the competitiveness of the insurance market. If the insurance market is competitive and individual insurers cannot increase the premiums they charge to their customers, they are from an economic perspective interested in reducing the number of accidents and the compensations they have to pay out. Reduction in payout is then a way to maximise profit. If, however, the insurance market is not competitive, insurers may increase premiums to compensate for greater payouts. In such a non-competitive market, a greater volume of damages may actually be an attractive scenario for insurers, since it increases turnover and profit. From an economic perspective, there may then be little reason not to hold manufacturers liable on the basis of product liability.

Another factor may be the sense of societal responsibility insurers feel. A highly developed feeling of societal responsibility may make an insurer more inclined to make decisions that are conducive to more safety on the road. Yet another factor may be the public opinion about insurers. Since the economic crisis of 2008 the financial sector has been subject to an increasingly intense public scrutiny. This may also provide a push in the right direction. Whether these effects materialise and how big they are cannot be determined without empirical research.

Below it will appear important that the interests of insurers be aligned with interests of "society". Although nothing definitive can be said here, there is no reason to be overly pessimistic in this respect. Nonetheless, it is outside the ambit of this research to precisely determine the position insurers will take and the factors that are of influence. Additional empirical research is needed. If and when necessary the competitiveness of the insurance market needs to be assured.

Framework condition: hold on to the functions of liability law.

As stated above, the functions of liability law are the incentive and corrective function and the compensation function. The provision of compensation to the victim is an important element to be included. If compensation to the victim is not guaranteed, the stakes in disputes ensuing from accidents with automated cars will be very high and victims will pursue compensation with more zeal. This would only enhance chilling effects. We choose not to do away with the incentive and corrective function since it must be possible to act against manufacturers that deliver unsafe cars, even if these cars comply with all the formal standards about roadworthiness. This is also in accordance with statements by a representative of major car manufacturer in our stakeholder meeting that it will assume complete liability when necessary. Another important reason to hold on to these functions is that the state-of-the-art is not yet able to deliver sufficient safety for all traffic situations in which an automated car might find itself. This might not be a conclusive argument if we had rules about roadworthiness that precisely prescribe what safety an automated car must provide. The reality, however, is that certification authorities are, at the moment, far from able to specify the requirements that an automated car must meet to be roadworthy.

Framework condition: an EU-wide solution

A solution to the liability for accidents with automated cars should be EU-wide in the sense that it is relevant that the users of automated cars can use their cars throughout the EU and are not limited to their own country or a limited number of countries within the EU. If type approval of automated technology is harmonised throughout the EU, it is at least legal to use the type-approved technology in all member states. If there is no harmonised type approval, Member States would still be bound by the free movement of goods, but the free movement of goods is not unrestricted. The TFEU does allow for prohibitions justified on grounds of public morality, public policy or public security, the protection of health and life of humans, animals or plants, or the protection of

industrial and commercial property, as well as other mandatory requirements recognised by the Court of Justice (e.g. protection of the environment). Such prohibitions must, however, be proportionate and must not amount to arbitrary discrimination or a disguised restriction on trade between Member States.

Reduction of the chilling effects of product liability

The challenge is to provide a system in which the manufacturer is not overexposed to liability (this would lead to a chilling effect on innovation) but also not underexposed (this would undermine the functions of liability law, namely the prevention of accidents and compensation to the victim).

Insurance provides part of the solution. It ensures that the victim is being compensated. But it leaves two other elements to be dealt with. First, it is unclear whether insurers will be prepared to insure automated vehicles[40] and, second, it is not so clear how insurance affects manufacturers: will it lead to overexposure to liability if the insurer takes over the claim that the victim held or underexposure if no recourse against the manufacturer can be had?

For the first element, the two assumptions that we made above come into play. If automated cars are only introduced when they are statistically safer than present cars and if insurers have an interest in a reduction of accidents, then we can be reasonably optimistic that insurers will want to insure automated cars. It is then in their interest to stimulate the manufacture and use of automated vehicles.

But how should we think about the second element? If insurers have no recourse against manufacturers, the incentive and corrective function of liability are no longer effective. Hence some recourse against manufacturers is needed. But how can we create the right incentive? Here the second assumption comes into play. If insurers are interested in a reduction of accidents, they may make judicious use of their power to take recourse against the manufacturer. It diminishes their interest in pursuing manufacturers that conscientiously build automated cars, but are struck by bad luck. They are the manufacturers of the cars that reduce the number of accidents overall. Insurers do have an interest in taking action against manufacturers that deliver sub-standard automated cars.

In short, insurance reduces the chilling effect product liability may have on manufacturers in the following way.

[1] The victim is compensated by the insurer.

[2] The insurer benefits from robotic driving (fewer accidents) and therefore has an interest in manufacturers continuing to build robotic cars. This diminishes the incentive to sue the manufacturer for accidents, the prevention of which is beyond the state-of-the-art or to otherwise pursue compensation where this would drive manufacturers 'over the cliff'. This is of course no hard guarantee. Individual insurers may still exhibit opportunistic behaviour and sue manufacturers in the prospect of a payout. The proposed solution should be seen as an attempt to contain the problem and not as a

[40] In Italy, traffic-insurers are obliged to accept new customers; however, there are other Member States (e.g. the Netherlands) where insurers are allowed to decline applications for traffic insurance.

hard guarantee against chilling actions. A quantification of the effect of the solution cannot be given here. This requires empirical research.

[3] The insurer, not the victim, is a party to a possible legal dispute. This takes the emotion out of the case.

At the same time the incentive and corrective functions of liability law are retained.

Type of insurance and underlying law

The way in which liability law is given shape in a jurisdiction indicates what type of insurance covers damages caused by automated cars. There are different variants in place. Many countries have special rules about the liability of the driver of a vehicle, combined with a legal duty to take insurance coverage. Second, the holder of the license to a vehicle can be subject to liability and to a duty to insure. The conditions vary per country. Third, traffic accidents may be largely withdrawn from the field of liability and be covered by first-party insurance. This model is adopted in Sweden.

Liability of the driver

There are different systems for attributing liability to a driver. Liability attributions may be based on a fault of the driver or on the ground that it is in the societal setting at hand reasonable that the driver carries the burden of liability. The legislator may deem no-fault liability of the driver reasonable because driving a car introduces a risk in society or because the driver is obligatorily insured. These ways of attribution are often called fault-based and risk-based, respectively. There are clear differences between the legal systems in Europe. In the UK, the liability of the driver is fault-based.[41] In Germany the driver is assumed to be at fault, unless she can prove otherwise (Gasser, 2012: 19).[42] In France, the liability of the driver is risk-based (Giesen, 2001: 136). Both fault-based and risk-based system could be considered for automated cars with medium to high automation. However, driver-based liability may become problematic since the role of the human driver is decreasing and in the long run the human driver may be taken out of the loop altogether. Therefore, we will concentrate further on the two other systems: liability of the license holder and resolution outside the realm of liability law.

Traffic insurance

This is a system used in Sweden. It is here described in very broad lines. Indemnification of the victim is the starting point of the system. The victim of a traffic accident is compensated by a 'first party' insurer, i.e. insurance against damage, not liability (Hellner, 2001: 257). Persons travelling in a motor vehicle typically claim under the insurance of that motor vehicle. Persons not travelling in a motor vehicle typically claim with the insurance of the motor vehicle that is involved in the accident. Liability need not be established (von Bar 2009: 716). The motor vehicle insurance is obligatory. The advantages of the system are that victims are compensated more comprehensively. At the same time, some costs are saved because there is no need to determine who is liable for the accident, which might be complicated. A traffic insurer may however try to reclaim its costs with the traffic insurer of the motorist responsible for the accident. The Swedish

[41] Wing v. L.G.O.C. [1909] 2 K.B. 652.

[42] § 18 Abs. 1 S. 2 StVG.

model has some drawbacks. The following can be mentioned. First, the cost of insurance is borne by the victim, not by the tortfeasor. In Sweden, this drawback is mitigated through an elaborate system of social insurance that bears many of the costs associated with accidents. Social insurers cannot reclaim the costs with traffic insurers (Hellner, 1986: 631). Second, since the system is not based on liability, the incentive and corrective functions of liability law are absent. This is somewhat mitigated through higher insurance premiums for accident-prone vehicles (such as heavy motor cycles), which makes these vehicles less attractive. Third, the system may be more expensive, since it is easier to claim compensation.[43] However, this effect – if it occurs at all – is counterbalanced by diminished legal expenses. It is not completely clear what the net effect is (more expensive or not?) or how you should value a possible higher expense: more compensation to the victim and reduced legal expenses are in themselves no bad things and may even be worth a little extra cost.

What could this system mean for automated cars? A switch in other EU Member States to the Swedish model for all traffic accidents (also those involving non-automated cars) may be an option. But it is beyond this project to discuss this. Instead, this report is restricted to the question whether other countries could adopt the Swedish model for automated cars only? Assuming that there is a definition of what an automated car is (as discussed above) this may be possible. In Sweden, a victim of a traffic accident may still choose to hold the tortfeasor liable. However, the route via the first-party insurer is so much easier that the liability route is hardly ever chosen (von Bar 2001: 716). Therefore, it might be possible to put the Swedish system on top of a liability system. This would mean that a Sweden-type first-party insurance would be made mandatory for automated cars. A practical problem would probably be that this would make insurance for automated cars more expensive.[44] First, just like in Sweden, this insurance would attract many claims since it is an easier route for victims of accidents. Second, other countries beside Sweden may have a less elaborate system of social insurance, thus leaving more costs to be covered by the traffic insurance. A higher premium may have negative effects on the success of automated cars in the market. It may also be hard to justify that automated cars attract higher insurance premiums if they are supposed to be safer than human driven cars (as per first assumption). On the pro side, the loss of the incentive and corrective function with regard to the driver or user of an automated car is not so grave: the role of the driver/user is decreasing anyway with increasing automation. The traffic insurer may be given the chance to have recourse against the manufacturer.

Liability of the holder of the license to the vehicle

This is a liability of the holder of the license to the vehicle. He may be liable even if he is not the driver of the car at the moment an accident occurs. This is a type of liability with a strong risk element. That does not mean that a holder cannot make relevant faults. It would, for example, be the holder's fault to allow somebody who is clearly unable to drive to use the car. The holder is, however, also liable where he has not committed any fault. Typically, the idea behind this type of liability is that by putting a car on the road the holder introduces a source of danger into society. If and when this danger materialises, it is reasonable that he carries the cost of the accident. To protect the holder against claims he cannot pay, there is mostly a duty to insure against the liability risk he runs.

[43] See, for example, the US experience with no-fault-insurance : RAND, What Happened to No-Fault Automobile Insurance? http://www.rand.org/pubs/research_briefs/RB9505/index1.html .

[44] See, for example, the US experience with no-fault-insurance : RAND, What Happened to No-Fault Automobile Insurance? http://www.rand.org/pubs/research_briefs/RB9505/index1.html .

An example is the German "Halterhaftung" (liability of the vehicle-license holder). If the "Betrieb" (operation) of the car causes damage, the holder of the vehicle is liable and no further conditions needing to be fulfilled for this rule to apply (art. 7 StVG). The damage is covered by the insurance that the holder is required to have. In the Netherlands, the owner or holder of a vehicle is liable if the vehicle is involved in an accident and damage is done to persons or objects other than those riding the vehicle. There is an exception for force majeure, making this strictly speaking a form of with-fault liability. But since force majeure is difficult to establish the result comes close to risk-based liability (Giesen, 2001: 131). An important exception is that the owner or holder is not liable for damage done to free walking animals, another motor vehicle or people or objects transported by that other vehicle (art. 185.3 WVW). In essence, this provides strong protection for weaker participants in traffic, such as pedestrians and bicyclists. In France, liability for traffic accidents has been governed by the "Loi Badinter" since 1985. It established a risk-based liability for the driver or 'guardian' of a motor vehicle for traffic accidents (accidents de la circulation) in which the motor vehicle was involved by way of "implication" (Sterk, 1994: 51).

What is the potential benefit of liability of the holder of the license to the vehicle and the duty to insure for automated cars? The advantages of this type of liability and obligatory insurance are as follows: 1. It prevents discussion about who is driving: man or machine? So it has a strong element of technology-independence. 2. Insurance against liability is obligatory, leading to a large majority of all cars being insured. Where holders – contrary to their obligation/duty – are not insured, there are funds that compensate victims. 3. This type of liability already exists in Germany and many other states and does not necessitate the introduction of something radically new.

The challenges this solution leaves open are: 1. Not all Member States of the EU have a system where the vehicle holder liable and, as is apparent from what has been said above, the conditions diverge. 2. The damage to the user of the vehicle causing the accident is not covered. In the case of a "one sided" accident, there may for example be nobody to hold liable. These challenges are elaborated upon below.

Diverging rules about liability of the vehicle holder

If the liability of the holder in combination with the obligatory insurance is to give comprehensive protection to victims of automated cars, some form of harmonisation is needed. For example, the rules in the Netherlands do not cover the situation where two cars collide. This does of course not mean that there is no liability of any person. There is a fall-back on the normal rules of liability, such as the with-fault liability of the driver or product liability of the manufacturer. But these options are more cumbersome for the victim, may be difficult to apply to some automated cars (driver's liability) and may invite a chilling effect of liability law on innovation by the manufacturer (product liability). To take away uncertainties about liability risks run by manufacturers and to give equivalent protection to victims of accidents with automated cars some form of harmonisation would be needed.

Insufficient coverage

The liability of the vehicle holder may not cover all damages. For example, if the holder is driving himself and suffers damages, these are not compensated. The vehicle holder cannot hold himself liable. If the victim has first-party-insurance (in addition to his insurance against liability) he may claim his damage under that insurance. Such insurance is generally not obligatory and many drivers do not have such insurance. In the absence of insurance against damage the victim may seek direct recourse to contractual or product liability of the manufacturer of an automated car.

One option could be to leave this as it is. It is then up to the holder of the vehicle to decide whether he seeks voluntary insurance cover. For the manufacturer this may be considered a residual liability risk that may not have an appreciable influence on innovation. The other option is to close the gap by requiring mandatory insurance for damage that is not covered by liability. The latter choice will bring the system closer to the Swedish model in terms of victim protection, insurance coverage and costs.

4.4 Recommendations

If a chilling effect as a consequence of product liability cases is to be avoided, we need a system that allows a victim to obtain a sufficient compensation more easily through insurance than through product liability. This is certainly the case under the Swedish model and probably also under an obligatory and comprehensive third party liability scheme where the holder is liable on a no-fault basis.

At present, there are, however, large differences between EU Member States, with respect to traffic liability and insurance. If this leads to differential exposure of automated car manufacturers to product liability, there is a reason to harmonise traffic liability and insurance law. Whether such harmonisation should be inspired by the Swedish model or the more conventional liability of the holder of a vehicle cannot be determined here. The Swedish model gives more comprehensive protection to the victim and is easier in its administration. Further research would be needed to see whether it is more expensive. A system of liability of the holder is much closer to what many Member States already have in place, but it is still far from harmonised.

The legal analysis gives rise to the following recommendations for policy makers:

(1) There is a need for a public discussion about the safety society expects from automated cars. The outcomes of such discussion could make it easier to decide on the moment these cars or certain features can be introduced to the market.

(2) There is a need for research into the position of insurers with respect to automated cars with special emphasis on the question whether the interests of insurers are aligned with the values and interests held by society. In particular, it should be researched how conditions can be created to (make and) keep the insurance market competitive.

(3) In order to reduce chilling effects of product liability on innovation in the field of automated cars, it is recommended to – softly – separate the compensation function of liability law from its accident prevention function. Victims are compensated by insurers (compensation function) and insurers decide whether to claim product liability based on a rational assessment of what is necessary for accident reduction (accident prevention function).

(4) The Swedish model of traffic insurance is a promising model for compensation of victims of automated car accidents. Further research is advised in order to establish to what extent the model does (or does not) build on specific characteristics of Sweden (e.g. elaborate system of social security), what the financial implications of a broader (EU-wide?) introduction would be (more or less expensive?) and whether it could be introduced for one category of vehicles (viz. automated cars) only.

(5) It is relevant to monitor whether the differences in traffic liability and insurance amongst the Member States of the EU and differences in the compensations victims

receive under these systems lead to differential exposure of manufacturers to product liability.

Annex 1

This annex sets out a number of definitions devised by states that allow automated cars on the road.

The State of Nevada interprets 'the term "autonomous vehicle" to exclude a vehicle enabled with a safety system or driver assistance system, including, without limitation, a system to provide electronic blind spot assistance, crash avoidance, emergency braking, parking assistance, adaptive cruise control, lane keep assistance, lane departure warnings and traffic jam and queuing assistance, unless the vehicle is also enabled with artificial intelligence and technology that allows the vehicle to carry out all the mechanical operations of driving without the active control or continuous monitoring of a natural person.'[45]

In California, an autonomous vehicle is defined as follows: "Autonomous vehicle" means any vehicle equipped with technology that has the capability of operating or driving the vehicle without the active physical control or monitoring of a natural person , whether or not the technology is engaged, excluding vehicles equipped with one or more systems that enhance safety or provide driver assistance but are not capable of driving or operating the vehicle without the active physical control or monitoring of a natural person.[46]

In Michigan, an autonomous vehicle is defined as follows: 'Sec. 2b. (1) "Automated motor vehicle" means a motor vehicle on which automated technology has been installed, either by a manufacturer of automated technology or an upfitter that enables the motor vehicle to be operated without any control or monitoring by a human operator. Automated motor vehicle does not include a motor vehicle enabled with 1 or more active safety systems or operator assistance systems, including, but not limited to, a system to provide electronic blind spot assistance, crash avoidance, emergency braking, parking assistance, adaptive cruise control, lane-keeping assistance, lane departure warning, or traffic jam and queuing assistance, unless 1 or more of these technologies alone or in combination with other systems enable the vehicle on which the technology is installed to operate without any control or monitoring by an operator.'[47]

In Florida, an autonomous vehicle is defined as follows: (90) AUTONOMOUS VEHICLE.— Any vehicle equipped with autonomous technology. The term "autonomous technology" means technology installed on a motor vehicle that has the capability to drive the vehicle on which the technology is installed without the active control or monitoring by a human operator. The term excludes a motor vehicle enabled with active safety systems or driver assistance systems, including, without limitation, a system to provide electronic blind spot assistance, crash avoidance,

[45] NAC 482A.010 "Autonomous vehicle" interpreted. Available at: http://www.leg.state.nv.us/NAC/NAC-482A.html

[46] Par 227.02 sub b. Cal. Vehicle Code (?), available at: http://apps.dmv.ca.gov/about/lad/pdfs/auto_veh2/adopted_txt.pdf

[47] Available at: http://www.legislature.mi.gov/documents/2013-2014/publicact/htm/2013-PA-0231.htm

emergency braking, parking assistance, adaptive cruise control, lane keep assistance, lane departure warning, or traffic jam and queuing assistant, unless any such system alone or in combination with other systems enables the vehicle on which the technology is installed to drive without the active control or monitoring by a human operator.[48]

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3. Computer integrated surgical systems*

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1. Introduction

The spread of computer-assisted surgery, favoured by instruments which allow to overcome significant limits of the traditional laparoscopic surgery, points to this field as a crucial area to investigate within RoboLaw.

Surgical robots offer the opportunity to complement the action of human surgeons, providing it with greater strength, efficacy, precision and also reducing morbidity rates. By coupling human abilities with computer-based technology, they allow to implement an optimized interventional plan, that is produced combining statistical information and pre-operative patient-specific information, and then it is registered to the actual patient, and, in case it is necessary, updated in the operating room.

The planned procedure is carried out with the assistance of the robot, and it is constantly updated through additional imaging and sensing. After its completion, further imaging and data are collected and retained for the patient follow-up phase, but also for analysis and assessment in order to improve methods and procedures.

The advantages of such computer-integrated surgical systems have been widely highlighted, and can be summarized as follows:

- Improve the technical capability of the surgeon by augmenting the precision and geometrical accuracy of the intervention, and eliminating possible cause of perturbation like hand tremor;
- Allow less invasive procedures while guaranteeing the immediacy and dexterity of open surgery through real-time image feedback;
- Promote surgical safety through virtual barriers in order to prevent the surgeon, who is maneuvering the robot's surgical tool, from inadvertently causing damages;
- Enhance the follow-up phase and facilitate subsequent clinical research thanks to the detailed quality and quantity of data collected during the procedures and retained for future analysis;
- Possibly reduce the costs of interventions, by reducing healing time (therefore shortening hospital stays) and the need for surgical revision due to greater technical accuracy of the performed operations;
- Being apt for remote surgery, therefore allowing to perform operations in hostile environments, e.g. in order to avoid the surgeon's exposure to X-ray, in the battlefield, in space etc.

In turn, the main drawbacks of robotics surgery are identified in the lack of haptic feedback, which is of crucial importance for appreciating the force exerted by the surgical tools on the patient's tissue, and for tissue identification, e.g. for assessing tissue viability, detecting hidden blood vessels or distinguishing normal tissues from cancerous tissue. This current limit is being addressed by ongoing research trying to integrate sensors into the surgical instruments and improve methods to convey the sensed information to the surgeon.

Other downsides are the costs for both the initial purchase and maintenance, and difficulties related to the introduction of computer-integrated surgical system in the operating room, that has to be rearranged around a separate master console and slave robots. This is especially true for tele-

operated systems, less so for hands-on control that requires less hardware and can be easier to introduce into existing surgical settings. At the same time, hands-on control is incompatible with any degree of remoteness between the surgeon and the surgical instruments. In order to overcome other constraints of the traditional techniques, like the difficulty of reaching surgical sites inside the body and positioning the tools effectively, other devices like semi-autonomously moving robots, e.g. for epicardial or endoluminal applications, have been developed.

2. Technological Overview

Robots have entered the field of diagnosis, therapy and surgery quite recently, but nowadays they are quite spread in the healthcare systems: voice-activated robotic arms routinely manoeuvre endoscopic cameras, and complex master slave robotic systems are currently FDA approved, marketed, and used for a variety of procedures.[1]

When illustrating the appearance of robots in diagnostic and therapeutic procedures, two aspects have to be considered: 1) robots have been introduced essentially for improving the quality and precision of surgical procedures; 2) the initial evolution of robots in surgery is strictly related to the birth and evolution of Minimally Invasive Surgery (MIS) in the 80's. MIS consists in executing surgical operations without a direct vision of the surgical environment and a direct manipulation of tissues: a few small incisions are performed in the patient, a couple of long instruments are introduced through them and the internal scenario is monitored by a laparoscope, that is, a vision system also introduced through a small incision. MIS advantages are basically related to reduced risk of infections, reduced cost of hospitalization and reduced convalescence (Kim *et al.*, 2002; Fuchs, 2002). On the other hand, MIS introduces many technical limitations for surgeons (e.g. loss of haptic feedback, unnatural hand-eye coordination, limited dexterity, loss of direct 3D depth perception, counterintuitive motion of instruments due to the fulcrum effect) that can be partially addressed and solved by robotic technologies.

Alongside the introduction of laparoscopy, the first real robot was employed in surgery: the industrial robot Unimation Puma 200 was employed in 1985 to perform neurosurgical biopsies with high precision and without using traditional stereotactic frames (Kwoh, *et al.*, 1988). Once the target area of the brain was identified on the computer tomography picture, a simple command allowed the robot to move to a position so that the end-effector probe guide pointed towards the target. This resulted in a faster procedure than the one performed with a manually adjustable frame. However, the most important advantages were the improved accuracy, which could be reached by properly calibrating the robot, and the full interface between the CT scanner and the robot driving the probe.

Around 1990, researchers understood the potential of robots in orthopedic surgery. In principle, since bones are more rigid than other organs (such as brain, prostate, etc.), the accuracy of robots is transferred entirely to the surgical tasks, thus opening the possibility to achieve a previously never met precision in orthopedic surgery. The ROBODOC robot from Integrated Surgical Systems was introduced clinically in 1992 to mill out precise fittings in the femur for hip replacement. ROBODOC showed superior performance in cutting the desired shape of the bone to host the customized implant while monitoring cutting forces, bone motion and other safety sensors.

[1] A detailed overview is offered by Menciassi & Laschi (2012).

ROBODOC was the first surgical robot finally approved by the FDA.

In the 90's the scenario of surgical robots became more diversified and several classifications of robots were introduced based on their application, level of autonomy, core technology etc. A general trend in the last decade has shown the integration of compact miniaturization techniques into surgical robots, in order to improve the performance of traditional hand-held tools and to generate robots purposely designed for specific tasks in surgery.

A paradigmatic example is offered by the AESOP (Automated Endoscopic System for Optimal Positioning) robot produced by Computer Motion Inc. which obtained FDA clearance in 1994. AESOP is a robotic arm that is not intended to perform a surgical task; its purpose is to cooperate with the surgeon in holding the laparoscopic camera and understanding the surgeon's intentions in a natural way. Precision, accuracy, fast response time for the robotic arm are still required but these features come together with technology for voice control or for smooth displacement.

The core technologies of AESOP, as the core technologies of the more famous da Vinci telesurgery robot, were nurtured - partially or entirely - at the National Air and Space Administration (NASA) Ames Research Center that started a program on virtual reality telepresence surgery in the late 80's (Satava, 2002). Telesurgery became one of the main driving forces behind the development of surgical robots. These research activities led to the birth of two telesurgical robots: the ZEUS robot, by Computer Motion Inc., and the da Vinci robot, by Intuitive Surgical Inc., which in 2003 acquired also the ZEUS system.

More recently, autonomous robotic systems have begun to transform their mechanical drillers and tools with laser radiation from other energy sources, thus opening the field of real therapeutic robots. A prominent example of this generation of surgical robots is the Cyberknife (http://www.accuray.com/) which represents an entirely new approach to radiosurgery. It incorporates a compact, lightweight linear accelerator mounted on a robotic arm, and it provides the surgeon unparalleled flexibility in targeting. Advanced image guidance technology tracks patient and target position during treatment, ensuring accuracy without the use of an invasive head frame. The imaging information is registered between the computer's coordinate system and the robot so that it may compensate for any changes in patient position by repositioning the linear accelerator.

Telerobotic technologies have been recently proposed also for endovascular interventions. In endovascular interventions, the main difficulty is driving endovascular catheters towards the target regions by moving just the proximal part of the catheter itself. Robots have been proposed to magnetically steer a magnetized catheter towards the target regions: the catheter is moved thanks to interaction with an external magnetic field finely adjusted by robotic arms (http://www.stereotaxis.com/); a similar goal is achieved with a different robotic technology that allows a catheter to be steered into difficult heart anatomies by merging 6 D.o.F. driving systems, force reflecting technologies, and advanced visualization facilities (http://www.hansenmedical.com/).

A recent and exhaustive research summarizes the medical fields in which surgical robots are currently utilized (Beasley, 2012).

a) *Neurosurgery*. Neurosurgery robots are machines for image-guided cannualae or other tools positioning/orientation. The NeuroMate system (by Renishaw, previously by Integrated Surgical Systems, previously by Innovative Medical Machines International),

which has received the CE marking and the FDA clearance, is adopted for biopsy, deep brain stimulation, stereotactic electroencephalography, transcranial magnetic stimulation, radiosurgery, and neuroendoscopy. Another robotic system, Pathfinder (Prosurgics, formerly Armstrong Healthcare Ltd.) has been cleared by FDA in 2004 for neurosurgery, and it is used by the surgeon to indicate a target and a trajectory on a pre-operative medical image, so that the robot guides the instrument into position with submillimeter accuracy. Again, there is the Renaissance robot (Mazor Robotics, the first generation system was named SpineAssist), which has the FDA clearance (2011) and CE marking for both spinal surgery and brain operations (2011). The device consists of a robot the size of a soda can that mounts directly onto the spine and provides tool guidance based on planning software for various procedures including deformity corrections, biopsies, minimally invasive surgeries, and electrode placement procedures.

b) *Orthopedics*. The most relevant advantage related to the robot assistance in orthopedics is represented by an accurate and precise bone resection. The first robot used in this field – in 1992 for a total hip replacement – was Robodoc (Curexo Technology Corp, originally by Integrated Surgical Systems), which received the CE marking (1996), and FDA clearance for total hip replacement (1998) and total knee replacement (2009). The Robodoc system is constituted by two components: Orthodoc, a 3-dimensional surgical planner, and the Robodoc surgical assistant, the robot employed for hip replacement intervention. A direct competitor of Robodoc, although no longer for sale, was Caspar, a robotic system for knee and hip surgery, launched in 1997 by OrtoMaquet. In 2008, the Rio robotic arm (Mako Surgical Corp, previous generation called the Tactile Guidance System) was released and received FDA clearance; the Rio is used for implantation of medial and lateral unicondylar knee components, as well as for patellofemoral arthroplasty. It is worth to observe that robotic arm of Rio already offers a tactile feedback to the surgeon. iBlock (Praxim Inc., an Orthopaedic Synergy Inc. company, previous generation the Praxiteles, FDA clearance 2010) is an automated cutting guide for total knee replacement mounted directly to the bone, in order to reduce the robotic influence on the cutting instrument. The Navio PFS (Blue Belt Technologies, CE mark 2012) does not require a computed tomography scan for unicondylar knee replacement, instead using an intraoperative planning. The Stanmore Sculptor (Stanmore Implants, previous generation the Acrobot Sculptor by Acrobot Company Ltd.) is a synergistic system similar to the RIO, with active constraints to keep the surgeon in the planned workspace; this system received FDA clearance in 2013.

c) *General laparoscopy*. Apart from the da Vinci system (see § 2.2), other laparoscopic robots are Zeus, FreeHand and Telelap ALF-X. Technically, Zeus should not be considered as a robot: it is a remote computer-assisted telemanipulator with interactive robotic arms, but it does not follow programmable motions. With Zeus an operation has been accomplished for the first time, in which the surgeon and the patient were separated by a distance of several thousand kilometres. The FreeHand robot (Freehand 2010 Ltd., previously Freehand Surgical, previously Prosurgics, the previous generation was called EndoAssist, FDA clearance and CE mark 2009) is a next-generation endoscope holder, equipped with an arm more compact, easier to setup, and cheaper than its predecessor. Telelap ALF-X (CE mark 2011) is a four-armed surgical robot projected by sofar s.p.a. to compete with the da Vinci: compared with that robot, Telelap ALF-X moves the base of the manipulators away from the bed (about 80 cm) and has a realistic tactile-sensing capability due to a patented approach to measure tip/tissue forces from outside the patient, with a sensitivity of 35 grams.

d) *Percutaneous*. InnoMotion (Synthes Inc., previously by Innomedic GmbH, CE mark 2005) is a robot arm designed to operate within a computed tomography or magnetic resonance imaging in the noncatheter percutaneous procedures in order to guide a needle to its target with the assistance of three-dimensional intraoperative imaging.

e) *Steerable catheters*. Vascular catheterization is used to diagnose and treat various cardiac and vasculature diseases, including direct pressure measurements, biopsy, ablation for atrial fibrillation, and angioplasty for obstructed blood vessels. The catheter is inserted into a blood vessel and the portion external to the patient is manipulated to move the catheter tip to the surgical site, while fluoroscopy provides image guidance. The Sensei X (Hansen Medical, FDA clearance and CE mark 2007) uses two steerable sheaths, one inside the other, to create a tight bend radius. The sheaths are steered via a remotely operated system of pulleys. The Niobe (Stereotaxis, CE mark 2008, FDA clearance 2009) is a remote magnetic navigation system, in which a magnetic field is used to guide the catheter tip. The magnetic field is generated by two permanent magnets contained in housings on either side of a fluoroscopy table.

f) *Radiosurgery.* Radiosurgery is a treatment (not a surgery), in which focused beams of ionizing radiation are directed at the patient, primarily to treat tumors. By directing the beam through the tumor at various orientations, high-dose radiation is delivered to the tumor while the surrounding tissue receives significantly less radiation. The CyberKnife (Accuray Inc., FDA cleared 1999) is a frameless radiosurgery system consisting of a robotic arm holding a linear accelerator, a six degree of freedom robotic patient table called the RoboCouch, and an X-ray imaging system that can take real-time images in two orthogonal orientations simultaneously. Another frameless system with a linear accelerator, but with micro-multileaf collimators for beam shaping, is TrueBeam STx (BrainLab Inc. and Varian Medical Systems, previously Novalis and Trilogy, initial FDA clearance 2000). The principal difference between this robot and CyberKnife is that the CyberKnife's radiation source has more degrees of freedom to be oriented around the patient.

g) *Emergency Response.* This category does not concern surgical robots, but robots which are employed in disaster response and battlefield medicine. The researches involving this technical sphere aim to realize machines able to accomplish extractions of patients from dangerous environments, fast diagnosis of injuries, and semiautonomous delivery of life-saving interventions. AutoPulse Plus (Zoll Medical Corp., previously by Revivant) is an automated, portable device that combines the functions of the AutoPulse (FDA clearance 2008) cardiopulmonary resuscitation device and the E Series monitor/defibrillator (FDA clearance 2010). The LS-1 suitcase intensive care unit (Integrated Medical Systems Inc., previous generation called MedEx 1000, previous generation called LSTAT, FDA clearance 2008) is a system which consists in a ventilator with oxygen and carbon dioxide monitoring, electrocardiogram, invasive and non-invasive blood pressure monitoring, fluid/drug infusion pumps, temperature sensing, and blood oxygen level measurement.

2.1 Minimally invasive surgery (MIS) and the da Vinci system

As said, the need for robotic surgical systems is particularly linked with the emergence of minimally invasive surgery (MIS), giving important advantages over traditional laparoscopic procedures providing high degrees of dexterity in very constrained spaces inside the patient's body.

Manual laparoscopy is affected by several limitations and adverse effects, which can be summarized as follows: this technique only allows a two-dimensional (2D) vision from a conventional monitor, and that reduces the perception of depth; it permits just a scarce eye-hand coordination, decreasing the surgeon ergonomics and dexterity. Laparoscopic instruments demand a direct guidance, which requires ambidextrous manual activity; they are long and rigid, so that the surgeon's natural hand tremor is amplified; these tools exclusively present five degrees of freedom: four for positioning the tip and one for actuation, and this aspect restricts the surgeon's natural range of motion and decreases his dexterity. In the laparoscopic operations there are fixed abdominal entry points in the patient's body, so the workspace reachable with the instrument's tip is limited; instrument tip and handle move in opposite directions, giving origin to the technical drawback known as the fulcrum effect, which decreases the motor perception capability; the camera instability contributes to surgeon fatigue; the tactile feedback is limited, and it reduces the surgeon's dexterity (Freschi *et al.*, 2012). Laparoscopic and thoracoscopic surgery therefore impose significant ergonomic restrictions on the surgeon, increasing his difficulty in execution of major abdominal and thoracic operations. Moreover, the approach of the manual laparoscopy is uncomfortable for the surgeon, who has to maintain an awkward stance during the operation.

Robot-assisted laparoscopic technology is directed to surmount these limitations. The most widely reported advantages of tele-operated robotic surgery stem from wristed instrument motions with seven degrees of freedom, scaling for precise movements, elimination of hand tremor, stereoscopic vision and improved ergonomics (Freschi *et al.*, 2012). Another advantage is represented by the ability to eliminate innate handedness, proved by results obtained by surgeons performing tasks with both dominant and non-dominant hands (comparable performance with either hand) (Mucksavage, Kerbl & Lee, 2011). A further advantage of surgical robots like the da Vinci consists in the high quality of the image transmitted to the display on the surgeon's console. In fact, in laparoscopic surgery the video image has a decisive role, because it is the unique interface between the surgeon and the patient, due to the lack of tactile and force feedback. In manual laparoscopy two-dimensional screen are used, with consequent loss of the depth perception, whereas natural stereoscopic view with more depth cues enables more accurate and efficient endoscopic manipulations. The first studies dedicated to the benefits of 3D visual were contradictory, since only some surveys showed that this technology allowed to achieve better results than with the use of the 2D visual; but this was due to the fact that the pioneering comparative studies adopted the first-generation, non-stereoscopic 3D systems with lower resolution, and eye-shuttering technologies (LCD or polarizing glasses) not used in the da Vinci system, which provides immersive stereoscopic vision based on true retinal disparity (Freschi *et al.*, 2012). In particular, a research demonstrated that the stereoscopic mode reduced execution time for every task by one-third and improved dexterity by 25%, as measured by the reduction of the number of movements and distance travelled. Accuracy, based on error reduction rate, improved by nearly 100% (Munz *et al.*, 2004). On the other hand, a different study affirms that only complex tasks are performed more easily and quickly with stereoscopic vision (LaGrange, Clark, Gerber *et al.*, 2008); but, in the end, it is rather ascertained that stereoscopic vision allowed for significant improvement in execution time and error rates for both inexperienced residents and advanced laparoscopic surgeons (Byrn *et al.*, 2007).

In order to point out the legal implications of surgical robots, the research has especially focused on the da Vinci system, at present the most widespread (Rosen, Hannaford & Satava, 2011) surgical telemanipulator, produced by Intuitive Surgical Inc.

The first studies on surgical robots were conducted by SRI International, an independent non-profit research institute, and funded by the US Army. The purpose of that research was to generate a technology by which surgeons could operate wounded soldiers from a remote and safe place. The first prototype system showed immediately its potentialities, but in the military environment the original idea was never realized, due to the great difficulty to perform a surgical operation without any physical contact between the surgeon and the patient.

In 1995 Intuitive Surgical acquired the rights to SRI patents and began working on the telerobotic system. The first version of da Vinci had no instrument-specific arm, while in 2003 a relevant improvement of the system was introduced by Intuitive, which equipped the robot with a fourth instrument arm, specifically dedicated to the camera–telescope.

da Vinci design and system description

In the current version, the da Vinci system is composed by two units: the surgeon's console unit, that holds the display of the system, the user's interface and the electronic controller; and the second unit, which consists of four slave manipulators: three for telemanipulation of surgical tools and one equipped with an endoscopic camera (Figure 6).

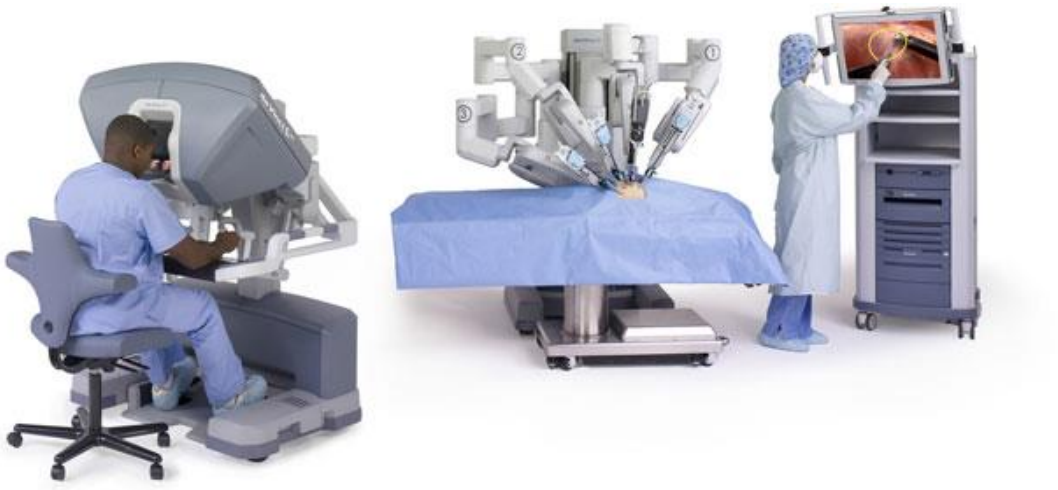

Figure 6 The surgeon at the console and the patient side cart of the da Vinci Si HD Surgical System (http://www.intuitivesurgical.com)

With the surgeon's console the system offers to him an immersive operative environment, with a high-quality stereo visualization and a man–machine interface that directly connects the movement of the hand of the surgeon to instrument tip movement inside the patient. The surgeon visualizes stereoscopic images via a 3D screen above the hands, recovering hand–eye coordination and providing natural correspondence with manipulations. Furthermore, the controller transforms the spatial motion of the instruments into the camera reference frame, so that the surgeon has the virtual sensation of operating within the patient's body. Then, the da Vinci system restores degrees of freedom lost in conventional laparoscopy; the three degrees of freedom wrist inside the patient

allows natural wrist pronation/supination, bringing a total of seven degrees of freedom for instrument tip control (three orientations, three translations and grip) (Figure 7).

Figure 7 The da Vinci handle used to remotely move the instrument's tip (http://www.intuitivesurgical.com)

The da Vinci control system filters out surgeon tremor, making the tools tips steadier than in the traditional laparoscopic surgery. Furthermore, the system allows variable motion scaling from master to slave; for example, a 3:1 scale factor maps 3 cm of translation on the masters into 1 cm of translation at the slaves, and this possibility, combined with the image magnification, makes delicate motions easier to be performed. Finally, the operations carried out with the robot can even require a minor amount of transfused blood (for example, in the radical retropubic prostratectomy), a shorter hospitalization (i.e., eight days instead of ten) and a reduced postoperative pain compared with the laparoscopic surgery (Freschi *et al.*, 2012).

In general surgery, the da Vinci has been used to perform over 500 procedures, concerning a wide variety of surgeries: Nissen fundoplication, cholecystectomy, hernia repair, tubal reanastomosis, gastroplasty, appendectomy, arteriovenous fistula, intra-rectal surgery, lysis of adhesion, hysterectomy, lumbar sympathectomy, toupet surgery and colorectal surgery. A significant area of interest is represented by cardiac surgery, due to the complexity of the procedures and the potential benefit to the patient of minimal access to the heart. In this field, the da Vinci system was used also to accomplish endoscopic coronary artery bypass grafts (Guthart & Salisbury, 2000).

