THE CHALLENGE OF INNOVATION IN LAW

The Impact of Technology and Science on Legal Studies and Practice

AMEDEO SANTOSUOSSO, OLIVER R. GOODENOUGH and MARTA TOMASI (Eds)

Law, Sciences and New Technologies 1

PaviaUniversityPress

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Law, Sciences and New Technologies

Open Access Series of the Interdepartmental Research Centre
European Centre for Law, Science and New Technologies (ECLT)
University of Pavia

URL: <http://www.paviauniversitypress.it/collana/LSNT/17/>

Texts published in the series "Law, Sciences and New Technologies" have been peer-reviewed prior to acceptance.

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The Challenge of Innovation in Law : the Impact of Technology and Science on Legal Studies and Practice / edited by Amedeo Santosuosso, Oliver R. Goodenough and Marta Tomasi. – Pavia : Pavia University Press, 2015. - XVI, 296 p. ; 22 cm.
(Law, Sciences and New Technologies ; 1)

http://purl.oclc.org/paviauniversitypress/9788869520075

ISBN 9788869520068 (brossura)
ISBN 9788869520075 (e-book PDF)

ISBN: 978-88-6952-006-8

eISBN: 978-88-6952-007-5

UPI UNIVERSITY PRESS ITALIANE

Opera sottoposta a peer review secondo il protocollo UPI

Peer reviewed work in compliance with UPI protocol

First edition: July 2015

Pavia University Press – Edizioni dell'Università degli Studi di Pavia
Via Luino, 12 – 27100 Pavia, Italia
http://www.paviauniversitypress.it – unipress@unipv.it

Printed by DigitalAndCopy S.a.S., Segrate (MI), Italy
Printed in Italy

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Innovating about Innovation: An Explanation and an Introduction

Amedeo Santosuosso, Oliver R. Goodenough, Marta Tomasi

1. Law is changing

Law is not static. Although both specialists and society as a whole often act as if it is an un-changing monolith, any rational commentator must note that law has evolved over time. Changes do occur, in doctrine, in procedure, in jurisprudential understanding, and in legal education. The factors which drive innovation in law include social transformation, cultural change, and, importantly, the technological possibilities of the times for creating, storing and applying legal information. New technologies can also require new doctrinal developments. As this volume will illustrate, for instance, the advances of robotics are forcing us to enumerate a new doctrine of robo-law.

Such changes often do not come easily for the legal system. The myth of stability is maintained in part because the acceptance by the public rests on this assumption. It remains a myth, nonetheless. The noted American judge and legal scholar Jerome Frank wrote, in his book *Law and the Modern Mind*:

> Even in a relatively static society, men have never been able to construct a comprehensive, eternized set of rules anticipating all possible legal disputes and settling them in advance. [...] How much less is such a frozen legal system possible in modern times. New instruments of production, new modes of travel and of dwelling, new credit and ownership devices, new concentrations of capital, new social customs, habits, aims and ideals – all of these factors of innovation make vain the hope that definitive legal rules can be drafted that will forever after solve all legal problems. (Frank at page 6)

This self-proclaimed "modern" understanding was published in 1930. The sources of change which Frank enumerates have only proliferated and accelerated as we move into a world of synthetic biology, neuro-imaging, robotics, and digital computers. Notwithstanding its inherent dynamic of conservatism, and the personal commitment to traditional modes of thought by lawyers, judges and legal academics, law is changing.

The response to change can be reactive, trying to keep up after the fact with bursts of unreflective improvisation, or it can be proactive, with an eye toward intelligent analysis, planning and invention. This later strategy is a true process of innovation, where human intelligence helps to shape the new world ahead of us, with the potential to create better juridical tools and better social outcomes as the process of change rolls forward. This book is about legal innovation; our hope is that it can both spark a purposeful conversation about change in legal practice and legal education and also provide some suggestions on the way that those changes might be more successfully envisioned and implemented.

2. The case for Darwinian adaptation: how this book came to be written

This book, together with the course established at the University of Pavia on *Innovating Legal Studies and Practice*,[1] is one of the principle outcomes of a two-year project funded by *Cariplo Foundation* (Milan).[2] The project, as conceived, was very ambitious from both the theoretical and educational point of view – a number of young scholars were to have been recruited in order to work on the specific issues.

The theoretical aim was to verify how and if science and technology may offer tools in order to improve the law making process; the exact title was *Applying Research from Science and Technology to Improve the Law Making Process*.

The basic assumption was that contemporary regulatory systems are increasingly inefficient and unable to respond adequately to the challenges of our times and that these challenges are all, directly or indirectly, referable to the current incremental scientific and technological progress. In the field of law, the crisis of outdated theoretical models, based on the foundation of national states, is evident. The traditional system of normative sources allowed the legal system organized within a national state to establish an order of stable rules to govern the case to be decided. Today, however, this order is extremely various, changeable, controversial and, sometimes, unclear even within the same geographical area, international organization (e.g. the European Union) or national state.

Although the problem is common to all fields of law, the law of emerging technologies (such as biotechnologies, neurosciences, nanotechnologies and

1 A report on the course is offered in the Chapter by Maria Laura Fiorina and Giulia Spinoglio.

2 More information at URL: <http://www.fondazionecariplo.it/en/index.html> [last accessed: 09/05/2015].

computing and other informational technologies), and law and economics are particularly troubled fields. These areas of activity have an underlying structure of universality inherent in both their technologies and the economics of their production and use. They also frequently encompass transnational players and events.

The project stresses that the legal regulations of conflicts arising from these areas very often have both a local/national and a transnational dimension. Conflicts arising in the field of cloud computing, for instance, implicate a number of different jurisdictions and rule sets. Finding and applying rules with application across these varying dimensions involves an intense exchange between national systems and supranational levels and entails the coexistence of different languages, with serious problems of legal communication (legal multilingualism).

Our idea was that science and technology are both a cause of the problem (given the speed and transnational nature of scientific progress) and the source of a remedy for understanding and managing the present situation. There is a need to reconcile the expression of legal institutions that have developed in different languages, cultures and cognitive traditions. There is also the opportunity of bringing new modes of conceptualization drawn from science and technology to this task. Identifying the barriers to this reconciliation and providing both modes of an analysis and technological tools that will help to remove those barriers was the work of the proposed project.

We were aware that bringing scientific approaches to law is not simply a matter of imitation. Law should discover that it is less different from science than traditional legal scholarship has taught us and that it has several basic theoretical questions in common with science. At the theoretical level, the project aimed at drawing on developments in the understanding of institutional and mechanism design to help model both the dilemmas of productive sociality and the solutions that are available for instantiation in institutions like the law.

As for the need to overcome the challenges of multilingualism for the transnational exchange of legal institutions, the project proposed the use of an innovative experimental tool, a database collecting caselaw and legislation in the field of science and law: the Multilingual Archive on Law, Science and New Technologies (ALST), an ICT Platform, partially already existing. Meeting the linguistic challenges of transnational law-making through a technologically based experimental methodology has been one of the principal goals and innovations of the whole project.

Thus the two main innovative aspects of the project were: a) the integration of legal concepts and models with those of science and technology to produce a new methodology that can inform a better approach to law making; and b) testing theoretical hypotheses about legal institutions on a multilingual database of cases and materials, that works both as a legal laboratory bench for empirical tests and as a multilingual tool that will be offered to legal community and society as a whole.

As originally conceived, the educational plan was that two researchers (to be recruited with a research contract) were to be added to the existing PhD students already having a scholarship. The project was based at the interdepartmental research center, *The European Centre for Law, Science and New Technologies* (ECLT), and coordinated by Professor Oliver R. Goodenough and Professor Amedeo Santosuosso.

As with many human endeavors, our actual possibilities have been constrained by our resources. For many reasons (totally not depending on the *Cariplo Foundation* nor on the ECLT at UNIPV) the funds available were around one fifth of the original budget set when we envisioned the project.

At that point the Darwinian adaptation played a major role. Clearly we had to change (innovate?) some important parts of the project, and thus we reshaped our plans for the program, focusing on *Innovation in law.* Our principal actions included:

- we confirmed the main theoretical pillars of science-technology-law and multilingualism;
- we confirmed the Archive ALST as one of the main assets of the ECLT and of the project;[3]
- we decided to take advantage of the great interest of judicial institutions in Milan to contribute to a very original (the first one in Italy and in the EU) project of experimental teaching to students innovative theories of law, giving them a practical grounding in some important technologies in law. This resulted in the ILSP course;
- we decided, finally, to take advantage of the existing group of young researchers at the University of Pavia that have coalesced over the years of Amedeo Santosuosso teaching and researching at the University of Pavia and the Center ECLT.

We asked this group of people not to change their own researches in progress (as we were not able to fully fund them). Rather we asked them to look at

[3] The project was nominated for the *Innovating Justice* competition in 2013, more details at URL: <http://www.innovatingjustice.com/innovations/legal-information-querying-across-different-languages> [last accessed: 10/05/2015].

their research fields with the eyes of innovation in law. They responded with great interest, actively participated to the seminars given by Oliver R. Goodenough and Amedeo Santosuosso, presented and discussed some of their researches and, day by day, discovered the importance of a wider point of view in their work. On the other side, we involved a group of talented law clerks in the Court of Appeal of Milan in tutoring students in the course ILSP and invited them to develop in this book a wider reconsideration on the training process of young lawyers in Italy.

We believe that the result, shared in the volume, is interesting and useful. We are able now to present the work of this network of young scholars (belonging to a number of Italian and EU institutions), who have experimented the possibility to carry on specific researches in law without losing the bigger picture of what is at stake, the role of science and technology in our society. They have shown the importance of the law to discover the deep connection it has with the main conceptual background of science and technology.

3. The contents of this book

This book aims at analyzing the impact of innovation on law. This kind of objective is clearly two-fold: on the one side, innovation invests the way law is created, managed, and applied. On the other side, the emersion of new technologies calls for a reshaping of existing legal norms, either by means of an evolutionary interpretation of them or, in some cases, through and abandonment of old-fashioned anachronistic sets of rules, unable to answer challenges coming from the innovated reality.

In accordance with the description of these two paths of innovation, radically changing the face of the law, the book is divided into two parts.

The first one offers a general overview on the systemic, technologically-driven change law is going to face in the next few years.

The idea is that of offering a key for reading current and future trends of innovation (as described, in part, in the three-stage framework offered by Oliver R. Goodenough), in order to oppose the "long-lasting reluctance of legal academy and professionals to recognize and face some occurring changes in law today" (Amedeo Santosuosso). The *leitmotiv* of the book is the relationship between law and technology and the cross-fertilization between entities that cannot be considered as clearly separated and mutually independent. Such an approach allows our authors to detach themselves from views interpreting technology as a tool and law as a mere technique. Rather, they seek to understand how, with both of them embedded into reality, law and technology together represent the environment in which we live. The "technological side" is nowadays part of the very nature of law, of its essence. Technology gives a privileged viewpoint to understand how law lives in reality, how it moulds reality, and how it is shaped by it.

A clear example of this is how AI has been increasingly transforming the law and the legal reasoning and how predictive technologies and complexity measurement tools can represent reliable means to overcome the "complexity swamp" of the contemporary conception of law (Alessandra Malerba).

Even if something is moving forward, the aspect of law apparently more affected by resistance and opposition against innovation is legal practice. In particular, one of the main challenges in Italy, in Europe and worldwide is that of understanding how jurisdictional IT can transform jurisprudence. A few legal systems are opening trial mechanisms, traditionally based on paperwork, to the wind of change through legal process automation.

An evolution of the judiciary's attitude toward the way we practice, interpret and apply the law entails a full process of cultural change, not merely a procedural one. Successful advancement in this field passes through the construction of a fresh and novel mind-set based on a strong collaboration between justice professionals and users, representing the real guide towards innovation (Enrico Consolandi, Pietro Consolandi).

And if it is true that everything starts from the beginning, education is a cornerstone of this book. To provide present and future students with a profitable, "fit-for-purpose" education, law schools have to consider the way technology is shaping legal practice as a priority.

In accordance with the practical approach of the book, two Italian experiences are described as possible answers to the challenges stemming from innovation processes.

One is represented by judicial clerkship, introduced by the Italian legislator in 2013, as an opportunity for boost preparation and competencies of young legal professionals in order to access the job market. In a bi-univocal perspective, based on the intention of filling the existing gap between the university education and the work as professionals, students can benefit from the incentives coming from the vivid and challenging court environment, while the whole judicial system can take advantage from young lawyers' energetic and dynamic contribution (Maria Eleonora Benini, Chiara Colicchia, Federica Fazio).

The second cutting-edge experience is described through an overview of the contents of the new born "Innovating Legal Studies and Practice" course, added in November 2014 to the curriculum of the Law Department of the University of Pavia, providing students with theoretical and practical insights into the meaning of being a lawyer today (Maria Laura Fiorina, Giulia Spinoglio).

Following the first part, dedicated to how technology is affecting the general legal theory and practice, the second part of the book is composed of contributions focusing on specific areas of the law deeply affected by technologies and on concrete consequences, within defined thematic areas, of the innovative trends described above.

The proposed overview encompasses both traditional fields of law and futuristic scenarios which, being not too far away in time, deserve current exploration. The analysis of the first stages of innovations gives a starting point for our discussions.

As a matter of general example, the gigantic dimension which the Internet is assuming in all aspects of life is driving an evolution of private subjects' role in society and, in particular, of Internet intermediaries. These are defined as subjects who mediate online communication, enabling various form of expression and easing transactions between parties on the Internet. Such entities can certainly contribute to the development of democratic movements but they simultaneously hold the technological power to heavily influence users' rights. Law has therefore to reflect upon this emerging role of private actors in order to properly identify duties and responsibilities and to ensure a full protection of individual rights (Maddalena Neglia).

More specifically, the revolutionary strength of technology can be fully appreciated in one of the most traditional fields of the law: the regulation of employer/employee relationships. The introduction of new technologies in the workplace challenges the role of law within the so-called Industry 4.0, characterized by the rise of smart production systems, smart logistics, and acceleration through exponential technology. This trend is eroding the boundaries of workplace and workday. Since rapid innovation is becoming one of the main interests of companies, law has to play its role in striking a proper balance between fostering the development and renovation of the industry and, at the same time, protecting workers' rights with the most flexible and accurate regulations (Barbara Bottalico).

Another very traditional set of rules can be challenged by a technology-driven revolution: neuroscience holds the future promise for the evaluation of witness testimony and the possibility of detecting deception. Federica Coppola adopts a prospective view that temporarily sets aside unresolved elements about the scientific validity of the described techniques. Her analysis anticipates that once these are solved, the law will need to take account of the emerging threatens to witnesses' cognitive and moral liberties, as well as to the privilege against self-incrimination. She sketches a potential normative framework which might plausibly regulate the use of these techniques in full compliance with witnesses' procedural and substantive rights.

Turning to topics where the impact of technologies is even more intuitive, further challenges come from the need to regulate the biomedical field, where law is once again torn between the need to allow scientific progress and the necessity to protect human rights. Two different approaches are offered, both reflecting on the role of patents, on the structure of their regulations and on the effects of their interpretation with the aim of balancing, in a reasonably flexible manner, biotech medicine, scientific research and moral rules (Carlo Colombo and Avgi Kaisi).

Among emerging technologies a relevant position is occupied by synthetic biology. Such a controversial discipline offers law the chance to inaugurate a fresh approach aimed at avoiding both irrational fears and a complete abandonment to hype and hopes. The equilibrium point between delayed legal interventions in front of new technologies and hypertrophic attitudes can be found in a reasonable "prudent vigilance" approach, entailing "an ongoing and periodically revised process of assessment and management of all the risks and concerns, taking into account the interests of all the stakeholders in a dynamic, cooperative, democratic, open and transparent manner" (Ilaria Anna Colussi).

The same approach, based on a critical observation of reality and its developments, is suggested with reference to another promising technology application. The possible implementation of whole-genome sequencing techniques in newborn genetic screening is a further example of how new technologies are augmenting complexity in society and in the law today. Dealing with the sheer amounts of data to be governed over times determines a stretching in space and time of traditional rights and interests, calling for a full understanding of the object to be regulated (Marta Tomasi).

Two more chapters are dedicated to the field of robotics, presenting features so peculiar to be considered as innovation itself. Robotics, progressively taking more and more importance in the future of our societies, is intrinsically different from every other previous technology, "since it combines data information with the presence in the real world and the capacity to perform physical actions which cannot be completely predetermined" (Chiara Boscarato). There is a strong need for investigating difficulties in accepting machine having human-like properties and high level of intellectual abilities with the aim of identifying the impacts relationships between human beings and machines can have on the law in different fields (Paola Giulia Belloli).

The book, addressed to academics, professionals and students, aims at inspiring critical reflections about theoretical and practical interplays and synergies between innovation and the law. Although most of our contributors are Italian, and the work is the product of an Italian initiative, we have nonetheless chosen English as the language for our contributions to this book. We have done so in recognition that, for the moment at least, English is a more widely understood basis for exchanging ideas in the globalized world of legal scholarship.

In addition, our work on Innovation in law (mainly the course on Innovating legal studies and practice, ILSP) is the result of a cooperation also with other Italian and European academic institutions. We are presently working on the project of an International Network on Innovation and Law and, in this light, English can help again.

4. Acknowledgments

This book and all the activity of the project is the result of the cooperation of many actors. We want to express our gratitude to the University of Pavia as a whole, whose Rector, Professor Fabio Rugge, personally and through the Delegate to research, Professor Stefano Govoni, has always encouraged the project and the initiatives in the field of Science and Law. Needless to say, the Pavia Department of Law, in the persons of the Director, Professor Ettore Dezza, and of Professors Cristina Campiglio, Sergio Seminara and Giampaolo Azzoni, has constantly offered support, advice, organizational help and encouragement.

We want to express our personal gratitude to Professor Belvedere, who, in his quality of one of the founding fathers of the research center ECLT and of Rector of the *Collegio Ghislieri* (Pavia), has been the safe harbor when difficulties of any kind have put our activity at risk. The *Collegio Ghislieri* has contributed to the project and particularly to the progress of the Archive ALST. It is also co-organizer of the ILSP course. On a personal level, Professor Belvedere has helped and advised in all academic and organizational passages.

On the judicial side a special thank has to be given to the Chief Justices of the Court of Appeal of Milan, President Gianni Canzio, and of the Tribunal of Milan, President Livia Pomodoro, and the past President of the Milan Bar Association, President Paolo Giuggioli (who sadly died few months ago). Their enthusiasm in supporting the idea of bridging the judiciary, the bar and the academy is something of great value. We need more people like them in

order to look at the future with a wise dose of optimism and without being blocked by the fear of being considered as disrupters.

Finally, we want to express our great gratitude to the *Cariplo Foundation* for funding a research project, which has been not only successful from a scientific and educational point of view, but also a wonderful occasion for strengthening the cooperation and friendship of an emerging group of young scholars, who, with their enthusiasm and intellectual richness, have made all this possible.

PART I.
Innovating the Thinking and Practice of the Law

Getting to Computational Jurisprudence 3.0*

Oliver R. Goodenough

1. Introduction

The impact of technology on law is moving forward with all the subtlety of a charging rhinoceros. Legal tech is transforming the methods of traditional practice, spawning new forms of "legal service" delivery. Technology companies showcase their wares at trade shows like LegalTech in New York and San Francisco, the ABA TECHSHOW in Chicago, the British Legal Technology Forum in London and LawTech Europe Congress in a variety of cities across the continent.[1] The hubbub is getting the attention of players as diverse as judges, practitioners and venture capital investors.

Legal education, whether in the US, Europe, or beyond, often sits at the tail-end of actual legal developments. Law professors who have made their reputation in established knowledge too often have little incentive to tackle the new. And younger scholars are all too often beholden to the prejudices of the senior academics who can control their fates. But even university legal faculties are waking up to the onrushing colossus. The European Centre for Law, Science and New Technologies at the University of Pavia, which is the sponsor of this volume of essays, may be one of the locations that is out ahead on the topic, but it is not

* This essay draws on material previously published by the author, including Legal Technology 3.0, Huffington Post, February 4, 2015, [online], URL: <http://www.huffingtonpost.com/oliver-r-goodenough/legal-technology-30_b_6603658.html?utm_hp_ref=tw> [last accessed: 26/04/2015] and Justice Holmes, Meet Dr. Turing: Law is Computation, Huffington Post, May 7, 2015, [online], URL: <http://www.huffingtonpost.com/oliver-r-goodenough/justice-holmes-meet-dr-tu_b_7233772.html> [last accessed: 08/05/2015].