Data on performance, training and proficiency with the da Vinci system are numerous and consistent. A laboratory study *in vitro* shows that the inexpert surgeons can accomplish all tasks more quickly and more precisely with the robot than with conventional laparoscopy, in particular for the more difficult tasks, confirming the usefulness of the da Vinci for the interventions which demand fine movement and optical magnification (Sarle *et al.*, 2004).

System limitations and malfunctioning

The main limitations of this system are the lack of a force feedback, the possible collision between tools inside the patient when the surgeon has limited experience, and the encumbrance of the overall robot, requiring a complete re-arrangement of the operating room. The most relevant drawback is considered the lack of haptic feedback, which is perceived as significant especially during the execution of complex tasks. This aspect has two important adverse consequences: first, the surgeon is not in the condition to identify tissue consistency, so that he cannot use this approach to distinguish between tumor and normal tissue (Tholey, Desai & Castellanos, 2005); second, it becomes difficult to accomplish intracorporeal suturing and knot tying, especially with

fine suture material (Ricchiuti *et al.*, 2010), when the breakage of the suture frequently occurs (Freschi *et al.*, 2012).

Several researches document the system malfunctions of da Vinci robot. Malfunctions can stem from set-up joint malfunction; arm malfunction; power error; monocular monitor loss; camera malfunction; breaking of surgeon's console hand piece; and software incompatibility (Freschi *et al.*, 2012). A recent study shows that between January 1, 2000 (i.e. since the Food and Drug Administration (FDA) approval of the robot-assisted general laparoscopic surgery) to August 1, 2012, a total of 245 events were reported to the FDA, including 71 deaths and 174 nonfatal injuries (the producer of the robot-assisted surgical system has the obligation to timely report known adverse events to the FDA after it becomes aware of them). The survey suggests that FDA reporting could not be prompt or standardized for some reasons. First, it may be difficult to separate poor surgical skill from device-related injuries; second, there is little oversight regarding reporting and, on the other hand, there are not significant incentives to improve reporting practices, while better reporting systems can help elucidate the risk factors associated with injuries (Cooper, Ibrahim, Lyu & Macary, 2013). This is confirmed by the same FDA, which observes that complaints or adverse event reports do not necessarily directly indicate a faulty or defective medical device, so that adverse event reports alone cannot be used to establish or compare rates of event occurrence (Kaiser Health News & Evans, 2013).

Nevertheless, several surveys show that many recoverable mechanical problems during surgery are linked to robotic instrument malfunction, including broken tension wires or wire dislodgement from the working pulleys, non-recognition of the instrument by the robot (despite available residual use) and a locked instrument. However, these errors can be corrected or bypassed (although with additional operating room time). The incidence of critical failures depending on technical problems which demand conversion appears very low compared with the conversions reported during manual laparoscopic operations, which are reported to reach up to 16% for some major procedures (Nguyen *et al.*, 2013). This low rate of technical problems is likely the consequence of da Vinci's specific characteristics: robust mechanical tools and the use of traditional and established technology for building links, joints and power transmission (except those of the surgical instruments) (Freschi *et al.*, 2012).

The da Vinci system as case-in-point

For its specifications, the da Vinci currently appears as the most advanced and versatile surgical robot on the market and it represents a paradigmatic example among telesurgical systems. Moreover, in the perspective of the present analysis it seems preferable to concentrate on the paradigm of teleoperated robots rather than on "autonomous" robotic systems, not directly commanded by a surgeon, that automatically perform an operation according to previously given instructions. In the use of the latter type of robots, two kinds of accidents can occur: a human error of the surgeon in the choice of the operation or in programming the robot, and a malfunctioning of the system. These errors may certainly occur also with regard to teleoperated robots, but in that context a third type of error shall be considered, related to an incorrect movement of the surgeon who sit at the console, given that every movement of his/her hand is directly connected by the man-machine interface to the instrument tip movement inside the patient (Freschi *et al.*, 2012). For this reason, the analysis concerning teleoperated robots results as the most complete and inclusive.

3. Ethical Analysis

3.1 Introduction

According to the RoboLaw approach developed in D5.5 (Bisol, Carnevale & Lucivero, 2013), the current document presents the analysis of relevant ethical issues arising through the deployment of computer-integrated surgical applications. The ethical dimensions are extremely diverse as they involve different fields of special ethics, such as medical ethics, technology ethics, roboethics, journalism ethics, public health ethics, research ethics and training ethics.

To evaluate computer-integrated surgery with respect to the stakeholders involved (patients, surgeons, caregivers, researchers, industry, health-care systems, hospitals, and society), a mere bioethical approach would fail to deal with such a complex context. In D5.5: Methodology for identifying and analysing ethical issues in robotics research and applications, the basic features of this analysis have been outlined: RoboLaw ethical analysis will not provide a one-sided assessment of a specific technology, but will try to present the different elements that make up the ethical landscape related to certain robotics applications in a structured way. Furthermore we do not embrace a specific set of principles; rather, as Nida-Rümelin (2005) pointed out, for different areas of human practice there are different appropriate normative criteria, which cannot be reduced to a single system of moral rules and principles. At least it appears heuristically appropriate that larger complexes of human practice, each of which has specific characteristics (such as robotics research and applications), undergo an independent normative analysis. Instead of applied ethics, with their different focuses, one would rather speak of "special ethics". According to this view, the ethical analysis of computer-integrated surgery is a case of special ethics.

In line with those considerations, RoboLaw ethical analysis is going to offer a hybrid framework to tackle the ethical landscape of computer-integrated surgery. The principal intent of this chapter is to develop an ethical analysis that can help legal scholars to find regulatory proposals, which are able both to protect patients and support the dissemination of the benefits of this evolving technology in society. As robotized surgery is an emergent field in which the linkage between research, development and application is strong, regulation is crucial for promoting safe and just implementation.

3.2 Ethics and computer-integrated surgery: An increasingly popular system

Minimally invasive surgery (MIS) is getting more and more popular because it causes fewer traumas to the patients and ensures faster recovery. Minimal invasive surgery performed through computer-assisted surgery, like the da Vinci Surgical System, meets the individual preferences of surgeons, hospital staff, management and patients. Robotics supporting medical interventions is therefore not only widely accepted but also desired by patients, surgeons and hospitals. Growing acceptance is communicated through media and is conveyed by hospital policies. Increased desire for the use of technology is promoted by heavy media coverage and advertisement. According to Intuitive Surgical Inc., computer-integrated surgery is expected to increase safety and efficiency. But this can also produce undesired outcomes: Will the surgeon recommend the use of robotic surgery in all interventions because it benefits the patient or because it increases his/her prestige? (Fingerhut, 2011). The same can occur in the case of hospital policies: will "soft paternalism" find its way into hospital policies? Will robotic surgery become the default solution (perhaps in order to help amortize the cost of the machines)? Once a robotic system is installed in a hospital, we expect that there will be both subtle and overt pressure by hospital administrators on patients as they will have an interest in using the system as extensively as possible (Beckey, Lin & Abney, 2011).

On the debit side, computer-assisted surgery will often be more demanding and complicated for the surgeon (and his/her team) because everything has to be done through a few small holes and through specialized tools and instruments – e.g. cameras, mechanics, orientation support and intra-operative imaging systems – that have to be changed and put together during the intervention. This takes time, as for example a surgery of four hours needs one extra hour just to change the tools. The effect is that the entire intervention is slowed down and lasts longer. This burdens the team. The drawback for the patient is that he/she has to undergo longer anaesthesia periods than in normal MIS. Furthermore, as the surgeon is looking on a display, he cannot see directly, smell or feel what he is working on. Robotic assisted surgery only allows instruments, and not the hands of the surgeon, to touch the human body during an operation. Moreover, the use of instruments is less haptically intuitive.

On the merit side, robot-assisted surgery helps by providing a more ergonomic and user friendly intuitive interface for those instruments, thereby increasing precision (7 degrees of freedom) and filtering tremor. This user interface does not have to be right above the operating table. The surgeon sits in a comfortable position and can control all the instruments through special ergonomic handles and see a 3-D image, which is intuitively spatially oriented. Difficult or rare procedures can be performed and remote controlled by specialized surgeons (special consultations and telemedicine: see § 4.4.3).

Given these contrasting elements, it is important to determine in which kind of surgical intervention the deployment of the da Vinci Surgical Robot is effective. At the present moment, da Vinci is used very extensively. This usage should be limited to that particular kind of operation where robot-assisted surgery has proved to be especially helpful.

It is also important to require a licence for surgeons that will operate through the da Vinci Surgical Robot. At the moment, use of da Vinci is not restricted. Every surgeon can use it. And every surgeon can use it as extensively as he/she sees fit. If surgeons are to be licenced an additional problem arises. A notified body would have to be established, which is able to evaluate and assign the license to operate the da Vinci Robot.

Our interviews with surgeons suggest that the use of da Vinci leads to a reassignment of roles in the operating room and within the team that works there. They report that every team member perceives their individual actions to be part of a collective agent. Actor-Network Theory (ANT), which was developed by scholars working on Science, Technology and Society (STS), confirms this subjective observation of surgical personnel. This theory predicts, furthermore, that this social process is subject to dynamics. Collective action structures may appear and dissolve from time to time (Turner, 2009). Moreover, Bruno Latour highlighted the asymmetrical significance of ANT. When it comes to a successful implementation of an innovative technology, it is relevant to find out how the actor-network arises. When it comes to failures, it is important to explore at which point the network has been damaged (Latour, 2005: 602). This double perspective allows us both to explain the novel elements mediated by the introduction of the computer-assisted surgical systems in the operating theatre and to examine and display the responsibility in the case of failure. Responsibility seems not to be all-or-nothing affair. Rather, it seems to come in degrees. Latour may be interpreted as speaking of creating a collective subject composed not only of the surgeon and the machine, but also of the whole operating team; he also distinguishes between success and failure. In the case of success, it is relevant to explore how the alliance has been created. In the case of failure, it is relevant to explore where the alliance broke. Further research is needed to explain which precise consequences follow from ANT for da Vinci and whether ANT is, in fact, capable of framing the problem in an adequate way.

In order to explore the causes of possible failures of the machine, everyone who is involved in the operating process should be given access to relevant data which may reveal possible sources of error (Cooper *et al.*, 2013). The current system may have skewed our perception of da Vinci since privileged access to data that would reveal failures is only given a few select individuals. The problem of underreporting complications has to be avoided (Cooper *et al.*, 2013).

Decker (2014) has also suggested using a black box system. However, he focuses not on preventing mistakes. Rather, his intent is to better understand learning processes in robotic systems. In his recommendation, this opens up the chance for robots to adjust to new environments and persons. In particular, he says that

'The introduction of a non-manipulable black box, i.e. a recording device that cannot be modified from the outside and that documents precisely the modifications in the robotic system that are induced by the robot's learning algorithm, would also mean that the robot would make a detailed recording of its environment. The robot's sensory data are a central element of the possibility for it to be able to suggest adjustment measures. They thus also reflect the robot's immediate environment and possibly even properties of the person using it. Precisely in the context of care giving, the collection of physiological data plays a special role. This brings in its wake corresponding problems with the respective user's privacy (Böhle *et al*., 2013). *On the other hand, the black box can ensure that the reason that the robotic system learned something is always comprehensible. This can, in turn, play a special role in legal disputes'* (Decker, 2014: 84).

For our purpose, an approach, such as Decker's, is equally well suited as a solution for finding device malfunctions.

A further issue concerns justice and the potential exclusion of those who cannot afford such a high-end system as the da Vinci. Datteri & Tamburrini (2009) suggest that aside major ethical problems associated with robotic surgery outlined above, are problems concerning cost and justice. Systems like the da Vinci are expensive. The latest models of the da Vinci cost about US$1.75 million, not including annual maintenance and operational costs that could be in the hundreds of thousands of dollars. In Italy da Vinci seems to be more expensive than in the US and in other European Countries. These costs suggest that its use will be limited to relatively wealthy patients, wealthy communities and wealthy countries.

3.3 Uncovering normativity

Da Vinci is a system that is already in frequent use. According to the RoboLaw approach in D5.5, however, a more detailed examination of the implicit and explicit values that are presumably at stake when this kind of surgical robot is even more widely used must be conducted. This is the purpose of this part of the analysis, which will be done in two different steps: the first step concerns the machine itself; the second step pertains to the use of the robotic technology under investigation.

3.3.1 Uncovering values in the artefact

As already mentioned, the da Vinci Surgical System is a robotic device that is intended to extend the benefits of current minimally invasive surgery (MIS). Surgery robots are technical artefacts that must interact with humans. It is claimed that moral issues are taken into consideration in the design. In the first step, we want to understand which kind of moral considerations have in fact been taken into account at the design stage. In order to uncover the ethical issues and problems, the technical side involved has to be tested and experienced empirically. In order to address this issue, we were supported by the engineers of BioRobotic

Institute (SSSA), which make researches on robotics surgery (Taylor *et al.*, 2008) and by Endocas (Prof. Ugo Boggi, Endocas http://www.endocas.org University of Pisa). Furthermore, we underwent a test run with the da Vinci Simulator and the da Vinci robot itself under the supervision of Dr. Fabio Vistoli (University of Pisa). We observed that da Vinci does indeed run certain protocols that constrain and regulate human behaviour in a minimally moral sense and slow down procedures. However, substantive moral values that can influence human behaviour in a more encompassing way are nowhere to be found. Intuitive Surgical Inc.'s advertisements insinuate that da Vinci can make surgeons into super surgeons. But this idea seems to lack adequate support. Suffice it to say that we did not, in fact, become expert surgeons in the process. It is therefore no surprise that Intuitive Surgical Inc.'s marketing messages have been widely criticized. Prof Ugo Boggi's remark is a case in point. As he aptly noted, it is not enough 'to wear the shirt with the 10 to make a good scorer'.

3.3.2 Uncovering values in the use of the artefact

At this second step, we aim to understand the values that lie in the use of surgical robots.

The interviews with surgeons at the University of Pisa have highlighted the phenomenon described by the theory of ANT. With the introduction of da Vinci, personal relations in the operating room have changed. This change does not affect only the surgeon, but rather the whole team. The relationship between agents has been strengthened. Through the interaction and cooperation of humans and machines, both are more and more dependent on each other and on each other's skills and actions. It creates an alliance between humans and machines that creates the perception of being part of one collective agent. In the event of an accident it becomes very difficult to analyse and reconstruct the individual action and responsibility.

The current selection process of surgical trainees does not include testing for the psychomotor and manipulative skills of the candidates (Moglia *et al.*, 2014). With the introduction of da Vinci future surgeons have the possibility to experience operations through an advanced virtual reality surgical simulator. In the process, it has become increasingly clear that surgeons should, in fact, be selected based on their performance in the operating room, which can be simulated using da Vinci Simulator. To that extent, da Vinci has indeed made the academic community – and especially those who train young surgeons – more aware of the fact that surgery is a craftsmanship and not a mere academic exercise.

Furthermore, gender issues should be investigated. Since surgery is a male domain it needs to be investigated whether the machine supports the status quo or is able to promote a new vision of gender equality.

Above that, hospital policies may be affected negatively by the economic interests that go along with the use of the da Vinci robot. E.g., its steep costs have to be paid off. Surgeons are hence likely to advise in favour of the use of the robot even in cases where it is not, in fact, advisable. An additional point that should be noted in this context is the prestige of the system and its implications for the practice of surgeons. Using the robot may function as an ego boost. And surgeons may feel inclined to advise its use even if it is not entirely in the interests of their patients.

3.4 Mapping critical issues

After the examination of the value in the artefact, we are now going to map out the critical issues that attach to da Vinci and its use. We believe that the main critical issues revolve around the following aspects.

- Changes in human-human interactions
- Safety
- Autonomy
- Justice and New Technologies
- Responsibility
- Privacy

Before we go into detail about these aspects we mention, however, that this list is not exhaustive. It is hard to tell in advance which ethical problems da Vinci will give rise to in the future. The best we can do, at this stage, is to consider past experiences with surgical robots and learn lessons from earlier warnings about surgical devices that have been used in the past as, e.g., ROBODOC and CASPAR (Caetano da Rosa, 2013).

3.4.1 Changes in human-human interactions

Most current examples of robotic surgery are developed to enhance the senses of surgeons, not to replace them, and as an addition to existing practices, not as their substitutes. Whenever the robot is used as a replacement or substitute for human action, then the robot might threaten to reduce the amount of human-human contact. According to the Actor-Network-Theory (ANT), which we have mentioned previously, an interconnected collective entity emerges. This new subject is made by humans (surgeon and nurses) and da Vinci.

Surgical Ego is given a boost through the use of da Vinci, which may lead to problems. Above we have asked whether surgeons will recommend the use of robotic surgery in interventions because it benefits the patient or because it increases his/her prestige. At this point, we should reemphasize this problem. Since da Vinci is considered to be cutting-edge technology, its use does undoubtedly bring with it great prestige and will likely incite surgeons to use it – perhaps more than necessary and/or advisable. The same risk exists mutatis mutandis in the case of hospital administrators. Given the high status of da Vinci, they may push for its extensive use to boost the image of the hospital. Patients, who are medical laypeople, may play a role in this process. It is not unreasonable to suspect that they will give preference to hospitals that pride themselves with da Vinci.

The preliminary evaluation through da Vinci in the assessment process, that precedes medical training, will undoubtedly help to judge the capabilities of an aspiring surgeon more accurately than the current system, which is essentially based on academic merits. This will arguably affect the quality of surgeons' work in the future. Similarly, surgical training will be strongly and positively influenced by the possibilities that the da Vinci simulator offers.

Gender issues may arise through the use of the da Vinci system. However, in order to assess its effects accurately further research is needed.

3.4.2 Safety

More research is needed in order to establish the clinical effectiveness of da Vinci Surgery where its use may be indicated. This research would have to test not only the functionality of da Vinci, but also its possible consequences for patients. As Cooper *et al.* (2013) point out, robotic surgery complications may go unreported. In order to avoid this we have already suggested to use a black box system that may identify device malfunctions.

Further measures should be taken to ensure safety. For one thing, a notified body that assesses whether da Vinci meets the required standards for a given field of surgery has to be established. In addition, surgeon who would like to use da Vinci should be required to undergo proper training and to obtain a licence for its use.

3.4.3 Autonomy

The patient's autonomy in choosing the robotic operation seems to be threatened by two conflicting interests, as we have already stated. Firstly, given the costs of a da Vinci system, hospitals will seek returns on their investment. This will, as we have remarked previously, likely manifest itself in a tendency to over-recommend da Vinci use. Furthermore, ambitious surgeons may be expected to strive a boost in prestige through their use of da Vinci, which may lead to similar effects.

3.4.4 Justice and the new technologies

Whenever new technologies are introduced, issues of equal access and distributive justice arise. There is, after all, a tension between the introduction of new technologies and an equal opportunity to use them. Since the development of new technologies is associated with heavy investments, developers will seek monopoly prices. This, in turn, may bar socioeconomically disadvantaged members of society from use. Many influential theories of justice will take exception to this (e.g. Rawls, 1971/1999) and will require that society ensure universal access. As Datteri (2013) has pointed out, this problem may arise in the case of da Vinci, too. The latest models of da Vinci cost about US$1.75 million, not including annual maintenance and operational costs that could be in the hundreds of thousands of dollars. In addition, da Vinci may be more expensive in certain countries (e.g. Italy) than in the US and in other European countries. Given these costs, its use will be limited to relatively wealthy patients, wealthy communities and wealthy countries, which is unacceptable. (Datteri & Tamburrini, 2009).

3.4.5 Responsibility

When human beings act without using technologies it is sometimes hard enough to determine who is responsible for what. The introduction of technologies artefacts makes things even more complicated. Surgical robots, in particular, and their use in healthcare add complications for the ascription of responsibility, if something goes wrong. As Friedman, Lendvay and Hannaford (2013) point out, patients may conceivably be severely harmed by medical practitioners if a robotic system malfunctions. In that case, the question arises who should be blamed. The surgeon? The manufacturer? The hospital? The legislator? The personnel in charge of maintenance? As we have already suggested above, the black box system may provide a partial solution here as well. Not only would it help us to explore possible causes for failure and give the da Vinci system an opportunity to learn. In the case of complications, it may also give us the chance to find out what happened and to which extent human failure played a role. This holds, however, only on the condition that everybody is involved in the surgical process.

3.4.6 Privacy

We mentioned in the previous section that a black box system, if it is to address issues of responsibility effectively, has to provide access to information. Some of that information will undoubtedly concern aspects of the patient and his/her condition that she may be entitled to keep private. This means that there is a potential clash between the goal of ensuring fulfilment of responsibility and the notion that personal data ought to be kept private (Böhle *et al.*, 2013). The

resolution of this problem can, it seems, only consist in an appropriate weighing of both concerns. This means that regulators have to strike an appropriate balance. They will need to decide how long data can be store, who gets access, whether patient need to consent and so on.

3.5 Policy considerations

The ethical analysis of the da Vinci suggests a number of recommendations for policy makers.

Even though da Vinci is already in use, surgical robotics is a new field that we should be open to. Technological progress proceeds at a rapid pace and can often be perceived as threatening. It is, however, the basis for the future welfare of society and should thus be allowed to progress, if this is done responsibly. This said, there are a number of ethical concerns, which need to be addressed.

- Firstly, we would like to reemphasize that stakes are high and that it is thus incumbent upon us to learn from past experience. There have been a number of surgical robotic systems (e.g. ROBODOC and CASPAR) that were applied and tested in the past. Some of the tests have come out negative and we should not repeat the mistakes that were made here.
- The second point to be made is that overly enthusiastic reactions to da Vinci are not advisable. If the system performs well it should be used – but not, we believe, as a replacement of current surgical practice. Instead, it should be used when appropriate and as an augmentation of the *status quo*.
- Adequate policy making will have to address and factor in various perspectives from various fields (e.g. medical professionals, developers, legal experts, ethicists, patients, etc.). For this reason, it is advisable to establish a standing committee that discusses the ethical, legal and technical issues surrounding da Vinci and to ensure that there will be an adequate platform for debate. It should be stressed, in particular, that a patients' association will need to partake in this process of discourse at every step of the way.
- The possible use of the black box system will have to be investigated further in order to address issues to do with responsibility and safety as well as privacy.
- Our investigation furthermore yielded the finding that marketing messages are often to be taken with a pinch of salt. They do not always convey fully accurate information but are naturally biased in favour of developers of innovative surgical systems. Hence, it is advisable to analyse which types of regulation may have to be imposed on marketing, journalism as well as the media as a whole.
- The positive impact of da Vinci on the training of young surgical professionals should be stressed once more. It is certainly advisable to trace how the system may be used in medical training in order to harness the whole potential of medical personnel.
- Finally, the issue of justice will have to be taken very seriously. As we have explained above, new technologies like da Vinci tend to have exclusionary tendencies – at least when they are first introduced – since developers will seek to maximize their return on investment. However, once a technology becomes the new state of the art, the most influential theories of justice will require some form of fairness in healthcare access. The allocation of da Vinci, too, may have a tendency towards inequality, which must be resisted through adequate social policies. It must be ensured that the human right to the best possible standards of care is granted to all.

4. Legal Analysis

4.1 Introduction

The aim of the legal analysis is to identify and discuss the legal implications related to the use of surgical robots. The technology is first framed within European law, by focusing on the legal definition that surgical robots receive according to the European directive 93/42 (§ 4.2). Other relevant legal aspects are then considered: training and skills of the users of the da Vinci (§ 4.3); in the context of medical practice, informed consent (§ 4.4.1), civil liability of the surgical team involved in computer-assisted operations (§ 4.4.2), and the prospect of using surgical robots for telemedicine (§ 4.4.3); the availability of digital evidence in case of a malfunctioning of the device (§ 4.5) and issues of privacy (§4.6). The analysis ends with some remarks about the costs of computer-assisted surgery, that present significant repercussions also on the legal stance (§ 4.7).

4.2 Surgical robots as medical devices: the Directive 93/42/EEC

The da Vinci system (CE 0543) belongs to the category of Class IIb medical device according to the classification based on the Annex IX of the Council Directive 93/42/EEC of 14 June 1993 (henceforth MDD).[2] Art. 4 MDD provides that Member States (MS) shall not create any obstacle to the placing on the market or the putting into service, within their territory, of devices bearing the CE marking. In order to obtain the CE marking, and thus meet the safety requirements, that allow the distribution of the product within the European market, Class IIb devices need to undergo either the procedure for the declaration of conformity set out in Annex II (full quality assurance), or the type-examination set out in Annex III.

In the first case, the examination of the design of the product (point 4 of Annex II) is not required; in the second case instead, the manufacturer is also required to comply with one of the three procedures set forth respectively by Annex IV, V or VI, namely the EC verification the EC declaration of conformity (production quality assurance), or the EC declaration of conformity (product quality assurance).

The EC type-examination is the procedure whereby a notified body ascertains and certifies that a representative sample of the production covered fulfils the relevant provisions of the MDD (point 1 Annex III). The notified body is a third party – either a national public authority or a non-governmental entity, designated by MS, and notified to the Commission and other MS (art. 16 MDD) – that assesses the conformity of the devices, by carrying out the procedures referred to in art. 11.

The Commission periodically updates and publishes in the *Official Journal of the European Communities* a list of the notified bodies, together with the tasks for which they have been notified, assigning an identification number. To obtain the CE marking, medical devices have to respect (art. 3) the Essential Requirements included in the Annex I, distinguished in General Requirements (Section I) and Requirements regarding Design and Construction (Section II). The former aims at ensuring that the devices are designed and manufactured in such a way that, when used under the

[2] On 26 September 2012, the European Commission adopted a proposal for a Regulation of the European Parliament and of the Council on medical devices. This regulation should replace and repeal the Directive 93/42/EEC: see the proceedings of the Symposium on the EU's New Medical Devices Regulation Framework (Denoon & Vollebregt; Singh; Altenstetter; Bergkamp & Kogan, 2013).

conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or other persons.

The latter require that the solutions adopted by manufacturers for the design and construction of the devices abide safety principles, take into account the generally acknowledged state of the art, and conforms to the following principles: eliminate or reduce risks as far as possible (inherently safe design and construction); where appropriate, with respect to risks that cannot be eliminated, take adequate protection measures including alarms; inform users of the residual risks due to any shortcomings of the protection measures adopted.

For the devices, which already have received the CE marking, a control and surveillance procedure is established by the article 10 of the directive, pursuant to which MS shall take the necessary steps to ensure that any information brought to their knowledge regarding some specific incidents (involving a Class I, IIa, IIb or III device) is recorded and evaluated centrally. The incidents taken into account are: (a) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health; and (b) any technical or medical reason in relation to the characteristics or performance of a device for the reasons referred to in sub-paragraph (a), leading to systematic recall of devices of the same type by the manufacturer (to this purpose, for example, the article 9 of the Italian legislative decree 46/1997 says that every public and private healthcare professional must inform the Department of Health in case of incident concerning medical devices).

Where a MS requires medical practitioners or the medical institutions to inform the competent authorities of any incident mentioned above, it shall take the necessary steps to ensure that the manufacturer of the device concerned, or his authorized representative established in the Community, is also informed of the incident. In fact, the manufacturer, if possible, should be involved in the assessment which MS have to do – without prejudice to the faculties provided for the article 8 – before informing the Commission and the other MS about the incident and the measures that have been taken or contemplated to minimize the risk of such events.

Art. 8 of the directive sets forth a "safeguard clause" pursuant to which the MS which ascertains that the device, when correctly installed, maintained and used for their intended purpose, may compromise the health and/or safety of patients, users or other persons, irrespective of the circumstance that the device itself carries the CE mark, shall take all appropriate interim measures to withdraw such devices from the market or prohibit or restrict their distribution; such decision should then be immediately communicated to the Commission, indicating the reasons for a similar decision[3].

At this point, the Commission shall enter into consultation with the parties concerned as soon as possible, and should it decide that the measures adopted are justified immediately informs all MS.[4]

[3] Non-compliance with the Directive may be due to: (a) failure to meet the essential requirements referred to in art. 3; (b) incorrect application of the standards referred to in art. 5, in so far as it is claimed that the standards have been applied; (c) shortcomings in the standards themselves.

[4] Where the decision referred to in paragraph 1 is attributed to shortcomings in the standards, the Commission shall, after consulting the Parties concerned, bring the matter before the Committee referred to in art. 6(1) within two months if the MS which has taken the decision intends to maintain it and shall initiate

Differently, if after the consultation with the interested parties the Commission finds that the measures are not justified, it shall immediately inform the MS which took them and the manufacturer or his authorised representative.

4.3 A European "qualifying certificate" for the use of surgical robots

As said in the previous paragraph, the MDD already allows a strict control on safety and performance of surgical robots. Indeed, European law allows both the MS and the European Commission to adopt significant measures through a specific procedure – eventually leading to the prohibition of further distribution onto the market and the retrieval of devices already released – if a device, after obtaining the CE marking, is still deemed capable of compromising the health and/or the safety of patients, users or other person. An aspect that was instead so far completely neglected by European law is the one of the technical training and requirements of surgeons operating with the device.

In fact, in robotics 'there are no innocent bystanders and the people involved can be given special training to prepare them to use the robotic system optimally. The human actor retains responsibility in this context' (Decker, 2014: 83). Indeed, at present, surgical robots are regarded by the law as any other medical device employed in surgical operations, and their usability is only subordinated to the maintenance of the objective conditions required to keep the CE marking. However, to treat surgical robots as a simple medical device tends to be misleading, for it puts the robot on an equal footing with other surgical instruments which are medical devices as well, but much less complex and sophisticated (for example, a stapler or a scissor are also medical devices, which in spite of their possible technical evolutions, still maintain the same function). In fact, the MDD only regulates the function, design and construction requirements of devices, and does not address the opportunities and risks involved in the computer-assisted surgery, among which the subjective qualifications of practitioners called to use it.

The most relevant differences which distinguish robot-assisted surgery from open surgery and traditional laparoscopic surgery were presented above. The need to acquire familiarity with the surgeon's console (i.e. with the display, the interface and the electronic controller) and with the movement of the four slave manipulators, the enhancement provided by the seven degrees of freedom given by the robot are innovative and extraordinary factors, which certainly require adequate training and preparation on the side of the surgeon in order to be fully – and safely – exploited. This remark leads to suggest to adopt a European common protocol of minimum professional training. In particular this should involve practising through the use of computer simulators and taking part at real operations, assisting an experienced surgeon while sitting at a second console[5], in order to learn in conditions of maximum safety for the patient. Moreover,

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the advisory procedure referred to in art. 6(2); (ii) when necessary in the interests of public health, appropriate measures designed to amend non-essential elements of the dir. 93/42/EEC relating to withdrawal from the market of devices referred to in paragraph 1 or to prohibition or restriction of their placement on the market or being put into service or to introduction of particular requirements in order for such products to be put on the market, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in art. 7(3). On imperative grounds of urgency, the Commission may use the urgency procedure referred to in art. 7(4).

[5] The da Vinci system can be configured so as to present two consoles, both connected with the operating arms. Such a configuration may allow surgeons to follow step by step the operation performed by a trained and skilled practitioner, or – in a subsequent stage of their formation – operate while being completely supervised by an instructor.

courses held by experts chosen by the producer or importer and qualified surgeons would also provide the necessary theoretical background, to transform a traditional surgeon into a specialist capable of making full use of robotic technology.

Indeed, it is worth noting that in the US numerous lawsuits have been filed against Intuitive Surgical, Inc., accusing the company of not properly training the surgeons before they made use of the robot. However, in a recent decision of the Kitspa County Superior Court of the State of Washington (Superior Court of the State of Washington – Kitspa County Superior Court, No. 09-2-03136-5, 25 March 2013), the jury found that the defendant did not fail to adequately prepare the doctor who performed the surgery on a patient who later died. Yet the manufacturer, together with the U. S. Department of Defense identified ten research institutions and hospitals, which are renowned for their experience in operating with the daVinci system (among which EndoCAS[6]), to develop a training protocol called '*Fondamenti di chirurgia robotica'* (Foundations of robotic surgery)[7]. This initiative aims at producing an internationally recognized standard of qualification for surgeons intending to make use of robotic devices, as already required since 2009 to surgical trainees specializing in laparoscopy in the United States.

It seems therefore necessary that the European Union defines the minimal professional requirements that the surgeon must show in order to be allowed to use a greatly complex device like the surgical robot. To this purpose, specific training which allows the surgeon to obtain a European certificate of his abilities to perform robotic-assisted operations, after passing a final exam, could be introduced. This procedure, that in the MS could be arranged by the Faculties of Medicine or by University Hospitals, should provide for a certain amount of hours including theoretical lessons, training with the simulator, and participation in the computer-assisted interventions. Moreover, the qualified surgeons should periodically attend continuing education courses to renew the validity of their certificate and eventually update it for the use of more advanced devices over the time developed and acquired by hospitals.

The need for a similar regulation and standardization was repeatedly stressed even by the surgeons interviewed during the project, who pointed out how, at present, no legal tools prevent a surgeon lacking adequate experience to undergo a robotic operation; the only limit being represented by the negative opinion of the Ethics Committee of the hospital, which still does not address directly the surgeon's experience, but rather the adequacy of the solution proposed in a therapeutic perspective.

A European regulation on the qualifying certificate for using surgical robots would also promote the free movement of professionals among MS, as well as ensure a more efficient and transparent recognition of professional qualifications, as stated in the Proposal for a directive of the European Parliament and of the Council, amending Directive 2005/36/EC, on the recognition of professional qualifications and Regulation on administrative cooperation through the Internal Market Information System, as emended by the legislative resolution of 9 October 2013 of the European Parliament (*whereas* 4).

[6] http://www.endocas.org/

[7] http://www.unipi.it/index.php/tutte-le-news/item/4449-arriva-la-patente-per-operare-con-il-robot-da-vinci

In fact, should some MS fix specific subjective requirements to perform robotic-assisted operations, the surgeons coming from other MS would not have full access to the profession.[8]

4.4 Robotic surgery in the context of medical practice

Most surgical robots are based on a master-slave control concept. As already said, the da Vinci system consists of two units: the surgeon's console unit and the second unit made up of four slave manipulators; through a telemanipulator the movement of the surgeon from the master console are exactly replicated by the arms of the robot (slave).

There are well reported cases in medical literature of system breakdowns which have imposed to convert a robotic-assisted intervention to open surgery or to the conventional laparoscopic surgery. But a system malfunction could even injure the organs of the patient, for example, with a sudden and uncontrolled movement of the robot's arm which has not been put into action by the surgeon. In a similar hypothesis, if the robotic-assisted operation does not have a positive outcome because of a malfunctioning of the machine, the hospital (public or private) must initially bear the costs deriving from the compensation of the damages suffered by the patient. In fact, according to the general principle of the law of obligations, the hospital is responsible not only for the behaviour (and the mistakes) of his doctors, but also for the means employed in the execution of its – surgical – performance. At the same time, it would be unfair to burden the patient with the weight and costs of a legal action against the robot manufacturer; in fact, the patient may not be able to acquire the necessary information in order to demonstrate the malfunctioning of the device, not having access to the needed technical data.

4.4.1 Informed consent

Most certainly the patient's – informed – consent to the operation cannot be interpreted as a liability waiver in favour of the hospital. It is indeed well known that the physician should obtain the patient's consent after having previously informed him/her about the principal aspects of the treatment. In the field of robotic surgery, this duty in particular involves the differences between the use of a surgical robot and a "conventional" treatment. It is in other words necessary that a physician not only explains to the patient (or his/her proxy) that he is subjecting him to "a non conventional" treatment, but also which aspects could hypothetically produce a greater risk, as well as all collateral effects of the therapy, together with the reasons pursuant to which robotic surgery is expected to prove advantageous. In so doing, the doctor should make reference and explain the sources, which legitimize such conclusions, so that the patient is at least theoretically and hopefully put in the position to estimate the reliability of the scientific data upon which the doctor grounds his opinion, and eventually opt for a more traditional treatment.

[8] See art. 4f: the competent authority of the host MS shall grant partial access, on a case-by-case basis, to a professional activity in its territory only when all the following conditions are fulfilled: (a) the professional is fully qualified to exercise in the home MS the professional activity for which partial access is sought in the host MS; (b) differences between the professional activity legally exercised in the home MS and the regulated profession in the host MS as such are so large that the application of compensation measures would amount to requiring the applicant to complete the full programme of education and training required in the host MS to have access to the full regulated profession in the host MS; (c) the professional activity can objectively be separated from other activities falling under the regulated profession in the host MS. For the purpose of point (c), the competent authority of the host MS shall take into account whether the professional activity can be pursued autonomously in the home MS.

4.4.2 The liability within the operating team

The accomplishment of a surgical operation with a robot may require the cooperation of a medical team comprised of more than one surgeon. In this respect, careful consideration should be devoted to the problem of shared liability. Civil liability rules generally concerning the responsibility of all the surgeons in the team, do not perfectly suit malpractice cases involving surgical robots, where the surgeon operating the console makes a mistake during the intervention.

Normally, in the case of medical malpractice, all the members of the surgical team are jointly responsible, because everyone is bound to act with diligence as much as to diligently supervise the work of the other, and if necessary to remedy evident errors. Despite this joint responsibility, the part of liability of each surgeon can be different, depending on who in actual fact has made a certain decision or has carried out the harmful act on the patient's health.

This state of things is coherent with a dating tradition of civil law. The article 2055 of Italian civil code states that if the tort is imputable to more than one person, everyone is jointly liable to compensate damage; § 830 I S. 1 BGB, analogously, says that if more than one person has caused damage by a jointly committed tort, then each of them is responsible for the damage. The same principle is not formally established in the French civil code, but nevertheless it has been affirmed by scholars and the law in action ('*la conséquence naturelle de la pluralité de responsables est l'obligation* in solidum*, également dénommée obligation solidaire*': Corgas-Bernard: 5; and Cour d'Appel de Colmar, 20 février 2002).

A similar statement, which contains also a punitive value (because someone in the first instance could be bound to compensate the full damage although his role in the causation of it was only marginal) (Medicus & Lorenz, 2010, 495, say that the § 830 presents a '"strafrechtliche" Teil'), seems particularly iniquitous and irrational if applied without discrimination to the liability of the entire surgical team involved in a robotic-assisted operation, because in robotic-assisted interventions the position of individual operators cannot be considered on the same level. In fact, only the surgeon who sits at the master console can command the robot and, more specifically, only this subject takes advantage of the 3D display above his hands, giving him the virtual sensation of acting within the patient's body, while the rest of the team receives images of the operating field only by a 2D screen which is not part of the surgical robot's system.

In other words, the surgeon who controls the robot at the console is able to act on the basis of privileged information that neither can be shared with other team members – unless a second console is connected with the operating arms of the robot (see §4.3, fn 4) –; nor directly observed by the latter, for the operating field remains concealed since the robot uses laparoscopic tools. Given this setting, the surgeons will not have the opportunity to discuss and to confront each other in real time on the many decisions made by the surgeon at the console.

For these reasons, the liability rules concerning computer-assisted surgery should be excluded for the surgeons who are not at the master console, whenever the damage to the patient was provoked by an action of the robot triggered by the user, due to a wrong evaluation which the other team members were not able to correct on the basis of the images transmitted only by the 2D screen, which ultimately is not even part of the robot.

Furthermore, it also needs to be considered that in the case of damage depending on intentional or heavily negligent conduct of the surgeon at the console, the other surgeons are not always in the position to intervene in adequate time on the patient – unless a second console is

being used, both connected to the operating arms of the robot (see §4.3, fn 4) –, because it could be necessary to stop the robot and to continue the operation in open or laparoscopic surgery.

Similar considerations lead us to conclude that civil liability rules should not be modeled on the basis of the identification of narrowly tailored illicit conducts, which automatically give rise to a duty to compensate damages suffered by the patient. Rather, existing negligence standards – provided for by all MS legislations – do offer adequate elasticity when assessing the appropriateness of the surgeon's conduct. Therefore, should the European Union decide to intervene in order to regulate, directly or indirectly, the issue of the liability of a surgeon operating with robotic devices, negligence still appears to be the preferable solution, requiring the judge to take into account every relevant circumstance in which the harmful event occurred, as well as the reasonableness of the choices made by the practitioner.

4.4.3 A not so distant future: Telemedicine

Another issue, which can emerge from the potential offered by robotic surgery in a more – but not so – distant future is that by means of a robot theoretically any practitioner may treat a patient lying in another place or country. Therefore, telemedicine might give rise to problems concerning the area of conflict of laws (or private international law), triggering forum shopping mechanisms. Doctors may indeed decide to go operate in the country, whose rules would be more favourable – for instance by (i) excluding criminal sanctions, or (ii) providing a different partition of the burden of proof, or (iii) allowing more modest compensation in case liability is established – should a malpractice action be filed against them. Similar practices may favour a race to the bottom in standards of medical liability, which is certainly not advisable, and may thus be averted through the adoption of uniform rules.

A further aspect of relevance, connected with the practice of telemedicine, is that of insurance contracts. Existing products may specify whether they apply and offer coverage to cross-border practices, but often uncertainty remains, with respect to the applicability outside the jurisdiction for which they are conceived (Dickens & Cook, 2006). It is therefore advisable that practitioners and hospitals, who decide to practice telemedicine by means of robotic surgery, preliminarily verify whether such practices fall within their insurance contracts coverage.

Besides, it should be recalled that different regimes of confidentiality and privacy might apply in different countries, and yet, as emphasised by the 1999 World Medical Association statement on telemedicine, the principles of medical ethics globally binding upon the medical profession must never be compromised (World Medical Association. Statement on accountability, responsibilities and ethical guidelines in the practice of telemedicine, adopted by the 51st World Medical Assembly, Tel Aviv, Israel, October 1999).

As telemedicine and robotics develop and become more and more frequent, it is conclusively advisable the introduction of uniform rules, at least in the EU, favouring cross-border practice, guaranteeing legal certainty and high standards of safety and respect of the patient.

4.5 Malfunctions of the robot and digital evidence

In case of a malfunctioning of the robot unrelated to the conduct of the surgeon, the hospital can claim damages from the manufacturer or importer of the machine.