1 For information on these events, see: LegalTech, URL: <http://www.legaltechshow.com/r5/cob_page.asp?category_code=ltech> [last accessed: 08/05/2015]; ABA TECHSHOW 2015, URL: <http://www.techshow.com/> [last accessed: 08/05/2015]; British Legal Technology Forum 2015, URL:<http://britishlegalitforum.com/> [last accessed: 08/05/2015]; and LawTech Europe Congress, URL: <http://www.lawtecheuropecongress.com/> [last accessed: 08/05/2015].

unique. In the United States, Stanford's CodeX Center for Legal Informatics, Harvard's Berkman Center for Internet & Society, and Vermont Law School's Center for Legal Innovation are just a sampling of the institutions pushing into the field (selected here because the Author has worked with each of them).

Disappointingly, much of the commentary, particularly by academics, has a backward looking perspective, as though all of the swirling events will just enhance the existing system, leaving it essentially intact, but with certain processes improved. This view is short sighted. If the experience of other fields undergoing the effects of technological innovation serves as a guide, systemic change is around the corner – think of it as Computational Jurisprudence 3.0. This Chapter will first suggest a three-stage framework for considering such changes, and will then explore the economic and computational characteristics of those stages. It will draw principally on sources and activities in the United States, not because there are not interesting examples in Europe and elsewhere around the globe, but because the author is a legal academic based in the United States, and is most familiar with developments there.

2. Stages in technologically driven change

History suggests that the course of technological change for an industry can often be usefully broken down into three stages. The now clichéd, but still useful, terms of 1.0, 2.0 and 3.0 can apply. In 1.0, technology *empowers* the current human players within the current system. In 2.0 it *replaces* many of the human players within the current system. In 3.0 it *overturns* much of the current system and replaces it with something else.

2.1. Legal technology 1.0

In the first stage, 1.0, *technology empowers the current human players within the current system*. For law, many legal tasks get better, faster, and cheaper. Think of computer assisted legal research, now conducted through LexisNexis,[2] Westlaw,[3] Justia.com,[4] etc. Think of computer assisted document production, accomplished through WordPerfect and Word. Think of computer assisted

[2] See Lexis Advance, LexisNexis, URL: <http://www.lexisnexis.com/en-us/products/lexis-advance.page> [last accessed: 08/05/2015].

[3] See WestlawNext online legal research, Thompson Reuters, URL: <http://legalsolutions.thomsonreuters.com/law-products/westlaw-legal-research/> [last accessed: 08/05/2015].

[4] Justia, URL: <https://www.justia.com/> [last accessed: 08/05/2015].

practice management, facilitated with Clio[5] and Time Matters.[6] Think of first stage e-discovery, before predictive coding, enabled by Recommind[7] and Symantec.[8] All of these applications improved what we already did as lawyers and, as often as not, created more legal work, as an arms race of deployment raged. Powerful search tools prompted more extensive supporting citations, not less work. The proliferation of discoverable content made firms hire more associates to pour over the increased elements in the record. Lawyers have pretty fully implemented legal technology 1.0. Tech companies are still developing useful tools and redesigning existing tools as mobile apps, but the market is well developed and its impact largely digested.

2.2. Legal technology 2.0

In the second stage, 2.0, *technology replaces an increasing number the human players within the current system.* Technologically driven legal innovation is becoming disruptive, and not just enabling. Law practice is part way into this new phase. In e-discovery, for instance, predictive coding and other machine learning approaches are subtracting many of the lower-level document review jobs that the 1.0 stage created. Drafting software makes partners more productive, eliminating associate jobs in small firms. Analytic services like Lex Machina[9] are replacing the specialized judgment of experienced lawyers with the insights of big data. Companies like Exari[10] are marrying word-processing with expert systems to create contract document assembly systems that non-lawyers can operate in the field. Sales representatives in the field can conclude deals without review by the dreaded (and expensive) "suits" in the legal department.

On a less immediately threatening level for the legal status quo, the extension of legal knowledge and services through technology-enabled interfaces empowers many who can't (or won't) afford legal representation in a tradi-

5 Clio helps lawyers build a better practice, URL: <https://www.goclio.com/> [last accessed: 08/09/2015].

6 Time Matters® Client, Case and Document Management Software, Law Firm Practice Management, URL: <http://www.lexisnexis.com/law-firm-practice-management/time-matters/> [last accessed: 08/05/2015].

7 Recommind, URL: <http://www.recommind.com/> [last accessed: 08/05/2015].

8 Symantec eDiscovery Platform powered by Clearwell, Symantec/Enterprise, URL: <http://www.symantec.com/ediscovery-platform/> [last accessed: 08/05/2015].

9 Lex Machina, URL: <https://lexmachina.com/> [last accessed: 08/05/2015].

10 Introducing Exari Contracts Hub, URL: <http://www.exari.com/> [last accessed: 08/05/2015].

tional way. As Clayton Christensen points out in his widely cited work, disruptive innovation often first flourishes in the "bottom" of the marketplace.[11] At the consumer and public service level, cheap and even free legal advice/drafting is already with us. Some providers are commercial services like the well-established LegalZoom[12] and Rocket Lawyer[13] and the upstart Shake.[14] Others are public minded non-profits like CALI,[15] or a government provider like Nevada's Silverflume LCC operating agreement.[16] Some argue that a combination of humans and machines using services like these can extend the affordability of lawyers and create more overall activity in the process. The lawyer as paid-help-desk-supplementation is now built into both Rocket Lawyer's and LegalZoom's platforms. Whether the expanded market actually makes up for the diminished role is an open question.

The logical extension of legal technology 2.0 is that law often becomes a free utility in a larger service platform. Good expert systems can be expensive to set up, but they can also be cheap to run and scale. Google offers its highly capable search system to users for free in order to bring them to a platform where the company makes money in other ways – principally by selling access to the eyeballs of those users to commercial advertisers. One can imagine a world where many aspects of law are treated similarly. Some company will automate and offer basic legal elements of a domestic real estate transaction, contracting, deed, title, and other legal products as a "free" service of the broker handling the underlying deal.

In a world like this, the traditional notions of the law as a regulated professional activity, carried on as an artisanal activity by licensed attorneys, loose much of their justification and come under sustained attack. The disciplinary rules that govern the professional model are circumvented or bend and break. The new category of "legal service provider", pioneered by companies like Axiom Law[17] and

11 Disruptive Innovation, Clayton Christensen, URL: http://www.claytonchristensen.com/key-concepts/ [last accessed: 08/05/2015]; see Christensen (1997).

12 Legalzoom, URL: <http://www.legalzoom.com/> [last accessed: 09/05/2015].

13 ROCKETLAWYER, URL: <https://www.rocketlawyer.com/> [last accessed: 09/05/2015].

14 Shake, URL: <http://www.shakelaw.com/> [last accessed: 09/05/2015].

15 CALI: The Center for Computer-Assisted Legal Instruction, URL: <http://www.cali.org/> [last accessed: 09/05/2015].

16 SilverFlume: Nevada's Business Portal, URL: <https://www.nvsilverflume.gov/home> [last accessed: 09/05/2015].

17 Forget everything you thought you knew about legal services, URL: <http://www.axiomlaw.com/> [last accessed: 09/05/2015].

Novus Law,[18] comes of age. Maintaining principles such as competence, trustworthiness, and confidentiality is important; the means for accomplishing this may look very different from our current rules.

Legal tech 2.0 is frightening to the incumbent providers whose economic base it threatens. On the other hand, it is probably welcome to its consumers. Desired or not, it is still embedded within the existing system. The current web of natural language rules and contracts, the court-based adjudication of disputes, and the legislative/regulatory state remain largely intact. Jurisprudence evolves, but does not radically shift. This is not the end of the process, however.

2.3. Legal technology 3.0

We are fast approaching a third stage, 3.0, where *the power of computational technology for communication, modeling and execution permit a radical redesign, if not a full replacement, of the current system itself*. Fed Ex speeds up the delivery of a letter; faxing makes delivery almost instantaneous without a human delivery agent. E-mail and text messages replace letters completely. In the law, it turns out that computer code is considerably better than natural language as a means for expressing the logical structure of contracts, regulations, and statutes. Laurence Lessig's now classic insight that "code is law" has literal validity (Lessig 2000 and Lessig 2005).

If the United States Internal Revenue Code or its Clean Air Act were embodied in code as their original mode of enactment, a good technological parsing engine (rather than the limited biological parsing engine of a lawyer's brain) could give advice on compliance quickly and cheaply. But, in a true 3.0 environment, both of these legal domains probably reshape themselves around somewhat different questions and outcomes. Technology can drive jurisprudence. Stated in computer code, complicated consumer credit transactions become transparent to a consumer with a good outcome "dashboard", perhaps run by the US Consumer Financial Protection Bureau.[19] Regulatory compliance could be built directly into computational objects like a "smart security", which would keep track of its ownership and the applicable trading rules. Online dispute resolution could look significantly different from

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[18] NOVUSLAW the Measure of Certainty, URL: <http://www.novuslaw.com/> [last accessed: 09/05/2015].

[19] CFPB Consumer Financial Protection Bureau, URL: <http://www.consumerfinance.gov/> [last accessed: 09/05/2015].

current courts, as the offerings of Modria[20] already demonstrate. Aspects of computational jurisprudence 3.0 sound a bit like science fiction, but so did the functionality of a smart phone a few years ago. The conceptual and technological pieces for radical redesign are falling into place. Even the traditional and conservative field of law will innovate at the systemic level when world changes. The pace and shape of this change, however, will be shaped by factors that include both the economic and computational characteristics of the stages. This remainder of this essay will examine these two domains and their likely effect on the stages of computational jurisprudence.

3. The economics of computational jurisprudence

Each of the three stages suggested here for the incorporation of technology into the practice, delivery and specification of law has a different economic structure. Neo-classical economics emphasizes a focus on *incentives*, or the potential of outcomes to provide attractive rewards as understood by a near-term, benefit maximizing, rational actor. In this essay, I will also look at the *capacities* of a system to generate and effectuate change, looking at characteristics like network effects, generativity, and strategic and institutional structures. The difference between incentives and capacities may be illustrated by my desire to fly without mechanical assistance. There are huge incentives for me to be able to take flight like a bird; the monetary rewards if I could leap into the air and flutter would clearly be in the millions. Unfortunately, in my current human body form I simply lack the capacity to make that happen.

Network effects emerge when a particular practice or product must interact positively with similar items used by other actors. Deciding that Italian is a superior language to English might be a rational evaluation; deciding to use Italian as the means of taking an American history examination in a US high school would probably lead to complete failure as a matter of network limitations. Generativity is a somewhat different limit.[21] It reflects whether the rules and structures of a system have the capacity to allow the construction of outcomes not anticipated when that system was put in place. Contract and corporate law are generative. We can create many new structures of obligation and finance. Prohibitions against Genetically Modified Organisms are

[20] Modria, URL: <http://www.modria.com> [last accessed: 09/05/2015].

[21] For a more developed discussion of the concept of generativity in the context of law, see Goodenough (2015) and, generally, Zittrain (2008).

non-generative in that they forbid the unforeseen outcomes of such modification – both for good and ill. The strategic structures of a set of possible developments reflect the potential for defection and abuse that exist, and which can inhibit a party from going forward with a transaction that might be beneficial. Legal institutions like contract, property, and consumer protection can help to modify those structures to make a productive outcome likely for all parties, and thus lowering barriers to going forward.

3.1. Stage 1.0

The economics of stage 1.0 are quite favorable to its occurrence. From an incentive standpoint, the principle actors in the legal system – lawyers, judges and lawmakers – have every reason to want to adopt enabling innovation. There are, of course, some losers, but these are mostly from peripheral services to the underlying activity of law. Word processing, for instance, has largely replaced the commercial printers who specialized in typesetting legal documents. I am old enough to have spent nights as a junior lawyer in a beautifully appointed conference room in a factory building in Manhattan's "printers' district", negotiating and proof-reading public offering filings that were being typeset on the industrial floors below. Microsoft Word, Word Perfect and Adobe now fill most of that space with desktop capacity. The printers of course regretted this replacement, but they had little leverage to stop it.

A corollary of this incentive structure is that the goods and services of stage 1.0 generally constitute "private goods".[22] The products and activities that characterize this phase can be effectively provided through bargained exchange of two private parties in an open market transaction. A law firm can contract with a provider of practice management or search software on the basis of their bilateral needs, without much concern for regulatory or other network constraints. While e-discovery practices do need some approval by the courts involved, the early emergence of relatively flexible standards have allowed a number of companies and approaches to bloom; the rules have had openness and a capacity for generativity.

[22] The private goods/public goods distinction is widely made and recognized in economics. A good introductory discussion of the types of goods recognized in economics and their characteristics is available at Vincent Ostrom and Elinor Ostrom, Public Goods and Public Choices (2012), URL: <http://johannes.lecture.ub.ac.id/files/2012/02/Public-Goods-and-Public-Choices.pdf> [last accessed: 09/05/2015].

The adoption of technology raises some strategic concerns. The decision makers within the adopter, whether a court, law firm, or client, are generally not very well versed in how the technology works; this makes it something of a "credence good" (Wolinsky 1995 and Goodenough 2013, section 5, Trust), where the buyer's own expertise is not sufficient to judge the claims of the provider. Typical credence goods include automobile repair and legal advice. In 1.0 legal technology, the credence good problem can be alleviated by developing in-house expertise in the firm librarian or court IT specialist, by hiring a third party consulting expert, or by adopting widely shared services provided by established companies with reputations at stake. We see all of these at play in the 1.0 marketplace.

3.2. Stage 2.0

The economics of 2.0 get a bit more conflicted. By definition, the existing players at the centre of the legal system start to be replaced. Now there is incentive for some of those with the power to resist to do so, and the existing paradigm of professional rules, largely non-generative, are invoked to preserve the status quo. The incentives from a buyer's standpoint, however, now lie cross-wise to those of the providers. Individual consumers and small businesses patronize innovators like Legal Zoom and Rocket Lawyer while law practice regulators resist their development (Ambrogi 2014). Corporate clients move away from traditional firms toward law service providers of various kinds. Some are the outgrowth of accounting and consulting, like the moves of the "big 4" accounting firms PricewaterhouseCoopers LLC, Ernst & Young Inc., Deloitte, and KPMG, all of which are investing in legal branches (Strickler 2014 and Johnson 2014). Others are new formations like Ravel[23] and Axiom Law, which provide work on legal projects directly to corporate general counsels and other legal providers. Most of them make use of a combination of technology and better work management to offer service levels and cost discounts that are increasingly hard to ignore.

In the public sector, e-government is moving beyond information-providing websites and starting to imbed interactive access to the functions of government into technology.[24] This creates smart systems that will speed the

[23] Ravel, URL: <https://www.ravellaw.com/> [last accessed: 09/05/2015].

[24] See, e.g., Center for Digital Government, URL: <http://www.govtech.com/cdg/> [last accessed: 09/05/2015]. See, generally, e.g., What is e-government? E-GOVERNMENT FOR DEVELOPMENT, URL: <http://www.egov4dev.org/success/definitions.shtml> [last accessed:

processing of applications, returns and other citizen-government contacts, reducing or even eliminating the need for a human touch. The human expertise is built into an "expert system" that allows it to scale.[25] Such smart systems are classic examples of 2.0, where technology replaces an increasing number of the human players within the current system – saving money, speeding processing, and eliminating the drag of human contact. This process affects courts, and e-filing systems and online communication systems like the Italian Consolle open efficiencies for all concerned.[26] This systemic innovation needs leadership from the top. From a network standpoint, such e-filing can depend on standard setting, like prescribing the use of the PDF format, so that the players can effectively interact with each other. The adoption is such a system, requiring short term individual investment and sacrifice by its individual players, to create a larger mutual prosperity has many characteristics of a public good, which may resist achievement through un-coerced individual decision making.

3.3. Stage 3.0

The systemic changes that make up the 3.0 transition face even greater public goods concerns. The system of justice as a whole is clearly in the public good category. It also will face network effect obstacles. These grow out of the fact that the system as a whole has standardized elements that must interact with each other. By way of a relatively simple example, court filings in most systems must meet certain formal requirements that facilitate record keeping and mutual intelligibility. A move to a new form of filing, even if much improved, needs to be accepted across the network of legal actors in order to be effective.

Both of these concerns suggest that a 3.0-style overhaul or replacement of systemic elements may require a public catalyst. Sometimes this will simply be at the coordination level of standard-setting. At other times, the cost of the new system will need to be funded through some kind of public finance.

09/05/2015]; Public sector innovation and e-government; OECD, URL: <http://www.oecd.org/gov/public-innovation//> [last accessed: 09/05/2015].

25 See, e.g., Expert systems: how far can intelligence be automated? Paris Tech Review (April 29, 2014), URL: <http://www.paristechreview.com/2014/04/29/expert-systems/> [last accessed: 09/05/2015].

26 For information on the Italian courts' programs, see URL: <http://pst.giustizia.it/PST/en/homepage.wp?request_locale=en> [last accessed: 09/05/2015]. For information on court automation in Europe more generally, see Velicogna 2007.

That said, sometimes a new system can simply grow up next to the old. In the realm of dispute resolution, for instance, the American firm Modria has taken online mediation techniques originally deployed on eBay and PayPal and turned them into an integrated service that can be adopted by companies and governments. Its success suggests that private efforts and investment can create new networks that can stand beside the old when the conditions are right.

4. Computation and law

In his famous work of legal theory, The Common Law, Oliver Wendell Holmes, Jr. memorably declared: “The life of the law has not been logic” (Holmes 1881). This pronouncement sums up a deeply held tenant of American legal theory. Most lawyers in the United States believe that there is an element of irreducible human uncertainty that is somehow an indispensable ingredient in law. European lawyers, with their code-based traditions, may be less skeptical of the role of logic in the system. Whatever its merits in history this assumption is running squarely into the developments of legal technology and computational law. If they were not both dead, Justice Holmes, would need to meet Dr. Alan Turing.[27]

Turing was a British mathematician famous for a number of foundational accomplishments in computation theory, only hinted at in the recent biographical film “The Imitation Game”.[28] Computation theory, as expounded by Turing and its other practitioners, is not just about computers.[29] Rather, a “computation” is any rule governed, stepwise process. These processes are surprisingly common in both the natural and human-constructed worlds, including such diverse examples as many biological functions, the manufacturing assembly line, and games ranging in complexity from Chutes and Ladders (snakes and ladders to the British) to poker or chess.[30] Computation theory provides a means for specifying such processes in a formal way, a bit like how

[27] A comprehensive biography of Turing is available in Hodges (1983).

[28] “The Imitation Game” (2014), directed by Morten Tyldum.

[29] This discussion draws extensively on an excellent introductory treatment of computation theory, Sipser (2006), and has been further informed by Date (2000). The author is also extremely grateful for the collaboration of Mark Flood on their joint paper (Flood, Goodenough 2015), as well as for the patient explanations of Michael Genesereth (Stanford, Computer Science) and Jeannette Eicks (Vermont Law School) on computation theory. Any mistakes are of course the author’s.

[30] See the discussion of games in Sipser (2006), pp. 315 ff.

the alphabet and writing allow the specifying of language formulations in print for current storage and later reconstruction.

Using a computational approach, a stepwise process like a board game can be fully described in its stages, inputs and transitions. This careful specification both clarifies and records its elements. The terms of that description can be in words, in computer code, in the gears of a mechanical calculator, or even in pictures, like a flow chart. And here comes the really potent next step: a computation specified in one mode of description (including in a "natural language" statement like the written rules for poker) can also frequently be specified in some other mode, like the binary code used by our digital computers.[31] Put a few programming steps in between, and you get internet poker.

The "Turing Machine", a formal proposition rather than an actual physical construct, is posited as having the capacity to describe any computable process. Digital code and computer processing may not have quite this reach, but they do a lot of computational work. They have enabled us to take many of the computational processes in the world and embody them into the on/off descriptions of binary code which our actual machines can then read and implement. From self-driving cars to cell phone apps, the astonishing tech-driven advances of our time all depend on this transformation.