To this aim, the plaintiff must support his action with the evidence of the malfunctioning and therefore he shall have the right to access the digital data elaborated by the robot, and collected

in a kind of internal "black box", which records every command given and every process executed, together with the incidental system errors. According to the actual terms of sale, this data is not accessible by the hospital, even when it is the owner of the robot, and they can be extracted only with the intervention of a technician sent by the manufacturer or the importer. The robot is also connected with an external monitoring system managed by the producer or the import company, which controls all the activities of the machine and signals any error; however, this information is inaccessible for the robot's owner as well.

This inconvenience is a serious constraint for the hospital to advance its rights, since that data allows to determine whether a certain action may be attributed to the robot or to the operator, and consequently establish if the cost of damages must be borne by the producer or by the hospital. European law should prescribe the obligation for the manufacturer to install on the robot a software which enables the user to retrieve these data strings and decode them, or, alternatively, the obligation for both the manufacturer and the importer to provide the same data upon request of the robot's owner or holder. It shall be further stressed that the digital data must not only be made available, but also unequivocally decrypted, perhaps through the intervention of a third independent subject like the notified bodies identified for the purposes of the MDD.

4.6 Privacy

In general terms, the use of robotic surgery at first sight does not seem to create specific problems in comparison with traditional systems. In fact, in both cases principles assessed by DPEC apply.

Therefore, it is possible to suggest that, as in "traditional" surgery, the collection and storage of personal data should be limited in compliance with the so called "data minimisation" and "finality" principles, by virtue of which the informative systems and the programs are shaped reducing the use of personal data, and data collection must be adequate, relevant and not excessive in relation to the purposes for which it was collected and/or processed.

Moreover, the adoption by the producers of security measures – including passwords, firewalls, and other necessary devices –, is mandatory as well as their continuous updating by the users (Art. 17 DPEC). The adoption of the above cited appropriate security measures should prevent 'the risks of destruction or – even accidental – loss of data, of unauthorised access or of unlawful processing of personal data' (see. e.g. Art. 31, Italian D. lgs. n. 196/2003).

It is also necessary to stress that the lack of compliance with the above mentioned security measures may result in civil and criminal liability. For instance, as to the former, in Italy a quasi-strict liability rule applies (according to Art. 2050 of the civil code and Art. 15, D.lgs. n. 196/2003), which means that the negligence of the tortfeasor is presumed and the latter is liable for any damages deriving from his conduct unless he proves to have adopted all the suitable measures to avoid the damage. The suitability of those measures is to be assessed pursuant to the state of the art and more rigorous a regime is established for health-related data, due to its peculiar nature.

4.7 Economic perspective on robotic surgery

A problematic aspect of computer-assisted surgery is that of its costs, that nowadays are extremely high. In addition to the high cost of the device (the da Vinci currently costs approximately 2,5 million euro, while in the USA it is retailed for a price ranging from 1 to 2,5 million dollars), its maintenance is also expensive (in Italy it is free for the first two years, then amounts to 10% per year of the robot purchase cost). The surgical end effectors must be replaced

every ten operations, and the setting of the operating room is more complex and expensive compared with the setting required by the manual laparoscopic surgery; besides, operating room time is normally longer with the robotic approach than with the manual laparoscopic approach. Finally, in order to learn to operate the da Vinci a computer simulator is provided, which itself costs about 500.000 euro (for a detailed economic analysis, see Turchetti, *et al.*, 2012).

The purchase of the robot (and of the simulator), its maintenance and the frequent replacement of the surgical instruments demand therefore considerable economic resources, without taking into account the varying and higher cost connected with the operating room setting.

A first response to the problem of the high costs of robotic surgery is to recommend that public hospitals use such devices only for operations which cannot be accomplished through manual laparoscopy. Only in cases where the robot ensures better results and a shorter hospitalization of the patient should this technique be employed. For example, a recent study shows that robotic surgery first gained prominence for prostatectomy because it essentially offered the only minimally invasive surgical approach for the procedure. Instead, hysterectomy, unlike prostatectomy, already is performed with a number of alternatives to open surgery: laparoscopic hysterectomy is a well-accepted procedure and vaginal hysterectomy allows removal of the uterus without any abdominal incision (Wright *et al.*, 2013). Also the American Congress of Obstetricians and Gynaecologists released a statement in March 2013, advising patients that «robotic hysterectomy is best used for unusual and complex clinical conditions in which improved outcomes over standard minimally invasive approaches have been demonstrated». The ACOG statement noted furthermore that «if robotic surgery is used for all hysterectomies each year», it would add an estimated $960 million to $1.9 billion to the annual cost of hysterectomy surgeries (Kaiser Health News & Evans, 2013). As it was observed by some stakeholders, an efficient employment of robots should persuade the hospitals to address their computer-assisted activities towards specific sectors, with the scope to achieve peaks of excellence in certain surgical specializations in the national landscape; instead, the hospitals often prefer an indistinct use of the robot, especially "to justify" its costs in front of the local community. In this sense, a particular role may be played also by the "surgical ego" of the doctor, who can be brought to believe, also thanks to marketing strategies, that the robot will allow him to accomplish every operation, even those that he is not otherwise capable of performing (on the concept of "surgical ego", see Fingerhut, 2011).

The very high costs of robotized surgery may probably decrease with the emergence of new robots on the market and the beginning of an effective economic competition among the players. So, if the Commission regards robotic surgery as a new strategic field to improve the quality of healthcare in the European landscape, it should consequently adopt policies that make this technology more accessible and widespread, through the elaboration of specific funding programs to encourage private investments in this area.

Indeed, the economic factor is a real stumbling block to the development of technologies for robotic surgery and for the improvement of the existing ones. Indeed, the initial costs of design and development of new devices, and the long-term return of the investments, may delay the emergence of new players on the market. At the same time the lack of an effective competition does not provide adequate incentives to manufacturers to improve and innovate existing technology. For example, on the basis of the current technical knowledge, surgical robots could be equipped with applications to restore the haptic sensation of the surgeon, or to prevent the arms of the robot from colliding with one another in case of mistakes of the surgeon; nevertheless, without a pressing competition among the manufacturers which incentivizes them to renew their products, the implementation of new technical possibilities advances inevitably more slowly (Nosengo, 2013).

Another factor of uncertainty that may affect the costs of surgical robots, as well as deter potential investors, could be represented by the cost sustained or feared due to the risk of civil liability claims. To this regard it must be taken into consideration the Council Directive of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the MS concerning liability for defective products (henceforth DPD). In fact, robots are product, pursuant to the definition provided by art. 2 of the DPD, whereby 'product' means all movables even if incorporated into another movable or into an immovable, and to this end the importance of the software does not change the inference, because software commonly is considered as a thing integrated into the hardware (for a more detailed discussion of the DPD and its application see Bertolini, Ch. 4, § 4.2.1 and Schellekens, Ch. 2, §§ 4.2, 4.3, as well as Bertolini, 2013 and Decker, 2014). Since many claims, which are currently brought against medical structures – namely hospitals – and practitioners, may – once the use of robotic surgery becomes more common – turn into defective product litigation against the manufacturers of such devices, in particular in terms of defective design of the robot, the DPD may be perceived as a further and significant obstacle to the emergence of new players in the market of surgical robots, producing an overall technology chilling effect.

Indeed it could be argued that sufficient protection is offered to the producer pursuant to art. 7 of the DPD (for a discussion see Bertolini, Ch. 4, § 4.2.1), ultimately transforming a strict standard into a rule of negligence (on the meaning of fault, Koziol, 2012, 200 ff.), and that anyway the safety of the devices ought to be the major concern for the legislator in this field (but see above Bertolini, Ch. 4, §4.2.5 for considerations on the effect on safety of the DPD).

That said, two conclusive remarks can be formulated. Firstly, the liability rules for defective products may become a source of uncertainty for the economic players if their application were not certain, as it might happen if the producer liability, although excluded according to the Directive, was assessed through the use of other national and more general provisions (e.g., article 2050 of the Italian civil code on responsibility for dangerous activities), which is always possible (see for instance Castronovo, 2006). Secondly, even though the DPD may not appear so exceptionally burdening for the producer of surgical robots, in order to encourage the emergence of new – and eventually even European – players onto the market the European Commission could even consider the perspective of striking a new balance – even if temporary, i.e. by the use of the specific "sunset rules" – between the interest of the patient to sue the producer directly and the interest of scientific progress.

4.8 Recommendations

The legal analysis of surgical robots allows us to formulate the following recommendations for policy makers:

(1) Professional requirements: European law should fix the professional requirements that the surgeon must exhibit in order to be allowed to perform operations using robotic devices. In particular:
   (a) specific training should be required for the surgeon to obtain a European certificate of his abilities to perform robotic-assisted operations, including a final exam, both theoretical and practical;
   (b) such professional requirements should involve a duty of constant formation and updating autonomous from those normally demanded to practitioners.
   (c) It may be considered the possibility to tie the certificate with the use of a specific surgical robot. As a result the surgeon would be allowed to

perform operations using that specific device only, and should he desire to extend his licence to include other robots he would be required to receive further training and pass the corresponding exam as indicated under (a) above.

(d) Such licence once obtained should require the surgeon to execute a minimum number of operations per year, in order to maintain validity.

(2) Informed consent: In case of a surgical operation, the physician must obtain the patient's consent after previously having informed him/her about the principal aspects of the computer-assisted treatment. This shall include:

(a) the differences between the use of a surgical robot and a "conventional" treatment, specifying
  (i) the aspects that could hypothetically produce a greater risk,
  (ii) all collateral effects of the therapy,
  (iii) the reasons pursuant to which robotic surgery is expected to prove advantageous.

(b) In so doing, the doctor should make reference and explain the sources, which legitimize such conclusions, so that the patient is at least theoretically and hopefully put in the position to estimate the reliability of the scientific data upon which the doctor grounds his opinion, and eventually opt for a "traditional" treatment.

(3) Civil Liability:

(a) the liability rules concerning computer-assisted surgery should make clear that the liability is excluded for the surgeons, participating in the operation, who are not at the master console, whenever the damage to the patient was provoked by an action of the robot triggered by the user due to a wrong evaluation which the other team members were not able to timely correct.

(b) If liability concerning computer-assisted surgery were to be directly or indirectly regulated at a European level, a negligence rule should be adopted in order to require the judge to take into account every relevant circumstance which led to the damage.

(c) Since telemedicine might generate problems concerning conflict of laws, the introduction of uniform rules, at least in the EU, in particular with respect to liability and insurance standards would be advisable, in order to favour cross-border practice and guarantee legal certainty.

(4) Access to the data resulting from the operation performed using the surgical robot.

(a) In case of a malfunctioning of the robot unrelated to the conduct of the surgeon, the plaintiff (generally, the hospital claiming damages from the manufacturer or importer of the machine) ought to be entitled to obtain by the manufacturer or importer the release and decoding of digital data, elaborated by the robot and collected by it in the internal "black box"

during the operation, including every command given and every process executed by the machine, together with the incidental system errors.

(5) Privacy: In general, robotic surgery does not seem to create specific problems about the privacy of the patient, in comparison with traditional surgical methods; therefore, as in "traditional" surgery, the storage of personal data should be limited in compliance with the so called "data minimisation" and "finality" principles, in virtue of which the informative systems and the programs are designed reducing the use of personal data and data collection.

(6) Economic aspects of surgical robots.

(a) In order to lower costs associated with an excessive and irrational use of surgical robots public hospitals should be allowed to make use of such devices only for operations which cannot be accomplished through manual laparoscopy, or where the robot ensures better results and a shorter hospitalization of the patient.
(b) Policy choices ought to be adopted in order to make this technology more accessible and widespread, through the elaboration of specific funding programs to encourage private investments and researches in this field.
(c) Greater competition in the market for surgical robots should be incentivized by the European Union so as to lower the prices of such devices, and foster innovation. To this end various alternatives may be considered, including modify (even temporarily) the application of the Defective Product Directive to producers of surgical robots, by for instance impeding direct actions by patients, who should not substitute traditional medical liability actions with product liability claims.

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4. Robotic Prostheses*

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1. Introduction

Prostheses represent one of the most relevant kinds of robotic applications currently researched, in different ways. In a technological perspective, the development of robotic devices (see §2 and §4.1) controlled through Human-Machine-Interfaces (see §2.2) and provided with independent motors, actuators and microcontrollers represents a substantial advancement over passive – and even powered-mechatronic – ones, allowing a much greater number of degrees of freedom and the possibility to simultaneously perform different movements, thus implementing the desired behaviour of the wearer.

In lay terms this entails the chance for a person with disabilities requiring the replacement of a limb, in the medium run, to come close – if not equate – the functioning of a – missing or functionally impaired – natural limb. In the long run instead it may lead to overcome those limits that today are deemed intrinsic of human nature.

The desirability of such a technology with respect to the substantial improvement of the living conditions of people with disabilities is self-evident, enabling a much more relevant – independent – participation in society of a large share of the population. The adoption of concrete measures to favour the development of robotic prostheses can be justified on legal grounds (see §4.2.3), but the duty to make all possible efforts to allow a more profound integration of people with disabilities in society goes well beyond the existence of specific rules, being rooted in the respect owed to every human being and human life.

So long as enhancement is concerned instead, its potential of innovation cannot be hidden, rather it requires to be clarified – both in a technological and ethical perspective –. All its possible implications need thus to be assessed and weighed in order to adopt, after attentive consideration, those decisions and policies, that permit to fully exploit its beneficial potentials, assuming those risks that are deemed acceptable.

Moreover, these applications represent a highly relevant economic opportunity too. Pursuant to recent studies (Manyika et al., 2013: 73-74) the aggregated impact of robotic surgery and prosthetics could amount to as much as $800 billion to 2.6 trillion annually by 2025, allowing a productivity gain ranging from $240-390,000 per person for extended/improved quality of life, much of which could be consumer surplus accruing the users of the devices[1].

Therefore, even if technological advancement is incremental, the numerous ethical and legal issues raised by such applications need to be addressed at the earliest stage possible, both for their immediate implications – eventually even the adoption of measures to favour their emergence onto the market (§4.2) – and for the wide array of possibilities that such devices could uncover.

The ethical analysis will sketch the essential trends of a complex debate around human enhancement (§3.2), and moves on to clarify the notion of human body and body part to address the relationship of humans with their corporeity as a means of interaction with the world (§3.3), ultimately formulating some policy considerations (§3.5).

[1] The study uses a QALY approach

The legal analysis will attempt to provide viable normative definitions of prostheses (§4.1), clarify – in light of the philosophical analysis – the kind of consideration that such devices should be granted (§4.1.2), address the issues of liability (§4.2), and that of the regulation of human enhancement through existing legal criteria (§4.3), ultimately leading to the formulation of some recommendations.

It shall be noted that the technological overview addresses orthoses and exoskeletons too, as potentially alternative technological solutions to the issue of medical rehabilitation and functional substitution in patients with injured or impaired limbs. This, on the one hand will allow to identify the differences that distinguish prostheses from other hybrid bionic systems, on the other hand it will underline possible similarities. Both the ethical and legal analysis will instead focus on prostheses, and so will policy considerations and recommendations. The possibility to extend some of the considerations made will be addressed in the Conclusions to the entire deliverable.

2. Technological Overview

In the medical field, the terms prostheses, orthoses and exoskeletons have different meanings. The purpose of this section is to provide the reader with a simple overview of their most widespread definitions. Technical details concerning the working principle of each device will be provided in §2.1 and § 2.2.

A prosthesis is defined as 'a device that physically replaces a missing body part, which may be lost due to physical injury, disease, or congenital conditions' (OED, 2014). The term prosthesis was first used in linguistics in 1550, meaning in Late Latin, 'addition of a letter or syllable to a word', from Greek prosthesis "addition", from *prostithenai* 'add to'. The meaning "artificial body part" is first recorded c.1900, from earlier use to describe the medical art of making artificial limbs (1706), on notion of "that which is added to" the injured body' (ED, 2014). While the prosthetic field also includes internally implanted artificial body parts (like hip bone, auditory prostheses, teeth), this section will focus on limb prostheses – which may include both upper and lower body extremities – since they are more related to biomechanics and kinesthetic.

An orthosis is 'a brace, splint, or other artificial external device serving to support the limbs or spine or to prevent or assist relative movement' (OED, 2014). The origin of the term goes back to the 1950s and it derives from Greek *orthosis*, meaning 'making straight', from *orthoun*: 'set straight' (OED). According to the definition given by the International Standard Organization, an orthosis is 'an externally applied device used to modify the structural and functional characteristics of the neuromuscular and skeletal system' (ISO 8549-1:1989).

An exoskeleton is a term used in zoology to refer to 'a rigid external covering for the body in some invertebrate animals, especially arthropods' (OED, 2014). It is a compound word consisting of 'exo' from Greek 'outside' and skeleton. It goes back to 1847 and was introduced by English anatomist sir Richard Owen, (ED, 2014). The term shifted to the machine-design field as it well represented an external shell-like articulated apparatus with a mayor structural role (as insects' and arthropods' exoskeletons are in charge of maintaining their shape and defend them from external shocks, as well as permit them to move), within which a human user can fit and still maintain his mobility. First research goes back to the 60' and its objective was the augmentation of human capabilities for military purposes. Only recently, the term exoskeleton has started to be used

in the medical field with the same meaning of an active orthosis, namely, to support /aid people with motor disabilities. Robotic exoskeletons are defined as: 'wearable robots exhibiting a close cognitive and physical interaction with the human user. These are rigid robotic exoskeletal structures that typically operate alongside human limbs' (Pons, 2010: 59).

It should be pointed out, that the adjective robotic, which often accompanies technological devices like prostheses, orthoses and exoskeletons, not only distinguishes simply passive adjustable devices from – usually electrically – powered mechatronic systems (the adjective active is enough for this scope), but also specifically addresses the presence into this device of actuators, sensors and microcontrollers, together with an intelligent control system implementing a desired behavior (i.e. actuators return given responses on the basis of sensors data).

Often, in the medical field orthoses, exoskeletons and in general external devices are confused with prostheses. This is due to the fact that, recently, researchers have successfully applied exoskeletons to medical rehabilitation and functional substitution in patients with injured or impaired limbs (Pons, 2010: 57), a role that until some decades ago was strictly concerning only prostheses. However, there still exists a substantial difference between them: while prosthesis implies the replacement of a body part or an organ which is physically missing (such as in a limb amputee), an exoskeleton or an active orthosis are meant to improve the functionality of a body part, which is still existing, although it has reduced or no functionalities left. In other words, an exoskeleton or an orthoses are not meant to physically replace a body part, but to replicate or enhance its function.

From a theoretical standpoint, besides their differences, prostheses, orthoses and exoskeletons can be grouped together under the rubric of hybrid bionic systems (Micera et al., 2006). An HBS is a system consisting of 3 elements: 1) a biological (i.e. human or animal) part that is linked to 2) an artificial part (i.e. prosthesis, orthosis, exoskeleton, etc.) by means of 3) a control interface. Depending on the configuration, HBSs can be 'artificial systems with biological elements or subsystems, where the biological system is a complementary or supplementary element to the technical system or a biological systems with artificial elements or subsystems, in which the artificial subsystem, e.g., a robotic artefact, is a complementary or supplementary element to the biological system.' (Micera et al, 2006: 1753).

HBSs can be further characterized according to three levels: 1) the "level of hybridness", which depends on the proximity between the artificial device and the human body (i.e. it ranges from devices working detached from the human body like in a teleoperation system, to devices that are connected anatomically and functionally to the body, like a prosthesis); 2) the "level of augmentation", which is related to the number and type of human capabilities empowered (it may be targeted at the senses or/and at the perceptual and motor capabilities). In the case of medical applications, it should be considered the "level of assistance", that is, the number and type of human compromised functionalities restored or supported. Finally, 3) the "level of invasiveness" with the nervous systems of the control interface used to connect the biological and artificial elements together: it is possible to distinguish between indirect interfaces, such as a joystick, that are not invasive, and direct interfaces, which are connected with the central or peripheral nervous systems, such as brain-computer interfaces (BCI) (Micera *et al.*, 2006: 1754) which can be invasive (such as implanted electrodes) or non invasive (such as EEG).

The remaining part of this section is organization according to the structure of an HBS: it is divided into two main: artificial devices (§2.1) and control interfaces (§2.2). The latter deals with the type of interface used to control the devices while the former with the robotic artefact. As far as

the biological element of an HBS is concerned, it will suffice to say that in this study the focus is on human beings only, in either healthy or pathological conditions, and therefore systems consisting of non-human biological elements, like animal brain cells used to control artificial devices will not be taken into account.

2.1 Artificial devices

In this study, the focus is on three artificial devices: robotic prostheses, orthoses and exoskeletons. Their applications in the medical field are different, depending on the intended purpose.

In order to provide the reader with an overview of the working of a robotic prosthesis, the focus will be on upper limb prostheses only. As a matter of fact, many of the technical considerations made for prostheses can be extended also to the working of lower limb prostheses. Likewise, orthoses and exoskeletons will be discussed together since from the engineering point of view they present many similarities.

Each section is divided into an overview of the working and components of the technical device, state of the art and finally main challenges and future directions.

2.1.1 Upper limb prostheses

Hand prostheses represent a technological aid for upper limb amputation. In contrast with other kinds of prosthesis, a robotic prosthesis can be described as a mechatronic, powered device designed to replace physically and functionally a missing limb. As a matter of fact, there exist three types of hand prostheses: (i) *passive* (cosmetic), (ii) *body powered* and (iii) *myoelectric* or *robotic*.

Passive types reproduce the missing limb in terms of appearance (i.e. cosmetic gloves) but without providing any functionality or mechanical appendix (such as hook or fixed tool) to allow an amputee to carry out specific actions. The grasping function can be primitively restored using an active prosthetic hand, either a body-powered or battery powered prosthesis. In *body-powered* prostheses, the person uses gross movements of his/her own body to control the prosthesis. A Bowden cable is used to transmit the forces developed by the body movements allowing to open/close a mechanical hook as showed in Figure 8A. In technologically advanced battery-powered prostheses, *electromyographic* (EMG) signals from residual muscles are tapped through surface electrodes and electrically processed to functionally operate an electromechanical hook/hand with electrical motors connected to a terminal device (Figure 8B): either a split hook or a mechanical hand (Antfolk *et al.*, 2013).

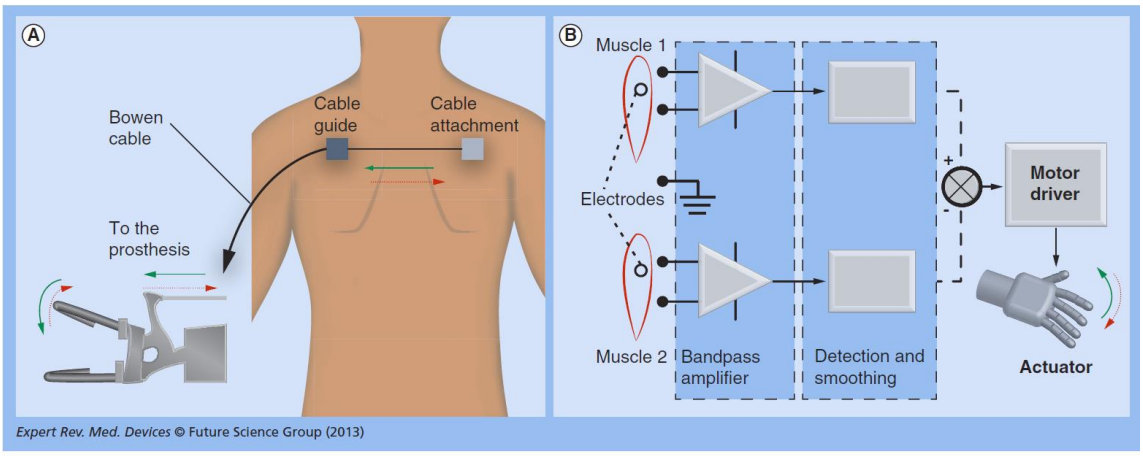


Figure 8 Commercially available active hand prosthesis from (Antfolk *et al.*, 2013). (A) Body powered prosthesis exploits the movement generated by a body part to move the hand/hook terminal by means of a cable running into a guide (in the example here it is showed the biscapular abduction). (B) In battery-powered myoelectric prosthesis (i.e. robotic), the signals recorded superficially from the residual muscles are processed to open/close the degrees of freedom of the prosthesis.

Current status of research and market in the field

Today research in prosthetics is still very active. In the last decade several commercial medical prosthetic hands with more degree of freedoms (DoF) have been introduced in the market, but only recently they have been provided with active movement of the thumb abduction/adduction joint. A few examples of prosthetic hands currently available in the market are: the Michelangelo (developed by the Ottobock in the 2012), the I-Limb Ultra (developed by the Touch Bionics in the 2013), and the BeBionic v3 (developed by the RSL Steeper in the 2013) prosthesis.

Yet, surveys on the use of these artificial hands reveal that 30-50% of amputees do not use their prosthetic hand regularly (Atkins et al., 1996). This is basically due to its low functionality, poor cosmetic and unnatural appearance, lack of sensory feedback, and low controllability. Indeed, despite massive scientific and technological efforts at research level, current commercial prosthetic hands are very simple gripper with few active DoF and poor cosmetic appearance. This situation calls for the development of a versatile prosthetic limb with intuitive motor control and realistic sensory feedback that will allow amputees to perform tasks that are necessary for Activities of Daily Living (ADLs).

Main challenges and limitations

At the moment, the main limitations that are affecting the development of prosthetic hands are related to the number of communication channels of current user-prosthesis interfaces: only few intentional commands generated by the amputee can be recognized for control of a prosthesis; this reason prevents manufacturers from developing hands with a large number of DoFs (Controzzi *et al.*, 2014). The most natural/intuitive control is one that is driven by neural signals tapped from the human central (CNS) or peripheral nervous system (PNS) (Bortole *et al.*, 2014). In particular recent research groups (such as in (Raspopovic *et al.*, 2014) showed how with the use of a neural interface directly connected to the PNS or CNS it could be possible to replace the sophisticated bidirectional link between the brain and the hand actuators and sensors. While an acceptable level of grasping function is often gained through active prostheses, the restoration of sensory function

remains one of the open challenges in this field, which contributes to prevent a wider acceptance and ease of use of these devices, as reported by surveys among amputees (Kyberd *et al*., 2007; Biddiss *et al.*, 2007). Nowadays, none of the prostheses used in clinical practice have purposely designed closed-loop controllers. Control is achieved by the individual, by means of visual feedback and incidental stimulation (e.g. audition, socket pressure, harness, etc.) but not often through design intention. With body-powered devices, users can sense the prosthesis state and grip strength through the reaction forces transmitted by the control cable and harness on their skin/body. Even though this type of feedback is limited, it most likely contributes (together with the low weight and cost) to the choice of body-powered prostheses over myoelectric ones (Antfolk *et al.*, 2013).

2.1.2 Orthoses and Exoskeletons

Both orthoses and exoskeletons can be defined as mechanical or mechatronics devices 'that are essentially anthropomorphic in nature, are "worn" by an operator and fit closely to the body, and work in concert with the operator's movements.' (Herr, 2009).[2] As pointed out in §2, the difference between orthoses and an exoskeletons lies in the purpose rather than in the technology: 'in general terms exoskeleton is used to describe a device that augments the performance of an able-bodied wearer, whereas the term orthosis is typically used to describe a device that is used to assist a person with a limb pathology' (Herr, 2009).

From the technological standpoint (i.e. hardware, actuators, sensors, and control system), robotic (or powered, active) orthoses and human exoskeletons devices have similar components and share many of the same challenges and constraints, 'particularly those related to portability and interfacing closely to a human operator' (Dollar & Herr, 2008: 144). In this section, the term exoskeletons will be used when the intended use of the device is augmentation of capabilities in non pathological humans, while the term active orthosis will be used when the device is designed to assist physically challenged persons. Within this framework, the only relevant difference among the two terms lies in the power exerted by the actuators, which reflects in the size and encumbrance of the robotic system: 'robotic orthoses' aim to functionally restore impaired or missing user's performances (their symbiosis with the user shall attain an healthy motor behavior), while 'exoskeleton' are suited for enhancing them (the user can perform task which are unsuitable for a human person).

The blueprint of a human exoskeleton or active orthotic device consists of the conventional components of almost any mechatronic device: hardware, joint actuators, sensors, and control systems. The design of the device depends on the intended use (i.e. assistance to individuals with limb pathology or augmentation of intact limb function), but in general the main challenge is due to the wearability.

On the contrary of teleoperation system in which the operator controls the device via the master, exoskeletons and orthoses are contact devices, i.e. they imply a direct physical interaction between the device and the human body in multiple points (at least one for human body segment), as illustrated, for instance, by orthotic devices used for functional compensation of human gait. The interaction concerns the transfer of power, that is, the application of controlled forces between the

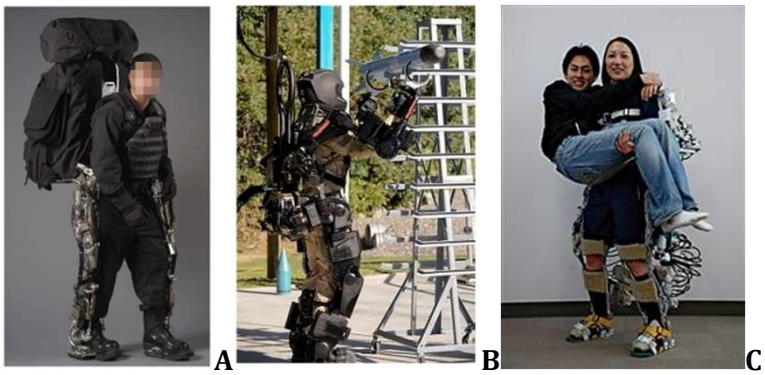
[2] As pointed out by Herr, 'it is perhaps worth noting that the term "exoskeleton" has come to describe systems that are comprised of more than just a passive protective and supporting shell, as its usage in biology world suggest' (Herr, 2009, p.1).

device and the human body. In order to ensure wearability, ease of use, and operator's comfort, the interaction must take place smoothly and safely, but at the same time the physical interaction is in charge of transferring robot power efficiently and promptly: these two set of requirements are antithetical, and matching a good trade-off represents the biggest technological and scientific challenge faced by the wearable robotics field.

As to the interface used for controlling the device, depending on the intended use, it is possible to distinguish three types: a) Brain-controlled devices, which uses invasive and non invasive interfaces with the Central Nervous System (CNS); b) Neural-controlled devices, which use the Peripheral Nervous System (PNS), and finally c) Movement-controlled devices, in this case, the user's limbs movements are used as control strategy, as it happens, for instance with devices for reducing limb tremors, which measures the limb motion by means of inertial sensors and then apply a canceling force to suppress tremor (Pons, 2010: 60). The current trend in control strategy is to combine the three different interfaces in order to increase robustness of control.

Current status of research and market in the field

Human exoskeleton are mainly used to augment the abilities of healthy human beings; this application finds its main market in the military field (e.g. lifting heavy loads or carrying heavy weapons by reducing fatigue, and in general increasing endurance and strength). Within military applications, it is noteworthy to mention the DARPA program, called Exoskeletons for Human Performance Augmentation (EHPA) (Eprahim, Sater & Main, 2002), which was launched in 2001 and produced several working prototypes, such as BLEEX (Berkeley Lower Extremity Exoskeleton), a half body exoskeleton, which was as energetically autonomous and SARCOS, a full body exoskeleton. However, the development of performance-augmenting exoskeletons has also been applied to civilian applications, such as in search and rescue operations (Guizzo & Goldstein, 2005) and in nursing, to help nurses lift and carry patients (Yamamoto *et al.*, 2003) Figure 9 A, B and C.



A **B** **C**

Figure 9 A: BLEEX (Kazerooni & Steger, 2006); B: SARCOS (http://spectrum.ieee.org/automaton/robotics/robotics-software/sarcos_robotic_exoskeleton); C: Nursing exoskeleton (K. Yamamoto, *et al.*, 2003).

As far as active orthoses are concerned, among the main applications there are therapy, rehabilitation in stroke or spinal cord injury patients, functional compensation, and even functional substitution. Among the most widespread applications at research and commercial level is the development of assistive devices for rehabilitation or compensation of leg pathologies affecting locomotion. Only in the US, it is estimated that 4.7 million people could benefit from an active lower

limb orthosis (Dollar, 2008: 150). It is argued that human exoskeletons could provide a promising alternative to human mobility with wheel chairs (Figure 10). With respect to wheels, exoskeletons could provide humans with biped movements, at enhanced speed and with reduced effort and metabolic costs (Herr, 2009: 7). If one consider that about 60 million people in the world make use of wheelchairs (1% of the entire population) (Herr, 2009:7), the pervasiveness that exoskeletons could reach is quite relevant. According to Herr, the goal is to achieve a new way to mobility, comparable to and replacing automobile (Herr, 2009:7).

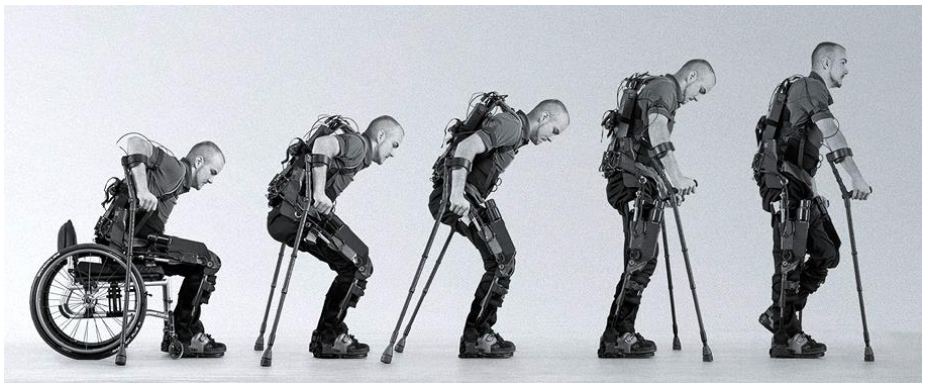


Figure 10 Ekso Bionics exoskeleton (http://robohub.org/eksobionics-goes-public-for-20-6-million/)

However, the potential applications of exoskeletons are many; for instance, they could be used to assist people affected by the physical dysfunctions associated with progressive ageing. Indeed, according to recent statistics, people older than 65 years reached 17.5% of population in European Member States in 2011, and its trend is estimated to reach 29.5% in 2060.[3] The use of exoskeletons in the medical field is still carried out mainly at research level. However, in 2012 Ekso Bionics in the U.S. released the first commercial version of an exoskeleton to rehabilitation centers by successfully compiling with the FDA requirements. HAL 5, developed in Japan by the Tsukuba University, is an assistive whole-body suit controlled by user muscular activation (Sankai, 2011). Commercialized by the CYBERDYNE, it has been used in several Japanese institutes and research centers, and it firstly received the safety certification in 2013 (Figure 11).

[3] E. Commission, Population structure and ageing, http://epp.eurostat.ec.europa.eu/statistics_explained/index.php/Population_structure_and_ageing, 2012.

Figure 11 HAL-5 (http://www.cyberdyne.jp/english/)

Main challenges and limitations

According to Pons there are 3 critical aspects in the working of active orthoses and exoskeletons 1) the cognitive interaction between the artificial device and the user, that is, the way in which the device is controlled by the user; 2) the physical interaction between the exoskeleton and the limb or the part of the body in contact with the device; 3) and finally, the usability and acceptability.

The main challenge concerning the control interfaces is to simplify as much as possible the operations needed to drive, command and control the device and, at the same time, to ensure accurate decoding of the user intentions. In other words, to understand the wearer's desired motor tasks by means of natural interfaces, that is, by deriving information directly from cognitive processes. Such an approach presents several advantages, for instance, it avoids translations procedures (e.g. moving a joystick to change joint configuration), it exploits an optimized mechanism already in use in humans, it does not require training and it reduces fatigue for users (Herr, 2010: 58). The WAY project[4] is an example of research activities aimed at developing BMI-controlled exoskeletons for rehabilitation of hand disorders in patients affected by stroke. More details concerning the possibilities and challenges of research in natural interfaces will be addressed in § 2.2.

As to the physical interaction between device and human body, among the main challenges is to ensure the kinematic compatibility between the exoskeleton and the limb anatomy. This can be achieved by designing devices customized to fit the wearer's outer anatomical feature and physiological demands, so as to become a sort of second skin. In order to achieve this, it is necessary to avoid relative movements between the exoskeleton inner surface and the wearer's own skin, thus eliminating skin sores resulting from device rubbing. Kinematic incompatibility can be due to 'real-life variability of biomechanical parameters between subjects and also the variability of some parameters within individual subjects during movement' (Herr, 2010: 60). Among the most valid solutions proposed to ensure compatible kinematics is redundancy of joints instead of matching exactly human joints. This becomes really important for upper-limb exoskeletons: upper limb motion is deeply three-dimensional and involves many anatomical joints in very complicated synergies – shoulder blade over the chest, glenohumeral and acromiocalvicular joints, resulting in shoulder centre vertical and horizontal displacements (Schiele & van der Helm,

[4] Wearable interfaces for hAnd function recoverY, http://www.wayproject.eu/.

2006). In order to ensure a safe and comfortable interaction, it is necessary to ensure compatibility between the device and the limb anatomy during motion, e.g. kinematic joint centers misalignment between user and robot must be compensated (Cempini *et al.*, 2013).

In order to guarantee an intrinsic level of safety, it is important to design the interface in such a way a physical compliance between the robot actuators and the orthotic cuffs is realized: the CYBERLEGs[5] project attempts to develop a whole ortho-prosthesis completely based on compliant actuation technologies.

In portable exoskeletons or orthosis – which are usually the case for lower-limb devices – the selection and design of actuators are determinant for the quality of the physical interaction. The most commonly used are pneumatic, hydraulic and electromagnetic actuators. However, they present several drawbacks, especially concerning weight, power and torque: this is typically the case of lower-limb devices. Walking gait is well represented as a planar periodic motion: in this case, most issues come from the tremendous kinematics, resulting in high instantaneous speeds and power peaks (proportionally increased if the device is foreseen to carry additional payload), which common portable technologies are not able to provide, unless finely designed and sized (Ferris, Sawicki & Domingo, 2005). A promising new actuation alternative, especially in rehabilitation and functional substitution is the methods called Functional Electrical Stimulation (FES). This approach is based on the exploitation of the residual musculoskeletal system and structures as actuators by means of electrical stimulation. Such an approach could have advantages in terms of wearability, portability and also acceptance and usability (Herr, 2010: 62). Other major challenges are related to the type of material used for the skeleton, which has to be strong but at the same time lightweight, and the related manufacturing – worth to note are the novel hand exoskeleton realized through a 3D-printing laser-melting process from titanium powder (Cempini, Cortese & Vitiello, 2014), and the whole carbon-fibre-made waist-hip-leg support realized within the CYBERLEGs5 project. Finally, special care is necessary to include into the design protection for sensors, electronics and hardware components from environmental disturbances (dust and moisture, but also user's own sweating).

As far as the usability and acceptability, they are relevant aspects of dependability, that is, they affect the safety and performance of the device (Herr, 2010: 58). Among the main aspects concerning wearable devices is contact pressures, which may alter comfort and also safety. To identify the contact areas in the human body and evaluate their pressure tolerance is determinant for ensuring acceptability, including portability. According to Herr 'a portable leg exoskeleton has yet to be developed that demonstrates a significant decrease in the metabolic demands of walking or running. Many complicated devices have been developed that increase consumption' (Herr, 2009: 8), mainly due to their substantial weight. Cosmesis is another critical factor affecting acceptability. The challenge here is to reduce noise during operation and to design anthropomorphic devices with a natural shape, in order to ensure comfort for the wearer. Finally, among the main constraints of the current power supply for exoskeletons or orthoses is that they do not allow devices to operate for extended periods without recharging, especially for full body exoskeletons.

[5] The CYBERnetic Lower-Limb Cognitive Ortho-prosthesis, http://www.cyberlegs.eu/.

2.2 Human-machine interfaces

Among the most natural and intuitive means for controlling an artificial device are direct interfaces, that is, interfaces that allows to directly enter commands in a device (by the act of think for instance) without recurring to intermediate sub-devices (e.g. a joystick). Human-machine interfaces techniques discussed in this section refer mainly to the upper limb prostheses, but they can be extended also to the interface techniques used to control exoskeletons for augmentation of capabilities in abled-body people and orthoses for the rehabilitation and compensation of different pathologies derived from neurological disorders, such as spinal cord injury or stroke.

In the specific case of a robotic prosthesis for upper limb, an intuitive control of a device may be developed by extracting the amputee's intention from signals recorded in non-invasive or invasive ways from the peripheral nervous system (PNS). Electromyographic (EMG) signals, collected at the skin surface, have been used for the control of upper limb prosthetic devices since 1948 (Reiter et al., 1948), because they provide an easy and non-invasive access to physiological processes that cause contraction of the muscles. At present, EMG signal processing is the most common approach used for controlling active prosthetic hands (Micera *et al.*, 2010a). On the other hand, invasive interfaces (Grill *et al.*, 2009; Navarro e al., 2005) with the peripheral nervous system (PNS) are another interesting way to create a bidirectional link between the user's nervous system and an artificial device. These interfaces can be used to induce activity in nerve fibers through electrical stimulation and to deliver information into the nervous system. Conversely, information from the nervous system could be retrieved by recording the electrical activity of the nerve, the electroneurographic (ENG) signal. Given a chronically stable device acting on an appropriate set of nerve fibers, such an interface could be used in a brain-controlled prosthetic hand application (Micera *et al.*, 2010a, Raspopovic *et al.*, 2014).