Legal rules, whether set out in contracts, regulations or judicial decisions, often look like a Chutes and Ladders game writ large. They have the same kind of stepwise branching logic, although the American federal tax law set out in the Internal Revenue Code has orders of magnitude more chutes and ladders than the board game. Complexity matters, but it doesn't contradict the core point: *law is often computation too*.[32] And when law is computation,

[31] It should be noted that computation theory itself has several interchangeable means of representation, including automata, lambda calculus, or, as Turing famously asserted, a human with pencil, eraser, and paper (and a great deal of time), Alan Turing. 'Intelligent Machinery'. National Physical Laboratory Report (1948), reprinted in Meltzer, Michie 1969. This ability for multiple expression is encompassed in the Church-Turing Thesis. See Copeland (2008). The proposition advanced here is a related one: Once humans with pencil, eraser and paper have specified a computational process, which can include at least many kinds of legal processes and formulations, it can be translated into many other forms for expressing computation, including those which can be implemented by a digital machine. This can be thought of as a Church-Turing Corollary.

[32] See Flood and Goodenough, supra note 29. Determining the boundaries of this statement is an ongoing research project of legal informatics scholarship, including work by the author of this paper. See, also, Love, Genesereth (2005). See, generally, The International Association for Artificial Intelligence and Law, URL: <http://www.iaail.org/> [last accessed: 10/05/2015].

we can represent it in software as well. Not emulate it in software, but represent its logic and process directly in the code.

That said, in some areas of law, such as those where the processes of judicial interpretation have created not only complexity but variability and uncertainty in its specification, we can approach the modeling process from the other direction, using learning algorithms and other sophisticated data mining tools to look for emergent patterns that do emulate rather than replicate the process.[33] The two choices to some degree reflect the common law/civil law divide; both have their place in the world of computational law.

4.1. Stage 1.0

It isn't necessary to jump all the way to replacing judges with artificial intelligence to have useful applications of computation to legal problems. The solutions of 1.0 are by their nature limited to helping current players, and the legal technology industry has already picked some of the low hanging fruit of legal sub-processes, like time-keeping, billing and legal research. Computation is substituting for human services in the legal process, but isn't yet touching the core analytical and expert functions of the traditional lawyer or judge.

4.2. Stage 2.0

Once we express true legal formulations themselves in computational terms, however, we can begin to replace the lawyers as well. An "expert system" can embody a great deal of both basic and interpretive knowledge on a legal subject like income tax. As discussed above, the H & R Block and TurboTax software applications are both products in this field. With such an application figuring out the implications for a particular set of facts (such as income and deductions) becomes a quick exercise in technology.

The reach of such systems could be broad. Many US states now offer internet services to create fillable court papers for family law and landlord/tenant matters.[34] These filings are a significant step forward for the 80% or more of such cases where at least one of the parties appears unrepresented by a lawyer. If the credit card companies had to file a computer code version of their

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[33] See, e.g., Katz *et al.* (2014).

[34] See, e.g., CALI, A2J: Now Helping Pro Se Litigants in New York State Courts (June 23, 2009), URL: <http://www.cali.org/blog/2009/06/23/a2j-now-helping-pro-se-litigants-new-york-state-courts> [last accessed: 10/05/2015].

contracts, you could press a couple of keys and find out what happens when you miss a few payments and the rates triple. Want to contract to sell your house? There'll be an app for that. Many areas of computable contracting are happening without our realizing it. For instance, if you buy an e-book with one-click from Amazon's Kindle service, the terms, billing, and delivery all flow in an automated process.

4.3. Stage 3.0

In some ways, the Amazon transaction can be viewed as a 3.0 precursor. One way the system changes is by becoming an invisible element in a technologically mediated process. Often, the software embodies not only the rules of the interaction, but also the process by which it takes place. In a world that incorporates "the internet of things", we can embed the rules directly into the objects they govern. I recently tried to sync up my phone to the Bluetooth in a rental car – the technology made me stop the car so that I could proceed more safely with the process. Imagine a "smart security", like a share of stock that knows who owns it and will implement any legal rules about selling it directly into the proposed transaction. If you imagine it carefully enough, and specify it as a computation, computer engineers can make it happen on a digital device.

Not all of these developments will be welcome – the mobile phone cop in my car may have been correct, but it was also annoying. Furthermore, none of this will squeeze all of the uncertainties out of law. There will still be places for human interpretation, where good software will stop and ask a person for guidance. On the whole, however, an explicitly computational approach to legal design will serve to make the law more available, transparent, and predictable, and put a bit more logic back into the system. Even Justice Holmes should approve of that.

5. Conclusions

The shape of the innovation that legal technology is bringing to law can be relatively graceful or clumsy. The stakes for success are high: social stability and individual well-being are at stake in the maintenance of an effective rule of law. While some of the change will be organic, bubbling up from the unreflective actions of technologists and practitioners just looking to solve an immediate problem, policy makers and scholars also have a role to play as this happens. If we anticipate the more radical changes coming at us and design safeguards into these processes with some intelligence and attention to the public good, maybe we can improve the outcomes. We can help a system intended to create justice to do just that. Practitioners who anticipate and adapt to change can prosper in the new world. This essay and the other papers in this volume on legal technology seek to provide some background and guidance to this more thoughtful approach. We are grateful to the *Cariplo Foundation* that has provided the financial support for our efforts, with an eye toward making legal innovation a desirable outcome and not just an inevitability. Or maybe the rhinoceros tramples its way through unguided, and we hope for the best.

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Technological Innovation in Law: Just an Option or a Strict Necessity?

Amedeo Santosuosso

1. What is law in a highly technological environment?

When we talk about issues such as innovation in law, the impact of technology on law, the changing of legal professions or the training of young lawyers, we imply that we already have a sufficiently clear idea of what the law is in present times and in our Western societies.

The present tension between the incremental technological change in our society and the long-lasting reluctance of legal academy and professionals to recognize and face some changes occurring in law today makes such an implication less clear. Even though something new has recently started moving, as this book witnesses, it is still too little if compared with the impressive recent and coming technological developments.

The fixity of academic disciplinary partitions over the last decades is astonishing especially if we remind the authors who many years ago, after the Second World War, had clear insights on what was already happening at that time. Legal scholars mostly ignored for decades Philip Jessup's description of the presence of a new kind of law that regulates actions or events that transcend national borders and which shares elements with international law, public and private; such rules that do not correspond exactly to the traditional categories. He uses the concept of "transnational law" in order to refer to "all law which regulates actions or events that transcend national frontiers. Both public and private international law are included, as are other rules which do not wholly fit into such standard categories" (Jessup 1956, p. 2).

As a result of such a scarcely reactive theoretical attitude among jurists the academy has largely overlooked some major changes. It is difficult to find a justification for all this; explanations include the lack of knowledge of foreign languages, if the traditional nation-based background of lawyers, if the feeling of committing betrayal when referring to laws from other countries, and more.

On one side there is the reluctance toward deploying the increasing presence of updated and complex computer tools in the judicial and legal professions. Indeed, many lawyers, judges and also professors of law still use them as word processing instead of taking advantage of their huge computing capacity.

As for legal theory jurists have received powerful stimuli especially from the building of the European Union (EU), a process that is both so messy and so intellectually challenging. We also see the extremely interesting field of the domestic effects of globalization of law, which have been increasingly recognizable over the decades and years. Plenty of cases and novelties can be also recalled, from the EU legislation and its interaction with national legal systems, to the role of national Constitutional Courts in relation with the judgments of the European Court of Human Rights (EHRC) and the European Court of Justice (ECJ), to the very particular transnational dynamic that the Charter of Nice is driving, to rules coming from the Council of Europe and other international organization, such as WTO, and more. In recent years some of these phenomena have been discussed in academic and professional circles. They seem, however, to be withdrawn from the theoretical training and professional development of new lawyers.

The logic behind this omission seems to be as follows: for their training, students and young professionals have to learn the *law as it is* (supposing it is still more or less the same, as always!), while all the rest belongs to more or less theoretical or practical visionary people of the digital age.

Hereinafter (par. 2) I draw a picture of the experience of some major universities in the USA and in the EU. Then (par. 3) the law in action v. law on the books opposition is discussed and (par. 4) some differences in focus between EU and USA are presented. In paragraph 5 the issue of how the technological embedment of law changes law itself, in its fundamental categories and assumptions. In paragraph 6, I will address an apparently banal question, whether we need or not a general theory of law and technology. In conclusion (par. 7), the reply will be that technology is already intertwined with law and that innovation is a strict necessity.

2. The experience of major USA universities and in the EU

The need to innovate in the field of law is finally widely recognized. The initiatives in this direction are becoming more frequent in recent years in many countries.

In the US there is a strong movement in this area, and some important universities have included courses and programs in their curricula dedicated to exactly this topic. Meaningfully the Stanford Law School stresses exactly this point in the home page of its website: "Excellence, innovation, and a commitment to the future — these are Stanford Law School's legacy to each new generation of law students and lawyers". At the same School there is an active center, called CodeX, whose inspiration is again particularly interesting:

> At CodeX - The Stanford Center for Legal Informatics, researchers and entrepreneurs design technologies for a better legal system. CodeX's broad mission is to create legal technologies that empower all parties in our legal system and not solely the legal profession. These legal technologies help individuals find, understand, and comply with legal rules that govern their lives; they help law-making bodies analyze proposed laws for cost, overlap, and inconsistency; and they help enforcement authorities ensure compliance with the law. All of these advancements lead to the next frontier of legal technology, bringing new levels of legal transparency and individual empowerment.[1]

It is a much larger movement. At Georgetown University, for example, they offer a course on *Technology, Innovation, and Law and Practice* and at the Vermont Law School a Center for Legal Innovation has been established, while similar initiatives are underway at Harvard and elsewhere, such as the Brooklyn Law School, where an international meeting on these issues was organized in 2014. Oliver R. Goodenough, one of the leading scholars of this movement and Director of the Center at the Vermont Law School (USA), argues as follows:

> Legal education must take as a starting point that we need to create useful capacities in our students. While there are many more abstracted fields of study, from sociology and literature to economics, which can help inform a capable understanding of law, law itself is an applied discipline involved in the creation and operation of critical institutions through which humans order many of their most important social activities. […] for the vast majority of our students, such training is exactly why they come to us. In a first year class I recently asked students to indicate which of the following approaches better represented their reason for choosing to come to law school: (A) to learn a set of knowledge and skills that would enable them to have an effective and rewarding career in the American and global legal profession, or (B) to learn a set of policy, argumentation and analytic approaches that would enable them to have an advanced knowledge of the social, political and legal institutions that shape America and the world. It will come as no surprise that most of the students chose A, or that a reasonable, but relatively small minority chose B. Of course, the law-professor answer is that A and B are not antithetical, and by teaching B we enable A. I personally like high theory […] but B should serve A, not replace it. (Goodenough 2013, pp. 847-848)

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1 At URL: <https://www.law.stanford.edu/organizations/programs-and-centers/codex-the-stanford-center-for-legal-informatics> [last accessed: 03/05/2015].

In Europe, but with a forward-looking approach to the world, it is worth noting the project Innovating Justice, an initiative launched in 2009 by the Hague Institute for the Internationalization of Law (HIIL), the Microjustice Initiative (MJI), the European Academy for Law and Legislation (EALL) and the Center for International Legal Cooperation (CILC). Their inspiration is worthy of note:

> The Rule of Law and justice sector is crucial for sustainable communities, relations between communities and for individuals to realize their full capabilities. It is also an industry in and of itself, in which billions of dollars are spent each year. Improving the Rule of Law has been a priority for the international community for quite a while now, and it continues to be so in both developing and developed countries.[2]

3. The fading of the law in action v. law on the books opposition

The need for profound innovation in the field of law has various origins, which are largely common to all the countries of the Western tradition. We can just call to mind some of them: i) the crisis of basic legal categories (as a result of the crisis of the nation state); ii) coming to broader realization of phenomena started many years ago (see above what Philip Jessup wrote in the 50s of last century); iii) the development (and even some uncertainties) of the European Union (where sometimes just the lack of clarity of some political and institutional developments seems to evoke the need for more legal creativity), and in the background, iv) the extraordinary development of information technology.

In general, one can say the change has reached a critical mass that does not allow another oversight and underestimation, and that any delay in the review of our ideas about what is law now and what are the terms of legal professions should only increase the debt that law practitioners and academics have toward young lawyers.

Before proceeding further a possible misunderstanding must be debunked. What we are talking about is not a remake of the old opposition between law *in action* and law *on the books*. Nowadays the need for rethinking and innovating law concerns, with equal depth, both academic studies and the professional world. The academics may not claim a status of theoretical superiority and the professionals may not claim the superiority of living the experience of what is the true law, as practiced. Each is a necessary element in a full understanding.

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2 URL: <http://www.innovatingjustice.com/about> [last accessed: 25/04/2015].

Recognizing both the theoretical and practical challenges of legal innovation is at the basis of the course established at the ECLT-University of Pavia in the Academic Year 2014-2015. The course *Innovating Legal Studies and Practice* (ILSP) is the result of the cooperation between Court of Appeal and the Tribunal of Milano, the Milano Bar Association, the University of Pavia and the *Collegio Ghislieri* in Pavia (the course is reported at the Chapter by Maria Laura Fiorina and Giulia Spinoglio).

4. Differences in focus between EU and USA

While technologies applied to law are almost universal some interesting differences occur in the products put on the market, the fields of law involved, the public policies involved and more.

Just to cite few examples it is perfectly understandable that CodeX's third annual conference, FutureLaw2015, focused on how technology is changing the landscape of the legal profession, the law itself, and how these changes impact us all. FutureLaw 2015 (April 30, 2015) mostly addressed the academics, entrepreneurs, lawyers, investors, policy makers, and engineers spearheading the tech-driven transformation of legal systems. The issues proposed to the discussion were the state of the art of legal technology, the latest advances in big data law and analytics, regulators' responses to the economic and technological forces transforming the legal profession, best practices for consumer law companies and the adoption of legal tech within law firms and in-house departments.

Two aspects of Codex FutureLaw conference as well as of the New York Legal Tech exhibition immediately draw the attention of the European observer: a) the complete absence of attention toward what public institutions and the judiciary do and what role they play in the introduction of new technologies in the field of law; b) the almost total absence of technologies related to criminal law.

In the European Union some law firms use updated technologies and focus on their knowledge-management opportunities. However, in country like Italy there are plenty of advocates who work in very small law firms, sometimes as isolated lawyers. In cases like these, the use of legal technologies might be extremely helpful. However, by contrast, the small size is at the moment a main obstacle in order to fill the technological gap.

Moving on the public side, it is astonishing that while each European country is introducing informational tools in the judiciary, there is no global plan by the EU in order to have a uniform technical background to be shared by the different countries. Italy has an informational system for the civil cases, which is extremely interesting from a conceptual point of view (see next paragraph), even though it would require more resources (see the Chapter by Enrico and Pietro Consolandi).

5. How law changes because of its technological embedment

The embedment of law in a shared technological environment produces some interesting changes. Some of them are presented in this paragraph.

First, it can be said that the law of legal professions (judges, prosecutors and lawyers in the first place) is already widely intertwined with computer technology. It is undeniable that the law lives in a highly technologized environment and is intrinsically technologized.

Second, just think of the following points:

a) The traditional legal act performed or delivered by one of the parties in a trial (brief, judgment, order, decree, writ of summons, appearance, law, administrative action, and more), once inserted in a computational environment, undergoes some major changes:
   1. Firstly, it is delocalized from the author and the office of origin: it can be physically distant from the law firm or the office of the judge to a server, which can be in a remote location.
   2. Secondly, it is not simply an act/brief anymore. It is rather a provisional data aggregation, which can disaggregate and divide into its constituent parts. These parts can reshape in different data aggregations (act/brief), according to the intention and institutional and professional position of the author in a trial or other setting.
   3. The shape of the (new) aggregation depends on the position of the author of the aggregation: lawyer, judge, regulator, legislator and more.
   4. The constituents of these aggregates (legal data) may come from diverse sources, even external to the jurisdiction (international treaties, supranational bodies or transnational flow of legal concepts, and more). All this is clear if we assume that a source of law or a precedent from another country may be conceptually closer to the case to be decided than precedents or sources of law of the same jurisdiction.
   5. The constituents of these aggregates (legal data) may also be expressed in different languages. Thus, the need for a multilingual approach to law becomes stronger (Santosuosso, Malerba 2014).

b) If a) is true, it follows that the raw materials and the tools the different professionals involved work on are ontologically the same, while what is different is:
   1. The different power to have access, partial/total, to data (according to the institutional position).
   2. The type and purpose of the legal act that is being to be delivered, and consequently the kind and shape of the aggregation of materials (judgment, appeal, article of doctrine or theoretical, normative analysis in view of monitoring administrative or legislative changes, and more).
   3. The legal value of the new aggregation depends on the different backgrounds and authorships.[3]

c) If a) and b) are true, it follows further that the formation of young jurists and professional should be interchangeable, as the building blocks are the same (and the importance of this point in the EU countries might be great!) (see the Chapter by Maria Eleonora Benini, Chiara Colicchia, Federica Fazio).

6. An apparently banal question: do we need a general theory of law and technology?[4]

At this point an apparently banal question has to be addressed: whether we need a general theory of law and technology or, rather, a general reconsideration of law.

Technology offers both an extraordinary opportunity for improvement of our lives and a challenge to traditional ideas and conceptual categories. In the legal field the recent incremental development of technology has given rise to an apparently plain question: why should we look at each new technology in isolation? Indeed, the field where technology and legal disciplines interplay has a relatively high density: "e-commerce and contract law, electronic documents and litigation, organ transplantation and property law, the rise of industry and tort law, computer hacking and criminal law, and so forth. […] Over forty law journals claim to deal with issues of law and technology" (Moses 2007, pp.

[3] I described the disaggregation of law into elementary particles and their property to aggregate several times, even beyond linguistic barriers, in a previous paper of mine (Santosuosso 2011).

[4] In this paragraph I take advantage of my previous research about technology and law already published (Santosuosso 2013).

589-606). Are those regulators, judges and scholars right who mostly look at each new technology in isolation and, for instance, "focus on the study of either communications law or the law of medical technologies, often specializing in the legal study of a specific technology, such as the Internet or genetics"? (Bernstein 2007, pp. 441-447). In general terms the question is

> […] whether the assessment and reaction to each new technology in isolation is the best mode for technology regulation or whether a broader outlook would better serve the social accommodation of new technologies [and] whether the compartmentalized mode of regulation should be replaced or supplemented by a general theory of law and technology. Such a theory would provide a generalized legal approach to the use and adoption of new technologies, specifying guidelines for approaching instances in which a new technology threatens to destabilize existing social institutes, values, and norms.[5]

The question about *a general theory of law and technology*, has an apparent obviousness: Why should we not have a new theory of law – we already have plenty of them! – in order to have a better approach to one of the most important aspects of our present life? In reality, however, the question contains a number of extremely complex issues ranging from legal regulations on specific problems (how to deal with each of them in practical legal terms) to metaphysics (technology as something that deprives us humans of seeing the 'truth' of the world).

At the end the conclusion will be that there is no compelling necessity to create a new entity such as *a general theory of law and technology* or, at least, that the issues related to such a debate might be a chance for a redefinition of crucial aspects of legal theory in general terms.

6.1. Technology seen by law

The first points to be clarified are about technology, what it means and what we refer to when we use the term in general and, specifically, in the legal domain. General dictionaries have twofold definitions for technology, one referring to the application of practical sciences to industry or commerce and the other to the methods, theory, and practices governing such application.[6]

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[5] This is the very direct way Gaia Bernstein (Bernstein 2007) put the question in her introduction to the symposium "A General Theory on Law and Technology", whose proceedings are published in the *Minnesota Journal of Law, Science & Technology* (2007) vol. 8.

[6] "1. The use of scientific knowledge to solve practical problems, especially in industry and commerce. 2. The specific methods, materials, and devices used to solve practical problems":

A deeper analysis shows several further facets. As has been stressed, the term "technology" is not univocal. It has a range of meanings and has been used to refer to:

> (1) tools and techniques; (2) organized systems such as factories; (3) applied science; (4) those methods that achieve, or are intended to achieve, a particular goal such as efficiency, the satisfaction of human needs and wants, or control over the environment; and (5) the study of or knowledge about such things. The term 'technology' thus sometimes includes what might also be called 'technique'; making organization, bureaucracy, and even law itself into technologies. (Moses 2007, p. 591)

Law deals with all these aspects (as with all aspects of the social life) and recasts them in proper legal terms: how law ought to face social relationships and the conflicts that stem from or are in some way linked to the introduction of new technologies in society. In the last decades the world of lawyers has moved very quickly from a generalized undervaluation of technology (mostly due to lack of knowledge of it) to what sometimes looks like an overemphasis on its impact and of its being a threat to our lives. In general terms, we may say that the theoretical and practical interest toward the impact of technology on law has increased.

Two main attitudes towards science and technology

Arthur Cockfield and Jason Pridmore impressively describe the landscape of law&tech studies as dominated by two main theories or approaches, the first called instrumental theories and the second substantive theories (Cockfield, Pridmore 2007, pp. 475-513):

> Instrumental theories tend to treat technology as a neutral tool without examining its broader social, cultural, and political impacts. In contrast, substantive theories emphasize the ways in which technological systems can exert 'control' over individuals, often without their knowledge.

The most widely accepted view of technology seems to be the instrumental perspective. Technology is simply a tool, an instrument of the social, political, or economic group or individual that chooses to develop and use a certain technology.

Collins English Dictionary: Complete and Unabridged (New York: Harper Collins, 2003). Similarly *The American Heritage Science Dictionary* (Boston: Houghton Mifflin Harcourt, 2005).

On the other hand, a typical substantive position is that of Heidegger. Technology for Heidegger is not just machines; it is a fundamental way of viewing the world, a way of seeing that reduces the world to a mere stockpile of resources waiting for human use. This extends to the way of seeing humans themselves. If, however, revealing the world is the fundamental task of Being, then this creates a danger. By occupying this place within modern existence, technology deprives us humans of seeing the 'truth' of the world (Tranter 2007, pp. 449-474). Arthur Cockfield and Jason Pridmore maintain that a synthesis is necessary between the two main approaches:

> Each theory, standing alone, has disadvantages that reduce its potential for interfacing with legal analysis. Instrumental theories fail to recognize the contextual complexities that should inform all legal analyses. This failure is profound when that analysis is employed in the search for optimal policy solutions in an environment of changing technology. Substantive theories, on the other hand, appear to over-emphasize the need to address the social impact of technological structures while downplaying the relevance of human agency. They also tend towards abstraction and undervalue the need to examine each case on its particular facts and circumstances. (Cockfield, Pridmore 2007, pp. 475-513)

It is interesting to note the emphasis Arthur Cockfield and Jason Pridmore put on human agency. Indeed the question of human agency is inescapable in legal (and even political) reasoning, where the question of imputation of acts to people has a crucial importance, whatever the idea of law each author may have. Arthur Cockfield and Jason Pridmore stress a very interesting point:

> Liberalism respects the rights of individuals to determine, and be responsible for, their own destiny. More contemporary visions of liberalism strive to develop institutions to promote this goal, while recognizing that there are serious impediments to its attainment, including family wealth disparities and systemic barriers such as racism. As such, liberalism is loosely related to the proposed synthetic theory that strives to respect human agency via the instrumental perspective, while recognizing a need for the law to address the deeper and often less apparent ways that technological developments may be thwarting or inhibiting the attainment of just policy outcomes.

The proposed synthetic theory, that has connections with and can take advantage of several theoretical contributions, such as the works of Science and Technology Studies (STS),[7] is interesting in many respects as it is realis-

[7] STS focus on understanding "science and technology as social relations and as socially constructed".

tic: creating a new theory of law that is both *general* and strictly related to a *specific* field (technology) seems to be risky and may be too broad or too narrow. Cockfield and Pridmore try to put themselves on the safe side by calling for a synthesis of the two main approaches in the field of law&tech and taking the best from them. At their core, they cannot avoid two crucial points: what is the idea of technology they share and, mostly, the idea of law they assume.

Technological exceptionalism and the invisible ontology

Going back to the idea of technology and the attitude in recent decades in the world of lawyers, some words have to be dedicated to the overemphasis on the impact of technology and on its being a threat to our lives. This attitude, sometimes called exceptionalism, implies that new problems require, by definition, the creation of new rules and principles.

In my opinion, the mistake of exceptionalism is both historical and conceptual. From a historical point of view, considering the impact of technology on society as a new problem is contrary to the evidence from the past, as "philosophical reflection on technology is about as old as philosophy itself. It started in ancient Greece". Indeed technology has been, in different respects, at the center of philosophical speculation since Democritus, Plato and Aristotle (Fransen *et al.* 2010). Of course new technologies (sometimes) may pose new problems; this does not imply, however, that the relationship between law and technology as a whole is a new problem, nor that facing new problems requires by definition the creation of new rules and principles (which is the typical mistake of exceptionalism).

From a theoretical point of view there are at least two important aspects to be considered: (a) exceptionalism suggests that technology (in general) is something added to our social reality (and, thus, something that can be avoided or whose arrival can be delayed), (b) even specific techniques/technologies are considered as isolated entities that are added randomly and then require to be 'reunified' in a general frame. In my opinion, those ideas do not account for the present reality, as technology is already present in almost all aspects of our social life, including law. It is already in our societies. It is not added to them but rather stems from them.

Looking at law, this implies that: (a) even law (in general terms) already is, in many respects, a *law of technology* in so far as it deals with any aspect of social reality, and that (b) law itself is a technologized entity, not only in the sense 'of law as technology' (see below), but also in the sense that law (however defined) lives with present technological means (e.g. legal databases on the web).

Thus, I maintain that rather than talking about "how to deal with technology" we should admit we live in a highly technologized environment, even in the law, so that talking about technology *per se*, at least in legal terms, does not make any sense.

Recent technological developments in Ambient Intelligence (AmI) and ubiquitous computing perfectly demonstrate what I mean. AmI is characterized by systems and technologies that are embedded (many networked devices are integrated into the environment), context aware (these devices can recognize you and your situational context), personalized (they can be tailored to your needs), adaptive (they can change in response to you) and anticipatory (they can anticipate your desires without conscious mediation). In this situation it is almost impossible to find something that is not affected by technology and, as a consequence, there is nothing that can be freshly contaminated with technology.

This example gives the opportunity to clarify two points:

(a) In social terms, we need to *discover* technology we already live with (as a component of our societies) rather than being afraid of technology and fighting against its *forthcoming* applications.

(b) In legal terms, if the law in general is *law of technology*, at least two consequences follow: (i) the law has no reason for dealing with technology in a way that is different from any other social factor; (ii) when talking about any aspect of our legal reality, we might discover its (sometimes hidden) technological origins.

The approach I propose reflects the insights of John Searle, who, in one of his more popular works, tells the story of himself in a café in Paris: "I go into a café in Paris and sit in a chair at a table. The waiter comes and I utter a fragment of a French sentence. I say, "*un demi, Munich, à pression, s'il vous plaît*". The waiter brings the beer and I drink it. I leave some money on the table and leave" (Searle 1995, p. 3). Searle then points out that the scene is more complex than it may appear at a first sight and starts uncovering its hidden aspects:

> [T]he waiter did not actually own the beer he gave me, but he is employed by the restaurant which owned it. The restaurant is required to post a list of the prices of all the boissons, and even if I never see such a list, I am required to pay only the listed price. The owner of the restaurant is licensed by the French government to operate it. As such, he is subject to a thousand rules and regulations I know nothing about. I am entitled to be there in the first place only because I am a citizen of the United States, the bearer of a valid passport, and I have entered France legally.

Searle's conclusion is that the scene has a "huge invisible [legal] ontology" (Searle 1995, p. 3).

We may say that Searle's ontology, as a legal ontology, deals with what in this paper is called *law of technology*. Thus, techniques, technological tools, devices, theories, applications and so on do not affect law in a way that is different from any other, institutional or brute, fact. This does not exclude that we may sometimes see in the texture of the "huge invisible [legal] ontology" traces of their technological origin or contamination.

6.2. Hidden assumptions about law

Is law itself a technology? This is a point to be clarified before starting to discuss the ideas of law that are assumed in the law&tech debate. It was Arthur Cockfield, dealing with the possibility of a law&tech theory, who argued that often, in the context of law and technology, "law is technology" (Cockfield 2005, p. 402). In general terms, the issue is not new and Carl Schmitt was one of the first legal theorists to recognize that law in modernity is another technology (Tranter 2007, p. 459). According to the traditional view

> […] law is seen as power which can be used for good, or more precisely to achieve good within society. However, this good is not intrinsic to law. Like the monster law is beyond good and evil, a pure power, and it is only when subject to the will of the lawyer/technician that its power can be harnessed for good. The irony is in invoking law to save society from the possible depredations of monstrous technology what is unleashed is another monster, the 'tame' monster of law. (Tranter 2007, p. 454)

Kieran Tranter stresses also that "in regarding law as technology, what is disclosed is the nomology of sovereignty, which legal theory has charted as involving law as malleable rules emanating from a sovereign that, in the extreme moment, can violently reduce humans to animals to be used and sacrificed at will" (Tranter 2007, p. 473).

Of course the issue of the relationship between the law and political power is open and endless. Here we can simply notice that such an approach is not neutral in describing law. It assumes an instrumental idea of the law, as a tool which is ready to be used by the sovereign or any other powerful social actor (even jurists and judges), whatever their ends and aims.

This idea is typical of positivistic scholarship and not universally accepted. Personally, I share the idea that law cannot be considered as a tangible thing, whose existence and shape are uncontroverted, and a tractable tool. Talking of law as a technique is, at least, far from all legal theoretical approaches that, in opposition to a strict positivistic view and logical positivism[8] (i.e. focused only on law as act of the legislative power), stress the historical origin of law and its spontaneous order rather than viewing law as the result of a political decision (Hayek 1982).

The importance of historical development is also emphasized, even if from a very different disciplinary point of view, in the works of Joseph Weiler:

> I am interested in the past not per se but primarily in the sense that it can illuminate the present. Second, and more importantly, whereas the classical historical method tends to periodize, geology stratifies. History emphasizes change; geology emphasizes accretion. Typically, a geological snapshot is taken and then the accumulated strata of the past are identified, analyzed, conceptualized. By stratifying geology folds the whole of the past into any given moment in time – that moment in which one examines a geological section. (Weiler 2004, p. 549)

The relevance of the historical stratification in law is undeniably true both in civil law and common law systems, as even in systems based on the rule of precedent jurists and judges do not have any freedom to change at will the legal state-of-the-art received from the past.

7. Conclusion

In general terms, law already is, under many respects, a *law of technology* in so far as it deals with any aspect of social reality. Furthermore, law itself is a technologized entity, not only in the sense 'of law as technology' (see above), but also in the sense that law (however defined) lives with present technological means (e.g. legal databases on the web and more).

Thus, I maintain that rather than talking about "how to deal with technology" we should admit we live in a highly technologized environment, even in the law, so that talking about technology *per se*, at least in legal terms, does not make any sense. A further consequence is that technological innovation in law is coessential with law today and, thus, a strict necessity, rather than just an option we can exclude in our choices.

Finally, we can say that today high level initiatives are possible in order to make legal education up to date and to have a closer interaction between legal studies and the practice of law. The time is ripe for opening an international

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8 See, recently, the Special Issue on "The Many Fates of Legal Positivism" (1 February 2011), *German Law Journal*, 12, pp. 599-826.

workspace for innovation in the study and in the practice of law, and for the EU and Italy to take part to this change.

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Informatics and Judiciary in EU: Is Italy Leapfrogging?

Enrico Consolandi, Pietro Consolandi

1. Innovating trials through IT: the experience of Italy

Every trial is a logical and chronological scan of events, a ritual to be celebrated. As every ritual, it is by nature rather conservative; it is a force opposing change that backs up the natural tendency of jurists to apply *stare decisis* as the times change, behaving in ways according to examples rooted in different times, when modern age media and databases did not exist. The hesitant nature of jurists represents an obstacle to the implementation of a telematic trial and is one of the main reasons why the traditional trial system, based on paperwork, looks like a conservative monster *per se* resisting any innovation. By a "telematic trial" we mean one conducted through a technological interface that allows some or all of the proceedings, including the creation of the background file, to be conducted through computerized means of information technology ("IT") via the internet or other medium of remote communication. By the term "trial" we do not mean just the live court procedure or hearing in front of a judge, but rather the more expansive process of the entire civil litigation.

However Italy is a member of the OSCE's (Organization for Security and Cooperation in Europe) and has to conduct its activity in light of the recommendation given by the report about access to Court decisions:

> The Council of Europe Recommendation of the Committee of Ministers to member states on the delivery of court and other legal services to the citizen through the use of new technologies R (2001) 3 (28/2/2001) is indicative of the general practice of member of the Council of Europe to make court decisions public and the desirability of making accessibility to court as easy as possible to the general public.[1]

[1] OSCE "Access to court decisions, a legal analysis of relevant international and national provisions". [online], URL: <http://www.right2info.org/resources/publications/publications/OSCE_AnalysisAccesstoCourtDecisions17092008.pdf> [last accessed: 10/06/2015].

Italy established an experimental period, starting in 2001,[2] during which the use of IT in civil trials was given limited authorization, which was granted only in departments and cities that had a proper level of technological development. Since the beginning it has been clear that significant collective savings were possible simply from reusing data relating to the proceedings. The figure below shows some of the savings (Figure 1).

Rate	Days by PCT (median)	Cost IT Procedures (5.711.977 *rate* days)	Days by paper (median)	Cost Paper Procedures (5.711.977 *rate* days)	**Savings**
2%	12	3.755.821	94	29.420.599	**25.664.777**
3%	12	5.633.732	94	44.130.898	**38.497.166**
7%	12	13.145.374	94	102.972.095	**89.826.721**

Figure. 1. Total value of payment orders served by PCT since 01/01/2008 to 31/12/2010: € 5.711.977.909.
Source: Milano Tribunal database [last accessed: 10/06/2015].

The present functional scheme of the Italian PCT (*processo civile telematico*) is rather complex and involves the State as the principal actor responsible managing the data. Data are communicated to the public system by lawyers, via electronic mail using specific XSD (Xml Schema Definitions) established by state regulations. Judges leave their decisions directly on the repository connected to the database. Figure 2 gives a schematic representation of the Italian PCT workflow.

The lawyers or judge's auxiliaries (named *soggetto abilitato esterno*) send their files with information in xml (*deposito atto*) through their providers (who own the Certified Electronic System of Signature: PEC) to the mail provider of the courts. Texts and data are then processed in a database (*registro informatizzato*) and ordered in electronic files (*fascicolo informatizzato*), where they are accessible and used for trials by judges and clerks. On the other side, judgments and opinions delivered by judges are registered in the database as electronic files and are sent by certified electronic mail to lawyers, who must be inscribed in a public list of electronic addresses (*registro generale indirizzi elettronici*).

The Italian Ministry of Justice estimates that just the step of communication by mail, about 12 million a year, instead of by a bailiff, produces savings for 44.000.000,00 Euros yearly.[3] In addition, the xml applied to the lawyer's

2 Decree of the President of the Italian Republic no. 123/2001.

3 URL: <http://pst.giustizia.it/PST/resources/cms/documents/Elaborazione_dati_PCT_31gennaio2015.pdf> [last accessed: 10/06/2015].

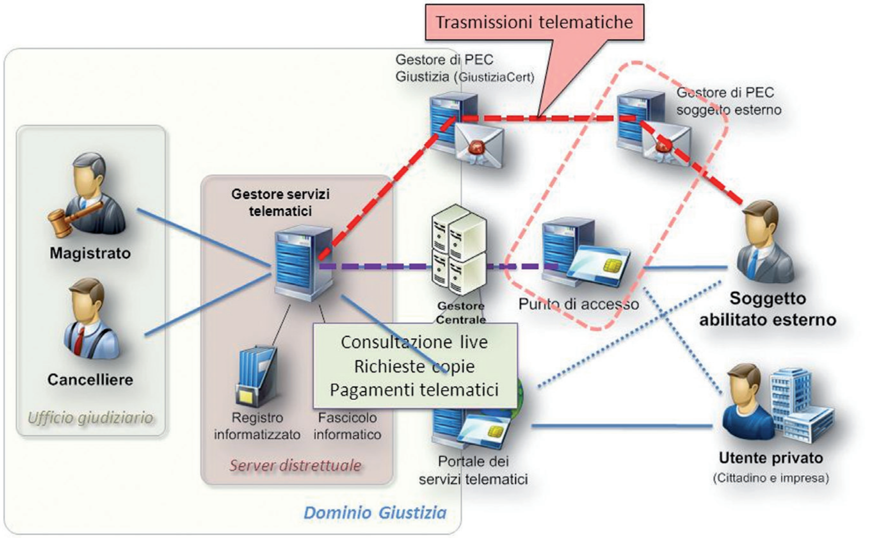

Figure 2. Representation of the Italian PCT introduced by Law Decree no. 193/2009 (converted into the Law no. 24/2010).
Source: S. Damiani. I nuovi servizi telematici. L'attuale architettura dei servizi telematici Dominio Giustizia Ufficio giudiziario Server distrettuale Gestore locale Depositi. URL: <http://slideplayer.it/slide/949215/> [last accessed: 10/06/2015].

texts allows the reuse of the data within the court database and, thus, reduces working times by clerks. So every civil trial can be served by IT, and since December 2014 it's compulsory to manage all lawyer acts with the courts follow-

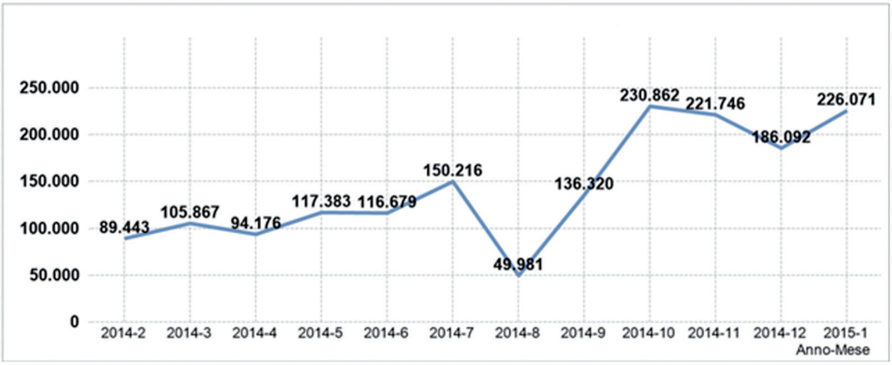

Figure 3. Number of acts delivered by judges via PCT per month.
Source: website Ministero della Giustizia. URL: <http://pst.giustizia.it/PST/resources/cms/documents/Elaborazione_dati_PCT_31gennaio2015.pdf> [last accessed: 10/06/2015].

ing this way. The use of PCT by judges is in an increasing phase as showed by the following graphic, which shows the increasing number of acts the judges deliver through PCT every month.

Problems and pitfalls

The PCT in Italy has often been described as a "leopard skin", to indicate the isolated spots where IT are used in courts. This local adoption can be viewed as happening in spite of the broader national context, which seems to be indifferent, or even contrary, to any technological innovation.

The following figure (Figure 4) shows this evolution in relationships to time and matters served by PCT in Italian courts, as authorized by Ministry of Justice in a limited manner applicable only in some of them. You can see that from 2011 to 2013 the Tribunals in which it was possible to serve payment orders by PCT has more than doubled, even though it was only 2/3 of all the Tribunals; for other kind of trials the increase has been considerable, even though the PCT was available in only 1/3 of all the Tribunals in 2013. In the Courts of Appeal the PCT was quite unknown until the end of 2013.

	End of 2011	**End of 2012**	**November 2013**
Orders of payment	34/165	54/165	87/140
Acts of bankruptcy	32/165	47/165	47/140
Trial's internal decisions in Tribunals (Tribunali)	5/165	24/165	53/140
Trial's internal decisions in Courts (Corti)	x	x	7/29

Figure 4. Number of Italian courts served by PCT in relation to time and matters.
Source: website Ministero della Giustizia. URL: <http://www.giustizia.it> [last accessed: 10/06/2015].

A further regulation (art. 16 bis Law Decree 179/2012) tried to end this discrepancy, exporting IT from the spots where it has already taken root to the rest of the country.

Using the PCT is now mandatory for many acts and this produced a sudden increase in the number of subjects using the PCT. Since not all of them are sufficiently expert users of IT, this represents a risk of failure for the new trial, with the possibility of rejection among many lawyers.

The next figure (Figure 5) shows how PCT is differently implemented throughout Italy. The graphic shows the unbalanced geographic distribution of the use of PCT throughout our territory and clear differences between the Courts of Appeal.