Several invasive PNS interfaces have been developed in the past (Grill *et al.*, 2009; Navarro *et al.*, 2005) and can be grouped according to their level of selectivity and invasiveness (Figure 12).Thanks to their low invasiveness, cuff electrodes are the most highly used PNS interface not only in research with animal models but also in human trials (Stieglitz *et al.*, 2005). The use of this electrode for the control of cybernetic devices is still limited by its reduced selectivity during recording (e.g., signals recorded are a mixed activity of the enclosed fibers) and stimulation.

Regeneration-type (or sieve) electrodes are designed to interface a high number of nerve fibers by using an array of via holes, with electrodes built around them, implanted between the severed stumps of a peripheral nerve. Although promising results on the use of regenerative electrodes have been achieved in experiments with animal models (Dario *et al.*, 1998; Lago et al., 2005), their clinical usability is still limited by various challenges (e.g., high invasiveness, higher regeneration speed for small nerve fibers with respect to large nerve fibers, sensory and motor axons underrepresentation within the holes of the electrode, risk of compressive axonopathy at the sieve electrode level, and loss of normal topographical architecture in regenerated nerves) (Lago *et al.*, 2005).

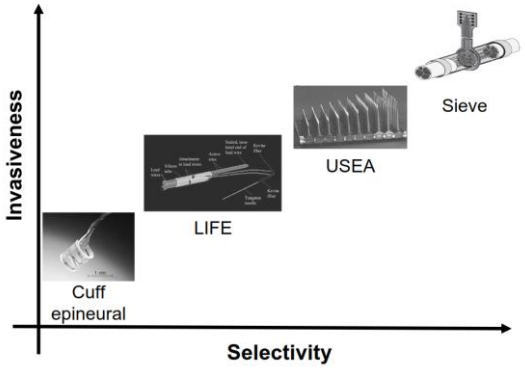


Figure 12 Schematic plot of selectivity and invasiveness of different implantable electrodes (Micera *et al.*, 2010).

Intraneural electrodes inserted into the PNS, and in particular, longitudinal and transverse intrafascicular electrodes (LIFE and TIME, see Figure 13) (Navarro *et al.*, 2005, Boretius *et al.*, 2010), represent another conceptual approach for the development of interfaces characterized by enhanced selectivity (with respect to extraneural electrodes) and increased signal-to-noise ratio of recordings. LIFEs and TIMEs have been recently implanted semi-chronically in amputees showing great promise as a selective neural interface for advanced prosthetics (Dhillon *et al.*, 2005; Dhillon *et al.*, 2005a; Micera *et al.*, 2010; Dhillon *et al.*, 2004; Rossini *et al.*, 2010; Raspopovic *et al.*, 2014).

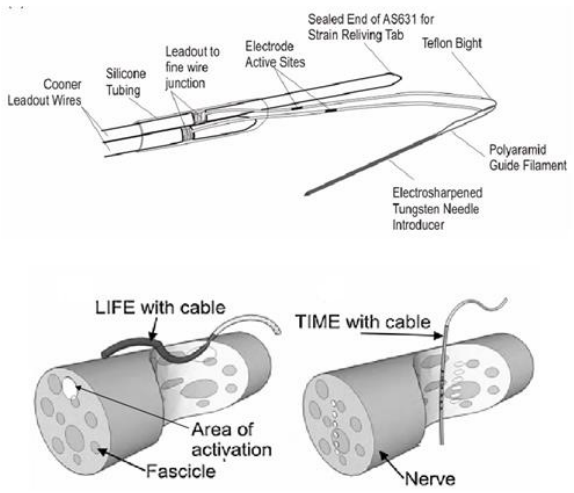


Figure 13 Top: Scheme of chronic dual channel wire LIFE (Yoshida *et al.*, 2010). Bottom: scheme of LIFE and TIME electrodes with predicted areas of activation during electrical stimulation (white areas) (Boretius *et al.*, 2010).

LIFE electrodes have been used to develop and test algorithms for the neurocontrol of hand prostheses in amputees (Dhillon *et al.*, 2004; Dhillon *et al.*, 2005; Dhillon *et al.*, 2005a; Jia *et al.*, 2007; Rossini *et al.*, 2010). In Dhillon *et al.*, 2004, subjects were able to control a cursor on a PC screen making missing limb movements. In another experiment (Micera *et al.*, 2010; Rossini *et al.*, 2010), a new version of LIFE electrodes (tfLIFEs) were implanted in the nerves of an amputee for three weeks. Nerve signals were used to control three different grips of a cybernetic hand prosthesis.

Moreover, LIFEs and TIMEs neural interfaces have shown to be an effective and natural approach to elicit a sensory feedback to the amputees by stimulating the afferent nerves through the LIFEs (Dhillon *et al.*, 2005; Dhillon *et al.*, 2004; Rossini *et al.*, 2010; Raspopovic *et al.*, 2014). Tactile or proprioceptive sensations have been elicited in amputees from one or more LIFE electrodes in Dhillon *et al.*, 2005a and Rossini et al., 2010. In a recent case study, TIME electrodes have been implanted in the median and ulnar nerves of one amputee for one month and they have been used to restore a natural sensory feedback during a real-time control of a hand prosthesis (Raspopovic *et al.*, 2014).

As far as challenges are concerned, in order to translate this technology to common clinical practice and even everyday use, the main steps involve: (i) miniaturizing the stimulation electronics used for the sensory feedback and obtaining a fully implantable system, (ii) developing amplifiers dedicated to nerve signal recoding, and (iii) developing electrodes that must remain implanted and functional without damage to the nervous system for many years.

3. Ethical Analysis

3.1 Introduction

This section provides an ethical framework regarding one of the most debated areas regarding robotics technologies: "prosthetics".

First, we propose a selective examination of a wide-ranging debate, which arose about twenty years ago and is related to "human enhancement". Within the general ethical and legal debate about the human being as person, the focus here is on the transformability of the human body and its legitimacy (§ 3.2).

This section also addresses the concept of the human body. We define it firstly by recalling the phenomenological approach developed by Merleau-Ponty (but also referring to recent developments in the domain of neurosciences), in order to grasp the fundamental nature of this concept as well as to uncover the intrinsic normativity implied in any discourse concerning this topic (§ 3.3).

This specific type of normativity requires a particular ethical discourse – and to this task is devoted the last Subsection of this section. First we attempt to define the domain of normative ethics involved in this discourse. We thus propose a reconsideration of two basic principles: teleological and deontological, with particular reference to the needs posed by prosthetics (§ 3.4).

Finally, this Section provides a brief set of policy considerations that constitute a summary of the analysis here proposed and tries to offer suggestions for further analysis (§ 3.5).

3.2 What humans could become: Reconsidering the debate around "Human Enhancement"

The debate on human nature – i.e. why humans exist as such, how they have been able to evolve, and who they can become in the future – constitutes a combination of questions that are constantly and inexhaustibly posed (for a recent discussion of the related debate: Downes & Machery 2013). This is perhaps due to an intrinsic specificity of human beings, for whom technology (or more precisely the need for technological development) plays a fundamental role, as

with no other living species (Gerhardt, 2008: 98). Almost every animal species is able to implement "techniques" in order to improve its living conditions, by producing tools or structures that improve its ability to procure food and defend itself. No animal, however, to the same extent as humans, seems unable to do without the constant innovation of their own capacities and outcomes. This is an expression of both a fear of inadequacy and a restlessness to improve their own condition.

These two characteristics constitute a trait which unequivocally connotes our human condition and allows us to think of the human being as a person: not only as a being who is "simply" leading a life, but as an extremely complex organism whose behavior cannot be confined within established standards. Such characteristics refer to the inexhaustibility of the "human" / humanity that represents one of the most relevant issues in the entire philosophical path in the west.

And perhaps the same echoes of such philosophical orientations are active in one of the most virtuously interdisciplinary debates taking place on the contemporary scene and which is often referred to as human enhancement (Battaglia & Carnevale 2014). The point of reference is always the human being as person, but the main focus is the (questionable) possibility of solving this "fear of inadequacy" and "restlessness to improve" through the increasing world of technological devices that directly affect the human body. The goal is therefore to develop the human being as person through an attempt to partly change the human body by technological apparatuses, devices or products, namely, by trying to overcome weaknesses or limit aging effects, to maintain "natural" levels of physical or mental efficiency, or by improving both.

The expression "human enhancement" originally referred to an intervention 'to develop the appearance or functioning of the human being beyond what was necessary to sustain and re-establish good health' (Juengst, 1998: 29). Similar definitions, which have been particularly influential, focus exclusively on the dichotomy of illness/health. The debate then developed rapidly, introducing different definitions of the very concept of human enhancement which, together with "health", involve the concept of "normal functioning" but also "therapy", "well-being", and "dignity".

A particular characterization of this debate, developed throughout the first decade of the 21st century, has been polarized into two main positions, often presented as ideologically opposed, transhumanists and bioconservatives. Transhumanism holds that the current form of the human species, on both a somatic and cognitive level, is merely a specific stage of human evolution, and in addition we have only just begun to grasp the extent of possible future integrations between the natural and artificial. Bioconservatism stresses the need to investigate the significance and the implications of the transformations concealed behind the apparently neutral technological development involving humans. This thus places the concepts of nature and human dignity as points of reference and insurmountable limits.

Whilst transhumanists are criticized for being entrenched in an implicit (and naive) determinism regarding the progressive unproblematic development of the human species, bioconservatists are chastised for their excessive "metaphysical" vagueness regarding the basic concepts introduced in defense of more cautious positions.

The core point of the further development of the debate can be seen in terms of invasiveness, non-reversibility and growing technological integration. Technological progress is providing new equipment, and the researcher's concern is to examine their actual and possible consequences carefully. An indication of this awareness has been and still is the increasing trust, on

the part of public bodies and institutions, in research aimed at better mapping a phenomenon that is difficult to contain and which has potentially unpredictable outcomes.

Today we have definitions that are decidedly "broader", or at least "more comprehensive" regarding the various possible aspects of the phenomenon. A paradigmatic example is the work commissioned by the European Parliament and involving the research group coordinated by C. Coenen. Here, human enhancement is mainly seen as 'a modification aimed at improving individual human performances and determined by interventions carried out on a scientific or technological basis on the human body' (Coenen et. al. 2009: 17).

It is clear, from definitions like this ('a modification aimed at improving individual human performances…'), that there is awareness that the rationale of human enhancement goes much beyond the borders of illness/therapy or, in any case, can no longer be limited to that restricted and (*per se*) vague dichotomy. At the point where the label "human enhancement" is used for high-value technological interventions ranging from aesthetic surgery to pre-implant genetic diagnosis, from empowering chemical compounds that determine enhanced performances to bionic prostheses or wearable exoskeletons, there appears to be much more than the medical sphere involved. There is the perception that the entire "human condition" comes into play (Arendt, 1958).

Taking into account this entire framework, what follows seeks to closely follow a pragmatistic point of view, in order to put different theoretical-critical modalities to the test. The need for an anti-monistic and anti-reductionist approach, together with the need to appreciate the contextual conditions in which particular forms of the so called "enhancement" should be placed and with the requirement of examining case by case with its risks and opportunities constitute an overall methodological framework that we will take into account also in the present context.

The profound reflection that such a radical upheaval will cause in the near future must depart from some basic assumptions that are already transversally well-known. Above all, it appears that we can reject monistic viewpoints, those in absolute agreement or absolute disagreement as regards this set of modifications, of unprecedented complexity and extremely rapid quali-quantitative growth. Secondly, it does not seem that an understanding of that issue can be entrusted to a single analytical perspective, but certainly requires a decidedly interdisciplinary approach. Thirdly, it appears to be a particularly demanding task to identify precisely the very object of this approach, which is to distinguish a clear "set" of technologies explicitly oriented towards human enhancement. This is particularly the case given the highly diverging and incomparable characteristics they represent, from interventions on single cell groups to structures or bio-robotic prostheses, from neurological interactions with external computers on individuals to tools involving the sensorial enhancement of touch or sight, to cite but a few examples.

In other words, we should recognize that the debate seems to have grasped the point from a still general point of view, while particular focus on each specific issue is recommended. Therefore, starting from a clear awareness of the extremely differentiated areas of questioning about this topic, and in line with the state of the art presented above, we limit here our attention to the outlining of a possible map of an ethical analysis of bio-technological prostheses for the human body.

3.3 (My) body and (my) world – Uncovering an intrinsic normativity

For a specific ethical analysis of prosthetics, we need to clarify some fundamental terms and concepts. First we need an adequate definition of the human body, by addressing at the same time various systematically – but often implicitly – related issues, namely the limits of my body, as well

as the relationship between the self and the world or, in other terms, between the self and the other-than-the-self, the otherness.

3.3.1 What is a human body? An initial phenomenological defining range

Of the classical philosophical contributions that should be taken into account Merleau-Ponty is particularly relevant. In the first part of his most famous work The Phenomenology of Perception (2002 [1945]), entirely dedicated to the theme of the body, the French philosopher leads a phenomenological reflection through a fundamental dialectic between the consideration of the "body as object", typical of mechanistic physiology, and the idea of the "experience of the body", which is the basis of his own view. He makes an initial qualitative distinction between the two points of view by taking into account the specific meaning of "presence" and "absence" regarding the body. What he refers to as "mechanistic physiology", as well as "classic psychology" had already attributed to the human individual's body, the typical characteristics of an object. As is phenomenologically evident, any object can be distanced and can therefore vanish from view. Its presence can never be excluded from an absence which is always possible.

Diametrically different is the situation of one's own body. Its permanence can never shift to absence, it is not a simple 'permanence in the world, but a permanence as regards me' (*Ibid.*: 141), it is a part of my being in the world, to the point of constituting 'the primordial habit, the habit which conditions all the others and thanks to which they are understandable' (*Ibid.*:142).

The first approach remains trapped in the scientist or naturalist illusion of being able to separate, in observation, what depends on the observer from the properties of the object itself. It thus lives in the illusion of being able to recognise "from outside" and, precisely, "objectively" all that is observable – the body being no exception. Consequently, within the context of classical psychology, "the experience of the body" is degraded to a "representation of the body" (*Ibid.*:146) within our consciousness; consequently: the body is an object like any other.

According to Merleau-Ponty, we need to embrace another point of view: our human condition as embodied beings coincides with our being in constant contact with our surroundings, in the widest metaphysical sense, or rather with "being an experience". This means having to consider the frontier between one's own corporeity and the rest of the world (Pirni 2013; Pirni 2014c). One's own body is not an aggregate of organs juxtaposed in space. Rather its parts relate to one another in an original way, according to what has been referred to as a "corporeal scheme". By this Merleau-Ponty means a dynamic that makes one's body seem to be an experience with regard to a particular ongoing or possible task. The difference is between a simple object, which possesses a mere spatiality of position (it is or is not positioned in a determined space) and a body, which instead possesses a spatiality of situation.

Thus, the "corporeal scheme" in its phenomenological meaning becomes a way of saying that "my body is in the world" (*Ibid.*: 153-154); which is immersed in a network of manifold spatialities of position, which it manages to distinguish in so far as it is capable of using them, or rather to "bring them to itself" and also to establish relations with them in potentially infinite ways. Therefore, corporeal space constitutes a kind of third element between the external space and positional space of single objects. This is necessary for our perception in order to highlight the multiplicity of objects of the experience and to create a unitary "reading" which we are also a part of.

Our body thus makes us aware that our existing does not make experience, but is experience, in the sense of being entirely constituted by our being constantly at the crossroads of these two fundamental forms of spatiality.

3.3.2 Establishing "contact" with the world

One's own body therefore constitutes the fundamental – and the only – way possible, as human beings, to "enter" into the "external spatiality" and to be a stable part of it: my body is my way of establishing contact with the world and, by means of it, of becoming what I am: a being-experience of the possible.

However, by thus approaching prosthetics more directly, if the body is the way for humans to establish contact with the world, we could further affirm that touch is the way in which we "make contact with contact".

Therefore, if the body is the vehicle of my being in the world as humans, it is also "the pivot of the world" (Merleau-Ponty 1945, 130), of my world. It is the thing around which all the spatiality I am able to perceive "revolves", according to my daily habits; it is my force, but also my limit. Merleau-Ponty clarifies this, by saying that, exactly at the moment in which my usual world brings about my habitual intentions,

I can no longer, if a limb has been amputated, unify myself to it: precisely because objects have to be handled, and objects to be handled question the hand which I no longer have. In this way, in the wholeness of my body there are regions of silence. The disabled person therefore is aware of his disability precisely because he ignores it, and he ignores it precisely because he knows it (*Ibid.*: 130).

In the life of that "being-experience" a moment or an event could exist which is the creator of an irreparable gap between a "before" and an "after". Thus an unbridgeable fracture is created between habitual body and current body, in which the first constitutes a sort of guarantor of the second, in the sense of offering to the consciousness and memory of the individual a confirmation of the spatiality of position of the objects surrounding them and which they cannot handle. In short, a corporeal prism that is split apart, dichotomised, can only give back the experience of a world that is itself "split apart", or rather diminished and more limited, and more distant and less directly useable.

The French philosopher then makes an interesting parallel between the illusion of the phantom limb and the psychological concept of removal, however he stops at a point where technological contemporaneity is evidently making progress in leaps and bounds. For example, Merleau-Ponty could not envisage operations involving dexterous, sensorised and anthropomorphic hand prostheses, that is to say the so-called robotic hand which is at present one of the most promising research areas within the bio-robotic's field.

The phenomenological path outlined above should be considered as still being one of the most profound, fascinating and fruitful modalities for understanding the problem of body in forms which appear adequate both to our time and to an ethic-philosophical framework. However, we are aware of a real range of different options and approaches to addressing the question.

3.3.3 Towards new modalities of cognitive experience?

From the point of view of the amputated subject, the possible answer to the question "what is a human body?" acquires quite a different connotation. What do "cohabit with my body" and "perceive through my body" exactly mean for a persons who has no upper or lower limbs? Depending on whether an individual has a congenital condition that cause an underdevelopment of the limbs, or has suffered diseases or traumas, they will experience in different and non-predictable ways physical, psychological, and social challenges.

The deep sense of inadequacy that accompanies the experience of amputation is expressed first in reference to the physical sphere, by simply thinking of decreased mobility and an increased dependence on others. This, as we know, frequently constitutes the core interest of scholars in robotics. However our focus is on a much larger sphere of challenges and problems – what scholars of different disciplines call the body image.

In its simplest terms, an amputation produces an evident modification of the human body which is no longer reversible. This causes significant distress for the affected individuals and, from a psychological point of view, it can frequently bring about profound changes to a person's self-worth regarding the ability to pursue personal and professional goals.

In addition, there is the social dimension which manifests itself in a diminished willingness for social contacts and relationships, a frequently experienced social self-marginalization together with less public participation and sharing of individual and group experiences. In our opinion, with reference to the RoboLaw project, one of the most promising ways of addressing this issue is to introduce the concept of "recognition" into the debate on robotic emerging technologies, as described elsewhere.

Furthermore, the previous Subsection ended by raising the question about perceiving the external world from the point of view of the amputated subject; i.e. a subject that has to manage the twofold contact with him/herself and the external world through a diminished "current body", to recall Merleau-Ponty's terminology. Now, putting the question more in line with the main aim of the present Section, it is thus important to mention the possibility of being "rehabilitated" to a full experience of the world through a robotic prosthesis.

Technological (robotic) devices can to varying degrees – even if through still very relevant limitations – restore the capability of physical mobility, and thus help to rebuild a renewed body image. Such a renewed body image should not be understood in static terms, or as an objective that can be reached definitively. Rather, it presupposes a continuum of adjustments, namely an adaptation which is affected by numerous clinical and demographic characteristics, as well as psychological and social factors.

"Experiencing the world" first evokes the cognitive sphere and, from the agent's point of view, the capability to acquire adequate knowledge of him/herself and of the external world he/she can manage within the limits of individual agency.

We can perhaps surmise that, also in the case above, a possibility to perceive the continuity between body-objects-world from the inside continues to exist. We can still think of ourselves as a co-extended totality, which is located in that same spatial and reticular continuity with the rest of the world: that is with external spatiality and with the universe of objects that can potentially be reached and manipulated.

Nonetheless, the amputee's uneasiness regarding their "being different" from others is important: both in material terms and concerning aesthetic appearance. There is a distance between natural and artificial, between "biological body" and the plastic or metallic material that is now part of our "recovered body" and that appears and is as much as possible "naturally linked" to the first. An individual must "react" towards these "distances" in terms of living together with what was originally "other-than-the-body" but, from a certain moment onwards, with what can no longer be understood as separate, namely "other-than-the-body" itself. It is a form of re-acting to the unease – namely: that continuum of adjustments mentioned above, which has a sole and fundamental, but extremely complex goal: to recover as much as possible a sociality able to share in innovative manners such a bio-technological "recovery" or "restitution" of experiential spatiality which is now part of our biographical life.

This is a point of great importance and which, beyond the phenomenological perspective of Merleau-Ponty, contemporary cognitive psychology has emphasized: a primitive sense of the self is developed from the perception and the representation of the body agent at both an individual and group level, namely of the body that is carrying out an action in the short term, pursuing a task in the mid-long term, or constructing something from scratch (Gerlucchi & Aglioti, 1997; Gallagher, 2000; Cash 2012). Thus, neurological research has shown that these processes maintain individual cognitive unity and stability despite the constant changes to which the body is subjected, with regards to physiological conditions (increases or decreases in weight, aging) as well as pathological ones (amputation of part of the body, prosthesis).

Other researchers have identified an area of the occipito-temporal cortices (EBA: Extrastriate Body Area), in which a selective increase in neuronal activity in the presence of visual activity directed to parts of the body has been observed (Peelen & Downing, 2007; Urgesi *et al.*, 2007). In addition, it is also been observed that alterations in the mechanisms of visual recognition of one's body linked to EBA may contribute to the onset of psychiatric disorders of bodily self-representation (Suchan *et al.*, 2010).

Thus, it now seems legitimate to claim on a neurocognitive experimental basis that there is a link between the visual recognition of one's body and one's sense of belonging to one's body. This link is related to the "natural need" of every human agent – and therefore of every amputee with prostheses – to "establish contact with the world".

Yet the same concept of "prosthesis" can also be understood as a "replacement" of a limb that – as amputees – is fundamental for our body and, extensively, for ourselves as persons in the most comprehensive sense of the word (and we know that this is a replacement that involves several problems of "adaptation" in cognitive, psychological and social terms).

However, having a prosthesis can also be experienced as an "opportunity" not only to rehabilitate, but also to increase the person's ability to "make contact with the world". This can be explored by taking into account both the cognitive and the material spheres.

To understand the cognitive sphere, let us first look at the "Extended Mind Hypothesis" (EMH), originally set out by Clark and Chalmers (1998), and then developed among others by the same Clark (2001; 2005; 2008) and by Di Francesco (2004; 2007; 2010; 2011). EMH concentrates first on the cultural and technological artefacts that pave the way for cognitive enhancement. Such processes involve forms of "enhancement" – concerning the individual's awareness, cognition and knowledge – that trigger a wide rethinking of the understanding of the burden between the individual's mind and the "external" world. This rethinking argues in favour of the situatedness of

all human knowledge, which fundamentally depends on our body, on its possible technological enhancing devices and on the natural/cultural environment in which any cognitive act by a single subject is collocated.

The RoboLaw project has already tested the EMH, by concentrating on the theoretical construction of a 'Radical Embodied Cognition Thesis' and applying it to robotic technologies. This thesis focuses on a basic – and, again, phenomenologically evident – issue concerning the necessary situatedness of the mind of human subjects in a shaped body and a structured environment. Human cognition (thought, perception, emotion, and experience) cannot be explained by focusing on the brain, but must instead include references to the body and its interaction with the surroundings.

EMH also refers to a "cognitive hybridization" that opposes the reductive mind-brain models which reconstruct the cognitive processes that do not take into consideration the complexity and embeddedness of mental states in the actions of the whole organism. Rather, in order to account for what is experienced by human beings and agents, we need to consider them as "embodied" and "embedded" in their social environment, and as such cognition no longer needs to be considered as an established physical-mental dichotomy but as a functional embodied and enactive function of humans (Pfeifer & Bongard, 2007).

Secondly, concerning the material sphere, the increasing and not always conscious use of external technological devices as part of our body and, therefore, as part of our "making contact" with the external world, could be considered. Through the use of such devices our "making contact", namely our cognitive awareness, is undoubtedly enhanced or, if nothing else, profoundly transformed.

So far we have argued that our knowledge is "hybrid", namely it is the result of the interaction between mind, body and the external environment. Now we can assert that this interaction is increasingly driven and achieved through technological devices. The use of technology is becoming increasingly inevitable and thus constitutes a sort of a "second level hybridization".

A recent survey carried out within the project "Net Children Go Mobile" revealed that more than half (56%) of 9-16 year olds in Europe demonstrate very high levels of all three traditional indicators used to measure digital abilities: skills, activities and self-confidence. This implies that ICT digital devices are mostly considered by children in Europe as a common and socially accepted technological "prostheses", namely a sort of "material extension" of their own bodies.

These "prostheses" or "extensions, which often mask the over dependency on such devices, are part of a "connected presence", associated with a feeling of perpetual contact with friends and family.

Both adults and children are often unaware of their addiction to such devices, or tend to underestimate the long-term effects of their usage. However more surprisingly, when parents intervene by completely prohibiting their children from using technological devices the children react very strongly. Aside from suicide, which has also occurred, the most common feeling is strong anger mixed with fear. This first generation of "digital natives" experience this deprivation as a direct attack on their person and their own growth, as if they were being asked to walk without a leg, due the fact that the technological device is seen as a real part of their own body, which binds them to their reference groups.

3.3.4 The human body and its role: some concluding remarks

Following the phenomenological perspective by Merleau-Ponty, we have first defined the body as "being experience of the possible". We have thus underlined the exclusive relationship that everyone holds with his/her body from a phenomenological point of view, as the unique way of "establishing contact with the world". Here "contact" is a fundamental feature of the human being that can be experienced in psychological, social and cognitive terms.

This contact can be altered "by nature", in terms of being limited (by congenital malformations or as a result of a traumatic event), or rehabilitated (through the implantation of various types of prosthesis), or enhanced (again through prosthesis). Although the distinction between "therapy" and "enhancement" remains an open question (Lucivero & Vedder, 2013), there is still a fixed point which is the transformation that natural events (congenital or traumatic) as well as technological developments lead us to consider as being inevitable.

This transformation unequivocally helps to shape another fundamental feature of the human being: fear of inadequacy combined with anxiety for improving one's condition.

This double feature has been accounted as "anthropology of vulnerability" (Coeckelbergh 2013). Vulnerability – namely, the possibility of being hurt or violated – is one of the fundamental aspects of the human condition that humans have always tried to tackle or limit through technology. However, at the same time as technology counterbalances or eliminates one form of vulnerability, it indirectly creates new and more sophisticated forms of it (Coeckelbergh, 2013, Sect. 1.3, 2.1, 2.2).

This first and unavoidable "descriptive anthropology of vulnerability" leads to the consequent "normative anthropology of vulnerability" (87 ff.). Coeckelberg's main goal is to shift the focus from "human nature" to "human being". He explicitly legitimates the normative possibility of answering – from the first person point of view – the question not only about what the human being is, but also – and fundamentally – about what the human being can and wants to be.

On the one hand, this approach is in line with the human potentiality as "experience of the possible" outlined in the above sections. The very possibility of such an experience passes through the body, namely through establishing contact with the world. This possibility regards a fundamental characteristic of the anthropological constitution of the human being, which is nonetheless exposed to be wounded or diminished by the experience of amputation. This experience allows us to know – from the first person standpoint – a new and deep meaning of the "anthropology of vulnerability". Prosthetics is an attempt to reverse the sense of this experience, but it is also the main cause of a number of physical, psychological and social problems.

On the other hand, the argument developed here differs from Coeckelberg's. According to the context-sensitive approach developed in Robolaw D5.5 (Bisol *et al.*, 2013), in this chapter we decided not to explicitly separate the descriptive from the normative level. Rather we attempted to bring out the "intrinsic normativity" that the concept of body implies from a phenomenological point of view.

Nonetheless, our path is convergent with Coeckelberg's final objective: to prepare the field for a renewed normative sphere capable of contemplating both the ethical and the juridical attempt to tackle the role of new technologies – more specifically, of technological prostheses – devoted to human beings.

To conclude, the human body plays a fundamental and unique role in terms of what each human being can and want to be. Such a "vehicle" of our being at world, of our "establishing contact with the world" thus possesses an intrinsic normativity that has to be uncovered. Moreover, after having been uncovered, that specific normativity needs to be "protected", namely to be explicitly articulated into a specific ethical discourse that will be conclusively addressed to new prosthetic technologies regarding the human body.

3.4 Reframing the ethical discourse regarding prosthetics: A possible schema

3.4.1 The first defining range

We now identify the domain of ethics which is specifically related to technological devices (in our case prosthetics), within the western philosophical tradition of ethical discourse. We intend to do this by synthetically constructing the argument as a series of concentric circles, in order to progressively identify the specific issue here at stake.

In our first concentric circle let us consider a basic definition of ethics. Ethics is a normative structure characterized by prescriptivism, providing a set of commands, prohibitions, and obligations, which constrain people's behaviors. The main aim of such constrains is to guarantee a minimum degree of social cooperation necessary for survival, welfare, or self-realization of members of the society (Fabris, Bartolommei & Datteri, 2007).

There are four main fields of contemporary ethics, and this preliminary distinction is presented here as our second concentric circle.

First, descriptive ethics is a form of empirical research about peoples' beliefs and practices with explicit relevance to morality. Consequently, descriptive ethics research focuses on those systems of beliefs that are adopted by people and guide their life.

Normative ethics is the study of ethical theories and principles that determine and prescribe how people ought to act. Furthermore, normative ethics is concerned with the analysis of substantive ethical theories that enter in concrete moral debates (ontological metaphysical personalism, natural moral law theory, Kantian ethics, utilitarianism, contractualism, virtue ethics, and so on). It is used to distinguish two broad classes of normative ethics: teleological or consequentialist ethics (also known as ethics of goodness) and deontological ethics (or ethics of duty).

Consequentialist ethics develops around some notion of "goodness", whose meaning is specified according to some theory of values, and evaluates the morality of actions on the basis of their effects or consequences, independently from any principle or intention which motivated them. On the contrary, deontological ethics is concerned with isolating those norms, laws, or properties of actions which are assumed, in specific contexts, as the basis for judging what is right or wrong to do. In a deontological perspective, actions are evaluated according to their intrinsic character, or to their conformity to norms, independently of their consequences. A paradigmatic example of consequentialist ethics is utilitarianism, according to which actions are judged on the basis of the "goodness" of their consequences; Kantian ethics is instead representative of the second approach, insofar as the conformity of actions to some duty is evaluated, with no (or poor) consideration of their consequences (Fabris, Bartolommei & Datteri 2007: 7-8).

In turn, meta-ethics concerns the study of what ethical terms and theories actually refer to. It deals with the nature, the meaning, and the logic of moral languages and therefore it is mostly committed to linguistic analyses about contexts and rules of specific concepts of moral relevance.

Finally, applied ethics is a branch of ethical research that arose in the second half of the 1960s, due to a deep dissatisfaction with the pure analyses of meta-ethics, that appeared as incapable of solving concrete and urgent problems related to ecology, peace and war, biomedicine or communication technologies, sustainability, business related issues, and so on. Examples of applied ethics include bioethics, environmental ethics, animalistic ethics, business ethics, communication ethics, bio-culture ethics, last but not least: techno- or robo-ethics.

Recalling one of the main assumptions taken from the methodology developed in D5.5 (Bisol *et al.*, 2013), related to the exclusive specificity of each ethical discourse linked to robotic technologies, the third concentric circle could be seen more as an ellipse than a sphere. According to the image of an ellipse we must thus consider two "centers" of reflection and not one within this level. This is to the need to consider a link between two of the four sectors just mentioned, namely the normative and the applied ethics sectors.

The image's aim is to give plastic reference to a twofold character of the ethical discourse appropriate to prosthetics, that has to keep a strong link between the requirement of concreteness or the urgency of application on the one hand, and the need of a wider theoretical grounding for the normative regulation, on the other.

Our reference to the applied ethics sector could appear trivial, if we simply recall the fact that we are preparing the field to offer practical ways for regulating robotic technologies. In other words, the stress on this sector of ethics sounds obvious, due the fact that we are focusing on issues that could not be other than applied. Conversely, the reference to the normative ethics sector, namely to a sector that maintains its intrinsically theoretical and not-applicative character, could sound less obvious. Therefore we would like to give reasons in what follows about the specific framework and meaning under which we introduce the latter sector as the second "centre" of our hypothetical ellipse.

3.4.2 A reformulation of two fundamental principles

Normative ethics can be subdivided into two theoretical families: teleological and deontological ethics. Therefore, when considering normative ethics as a useful point of reference for dealing with prosthetics issues, a "compatible" reformulation of both teleological and deontological principles is needed.

A general teleological principle could thus be:

- The normative ethics applied to prosthetics issues according to a teleological understanding should contemplate the maximum and plural (in the sense of a plural meaning, namely: physical, psychological, social, and so on) wellness for the final user as its main goal.

On the other hand, a general deontological principle related to prosthetics issues could be:

- The normative ethics applied to prosthetics issues according to a deontological understanding should consider the principle of the maximum

and plural wellness for the final user from the point of view of the equal opportunities for each human person as a citizen of a juridical community.

Both principles ("maximum and plural wellness" and "equal opportunities") need further specifications. First: normative ethics related to prosthetics should combine a teleological with a deontological principle. Alternatively, it should combine the individual with the intersubjective perspective, namely, it should link the first person point of view with both the second person (i.e. the "I-you perspective" or recognition perspective) and the third person (concerning the external observer) perspective.

An extended clarification of both principles "in the field" as well as the plausibility of their connection within a juridical framework will be the focus of the following chapter (see Sect. 4 on the juridical analysis).

In this context, we only give a preliminary explanation of the comprehensive – and in turn "plural" – meaning of the expression "equal opportunities", in order to start outlining new lenses according to which we can consider this concept. We hope that these lenses will in turn be able to trigger innovative juridical ways to reconsider the overall territory in which individual wellness, social needs and new technologies may encounter and combine one another within a fundamental democratic framework.

In the sense we have been using above, the expression "equal opportunity" implies four basic meanings:

(a) a fundamental "moral" right to rehabilitation following an innate disability or an injury, according to existing technological possibilities. By "fundamental moral right" we mean a normative claim that it is morally justified, even if not recognized or not yet recognized as a right in legal terms. This right directly relates to one of the most common constitutional rights, namely, the right to health. Here equal opportunity leads both to the ethical and legal commitment to the individual who needs a robotic prosthesis to pursue some tasks, which are regarded as fundamental for his/her wellness. What may be "fundamental for wellness" needs to be assessed after establishing what wellness is, starting with a profound reconsideration of such a multifaceted concept. That reconsideration should be explicitly and specifically oriented to what is offered to disabled or impaired persons by recent developments in robotics (Pirni & Lucivero, 2013). Finally, this process should be completed with the articulation of a taxonomy legally fixed, as a list of opportunities that robotic technologies have opened up and that are now possible object of request by every single citizen. In other words: thanks to robotic technologies we now have the possibility to set out new needs, new questions that can receive answers in concrete terms. These needs shall be subjects of public discussion and evaluation, but in the end could be incorporated into a list of opportunities (a sort of "taxonomy of standard levels of wellness" for impaired persons that robotic technologies are able to provide) and that are guaranteed to all citizens by the State.
(b) the reference to a fundamental "moral" right to the legitimate human enhancement. Here "legitimate" is used to mean "not distorting the fair rules of competition in the social domain". By using "fair rules of competition" we are not referring to the market, but to the unavoidable social antagonism regarding the acquisition of any role in the working sphere and, more in general, in any context in which different performances (e.g. in speed, problem solving, cognitive terms, physical strength or

being more suited to a material task,) can elicit different social roles or economic positions. Furthermore, we are implicitly affirming that the "not-distortive" character should be normatively determined. In other words, not everything that can be done must also be achieved (for example the voluntary and informed use of doping by an athlete, but also a possible neural implant which unexpectedly emphasizes cognitive or memory capacities). Abusing the capabilities of our body and brain with ever new technologies can also open the door to distortions of social cohesion and free competition between individuals within a community. The risk of damage that is difficult to evaluate diachronically is clear: an individual advantage could turn out to be a social loss and an undeserved human improvement could trigger chains of iniquity that are difficult to compensate.

(c) an opportunity which is equally shared between men and women regarding the access to and the customization of robotic prosthesis. Firstly, like the right to health, we should not forget that in a large part of the world the right or the simple access to medical care is denied to large numbers of people for various (political, economic, legal, religious, racial, gender) reasons. As we know, this is not the case for Europe. But for the same reason, the leading and responsible role that Europe plays in terms of promoting equal gender opportunity not only in the field of health should embrace also the sphere of technological innovations devoted to humans and specifically the prosthetics.

Moreover, if this meaning of equal opportunities was not normatively defined and imposed, there may be prosthetics manufacturers that are not interested in gender customization of their products in order to save on production costs. As we can easily understand, the lack of gender customization could increase the challenges related to the continuous adjustment of the body image, with related psychological, social and cognitive problems.

(d) an equilibrium with respect to policy making: to ensure that public resources dedicated to amputees will not impact negatively on other sectors of public health. Cost / benefit calculations are thus needed in order to distribute resources to promote individual wellness in each sector.

In order to address ethical issues related to prosthetics we identified first the general ethical frame adequate to it: a shared problematic area between applied ethics and normative ethics. We tried then to understand what we mean here by normativity. With regard to prosthetics, we suggest that this concept should connect a teleological with a deontological principle and their respective implications. The comprehensive framework here outlined, as well as the need to co-ordinate the teleological principle (or: the single subject point of view) with the deontological one (or: the point of view of society, according to the terms described above) appears an innovative field of analysis that require to be elaborated further as a common research area for both ethical and legal scholars.

In conclusion, this is a field in constant evolution due the ever-increasing availability of new technological achievements. What we must become aware of, is that also ethics and legal research needs constant updates to be able to follow this development, to monitor the effects on people, to avoid the more clearly unjust results.

3.5 Policy considerations

This Subsection focuses on a specific and twofold task: on the one hand, it would like to recapitulate the ethical analysis developed above by offering concrete hints and a comprehensive key lecture. On the other hand, because of the extremely differentiated area of challenges that prosthetics raises, it intends to put forward some basic policy considerations and at the same time point to new or still unexplored fields of research that should be addressed in the future.

- Ethical research on prosthetics has developed a phenomenological analysis of the concept of the "human body". Although the human body lies at the center of this research field, it is frequently considered as unproblematic, just like any "object" available to man. Taking a different stance, and touching upon the debate on human enhancement, from a phenomenological point of view we highlighted the fundamental role of the body as our only way of "making contact with the world". Only through our body are we able to experience life as human beings, understood as a "fundamental openness to the experience of the possible". We are in the world thanks and through our body, and any impairment or amputation involves a substantial "reduction" of our " contact" and "being in the world", understood as our fundamental anthropological characteristic. Impairment or amputation of a limb, for whatever cause, results in the need for a constant readjustment of our image of ourselves (body image). And this has an immediate impact on the physical, psychological, emotional-affective, social, professional, and cognitive level.
- The awareness of the central role of the body for the human being needs to be strengthened, and the need to renew its fundamentality on an anthropological level needs to be stressed. The ways in which the body makes it possible for human beings to experience "the outside world" and how its transformation can inhibit or change such an experience still need to be investigated from scientific, philosophical, and legal perspectives.
- The reaffirmation of the anthropological centrality of the human body should inform the discussion on human enhancement through robotic technologies and promote a more cautious attitude towards easy assents to changes of which we are not able to fully comprehend the medium-long term consequences for the individual at a psychological, social and cognitive level.
- A renewed "normative" ethical discourse, which is context-sensitive and which can also connect the normative profiles to applied ethics) is needed. Such a discourse, which could be developed within the same theoretical framework above presented, should be specified for each type of prosthesis and exoskeleton.
- The upper limb prostheses refer to what we could call the universe of manipulation. The possession and full use of the upper limbs provide us with one of the most important functions that give sense to our being in the world. "Being part of the world" means first of all to be in contact with it, to receive tactile sensations, or to manipulate parts of that world, to create new ones through our gestures, our manual agency. The possession and full use of the upper limbs is the basis for managing the personal (and domestic) sphere of our lives, as well as the interpersonal sphere, namely family, friendship, sociality, work. In short, the entire universe of our personal and social life passes first within the universe of manipulation. The problematic area of upper limb prostheses should be therefore related to the realm of freedom, privacy, social interaction and socialization.
- In turn, the lower limb prostheses refer to the universe of access. This latter type of prosthesis shares with upper limb prostheses an obvious portion of the same analysis:

both relate to the management of personal and social life. But missing one arm is intuitively different from not having a leg and has diverse implications in terms of portability (not all subjects may be able to bear an important extra weight on their body structure). Other problematic aspects become evident regarding the issue of free access to places, that could certainly be limited, or require major redevelopment as well as more space to accommodate individuals (e.g. the problems that a subject with prosthesis might encounter with respect to driving vehicles, or accessing public transport).

- This intuitive difference should become the subject of a more specific ethical analysis and possibly legal analysis. While the absence of upper limbs and the correlative substitution through technological prosthesis refers to the freedom of socialization, deficiency in one or both legs is a matter of freedom of movement and of the underlying fundamental right. With regard to the even more significant impact on body image and on any limitation/specificity regarding the access to places, a specific ethical analysis devoted to the application of exoskeletons is needed, especially those supporting the mobility of the lower limbs.
- The opportunities and risks brought about by prosthetics require a renewal of the concept of "informed consent" from an ethical and legal point of view. The characteristics of advanced prosthetics where the concept of informed consent and procedure need rethinking include the experimental nature of these devices; the lack of follow-up studies and investigation on the medium-long term effects of the implant; the invasiveness and (often) non-reversibility of the implant; and the effects on the psychological, social and cognitive modifications resulting from the use of these technologies.