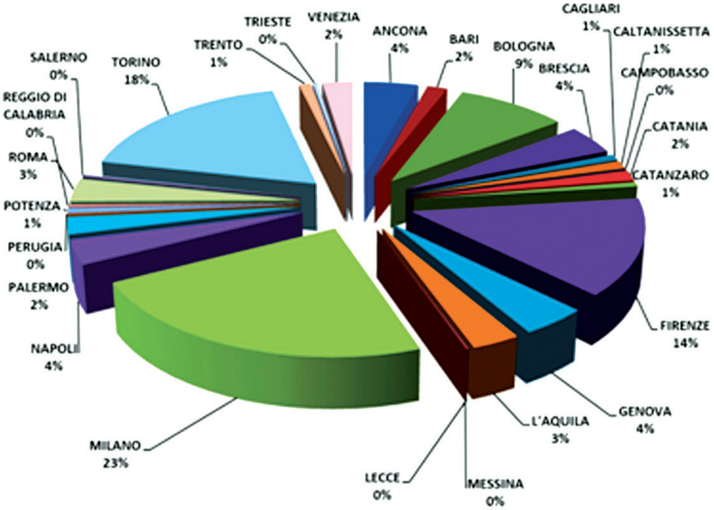

Figure 5. Distribution of the use of PCT throughout different Courts of Appeal in Italy (total of 517.486 acts served).
Source: website Ministero della Giustizia. URL: <http://www.giustizia.it> [last accessed: 10/06/2015].

The top-down approach chosen by Italy should require a planning process that carefully evaluates the available resources and the needed normative changes. However, the Italian government failed to conduct this planning and the result is an unclear situation. There are some similarities between the Italian and the Spanish experiences. Spain also tried to use a top-down approach to introduce the telematic trial in 2008 with its *Plan de Modernizaciòn de la Justicia* (*eJusticia*): although well funded, the plan encountered strong resistance among judges and professionals, and at this point the use of IT is still limited to the video recording of hearings.

An interesting aspect of the Italian situation is that, in spite of the governmental lack of efficiency (or, perhaps, because of it!), in some districts of the Court of Appeal a strong (and just few years before unthinkable) cooperation has developed among judges, lawyers and jurists from the academy, who have developed many kinds of organizational support for technological innovation and for the PCT. The innovation path relies nowadays much more on this kind of local action rather than on the hesitant action of the Ministry of Justice and the Government as a whole. The most interesting experiences have developed in Milan, Florence, Bologna, Prato and Verbania and have spread in other courts, extending the network supporting innovation thanks to the imitation, working as a sort of peer pressure.

In conclusion, in Italy a simple viral process is working more effectively than the top-down Ministerial approach. Even though Italy and Spain chose a similar path, a centralized one aiming to impose the changes from a centre of power on the peripheral areas, Spain was blocked by the local elites resisting innovation, while Italy is progressing thanks to an original and unexpected mix of centralized interventions (regulations and poor resources) and the horizontal cooperation developed locally between different professional entities and people (judges, lawyers, bar associations and academy). The result is that the Italian system now provides the opportunity to make proceedings based on computer signed documents, and this possibility is already rather widespread. In some courts it represents the 50% of decisions. At the same time, the ECLI (European Case Law Identifier) code enables the decisions to be published in a system accessible to lawyers and judges.

2. The European road: to manage the crossing or to build collaboration?

As we have seen Italy is the country where the telematic trial is becoming widely diffused. This is not happening according to a European standard, which does not yet exist. Progress at the EU level is occurring, however.

To obviate the diversity between European countries the EU has projected a common system of e-court interoperability, called E-Codex. It is intended to enable communication from lawyers to private parties and to the courts, crossing various e-justice systems adopted by each country members otherwise without coordination. At this moment E-Codex is available only for the EPO (European Payment Order) and cross-country small claims procedures and only between some member states. E-codex also provides exchange of information from business and companies registers.

This progress is limited, however; the e-codex project is still developing these specific pilots, not yet a real and extended way to conduct trials.

Some countries have developed initiatives in particular fields, as England and Wales for money claims, but few have yet attempted to build up a general trial informatics system, and those that have, as already said, have employed different systems.

E-codex is influenced by this parcelling, because "translating" the countries' individual sectorial initiatives doesn't mean building a communication system intended to give a unique shape to national systems. E-codex aims to bridge the gap between countries, but does not create a common blueprint for the core telematic trial project itself. In this way does not draw the developmental lines of the national computerized procedures to a shared basic path. It would surely be preferable to eradicate the Babel of different possible developments of IT in trials, rather than create a system – E-codex – that tries to manage this Babel once it has occurred.

In conclusion, Europe doesn't have at the moment any directive to build a shared approach to telematic trials, beyond the mere interoperability between systems that are still legally and technologically different.

3. Some concluding remarks

We might remember Marshall MacLuhan, who said that "the medium is the message" (see "Understanding Media: the Extensions of Man" originally published by Mentor, New York). It's clear that communication means used in a trial fundamentally influence the trial itself and the rights born from it.

In Europe, Italy represents the most advanced attempt to implement widespread adoption of IT in the civil trial, but today the leadership collides with problems arising from the deep cuts in funding in the exact moment in which a qualitative and quantitative leap was needed.

However, the Italian experience of horizontal cooperation shows that inserting an IT-based procedure in a traditional trial system mostly based on paper inevitably leads to a broad revision of the trial itself. Our country has not yet faced this revision in an organic way, but the need for this is felt exponentially more in the community of legal innovators, as the evolution of the civil telematic trial proceeds.

In closing, we might say that the most important element in technological innovation is a cultural change, and not a merely technical one. Even a technological application that aims to change the rules will not produce successful innovation without a process that encourages thinking about *how* rules are changing because of the new technological environment. The process of implementation is as important as the technology itself.

Is AI a Driving Force of Innovation in Law? The If and How of a Historical Opportunity

Alessandra Malerba

1. Innovating the law in a changing world

The legal landscape has lately undergone significant transformation, and the way we were used to conceiving of the legal profession has deeply changed as a consequence. Looking at these modifications could provoke an awkward sensation of bewilderment: are our certainties as legal professionals and hopes as citizens subject to the law being turn upside down once and for all?

We have been witnessing a sort of "porousness" of the state boundaries (Santosuosso 2011). Governments are required to deal with once unusual actors: not only international organizations and supranational authorities, but also private subjects (nongovernmental international organizations, multinational companies, law firms, and so on). Further, we have been experiencing considerable changes in the traditional law-making process, both at the international and domestic level. Last but not least, national judges have been playing an important role in clarifying this intricate legal picture, exceeding the traditional limits of the judiciary.

All these phenomena fall under the wide-ranging category of legal globalization, whose pros and cons scholars have extensively discussed in the last few years. Although it is not the purpose of this work to directly address the issue, I will just touch upon it in these introductory observations, since it is one of the main causes of the revolution hitting both law and legal practice. But it is not the only cause worthy of attention.

Information and Communication Technologies (ICTs) have brought about a revolution as well. Floridi has expressively named it the fourth revolution and described its contours as follows:

> ICTs are now making us realise that we are not disconnected agents, but informational organisms (inforgs), who share with other kinds of agents a

> global environment, ultimately made of information, the infosphere (Turing revolution).[1]

The point is, we undoubtedly live in the information age.

Thus, globalization on the one hand and the role of information and the new ways to access to and process it on the other are propelling the ongoing changes. Relations across borders show different features from the past, pervasive new technologies require legislators to think of uncommon approaches and innovative solutions, and legal practice has to adapt to a mutable job market and fresh needs. Information and data sets are now available in massive quantities at incredibly high speed and the internet put them at your disposal wherever you are. All this potentially conveys a burden of risks (e.g., in terms of privacy), but also prepares the ground for unexpected innovations in both the law and the legal practice.

Many research perspectives, interdisciplinary in kind, open up in such a challenging scenario and shed light on unforeseen paths. Artificial Intelligence (AI) and Law is one of those. In the next few pages, I will examine how AI has been increasingly transforming the law, legal reasoning, and the way we both apply and look at them. Then, I will consider how legal complexity in particular has stood out as a prominent challenge. Both as an intrinsic feature of the legal reality in our more and more litigious societies and as a consequence of the massive impact of Information Revolution and Big Data, complexity has challenged the predictability and certainty of the law. I will present predictive technologies and complexity measurement tools as a way out of the impasse. I will conclude by reporting about two other research lines that will probably strongly impact on our concept, as well as our daily experience, of law in the near future.

2. The computational approach of AI

AI and Law is a subfield of AI. Theorized for the first time at the Dartmouth Conference in 1956, AI has its roots in the pioneering work of the mathematician Alan Turing. His famous machine embodied the idea that a piece of machinery could be provided with an intelligence similar to the human one and therefore be able to carry out many tasks as a human being would.

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1 See [online], URL: <http://www.philosophyofinformation.net/books/the-fourth-revolution-how-the-infosphere-is-reshaping-human-reality> [last accessed: 28/04/2015].

AI as an independent field of research has grown out of this wish to recreate human intelligence in artificial systems, so that the mind-brain relation could be studied and finally fully understood. In doing so, AI scholars have attempted to model behaviors that are normally regarded as intelligent when humans perform them.

Generally speaking, and leaving out how the discipline historically developed, one of the main endeavors of AI is to design an artificial agent that can "maintain itself in a harmonious relationship with the world" (Kowalski 2011, p. 43).

In order to maintain a good relationship with the world, the agent needs to represent the environment in its own "mind" in such a way that it can properly and effectively react to threats as well as opportunities that eventually arise in there.

This can be fundamentally seen as a two-step process.

Firstly, the agent should have a clear representation of the world. Thus, knowledge has to be shaped in a language that is comprehensible to the agent and that can be effortlessly processed by it. The knowledge representation step is challenging and tricky at the same time (Kowalski 2011, p. 74). On the one hand, over-simplification of the reality should be avoided. This means that the formalization of the knowledge base has to deal with far from trivial issues featuring real scenarios, such as temporal conditions: when does a specific property of an object hold? Does this property continue to be true in a following moment? This presents quite a fascinating challenge, in which philosophers have also been engaged. On the other hand, AI experts have to choose what information is relevant for the agent's purposes and so needs to be formalized and included in the knowledge base. Real-life situations make available a huge amount of information, varied in kind, and relevance is *per se* an elusive and thorny concept. As (Kowalski 2011, p. 74) says, "it is this knowledge representation problem […] that is the major bottleneck in developing Artificial Intelligence".

Secondly, the agent should be able to make appropriate use of the knowledge at its disposal. Put it differently, it should have the capability to perform reasoning abilities starting from the knowledge base. Moreover, its reasoning performance should be flexible and efficient.

This view of knowledge and reasoning is shared with cognitive science. Thinking is "understood in terms of representational structures in the mind and computational procedures that operate on those structures" (Thagard 2014). Logics and rules of inferences allow the agent to use the knowledge base and perform reasoning activities.

3. AI and Law: a thriving interdisciplinary research field

This is a sketch of the conceptual framework along which AI research has developed since the second half of the last century. In its wake, AI and Law, as any other branch of AI, has been trying to perform or simulate behavior considered intelligent in the specific domain of the law. Accordingly, the main focus of AI and Law has been on "designing computer programs – computational models – that perform legal reasoning" (Ashley 2013, p. 783).

I will analyze along which lines these computational models have developed over the years, but before I will mention why AI and Law, considered as different domains of knowledge, can be found to be reciprocally interesting. They have even ended up with giving life to a flourishing interdisciplinary research field, and not to a mere "applications area" (Rissland *et al.* 2003, p. 1).

AI experts have been interested in the fact that some peculiarities of the law allow for powerful insights into representation, reasoning and learning, core of AI investigations. Legal language, open-textured concepts, legal reasoning, decision-making process, justification, argumentative strategies, information retrieval and extraction from legal documents are just a few of the difficulties AI has been strongly fascinated about. Moreover, law has exerted an appealing force because it is halfway between a purely technical domain, the area of expertise of AI scholars, and common sense knowledge, an out-and-out challenge to AI.

However, legal professionals and scholars have also been attracted by the inherent potentialities offered by AI. This has concerned both the theoretical level (could AI reveal new ways to address ancient issues concerning the nature of the law and thus provide the theory of law with unexplored conceptual framework?) and the application level (could AI ease their daily activities through tools supporting the decision-making process or data mining software?).

What is most stimulating is that solutions and ideas coming from AI and Law research have actually led to significant developments in other disciplines such as ethics, psychology, philosophy, and informal argumentation.

3.1. The use of logic in the legal domain

In any case, with such ambitious objectives in mind, researchers of both domains have paid great attention to properly representing legal knowledge in a formal way. Legal knowledge is expressed in natural language and therefore requires to be articulated in a logical language in order to be understood by a computer.

At first sight, logic and law show some common grounds: both stress the importance of correct reasoning in order to reach the conclusion. This assumption initially led to "some simplistic expectations" (Bench-Capon, Prakken 2008, p. 1): the law could be simply represented as a logical theory, and so conclusions could be deduced as mere consequences of that theory. This is the judicial syllogism: the legal rule is expressed in the form of a conditional ("if… then…") and constitutes the major premise, the fact is ascribed to the rule and represents the minor premise, the conclusion is drawn applying the rule to the facts.

Although the syllogism is still what gives structure to the judicial reasoning (Sartor 2009, p. 12), the approach may be seen as a "naïve deductivist view on legal reasoning" (Prakken 1997, p. 19):

> It is the old-fashioned view that the law is a consistent and complete body of rules which can somehow be discovered. In this view, all there is to legal reasoning is finding the valid rules and applying them to the facts in a deductive manner. […] essentially, the naïve deductivist view on law is the axiomatic view on legal reasoning supplemented with a belief in the fact that the truth or validity of the premises can easily be established.

The law is merely considered as a set of well-defined rules from which the conclusion can be easily derived. The law is far from being just this: general norms, exceptions, abstract concepts, conflicting rules, gaps of legislation, vagueness, open-texture concepts are typical of the experience of law and cannot be properly captured by such a formalization. Beyond pure and simple formalizations, reasoning and its fundamental structure have to be taken into account in order to deal with additional information, conflicts between conclusions, rejections of previously stated positions, contextual information, and disagreements.

A broader conception of logic was needed, and standard non-monotonic logics became soon a reference. Non-monotonic logics is a formal logic devised to represent defeasible inference, i.e., "that kind of inference in which reasoners draw conclusions tentatively, reserving the right to retract them in the light of further information" (Strasser, Antonelli 2014). This definition seems to fit the legal experience: it may happen that a legal conclusion needs to be abandoned when further pieces of information become available. So, what in an initial moment appeared to be reasonable to accept as a conclusion, later on can be replaced by another conclusion, although the first premises still hold. This is something that classic logics (e.g. first-order predicate logic) does not allow; the truth of the premises guarantees the truth of the conclusion, no matter what additions to the starting set of premises may occur.

Defeasible reasoning no doubt sees logics as having larger objects of study and areas of application compared with the mere analysis of deductively valid reasoning, and defeasible reasoning has proved useful when dealing with conflicts and uncertainties.

4. Lines of research

Many trends may be identified within AI and Law. These are sometimes expressions of conceptual frameworks relating to the traditional distinction between civil law and common law countries. The following subsections present an overview of some lines of research that have been developed so far. Before considering them, a few introductory remarks are needed.

First of all, I will take Ashley's article "Teaching Law and Digital Age Legal practice with an AI and Law Seminar" (Ashley 2013) as a chief reference. I share Ashley's opinion about the increasing importance of the contributions of AI and Law research to the legal domain. This is true both in designing useful tools for legal professionals and, when its study is introduced in Law Faculties' curricula, in providing law students with powerful insights and a better comprehension of the law.

Secondly, I will pay particular attention to the difficulties that challenge each of these approaches.

Last but not least, the focus will be primarily on "declarative approaches" (Bibel 2004, p. 178), i.e. those meant to design knowledge systems through formalization methods applied to the law. Nevertheless, I will briefly mention connectionism as an alternative point of view in the light of the Human Brain Project (HBP), recently funded by the European Union (EU).

4.1. Expert Systems and computational models of legal reasoning

As I stressed above, how to represent knowledge in a machine-readable format sounds like one of "the" questions of AI. Over the years, with a peak in the '80s, expert systems (ESs), also known as knowledge-based (KB) systems, have been designed with the explicit purpose to reproduce the decision-making skills of a human expert in a precise field of knowledge.

KB systems are computer programs able to process the knowledge stored in a database in order to solve problems. They use the formalized knowledge of a specific domain and implement computational models of reasoning. In order to design these artificial problem-solvers, it is necessary to choose a proper formal language.

In the legal domain two different ways of modeling legal knowledge and legal reasoning can be distinguished: the first one is based on rules, whereas the second one focuses on cases and precedents.

Rule-based reasoning

The idea behind legal expert systems reasoning with rules is that each legal system can be, in effect, considered as an ordered set of rules.

The rule, regardless of any deontic implication, stands for a conditional statement which connects two elements, an antecedent and a consequent, through an inference. This inferential scheme corresponds to the *modus ponens* in classical logic: $A \rightarrow B, A \vdash B$.

Each legal provision that is relevant to the concrete case in front of the judge is seen as a "if… then…" sentence. If the facts of the case can be subsumed under the rule, eventually the legal conclusion can be drawn.

Another way to look at it is to consider both legal provisions and facts as distinct sets. Considering the union of them as premise, the reasoner can derive the conclusion through deductive inference. In both cases, if the premises hold, the conclusion can be justifiably inferred, since the truth of the conclusion is guaranteed by the truth of the premises. Judicial syllogism is grounded on such assumptions. An axiomatic understanding of the law hides behind this perspective: indeed, statutory provisions are the axioms of the theory and legal reasoning is deductively performed starting from them.

In the '80s, Waterman and Peterson modeled an expert system that could assist in the settlement of product liability claims (Ashley 2013, pp. 803-805). There were three major hurdles to overcome: 1. how to specify the concepts of product liability, strict liability and negligence; 2. how to deal with indefinite legal terms and unpredictable jurors; 3. how to concretely compute damages. Their program included three kinds of rules corresponding to each issue and was designed to bring about an inference tree as output.

Many difficulties faced by legal ESs designers are nothing but intrinsic features of the law: abstract, unspecified or ill-defined concepts (e.g., negligence) and consequent semantic ambiguity, logical ambiguities (often, natural language does not pay much attention to the scopes of logical connectives), statutory complexity, unstated conditions. In short, rule-based systems find it difficult to cope with inconsistency in the knowledge base, an inconsistency that can be often attributed to specific political choices.

Among the many I have pointed out, two issues especially challenge this rationalistic approach: conflicting norms and Hart's open texture.

As undergraduates are taught in their first law courses, conflicting norms may occur either when there could be various interpretations of a legal text or when conflicting rules could be drawn from different legal sources. AI and Law researchers have showed great interest in conflict-resolution and in the idea of modeling of reasoning about preference criteria (Bench-Capon, Prakken 2008). Conflicts occurring among norms of a legal system have been addressed in the mid-Nineties (Sartor 1992; Prakken, Sartor 1995). Basically, rule-based systems have been improved through the implementation in their knowledge base of other rules that settle a hierarchical order. In doing so, it is possible for the artificial system to choose between the conflicting rules applying a principle that assigns a predominant value to one of the two. Among these legal principles are a) *lex specialis* (i.e. the specific law derogates the general law), b) *lex superior* (i.e. the higher law derogates the lower law) and c) *lex posterior* (i.e. the recent law derogates the older law), borrowed from the Roman interpretive tradition.

Open texture on the other hand calls attention to indeterminacy. Many legal concepts are often left undetermined: I have already referred to the illustrative example of 'negligence'. Speaking of this problem, Hart used the well-known case of the term 'vehicle'. Consider the following sentence: "Vehicles are not permitted in the park". It raises some doubts concerning what in concrete might be defined 'vehicle'. There is reasonable consent about the fact that a car is included in the concept and therefore is not allowed in the park. But what about skates, bicycles, motorcycles, and so on?

In classical logic, any member of a set cannot belong to another set as well. So, classical logic cannot help to perform a flexible reasoning that attributes meaning to open legal terms. There have been some research attempts to apply fuzzy logic to such situations (Philipps, Sartor 1999). Roughly speaking, fuzzy logics allows us to shift from natural language to numeric data and makes the agent able to perform approximate forms of reasoning.

In general, classical logics proves insufficient when it comes to modeling how lawyers and judges actually reason. In its frame, you cannot argue for a proposition and its contrary, and if you start from determined premises, you cannot withdraw them just because new information is available. They still hold true, and so holds the conclusion they guarantee. This is not always the case in legal reasoning. Lawyers are trained in finding opposite arguments, although they start form the very same premises. And contrarily to what classical logics says, they are still performing a sensible reasoning.

Case-based reasoning

In contrast to rule-based reasoning and classical logics applications to the law discussed above, the case-based (CB) reasoning model will be the focus of this subsection. CB systems are often applied in those countries belonging to the common law tradition and, from a legal theory perspective, are at the root of the American realism school of jurisprudence. Accordingly, the moment of the rendering of the judicial decision is more important than the influence that statutory law may exert on the judge. The law itself can be seen as a set of individual decisions.

In such a conceptual framework, previous decisions become of utmost significance: they are the main reference in order to perform reliable predictions on the content of the law at question in those judicial opinions. As I will better stress later on, prediction regarding future cases is what case-based reasoning is really interested in. This approach is no doubt practical and not really concerned with the outline of a plausible theoretical schema.

Dealing with cases stirs up some troubles. They can be put in the form of questions as follows:

1. How can hard cases be distinguished from easy cases?
2. How can analogical reasoning be performed in such a way that not only the system is able to compare cases, but can also distinguish relevant similarities and differences with the case to solve? How is the distinguishing process performed?

In such a system, there is an undeniable need to include in the knowledge base sufficient factual information regarding cases so that the ES can perform analogical reasoning, make a comparison, and find out similarities and differences. In doing so, it will point out, somehow predict, possible solutions to the problem's scenario.

HYPO (Ashley 1991) illustrates how a CB reasoning system can work in practice. It is a computer program that, provided with an appropriate set of facts concerning trade-secrets law, generates the skeleton of a legal memorandum. The memorandum includes legal conclusions, cited opinions, hypotheticals and counterexamples. The output is not simply the right answer, rather it sheds light on possible alternative paths. In short, it allows the consideration of hypothetical cases and alternative reconstructions of the facts of the case.

In HYPO, cases are described in accordance with a three-ply abstraction system: case and situation representation language, relevant factual predicates, and dimensions, i.e., legally relevant aspects of the case. This description should point out to the parties the weaknesses and strengths of the various positions. The construction of arguments draws on the analysis of the described cases.

However, there is no way for the user to check the validity of the arguments so obtained. The proposed solutions remain unjustified. This may be seen as a flaw of case-based systems. Legal systems and the judiciary are grounded on justification.

In any case, the attempts of AI and Law to model similarities and differences all tend to provide descriptions of the factual scenarios of cases, to include them under patterns and to extract facts considered significant by judges in their opinions (Ashley 2013, pp. 811-812). This shape the idea of a law emerging from the practical experience, that can be categorized under precise recurring schemes and so predicted in its judicial outcomes.

4.2. Artificial Neural Networks

I have showed how the declarative approach to legal knowledge has been extensively explored by the research community. Although the approach faces undeniable difficulties, it still has some interesting prospects of development.

AI researchers have also been considering connectionism as an alternative approach. Connectionism seeks to model mental activities as processes emerging from interconnected networks of simple units.

The more common connectionist models are artificial neural networks (ANNs). ANNs draw their inspiration from biological systems and, specifically, from the way the brain processes information. Just as the brain is able to work because of the connections among neurons, the artificial neural network uses a large number of highly interconnected processing elements (PEs) to solve specific problems. Neural networks usually consist of three layers: input units, hidden units and output units. PEs are linked up with a specific weight interconnection: only when the required weight is reached, do the neurons activate and give the appropriate outcome, applying a threshold mathematical function.

Applications of ANNs in the legal domain dated back to the Nineties (Bench-Capon 1993; Zeleznikow, Stranieri 1995; Bochereau *et al.* 1999). For example the Split-Up project (Zeleznikow, Stranieri 1995) made use of machine learning techniques based both on rules and ANNs to model how an Australian Family Court judge could divide marital property following divorce.

Law presents features difficult to deal with for an ANN: contradictions, exceptions, gaps in the legislation, judicial discretion. Contradictory legal data may mislead the neural network's generalization mechanism. Indeed, the ANN internalizes the cases, examples or rules it has been exposed to during training (through a method similar to the analogy-based reasoning), and exceptions are not easily recognized.

Moreover, it is impossible to completely justify how the neural network has reached one output instead of another one. Hidden units act without deterministic algorithms: the ANN itself organizes its activity flow and the path taking to that specific result cannot be retraced *a posteriori* and by an external witness.

These shortcomings have prevented further investments in this line of research in the legal domain. The recent funding of the Human Brain Project (HBP) by the EU, however, may represent a turning point and smooth the way for a revival of this perspective. The Project aims to better understand the human brain with the goals not only of new insights into our nature but also of the development of "brain-inspired computing technologies" and "interactive supercomputing". As the HBP website, describes it:[2]

> HBP Neuromorphic Computing Systems will use brain-like principles of computing and architectures to achieve high-energy efficiency and fault tolerance, together with learning and cognitive capabilities comparable to those of biological organisms.

There is a chance therefore that bottom-up and parallel approaches to knowledge may be tentatively implemented in the legal field. Especially, supercomputing abilities could allow processing growing legal data in a more and more efficient way. While these now sound as mere conjectures, there is great potential for productive analysis of big quantities of legal information and for designing of practical tools that may assist the legal practice in future.

5. Law and complexity: an inseparable couple

In my introductory remarks, I made a point on which all this Chapter pivots. The world we live in is increasingly complex. Massive movements of people across state borders, societal changes, new transnational relations, technological advances, scientific progress, huge data flows are some of the underlying forces that are boosting complexity in many ways. And the list is far from being exhaustive.

2 See [online], URL: <https://www.humanbrainproject.eu/> [last accessed: 25/04/2015].

Clearly, the law cannot be indifferent to how earth tremors of this size and scope are shuffling the cards. It is primarily a social phenomenon and as such it mirrors the world it is meant to regulate and therefore its complexity (Kades 1997).

Computer science and AI have strong interest in complexity (e.g. developments incomplexity theory) and may provide valuable approaches to face the phenomenon in the law.

5.1. Sparks of complexity in the legal landscape

Before addressing the core issue of this section, a small step back may proves useful. The law is somehow inherently characterized by complexity. There are some high-level concepts around which legal systems are built (e.g. constitutional principles) that have an open texture. Sunstein talks about "incompletely theorized agreements" (Sunstein 2006) precisely to define the agreements the society reaches on general principles, leaving unspecified their applicative details. According to the author, a general principle of this kind would allow social stability, would avoid lasting political conflicts, and would boost the moral progress of the society.

However, in the recent years, legal complexity has grown considerably. Our society is more and more litigious, and national courts are generally overwhelmed by ever-growing amount of lawsuits. This frequently leads to contrasting judgments and to a general lack of legal unity (Bibel 2004).

Moreover, some branches of the law (e.g. tax law, both at the international and domestic level) show a particular intricacy and pose real "cognitive difficulties" (Kades 1997) for judges and lawyers. Indeed, these legal sectors make use of a highly technical and specialized language, sink in details and are full of cross-references and interconnections with other pieces of legislation.

Last but not least, the number of statutes and regulations has literally exploded (Bibel 2004), at any level and on any subject. The occurrence of overlapping and accidental interrelationships is on the agenda of the legal expert, and whoever approaches this messy scenario feels disoriented. Needless to say that democratic principles and the rule of law are endangered as well: common citizens may experience the sensation of being unable to understand what their rights are and what the legislation in force is.

5.2. Big Data and Information Revolution: What about the law?

Legal complexity has also been amplified by the disruptive emergence of Big Data.

The term, coined by computer engineers and scientists, refers to large-scale data sets collected through sensors, computers, smart phones and the like, to deal with which traditional data processing tools are falling short. Indeed, they cannot cope with large, chaotic, unstructured and fast moving data. In 2010, *The Economist* devoted a special report on the management of information, and I will partly refer to those early, comments.[3]

The massive and increasing amount of data makes tough demands in terms of storage capacity, data security and privacy protection. The promises of Big Data are high, in the sense that many areas will probably benefit from a proper use of the information flow (Marr 2013). Consider the plausible effect on health care, scientific research, or financial trading. But the most intriguing challenge is to give an answer to the following question: how can we "make sense of all these data"?

Our economy is deeply data-centered and various multinational companies (e.g. IBM, Google) are struggling to get the most of it, investing significantly on research to develop more and more sophisticated algorithms and data analytics tools. The raw data available in strikingly huge quantities must be managed meaningfully. How to extract knowledge from data is what will make the difference in the end.

Living the Information Revolution, every day we make use of innovative technological devices and face challenges never seen before. The way we conceive of our identity and of the society in general is undergoing momentous transformation (Floridi 2014), and information often conveys such explosive changes. But what is information? Floridi gives a definition in terms of the mathematical theory of communication: information reduces uncertainties about the world (Floridi 2015). According to this view, information can be measured in bit units through an equation. A result of this calculus is "the average informativeness per symbol". As Floridi argues, information is defined as being composed of well-formed and meaningful data: data not only have to follow a syntax, but also have to refer to a precise semantics (Floridi 2015). Thus, information is denoted by a semantic content that allows a cognitive observer to acquire knowledge from it. The shift from syntax to semantics is therefore unavoidable and desirable.

How is the law affected by all this? For a start, as in any other field of knowledge, data in the legal domain have grown exponentially. In US, the

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[3] See [online], URL: <http://www.emc.com/collateral/analyst-reports/ar-the-economist-data-data-everywhere.pdf> [last accessed: 28/04/2015].

discovery phase in civil trials has become extremely challenging: imagine having to manually search for proofs of a case in millions of emails.

In addition, data are collected in multiple ways, often without any previous consent of the person they concern. Even if the data are anonymized, with the help of advanced algorithms it is often possible to trace back to a particular person. Clearly, this questions our real capacity in such a scenario to protect sensitive data and to provide for an adequate regulation of privacy.

Lastly, data mining software allows its users to extract patterns of behaviors from large amount of data applying probabilistic theory. There have already been cases of the identification of criminals through the extraction of uncommon behaviors detected in a sample by the algorithm. The impact of such tools on legal theory, jurisprudence and the rule of law promises potential turmoil.

5.3. Ways through or ways out? Quantitative predictive technologies and measurement of legal complexity

I have analyzed quite extensively the computational approach of AI and its main outcomes as regards AI and Law. These are not interesting only for that community. Indeed, computer science, computing techniques, and general technological advances are already transforming both "what it means to practice the law and to think like a lawyer" (Katz 2013, p. 911).

Most of all in common law countries, one of the chief objectives of legal practice has all along been prediction. Competent lawyers should be able to provide their clients with reliable predictions about the possible outcomes of their case, the plausible opinion the judge will express to decide it, and the likely costs the legal procedure will have. Decreases in data storage costs and increases in processor speed (also known as Moore's Law) have brought about a proliferation of electronically stored documents, whose analysis is required in order to find relevant pieces of information for a case (so called E-discovery).

In such a context, it does not really matter whether the prediction is produced "by a mental model or a sophisticated algorithm" (Katz 2013, p. 912). This is exactly where quantitative predictive technologies (QLP) leap out. In the "age of data-driven law practice" (Katz 2013, p. 913), QLP is shaping the legal service business trying to predict costs, outcomes, and the financial exposure of the case. Katz presents a far-reaching work where "soft" AI tools may serve the purpose of intelligently reaching prediction outcomes starting from legal data and applying case-based reasoning approach (Katz 2013).

Katz and Bommarito put forward another interesting project that tries to measure legal complexity and tries to go one step further towards predictability (Katz, Bommarito 2014).

> In this paper, we address this need by developing a proposed empirical framework for measuring relative legal complexity. This framework is based on "knowledge acquisition", an approach at the intersection of psychology and computer science, which can take into account the structure, language, and interdependence of law. (Katz, Bommarito 2014, p. 337)

The idea is to apply to the United States Code computational methods in order to scale the dimension and scope of that large body of law. The computational approach has some undeniable advantages: it gives mathematical representation of the object of study and at the same time produces a measurement strategy for it. Basically, Katz and Bommarito have identified the hierarchical structure of the pieces of legislation composing the code and the citation network among them (Katz, Bommarito 2014). The combination of these two elements brings about the US code as a whole. Furthermore, the system is set up to provide a composite measure of the code based on three components: structure, dependence and language.

Without going into technical details, Katz and Bommarito have shown a path to measure the complexity of legal rules and pointed out how computational methods can effect on empirical legal studies (Katz, Bommarito 2014).

The world is changed. Not so many years ago, De Mulder *et al.* (2010) tried to smooth the way to jurimetrics as a useful support for the law in the information age. They gave a harsh judgment on how late the legal practice actually was in that respect:

> […] the legal profession and legal services have hardly changed their modus operandi. Most lawyers are simply not familiar with quantitative, empirical or computer supported approaches. Furthermore, they try to avoid such contact as much as possible. In some cases this reluctance could possibly be explained in terms of a perception of their self-interests. This negative attitude towards innovation will, however, turn out to be too costly. In the modern world of globalisation, innovation is essential for all organisations and those in the legal field will not be an exception. (De Mulder *et al.* 2010)

Times are now ready for a thorough reconsideration of the role of the lawyers and of the ways they perform their tasks. Data and AI are resources for this reconsideration and can prove useful if properly implemented. There is no reason to keep on tilting at windmills. Legal practice will survive the ongoing massive changes if it keeps an open attitude towards innovation and brand-new perspectives.

6. Upcoming developments: how will be the law of the future?

Technological progress is moving at incredibly fast pace, and we are running the risk of being overwhelmed if we do not find a way to reconcile the law with technology, information and AI. AI and Law has an important story to tell.

The aim of this Chapter was to show the historical opportunity we are witnessing: AI, at least in its "soft form", is developed enough to allow legal professionals to take precious advantage of it. Some research is definitely moving towards this goal.

As I have already noted, moving from syntax to semantics is one of the great challenges to AI. Many research efforts are going in that direction in the legal domain: application of Natural Language Processing (NLP) techniques to the law, modeling of legal ontologies, formalization of legal norms and legal reasoning, with an eye to the Semantic Web standards. The OASIS Legal Rule ML project is a concrete example of this endeavor.[4] Although an in-depth analysis of it is not within the scope of this Chapter, Legal Rule ML is perfectly in line with the plan that the AI and Law community has been sketching over the years. Indeed, it is a precious headway towards making computers able to understand the content of the legal data such rules are conveying. In the near future, judges and lawyers could be assisted by artificial systems capable of retrieving material relevant to the case making use of metadata relating to the content: a stunning innovation.

Another significant area of research destined to strongly impact on the very way we conceive of the law is that of Multi-Agent Systems (MAS). There is no unique definition of what a MAS is, but there is agreement on the fact that a MAS is a metaphor for a certain way of seeing the world. In other words, it provides a model of the world.

The term indicates an environment where many entities (i.e., the agents) act. 'Act' means that the agents have the ability to transform the environment. As such, MAS needs to embed knowledge, goals, beliefs, intentions, execution ability, decision-making skills. No doubt MAS are a simplification of the

[4] See [online], URL: <https://www.oasis-open.org/committees/legalruleml/charter.php> [last accessed: 28/04/2015].

world, but through them it is possible to study collective phenomena, involving rational entities that act in a stable and shared environment (Noriega *et al.* 2013). This kind of social world requires institutions and rules.

This brief overview on MAS gives an idea of its interest from the legal perspective. The law is not external to the system and imposed from high on. Rather, norms need to be embedded in the system through ontologies and are modeled in logical language. Many types of logics may fit for the purpose, depending on what has to be formalized (e.g., time, interactions, epistemic components). Game theory has been referred to in order to better model the mutual interactions among agents. Moreover, agents' compliance with rules is mainly assessed through identified behavioral patterns. Trying to abstract from MAS, sheds a different light on the law as a social phenomenon and empirical science. 'Legal' is what can be categorized as a (previously defined) compliant behavior. This theoretical shift is linked also to the progress in automated reasoning systems and data mining tools that are designed to detect relevant data and classify them and that are being employed in detecting recurring patterns of personal behavior. Think of sensors in the context of a smart house that can recognize emotions and feelings of the person living in the environment. Leaving aside here the trickiness of the privacy issues involved, this clearly changes what we intend with 'law'.

These research trends will end up with impacting critically on the law considered at large: law as a knowledge field, law as a social phenomenon, and law as a professional practice.

The opportunities are many, and many are the perils as well. Still, the legal world cannot exempt itself from taking the reins if it wants to have any control over what is going on. Innovation, not denial is the only walkable path.

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The Education towards a Legal Career in Italy Today: An Innovative Path

Maria Eleonora Benini, Chiara Colicchia, Federica Fazio

1. Introduction

Innovation means considerably more than just the advent of something new. The inner process of the human progress and its concrete achievements bring along continuous challenges in everyday life. IT tools and advanced digital technologies have already led to a change, since they have become essential in many fields in order to work efficiently and to organize and give an order to the constant information flow. In particular, the legal profession is now facing the challenge of innovation.

The education of a young legal professional requires the acquisition of a sharp and quick legal reasoning, a problem-solving approach, legal writing skills and a broad preparation with respect to IT tools and digital technologies. While universities and post-graduate courses are already playing their part in this process by opening the door to international mobility, through legal research in databases and legal catalogues or through an in-depth preparation for competitive exam for state jobs, recent reforms in the Italian system have provided a new opportunity that will boost the preparation and the competencies of a young legal professional in order to access the job market: judicial clerkship.

The Italian Law Decree no. 69/2013, by its article 73,[1] allows students to access the judiciary system by assisting a judge as law clerks. This judicial clerkship helps students gain an excellent and a high-standard knowledge of the legal institutions and of the application of these institutions to the case law in order to solve the matters raised before the Court. This typology of work, combined with the supportive assistance of the judge, entails several "driving forces" that are leading young legal professionals to build strong and competitive skills so as to succeed in the legal careers.

[1] Law Decree no. 69 of 21st June 2013, converted into the Law no. 98 of 9th August 2013, emended by the Law no. 114 of 11th August 2014.

This Chapter will first review the traditional contours of Italian legal education. These have been shaped by the reforms of European university education arising from the Bologna Process and by the possibility of post-graduate specialty education. It will then review traditional requirements for "on the job" training before turning to the innovative possibilities of the judicial clerkship.

The methodology used in this Chapter to detect and to objectively analyze the driving forces behind the clerkship experience has been based on a survey submitted to the law clerks of the Tribunal, of the Court of appeal of Milan and of other judicial offices at the national level. The survey has provided extensive data and feedback about the judicial clerkship, and it allows us to draw a picture of the current framework in which a judicial clerk acquires and improves the necessary skills to become a legal expert and professional.

In summary, the judicial clerkship *ex* art. 73, *breviter*, is an answer to the challenge of innovation in law. The Court and the judiciary system provide the kind of environment that offers a complete preparation, even in comparison to other contexts, such as the Specialization School for Legal Professions (SSPL), law firms or companies' legal offices, offer a complete legal preparation. Clerkship fills the existing gap between the university education and the work as professionals. The challenge of innovation in law also includes young professionals' energetic and dynamic contribution to the judiciary system, in respect to both the reduction of the backlog work and the employment of IT tools and digital technologies.

2. University studies

2.1. The historical excursus and the Bologna process

Italian universities are among the oldest in the world. In particular, the University of Bologna, founded in 1088, is considered the most ancient university of the Western world. Most Italian universities are state-supported: for the majority, universities are state-funded public institutions. Some, however, are funded by other public authorities (such as Provinces), such as, for example, the Free University of Bozen-Bolzano. There are also several private universities that are officially recognized by the Ministry of Education.

Historically, Italy played an important role in the development of a system of higher education, and it is still part of the current process of transformation affecting universities' inner structure, in the framework of a larger European university reform, named "the Bologna process". The Bologna Process is a series of ministerial decrees, such as D.M. no. 509/99 and D.M.

no. 270/2004,[2] resulting from the agreement between European countries, the European Higher Education Area, aimed at equalizing standards and the quality of higher education qualifications. The Bologna Declaration was originally signed by 29 European countries and now includes 47 participating countries and 49 signatories.[3] This innovative reform seeks not only to enhance students' mobility within and outside Europe, but also to improve the university academic offerings and the related professional competencies, in order to boost career opportunities for recent graduates and facilitate the access to the job market.

2.2. Current framework

Since 1999, by D.M. no. 509/99, university studies in Italy have been fully reformed so as to meet the objectives of the Bologna process.[4] The reform, also guided by the amendments made by D.M. no. 270/2004, sets a new academic qualification framework, which is organized in three cycles.

The first cycle academic degree is the *Laurea*, a 3-year course, for a total of 180 ECTS, that provides access to the second cycle, the *Laurea Specialistica/ Laurea Magistrale*, that has a 2-year duration for a total of 120 ECTS. The completion of the second cycle grants access to the third cycle, the *Dottorato*, with a legal length of 3 years. With respect to the third cycle, the ministerial decree does not set credits for the research doctorate, since it is essentially based on individual research activities.