4. Legal Analysis

Robotic prostheses raise different legal issues. In some respect, they do not appear to differ from traditional implants: they are artefacts created by human labour and creativity to replace a lost function. Yet, on the one hand, in a not so distant future they may allow us to acquire and develop new capabilities, or substantially improve already existing ones beyond those limits, that today appear to be inherent to human nature. On the other hand, they may induce different considerations on what the human body is and which parts constitute it, and ultimately even what human being itself means.

Both aspects highlight a problem with definitions (§4.1 ff). Robotic prostheses need to be defined in a legal perspective in order to identify which part of existing regulation applies to them, and what should in the future, even in light of possible recommendations on how the legislator ought to intervene. This includes the problem of whether a prosthesis is a medical device according to different European directives (§4.1.1), as well as whether it may be deemed a body part or rather an external and independent object, resting on the fundamental philosophical considerations on what the body is and how we relate to it.

This aspect has a direct impact on public law issues, that are both general and of extreme detail: shall a person be allowed to identify himself through a prostheses or with it? Is the person entitled to wear a prosthesis when being portrayed in a picture for the release of an official ID (§4.1.2).

Once defined, it may be observed that prostheses are products, even if of a peculiar kind (Bertolini, 2013). This consideration leads to the application of some relevant liability rules – namely the defective products directive – that provides specific incentives (§4.2) both to the industry and users of such devices, that may though be less than optimal (§§4.2.1, 4.2.2). Since arguments may be advanced to justify the adoption of alternative paradigms (§4.2.3) other liability rules will be considered (§4.2.4) addressing both issues of safety (§4.2.5) and compensation (§4.2.6).

Finally, since the current analysis refers to a greater extent to a given type of technology, which–it may be assumed–will be available in the medium run, the issue of the regulation of human enhancement appears to be less imminent and dramatically relevant. Yet, it is to be taken into consideration as a horizon (§4.3 ff.) that some of the policy choices suggested may influence, creating different path dependencies. Towards the same end, constitutional principles need to be taken into account, so as to discuss whether they appear to be adequate in managing existing or reasonably foreseeable issues (§§4.3.2, 4.3.3).

4.1 Definitions

Before we can proceed with the analysis, we have to more precisely define the kind of applications we are considering, namely robotic prostheses.

Robotic prostheses are mechanical devices provided with motors capable of operating simultaneously and independently in order to replicate or enhance the movements and functions of a natural limb they are intended to replace, to this purpose using a Brain-Machine Interface (BMI) *that receives the biological signal generated by the nervous system and process it into a signal the device can identify and manage, controlling the movements of the motors and actuators the machine is provided with.*

The purpose of a similar technology is to radically improve the quality of life of the implantee by granting the highest possible number of degree of freedoms and the possibility to execute complex movements involving the actuation of multiple joints simultaneously.

4.1.1 Regulating a new kind of technology

Existing applicable regulations are the Directive 2006/42/EC on Machinery (henceforth MD), the Directive 90/385/EEC on Active Implantable Medical Devices (henceforth AIMDD)[6] or the Directive 93/42/EEC on Medical Devices as recently reviewed and amended by the 2007/47/EC (henceforth MDD)[7], and the Directive 85/374/EEC on Defective Products (henceforth DPD), which

[6] Which at art. 1 defines them [2° paragraph, let. (c)] as «*any active medical device* [thus requiring a source of power other than that directly generated by the human body, see let. (b)] *which is intended to be totally or partially introduced, surgically or medically into the human body [...] and which is intended to remain after the procedure*».

[7] Which at art. 1 defines them [2° paragraph, let. (a)] as «means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of: — diagnosis, prevention, monitoring, treatment or alleviation of disease,— diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, — investigation, replacement or modification of the anatomy or of a physiological process, — control of conception, and which does not achieve its principal

will though be discussed below in §4.2 ff. The MD having an extremely broad scope may to some extent involve prostheses as well. Machinery is in fact defined as (art. 2, a):

'an assembly fitted with or intended to be fitted with a drive system other than directly applied human or animal effort consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application'.

The directive – analysed in greater detail by (Leenes, 2012) – sets forth safety requirements that need to be taken into account before commercializing the product onto the market. The regulation is indeed general and broad, fixing principles, which could even be applied to prostheses, despite being obvious from the outset that the main intended object of the regulation was not that of robotic implants.

The AIMDD instead probably fits prostheses best, since it is aimed at regulating the safety aspects involved with the production and commercialization of medical devices (see art. 1) which make use of electricity for their functioning (let. b), and can be permanently implanted onto the body (let. c).

Pursuant to the latter, (in particular art. 2), MS shall only allow their trade so long as '*they do not compromise the safety and health of patients, users and, where applicable, other persons* […]', which ultimately leads to the requirement of meeting the standards of safety set forth by annex 1, and therefore gain the right to affix the CE mark onto the product pursuant to the alternative procedures recalled by art. 9 (itself recalling annexes 2 to 5).[8]

The scope of the MDD is possibly even wider and, within the devices here considered, may be applicable to different kind of orthoses and exoskeletons. The requirements set forth for the attribution of the CE marking aim at the development of high standards of safety for the devices to be distributed on the European market; this outcome is also granted through a "safeguard clause" (art. 8), requiring MS to retrieve those devices from the market, that despite carrying the required label, still appear to be dangerous for patients or users.

Neither the AIMDD nor the MDD identify requirements that could be deemed specific for robotic prostheses, nor the European Standard Organizations (ESOs) CEN and CENELEC, have so far developed narrowly tailored standards for such devices.

Finally, even the International Standard Organization (ISO) has not so far released a specific standard for robotic prostheses.[9]

In light of the considerations which are made below (§4.2 ff) for the purpose of the identification of a preferable liability rule, it may be advisable that more specific technical regulation is introduced for robotic devices, setting forth narrowly tailored safety requirements.

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intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means».

[8] An exception is granted for custom-made devices, which still need to meet the same standards of safety but may be commercialized so long as the manufacturer draws a declaration conforming to annex 6.

[9] Even the numerous standards developed by ISO for prostheses and orthoses do not directly address robotic devices autonomously, see http://www.iso.org/iso/home/store/catalogue_tc/catalogue_tc_browse.htm?commid=53630.

4.1.2 My body and my world: the prosthesis as a body part and its constitutional law implications.

Building onto the philosophical discussion of §3.2 it may be stressed that despite the prosthesis being an artefact, and thus an object, its essential function – enabling the person to interact with the external world – does not allow to identify it as any other material possession.

While before being implanted the prosthesis does indeed qualify as a thing and should be regarded as such, once onto the body it becomes a natural extension of it and therefore should be protected with the same guarantees offered to the human body.

No public office or space should be allowed to restrict access to wearers of similar devices and other kinds of prostheses or require the removal or deactivation of the device in order to gain access, except for reasons of safety of the wearer and third parties.

Similarly the same rules for search and seizure should apply to those devices as to the human body, since once installed they cease to be mere objects and property and become body parts at all effects. This shall also include the possibility to access possible recording mechanisms installed onto the device in order to keep track of the received and processed biological signals as well as the signal then transmitted to the motors and actuators allowing the movement of the device, irrespective of whether a similar access could be pursued with invasive or low invasive techniques.

Finally, should the prosthesis be damaged in an accident, compensation ought to allow the party to recover the economic loss connected with its replacement. It may be also discussed whether compensation for non-pecuniary losses, which would otherwise be granted were a natural limb involved, may be liquidated.

However, for the purpose of the ascription of liability in case of malfunctioning of the device leading to an accident – including the harming of the sole wearer of the device – the prosthesis shall still be deemed a product, thus an object as discussed below.

Finally, despite the issue being of relevance only for other sorts of prostheses than those here considered, the implantee should be allowed to wear the device when being identified and portrayed for the purposes of the release of a public ID.[10]

4.2 Liability

With the brief technological description of robotic limbs as conducted above (§2 ff.) some of the peculiarities of these artefacts were highlighted. The aspects that appear to be of greater relevance in a legal perspective are: (i) the circumstance that they are not conceived to operate in a restricted environment, but are meant to follow the person in his everyday life and activities; that (ii) they are expected to replicate the movements of a natural limb, which are intrinsically complex – such as in the case of an arm –, and used to perform extremely diverse tasks, so that it becomes almost impossible to predetermine all risks connected with their use (and misuse). In particular,

[10] This was the case of Neil Harbisson, whose passport photo now portrays him with the device, that allows him to distinguish colours through sounds http://en.wikipedia.org/wiki/Neil_Harbisson

(iii) such implants interact directly with the human being, who may learn to use them in a way which was not originally contemplated, thanks to his intellectual interaction and training.

4.2.1 Prostheses as products

In a legal perspective, prostheses may be deemed products, thus subject to the DPD, and AIMDD or MDD. Despite the latter being construed around the safety requirement, specified as the ability of the device to bear the stresses which may occur during its use, providing an advantage which makes collateral risks acceptable (see annex 1, §I general requirements of both the AIMDD and MDD), the recognition of the quality of the product through the CE mark would not *per se* suffice in excluding any sort of liability pursuant to the defective products' directive. Indeed, not only could the single item be deemed defective (because of its construction), but also the CE mark may be considered wrongly attributed, and revoked.[11]

Therefore, if the marking represents the minimal condition for the product to be commercialized, it does not shield the producer from possible legal actions for the harmful consequences connected to the use of this device. The defective product's directive is thus neither superseded by the AIMDD nor by the MDD.

A comprehensive analysis of the DPD falls beyond the purpose of this analysis but some of the peculiar aspects of the discipline shall be sketched, namely (i) the objective nature of liability (art. 1), and its defences (art. 7), among which – particularly relevant for our subject matter is – the so-called (ii) development risk defence (set forth by let. e); finally the (iii) notion of defect.

The objective nature of products liability is affirmed by art. 1 of the EU directive, where there is no mention of fault, but the mere existence of a defect and a subsequent damage. The proof of defectiveness is reached by showing that damage arose as a consequence of the – normal – use of the product. Moreover, provided that pursuant to art. 7, §1, let. B, the producer may be liberated by proving only that it is probable that the defect did not exist at the moment the good was commercialized, it is correct to assume that the opposite is also true. Therefore, for the claimant to ground his case the demonstration that it is probable that the damage occurred as a consequence of the use of the good may as well suffice (Castronovo, 2006).

The development risk defence has instead been at times criticized, since it excludes liability in those cases where it is harder to foresee the risks connected with the activity. According to such theories, holding the producer liable even in those cases may prove the most effective allocation of costs (in particular if coupled with a liability cap such as the one set forth by art. 16 DPD) since the party may more easily insure himself than the single consumer. However, the application of this defence is limited and not uniform across MS; moreover, single national laws could override the exclusion by allowing the use of general tort law principles.

Finally, despite product liability rules in Europe appearing not to put emphasis on the type of defect, different kinds may be identified, posing different issues. Fabrication defects derive from normal mass production techniques and to some extent can be foreseen, and the frequency of their occurrence assessed. With respect to this kind of defects, much can be done when the correct

[11] In fact the member state may be called to withdraw a device, which despite bearing the quality mark, is ascertained as being dangerous for the health and safety of patients (art. 7 AIMDD). For the MDD see art. 8 and the considerations above §4.1.1.

incentives are provided and it is possible for the producer to determine how relevant the damages arising from the malfunctioning of the good can be. Such risks are often insurable.

Warning defects, understood as inadequate information being provided as per the inherent risks posed by the product, may ground a case of product liability; yet the opposite is not true that adequate information may exclude liability for a defective construction or design.

Finally, design defects appear to be the most problematic, requiring more complex assessments *ex ante* by the producer and *ex post* by the judge. In particular, case law has identified hypotheses where the product was deemed defective since it did not carry adequate safety measures for both normal and abnormal uses, when the latter was deemed foreseeable. It is indeed a matter of interpretation to determine which use of the given good is foreseeable, and therefore can be considered alternatively within the consumer's normal expectations, or a burden (risk) to be factored in the equation (Posner, 2007 and Owen, 2008) in order to assess the required standard of safety.

More generally if the rationale of product liability is to balance the interest of production with the one of safety, two general aspects need to be observed: the limited litigation levels based on product liability across Europe (Biglieri, Pupeschi, & Di Mauro, 2005; Torres Mingot, 2005; Meltzer & Freeman, 2003), and the possible moral hazard effect that a strict liability rule may induce, lowering safety investments by the user (Helland & Tabarrok, 2012). Pursuant to the former, the effectiveness of the regulation may be questioned,[12] while the latter may induce us to think that the incentives for the user shall be more narrowly tailored.

The specific problems arising from the interaction of product liability rules, as sketched, with robotic prostheses, in light of their functioning, is that the very purpose for which they are developed –increasing the life quality of the disabled – causes them to be used in unrestrained environments, and in limitless activities, in particular considering the intellectual interaction that allows the wearer to learn to use the implant often in new and originally unconceived ways. The more active participation of implantees in active life may raise social costs, through a certain increase in accidents that are likely to occur in particular at an earlier stage of development and diffusion of such devices, while still being desirable for the overall effect they produce (Calabresi, 1996) and demandable in light of applicable fundamental rights.

[12] Either the low litigation levels – for instance as compared with the US experience – is justified as evidence of the greater safety of products – and thus may be assumed that the deterrence effect of the applicable regulation forces an effective internalization of costs on the side of the producer, or it must be imputed to the system overall. Since it does not appear plausible that all European products are substantially safer than North American ones, then the latter has to be the appropriate explanation; hence the fact that few actions are brought under the DPD may only be argued pursuant to two considerations: (i) sufficient compensation for the damage suffered by consumers is offered by other norms present in the single MS legal system, or (ii) procedural or other aspects of the single MS legislations impair the application of the DPD preventing it from being used more often. If (i) is true one may conclude that the introduction of the DPD did not increase the overall protection offered. If (ii) is true then the DPD appears still ineffective and reform may be considered, tackling those aspects which are identified as impairing its desirable and sought-after functioning.

4.2.2 Identifying relevant issues through a case study

To better explain the issue, an example may be construed starting from the real-life case of Christian Kandlbauer, the Austrian bilateral amputee, whose arms were replaced by two different prostheses by Otto Bock, one of which made use of the biological signal derived from the nervous system.[13] Mr. Kandlbauer died in a car crash while driving a vehicle especially designed for his needs, and approved by traffic authorities.[14] In the case, it was impossible to ascertain whether the accident was due to a malfunctioning of the prosthesis, and in no way in the present document we are assuming that it indeed may have been. Purely for the sake of conducting a theoretical analysis, the example will be used and fictional assumptions made in order to stress different aspects of the problems connected with the use of similar devices.

First, if indeed it were impossible, in similar cases, to technically ascertain whether the accident was due to a problem in the control of the prosthesis, attributing liability may be problematic even under current product liability rules, since the burden of demonstrating both the defective nature of the device (and thus its malfunctioning) and the causal nexus rests on the consumer (art. 4 DPD) (Castronovo, 2006; Foerste & Graf von Westphalen, 2012).

Theoretically, a way to assess what happened to the implant is to require producers to install recording devices – black boxes – that keep track of all signals sent back and forth to the BMI. A similar solution may be complex to implement,[15] and still not solve the problem completely. In fact, while the device could help detect mechanic and electric malfunctioning (such as low battery, detachment of an electrode, and breakage of a wire), it could allow much less to determine whether the prosthesis misinterpreted the user's intention, or rather the implantee actually determined himself to accomplish that very action, which resulted to be wrong in the given circumstances.

Finally, it is still disputable that one could isolate the single action that led to the accident in order to precisely identify what signal was potentially misinterpreted.

Moreover, even though it were possible to ascertain that a problem occurred with the interaction of man and machine that led to the crash, it should still be determined whether the producer ought to bear its consequences (legal causation), thus if a defect actually may be identified.

It is clear that the prosthesis being a product that caused damage to the wearer and third parties involved in the accident, a liability case may be grounded against the producer held objectively liable for the defectiveness of the product. Most likely the defective nature of design would be debated and the availability of preferable alternatives considered; the foreseeability of the use of the prosthesis may be disputed[16]; or a development risk defence could be opposed, to

[13] http://www.ottobock.com/cps/rde/xchg/ob_com_en/hs.xsl/11443.html

[14] See also the information available on the press of the time of the accident http://www.theguardian.com/world/2010/oct/22/christian-kandlbauer-arm-dies-crash

[15] The amount of data generated by the interaction of the human being with the BMI controlling the prosthesis is particularly relevant and adequate storing capacities may require a large device, reducing portability, an essential aspect for a prosthesis aimed at replacing a biological limb. Power supply may then be an additional concern.

[16] As per the foreseeability it shall be stressed that the same malfunctioning occurring in different circumstances may cause very different damages to the wearer and third parties involved. Moreover not all

state that in light of scientific and technological knowledge available at the moment the product was introduced onto the market nothing more was demandable. Finally, even such an argument may not prove sufficient since actions may be brought against the producer pursuant to other rules (general tort liability provisions in different legal systems of the MS). A similar litigation would be extremely complex, most likely leading to different outcomes in different jurisdictions.

Predictably a producer may try to (i) limit the way a prosthesis is used, by inserting warnings and liability disclaimers to induce the wearer not to undergo some activities, (ii) delay the development of technologies to minimize potential unforeseen consequences, and (iii) attempt to transfer part of the cost to the resale price, and thus to the final user.[17]

Unilaterally stated liability exemptions would most likely be ineffective – if not radically void – and even if drafted in terms of user's instructions – in order to prevent a warning defect claim – they would not exclude that a given (mis)use is later held as foreseeable or falling within reasonable expectations, thus burdening the producer with the negative consequences of the accident. Moreover limiting the ways an implantee may learn to use his device in order to improve the overall quality of his life would most likely defeat the very purpose for the development of similar devices.

It may be claimed that the producer could purchase insurance for the damage deriving from his business. Yet it should also be pondered that considering the limitless numbers of ways one of these prostheses could be used in, and the numerous scenarios of daily life where the same malfunctioning may occur causing extremely diverse types of negative consequences, an all-inclusive insurance may be hard to obtain.

4.2.3 Justifying the adoption of alternative standards

Similar considerations are often made with respect to other kinds of products, and fundamental criticism is often brought to product liability rules as such. Yet criticizing the overall functioning of the system falls beyond the purposes of the present analysis.

It shall instead suffice to highlight how the burden represented by existing regulation would on the one hand certainly create a high degree of uncertainty on the side of the producer, thus delaying the introduction of new technologies in the field of prostheses (technology chilling effect), and probably raising the cost of such devices.

On the other hand, because of their functioning, it may be extremely complex – in particular with respect to BMIs – for the claimant to demonstrate in a court that the accident was a consequence of the malfunctioning. Evidence may be particularly hard to acquire, both for the wearer and for third parties.

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activities could be enumerated or regulated *ex ante*: if the use of a motor vehicle may be prohibited, other activities which involve the same kind of movements could simply not be completely anticipated or identified as being potentially dangerous for the wearer or third parties.

[17] This is often discussed in the law and economics literature as one of the three – desirable – effects of product liability rules, signalling the riskiness of a given product, which otherwise may be underestimated by consumers; much less it is identified as relevant in the traditional legal discourse as well as in policy decisions. Indeed, some authors argue that a more relevant effect may be obtained through market forces (due to availability of information to the public at large), and to some extent offset by the use of first party insurances. See (Polinsky & Shavell, 2009-2010)

Finally, an argument can be made which allows us to consider alternative – and possibly preferable – allocations of risks and liability among the different parties involved, ensuring an adequate product's safety while favouring the development and diffusion of such applications.

Despite many provisions in MS constitutions and in the European Charter of Fundamental Rights (henceforth ECFR, see for instance art. 1 on human dignity, art. 3 on the Right to physical integrity, and more specifically art. 26 on the integration of persons with disabilities) could be used in order to argue in favour of the need to foster the development of technological aids for people with disabilities, a very precise and straightforward claim in this respect is set forth by art. 4 of the UN Convention on the Rights of People with Disabilities (henceforth CRPD), which the European Union, together with many single member states, ratified on December 23rd 2010 (Schulze, 2010).

Art. 4 CRPD states that:

> 'States Parties undertake to ensure and promote the full realization of all human rights and fundamental freedoms for all persons with disabilities without discrimination of any kind on the basis of disability. To this end, States Parties undertake: [...] g) To undertake or promote research and development of, and to promote the availability and use of new technologies, including information and communications technologies, mobility aids, devices and assistive technologies, suitable for persons with disabilities, giving priority to technologies at an affordable cost; [...]'

A similar provision may be understood as requiring the adoption of a regulatory framework favourable to the development of robotic prostheses and thus including even alternative liability criteria, providing incentives for the development and emergence onto the market of such products. Their discrimination – with a more favourable liability regime – would therefore be neither unreasonable nor unjustified.

4.2.4 Alternative Liability Mechanisms

It shall be stressed that the adoption of a different liability rule does not entail making products more dangerous. In fact, there is no evidence that existing product liability rules contribute to increasing product safety. Theoretically, it may be disputed that a strict liability standard induces extra care as opposed to a pure negligence standard, since strict liability implies that the party will be held liable irrespective of the effort it was put in making the product safe (Posner, 2007). Moreover, some empirical studies conducted in the United States raise relevant doubts about the effectiveness, to this end, of product liability rules (Polinsky & Shavell, 2009-2010) and even if such considerations may not be plainly transposed to Europe, they shall be taken into account.

Existing rules – considered the low number of cases decided pursuant to them – most likely do not provide sufficient incentives to consumers to sue. Other remedies instead, may appear to provide sufficient incentives to product quality, in particular the Directive 99/44/EC of the European Parliament and of the Council of 25 May 1999 on certain aspects of the sale of consumer goods and associated guarantees. Market forces, then, do play an essential role.

Different are the alternative liability standards that can be conceived if the aim is identified with (i) providing safe implants and (ii) adequate compensation for those – wearers and third parties – involved in an accident related to the use of such devices.

On the one hand, pursuant to art. 16 DPD, MS may limit the producer's liability to 70 million ECU. Such a limit though appears considerably high if the aim is to encourage the development of these devices, in most cases in fact damages may be expected to fall below such limit. Only theoretically, though, a cap may be narrow-tailored enough to provide an adequate incentive to adopt safety measures: such an approach would in fact entail an *ex ante* assessment of what the average value of damages may be, its likelihood together with the identification of a socially desirable burden. Such a decision is probably better made *ex post* and in single cases by a judge; presumably once more information is available.

More generally, the idea of a liability cap would not solve the issue of the complex assessment of whether the damage derived from the malfunctioning of the prosthesis and if a different and higher standard of safety could be demanded (eventually in the form of an alternative design). It shall be noted, that both an objective as well as a negligence standard of liability pose the same problem.

Alternatively, two other options can be identified: (a) a liability exemption, (b) a no-fault scheme. The two could also be combined together so as to provide a more effective scheme.

4.2.5 Liability exemptions and product safety

The first aspect to consider is whether a liability exemption would cause products to be less safe. Liability exemptions were introduced in the US legal system for commercial aircrafts in 1994 with the General Aviation Revitalization Act (Act Aug. 17, 1994, P.L. 103-298, § 1-4, 108 Stat. 1552; Nov. 20, 1997, P.L. 105-102, § 3(e), 111 Stat. 2215, henceforth GARA). The particularly high number of product liability actions brought against civil aviation aircrafts manufacturers was causing the entire industry to collapse when the US government decided to intervene; shielding producers from all actions eighteen years after the airplane was first sold.[18] At the moment the regulation entered into force, many airplanes, which had already been distributed on the market, immediately fell under the exemption – thus their producers could not be sued pursuant to product liability rules in case an accident occurred involving the use of the aircraft –, and others followed in the subsequent years (the average length of use of commercial planes being above 24 years). A recent econometric study aimed at showing the impact of moral hazard concluded that, despite the exemption, the number of accidents declined in subsequent years, due to an allegedly greater investment in safety on the side of the user, identified as the person in the best possible position to adopt adequate measures and determine the appropriate levels of use of the product.

Three relevant things are though observed: (i) commercial aviation is a highly regulated industry, with high technical requirements imposed on producers; (ii) users – namely pilots – are sophisticated parties, with considerable knowledge on the technical aspects of the products and able to understand and process complex information about the correct usage of the machine; (iii) the safety investment decision made by the producer was undertaken – in the vast majority of cases – before the exemption was enacted, and thus when the producer was expected to be held liable pursuant to an objective rule.

[18] See GARA §2, stating that: '(a) In general. Except as provided in subsection (b), no civil action for damages for death or injury to persons or damage to property arising out of an accident involving a general aviation aircraft may be brought against the manufacturer of the aircraft or the manufacturer of any new component, system, subassembly, or other part of the aircraft, in its capacity as a manufacturer if the accident occurred--(1) after the applicable limitation period […]'.

These considerations could lead us to doubt that the conclusion drawn – namely that product liability rules do not substantially contribute to lowering the number of accidents – is correct, or anyway holds true for the case of prostheses, where different conditions apply. Indeed, there is not yet a comparably sophisticated regulation of technical standards for prostheses as for aircrafts, and implantees do not necessarily possess such a profound and complete understanding of the devices they wear as a pilot does of the vehicle he flies.

As per the existence of appropriate regulation, it was noted above (§4.1.1) that some technical standards for robotic prostheses ought to be developed by a competent body of experts, also to address the peculiarities of complex control systems, such as BMIs, that using a brain-generated signal elaborate the different messages contemporarily sent to single muscles.

As per the specific training and high technical understanding the user of an aircraft possesses, it may be assumed that since such devices require substantial rehabilitation and specific training after being implanted, the user of a prosthesis may still gain a profound understanding of both its potentials and risks (in case of malfunctioning, misinterpretation of the biological signal or delayed response). Considering the still experimental stage of many such devices, it could though be pondered if existing procedures may be adequate once they reach the market, or whether it would be preferable to conceive and adopt more specific rehabilitation and training protocols so as to make sure that patients reach a high level of – theoretical and practical – understanding of the functioning of the prosthesis before they start using it in normal days activities. A board of medical and engineering experts may provide the required indications to improve existing standards, when necessary.

The most relevant objection that could be raised though is that the investment in product safety made by commercial airplane producers in the case of GARA had been undertaken at the moment when product liability rules applied (and thus an objective standard of liability) and litigation on those grounds was at its highest. It could thus be argued that only models that are designed and produced after the introduction of GARA, with the liability exemption into force, the effect of the exemption on the overall safety of the design and construction of the aircraft could be appreciated.

Two specific counterarguments could though be formulated: a similar conclusion ignores the effect of market forces (the desire not to ruin one's reputation and to charge a higher premium for the recognized quality of the good), and the fact that the high levels of pre-GARA litigation had not increased product safety in an appreciable manner.

Next to such product-specific observations, it shall also be noted that if product safety considerably depended on the existence of product liability rules, then the very limited level of claims, grounded on such rules, in most MS could only be explained as a consequence of a substantially safer nature of the products retailed[19] in Europe as opposed to those retailed in the US, which *prima facie* appears implausible.

[19] Note in fact that product liability applies not only to products produced but also retailed in the European market (see art. 3(2) of the DPD). If the same product did not trigger the same level of litigation in different markets, it should then be concluded that litigation is a consequence of other factors (most likely the single legal system and propensity of the single consumer to sue) rather than of the safety of the product, thus excluding a correlation between product liability rules and safety.

Nonetheless, since the purpose of the current analysis is not to stress or prove the – either great or limited – overall efficacy of existing product liability rules in Europe, it shall suffice to claim that other specific regulative approaches may be used in order to ensure that robotic prostheses meet a high technical standard in particular with respect to safety (in case of malfunctioning, misinterpretation of the biological signal or delayed response to it).

Otherwise stated, a liability exemption shielding the producers of prostheses would not most likely impair the safety of the device, provided that adequate technical regulation sets high quality requirements for such devices.

4.2.6 Compensation and no-fault plans

Looking at the need for compensation however, if the producer is exempted of all forms of liability the cost associated with the use of the prosthesis would rest entirely on the person with disability. He, in fact, would have to purchase insurance against possible damages caused to himself or third parties. Most likely he would be in the best position possible to determine the most adequate level – and kind – of use of the device, and be put in the best condition to control and prevent possible malfunctioning (investment in safety), but at the same time may be over-deterred because of personal financial constraints.[20] These same reasons may render the possibility to acquire adequate insurance in the market even harder[21] for the user than for the producer, resulting in both a suboptimal use of the technology, its delayed development, and limited compensation to potential victims.

A mere liability exemption, impeding any action in tort (or even pursuant to the DPD) against the producer is thus not sufficient in effectively handling the issue of adequate compensation.

At the same time though product liability rules do not appear to be successful in fulfilling that function either: indeed, the limited number of claims brought pursuant to the DPD clearly shows that the incremental advantage theoretically offered by an objective liability standard, is extremely limited if at all existent. People most likely accept the compensation obtained through welfare systems, private insurances or actions brought pursuant to other norms, and thus the DPD does not substantially increase compensation.

Moreover, since the most relevant problem in establishing the liability of the producer rests with the ascertainment of a causal nexus between the alleged malfunctioning of a prosthesis and the harmful consequence borne by the wearer or third party (see §4.2.2 above), neither a negligence nor an objective standard of liability would ease the position of the claimant involved in the accident.

Absent a normative reform with respect to the burden of proof, courts could make use of a *res ipsa loquitur* reasoning to favour the user (or third party) over the producer. Such a technique

[20] The need for an implant of a prosthesis often comes with reduced working and therefore earning capacities.

[21] Insurance companies may decide not to offer any coverage for activities undergone with the usage of a prosthesis, or substantially restrict their use by ticking off those activities they deem more dangerous, thus discouraging the use of the device. Finally the price charged may be too high for some of the wearers, who may be forced to renounce to the operation.

would though place an excessive and unjustified burden on the latter, not allowing him to distinguish between cases where an actual malfunctioning occurred from those where the accident was independent from the prosthesis. Moreover courts across different MS may apply the theory to different extents, increasing discrepancies in the application of the DPD. The overall system would generate uncertainty and compensation would be assigned on potentially random basis. While in fact a mechanical failure may be more easily assessed, the misinterpretation (or delay in the interpretation) of a biological signal may be hard if not impossible to identify (see §4.2.2 above).

Overall the technical complexity of the product and the unlimited real-life scenarios and activities in which it could be used, would make the ascertainment of liability complex and uncertain, raising the administrative costs associated with the liquidation of damages.

A no-fault scheme (as hypothesized above *sub* b) could therefore prove a viable solution, replacing all traditional tort actions against the producer and wearer in cases where an accident occurred which involved the use of such devices. Both the producer and wearer would be exempted from all sorts of liability for damages involving the use of such devices, and compensation would be provided through an automatic compensation mechanism.

No-fault schemes were introduced in some legal orders in different fashions, either completely replacing the tort law system (New Zealand) or substituting it in a specific field (often motor vehicles circulation see (Anderson, Heaton, & Carroll, 2010) and work-related injuries.

Different opinions about their efficacy have been formulated and discussed in the literature. Those who oppose it most often theorize the negative effects on moral hazard and safety investments brought about by such a system; the proponents instead normally highlight the relevant reduction in administrative costs achieved, ultimately resulting in a greater portion of the overall investment reaching the injured party.

Only scattered data is available for different systems and conclusive considerations may not be here formulated on empirical grounds.

The moral hazard concern should though not be overemphasized. A no-fault system is similar to a first-party insurance, and both may induce the adoption of riskier conduct. The fee paid to the system may though prove a sufficient corrective, possibly in combination with administrative sanctions that may be added in order to discourage and repress opportunistic behaviour on both sides.

Moreover as per the device's safety it was already shown above that current liability rules (namely the DPD) do not appear to provide relevant and measurable additional incentives. Safety can be better ensured with more detailed *ex ante* regulation, technical standards and certification procedures assessing conformity and high quality of the device. Market forces do certainly provide relevant incentives for high-cost high-technology devices, and other form of sanctions can be conceived for grossly negligent or unlawful conduct, on the side of both the producer and the wearer.

Therefore in order to provide adequate compensation for the harm suffered by wearers of robotic prostheses and third parties involved in potential accidents, a no-fault scheme could be proposed, completely bypassing complex litigation and allowing more certainty and a form of liability cap to producers, so as to favour the development of these devices.

The system could be so conceived that if the party causing the accident was a wearer of a prosthesis and the accident – in light of the circumstances in which it occurred – was neither intentionally caused[22] nor evidently due to a different causal chain unrelated to the use of the prosthesis,[23] the wearer and all third parties who suffered damages would be entitled to file a claim to obtain compensation from the given fund.

Compensation for pecuniary and non-pecuniary losses[24] would be automatically awarded by the administrative body of the fund upon ascertaining, through a summary investigation, that (i) the accident involved the use of such devices, that (ii) it was not an intentional tort, and that (iii) the use of the device is not completely and radically irrelevant to the case. Eventually a liability cap could be determined, in order to limit the maximum compensation awarded, should concerns be raised with respect to the economic sustainability of the model.

From the amount of liquidated compensation sums obtained through national welfare system should be deducted in order to avoid double compensation.

The producer may be required to contribute to the fund a given amount (for instance in the form of a percentage of the resale price), and the wearer may be required to contribute trough a fee; finally national welfare systems may provide funds directly[25] as part of the obligation understood as arising from art. 4 CRPD.

The normally admitted advantage of similar systems is the relevant reduction of administrative costs, meaning that the greater part of each euro invested in the system reaches the harmed party – being either the wearer himself or a third party – and most importantly liquidation is not delayed by lengthy, complex and costly litigation. Moreover, it may be assumed that a greater degree of internalization of the cost is achieved as opposed to a system where actions for damages may be excessively discouraged.

In the producer's perspective, the *ex ante* identification of the amount of the contribution he is bound to pay to the fund would completely eliminate *ex post* uncertainties associated with litigation and allow him to factor it into his costs.

In order to mitigate moral hazard effects on the side of the producer it could be provided that he is held liable, and thus sued in court without the possibility to benefit from the exemption,

[22] Intentional torts irrespective of whether the limb was involved or even malfunctioned should not fall under the plan, shielding the wearer from liability actions brought against him by injured third parties. Compensation through the fund to such third parties may still be ensured if the use of the limb was involved, malfunctioning could not be radically and completely excluded and only in a subsidiary position, should the tortfeasor be insolvent.

[23] Meaning that there is radically no causal nexus between the use of the limb and the harm caused, for instance because only the natural limb was used in order to cause harm (the implantee hit even non-voluntarily a third party with his natural limb) or the harmful conduct was anyway totally unrelated to the use of the prosthesis (as in cases of negligence of the wearer).

[24] For the latter it may be conceived that only relevant prejudices to bodily integrity are liquidated and no other forms of pain and suffering and non-pecuniary losses otherwise demandable pursuant to existing regulation and case law in different MS.

[25] Indirectly they may also contribute to the extent that the prosthesis implanted was purchased by the national healthcare system of the MS.

should gross negligence (or scienter) be ascertained through a *prima facie* assessment, once the compensation claim is filed with the competent authority.

It could instead be discussed both in a technical and policy perspective whether such a system would be better organized through the participation of insurance companies or directly by an ad-hoc created public authority. Most clearly, the independency (even in a technical perspective) of such a body from external influence is to be ensured.

4.2.7 Discussion and conclusion

To summarize, three fundamental considerations can be made. The application of existing liability rules, namely the DPD, to robotic prostheses appears to be problematic. On the one hand, from a technical perspective, the functioning of the prostheses (and in particular the BMI) may cause the ascertainment of a malfunctioning as the actual cause of the accident to be extremely hard if not impossible.

On the other hand, from a policy perspective, placing an excessive burden – as an objective (or semi-objective) liability rule would, in particular with respect to a product that can be used in potentially unlimited ways and scenarios – would impair the development of a technology that is certainly beneficial and desirable, capable of radically improving the living conditions of people with disabilities (Manyika et al., 2013).

Normative bases can be identified to justify the adoption of a different standard, in order to favour the development and diffusion at an earlier date and for a wider public of these technologies: art. 4 CRPD may be understood as requiring similar measures by its underwriters, among which the European Union. Indeed, promoting a technology may entail removing those normative obstacles that delay its emergence and diffusion.

As per the function of civil liability rules their function is twofold: (i) provide incentives to behave in a desirable fashion – in the case at hand produce safe products – and (ii) provide adequate compensation to the harmed party.

The efficacy of product liability rules in increasing products safety can be questioned both theoretically and empirically; for the sake of the specific analysis though it suffices to say that the adoption of sufficiently detailed and specific technical standards (constantly updated according to scientific and technological development) (Zei, 2013) could provide adequate incentives to produce high-standard and safe devices.[26] Said otherwise, the application of product liability rules would not increase the level of safety offered by prostheses, and a liability exemption could thus be introduced without increasing dangers for wearers and third parties.

[26] See also the Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, 'A Strategic vision for European standards: Moving forward to enhance and accelerate the sustainable growth of the European economy by 2020', Brussels, 1.6.2001, COM (2011) 311 final, available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2011:0311:FIN:EN:PDF: '[...] in the future, European standardization will play a crucial role in a wide variety of areas, wider than today, ranging from supporting European competitiveness, protecting the consumer, improving the accessibility of disabled and elderly people to tackling climate change and the resource efficiency challenge'.

A liability exemption for all actions brought under product liability and normal tort rules should though not deprive the victims of accidents involving the use of prostheses of appropriate compensation.

To this end, compensation could be more effectively provided through a no-fault scheme, covering all accidents which involved the use of a prosthesis (and were not intentionally caused or due to a completely unrelated causal chain). The main advantage of a similar system is to dramatically reduce the costs of litigation, and eliminate any uncertainty both with respect to the risk for the producer of being sued for damages, which could not be foreseen – and thus insured – and for wearers and third parties not being able to provide sufficient evidence of a malfunctioning, which indeed occurred.

On the one hand, producers may control the risk they are exposed to, transformed in a form of tax (or percentage of the resale price of the device), which they would contribute to the fund.

On the other hand, wearers and third parties could obtain prompt compensation for the actual damage suffered simply by filing a request with the fund, saving on relevant *ex ante* costs related to litigation and possible uncertainties of the outcome.

MS could contribute to the fund directly (by paying a certain amount required to establish and maintain the fund) or merely indirectly (when they purchase through national welfare systems the device to be implanted). Compensation would be more certain, relieving the harmed of the negative consequences of the use of similar devices, spreading – and to some extent socializing – the cost of a more active participation of people with disabilities in society, a desirable effect the EU should pursue.

4.3 Regulating human enhancement

The more proximate technological horizon of prostheses does not directly involve the issue of human enhancement as sketched above in §3.1, and yet is profoundly tied to it. Prostheses are today and most likely will be in the medium run a fundamental device for people with disabilities to recover a lost function and increase the quality of their life. This is mainly due to the fact that existing technological constraints do not make these devices appealing for a wider public, since they still do not come close, much less exceed, the capabilities (Nussbaum, 2011) that a natural limb offers today.

Yet it is already possible to envision a more distant and yet not so remote future where even robotic technologies may be used as implants by people that today would not be considered having disabilities.

This will certainly happen once such devices are so developed that the person wearing them may be deemed at an advantage over non-implantees, either because the device pushes natural limits forward–by for instance making the person stronger or faster than normal–or provides the person with radically new capabilities.

Two examples can be used in order to better clarify these aspects: (i) Oscar Pistorius's participation in the Olympic Games; (ii) Neil Harbisson's eyeborg.

Pistorius, a bilateral amputee South African athlete, in 2008 was denied permission to participate in the Beijing Olympics by the IAAF since 'his prosthetic racing legs give him a clear competitive advantage' (Wolbring, 2008: 141).[27] The devices Pistorius uses for racing do not fall within the category of applications here considered – the prostheses he wears are in fact not robotic –, yet the problem is identical. The special equipment used made the committee conclude that rather than being dis-abled the athlete was at a material advantage over his "normal" competitors and thus to some extent super-able.

Neil Harbisson[28] is deemed one of the few living cyborgs, because of an antenna osseointegrated in his skull that transforms colour frequencies into sound frequencies, allowing him to even perceive colours that are outside human spectrum. The device intended to remedy his achromatopsia actually provides him with a different capacity, which no other human being possesses. Therefore if on the one hand he is not capable of seeing colours in a way someone not affected by his illness is able to, on the other hand, having extended his senses, he may perceive reality in a different way that does not fall within natural human capacities.

These two examples allow us to depict the essential aspects of the bioethical issue to be addressed.

So long as the development of devices permits the recovery of a lost function, the issue appears to be unproblematic, yet once we move beyond that point numerous questions arise, namely (i) which form of intervention on the human body should we be able to consent to? May limits be identified besides technological feasibility and safety – and how should these be defined? Should it include only biological considerations or psychological ones as well, and possibly issues of personal identity? – of the enhancement procedure as such?; (ii) who should be allowed to enhance himself, in which cases and under which conditions?; (iii) who shall be entitled to make such decisions; and (iv) according to what principles ought such decision to be taken?

The truth is though that even the distinction of mere recovery and true enhancement appears faded and hard to trace (Lucivero & Vedder, 2013). Indeed it rests on a notion of normality – healthy condition – which may only be statistically defined (Boorse, 2013), and not so unequivocally ascertained with respect to single individuals. For instance, should we need to determine to what condition the single individual ought to be restored, as it could be disputed which moment in time along the person's life ought to be taken into account. Should a middle-aged man lose one of his arms in a car accident, ought that arm be replaced with a prosthesis – supposing

[27] The case of Pistorius is here used for the sole purpose of identifying a possible form of enhancement, intended as the improvement beyond natural limits of a function commonly – yet not always – possessed by human beings (Boorse, 2013 and Machery, 2013), and thus beyond the real life case, which involved him as an athlete. It should however be clarified, that a subsequent decision of the Court of Arbitration for Sport (CAS) (Arbitration CAS 2008/A/1480 Pistorius v/ IAAF, award of 16 May 2008) determined that the prosthesis did not provide any proven biochemical or metabolic advantage over other athletes, thus leading to his participation in the London Olympic Games. In all further references though in the text, reference to Pistorius will simply intend to quickly recall to the reader the above sketched idea of a specific form of enhancement, which does not attribute human beings radically new capabilities, beyond those normally possessed.

[28] Basic information can be found at http://en.wikipedia.org/wiki/Neil_Harbisson; more recently http://www.ted.com/talks/neil_harbisson_i_listen_to_color, where he describes his personal experience with perceiving colours; while information about the Cyborg Foundation he set up can be found here http://eyeborg.wix.com/cyborg.

it were technologically available – (a) which enables him to perform the tasks he handled at the moment of the accident, or (b) those he could perform at a younger age or at a moment in time when he was more fit and perhaps stronger? Should one rather (c) take into account the capabilities of an average person of that same age and sex, and if so how specific ought the model subject to be – which elements and factors ought to be considered?

Finally, it ought to be discussed whether a similar decision is to be left to the person directly involved or rather to a medical team (or ethical committee of an hospital), or even to market mechanisms, thus allowing the individual to purchase the best possible device available at the given moment in time?

Providing satisfactory answers to such fundamental questions is an extremely complex task, which certainly falls beyond the purpose of the current analysis, in particular since the kind of prostheses directly addressed only allow us to identify this as a more distant issue, which will be materially relevant only at a later stage of technological evolution.

However, since a debate is most likely required in order to come to possibly shared conclusions, the framework within which a similar analysis ought to be conducted – in a legal perspective – shall be briefly sketched.

4.3.1 Disability as a transient status in everyone's life and the emergence of new capabilities and vulnerabilities

Most commonly western philosophy takes disability into account as a departure from an alleged condition of normality, rather than as a form of vulnerability that everyone experiences during his own existence, as a child first and elderly then and often through illnesses, which cause our bodies not to respond anymore to ourselves as we thought obvious (MacIntyre, 2009).

Moreover, the extension of human lifespan through technological development if on the one hand is aimed at improving living conditions, also increases the probability that one will experience such form of vulnerability and dependence on others directly, and thus not by simply observing it in others.

Vulnerability and dependence are also inherently rooted in human existential conditions, (Heidegger, 1996 and summarized by Coeckelbergh, 2013).

Therefore, if vulnerability is inherent to the human condition (Arendt, 1958), technology may only contribute to reshape it (Coeckelbergh, 2013) the dragon may be killed (Bostrom, 2005) but other monsters may claim his place, not necessarily less dangerous or scary.

Since the purpose of all legal systems is to allow different positions in society to be mediated and come together for a just and peaceful living, the framework here briefly sketched may be applied for the purpose of identifying a common ground between otherwise distant positions.

The metaphysical question on human nature (Habermas, 2003) – at least for the ethical and legal debate – could thus be narrowed down to the weighing of alternative options, entailing more limited policy decisions on which kind of vulnerability is – more or less – desirable (Coeckelbergh, 2013; Coenen *et al.*, 2009).

The criteria pursuant to which a similar choice ought to be made are although to be defined, and even if capabilities were taken into account (Nussbaum, 2011), it is not simple to determine in

an – as much as possible – objective – and thus balancing principles such as justice and self determination – fashion what forms of enhancement actually shall be favoured.

If this appears to be the most relevant limit of the current ethical discourse, legal analysis may benefit from the fundamental principles deriving from the ECFR as well as national constitutions, which are relatively unchangeable (although subject to interpretation and adaptation over time).

4.3.2 Existing criteria: freedom of self-determination and the precautionary principle

Some clear-cut boundaries can be identified pursuant to existing constitutional principles, among which the absence of a general duty to enhance oneself (Coenen *et al.*, 2009).

In particular, the fundamental rights to health and inviolability of the human body, expressly recognized by MS' national constitutions as well as by the ECFR,[29] prevent the person to be forced to receive medical treatment, even in cases where the refusal would certainly be detrimental and possibly fatal for the individual. The choice to intervene on the human body is indeed completely free and – needs to be – informed.

However, even granting freedom of choice in this matter is not completely unproblematic. Indeed, admitting the possibility to enhance oneself, when freely and informed consent by the single person involved may be expressed, still impacts other individuals' freedom of determination in at least two ways.

On the one hand, the mere fact of legalizing a behaviour causes that option to be perceived differently, modifying the way society identifies the issue – consider for instance pornography (Calabresi, 1996) –, and ultimately inducing a change in perspective, up to the radical subversion of the originally diffused opinion. Such an effect may, in some cases, be desired and actively pursued by the legislator, but may as well not be precisely pondered when adopting a given regulation. In the case of human enhancement, should regulation be adopted permitting some forms of augmentation as opposed to others, the perception of the public at large with respect to those practices would most likely vary, bringing more and more individuals to consider them as normal. At the same time, the very perception of a bodily or mental trait as illness to be remedied, would cause an undesirable pathologisation of some forms of the human condition (Coenen *et al.*, 2009: 131), reducing diversity and imposing a single vision of "good life" in overt contradiction with the fundamental values of a modern democratic society, such as the European (Fletcher, 2014).

On the other hand, once a technological innovation is accepted by a large share of the population, so that it becomes common and widely used, those who prefer not to make use of it may not be materially able to do so, since the cost of opting out may amount to being isolated and marginalized (Coenen *et al.*, 2009: 44, 132; Calabresi, 1996: 8). This is to say that were human enhancement to become as diffused as the use of internet technologies – or automobiles[30] – today,

[29] See for instance art. 32 of the Italian Constitution as well as art. 3, 35 of the ECFR.

[30] In the example provided by Calabresi renouncing the use of automobiles also entailed renouncing all other aspects that are indirectly connected with it, such as the possibility to make use of products – including nourishment and essential goods – that need to be delivered from distant places.

it would almost become impossible to renounce it without being immediately cast off from society.[31]

Such a consideration is particularly relevant for human enhancement, given the profound philosophical, ethical, moral and even religious issues it raises,[32] touching the deepest beliefs of a single individual's life. Said values and positions are indeed hard to compromise and mediate and for these very reasons, extreme precaution should be used when deciding to allow a given practice, and those interests ought to be taken into account – even in terms of increase in capabilities or reduction of vulnerabilities – which may belong even to eventual minorities. Decisions on such aspects need thus to be the purport of an extremely wide discussion and awareness of public opinion.

In this sense the European precautionary principle (art. 191 TFEU) may also be understood as inducing maximum caution not only with respect to the technological risks associated with the development and diffusion of some forms of enhancement,[33] which appear to be extremely problematic – genetic enhancement and deep brain stimulation being paradigmatic examples of techniques whose effects are extremely hard to foretell –, but also and in particular social risks, too often underestimated and marginalized in the debate.

The considerations sketched and the principles recalled appear thus to provide some relevant arguments for the refusal of radical enhancement techniques (as defined by Agar, 2010), but still do not allow to clearly identify an all-encompassing policy for all the different issues human enhancement raises.

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[31] This consideration is particularly true if other forms of human enhancement are considered, beyond the replacement of a otherwise functional body part with a robotic device, such as genetic and pharmaceutical enhancement.

[32] It shall be noted that even religious considerations may be taken into account without it being a violation of a principle of laity upon which European constitution rest, since the values and options at stake are deeply interwoven with the social self-perception of the individual. In this sense (Nussbaum, 2011) includes those among the values to be taken into account in the capabilities assessment and equally does (Coeckelbergh, 2013).

[33] The principle, affirmed in the field of environmental protection, is today considered as having broader application, so as to include other fields of scientific development, such as nanotechnologies, see the Commission Recommendation, 'On a code of conduct for responsible nanosciences and nanotechnologies research', Brussels, 7.2.2008 C(2008) 424 final, available at http://ec.europa.eu/research/participants/data/ref/fp7/89918/nanocode-recommendation_en.pdf, where at §3.3 it is stated: 'N&N research activities should be conducted in accordance with the precautionary principle, anticipating potential environmental, health and safety impacts of N&N outcomes and taking due precautions, proportional to the level of protection, while encouraging progress for the benefit of society and the environment.' Further reference shall be made to the Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, 'On the precautionary principle', Brussels, 2.2.2000, COM(2000) 1 final, available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2000:0001:FIN:EN:PDF, where it is stated: 'Although the precautionary principle is not explicitly mentioned in the Treaty except in the environmental field, its scope is far wider and covers those specific circumstances where scientific evidence is insufficient, inconclusive or uncertain and there are indications through preliminary objective scientific evaluation that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the chosen level of protection' (p. 9-10).

4.3.3 Human dignity and equality, and their limits

Within the broader framework here sketched some issues can be addressed, of more specific relevance for prostheses.

Should a technology be available which put the wearer – a person with disabilities – at an advantage over the non-implantee, should the latter be allowed to make use of the same kind of product and eventually voluntarily undergo the necessary operation when he had no physical condition needing to be treated or capability restored? Would it make a difference if the implant radically improved an already existing capability – like in Pistorius' case – or provided a radically new one – Neil Harbisson's case –?

One may attempt to answer the previous questions by resorting to two fundamental constitutional principles explicitly recognized by most MS constitutions as well as the ECFR, namely human dignity (art. 1 ECFR) and equality (art. 20 ECFR).

Human dignity is normally negatively defined through the identification of what is deemed to be violating it (Fabre-Magnan, 2007; Resta, 2002; Feldman, 1999; Dürig, 1956); in this sense it may be applied in order to prevent mutilations and interventions that despite being freely accepted and determined may undermine the integrity of the body permanently. One may freely decide not to undergo a specific medical treatment, ultimately leading to one's death, but still one is not equally entitled to dispose of the body in a fashion that would permanently diminish its functionality, except for some specifically approved reasons such as organ donation (the gratuitous nature of this act being decisive to qualify it as lawful).

It is also used in order to prevent life choices the person could make deeming them appropriate or satisfactory for herself, that instead are considered to contrast with non-negotiable core values and attributes of human beings as such.[34]

Absent a positive definition of human dignity in the law – and case law – it is extremely hard to envision its application to prostheses as a discriminating criterion in order to determine which kind of implant should be allowed and which prohibited. Human dignity may induce us to conclude that the voluntary mutilation of the human body for the purpose of replacing the natural limb with a more performing artificial apparatus shall be prohibited (see the considerations on the "intentional [...] disfigure[ation of] the human body" by Mordacci in Coenen *et al.*, 2009), but the opposite conclusion may as well be reached adopting other hermeneutical criteria, that are at times derived from this principle.

Moreover, human dignity negatively defined does not provide sufficient indications to determine whether, absent any purely therapeutic purpose, a prosthesis conferring radically new capabilities may be implanted on an otherwise healthy individual. Indeed, its use as a limit to the individual's freedom of choice is commonly related with activities that are deemed diminishing of human condition, to some extent involving the commercialization of the body (Resta, 2011).

[34] Stereotypical is the French case decided by the *Conseil d'État*, 27th October 1995, *Commune de Morsang-sur-Orge*. The case dealt with a person affected by dwarfism, who was paid to be thrown in the air for the amusement of the club's patrons and bystanders. The expressed consent was not deemed sufficient to qualify the behaviour as licit, since such a game violated human dignity, understood as an external and objective limit to all individuals' freedom of (self-)determination.

To the contrary, such considerations cannot easily be transposed to purely enhancing techniques, once technical concerns about the safety of the procedure are satisfactorily analysed and excluded: the application is in fact by definition producing positive – biological – effects, whence the argument, that such applications should not be opposed, rather favoured.

Although, the issue ought not to be reduced to a purely technical question of whether undesirable or harmful side effects can be identified or excluded; instead, social consequences ought to be considered and weighed together.

As per equality its application to human enhancement leads to opposite and contradicting considerations. On the one hand, if a non-amputee were denied permission to replace the natural and otherwise perfectly functional limb with an artificial – and more performing – one, it may be concluded that an unjustified inequality is being consented. The person with disability, who was allowed to enhance herself beyond the limits that are deemed natural for a human being through the use of a prosthesis would all of a sudden find himself at a material advantage over the non-amputee, who wanted to have the same device installed.

Such a solution may be deemed desirable as a form of affirmative action for subjects who have long been discriminated, yet a similar argument cannot prove satisfactory and certainly is not capable of radically solving the fundamental issue sketched. In the end, the principle of equality – formally understood – may be used to argue that the possibility should be granted to every individual to freely modify his own body – even by replacing a specific and fully functional body part –; this would most likely trigger a race for perfection,[35] that ultimately would impose everyone to undergo enhancement not to become alienated from society, as clarified above (see §4.3.2).

Nonetheless, should equality be used to affirm the single individual's right to modify his own body beyond purposes of mere recuperation of a lost – or missing – function, it still would not provide guidance in the assessment of which form of enhancement ought to be permitted, which denied. Equality, formally understood, is thus *per se* not sufficient.

Moreover, such a notion of equality still gives rise to further problems, in particular with respect to access to similar technologies. One of the risks associated with freedom of enhancement is in fact represented by the creation of an upper class of enhanced (super)human beings, opposed to a lower class of lesser – in the sense of non-enhanced – humans.[36] Such a distinction prevalently based on income, would ultimately foster further inequalities, and most likely prevent social mobility (Agar, 2010; Swindells, 2014). This argument could thus in some cases be used to justify the subsidization of some forms of enhancement for those who otherwise would not be able to afford them, according to the same welfare state mechanisms, that operate in single MS with respect to other necessities. If it were instead recalled in order to prevent – or to some extent limit – freedom of self-modification, it would still not provide sufficient guidance as to what kind of intervention on the body ought to be permitted and which not.

Finally, enhancement does not appear as a desirable tool for solving issues of redistribution in society (Coeckelbergh, 2013). It could in fact be argued that genetic differences causing some

[35] See for instance the considerations made within the FP7 Project Technolife (Project number: 230381), at www.technolife.no, and in particular the movie available at movie: http://www.youtube.com/watch?v=STiuB7nQn1w.

[36] http://spectrum.ieee.org/biomedical/bionics/we-will-end-disability-by-becoming-cyborgs

individuals to be smarter, more beautiful, and resistant to illnesses, do reflect themselves in the position the person will occupy in society. Such unequal biological lottery – it could be argued – ought to be controlled and limited – pursuant to a substantial notion of equality – through tools of (genetic) human enhancement, deciding behind a veil of ignorance what each single individual should obtain – in terms of genes rather than social position, as in Rawls' original version –. However, were this option technically available the principle of freedom of self-determination and informed consent already recalled above (see §4.3.2) would force us to exclude it as violating the related human rights, since similar procedures cannot be imposed not even for what may be considered a socially beneficial purpose.

4.3.4 Discussion and conclusion

The regulation of the issues briefly sketched above does, for the most part, fall outside the direct competence of the European Union as resulting from the Lisbon Treaty. Yet many of such aspects may be indirectly touched upon by other regulations. In particular, since the MS legislations substantially differ from one another on issues of bioethics, it is reasonably foreseeable that this will also be the case with human enhancement, thus raising multiple questions.

Would it be possible to consider human enhancement as a service, for the purposes of art. 56 TFEU, and thus permit the advertisement within one MS of those practices which are prohibited there but allowed in another one (see for instance the decision in Society for the Protection of Unborn Children Ireland Ltd v. Stephen Grogan and Others, Case C-159/90)?

Would it instead be possible to deny access in one European country to a European citizen, who underwent an enhancement practice prohibited there, that is instead allowed in the MS he comes from? May freedom of movement within the European Union (pursuant to art. 45 TFEU and EU Dir. 2004/38/EC) be used as an argument for the adoption of some fundamental and common principles in this subject matter?

For these grounds, despite the most relevant issues posed by human enhancement appearing to be remote and lying in the background of more pressing considerations, it is advisable that on the one hand an informed public debate is initiated – as well as further research publicly financed –, and on the other hand that the European Union takes timely measures to develop and adopt clear guidelines in this field.

In particular, within the horizon considered, the issue of human enhancement may be narrowed down to address the issue of the appropriate implant for the amputee and disabled needing to restore a lost function.

The fundamental right to health as well as the provision set forth by art. 4 CRPD provide legal grounds to conclude that national healthcare systems should provide these technologies, when available, to their citizens. Considerations of equality – of access – and of the national healthcare system regulation should provide necessary guidance in determining in which cases such technologies ought to be made available to the person for free or at a cost.

Nonetheless, access to such technologies shall not depend on the personal wealth of the individual both in the negative sense, that even people with lower incomes should be provided with these technologies, and in the positive sense, that the decision on the optimal device to be implanted should not rest entirely on a matter of cost. This to say that the principle of equality requires that even an amputee is not left free to choose the implant he will have installed.

The decision on which prosthesis best suits the needs of the patient should be made by a medical team taking into account the individual and his body structure, age and overall condition, with the aim of restoring the lost capability. If this concept is harder to define in general terms, the appropriate standard to which a person ought to be restored can be more easily identified by considering the single patient according to a case-by-case approach.

4.4 Recommendations

From the analysis conducted, the following recommendations may be derived:

1. A legal definition of robotic prostheses may be adopted (see above §4.1):

   Robotic prostheses are mechanical devices provided with motors capable of operating simultaneously and independently in order to replicate or enhance the movements and functions of a natural limb they are intended to replace, to this purpose using a Brain-Machine Interface (BMI) *that receives the biological signal generated by the nervous system and process it into a signal the device can identify and manage, controlling the movements of the motors and actuators the machine is provided with.*

   Such a definition may be applied for the purposes of determining which devices should comply with regulation eventually adopted pursuant to the considerations made hereafter at n. 3, and be protected by the constitutional and administrative guarantees as identified at n. 2.

2. Such devices ought to be deemed objects and treated as such before being implanted, but should be regarded as a body part at all effects once attached – even non-permanently – to the human body.

   Therefore, same guarantees offered to the human body should be extended to the artificial device. Rules for search and seizure should apply as if it was a natural body part and the person wearing such a device ought to be permitted to wear the device even for the purpose of being portrayed on official ID, and no restrictions to the access to public spaces may be legally imposed on wearers of such devices.

   In case the prosthesis is damaged in an accident, next to the pecuniary loss connected to its replacement, non-pecuniary losses may be attributed. (See above §4.1.2.)

3. As per liability the following aspects need to be considered:

   (a) Safety should be addressed through the adoption of *ad-hoc* technical regulation, eventually provided and constantly updated by a competent and independent body of experts. Such standards ought to be sufficiently high and stringent to grant an adequate level of safety (not just a minimal level of safety as EC markings currently do) and be narrowly tailored for robotic prostheses and implants, thus reaching a higher level of specificity than what the AIMDD and MDD currently do. (See §4.1.1 and 4.2.7 above.). Less emphasis should be put on liability rules as tools to provide additional incentives for the production of safe devices, since in particular product liability rules have not proved effective enough in achieving such an outcome.
   (b) The development of robotic prostheses ought to be favoured since on the one hand this technology could substantially improve the quality of life of the disabled – and this may be deemed an obligation for the European Union and its MS arising from

art. 4 CRPD (see above §4.2.3) – and on the other hand represents a potential market, whose proliferation is certainly of great—also strategic—interest for the EU.

(c) In order to incentivise researchers and producers of these technologies, an exemption from the application of existing liability rules and, in particular, the Defective Product Directive may be conceived, without lowering the level of safety of such devices. (see above §4.2.5)

(d) In order to ensure sufficient compensation to wearers and potential third parties possibly involved in an accident where the use of a similar device appears to be *prima facie* material – or at least not completely unrelated to the dynamic of the accident (see above §4.2.6) – alternative liability compensation schemes could be considered, in particular a no-fault plan.

(e) A no-fault plan – partially publicly and partially privately financed – may provide prompt compensation to the injured party, lower administrative costs (higher percentage of compensation paid per euro invested in the system), and at the same time allow the producer to assess *ex ante* his potential exposure for damages, turning it into a cost. (See above §§4.2.6, 4.2.7.)

4. As per the issues connected with human enhancement:

(a) It is advisable that public debate is initiated and further research projects dealing with the philosophical and legal issues of human enhancement funded.

(b) The European Commission should develop precise policy indications in this subject matter, in particular as a result of both public debate and ethical and legal research.

(c) While the development of robotic prostheses needs to be favoured, the choice of the optimal implant shall not be primarily left to the individual, but be decided by a medical team and/or ethical committee of a medical structure.

(d) For this purpose guidelines for the adoption of the correct decision in the given case should be adopted, resting on some fundamental principles:

i. The possibility to have the most appropriate device implanted should not depend on the personal wealth of the individual in a twofold sense: lower-income people should be granted the possibility to have robotic prostheses implanted through national welfare systems as a specific action for the protection of their fundamental right to health and bodily integrity. At the same time, even those individuals who could afford to purchase any implant available on the market should not be allowed, for this sole reason, to freely choose the device to be installed. The same considerations of appropriateness made below (ii) should be taken into account.

ii. So long as current and proximate technological development is concerned, prostheses should be primarily deemed tools for the recovery of a lost or missing function, and thus be treated as such. The conditions of the individual before the accident that led to an amputation – if relevant –, the statistically normal conditions of a healthy individual of the same age, sex and overall body condition should therefore be taken into account when deciding the most appropriate device to implant.

iii. Pure enhancement should only be allowed when a complete assessment of the physical consequences of the interaction of the technology with the human body are clear (precaution) and when social and ethical implications

of the specific technology are sufficiently clarified in order to exclude the existence of major concerns (responsible innovation).

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5. Care Robots*

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1. Introduction

In the Communication *Taking forward the Strategic Implementation Plan of the European Innovation Partnership on Active and Healthy Ageing* (2012), the European Commission defines demographic ageing as 'one of the most serious challenges Europe is facing'. The expected ageing of the population over the next 50 years raises considerable concerns for European and national governments, 'especially as it comes at a time of increasing pressure on public budgets, a steady decline in the number of health personnel and growing demands from older people for care products and services'. In addition to these concerns, in Europe there are 80 million people suffering a mild to severe disability who require measures to tackle physical, legal and social obstacles in their daily life (see European Commission, *European Disability Strategy 2010-2020*, 2010).

Advances in research in personal care robots could help to tackle these challenges. Robotic applications can potentially support the care system in providing more effective and personalized services. Robots could assist the elderly and disabled in many ways, for example by administering food or medication, helping them to bathe, as well as serving as a memory aid (see Koops *et al.*, 2013). Care robots could also provide benefits to care-givers and family members. However, the role that robots could play in the field of personal care is far from being perceived in the same way. The risks of affecting the dignity of elderly and disabled people instead of improving their quality of life, through isolation or, even, the dependence on technological devices, are just some of the reasons given for opposing the possible use of robots in the care system.

Despite differing opinions among experts, academic researchers, care associations and the public, the interest in the opportunities offered by care robots is clearly increasing, together with the rise in the numbers of companies producing robots for care (Sharkey and Sharkey, 2011). Thus, several social, ethical and legal issues need to be addressed in order to protect the rights of potential users and to develop a specific market.

This chapter offers an analysis of the key concerns in the field of care robots. First, a brief state of the art is provided (§ 2). Then, ethical issues are analyzed to identify the human values and the areas of social life which are challenged the most (§ 3). Legal issues are then examined in the light of the critical remarks highlighted in the ethical analysis (§ 4). Finally, the chapter ends with some recommendations for future policies and regulatory interventions.

The ethical and legal analysis was carried out taking as an example the European project ROBOT-ERA (2012-2015; www.robot-era.eu), funded under the FP7 and coordinated by the BioRobotic Institute of the Scuola Superiore Sant'Anna, Pisa. Besides representing one of the most advanced research studies on care robots, this project is a relevant case-study since: a) it contains many of elements that will be relevant in the future implementation of personal care robotic technologies, b) it has also been developed by a partner of the RoboLaw Consortium (the BioRobotic Institute of the Scuola Superiore Sant'Anna), with notable advantages in terms of mutual cooperation between the two projects, c) robots developed under the Robot-ERA project are not intended to be medical devices (see § 4.1).

2. Technological Overview

With the recent progress in robotics, robots have gained greater mobility, dexterity, flexibility, and adaptability, as well as the ability to learn from and interact with humans, and consequently they have greatly expanded their range of potential applications (McKinsey Global Institute, 2013). These advances in robotic technologies have stimulated the market of service robotics, resulting in several robotic applications. Due to the current demographic changes, work reorganization, and the economic crisis, the interest in the opportunities offered by Information, Communication and Robotics Technology (ICRT) has gradually increased, as well as research activities and projects aimed at developing solutions for sustainable healthcare services (Moschetti, *et al.*, 2014).

The sales of robots for elderly and handicap assistance will be about 6,400 units in the period of 2013-2016 and will increase substantially within the next 20 years (IFR Statistical Department, 2013). In fact, European and national programs have fostered many R&D&I strategies and several approaches have been proposed to develop solutions to enhance the quality of life of older people and strengthen the industrial base in Europe through the use of ICRT. In the last decade, companion robots and smart environments have been the main topics of several projects to improve the quality of life and independent living, promote active and healthy ageing, and reduce health and social costs. Since assisting elderly people at home has been one of the principal requested needs, most of these projects have concerned robotic solutions for home applications.

Robotic service solutions range from the simplest tele-presence functionalities to support caregivers, such as the Giraff (www.giraff.org) developed in the ExCITE project (Cesta, Cortellessa, Orlandini, & Tiberio, 2013), AVA (www.irobot.com/ava) and Luna (Ackerman & Guizzo, 2011), to the most complex, such as assistance for daily living activities (www.aal-domeo.eu), self-management of chronic diseases (Simonov, Frisiello, & Bazzani, 2012), well-being and safety as in the cases of Florence (Lowet & Frank, 2012) and Robo M.D. (Ven, Sponselee, & Schouten, 2010), and integration in a smart environment (Badii, *et al*., 2009; Cavallo et *al.*, 2013). On the other hand, very few robotic applications deal with social services in other environments, such as the garbage collection performed by DustCart (Ferri, *et al*., 2011), assistance in shopping centers (Kanda, *et al*., 2009), and smart office buildings (Chi *et al*., 2012; Veloso *et al*., 2012).

The increased demand for complex services that can operate in both indoor and outdoor environments, has led to the need for networked robots. Networked robots are a group of autonomous mobile systems that exploit wireless communications with each other or with the environment and living systems in order to fulfill complex tasks (Sanfeliu, Hagita, & Saffiotti, 2008). In such systems, sensor networks and other intelligent agents, for example wearable and personal devices, extend the sensing range of the robots and improve their planning and cooperation capabilities.

In this context, the Robot-Era Project represents a major example (www.robot-era.eu). It aims to develop, implement and demonstrate the general feasibility, scientific/technical effectiveness and social/legal plausibility and acceptability by end-users of complete advanced services framework using cooperating robots integrated with smart environments and acting in heterogeneous environments, such as the home, a condominium, and outdoors.

The cloud robotic paradigm has extended the concept of networked robotics. M. Inaba first introduced the concept of the “Remote-Brained Robotics” (Inaba, 1993), to improve the usability of standalone robots. This idea was based on the separation between the brain and the body, to

connect standalone robots to a high level remote control system. This innovative design opened the way for parallel powerful computers and for the provision of complex services to the user which the robots alone were not able to provide. In 2010 J. Kuffner defined Cloud Robotics as 'the combination of cloud computing and robotics'. Cloud robotics was not related to a specific type of robot, but to the way robots stored information and accessed a knowledge base. Cloud computing provided the opportunity to exploit user-centered interfaces, computational capabilities, on-demand provisioning services and large data storage with minimum guaranteed Quality of Services (QoS), scalability and flexibility. Cloud Service Robotics (CSR) could be defined as the integration of different agents that allow an efficient, effective and robust cooperation between robots, smart environments and humans (Cavallo et *al.*, 2014).

In this context, the implementation of complex and distributed services requires solutions to different technological issues, including task planning, human robot interaction, user localization, and the use of different robots able to cooperate to exchange objects and to navigate through environments inhabited daily by humans, such as urban areas, buildings and homes. It is clear that one of the most important aspects such a complex robotic system is to be socially acceptable and credible for the end-users [23]. Social acceptability and credibility means not only being endowed with high technological abilities and capabilities, i.e. physical and cognitive human robot interaction, agent robot cooperation, advanced navigation and manipulation, etc., but also being adequately supported by a systematic and interdisciplinary contribution and the continuous involvement of many other disciplines, such as human and social sciences to favor the social acceptability and facilitate their co-existence with humans, ethical, legal and social issues (Dario, Verschure, & Prescott, 2011).

3. Ethical Analysis

3.1 Introduction

In analysing the ethical issues of personal care robots [hereafter PCRs] we will use the methodological steps described in a previous deliverable of RoboLaw (Bisol *et al.,* 2013). Based on the case study project of Robot-ERA, we will investigate what kind of ethical landscape has been sketched by PCRs. In the first section, we explain briefly why we are interested in PCRs and under what terms we consider them ethically relevant (§ 3.2). In the second section, we elicit the elements of normativity involved in the way PCRs are designed and can be used in the future (§ 3.3). In the third section we outline the most significant ethical issues surrounding PCRs (§ 3.4). Finally, we offer a framework of policy considerations to understand and regulate PCRs, so that the legal scholars of RoboLaw can produce their recommendations (§ 3.5).

3.2 Ethics and personal care robots: A future perspective?

There are two principal philosophical challenges. The first concerns PCRs as issues of "*governance of technology*" (normative harmonization, regulation, standardization, etc.). The second area is much more philosophically complicated because it refers to PCRs as problematic objects that challenge us in the "*governance of society*".

- *Governance of technology*. There is still confusion about how we can separate robots that help people who are unable to interact physically with their immediate environment, from robots as technology-based solutions to assist people in fulfilling daily activities. For example, in the *Handbook of Robotics* there is a chapter on

"health care" and "rehabilitation" robots (Van der Loos & Reinkensmeyer, 2008). Due to the overlapping of medical and diagnostic technologies with care and assistive ones, roboticists and other stakeholders do not have a clear understanding of the roles that care robots should play, or the kind of support the robots should or should not provide, and the impact that robot care will have on their users. This confusion is not helped by the lack of an internationally determined normative that identifies and regulates this kind of technology. The *International Association for Standardization* has drafted a new ISO (13482) which should provide stakeholders and institutions with a useful tool to normalize the relationship between people and personal care robots. The meaning of "PCRs" is also defined: robots typically perform tasks to improve the quality of life of the intended users, irrespective of age or capability, excluding medical applications (ISO 13482, 2014; see also Virk, 2013). Furthermore, in Europe this standard should improve the efficiency of the EU Machinery Directive (2006). In addition, Robot-ERA shows that, in addition to the lack of distinction between "medical" and "care" robots, in the future there will also be the issue of the kinds of scenario that robots operate in. In this project there are three different scenarios involving different challenges of the governance of technology: 1) outdoor, 2) condominium 3) domestic.

- *Governance of society.* Safety issues are just one of the huge challenges that PCRs will present in the future. The increase in PCRs could open up issues that go behind the regulatory level and challenge the social structure of society. As *care ethics* shows (Tronto, 1994), the social structure of care is directly connected with work and the rule of specific groups (such as women or migrants) who today represent the effective agencies, that contextualize and promote the well-being of care-receivers through a network of social relations. It is clear that this structure is created by the 'work of dependence' (Kittay, 1999) of thousands of people and could be considerably transformed if PCRs become part of everyday life. As also shown in Robot-ERA , the introduction of robots into social systems will force us to review – in terms of respecting fundamental rights (see § 4.2) – the way we guarantee care and justice for people who live or work in conditions of vulnerability (Turkle *et al.,* 2006; Sparrow & Sparrow, 2006).

3.3 The vision on the application of personal care robots

Despite knowing that probably in the future the relevance of PCRs will increase and will involve ethical and social concerns, it remains unclear what people's expectations are of their future application. Understanding who the relevant stakeholders and actors are and why they are so interested in PCR will enable us to focus on a normative framework in order to regulate material (markets, insurance, liability) and immaterial interests (education, healthcare, social recognition) associated with PCRs.

In our analysis we used various documents: bibliographical materials from the scientific literature and the Internet; interviews conducted during stakeholder meetings organized by the RoboLaw consortium, and by studying the aims and outcomes of other funded projects that were directly, or indirectly, related to PCRs (organizing research meetings with the consortium of Robot-ERA).

A. The stakeholders. We observed some interesting features during our interviews. Despite the low diffusion of PCRs in society and the restricted cultural and scientific debate, when the stakeholders had to answer questions about possible *opportunities* and *risks* in the adoption of care

robots, they had clear ideas on how robots could be reasonably adopted and used[12]. Generally, there was not a negative attitude or refusal of assistive and care robotics. On the contrary, a broad-spectrum idea emerged that also had a normative content: *the more robotics comes from futuristic visions and becomes a concrete support to human life, the more robotics becomes accepted by its potential social actors and stakeholders*. PCRs are seen as an example of a sort of "humanization" of emerging technologies. It is obvious that, in taking account of the stakeholder positions, we also considered the role that psychological expectations and personal background could play in the formulation of judgments about the nexus between human care and emerging technologies.

B. The scientific debate. For many years, the main trend has been to bring medical, rehabilitation, and assistive robots under one big family calling it "healthcare robots" (Van der Loos & Reinkensmeyer, 2008; Datteri & Tamburrini, 2009). The birth of an ethics framework applied to robotics ("roboethics", see Veruggio & Abney, 2011) has continued to maintain this non-distinction between medical and assistive robots, sometimes overlapping the ethics of those who produce robots with the ethical concerns of the society within which the robots are introduced (Lin *et al.,* 2011). Consequently, the social and legal consequences are estimated using universal and abstract principles (Decker, 2008), based on the respect for human rights (Datteri & Tamburrini, 2009) or medical ethics (Feil-Seifer & Matarić, 2011).

However, now "vulnerability" is also seen in terms of a new category for reevaluating service robotics from technological, social and ontological points of view (Lisetti *et al.,* 2004; Sparrow and Sparrow, 2006; Turkle *et al.,* 2006; Coeckelbergh, 2010). Others see social robotics as important because it concerns how the technology at stake mediates human actions and interaction, and if different types of the same technology create new types of mediation or user responses (Verbeek, 2006; Lucivero *et al.,* 2011). These studies show the need for an ethical analysis in the form of case studies, discussing well-defined questions raised by a specific kind of robotic application in different contexts, avoiding abstract generalizations on "robotics" (Bisol *et al.,* 2013; Battaglia & Carnevale, 2013).

C. What European institutions fund. We examined the official documents and projects produced and funded in the field of European policies on the regulation of robotics (with particular focus on social and healthcare robotics) and emerging technologies:

- Funded research projects on social and care robotics:
  - Ethicbots (2005-2007) http://ethicbots.na.infn.it/

[1] Sample answers in this direction include: 'Robots will allow people to have helpers and assistance in their lives, improving the quality of life for all people, in particular those who suffer from physical momentary or permanent limitations'; 'Robots mean for some people independence from others' empowerment'; 'Robots in home security to give support and reassurance in the home for vulnerable people. i.e. automated locking doors'.

[2] Sample answers in this direction include: 'Certain decisions should be confirmed by humans'; 'Robotic deployment in home care should increase, NOT replace human interaction'; 'Robots for personal assistance must be adapted to its user and personalized'; 'Developing organizations (business, institutes, researchers, etc.) should encourage open and transparent information sharing to improve regulatory processes and public acceptance'; 'An assessment carried out to discover whether populations currently experiencing health and social care inequalities, and not accessing services, would experience benefits from the roll out of robot/tech support at home'.

- euRobotics (2010-2012) http://www.eu-robotics.net/
- ACCOMPANY (2011-2014) http://accompanyproject.eu/
- CA-RoboCom (2012-2013) http://www.robotcompanions.eu/

- Other European documents directly connected with care robots:
  - Robotics for Healthcare (2007-2008)
  - VALUE AGEING (2010-2014) http://www.valueageing.eu/

This overview highlights the trend in investing money to study and develop robotics focused on social services and healthcare. Despite the lack of a clear definition distinguishing medical from assistive robots, stakeholders and institutions tend to characterize robots not based on their technological function, but on the basis of their rules of interaction with human users. This trend is also confirmed by the outcomes achieved by the Robot-ERA consortium.

This "new wave" of robotics (RCC MANIFESTO, 2012) is in part due to the interests of manufacturers, who produce assistive technologies and thus try to create the most favorable societal conditions for marketing their products. In addition, governments are under threat because they are incapable of tackling the increase in public spending for healthcare. This means that valid alternative solutions must be found to ensure the quality of services and, at the same time, guarantee the rights of workers who are employed in assistance and care.

PCRs seem to promise a perfect combination between economy and rights, between manufacturers and people. In this regard, it is significant that the European model of funding research in personal care technologies has also become a case study for the Americans (see the report of WTEC, 2011). While the U.S. certainly remains at the forefront in the development and production of assistive technologies, in Europe technologies, such as PCRs, are increasingly regarded as strategic policies, which maintain both a high standard of competitiveness and provide alternative solutions for many societal challenges.

3.4 Uncovering normativity: The case of the Robot-Era project

Healthcare robots are technical artefacts that should interact with humans living in a temporary or permanent precarious condition for which they need help. The design of these robots thus already involves moral and philosophical considerations. Taking into account these considerations, in other deliverables of RoboLaw we adopted the Capability approach of philosophers Amartya Sen and Martha Nussbaum (see Lucivero *et al.*, 2013).

PCRs thus represent a clear example of the importance of the capability approach and the difference between "functioning" and "capability". Capabilities are a person's real freedom or opportunities to achieve a specific functioning. Thus, while travelling is a functioning, the real opportunity to travel is the corresponding capability. The distinction between functionings and capabilities is between achievements, on the one hand, and freedoms/opportunities from which one can choose, on the other. PCRs could enhance opportunities to achieve human functionings. Starting with design approaches of PCRs by which it can promote ideas of good (i.e. capabilities) that are intrinsic to a certain practice. The design can materialize (or contradict) the ideas of good embedded in the care practice. This is why we think it is useful to reveal the intra-normativity in social practices where robots are or will be used, as well as in their design choice and therefore a way to begin a discussion on values and norms (van Wynsberghe, 2013).

3.5 The criticality map of ethical issues

This section outlines some of the critical issues of personal care robots, through Robot-ERA experiences.

3.5.1 Safety

Robot-ERA shows how PCRs greatly change the concept of "safety" because, unlike industrial robots: (i) they need to be used for a wide range of requirements in environments that are not well defined; (ii) they are used by non-specialist users; and (iii) they share work space with humans. Consequently, safety standards are foe to the wider uptake and acceptance of PCRs. Acceptability norms must be formally defined at an international level with a new ISO specifically dedicated to "personal care robots" (ISO 13482:2014). From the stakeholders' and users' perspectives such standards should provide an effective safety framework, while also being flexible enough to respond to the rapid pace of technological development. However, there are three open issues regarding safety:

1. The kind of contact between robot and people is not always clear. Many problems can arise regarding the safety of "Assistive Robotics" (robots that assist a user) and "Socially Interactive Robotics" (robots that communicate with a user through social, non-physical interaction) (Feil-Seifer & Matarić, 2005). Future developments in robotics will involve network systems – as shown again by Robot-Era. However, the exact differences between the two different levels of security stills need clarifying.
2. Safety requirements and protective measures. These types of measures protect us from the danger of robots in terms of their being mechanical products, such as: battery charging; energy storage and supply; robot shape; emissions; electromagnetic interference; stress, posture and usage; robot motion; insufficient durability; incorrect autonomous actions; and environmental conditions. (Virk, 2013).
3. Safety related control requirements. This protects us from the danger of an excessive or incorrect interaction with robots e.g. turning off the robot; speed control; environmental sensing; stability control; force control; singularity protection; design of human interface; manual control devices; and operational modes (Virk, 2013).

3.5.2 Responsibility

The introduction of a robot into a healthcare situation becomes complicated in terms of liability e.g. potential damage to a patient, medical practitioner or equipment, if a robotic system malfunctions. Ethical issues arise in relation to agency and responsibility, with the need to establish who is in control and at what point a duty arises. Furthermore, future PCRs may well operate not only indoors, but also outdoors, and thus with different issues of responsibility.

3.5.3 Autonomy

The general public tend to believe that care robotics is useful, because it assists those who are disabled or strongly dependent on caregivers. However, disabled users (both severely and no severely) see the development PCRs as a significant issue in which they see PCRs as a way to achieve the highest standard of personal autonomy. This is also the main innovative feature of Robot-ERA, which shows how future care technologies can explore and exploit the many dimensions of autonomy. By caring for physical and cognitive functions through technology, it is

possible to free up resources that could be employed by people to enhance other individual and social capabilities (Lucivero *et al.*, 2013), thus improving self-perception (self-esteem, independence from the help of others). Furthermore, in the field of PCRs the concept of "autonomy" is no longer a lack of dependence from others (autonomy = 'I am a complete person, I don't need anybody'), rather it should mean the relational capability of a person to take care of his/her own forms of dependence (autonomy = 'I am a vulnerable person and thus I need to be helped in order to find my own way of being autonomous'). As Robot-ERA shows, robots do not replace human care; rather, they become human companions.

3.5.4 Independence

More complex than autonomy is the question of independence. Each assistive service performed by robots to promote a greater independence of the subject, in reality, starts from a context in which, obviously, there is also a dependency issue. The ethical criticality of this is controversial. In the universe of taking care, independence and dependence are two sides of the same coin. The robot should mediate this polarity, but this is not always so easy. In fact, paradoxically, the risk could even increase: an excessive use of technology to foster greater independence could lead, in turn, to a new dependence: on technology. While "autonomy" can be built in relational manners, independence involves a distance between one person and the other. These different conceptions may have a distorting effect in the formation of desires and expectations (and in the consequent use) of types of technologies. As shown by Robot-ERA, probably in the future developments of PCRs we will have to deal more with the issue of autonomy and less with the problems of independence.