As an example of the results achieved by the Bologna process, it is possible to draw a parallel between the Italian university qualifications and those of other European countries, such as those granted by universities in the United Kingdom. The first cycle is equivalent to the Bachelor of Science degree, while the second cycle corresponds to Master of Science and, finally, the third cycle is a PhD equivalent (Figure 1).[5]

In addition to the main qualification indicated above, the Bologna pattern recognizes two more degrees comparable to the second and the third cycle qualifications.[6] With regard to the second cycle, the *Master di primo livello* is

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2 Ministerial Decree for the regulations on didactical autonomy of universities no. 509 of 3 November 1999 and Ministerial Decree for amendments to the regulations on didactical autonomy of universities no. 270 of 22 October 2004.

3 Council of Europe, "European Cultural Convention", Paris, 1954.

4 URL: <http://www.miur.it/guida/capitolo3.htm> [last accessed: 05/05/2015].

5 URL: <http://www.iulm.com> [last accessed: 05/05/2015].

6 URL: <http://www.crui.it> [last accessed: 05/05/2015].

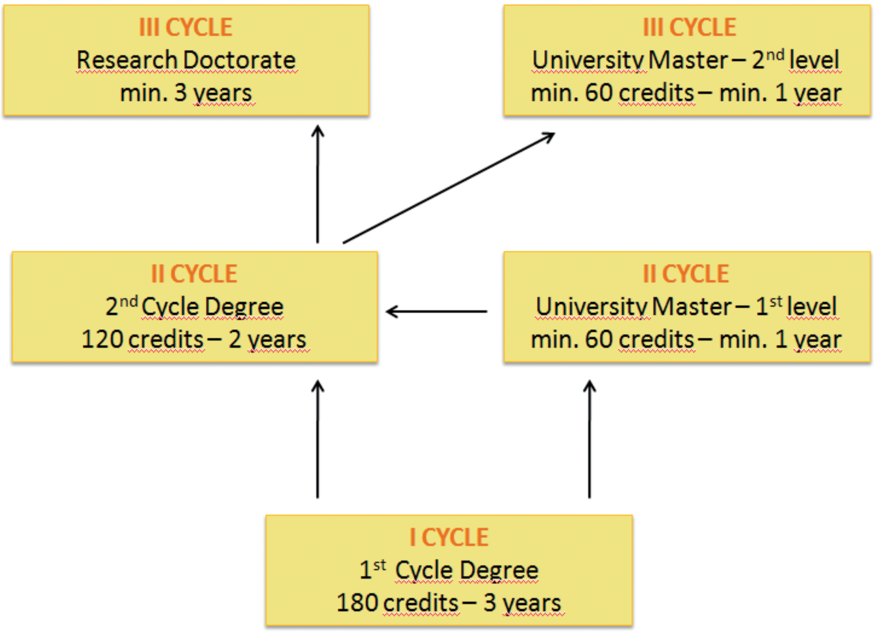

Figure 1. Scheme of academic education in Italy.

a 1-year program that provides a specialization in a specific field, generally connected to the *Laurea*. With regard to the third cycle, the *Master di secondo livello* lasts one year as well and provides a higher and even more specific education on a particular subject. The latter is almost comparable to a third cycle qualification, although it has a more practical approach rather than focusing on academic research like a PhD program.

2.3. European Credit Transfer and Accumulation System (ECTS)

These reforms have introduced a system of university credits (ECTS) for the first time in Italy. The credits represent the workload for a student to attend the course, including class time, individual study, exam preparation, practical work, etc. In this system one credit corresponds to 25-hours of preparation. Depending on the course and upon a reasonable justification, the university has the discretion to vary the amounts of corresponding credits for a maximum of 20% (1200-1800 hours). A minimum threshold of 50% has been set for the time reserved for individual learning or other individual educational and training activities. The students earn the credits once passed the examination or the specific assessment for each course or activity. It is not unusual, however, that universities recognize credits also for professional experiences, according to their regulations, as well as for post-graduate courses that have been set up in collaboration with the university.[7]

2.4. Academic mobility

The Bologna process has facilitated and improved the possibility for students to carry out a study-abroad experience by making it easier to recognize and convert credits and examinations carried out in universities of other European and non-European countries. Many programs, such as Erasmus, Erasmus Mundus, and Overseas, as well as foreign internships, post-graduate university courses and study grants for research abroad, through an application and upon possession of specific requirements, allow students to be competitive in the international scene and to build competences that are specific of the destination country, but that are also useful back in the home country.[8]

For these reasons, universities are increasingly interconnected and they cooperate towards a higher standard of education thanks to important institutional agreements. As a result, university courses are more interdisciplinary, with focus on other countries' comparable science and often offered in a foreign language. Specialized university institutions and language centers also offer economic language courses for learning a new language and obtaining a language certificate at their conclusion. Usually, these courses also include advanced language learning programs or even specific technical language levels, such as legal English courses.

2.5. The Laurea Magistrale in Giurisprudenza

The Ministerial decrees classify the degree courses in 47 different classes for the first degree *Laurea* and 109 different classes for the second degree *Laurea Specialistica*. The *Laurea Magistrale* in *Giurisprudenza* is catalogued among the second degree or second cycle qualifications. However, the *Laurea Magistrale* has an unusual pattern. It is a unique 5-year degree and counts 300 ECTS, corresponding to the sum of the first degree (120 ECTS) plus the

[7] URL: <http://international.polito.it> [last accessed: 05/05/2015].
[8] URL: <http://www.unibocconi.eu> [last accessed: 05/05/2015].

second-degree credits (180 ECTS). Thus, while other disciplines have the first cycle as a general degree and the second cycle as a more specific one, with the possibility to eventually make a choice even between more options, the *Laurea Magistrale* represents a sole and continuing course. During their academic career, law students generally can choose between several elective courses in order to specialize on a particular subject and write the final dissertation on it.

The *Laurea Magistrale* in *Giurisprudenza* provides students with an extensive knowledge of the national, the European and the international legal system, through the study of the laws, the Courts' jurisprudence and the legal doctrines that apply. At the completion of the *Laurea*, a student gains a deep understanding of the general principles of law and the relevant legal institutions as well as the analytical skills necessary to address problems of implementation and interpretation of the law, and she is able to understand the current legal framework in the perspective of the evolution of the law over time.

In Italian law schools, the majority of the examinations are in oral form, and this brings pros and cons. On the one hand, students are obliged to study the subject in-depth, since it is difficult to refer orally to something that has not actually been understood and to "deceive" the examiner. This generally implies the capacity to conduct individual study and a complete legal research on the topic, including the use of IT tools, such as databases and legal catalogues. The oral exposition forces students to hone their speaking skills and their legal vocabulary in the future expectation of dealing with clients, arguing with colleagues and presenting arguments before a Court. Oral examinations also improve self-confidence and the ability to reason over an issue on your feet.

On the other hand, students have very few chances to write about legal topics. Generally, the courses do not include writing workshops or legal writing laboratories. It is up to the student to find a course outside the university curriculum to improve her writing skills. This is a critical educational gap that has a negative effect on the future legal career that, with the advent of digital technologies, is mostly based on written activities. It also has a negative effect on preparation for the state competitive examinations that recent graduates are likely to take. As a result, a student, upon graduating, has not acquired the skills necessary to set clear legal texts such as deeds, briefs and contracts, or more generally to use the legal jargon to draft a document.

3. Postgraduate studies and training

3.1. The Specialization School for Legal Professions (SSPL)

After the *Laurea Magistrale in Giurisprudenza*, law graduates aspiring to become judges, lawyers or notaries may decide to attend the Specialization School for Legal Professions (SSPL). The School, a 2-year course, offers post-graduate students an advanced level of legal education, including all areas of law (from civil to criminal law and many others), in order to gain access to the competitive examination for ordinary magistrate. Moreover, the diploma obtained by passing the Specialization School's final test not only entitles to access to the judicial magistrate competitive exam, but it is also equivalent to 1-year internship to practice as a lawyer or notary.

The general regulation of the SSPL is set by the Decree of the Minister of Justice no. 537/1999 concerning the rules for the institution and organization of the Specialization School for Legal Professions.[9] However, Schools of law established the first Specialization Schools in 2000/2001.

Admission to the SSPL is granted by the possession of a second cycle degree (*Laurea specialistica* or *Magistrale*) and by passing the entrance test, but it is also subject to a more general assessment of qualifications (for example the GPA). Actually, the test is not a very demanding requirement, consisting of multiple-choice questions on substantive and procedural law. The number of students who desire to access the Specialization School is generally limited in comparison with the places available, with the result that the entrance examination is not competitive at all.

The first year of study is equivalent for all students, while in the second year each student has to choose to specialize in legal and forensic sciences or notary studies. Attendance to courses is compulsory, but is organized on a part-time basis. Students are required to attend about 500 hours of lessons per year involving both face-to-face lectures and practical exercises or exam simulations. Each year, the SSPL offers students a 100-hour training period in judicial offices, law firms or notaries' offices, according to the preferences expressed by the students. In fact, due to both the lack of collaboration with the legal professional environment and difficulties in organizing and paying the costs, the SSPL is not able to guarantee a practical experience to all the students.

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9 The Decree of the Minister of Justice no. 537/1999, emended by the Decree of the Minister of Justice no. 120/2004, implements the Legislative Decree no. 398/1997, in accordance with the Law no. 127/1997 and with the Law no. 341/1990.

During the courses, there are some intermediate tests concerning the courses that are evaluated by the school examination board, mainly composed of university professors and researchers, but also of legal practitioners (lawyers, judges and notaries). The tests are evaluated by marks in order to allow students to be aware about their own strengths and deficiencies.

Relatively few law graduates choose to attend the SSPL because of several critical aspects the School presents. First, the students have to pay the school fees, but they do not necessarily receive adequate preparation either in respect to the number of hours and courses, seminars and workshops offered or to practical training. Moreover, the classes focus on the theoretical apprehension of the legal institutions so that the students end up studying the subjects by heart and have difficulty in the comprehension of the *ratio* of each legal institution and its concrete implications. Despite the fact that students perform several written exercises and work on simulated case files, defensive deeds and judicial orders, all these activities are led by the lecturers, with the result that students do not really develop an autonomous problem-solving approach. Secondly, the SSPL does not provide the necessary skills to succeed in a legal profession, because courses mostly consist in an individual theoretical revision of subjects already studied during the university period, without the addition of a practical and more professional approach.

To satisfy the requirement of practical legal experiences, the SSPL usually sets up traineeships in judicial or professional offices. However, sometimes the students do not have the possibility to train at all, and even if they do, a 100-hour training experience per year is often so brief as to be quite useless.

3.2. The legal training in the law firm

In Italy, like in most countries in the world, future lawyers are required to undergo a period of professional training in a law firm. The duration of the traineeship used to be 2 years, but since 2012 it has been reduced to 18 months.[10]

The traineeship is generally regulated by the D.P.R. no. 137/2012.[11] However, specific regulations are separately set by each *forum*'s bar association ("Ordine degli Avvocati"). The registration as a legal trainee requires the

[10] Pursuant to art. 9, paragraph 6 of Law Decree no. 1/2012 (converted into Law no. 27/2012) on the protection of competition in professional services.

[11] Regulation amending professional rules in accordance with art. 3, paragraph 5 of Law Decree no. 138/2011 (converted into Law no. 148/2011).

prospective lawyer to have a second-cycle degree in law (*Laurea specialistica* or *Magistrale*) or to be in the last semester of the university career.[12] These requirements are mainly the same for each *forum*, even though additional requirements are at each bar association's discretion.

For the sake of convenience, we will focus on the rules set by the bar association of Milan. Under their provisions, all trainees are required to work diligently – on an every-day basis and for no less than fifteen hours per week – in a law firm and to attend a minimum of twenty public hearings every semester. At the conclusion of every semester, they are required to write in detail about at least five legal issues on which they focused during the traineeship and to indicate at least five judicial or non-judicial deeds they have drafted. Additionally, at the end of the twelfth month and of the eighteenth month of training, the trainee has to write a fully detailed report about the entire activity performed in the firm that must be handed in to the membership bar association. As mentioned before, the SSPL diploma corresponds to 12 months out of the 18 required for the legal traineeship.

During this legal traineeship, the trainees are supposed to study in their free time in order to prepare for the bar exam; therefore, the law firm should give the trainees the necessary time to study. Unfortunately, law firms generally ask the trainees to work for eight to twelve hours a day, thus offering them almost no time for individual study. The trainee is entitled to receive a fair remuneration and to be refunded for the expenses. However, most of the time, a trainee earns between 300 and 600 Euros per month, but in some cases the legal trainee does not even get paid.[13] At the completion of the 18 months and by passing a final oral examination, the trainee is qualified to attend the national bar exam.

The Italian bar exam is quite difficult and the procedures are extremely long. The bar exam consists of two parts: a first part, which is written; and a second part, which is an oral examination, that a student can only take by passing the first written part. The written part of the exam usually takes place in December every year and requires the test-taker to draft a defensive deed and two legal opinions on civil and criminal law. Candidates have to wait approximately until June of the following year to know the results of the written

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12 This provision, pursuant to art. 9, paragraph 6 of Law Decree no. 1/2012, remained practically unimplemented due to the lack of necessary conventions between bar associations and the Ministry of Education, University and Research.

13 Pursuant to art. 9, paragraph 4 of Law Decree no. 1/2012 the trainee is entitled to obtain a flat-rate refund of the expenses only after six months of training.

exam. The oral examination takes place between September and December. The bar exam has been very controversial. Every year there are accusations of bribery, forgery, and otherwise unclear and unmotivated scores. The bar exam does not guarantee a meritorious selection and it seems that it artificially limits the number of new lawyers entering the market every year on the basis of the legal market's demand.

3.3. The legal training at the judicial office

The opportunity for law graduates to improve their preparation by working as law clerks is quite recent in Italy. Inspired by the experiences of other countries,[14] some Courts, at the end of the last decade, promoted several experimental training programs. Those programs, started on the basis of specific agreements between the Courts and the bar associations, laid down the foundations of the current system.[15]

The possibility to serve as a law clerk was introduced on a national basis by Law Decree no. 69/2013, converted into Law no. 98/2013 and amended by Law no. 114/2014.[16]

Law graduates can apply, only once, for an 18-month clerkship at Courts of First Instance, Courts of Appeal, Surveillance Courts, Tribunal for Minors, Criminal Courts, State Procurator's Office, Regional Administrative Courts and Council of State. The admissions to the clerkship are based on the following requirements:

- the completion of a second-cycle degree;
- the integrity of the individual candidate as defined by R. D. no. 12/1941, article 42-ter;

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[14] For instance France, Germany, Sweden, U.K., Israel, USA, Canada, Mexico, Philippines, Pakistan, India and New Zeland.

[15] On the 20th of March, 2007 the Bar Association of Milan and the Presidential Office of the Court of Appeal in Milan signed a Convention concerning the traineeship in the judicial offices called "Progetto Ufficio del Giudice". Then, the Italian Superior Council of Magistracy (CSM), with its resolution on 19 July 2007, regulated this experimental project. The Legislature, with the art. 37 of the Law Decree no. 9 of 6 July 2011, converted into the Law 111/2011, provided a legal basis to the Conventions between the Chiefs of the judicial offices and the Bar Associations, the Specialization Schools of Legal Profession (SSPL) and the Universities with reference to the traineeship in the judicial offices. This traineeship was considered equivalent to 1-year of legal internship in order to attend the bar exam, of attendance of the SSPL and of a PhD program.

[16] Law Decree no. 69 of 21st June 2013, converted into the Law no. 98 of 9 August 2013, emended by the Law no. 114 of 11st August 2014.

– a GPA (grade point average) of 27/30 in the relevant subjects of: constitutional law, private law, civil procedural law, criminal law, commercial law, criminal procedural law, labor law, administrative law;
– a university final grade higher or equal to 105/110;
– being under 30 years old.

When more candidates than the open positions all fulfill the above-mentioned criteria, the recruitment committee ranks the candidates on the basis of higher GPA, higher university final grade score and younger age.

In order to be selected for the position, candidates must apply to the Chief of judicial offices, by attaching the documents that prove they meet all the requirements. Candidates may express their preference based on subjects they are more interested in for a specific judicial office they would like to be assigned to. The recruitment committee takes into account these preferences matching them to the needs of each different office. Selected candidates are then assigned to a judge who has ensured his availability beforehand. Each judge can supervise only two judicial clerks. The Minister of Justice has to provide each law clerk with computers, internet access, on-line databases and all furnishing and suitable office equipment.

The intern supports and assists the judge during his everyday activities that differ from Court to Court and from judge to judge. The clerkship encompasses a variety of tasks, such as: doing legal research, drafting opinions, keeping research and trial memoranda, performing legal analysis, and briefing the judge on various legal issues important to the ruling in a specific case. The work can be very demanding while assisting the judge under strict deadlines and a heavy workload.

In the courtroom, the judicial clerk prepares oral arguments, hearings and trials, as well as preparing trial memoranda for the judge and drafting orders and injunctions when necessary. The clerk is responsible for drafting opinions according to the judge's directions after the conclusion of the process by also summarizing the parties' briefs.

The judicial clerk builds a responsible relationship with the judge. The clerk owes the judge complete confidentiality, accuracy, and loyalty. Being aware of the respect due to the judge, in the deliberation process the judicial clerk should express and is often required to express her opinion on the ruling. The law clerk trusts the judge when possible divergences rise on the final decision, but the judge relies upon the clerk's research in reaching conclusions and, in case of conflicting opinions, the judge explains the reasons behind the final decision in order for the clerk to understand and agree on the judge's considerations. At the same time, the judge relies on the law clerk's confidentiality and must be able to count on complete loyalty. If this relationship of mutual trust between the judge and the clerkship fails, the judge may terminate the clerkship. An interruption may occur also for unforeseen organizational reasons, especially when the independence, impartiality, transparency or reliability of the judicial function might be compromised.

During the clerkship, law clerks can attend advanced professional conferences, and they are allowed to carry out other professional or academic activities, such as a legal traineeship in a law firm, postgraduate courses, and PhD programs, provided that they guarantee compatibility between the two activities and the performance of the clerkship tasks. Rules on the conflict of interest prevent the clerkship from accessing the case files that include parties that she directly knows or works with or for.

At the completion of the clerkship, the judge writes a report, giving an assessment of the law clerk's contribution to the office. If the evaluation is positive, the law clerk may attend the judicial magistrate competitive examination and has a priority in other state competitive exams. Furthermore, in case of positive conclusion, the clerkship is equivalent to one year of legal traineeship and of SSPL.

The judicial clerk is not entitled to a salary for her work, nor to social security contributions, but private grants are available most of the time. It is also envisaged in the Law that the Government will set aside some funds – whose amount has to be established by the Government itself – to offer State grants for a value of 400 Euros per month. Unfortunately, as of writing, the Government has not yet committed any resources to finance the program.

4. The driving forces to innovate legal education: the judicial clerkship

4.1. An objective perspective from the inside

Article 73 of the Law Decree no. 69/2013, by introducing the judicial training opportunity, undoubtedly made a change in the legal profession. In particular, it innovates how Italy governs legal preparation and the legal professional practice by overcoming the fruitless and long-lasting contraposition between "law on the books" and "law in action". Young trainees are able to understand the practical implications of the legal institutions under procedural and substantive law and to experience in first-person the "jurisdiction": they are present while the judge interprets and decides according to the law, as the Latin etymology indicates with the word *ius - dicere*. The presence of young professionals working in the Courts requires several changes in the organization of the work, with particular reference to digitalization and the implementation of IT tools due to the introduction in Italy of the telematic process called "Processo civile telematico" (PCT).

The judicial training in the Courts is an innovation since, for the first time, it has merged together theoretical and practical knowledge and has made the workflow in the judiciary offices more efficient. The Italian judicial clerks are aware of being central characters of this innovating process and they detected some relevant "driving forces" within the judicial training ex art. 73, *breviter*, which are behind this innovation in legal education and legal professional practice. What are those driving forces?

In order to answer this question, we have relied on a survey so as to give an objective view of this innovation in law. The survey, which has been submitted to the law clerks of the Tribunal and Court of appeal of Milan and of other judicial offices at the national level, consisted of several questions such as:

1. for how long have you been training as a law clerk?
2. what knowledge and skills have you developed or improved during the clerkship?
3. in your opinion, what are the main pros and cons? Do you think this clerkship guarantees a good balance between theory and practice in law?
4. are you an "innovation" in the legal profession environment? If yes, in which sense?