3.5.5 Enablement

The limitations and difficulties of these technologies in enabling human capabilities are anticipated in the debate on human enhancement (Battaglia & Carnevale, 2013). In so far as PCRs could in the future be introduced in the private and vulnerable areas of human relations, thus transforming the structure of care giving, they do not seem to challenge the basis of human nature. In contrast, this kind of robot challenges the social and political conditions that determine the rights and the culture of our commitment to the weakest members of society.

3.5.6 Privacy

This type of robotic technology will not be developed by implementing a single functioning (as in the case of robotic prosthesis). PRCs could mutate function and form by inserting or removing other electronic devices (smart phones, tablets, etc.) and various ambient-assisted living tools (including equipment for diagnostics, monitoring and control). This thus involves a mass of personal information that should be protected. Taking into account the example of Robot-ERA, we expect that assistive and care robotics will inevitably intersect with the developments of assisted-living technologies, ICT technologies, and "cloud robotics". This implies a further level of criticality of privacy statements, with personal information and machine software that could be downloadable and sabotaged by anyone with access to the network. Furthermore, in the name of privacy, we should not allow robotics companies to hide sensitive data, because this data represents useful information to reconstruct negligence in the case of robots malfunctioning.

3.5.7 Social connectedness

The question of "connectedness" at a social level poses the same difficulties as an individual level concerning the question of "independence". There is no doubt that these technologies could

encourage the de-hospitalization and domiciliation of healthcare. This entails developing innovative ideas and systems for personalized care, calibrated to the real needs of users and patients. Presumably, in fact, the introduction of PCRs in society could help to placate the effects of physical and cognitive limitation, freeing up resources to be used for other skills, thus favouring a better social distribution of talents. However, one could argue that an excessive domiciliation of care involves a collective disengagement in terms of the commitment to take care of the needs of the most fragile people. Since robots could be involved in caring for people whom we no longer want to look after, the collective responsibility toward those people could decrease.

Aside from the decrease in collective responsibilities, there is also an important ethical challenge for the end users. Human contact is one of the fundamental traits of human care, thus replacing the human factor with robots could dehumanize caring practices. In addition, it is not always possible to make the robot human-like. Moving beyond a certain threshold of robot similarity with humans produces a rejection effect and a sense of anxiety (something like the "Uncanny valley", see Mori, 1970). Thus, here the questions could be: should our laws govern how person-like the robotic caregiver is? Or, if a robotic caregiver has become someone's object of affection, should it be treated by the law as more than just an object/possession/tool?

3.5.8 New technologies and justice

The principle of justice governs the fair distribution of scarce resources. This can be very difficult when discussing experimental treatments such as a personal care robot. The use of PCRs in the healthcare setting is relatively new, still costly, and in most cases not regarded as essential and therefore generally not or only marginally funded/financed through public systems of insurance. Accepting that these technologies could be adopted in a few years by people with their own private income, this introduction into society could create an even wider gap between the haves and the have-nots. It is one thing to claim the individual's right to enjoy the benefits of robotic development in terms of personal care, but if the benefits cannot be fairly distributed, this conflicts with the commitment to social justice and also to human rights.

3.5.9 New technologies, ethics and scientific research

PCRs need to be investigated through interdisciplinary studies. Despite European research programs encouraging interdisciplinary approaches, there is still a large gap between the hard and applied sciences and social sciences regarding the scientific production of these kinds of technologies. The ethical consideration of robots continues to be seen under the label of "applied ethics", which aims at influencing policy makers or other social actors towards certain actions (for example, regulating a technological field). Thus, applied ethics must be concerned with the concrete problems of the "here and now". But the public and scientific focus on emerging technologies (including robotics) cannot be reduced to a "realistic" argument. The new technological trends involve *de facto* opportunities for individuals and for society that have appeal because they are both concrete and ideal.

However, the scientific and intellectual debate on new technologies could influence the opinions of the media and the general public, and thus create new needs and social demands that challenge the social concepts and views of the human condition. This represents an ethical criticality for researchers in that they may be aware of their scientific role as well as their social function in creating a diffused culture of the new technologies. Moreover, with manufacturers and companies pushing to create a market of robots, also by financing researchers, there could be a conflict of interest between academic and private interests (an individual's involvement in dual and

multiple roles within or outside an academic institution) which could compromise the independence, objectivity or the ethical duties of the researcher.

3.6 Policy considerations

This section outlines the ethical issues and then provides a framework of normative suggestions, in order to regulate the future diffusion of PCRs and, consequently, the different forms of interactions of PCRs-humans.

- *Techno-regulations*. A different legal perspective is needed. Robots are not only an "object" of regulation, but must also become "tools" of a different kind of regulating technology. It is necessary to pass from the regulation of the technology to forms of regulating human behavior with technology (van den Berg, 2011). Normally techno-regulation focuses on the ways in which technologies can be used as regulatory tools; a legal paradigm is now needed 'focusing not only on regulatory responses invoked in users, but also on the ways in which designers (intentionally, but often also tacitly) incorporate values, stereotypes and norms in technologies' (van den Berg, 2011).
- *Safety in the physical presence of the robot*. To better identify the social and legal implications when these robots are on the market, a normative framework is needed which clearly distinguishes between care and medical robots. One recommendation is to differentiate between robots that interact with humans through physical contact, and robots that interact using communication or social mediation.
- *Safety and interaction with the robot*. Security levels should be implemented for interactions with the robot. For example, including a "black box" in the robot, or in a network of interconnected robots. This would enable us to reconstruct human-robot interactions making a valuable source of information available on the consistency of robotic actions, including the various scenarios envisaged by Robot-Era.
- *Data security*. Diagnostic, monitoring tools or any other device can be placed on board robots, thus gathering data on their environment and people. These data could be shared with other platforms even on a global basis. Robot-Era is implementing the possibility to interface robotic applications and other technological devices (such as smart phones and tablets) with a cloud. Thus, legal questions about data security and privacy issues need to be addressed.
- *Home-based health care*. Regulatory policies should take into account the opportunity offered by PCR to promote the shift to preventive and personalized care.
- *Humanizing the design of a care robot*. The dissemination of these robots could trigger the tendency to replace the caregivers. This could lead to a social and institutional relief of responsibility, i.e. the increasing recourses to humanized technologies in healthcare could weaken our moral obligation to help those who live in the worst conditions. This ethical issue should be translated into the design phases and into the innovation processes performed by researchers and companies. We need care robots that enable people to be autonomous, but at the same time societies and healthcare systems must not forget to provide social and care assistance to needy people. It would thus also be useful "humanize" the healthcare systems. Together with the humanization of care technologies, it is important to focus on the appropriate elements of interpersonal dialogue that can be ethically transferred to a robot. Maybe in a healthcare system where the dialogue is well supported, the care receiver would still prefer to be taken care by a person instead of a machine that "pretends" to be a person.

- *Policies for training caregivers*. Again, patients and health institutions should be informed about the latent dehumanization and a possible alteration of human-human interactions.
- *Access and financing*. Many studies have confirmed that these technologies would save money for health systems, while maintaining (or even increasing) the quality of healthcare services. However, for the moment the costs are too high. A solution could come from European institutions, both with specific directives for national policies that can harmonize social assistance and healthcare, thus ensuring the emergence of public-private insurance systems.
- *Robotic research and society*. Many robotic applications are still in an experimental phase. However, more and more research projects are being funded with national and European money. For the future, we must foster research programs that include some mechanism for a short-term verification of the outcomes. In other words, not only attracting researchers interested in long-term possibilities, but also companies and/or health institutes that have an urgent interest in practical applications. This would help to understand (and without ideological stances) what the real risks and opportunities are concerning the dissemination of these technologies.
- *Robotic research and researchers*. In the scientific production of these kinds of technologies there is still a significant gap between the hard and applied sciences and social sciences. We need more interdisciplinary research, and also reasonable tools for quantifying such research. For example, the work of internal and external reporting on project deliverables and work-packages is often not considered when assessing scientific CVs for academic vacancies.

4. Legal Analysis

4.1 Definitions

There is no specific legislation on PCR and no legislation that could apply to PCRs (see Leenes et al., 2012) seems to provide a useful definition.

The only potentially useful classification is the legal definition of "medical device" given by the Directive 93/42/EEC, as amended by the Directive 2007/47/EC. It states that a 'medical device means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means'.

The notion of 'medical device' is clearly based on the purposes the device is intended for. Therefore, with respect to the functions personal care robots are designed for, the definition mentioned above could only cover those assistive robots that are capable of monitoring the health status of users remotely. Given the technological developments described in § 2, although a personal care robot may assist or remind a user to take a medicine, it does not fall under the definition of 'medical device' in terms of any other of its possible uses. PCR prototypes are designed to perform several tasks, thus the legal regulation on medical devices cannot be applied to PCRs purely on the basis of a single function (remote monitoring of health conditions) which meets the definition given by the Directive 93/42/EEC.

PCRs have been gradually moved from the general category of healthcare robots to an autonomous category due to the tendency to design a generation of robots for the personal care of consumers who want to be helped in everyday tasks by a robot. Whether or not PCRs will be used on a widespread scale by consumes, the category of medical devices is clearly not appropriate for PCRs.

The new international standard on PCRs (ISO 13482:2014) seems to have confirmed this interpretation by defining what a PCR is. Despite the non-binding nature of ISO standards, the relevance of the so called soft law in the field of emerging technologies is generally recognized (Palmerini & Stradella, 2013), especially when there is no hard law. Thus, in the case of PCRs, where a clear classification or specific legislation does not exist, the ISO standard currently represents the main normative point of reference which specifically refers to the category of robots we are dealing with.

ISO 13482 defines personal care robots as a 'service robot that performs actions contributing directly towards improvement in the quality of life of humans, excluding medical applications'. The standard also specifies that, to the scope of the document, three types of robot are considered as personal care robots: 1) mobile servant robots, 2) physical assistant robots, 3) person carrier robots. They all perform tasks to improve the quality of life of the intended users, irrespective of age or capability. The first are robots that are 'able to travel under their own control', the second are robots 'that physically assist a user to perform required tasks by providing supplementation or augmentation of personal capabilities', the third are aimed at 'transporting humans to an intended destination'. Examples of these categories of personal care robots include: 1) robot companion, 2) exoskeleton wearable robot, leg motion assistive device, etc., 3) wheeled passenger carrier, carrier with passenger standing on the foothold.

Nevertheless, there are some types of robot which are not included in ISO 13482, for instance robots travelling faster than 20 km/h, robot toys, water-borne robots or flying robots, and robots as medical devices.

4.2. Fundamental Rights

Personal care robots can potentially have a great impact on fundamental rights. Like any other robotic device, they present both benefits and risks for users. Although a tendency to widen the range of potential users has been pointed out, elderly and disabled people should still be still considered as the main beneficiaries of advances in this field. Care robots can assist the elderly or disabled people to perform daily tasks, help protect them through monitoring their movements and health conditions, or support their caregivers (Sharkey & Sharkey, 2010,). Daily tasks include bringing food or medication, feeding, lifting from beds, helping people to bathe or go to the toilet, serving as a memory aid and keeping watch to prevent elderly people from falling.

All these functions care robots are able to perform make it clear the potential of robots for helping users to improve the quality of their lives. Nevertheless, the use of care robots for the fulfilment of certain fundamental rights puts other rights at risk of violation. For example the fact that personal care robots are designed to increase, among other things, the safety of people in their home. However, ensuring that the robot itself is safe for users and could not infringe on their right to physical integrity is also a relevant concern.

While PCRs enable their users to live more independently, a close interaction with a robot and subsequent loss of human contact could lead to a sense of losing control over their lives and being treated as objects. The risk of 'objectification' of vulnerable people who are in need of assistance – namely, 'treating a person as if they were a lump of dead matter: to be pushed, lifted, pumped or drained, without proper reference to the fact that they are sentient beings' (Kitwood, 1997) – raises concerns about the respect for human dignity.

The use of robots for the remote monitoring of a user's behaviour and health status offers another example of how care robots could affect fundamental rights. Such robots would make it possible for the users' family to supervise them and check whether they were performing their daily tasks, were taking their medicine and, more generally, were safe. Also caregivers or healthcare assistants could monitor the health conditions of the user and, in case of assistance, interact with him/her. PCRs could also be used as an interface to communicate with relatives and friends (Sharkey, 2010). However, the remote monitoring of elderly or disabled people clearly invades the private life of the users. Therefore, the right to privacy and data protection needs to be protected.

These rights to independent living, to lead a life of dignity, the right to privacy, and the right to physical integrity are not the only rights protected under the European Charter of Fundamental Rights and national Constitutions which could be potentially challenged by the introduction of PCRs into the care system. Also the right to participate in social and cultural life (art. 25 and 26 EU Charter) is certainly affected by care robots, as well as the right to health (art. 35 EU Charter), although its relevance is partially limited by the tendency (as stated above) of research on PCRs to consider them as a separate category from healthcare robots. However, since the right to health is also meant to include the right to physical and psychological welfare, and in some Member States (e.g. Italy) even bodily integrity is considered as part of such a right, we can argue that the right to health is also challenged by PCRs. Finally, when dealing with robotic technologies, the crucial importance of the principle of equality (art. 20 EU Charter) should be considered together with concerns about the access of all people to the benefits of technological developments.

In the following sections we focus on: independent living and autonomy, participating in community life, equality and access, and then privacy (§ 4.4).

a) Independence and autonomy in the light of independent living

In the literature on robotic technologies, independence and autonomy are often considered as the expression of the same value and are sometimes used synonymously. However, a distinction is possible, and even required when dealing with the legal implications of care robots and their impact on fundamental rights.

Generally speaking, 'independence' is defined as the ability to live your life without being helped or influenced by other people, while 'autonomy' is meant to be the ability to make your own decisions without being controlled by anyone else. In the context of robotics for personal care, the notions of independence and autonomy can assume a more specific connotation with respect to the people in need of assistance.

As regards independence, it could be seen a condition of a person's everyday life that identifies his/her ability to manage daily activities (like eating, bathing, or getting out of bed) and to satisfy personal needs by his/herself. Robots can contribute to ensuring or improving the sense of independence of users by helping them to perform daily tasks and making them feeling that, due to the assistance of robots, they will no longer have to depend on another person (family member or caregiver). Thus, the impact of robots could be significant since users can have the feeling of being able to perform a certain task with the aid of a technological device, instead of requiring a person to carry it out. Independence is therefore a condition that can be empirically estimated: one can observe whether or not the independence of a person in need of assistance increases as much as s/he is able to perform daily tasks and activity by her/himself. Obviously, the risk dependence on robots is also an issue we have to deal with (see § 3.5.4).

Autonomy on the other hand, refers to the ability of the user to make his/her own decision with respect to the kind of assistance s/he would like to receive. Thus, autonomy is meant to be the expression of one's self-determination in the context of choices concerning personal care. Unlike independence, the level of a person's autonomy is harder to define. People who are in need of assistance often are not able to make decisions about themselves and, hence, choices concerning their care are made by the family. In such circumstances, the distinction between independence and autonomy is notably significant since the fulfilment of the corresponding rights may clash with each other. This could happen when, for the safety of the elderly or disabled person, family members and caregiver take measures (the use of technological devices, for instance) that do not comply with her/his desires, but nonetheless contribute to increasing her/his independence (Cocco, 2010); or, vice versa, when people who require assistance prefer traditional forms of personal care but, as a result, they need help and support from another person to perform daily tasks.

The relationship between the right to independence and the right to autonomy plays an important role in the context of public policies concerning the impact of care robots. All EU Member States recognize these fundamental rights, although the right to autonomy finds different levels of protection in national legislation (more libertarian countries are generally opposed to countries with a more restrictive policy; see Casonato, 2012). Nevertheless, with respect to the impact of care robots on such rights, both independence and autonomy could be protected under the umbrella of the right to independent living.

The right to independent living is expressly used in Article 19 of the UN Convention on the Rights of Persons with Disabilities, but generally speaking it identifies a philosophy of living that inspired a movement on disability rights in the United States in the 1960s. The idea of independent living is that disabled people (but also the elderly) have 'the same freedom, choice, dignity and control as other citizens at home, work and in the community' (source: Independent Living in Scotland, www.ilis.co.uk). Independent living is not merely being independent from other people, but 'having the freedom of choice and control over one's own life and lifestyle': thus, a combination of various environmental and individual factors that allow those who are in need of assistance to have control over their lives is essential 8source: European Network on Independent Living, www.enil.eu). Protecting and fulfilling the right of independent living 'is not just about putting in place the appropriate legal instruments and safeguards but also about ensuring that society itself is prepared to support the full and equal integration of persons with disabilities', as stated by the European Union Agency for Fundamental Rights in the report Choice and control: the right to independent living (2012).

Thus, the use of robots for personal care could play a role in the fulfilment of the right to independent living. In this regard, we should consider that:

- social assistance and care systems are fields of legislative competences of EU Member States. Hence, the adoption of measures that promote the use of robotic technologies essentially depends on national policies;
- within EU actions coordinating and supporting national policies there are relevant initiatives in the area of active ageing and disabled people. Extending active ageing and independent living through the development of ICT solutions is, for instance, a goal set out in the Communication of the European Commission Taking forward the Strategic Implementation Plan of the European Innovation Partnership on Active and Healthy Ageing (2012) and one of the three pillars of the Guiding Principles for Active Ageing and Solidarity between Generations (2012). However, these principles are not prescriptive. It will be up to national and local governments, companies and civic society organizations to make them effective;
- the relevance of national policies is strengthened by the shortage of legislative provisions at an EU level, allowing access to social assistance in Member States other than that in which the person in need of assistance is resident. The EU Directive 2011/24 on the application of patients' rights in cross-border healthcare, which opens up national healthcare services to EU citizens, expressly states that the directive does not apply to 'services the primary purpose of which is to support people in need of assistance in carrying out routine, everyday tasks';
- according to the report of the Academic Network of European Disability experts (ANED) on The implementation of policies supporting independent living for disabled people in Europe (2009), at national level factors impeding progress towards independent living are: 'a perceived prohibitive level of expense required to support independent living in the current economic climate; insufficient support/services in the community; concerns from carers (about e.g. isolation, bullying); lack of specific safeguards to prevent institutionalisation; and a view that in some instances, public opinion did not support deinstitutionalisation';
- promoting independent living through measures that support the introduction of robots in the care system should not mean replacing traditional forms of care. Interviews and meetings with stakeholders have pointed out that there are very different opinions on this point. To effectively respect and promote the right to the autonomy of potential users, several options are needed.

b) Participating in community life

Strictly related to independent living is the right of elderly and disabled people to fully participate in social and cultural life. This is recognized by Articles 25 and 26 of the EU Charter of Fundamental Rights and by several articles of the UN Convention on Disability Rights, especially Article 19. Like independent living, a full and effective participation of vulnerable people in community life represents a challenge we should address, not only to improve their quality of life but also to make the future European society more cohesive.

Information and communication technologies (ICTs) have already contributed to some extent to increasing the participation of elderly and disabled people in social life. However, a lot of work remains as it is clear from several European and national documents which affirm the need to remove barriers to equal participation in the public life and leisure activities of vulnerable people.

Care robots could contribute to this goal. There are many ways in which a robot could be of help, for example by helping users to get to polling stations to vote, by reducing loneliness through an interface for virtual visits by friends, enabling users to be informed of the latest news, social and political issues at local and national levels, or even by helping them to partake in leisure activities.

Nevertheless, there are several factors that may impede the use of care robots. Some obstacles are related to the availability of these robots, while others refer more specifically to the rights in question: for instance, a) limits deriving from the digital divide, which could be hard to overcome when dealing with people with cognitive impairment or serious difficulties due to ageing; b) the lack of social policies that promote and foster a widespread diffusion of ICT devices in the care system; c) significantly low levels of wellbeing within the weakest sections of the population linked to the fulfilment of other rights (e.g. right to housing, food and work) as overriding concerns rather than the participation of people in community life.

c) Equality and access

Issues concerning access and equal opportunities for all people in need of assistance are of course of great importance. The fulfillment of any other right through the use of care robots presupposes indeed that a) technological devices are available on the market, b) access to robots is effectively open to all potential users and (expected) high costs are partially covered by public policies in the field of social assistance and protection.

Accessibility and equality of opportunity are principles upon which provisions for the elderly and disabled people contained in the European Charter of Fundamental Rights and the UN Convention on Disability Rights are based. Moreover, in the above mentioned Communications of the European Commission on active ageing and disability strategies, it is stated that actions at European and national levels are needed in the field of accessibility and equality. This is on the one hand to make services accessible and to promote the market for assistive devices, and on the other hand to combat discrimination and promote equal opportunities. Nonetheless, these goals have not been achieved yet and much work is still to be done.

It should also be considered that:

- concerns regarding equal opportunities are strictly connected to the development and diffusion of almost all new technological devices. Generally speaking, robotic products are highly specialized and of limited availability on the market and cost more than potential users can on average afford. Therefore, when considering measures to promote the use of robots for personal care, public interventions assume an essential role to ensure accessibility to the lower-middle class, and to prevent only the wealthy from taking advantage of advanced technological services;
- European coordinating actions in this field may play a crucial role in promoting national policies in several areas, since an effective diffusion of robots in care systems requires transversal public interventions aimed at providing the necessary infrastructure and an intelligent environment for care robots to be successfully used. The implementation of the Robot-ERA project, for example, points out that the introduction of robotic services in everyday life will only be possible through structural intervention programs developed by public authorities and the private citizens involved;

- a widespread diffusion of robots in the care system could be limited by the existence of different care systems in EU Member States. Thus, the financing of research programs or activities which specifically investigate each national system of social assistance may be of crucial importance;
- technological advances in this field and significant differences between EU Member States care systems do not seem to require European legislation on the rights of EU citizens who ask for care services in a Member State other than the Member State of affiliation (for healthcare services, see EU Directive 2011/24). As stressed above, social services are aimed at supporting people in need of assistance in carrying out everyday tasks and, therefore, are strictly connected with the place of residence of the recipient. Thus, unlike health services, personal care services presuppose a steady relationship with a particular country and rarely lead people to move to another country to seek more efficient and advanced services, especially when the recipient suffers from mental or physical disorders.

4.3 Liability and insurance

Like all technologies and human activities, robots entail a risk factor (Vein, 1992). For example, the use of technological tools in the treatment and archiving of personal data can increase the risk of misuse. It is therefore necessary to analyse the possible sources of liability which might have a negative impact on the economic affordability of robotics.

Regarding PCRs, the demographic shift, which will be even more serious over the next few decades (see, for example, Morris *et al*., 2013), will probably focus on the elderly, the main target of this field of robotics. The aim of using such robots in elderly care is to supply aged people with continuous and professional assistance.

However, this does not mean that the use of robots will necessarily reduce the risk of damage since robots themselves may constitute a hazard. Therefore, it is essential both to ensure that robots are made safer and that users are instructed in the proper handling of robots. Consequently, robots should comply with the recently approved ISO 13482 standard (Robots and robotic devices — Safety requirements for personal care robots).

In analysing how civil liability impacts on PCRs we will focus on the robotic technologies developed under the Robot-ERA project (2012-2015), which makes use of three robotic platforms: outdoor, condominium and domestic robots; in addition, we will consider the research outputs of the DustBot Project (Salvini *et al*., 2010).

4.3.1 Robots for outdoor environments

Robots for outdoor environments could carry out door-to-door garbage collection on demand and/or for street cleaning and sweeping (as in the DustBot Project). Robots could also be used as a sort of personal assistant who goes shopping with its owner or autonomously (as in Robot-ERA)In both cases, we need to verify whether PCRs comply with domestic and supranational regulations on road traffic.

The 1968 Vienna Convention on Road Traffic applies, of which Art. 8 states:

1. Every moving vehicle or combination of vehicles shall have a driver.

2. It is recommended that domestic legislation should provide that pack, draught or saddle animals, and, except in such special areas as may be marked at the entry, cattle, singly or in herds, or flocks, shall have a driver.

3. Every driver shall possess the necessary physical and mental ability and be in a fit physical and mental condition to drive.

4. Every driver of a power-driven vehicle shall possess the knowledge and skill necessary for driving the vehicle; however, this requirement shall not be a bar to driving practice by learner-drivers in conformity with domestic legislation.

5. Every driver shall at all times be able to control his vehicle or to guide his animals.

Also Art. 46 of the Italian Traffic Code states that 'vehicles are all cars of any kind, which circulate on the roads driven by a human being'.

Robot-ERA (and DustBot) robots are not 'driven' by a human being, but possibly the human being in the control station (or the robot owner/user at home) can intervene in specific circumstances to control the robot's behaviour. Therefore, since both the Vienna Convention and, accordingly, the Italian Traffic Code (as well as all the traffic codes which are in compliance with the Vienna Regulation) require the existence of a direct relationship with the human being, such robots cannot be defined as vehicles (albeit "atypical"). On the other hand, it is very doubtful that they could be defined as pedestrians or animals either (Bertolini, 2013).

In conclusion, it should be stressed that to date robots seem to be defined as "unclassifiable moving objects" (Sanfeliu, *et al.*, 2009) and that a supranational legislative intervention is needed on this point, above all in case of the possible future massive use of such robots.

4.3.1.1 Liability in case of damage

a) Products liability

Assuming that some damage occurred to a third party, we first need to distinguish between damage that is attributable to the producer, manufacturer or designer and damage that is attributable to the user. Regarding the former, product liability will generally be applicable, which in Europe is governed by a European directive (85/374/CE). European countries enforce strict liability, which means that the victim does not have to prove negligence for the tortfeasor to be compensated. The manufacturer avoids liability only if they prove that the damage was caused by an act of God or by unforeseeable and abnormal use on the part of the consumer.

This is a way of easing the position of alleged victims, since damage is often characterised by a difficult burden of proof and, should the user prove the producer's fault and causation, in most cases s/he would not get compensation, due to the way in which manufactured products are usually made and merchandised, which fragments liability. It should also be noted here that an important cause of the exclusion of liability (so called "development risk defense") is mentioned in Article 7 letter (e) of the European directive cited above, according to which:

'The producer shall not be liable as a result of this Directive if he proves (…) that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered'.

Thus, as in the case of nanotechnologies, lack of scientific knowledge concerning the risks may lead to a limited ability to prevent damage (Mandel, 2008) and to the risk of an extensive use of the development risk defence. We should also consider that robot behaviour can be to some extent unpredictable, and therefore unavoidable by manufacturers and designers.

The possibility of avoiding liability by showing that the state of the scientific and technical knowledge de facto did not prevent damage, or that the robot behaviour was unavoidable, could therefore be very burdensome for users (also taking into account that the aim of such technologies is assistive in a broad sense), theoretically forcing users to purchase a first-party insurance.

It is also possible to assume that the need to incentivize personal robotics might lead, as has been proposed (Calo, 2011), to the limited immunity of manufacturers. In any case there is a need to balance the above mentioned favourable policies with the necessity to guarantee compensation for injured people, also remembering that the right to the integrity of the person, the right to an effective remedy and the rights of the elderly and of people with disabilities (who will probably be the most frequent users of care robots) are considered as fundamental by all European Constitutions and by the Charter of Fundamental Rights of the European Union (see Arts. 3, 47, 25 and 26 respectively).

Finally, in the case of damage or even death of the users, it is also necessary to ascertain whether the accident was due, at least partly, to human error (perhaps of the victim him/herself). However, the fact that many users might be legally incompetent (due to disability, age, or pathology) may mean that ordinary rules on contributory negligence should not be considered entirely applicable.

b) Users' liability

Similar attention should focus on the case of damage to third parties which is not attributable to producers, manufacturers or designers but to users. In this case the severity of the damage possibly created by the robot could lead *de facto* to the non recoverability of all losses, since the financial resources of the robot's owner might be insufficient. The magnitude and frequency of the damage possibly caused by assistive robotic technologies might therefore lead to the introduction of forms of compulsory third party insurance as in the hypothesis of motor vehicle related accidents. Alternatively, a purely compensatory approach could be opted for.

Considering the serial nature of the mass tort litigation which could be hypothetically generated by care robots, and the highly sensitive nature of the fundamental rights involved in the use of robotics for personal care (see again the right to the integrity of the person and the rights of the elderly and of people with disabilities: Arts. 3, 25 and 26 of the Charter of Fundamental Rights of the European Union), there might be room for the creation of a fund for those that are harmed by the use of such products.

Such a fund might be conceived both as a first party insurance, and as a system based on taxation, or even as a mixture of both. In fact, historically there are a huge number of examples of no-fault systems, allowing at least partial compensation of damages as in the workers compensation schemes usually used in job related injuries (Comandé, 1999). On the other hand, the creation of a fund (whichever the sources of funding) is very burdensome both for manufacturers and for users and, obviously, could create too heavy a burden on the emerging robotic industry. Furthermore, the cost of such insurances will impact on the users, which might be a disincentive to use the new technologies.

It might therefore make sense firstly to have sufficient data regarding the real risks of the robots, while to the best of our knowledge is currently lacking. It might then be possible to better assess the hypothetical forms of compulsory insurance or other forms of compensation. One possible solution, for instance, might be to limit the range of application for funds to personal injuries, thus excluding damage to things. In any case, should robotics become a mass phenomenon, perhaps in the near future, legislative intervention will probably be necessary.

The owners' liability is not based on fault, at least in Italy, where it might qualify as liability for chose in possession. In fact, according to Art. 2051 of the Italian Civil Code, anyone in possession of something is liable for the damage caused by it, unless s/he proves an act of God. There is therefore a risk that someone, maliciously or negligently, could introduce burning or exploding material into a robot. In this case, in addition to the liability of the person who inserted the material into the robot, the owner or user of the robot may also be held liable. It might thus be useful to recall various Italian legal cases relating to damage caused by flames propagated from the containers of garbage.

Some court sentences have found garbage collectors liable for the damage provoked to third parties by the fire of the containers (Corte di Cassazione, Civil Division, July 30th, 2004, No. 14606 and Giudice conciliatore Bari July 29th, 1996), while in another case the opposite was upheld (Pretura Perugia April 26th, 1994).

The problem arising here, therefore, is that recent cases did not qualify the conduct of unknown people inserting dangerous material in the container as acts of God. Hence, the user/owner might be held liable even when appropriate measures (for instance, fire detectors etc.) had been taken. The above mentioned outcome, if applied to assistive robots used in outdoor environments, makes the introduction of compulsory third-party insurance coverage even more compelling.

4.3.2 Robots for condominiums and domestic environments

The second and third kinds of robots developed under the Robot-ERA Project are to be used in a condominium and a domestic environment respectively.

Bearing in mind the similarities between the two situations, we have chosen not to analyze them separately, since in both cases the robots are used in similar conditions.

The fact that the robots are used in private areas certainly reduces both the frequency and the entity of the possible damage. Therefore, compulsory insurance coverage or an indemnification fund here is not conceivable (and, probably, too expensive). However, the fact that robot movements are more easily controlled and managed makes it even more difficult for the defendant to justify himself/herself in court in the case of damage in order to escape liability.

We should also bear in mind that even in this case the owner's and/or user's liability for chose in possession applies. However, even when a robot belongs to an individual owner, the condominium might also be held liable.

Lastly, the use of robots in common areas of the condominium must be approved by the condominium itself in consideration of the risks, at least theoretical, that their use may cause to the surrounding neighborhood and to guests at the condominium.

4.3.3 Assistive robotic technologies and long term care insurance

While today approximately 10% of the world's population is over the age of sixty, by 2050 this proportion will have more than doubled (Pollack, 2005). At the same time, social assistive robots are potentially aimed at the elderly and, more generally, to people with reduced capacities, many of them currently living in nursing homes.

The current system of long term care for the elderly and disabled people, which is based on nursing homes, is very expensive. However, the current system of institutionalised care, which is at this moment funded either by the social security system, by personal finances or by families, is not financially stable (Kapp, 2001). Some insurance contracts specifically aimed at protecting the elderly, such as long term care contracts, are widely used in the market and in the future their use will probably increase. It is common for long-term care to provide custodial and non-skilled care, such as assisting with daily tasks such as dressing, bathing, and using the bathroom. Increasingly, long-term care involves providing a level of medical care that requires the expertise of skilled practitioners to address the often multiple chronic conditions associated with older populations. Long-term care can be provided at home, in the community, in assisted living facilities or in nursing homes. Long-term care may be needed by people of any age, although it is more commonly needed for senior citizens or disabled people.

The above-mentioned situations are typically those where a personal care robot could be used. At the moment, however, such activities are generally carried out by care workers. Thus long-term care contracts would be useful that cover the use of care robots in performing such activities. The insurance company, in other words, would repay the cost of purchasing the robot and related expenses. Consequently the use of such robots might be stimulated, since the financial burden might be shifted to insurance company or be financed by people stipulating such insurances, before getting too old to do so.

Perhaps one of the most controversial issues of the application of robots in elderly and disabled care is that it is excessively costly. Moreover, social security may not provide sufficient income for most people during retirement and/or in the case of disability. It has also been argued that the substitution of unnecessary institutionalization of aged people or people with disabilities and the fulfilment of a comprehensive array of 'humane, independent-living-informed, community-based services and residential alternatives' might be seen as a political priority for the next few decades, both in the US and in the EU (Burgdorf, 2007). Assistive robotics might thus be seen as a tool to pursue this objective (Niemeijer *et al.*, 2010; Pollack, 2005; Broekens, Heerink & Rosendal, 2009).

Many elderly people prefer "aging in place", even this may be dangerous due to falls, burns and medicine-related poisoning (Cocco, 2011). Professor Jacobus tenBroek in his article The Right to Live in the World: The Disabled in the Law of Torts (1966) claimed that 'a policy of integrationism that is, a policy entitling the disabled to full participation in the life of the community and encouraging and enabling them to do so' should be carried out by institutions to better 'protect' disabled (and, we can add, also elderly) people.

Thus legislative measures to boost long-term care contracts, such as tax relief or similar incentives, and applying such incentives for the use of assistive robotics for elderly and disabled people, might cut down healthcare costs. Such political initiatives might also be seen as an affirmative action to fortify the civil rights of individuals with reduced capacities, in line with the "appropriate measures" that the 2006 UN Convention on the Rights of People with Disabilities

imposes on political parties to adopt in all their policies and programs to protect and promote the human rights of people with disabilities (see, for instance, Articles 31 through 40), (Friedman & Norman, 2012). We should also recall Art. 19, Living independently and being included in the community, of the Convention on the Rights of People with Disabilities.

Lastly, we need to mention the Principles for Older Persons enacted by the UN General Assembly on December 16th, 1991, according to which 'older persons should be able to live in environments that are safe and adaptable to personal preferences and changing capacities'.

4.4 Privacy

Personal information on the robot owners and/or of third parties will normally be saved in the memory of the robot. The functioning of the robot may also require an Internet connection in order to continuously monitor its operation and avoid malfunctions and possible damage. Another objective could be to allow the owner, anywhere in the world, to connect the robot with other hardware placed in his/her home. The robot may even be used as a kind of "electronic health record", for example, of the older people who are assisted by the robot itself. The aim would be to immediately notify health authorities in the case of illness or to have updated health data in an emergency if, for example, the owner is on holiday. In this case, specific measures would be needed to ensure that the medical practitioner only had access to health data that were strictly necessary for the relevant operation.

A greater flow of personal data produces an increased risk of possible fraudulent access or loss of data (e.g. cookies). Furthermore, the robot might be used as a sort of "big brother" to control the users' activities, generating 'the feeling of being observed and evaluated' (Calo, 2009). There would be conflicts of interest especially if the use of robots were financed through a long-term insurance: insurance companies might want to impose a specific lifestyle on the insured person to reduce the costs of maintenance. A similar conflict of interest could exist between the disabled or elderly person and his/her relatives, who might have an interest in controlling him/her.

The risks for users' privacy would be greater than the limitation of privacy caused by the "Granny Cam" monitoring systems adopted in nursing homes (Cottle, 2004; Adelman, 2002; Kohl, 2003; Bharucha et al., 2006). The personal data are likely to be particularly sensitive as they pertain to the health of individuals, their life choices, political, philosophical and religious beliefs, sexual habits, etc. and this could eventually lead to a real "death of privacy" (Froomkin, 2000).

Firstly, we agree that a surveillance and control system should not generally be permitted only in cases of the vulnerable health of a patient or user. It has been correctly argued that 'too often, it appears, we take the limitations imposed on the civil liberties of the elderly for granted as a presumed natural consequence of their degenerating health and of our well-intentioned, yet paternalistic, desire to ensure their medical well-being' (Eltis, 2005). Therefore, in general terms, the storage of personal data should be expressly agreed to by competent users or by their proxies or representatives.

The treatment and storage of personal data should also be limited and the information systems and the programs should reduce the use of personal data to a minimum. Article 6(1)(b) of the Data Protection Directive 95/46/EC of the European Parliament and of the Council of October 24th, 1995 stipulates finality principle according to which data controllers may collect data only as far as it is necessary to achieve a specified and legitimate purpose. Furthermore, who is allowed to operate a telepresence robot, as well as when, where and how the operator can control it must be verified in advance and communicated to the users. Similarly, additional measures will be

necessary to protect the privacy of users and people who are in the same space as the robot. For example, the operator may see high-quality video and hear full-quality audio in the telepresence of the robot's immediate surroundings, but diminished quality beyond (see: A Roadmap for U.S. Robotics From Internet to Robotics, 2013; Cocco, 2011: 105-106).

In addition, 'there should be more binding mechanisms to respect privacy when possible and to infringe privacy only when necessary. Although the principles of subsidiarity and proportionality are enshrined in many privacy and data-protection laws, they do not appear to have much effect on the privacy risks of technology. As a corollary of a privacy impact assessment, a control mechanism should be established that checks whether technologies are constructed in the most privacy-friendly way compatible with other requirements (such as information needs and security)' (Koops & Leenes, 2005).

Finally, the right not to use personal care robots should also be ensured (Ramachandran, 2009). For instance, long-term care insurance contracts conditioning the coverage regarding the use of assistive robots must not be allowed. If possible in relation to the kind of disease of the assisted person, we suggest that the robot should be designed in a way that the user can verify and even change the level of control s/he has upon the robot at any time. The mandatory adoption of security measures will also be needed, including passwords, firewalls, etc., by the producers, as well as being continuously updated by the users. Given that a robot might store not only its owner's data, but also third party data, therefore the adoption of updated security measures should not be considered only as a user's choice, but also as a specific legal duty. It is clear that the illicit treatment of the data is unlikely to be considered a responsibility of the manufacturer of the robot, but rather a liability of its user, who is the "holder" of the personal data. Compulsory insurance might thus be necessary covering pecuniary and non pecuniary damages which could be caused by the illicit treatment of personal data.

4.5 Legal capacity and legal acts by personal care robots

Finally, does the concept of personhood apply to robots? As stated by Asaro (2007) 'while a robot might someday be considered a person, we are not likely to face this situation any time soon'. Therefore, in our opinion the existing laws on agency and liability do not apply at least in the field of personal care robotics. Accordingly, robots can neither be granted the notion of legal (or electronic) personhood or capacity, nor are they subject to civil or criminal liability. Hence, only its owner shall be responsible for any unlawful act committed by a robot (or manufacturer, designer, testing agency, state regulation agency, etc.). In addition, no rights may be acknowledged to robots.

4.6 Recommendations

Advances in the development of robots for personal care have recently led to a major focus on the legal issues. The need for a legal framework has been seen as a precondition for turning robots from prototypes into products in the field of care, where the profound human-robot interaction risks affecting human rights. Of the questions currently debated by scholars and experts in law is whether the current legal framework is adequate to address the issues emerging from the deployment of robotic technologies. The analysis carried out above highlights that, in some cases, current legislation is still applicable and able to regulate conflicts that may arise from the use of care robots (see § 4.3.1.1, sub a). In other circumstances, specific legislation is needed (see § 4.3.3; 4.4). In yet other cases, there are no particular concerns as in the case of recognizing that robots have a legal capacity and rights (§ 4.5).

Future policies concerning the use of robotic devices in care systems should consider:

1. *Definition*. Currently, there is no need for a legal definition of personal care robots. However, the future development of polices in this field and the adoption of legislative measures which specifically apply to robotic devices in the care system may require a legal definition. The distinction between care robots and robots as medical devices should be particularly considered.
2. *Independent living*. Promoting independent living through measures that support the introduction of robots in the care system should not mean replacing traditional forms of care. As regards care services, several options should be available in order to ensure: a) the autonomy of the person in need of assistance, intended as the expression of one's self-determination in the context of choices concerning personal care, b) the enjoyment of the highest attainable level of independence. Although these rights are currently protected under the European Charter of Fundamental Rights and national Constitutions, extending active ageing and independent living through the development of technological solutions requires the adoption of legislative measures in the field of social assistance and care systems at the national level.
3. *Liability*:
    (a) In the case of damage which is attributable to the producer, product liability (directive 85/374/CE) will be generally applicable. Although a lack of scientific knowledge could theoretically lead to a limited ability to prevent damage, we do not share the opinion that the need to promote care robots should lead to the limited immunity of manufacturers. In fact, the need to guarantee compensation for injured people has its basis in all European Constitutions and in the Charter of Fundamental Rights of the European Union.
    (b) In the case of damage which is attributable to users, since its severity could lead de facto to the non recoverability of all losses, there could be room in the future for the introduction of compulsory third party or first party insurance.
    (c) Lastly, it is possible to envisage the use of long-term care insurance contracts as a way to finance the use of personal care robots. Therefore, we suggest the adoption of legislative measures to boost long-term care contracts, such as tax reliefs.
4. *Safety and security*. Firstly, we suggest the application of the rules regarding sales of goods, which should cover any consumer who buys or leases an assistive technology device from the manufacturer, regardless of whether the purpose is to aid an individual with a disability or for personal use. The law should also allow for a "reconsideration period", and manufacturers should not be entitled to construct non-statutory defenses.
5. *Privacy*. In general terms, the storage of personal data by personal care robots should be limited in compliance with Article 6(1)(b) of the Directive 95/46/EC, according to which data controllers may collect data only as far as it is necessary to achieve a specified and legitimate purpose. Furthermore, who operates a telepresence robot, when, and where and how the operator can control it, must be verified in advance and communicated to users. Similarly, additional measures are necessary to protect the privacy of users and people who are in the same space as the robot. Finally, the right not to use assistive robots should also be ensured: for instance, long-term care insurance contracts conditioning the coverage to the use of assistive robots must not be allowed. If possible in relation to the kind of disease of the assisted person, we suggest that the robot should be designed in a way that the

user can verify and even change the level of control s/he has upon the robot at any time. The mandatory adoption of security measures by the producers is also necessary, as well as their continuous updating by the users. The introduction of forms of compulsory insurance might also be advisable covering pecuniary and non pecuniary damages which can be caused by the illicit treatment of personal data.

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Conclusions*

* This chapter has been written with contributions by: Andrea Bertolini: §§1, 5.1, 5.5, 5.6 Andrea Bertolini & Fiorella Battaglia: §5, Erica Palmerini:§§2, 3, Erica Palmerini & Bert-Jaap Koops: §4, Erica Palmerini & Fiorella Battaglia: §5.4, Bert-Jaap Koops: §5.3, Antonio Carnevale & Fiorella Battaglia: §5.2.

1. Robotic as a strategic sector for the European market

Robotics represents one of the most relevant technological innovation of the current century (Gates, 2007), a revolution (Lin, 2012) capable of radically modifying existing economies at least in a twofold sense. On the one hand, those countries that more than others will invest in robotic applications, developing a strong industry in the field, will soon acquire a relevant strategic hedge over latecomers and other players, who nonetheless will be consuming such devices (Manyika, 2013). On the other hand, the advent of these technologies will profoundly modify the societal structure, changing required competences and skills, ultimately reshaping the overall labour market and income distribution (Manyika, 2013).

Different aspects profoundly influence such an outcome in an aggregated fashion, that cannot be easily disentangled; yet many such factors can be rooted back to the legal system, that most certainly determines the – conditions for the – development of a market.

Even a substantial investment in research if not coupled with adequate normative strategies may thus prove insufficient, delaying the emergence of some technologies, eventually impairing the development of a corresponding industry. A transparent regulatory environment is a key element for the development of a robotics and autonomous systems market, where products and services can be incubated, tested in real environments, and eventually launched. Even worse than the lack of legal clarity could be the effect of some actions – or policy choices – aimed at preventing the development or diffusion of a given application. These initiatives may only in fact impair the development of the supply side of the economy for that specific device,[1] at the same time reducing the possibility to effectively influence the way, that product is conceived, designed, and finally distributed onto the market, and thus the standards it needs to conform to.[2] In the end the robot will be out there, in the market, in the streets, in our homes, but it will adhere to the standards, values, social fabric of those countries, like China or South Korea, that are proactively confronting the economic opportunities offered by the advancements in robotics.[3]

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[1] Were too stringent rules adopted, raising initial costs for companies operating within a given legal system, competitors, originally operating in other markets and under other regulations, would find themselves at an advantage; most likely they would develop the application nonetheless, and push the companies operating in the more limited legal system outside the market for that technology. Later though the very product may be sold – unless that is expressly prohibited – in the country affected by more stringent regulations, to the sole advantage of those players, who originally managed to enter the market.

[2] The application produced outside the legal system prohibiting its development and use will abide the different standards set forth by the legal system in which it was researched and conceived. Unless the subsequent use is effectively prohibited in the former country – in case a similar prohibition may prove effective and possible to enforce, and society does not put pressure for the diffusion of the same technology despite the original prohibition – its later diffusion will produce the overall effect of imposing the legal system standards – even of normative relevance – which belong to the second, completely frustrating the original regulation's purposes.

[3] Korea has since long taken concrete action in order to favour the development of robotic technologies, see the Korean Act No 9014, 28 March 2008 on Intelligent Robots Development and Distribution Promotion Act (IRDDPA), available in an English translation at http://elaw.klri.re.kr/eng_mobile/viewer.do?hseq=17399&type=sogan&key=13, where art. 1 states: 'The purpose

These considerations do not entail stating that Europe should renounce regulating technologies and surrender to market forces, quite the contrary. The European Union should claim a relevant political role in the development of technologies and attentively pick the gifts of the evil deity (Calabresi, 1996) in a way that is aware and fully coherent with its desired objectives.

2. Regulating robotics: which role for Europe?

A bundle of technical, social, political factors play a role in the regulation of robotic technologies, and ultimately guide the choice among the array of available instruments and approaches. Different are therefore the elements to be taken into account.

On the one hand, technological innovation has an inherently transnational nature, being the result of the cooperation of articulated research teams spread over different jurisdictions in a cross-boundary phenomenon. On the other hand, it also presents a shifting and at time abruptly transforming nature, that cannot be easily captured by conventional legal instruments. These features call for relevant policy choices, inevitably grounded on fundamental values. To this purpose, it shall be stressed, that despite Europe being characterized by a framework of overarching principles, shared among all MS, the extremely general character they present requires further action, at the statutory and judiciary level to achieve concrete implementation.

Pursuant to these considerations, soft law appears to be the most appropriate option to handle the complexity of technological regulation. Developed by independent agencies, international organizations, non-state actors, it allows to take the transnational character of the phenomenon into account. Consisting of agile and flexible tools, it catches the dynamism inherent in technological innovation, otherwise at odds with long-term legal framing. Said otherwise, in order to escape the constraints of a "hard law" approach, legal systems are thus naturally steered towards "homeostatic" instruments, capable of adapting themselves to a changing landscape, which cannot be managed through statutory law (Rodotà, 2004: 409).

Technical delegation to independent bodies is also a tool used to handle matters characterized by a strong technological dimension, in order to keep pace with scientific advancements and to maintain a light quality to traditional legislation. Technical and safety norms and standards, that are formulated by administrative or non-governmental agencies, technical standard-setting bodies such as ISO and the European Standard Organizations (such as CEN & CENELEC), and professional associations, have increasingly become a tool for regulation in many science-centred sectors, and exert a decisive influence on the application of the law (for instance, contribute to define the concepts of negligence, due care, therefore have a bearing on the allocation of liability by means of the so-called regulatory compliance defence). Soft law measures are consistent 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 without the need for statutory intervention.

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of this Act is to contribute to the enhancement of the quality of life of citizens and the national economy by establishing and promoting a policy for the sustainable development of the intelligent robot industry to facilitate the development and distribution of intelligent robots and lay down the foundation therefor'.

Finally, documents like codes of conduct, that can be adopted on a voluntary basis, not necessarily at the central-national level, but by the operators of a certain sector,[4] are also characterized by a closeness to the context to be regulated that allows to neutralize problems of acceptability.

For these very reasons, if flexible regulation by means of soft law is deemed essential to enable, allow, and accommodate advanced robotic technologies, it does, however, present several relevant drawbacks too. Firstly, soft law does not allow the design of a sound regulatory framework, since it has to be consistent with several legal systems, potentially exhibiting relevant differences with one another. In order to meet this pluralism, it either remains at a very general and uncontroversial level, or provides detailed technical solutions to problems regarding primarily the safety of design and use of robotic products, while leaving ethical concerns and the respect of core values untouched. Nevertheless, this is insufficient to effectively govern complexity. Secondly, harmonization pursued by means of soft law depends on the voluntary compliance of multiple classes of agents, and therefore does not provide the actors involved with a sufficient degree of legal certainty.

The need to resort to technical delegation is also a constitutive feature of techno-regulation, that gives way to its private substantial nature, and ultimately to the growth of so called private transnational regulation (Cafaggi, 2011: 28 ff). Combining formal law and technical standards requires the private sector to be included in the legal order and raises problems of democratic control and legitimacy. The devolution of technical rule-making to independent agencies or standard-setting bodies ensures the continuous adaptation of norms, but raises doubts about their legitimacy, certainty and accessibility. 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. Organisms like ISO usefully develop safety standards for robots, but their activity is mainly directed, and should be, to ensure safety in activities that entail the use of robots. Industries can voluntarily embed in their protocols and products the standards suggested by technical bodies, but issues concerning the impact on fundamental rights deriving from every application to end-users or respect for their other interests not merely related to safety are not included in this form of regulation.

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 (Wynne, 2007). Open criticism of rules made by experts without democratic legitimacy underlies a 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-

[4] See, for instance, the Nanocode: *Code of conduct for responsible nanosciences and nanotechnologies research,* recommended for adoption by "national and regional authorities, employers and research funding bodies, researchers, and any individual or civil society organisation involved or interested in N&N research", through the Commission Recommendation on a code of conduct for responsible nanosciences and nanotechnologies research, C (2008) 424 final, 7.2.2008.

science is oriented toward social implementations that require political and public choice to be made (Stirling, 2006).

Finally, and more importantly, less formal and non-mandatory mechanisms do not satisfy a widely perceived need for a general frame of reference – possibly agreed on at an international level – on which technological advance can be grounded, providing sufficient legal certainty to the actors involved.

These considerations converge in indicating that a coherent frame agreed at the European level would better serve the purpose of fostering innovation in the robotic domain in Europe, while giving the correspondent market an important competitive push with external markets.

3. A common framework of fundamental rights and principles

The potential role of a set of overarching principles shared in the European legal order is multi-layered: (i) firstly, it allows to identify fundamental rights and freedoms that developments in the robotic field may infringe and that, on the contrary, have to be regarded as intangible.

The fundamental rights at stake in the domains affected by robotics have been identified throughout the research (see e.g. Koops *et al.*, 2013; Lucivero *et al.*, 2013). Their core essence is acknowledged in the multilevel systems formed by European and national law, and positively affirmed in the European Charter of Fundamental Rights and the European Convention on Human Rights. On the preventative side, this body of principles obliges to design safeguards and limits in the use of technologies, possibly originally embedded in the technical set-up. Robotic applications have to be devised and designed in such a manner that allows to protect values like human dignity, identity, health and privacy. In case a robot artefact might harm those values and the underlying rights, without being possible to prevent similar negative effects through careful design and users' information, a responsible attitude, which could even be supported by a legal ban or a moratorium, would be that of not producing and deploying it.

At the same time, those values can shed light over novel forms of aggression brought about by robotic technologies (Gasson & Koops, 2013) that it is possible to counteract by means of especially designed legal rules or inventive interpretation. For instance, the purpose of a constitutional understanding of advances in robotics could entail enlarging the scope of existing fundamental rights in the light of risks of infringements never confronted before.

(ii) Secondly, fundamental rights form an essential apparatus to use as a test-bed for the desirability of robotic applications. More precisely, they can contribute to identify the main goals and achievements expected by advancements in robotic research and industrial applications; thus, to pinpoint priorities and therefore justify rules that favour one application, which responds to values and needs deemed fundamental, over others. Robotic products and services, which ensure the fulfilment of fundamental rights, should in fact be subject to a favourable regime, in order to create incentives for their development. These anchoring principles could therefore operate not only in a shielding fashion but in a more proactive and orientating guise, by pointing to innovation in robotics that should be fostered through regulation (see §5.5) (Bertolini, 2014). Within the value-based structure given to the European Charter of Fundamental Rights, the principles of equality, solidarity, non-discrimination, and justice retain prominent relevance, while the rights of

the elderly (art. 25), and the integration of persons with disabilities (art. 26), the right to healthcare (art. 35), and to consumer protection (art. 38) are corollaries of these values, but their scope and level of implementation is also remitted to context-specific evaluation within the nation systems.

Robotics for healthcare is a case in point in both respects. Care and companion robots are being developed for the assistance of the elderly and the disabled, to help them live an independent life and be socially active; advanced prostheses and exoskeletons can improve the quality of life of persons with various types of disabilities and promote their social inclusion; surgical robots can dramatically improve the quality of medical treatment through high-precision surgery. These applications deserve special attention, since they meet qualified social needs – inclusion of vulnerable persons, supply of personal care, in the light of population ageing and demographic change, with expected shortage of (informal and professional) caregivers, better quality in healthcare – and allow to accomplish values we hold dear. Considering that these types of robotic technologies can be deployed in order to foster fundamental values, regulators should provide the right incentives for their development, which we deem desirable from a constitutional viewpoint.

At the same time, those very technologies exhibit features that can put the fundamental rights they are doomed to promote at risk. For instance, the perspective of using assistant robots for the elderly raises several issues related to the ethics of care and generates concerns for the emotional implications, and therefore the impact on the identity and privacy of the person, that such devices entail. Bionic prostheses, interfaced with the neural system, promise enormous benefits for people with disabilities, but again can be questioned for their bearing on the right to bodily integrity and to identity, and for creating new forms of vulnerability (see §5.3). Moreover, they open up a far-ranging set of problems, as the human-machine interaction on which they are based gives way to the dilemmas of human enhancement. Data protection and data security in the healthcare scenario also figure as relevant concerns to be taken into account from a human rights viewpoint, having in mind the great potential for the collection and storage of sensitive data that robotic technologies display.

To sum up, the healthcare domain, broadly intended, more than others requires regulatory intervention in order to protect fundamental rights, promote innovation responding to societal needs (see Ch. 1, § 7.2; DG Information Society, R4H. Robotics for healthcare, 2008), and foster the development of a truly European market for such devices (Manyika, 2013). A regulatory approach that supports the development of this kind of products should also create incentives to operate in this sector, aiming at overcoming economic constraints that make it not sufficiently attractive for private investments and also provide greater certainty for innovators (European Commission, 2013).

A general frame of principles could be accompanied by more specific regulatory instruments, endowed with binding force, either on distinct technological applications or on a cluster of themes, like liability for damages, which involve multiple technologies. These instruments would complement the extant legislation that already applies to robotic technologies, both at the European and the national level, providing a starting basis that could be further implemented.

4. RoboLaw and responsible research and innovation

The ambition of the European Union to promote innovation in the internal market and foster competitiveness makes robotics a strategic sector, to which the European institutions are

devoting considerable attention. At the same time research and industrial production in the domain of robotics have to grow in accordance with the complementary objective which is enshrined in the European legal system, that of being an area of freedom, security and justice. The competing goals of protecting consumers and more generally end-users from harm and fostering innovation have therefore to become embedded in the regulatory endeavour and in the innovation process itself.

The investigation carried out within the RoboLaw project has focused on the multi-layered interplay between robotics and regulation. The research moves from a request for a legal framework that can accompany the developments of robotics that comes from the actors who operate in this sector. Researchers and manufacturers who work on robotics both at the experimental and at the industrial level claim that they cannot properly appraise the risks and duties entwined in their activities until a clear analysis of this interplay has been made. The research has explored both the formal and the substantial aspects of the binomial robotics and regulation. On the one hand, it has focused on the different legal tools that can be employed in order to regulate technology in general, and robotic technologies in particular. On the other hand, the contents of the extant relevant legislation have been examined, with the aim of verifying whether they can already provide a systematic legal framework or other forms of regulation are needed, notwithstanding the adaptability and flexibility of the available rules.

Many regulatory issues raise the question of when regulators can or should intervene if they want or ought to regulate. Collingridge (Collingridge, 1981) pointed out an intrinsic dilemma in technology regulation: controlling a technology is difficult in its early stages because not enough is known of its possible or probable effects, and it is also difficult once the technology is well-developed because by then intervention is expensive, drastic, or impossible because the technology cannot be reversed. We therefore need ways to regulate in early stages when it is still possible, albeit in the dark, which calls for innovative approaches. One such approach that features increasingly on the policy and academic agendas is responsible research and innovation (RRI) (von Schomberg, 2011; European Commission, 2013).

This approach can be described as 'a transparent, interactive process by which societal actors and innovators become mutually responsive to each other with a view on the (ethical) acceptability, sustainability and societal desirability of the innovation process and its marketable products (in order to allow a proper embedding of scientific and technological advances in our society)' (*Ibid*., 9). The responsibility in innovation thus refers to incorporating social and ethical values or aspects in the innovation process, combining an ideal—something we strive for even though we realise it can never be fully attained—and a project: a joint enterprise of an increasingly large community of people who want to bring us closer to this ideal.

The development of the concept of responsible research and innovation has close parallels in legal theory and regulation studies. Regulatory innovation (Black, Lodge, & Thatcher, 2005) is a close relative of responsible (research and) innovation, and one that regulators need to take seriously if they want to address the regulatory challenges of complex technological developments that have broad and systemic implications for many social processes. Similarly, the rise of the study of 'code' or 'techno-regulation' parallels the development of value-sensitive design, in an enterprise of embedding, in a responsible way, values and norms in the design of technology.

The RoboLaw project has had as constant point of references the EU policies on Responsible Research and Innovation. The main concerns and meanings that are entrenched in this formula have been respected and applied, both from a methodological and a substantial point of view, thanks to the integration of a wide array of disciplines and competences in the project's structure

and team. The involvement of various stakeholders in the process of identification and discussion of the issues potentially raised by the advent of robotic technologies, has then relevantly contributed to letting needs, sensibilities, and perspectives emerge, which were then considered and discussed in the analysis (Ch. 1, §2).

Methodologically, all legal evaluations of robotic technologies were built upon their ethical appraisal, since the latter has not been considered an autonomous exercise deferred to experts of the field, but an integrating part of the analysis leading to distinctive features of the proposed solutions (see §5.2).

From the substantive point of view, RoboLaw has embraced the two requirements of ethical acceptability and orientation towards societal needs that identify the pillars of the concept of RRI. Not only do robotic products and applications have to comply with the core values embraced in the European context by the constitutional traditions of Member States, and positively affirmed by the Charter on fundamental rights, but particular attention, and possibly a peculiar legal status in some respects, should also be given to those technologies that respond to societal needs, therefore contribute to achieve normative goals such as equality of opportunities, justice, solidarity and to improve the quality of life of the European citizens, especially the more deprived and vulnerable.

The regulatory challenges posed by advancements in robotics have been addressed comprehensively and the project has tried to provide answers with regard to: the legal tools that better suit the goal of regulating technology; the type of ethical analysis that should be conducted on technological innovation, and the methodology to apply, in order to align our research to the EU policy on Responsible Research and Innovation (RRI); the contents of regulation, with special attention to the need of protecting the fundamental rights of European citizens.

The question whether fundamental rights are threatened by new technical opportunities purported by robotics has been tackled; but research efforts have been devoted also to investigate whether an efficient and proactive protection of fundamental rights and liberties proclaimed at the European level requires to foster innovation in robotics by means of especially designed legal rules or inventive interpretation. The latter perspective has led for instance to propose special rules in the context of liability for damages deriving from the use of robotic technologies in the field of healthcare, namely surgical robots, prostheses and care robots (REF). Robotics for healthcare is in fact a domain that more than others requires regulatory intervention and where legislation promoting innovation is called for. Demographic, social, technological, economic and political factors orientate towards the development of this sector, and make it a special case to be analysed from an ethical and legal perspective, and one that qualifies as an effective context of implementation of the EU policy action.

5. Main findings of RoboLaw

The analysis conducted within RoboLaw allows us to draw some conclusions with respect to both some methodological and substantial aspects of the regulation of technology in general, and robotics in particular. In the first place, we may discuss whether robots deserve a special case (§5.1), which is tantamount as asking whether arguments can be identified in order to justify a change in the existing legal paradigm to accommodate these new technologies.

Are extant laws sufficient to deal with the normative challenges of the technology, and if not, should some laws be adapted to include the new technology, typically by making the language

of the law more technology-neutral, or should rather *sui-generis* laws be created that are tailored to the specifics of the new technology? And eventually on which grounds?

In the second place, it is necessary to clarify the direct and indirect role ethics can play in regulating technology (§5.2), in particular by extending the object of the analysis from the artefact to include its meaning – and moral implications – for society, the way it is conceived and designed, and ultimately how it shapes the knowledge and democratic culture of technology.

In the third place, the issue of the transformations of both vulnerabilities and capabilities is addressed (§5.3), as a relevant case in point, exemplifying the approach just described. Technology conceived as a tool to overcome given vulnerabilities, inevitably generates new ones that may be physical, psychological or even moral, and involve single individuals as well as an entire society or parts thereof. The ethical assessment of such – intended and unintended – consequences of technological development provides criteria the legislator needs to weigh when adopting policy decisions, eventually in the early stage of design of specific applications. More broadly, the moral stretch exercises[5] (Coeckelbergh, 2013) performed to this end, also indirectly bring us to question our culture and understanding of technology, and raise fundamental questions about personal identity.

In the fourth place, the discussion steers to the issue of human enhancement (§5.4), which again represents a second case in point of particular relevance and sensitivity, that RoboLaw has at length discussed within the project's deliverables and publications (Lucivero, 2013; Battaglia, 2012; 2014), including the current document, in different perspectives.

In the fifth place, some further considerations will be devoted to liability (§5.5), applying the functional perspective described (§5.1), in order to determine how such rules can be used and shaped to modify the incentives of the different players, so as to favour the development of some devices, that are deemed desirable in particular in light of the positive impact they would have on fundamental rights and principles.

Finally, some brief remarks are dedicated to the possibility of generalization of the recommendations and conclusions formulated within this document, as an attempt to close the circle and move back from special to general.

5.1 Do robots deserve a special case?

Robots are often deemed "exceptional" (Calo, 2014), and different criteria are enumerated in order to support such conclusion. The consequence of this premise is that the adequacy of existing rules is questioned, most often in light of purely technical considerations regarding the robot's autonomy or ability to learn (Matthias, 2010), and the conclusion is drawn that alternative solutions – and liability rules – ought to be developed (Leroux, 2012).

Indeed the conclusion may be appropriate, yet the grounds that are used to support it shall be further discussed, since they may change the overall framework of analysis with immediate

[5] Considering that in the moment the technology is conceived it is not possible to precisely assess which vulnerabilities it is possibly going to create once it actually comes to existence, the attempt has to be made to imagine the impact it will have on society, both in terms of changes in needs, moral values and desires (Ferrari, Coenen, & Grunwald, 2012).

practical consequences both for an ethical and legal analysis. The need for *ad-hoc* regulation may be grounded on intrinsic aspects, connected with the design of the robot, and thus be ontological, or rather depend on considerations about the functions they serve and the utility they bring to society, hence functional.

By pushing the ontological argument further one may conclude that robots – in some cases at least, namely when autonomous – amount to subjects, rather than objects; hence some sort of – legal – personhood (Leroux, 2012) should be attributed to them, with all the consequences that may be derived therefrom in terms of rights and liabilities.

Refuting this idea however (Bertolini, 2014), does not entail stating that the law of robots is the law of the horse – borrowing the image that Easterbrook used to refer to cyberlaw (Easterbrook, 1996) – and ultimately that no special considerations are required in order to rationalize the emergence of robotic technologies in our society. More simply, even if robots may be considered peculiar it is not their autonomous nature or ability to learn – or any other technological aspect –, that turns them into agents (Gutman, 2012; Nida-Rümelin, 2011) in a philosophical sense. Thence, the overall analysis needs to be framed in a functional perspective, and the expediency – as well as the possibility – to adopt an alternative system or legal solution ought to be grounded on policy considerations, once the desired social outcome is identified and relevant – eventually even constitutional – values assessed and pondered (see §3).

At the same time, this entails stating that robots rather than exceptional are special, in some cases requiring novel solutions to be elaborated for their better development and diffusion in society, without any paradigmatic fracture like the one that draws on the ontological argument. In this aspect, the regulation of robotics does not substantially differ from other fields of law that are today established (environmental or product liability law, to name some specific examples). Furthermore, this implies that rules elaborated for this purpose may contribute to modify general beliefs and assumptions, as well as interpretation of general standards and principles of the law (Castronovo, 2006). In this perspective, even the choice of attributing robots legal personhood would not be grounded on the ontological nature of the machine, rather on a purely instrumental argument of the opportunity of limiting liability or identifying an autonomous centre of imputation of rights and duties, like in the case of a corporation.

5.2 The role of ethics in regulating emerging technologies

Ethics can play multiple roles in the perspective of regulating emerging technologies, both direct and indirect: (i) Ethics frames the social expectations towards emerging technologies; (ii) Ethics can be embodied in the design of new technologies; (iii) Ethics is a system of values involved in the construction of a democratic culture of technology.

(i) A considerable part of emerging technologies – especially in the case of robotics – are not yet available on the market, and we can only imagine if and how they will change the quality of our lives for the better or worse. Yet, despite the absence of a large market, social expectations are growing. Companies continue to produce various robotic prototypes for different services (mobility, logistics, medicine and healthcare, physical and emotional assistance, etc.). The civil society's demand for domestic and service robots is growing. The media increasingly present robots as an empathic form of assistive technology, thus stimulating the collective imagination on how life could change when these machines will finally be able to take care of our daily needs. In addition, governments' attention about the opportunities purported by robotics is being raised by

the fact that some robotic applications seem to offer solutions to social issues such as population aging, and spending review for social services.

However, next to these ever growing expectations even moral awareness on the side of the stakeholders interested in the development of robots is growing, for instance about the overly high costs of their commercialization, or the unacceptably low normative standards that ensure the products' safety and social acceptability. This knowledge and attitudes should be investigated and analysed, and specifically taken into account when approaching the challenge of the regulation of an emerging technology. Said otherwise, emerging technologies are increasingly exhibiting a social function, thus regulating them should entail regulating not only the technological artefact but also the social meaning associated to it.

(ii) But emerging technologies involve ethical issues not only because they create social expectations. Indeed, societal beliefs and values are embodied in the design. Robots illustrate such phenomenon paradigmatically.

Since robots have progressively left factories and reached for everyday life, this has progressively led to the integration of moral values into their conception, design, and development. Stakeholders demand user-friendly technologies in which the technical functions are integrated and complemented with the social experience of those technologies. Subsequently manufacturers need to start conceiving the processes of technological innovation as a value-laden phenomenon. To summarize, reflecting on the design of a new technological artefact is a task that unquestionably concerns meanings—be they symbolic, commercial, or of any other nature. Design lends itself to ethical interpretation, already entrenched into the obvious question of good versus bad design.

This means that ethics is challenged by emerging technologies not only in the perspective of future implications arising as a consequence of their use, rather it becomes of relevance already in earlier stages, when they are conceived and designed. Therefore, regulating an emerging technology from an ethical perspective should involve an ethically sound decision-making during the design phase.

(iii) Finally, there is also an indirect role that ethics can play in regulating technologies. In fact, all regulative processes have the function to rationalize the use and access to some good, and, at the same time, they contribute to indirectly create a culture of that good. Since having an intuition of what is 'evil' and 'good' and since being able to engage in relevant debate on what should be done is part of the human form of life, it is possible to act through technology regulation to create a shared moral knowledge and democratic culture of technology.

5.3 Robotics, vulnerabilities and human capabilities

Robotics provides a wide array of instruments that can be used to overcome human vulnerabilities, the most obvious example being (bionic) prosthetics, which can restore capabilities to people who have lost a body part. Other types of robots hold considerable promise in this respect too, such as companion robots that can help autistic children to learn certain forms of social behaviour, or care robots that can assist the elderly. Moreover, robots can not only restore functioning, but also improve functioning beyond "normal" or "average", and we can envision that at some point, also 'normal' people may want the benefit of prosthetics or companion robots, which will provide new regulatory challenges of ethical assessment and distribution of resources. This may occur particularly in the case where robotics provides new capabilities (such as perceiving colours in the non-visual spectrum, or of holding very hot objects in the hand).

At the same time, regulators should also be aware that developments in robotics may lead to the loss of existing human capabilities, such as the capacity to drive cars once self-driving cars become commonplace; such a loss in itself need not be problematic, but it may have side-effects on other human capabilities (such as the capacity to make decisions in split seconds, or eye-hand coordination). In this regard, it is important to realise that vulnerabilities do not disappear through technological interventions, but often change in scope or character, and new vulnerabilities arise as side-effects of risk-reducing interventions (Coeckelbergh, 2013). This implies that the contribution of robotics to addressing vulnerabilities cannot be assessed in isolation, looking only at how a certain capability is restored or improved; it should be assessed in its entire context, including the effect on other functions, social relationships, and on society as a whole.

A useful framework for assessing the role of robotics in relation to dealing with human vulnerability is the Capability Approach (see Ch. 1, §4.2), which aims at fostering human flourishing through looking at individuals' actual potential to realise human capabilities. This depends not only on the capability of bodily functioning *stricto sensu* (such as seeing colours or walking) but also on the actualisation of capabilities, which also depends on factors such as the person's mental attitudes or the environment's affordances. This approach reminds us that disabilities are socially constructed, and that using robotics to address human vulnerabilities can never be a matter of generically restoring specific human capabilities, rather of a personalised assessment of what specific individuals need, in the context of how they can flourish with their specific capabilities in their specific environment and given how they wish to live their lives.

This means that there are no general answers to policy questions of which robotics applications should be favoured to address which kinds of vulnerabilities. It is not useful to try to classify robotics interventions as (generally accepted) therapy or as (often contested) enhancement, as the distinction is highly fluid, context-dependent and dependent on individuals' perspectives and assumptions; rather, the question shall be how robotics can contribute to human well-being—but the answer to this question depends on deeply ingrained assumptions about being human and about the role of the state (Lucivero, 2013).

Nevertheless, public policy may have to make choices: which robotics applications to allow and which to stimulate, which applications to discourage and which to prohibit. The complexity of regulatory decision-making can be made more manageable in two ways. First, it helps to have analytic clarity in the discussion. The RoboLaw project has developed various analytic tools that can assist regulators in being conceptually precise and argumentatively sharp in inventorying, analysing, and normatively assessing developments in robotics, such as relevant distinctions in types of human capabilities, types of robotics' impact on human capabilities, and types of human-robot relationships at issue.

Second, robotics regulation should follow approaches that capitalise on the insights gained in the fields of "smart regulation" or "regulatory innovation" and of "responsible research and innovation". Both in regulation studies and in technological innovation studies, scholars have demonstrated the need for self-learning, interactive, multi-stakeholder procedures, using tools of early-warning systems, scenario-building, cyclic procedures (including, for example, mandatory evaluations and sunset clauses), and various methods of stakeholder involvement. A smart procedural approach to regulation has better chances of resulting in legal rules and procedures that are flexible and capable of serving the needs of different groups. This is vital, since the context-dependency of robotics' impact on vulnerabilities and human capabilities requires room for a case-by-case approach to regulation, which allows interpreting substantive (e.g., human dignity,

equality) and procedural (e.g., access to justice, access to technology, fair procedures) principles in light of specific individual capabilities, in specific individuals' personal and environmental context.

5.4 Human enhancement technologies: reframing the debate and policy suggestions

The path of evolution of the debate on human enhancement technologies has been retraced and analysed in all its ramifications. The reflection on the topic begins with pro-enhancement and anti-enhancement conflicting groups and then achieves a more reasonable and complex stance onto the ethical and social issues raised by technology-based visions of the future. For years, the discussion on human enhancement has stalled on unilateral and polarized positions, "transhumanists" v. "bioconservatives" being the most renowned opposition. Over the time, other approaches have emerged, which help to clear some of the conceptual ground without siding with or against. These attempts are of significance and it is important to learn from each rationale and ethical standpoint in order to reach a more sound approach to this theme. Ultimately, the aim of the analysis developed within the RoboLaw project is to go beyond sterile disputes between supporters and detractors of human enhancement.

There are two main difficulties with the current debate.

For one thing, it is coined by a discussion of the ambiguous notion of the "natural". Moreover, constantly the term "enhancement" has been defined in antithesis to "therapy". According to this characterization, enhancement is everything that goes beyond the mere restoration of good health or of a given normal functioning. This implies some assumptions: (a) an objective, medically founded concept of health; (b) a scientific notion of normal functioning. But such a narrow explanation does not even cover all those cases in which therapy produces effects that go beyond the mere restoration of good health or normal functioning.

The second problem is that the debate centres around naïve attempts to speculate about technology-based visions of the future. Recently some scholars, particularly in the European context, have proposed a more articulate concept of human enhancement (Coenen *et al.*, 2009; Coenen, Schuijff, & Smits, 2011), that reinterprets it in a broader sense in order to encompass not just the technical interventions aimed at "enhancing" the person, but the social and cultural dimension as well.

Firstly, we advocate a reoriented debate that can complement and inform ongoing work in the science and society field of research. We should move past the contemporary discussion on human enhancement and go beyond sterile disputes between its supporters and detractors. Human enhancement technologies feed new hopes and create social expectations, make available new tools both for individuals and society, foster threats and concerns, and present risks, that need to be dealt with in a public discussion and not only in academic or expert circles. Experts alone are partial actors for a successful decision-making process. Only a public, democratic debate can develop policies, which allow for an ethical use of enhancing technologies that improve the human condition.

This renewed approach should be informed by a broad interpretation of the notion of "human enhancement" in order to include not just the interventions themselves, but the social and cultural dimension as well. Technologies in fact are not just tools that humans use in order to interact with and experience the surrounding world. They also are means of mediation that shape their world and themselves.

Human enhancement affects society at large. Thus, it requires public debate and stands in need of regulation. Law and ethics are mutually involved in shaping the normative stance towards this phenomenon, which cannot be appraised from a purely technological standpoint.

A common European approach to the topic should be looked for. A policy identified at the European level would ensure consistency with the constitutional common framework and with the precautionary principle as broadly embraced in European science society. The issues at stake are safety and protection of health of European citizens; individual autonomy and human dignity possibly compromised by the risk of indirect coercion, inherent in the more radical versions of the discourse about human enhancement; justice in the access to human enhancement technologies, and of discrimination towards the enhanced-not (see also Ch. 4, §4.3.2-3).

Moreover, European institutions are also interested by the impact that diverse regulations may have on the free flow of goods and services between Member States. In this respect, transnational regulation would be necessary, in order to avoid that restrictive regulation or a ban in one country is weakened by a more permissive legislation in competing countries (Greely, 2005; Coenen, Schuijff & Smits, 2011; Ch. 4, §4.3.4).

Consequently, it would be advisable to develop EU policies on human enhancement that could support national decisions both at the regulatory and at the more practical level, in case hospital ethical committees will be called to decide on a case-by-case basis (see Ch. 4, recommendation 4, c).

5.5 Liability rules as a tool to incentivize safety but also spread desirable technologies

Regulation should be tailored in order to balance opposing interests, but also – once desired policies are identified – taking into account the concrete effects and impacts of the rules on the market, not relying entirely on general assumptions and unverified considerations about their presumed – or expected – consequences.[6]

In this perspective, some rules are of considerable relevance, namely liability rules.

Liability rules by shifting the cost connected with an undesired and harmful event force the wrongdoer to internalize the consequences on others of his actions and choices. Theoretically the adoption of the correct liability rule should *ex ante* induce the socially desirable behaviour, in terms of reduction of number of accidents and increase in safety investments, and *ex post* ensure recovery of the suffered harm by the single individual involved in the action.

In modern market economies next to traditional tort rules, generally applicable to any individual, product liability – and enterprise liability – rules were progressively adopted in order to provide better protection to consumers. These alternative systems, opting for strict liability (objective or semi-objective) standards, are intended at once (i) to ensure higher investment in products' safety and (ii) ease the consumer's position in grounding his claim against producers.

[6] For instance with respect to product liability, empirical studies would be required in order to determine if the desired incentive of an increase product safety is attained, and eventually to what extent and for what cost. Alternative rules may indeed prove more efficient in attaining this sough-after result. See also the considerations of Schellekens, Ch. 2, §4.4, in particular recommendations 2, 4 and 5.

The European solution, represented by the EU Dir. 85/374/EEC on Defective Products (henceforth DPD), is in this respect not so different from the North American one, as emerging from the Restatement (in particular Rest. 3rd on Torts: Product Liability, see (Owen, 2008)).

Both, the European and North American systems, have although been criticized for their overall effect. While the increase in safety standards cannot be substantially appreciated (Ch. 4, §4.2.5) such regulations in some cases produce a technology chilling effect (Ch. 2, §4.3), and in some cases raise the costs of compensation (reducing the percentage per euro invested that is used to make the victim of the accident whole).

Such effect could in fact delay or radically impair the development of at least some robotic technologies such as driverless vehicles and prostheses. In particular, with driverless vehicles the number of factors an automated system needs to take into account (street rules, other vehicles on the road, passers-by both abiding and violating the street code, complex environment) is quite relevant. Therefore, while it is conceivable that once technology has sufficiently advanced to produce a truly autonomous machine, producers may even feel safe assuming liability for all accidents caused, imposing a strict standard of liability on the producer in-between – before such level of product sophistication is reached – may discourage the very development of that technology (Ch. 2, §4.3).

A similar kind of reasoning can be extended to prostheses, where the complex interaction of brain and machine represents one major obstacle, together with the unlimited number of ways in which the artificial limb may be used. The producer is therefore exposed to all the harmful consequences the malfunctioning of the limb may lead to, which are potentially unlimited and extremely hard to assess ex ante, with similar discouraging effects on the development of this kind of applications (Ch. 4, §4.2.2)

The conclusion to be derived from this consideration is though not that all robotic applications should be – equally – favoured. Distinctions need to be made that do not rest – at least not entirely nor mainly – on technical considerations. It is thus not the autonomous nature of the machine that calls for the modification of existing rules, rather its social desirability, and therefore an actively assumed policy decision. Theoretically this entails admitting the possibility for governments to identify and chose the kind of technology they want to favour and adopt corresponding and coherent incentives; within the market perspective depicted above it means affirming the relevance of constitutional values and the protection of the individual as a priority (see §2-3).

At the same time, the solutions conceived for different – classes of – applications may be different. In some cases – for instance driverless vehicles – it may be ascertained – possibly through both theoretical and empirical analysis – that a correctly functioning insurance system counterbalances the possible shortcomings of applicable rules (see Ch. 2, recommendations n. 2, 3). In other cases instead – prostheses –, the adoption of a liability exemption – eventually coupled with an alternative compensation scheme for victims – may be considered a preferable solution (see Ch. 4 recommendations n. 3(d) and (e)).

It shall also be stressed that similar considerations do not entail accepting higher levels of risk or less safety investments in product development (Wallach, 2011), quite the contrary. Since it may be argued – at least in some cases – that the current system does not provide – adequate – incentives, alternative solutions may be considered, that eventually disentangle the issue of safety from that of compensation. Said otherwise, under certain conditions the fixation *ex ante* of high –

and narrow tailored – technical standards (which could be developed by competent technical bodies such as ESOs, see Ch. 4, recommendation n. 3(a)) the producer has to conform to before the product can be released onto the market, may provide sufficient indications on how to design safe devices. At the same time, the compensation of the – still inevitable – victims may be addressed through rules, whose primary objective is precisely that of distributing – socializing – a cost, rather than punish the violation of a desired standard (see Ch. 4, §4.2.6).

In any case the decision ought to be grounded on the weighing of all the mentioned factors – a technology push perspective on the one hand and safety on the other hand – in light of and pursuant to the prevailing social values and constitutional interests – desirability of the given technology –, which root the entire European system (see §3).

5.6 May we generalize some of the recommendations?

The field of robotics is too broad, and the range of legislative domains affected by robotics too wide, to be able to say that robotics by and large can be accommodated within existing legal frameworks or rather require a *lex robotica*. For some types of applications and some regulatory domains, it might be useful to consider creating new, fine-grained rules that are specifically tailored to the robotics at issue, while for types of robotics, and for many regulatory fields, robotics can likely be regulated well by smart adaptation of existing laws.

RoboLaw, by adopting a case study approach (see Ch. 1, §7), has attempted to identify possible recommendations and considerations, which address that problem directly. Time after time, we attempted to shed some light on those aspects that we thought might provide grounds to suggest the adoption of alternative standards and rules, differing from those otherwise applicable. For the same purpose, we have formulated broader policy considerations, which we believe should be taken into account when regulating robotic applications.

The question may though be asked, whether our conclusions and recommendations are so peculiar that may only apply to those sets – and classes – of applications that we have expressly considered and discussed, or may be – at least in some cases – further generalized.

There is no universal answer to this question, which is the precise reason why a case study approach was originally adopted, and yet some clusters of themes and considerations may be identified.

Liability certainly represents one of the most relevant and recurring themes. The considerations made in different chapters with respect to the overall technology chilling effect they may produce probably may be easily extended to other applications that were not openly discussed within RoboLaw, although the consequences that may be derived substantially differ.

While for driverless vehicles (Ch. 2) the analysis brought us to consider that the insurance system may prove to be a viable solution to the problem identified, it is disputable that the same conclusions may easily extend to other forms of vehicles (such as drones operating both in the air and sea) that still are not constantly supervised by a human being. The issue they raise, both for the technological characteristics they present, and the social relevance and – potential – diffusion they may have, leads us to conclude that the solutions proposed cannot be automatically extended.

The opposite conclusion may instead be reached with respect to prostheses (Ch. 4). Orthoses and exoskeletons, by serving a similar purpose as that of prostheses, may be deemed as desirable, and responding to the same social need. For these grounds the alternative liability

standards, which have been proposed for the purpose of facilitating their emergence in society, may well be extended to include even those devices, as well as others already existing and diffused such as cochlear implants.

Computer integrated surgical systems (Ch. 3) may be comprised in a wider class of robots used in medical treatment, and therefore the conclusions reached in particular with the possibility to exclude direct action to the patient against the producer may serve the same valid purpose of avoiding that all medical liability litigation is at some point shifted against producers of robotic devices used in healthcare. The necessity to favour the emergence of new players on the market for such products may as well prove to be a decisive argument.

Care robots instead (Ch. 5), for the peculiar function they serve, do not easily allow to extend the conclusions reached for instance with respect to long-term care insurance contracts to other kinds of robotic applications.

Finally, leaning more onto the ethical side of the analysis, we may conclude that the issue of human enhancement is indeed much broader than the specific aspects that have been here directly addressed. Nonetheless, both the policy considerations and recommendations, suggesting that an open and aware debated is started and overall a precautionary approach adopted, may easily be extended to cover also those forms of human enhancement through genetics and pharmaceutical products, that indeed are of great relevance and deserve particular attention and further efforts of understanding and rationalization.

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