According to the results of the survey, the clerkship brings along driving forces that help to innovate Italian legal education and professional practice. From the survey and from our personal experience, we have individuated five relevant driving forces and they will be addressed in the order in which the results rank them as more important:

- first, a good balance between theory and practice in law;
- second, critical thinking;
- third, excellent knowledge;
- fourth, work-sharing;
- fifth, digital skills.

The first driving force is the good balance between theory and practice in law. The judicial training fills the gap that emerges during the university studies and during other professional traineeships. Notably, the law is a social science aimed at resolving actual conflicts; therefore legal experts need to implement legal reasoning in the service of reaching a fair solution. In the same way, the law clerk learns to deal with real issues through a problem-solving approach and according to a strategic perspective that can be applied to several disciplines. Applying legal concepts, theoretically learned "on the books", to the case at hand is a difficult task to perform in every-day work. In fact, the legal reasoning is not an immediate consequence of logical reasoning and, for this reason, cannot be considered a spontaneous faculty. With particular reference to civil law systems, this technical skill is strictly connected to the knowledge of legal norms and can only be mastered during professional practice.

As mentioned in sections two and three above, because of the deficit of university studies and post-graduated specialization courses, judicial clerks experience several difficulties related to the application of the legal institutions to the case laws. Recent law graduates are not sufficiently acquainted with practical aspects of the legal profession, and, therefore, when working as law clerks, they experience several difficulties in understanding: (i) how the case file is construed; (ii) why the defensive deeds are filed according to a compulsory order; (iii) the delimitation of the *petitum*, that is the claims on which the Court can pronounce; (iv) the so-called *causa petendi*, the juridical reasons that allows the parties to apply before the Court; (v) which facts and documents are relevant and which are not; (vi) how to write the legal reasons of a judicial opinion. Thanks to the guidance and the supervision of the judges, the trainees learn to individuate the critical facts in complex issues, to develop practical solutions, to express their opinions clearly both orally and in writing, and to use technical language appropriately and effectively.

The second driving force involves critical thinking and the ability of prioritize. In particular, judicial clerks improve their analytical skills by focusing on the relation between the thesis and the antithesis of the parties, as they arise from the judicial deeds. Consequently, attention must be paid to the most relevant issues to be decided, drawing a hierarchical order among the legal concepts. This process makes judicial clerks develop a synthetic approach, involving critical thinking and the ability to prioritize relevant matters and follow a logical-juridical order. Without all of these, the trainees reading the defensive deeds for the first time might feel disoriented and might alternate their opinions from one party to the other. A trainee should think as a judge and evaluate both parties' arguments, but should not fully rely on them. In this sense, she should rely only on the norms and on the related jurisprudence and doctrine, so as to correctly apply the law to the case. While analyzing conflicting arguments, the law clerk evaluates with discretion the right application of the legal institution to the specific case law, moving from the "law in the books" to the "law in action".

Under such practical challenges, the judicial clerk really puts herself to the test. Indeed, she is responsible for the solution of the case law – always under the supervision of the judge – and her work must be the result of her legal reasoning and thoughts about the case law. The clerkship is not a mere mechanical performance of different tasks. The proposal of the decision submitted to the judge enlightens the law clerk's skills and competence, being the result of her comprehension and work.

The third driving force is the in-depth and excellent knowledge of the applicable legal institutions and the connected procedural aspects. When a graduate starts working in a law firm or in a company, many things must be done in order to keep up with the client's exigencies, not only on the legal aspects, but also in many other respects. Moreover, these tasks are often faced in a disjointed, unrelated fashion, and the trainee is frequently not aware of their real purpose.

Often the legal trainee is asked to take care of administrative work, like mailing and calling clients, and is usually not responsible for the problem itself, but for collateral issues around it, with the result that her contribution to the solution of the legal issues is minimal. In such a context, the legal trainee is not driven to do the best, since the problems look very far off and unrelated to the everyday work. To put herself to the test, a trainee needs an environment that allows her to understand the problem with her hands on the work and to be responsible for its solution as a whole. For someone starting out in the legal profession, it is very difficult to find an environment that offers this opportunity. Not many workplaces allow the trainee to give a serious contribution to the resolution of problems connected with the business reality.

Returning to the topic list, what does "excellent knowledge" mean? Excellent knowledge does not include only honors at the University (although, that is also part of the concept of "excellent knowledge"). It requires the student to go further and to understand the real meaning of the legal institutions, their actual application and social aims. Indeed, the law is strictly related to the exigencies of society and of people. Excellent knowledge – as we refer to it – cannot depart from the practical application, the social aim and its usage in the legal reality.

This being said, the clerkship enables the trainee to focus on both the intellectual and practical aspects.

On the intellectual one, the clerkship mainly involves the writing of orders, injunctions and sentences and the oral exposition of the case laws. In order to draft or to propose a judgment on a case, the law clerk needs a very high level of competence and an effective command of the legal institutions she is dealing with. For this reason, before reading of the documents and of the defensive deeds, the trainee has to master in depth the legal institutions. The general rule can be expressed with the Latin saying of *rem tene, verba sequentur*.

A good preparation allows a good application of the legal rules to the practical problems in the written work and in the oral discussions. For these reasons, the clerkship gives the possibility to attend some courses that enhance the trainees' preparation in respect to the most relevant legal issues, current jurisprudence as well as recent changes of the national, European and international legislation. These courses are addressed to judges, lawyers and judicial clerks, and focus on updates and practical guidelines of undergoing matters.

Excellent knowledge comes from the fact that the judicial clerk really uses all her skills to perform the everyday work. The trainee is fully aware that her work is important to draw a complete legal framework of the case law, for the judges in order to decide and towards a better justice. The law clerk feels her contribution is finally useful for society and for the people who are working with her.

Form a broader social perspective, the clerkship helps in diminishing the work backlog due to the over-duration of the process in the Courts for which Italy was sanctioned by the European Court of Human Rights.[17] In this respect, the collaboration with the Registrar in the coordination of the work of each judge and the management of the Court office is also important: the complete understanding of the resolution of the controversy does not override the necessity to follow the practical procedures that enable a sentence to be published in time and in relation to the deadlines of each case.

The fourth driving force is the work-sharing with the judge; the judge entrusts the law clerk with many tasks, duties and responsibilities, but she also constantly supports her during the performance of the tasks step by step in a close collaboration. As described above, the law clerk is mainly required to study the case file, the documents and the defensive deeds in order to draft the resulting rulings, injunctions or orders. Consequently, the law clerk needs to understand the legal reasoning and to develop a solution in legal terms; as a result her work is intellectually challenging. The nature of the work performed by the law clerks requires the judge to closely follow them in each step of the understanding and of the legal reasoning. It may sound obvious, but the supervision of the judge is useful not only in respect to the work the law clerk has to do, but also for her personal professional growth. The direct

[17] With reference to the sanctions for infringement of the Art. 6 of the European Convention on Human Rights (ECHR). Pursuant to art. 2, paragraphs 2 bis and ter of Italian Law no. 89/2001 the "reasonable duration of the process" is satisfied if the case is irrevocably settled within six years (3 years before the Court of first instance, 2 years before the Court of appeal and 1 year before the Court of Cassation).

contact with the judge allows her to test her way of thinking and logical flow. This helps the trainee in developing a clear and more efficient way to understand new concepts and intellectually challenging issues. Working side by side with a highly specialized expert like a judge and receiving feedback from her is a precious experience, in particular at the beginning of the professional career. The judge teaches the law clerk how to be a professional under many aspects: (i) the methodology in which she has to structure the legal reasoning, (ii) what to focus on and the relevant aspects of a complex issue, (iii) how deeply she should go in order to be efficient, but still complete, in structuring the legal reasoning.

Another important addition to the development of the legal reasoning of the law clerk concerns the expertise of the judge. The judge is an expert in the field the trainee is working in and, by her support and teachings, she enhances the knowledge and the comprehension of the topic the law clerk deals with.

In this respect, the work-sharing ensures that the law clerk and the judge build a deep and strict relationship where they must trust one another. Despite the different ages of the judge and the clerk, both of them give a precious contribution to the other. The judge trusts that the law clerk has the skills – in particular those connected to efficiency and the new digital era – to perform the tasks she is responsible for, and the law clerk trusts the experience of the judge. The law clerk does work for the judge, but they both work towards justice, so that the law clerk works "with the judge but without judgments".

There is no competition between colleagues, nor any sense of disrespect for the work that the judge and clerks perform in the Court, since they all put their efforts towards achieving justice. Cooperation, collaboration and teamwork are usually the keys to the everyday work. The law clerk has to be able to explain to other people what the problem is and how she would solve the problem, expressing her opinions and thoughts clearly in both oral and written form.

The fifth driving force concerns digital skills. A relevant aspect of the legal preparation is the close relation between law and new technologies. On the one hand, the Legislature and all the legal practitioners rely on information and communication technologies (ICTs) to produce and to circulate legal documents; on the other hand, the technological tools allow legal research on databases and legal catalogues. Thus, young legal professionals are required to be proficient in using advanced digital technologies, since mastering ICTs is a necessary skill in the practice of law.

The judicial clerkship enables the trainees to improve this skill. The judicial clerks work on Consolle, an IT platform used by lawyers, the chancellors of the Court and judges for reading, writing and exchanging legal documents. The digitalization of the Court is part of the so-called "telematic process", a mandatory system of legal circulation of judiciary deeds in Italy, called "*Processo civile telematico*" (*PCT*). IT tools facilitate the updating of legislative sources and of the national and transnational jurisprudence, through the use of the legal databases and law catalogues. The close collaboration among the law clerks and the judges fills the gap between "digital natives" and "non-digital natives", so that the judges become able to use digital, telematic and technological tools in the everyday work and in the completion of all practical procedures related to the Registrar and the issuing of the sentences.

In conclusion, the clerkship, on one side, is a unique educational path and professional experience for the law clerks, and, on the other side, is a partial solution to the challenge that innovation in law poses for the judges and the legal professional environment.

4.2. Critical aspects: are there any cons?

The judicial clerkship presents some critical issues since it is still relatively new. First, the clerkship is still unpaid and the state has not yet provided the necessary funds to do so. Despite the express provision of the law, the fixed remuneration for the law clerks has not been implemented.[18] As stated by the law, the Courts should make an effort to find the funds, through private sponsors or benefactors, as has already happened in some national Courts, or through public entities.[19] However, so far, there are very few scholarships, and these generally offer a low amount of money. In many cases, the absence of remuneration influences the choice of many meritorious graduates to renounce or quit this opportunity. Another side effect is the risk that the lack of pay will demotivate the law clerks, who make a continuous and substantial commitment but find themselves unable to cover basic expenses.

The second critical aspect concerns the limited workplace resources provided to law clerks. In particular, although the law provides the right of the judicial clerks to have their own PC, Internet connection, and access to online databases,[20] these resources are often missing. Sometimes, there are not even work desks and, therefore, the judicial clerks are not able to work at their best.

[18] Pursuant to art. 73, paragraph 8 bis of Law Decree no. 69/2013.

[19] Pursuant to art. 73, paragraph 17 of Law Decree no. 69/2013.

[20] Pursuant to art. 73, paragraph 4 of Law Decree no. 69/2013.

Other problems come from the lack of homogeneity among Courts of different size. In particular, little *fora* have less financial supports than bigger ones, so that each Court faces different problems. The Legislature faces difficulties when it seeks to establish the same rules for entities that present a very different structure.

4.3. Results and main innovative aspects according to the new generations of legal professionals

The Italian Legislature has introduced the role of the judicial clerk only since 2013, later than many in other European countries. Indeed, in Europe the clerkship is already a recognized role, and it fits in the legal framework of each country as well as in the professional scenario. The job market recognizes this professional activity and is aware of its high standard of preparation. The law clerk is a well appreciated professional who easily fits in all the legal environments – since her preparation is wide and deep under many respects with the result that the clerkship opens up many job positions. In particular, law clerks, at the end of the enriching experience in the relative Court, usually achieve prestigious positions in the legal field, as well as in finance and corporate contexts.

In Italy, due to the fact that the clerkship is a new opportunity for young legal professionals, there is not much awareness about this professional role. The clerkship is regarded as a continuation of the legal education path, and it is still not recognized as a professional figure *tout court*. This is something that differs from other European countries in which the law clerk can also be a remunerated job. Indeed, in other European countries the clerkship can even be a permanent job, while in Italy it is considered a traineeship that complements law graduates' education; therefore, law clerks will not be hired by the courts at the end of the training. Consequently, law clerks, after the conclusion of the clerkship, need to find a different job position in another professional environment. It is necessary to create a bridge between the judicial clerkship and other work environments. For these reasons, the Legislature and the Courts should recognize the great importance and utility of the law clerks, reflecting the high level of preparation and the multiple skills that a law clerk gains, and open new job positions for this unique figure. The skills of the law clerks can be defined as a unique *know-how*.

The clerkship provides the necessary skills to access several different work environments. These skills are considerably numerous and mainly concern critical thinking in respect to issues that are at stake, and the ability to apply the legal reasoning to real world problems and efficiently figure them out. The challenge for law graduates who want to upgrade to the professional level is "to make things speak": from the documents or the facts of the case file to the legal institutions and *viceversa*.

Secondly, during the clerkship the trainee learns to write complex trial memoranda, reports and also judgments by using the legal technical language. At the end of the clerkship, the ability to write of the law clerk is useful in many environments. Due to new technologies, the majority of our communication is written and it requires a good balance of the terms implied and an efficient and economical use of words. Written communication must be characterized by "lightness, quickness, exactitude, visibility, multiplicity and consistency" (Calvino 1988). Moreover, the dynamic work market experienced by present-day legal professionals requires a fast exchange of information and the ability to read documents and understand them quickly.

The clerkship also provides the opportunity to enhance oral communication skills. The law clerk cultivates dialectic qualities in several ways: first in the Chamber of Council when the law clerk has to report the case file focusing on the relevant aspects to be discussed and decided; secondly, during the public hearings while managing the case files with the chancellor and while assisting the lawyers at the moment of the oral discussion; finally, by practicing public speaking, i.e. during seminars or working groups or, even, in the everyday work with the colleagues.

As we said before, during the clerkship the law clerk focuses on both substantive and procedural aspects of the legal institutions until reaching a multi-areas specialization and a high level competence on the legal institutions also compared to other ordinary legal trainings. Thanks to this, the law clerk obtains a complete preparation in respect to many legal fields and a deep expertise on many legal institutions that allow him/her to succeed in several different careers.

At this writing, it is two years from the date of entry into force of the judicial clerkship *ex* art. 73, *breviter*, and we can make a first assessment of this experience. One of the most important new aspects of the clerkship is the use of IT tools. The law clerk develops a real expertise in the management of the digital process. Contrary to how a Court is perceived by other professionals, the administration of justice is actually fully based on ICT systems. Law clerks have an essential role in this. These technologies are easy to use for the law clerks to perform their tasks and duties. As a result, the law clerk can show a familiarity with all the new technologies that are also used in other countries, implementing a more modern concept of justice and of process.

In addition, the positive completion of the clerkship gives access to the judicial public exam and a right to priority in state competitive examinations. Furthermore, it is equivalent to one-year of the SSPL and of the legal training for the bar exam.

The number of the judicial clerks is continuously increasing and this positive trend will continue given the new perception of both a legal career and the legal professional according to the current market demand.

5. Concluding remarks

The real challenge for a young legal professional is the development of her own abilities. During the judicial clerkship, the trainee learns to be orientated with respect to new and different problems. Having experienced a long-term training mostly based on a problem-solving approach, the future legal expert will be comfortable and will succeed in every kind of legal professional field. A gaze at the future points to many bright opportunities for those legal experts that have been led, in their past experience, by the driving forces of innovation in law. Thus, the good balance between theory and practice, critical thinking, excellent knowledge, work-sharing abilities and digital technologies skills represent the necessary *know-how* to enter competitively into the work environment of legal professions. Nowadays, a notion-based knowledge is not enough for success in a career. The priority is the ability to deal with problems. Our present increasingly complex society requires professionals to be sharp, quick, smart and dynamic. The study and the practice in law should adequate to this *paradigma*.

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Innovating Legal Studies and Practice: An Experimental Course at the University of Pavia

Maria Laura Fiorina, Giulia Spinoglio

1. The birth of the course

In November 2014 the Law Department of the University of Pavia added to its curriculum a new course entitled “Innovating Legal Studies and Practice”. The idea of such a course was conceived about a year before by its promoter professor, and judge Amedeo Santosuosso, whose research interests covered, among others, the relationship between (technological) innovation and law. Noting that the topic receives no consideration in the Italian legal education system, despite its importance, he decided to create a specific course on this subject.

It is undeniable that technology is changing the practice of law and the meaning of being a lawyer today; moreover, legal practitioners and judges already use advanced technological tools in their everyday work. The traditional legal education system seems to ignore this reality, however, and, as a consequence, students are not trained to use technological tools that are already employed in legal professions. The students are not even aware of the existence of the new (technological) skills that are required by the legal market.

Having said that, the influence of technology on law is not limited to a practical level: in fact, technology affects law itself and its assumptions. Even theoretical legal studies will need to reconsider the way the law is conceived and conceptualized in its current transnational and global status.

All these considerations led to the decision to create a new course, which was aimed at offering a direct knowledge, both from a theoretical and practical perspective, of advanced technological tools, as well as an overview of the legal implications stemming from these technological innovations.

The creation of the course was possible thanks to the involvement of many institutions: the course is the result of an extraordinary cooperation between judiciary, bar and academy. The Court of Milan, the Court of Appeal of Milan, the European Center for Law, Science and New Technologies (ECLT) of the

University of Pavia, the University of Pavia and its Law Department, the Collegio Ghislieri and the Bar Association of Milan all agreed on the importance of offering such an innovative course and they signed a convention stating their common interests and aims. The result of this convention was a 30 hours course, entirely taught in English by an international faculty board, available to up to 20 students of Law, Political Sciences, Engineering and Economics; 4 positions were reserved for ELSA (European Law Students' Association) students.

The University of Pavia has been a pioneer in organizing such a course, which is a unique experience not only in Italy but also all over Europe.

2. Aims of the course

The course was aimed at offering to master degree students a deeper awareness and knowledge of legal technologies, in particular those already used in courts and law firms.

Many Italian courts have introduced the electronic civil process ("Processo Civile Telematico", PCT), whose core is represented by the platform "Consolle".[1]

Many law firms use knowledge management software in their everyday activity, which is able to interact with the PCT;[2] this innovation and the intersections it permits have fostered a great improvement in terms of efficiency in the law firms.

One of the purposes of the course was to offer students a practical demonstration of how these tools work and to familiarize the students with them. In order to achieve these results, both professors and legal practitioners (judges and lawyers) were part of the faculty board: their co-presence was aimed at reducing the gap between the academic world and the legal practice, whose dynamics and needs are often unknown to students.

In addition, the course was conceived as a starting point for research activities in the field of technology and law, in order to develop theoretical studies on the new dimensions of law in its technological and transnational current status.

In the event, the participants were only law students, even though the course was originally open also to students of Political Sciences, Economics and Engineering. The intent in making the course open to these students, was to offer them the opportunity to gain insights on how the legal environment

1 See par. 3.2.2.

2 See par. 3.2.1.

is changing, as well as to explore new possibilities of technological applications to the legal profession.

In a long-term perspective, the course is intended to offer basic tools to new categories of experts in the field of law and technology: including e-lawyers, legal knowledge engineers and technologists able to create and administer platforms available for lawyers and citizens.

3. Structure and contents

The course was entirely taught in English and was divided into two intertwined parts. The first was a *theoretical part*, in which the professors offered a theoretical frame of different topics related to the area "innovation and law" and introduced students to themes such as technology and law, legal informatics, legal interoperability, transnational law etc.[3] The second was a *technological practical part*, in which, under the supervision of lawyers and judges, each student had the chance to work at a terminal and familiarize with various innovative software platforms which are already used in courtrooms (*Consolle*), law firms (*Consolle* for lawyers and others) and in the university (ALST). Topics included virtual law practice, automated document assembly and electronic legal work on a multilingual database (ALST).

This second part was essential for the students, because it provided them with a direct experience of the ways in which technology is already employed in law and demonstrated how useful it is with regards to all aspects of legal practice; this chance was extremely precious if we consider how law is traditionally taught in an Italian university.

We will now briefly analyze the content of each lecture, following the chronological order, starting by making a short presentation of the teacher, in order to show her interest and involvement in innovation and law.

3.1. Innovation and law, innovation in theory and practice and application of computation to law (Oliver R. Goodenough)

Oliver R. Goodenough is currently a Professor of Law and the Director of the Center for Legal Innovation at Vermont Law School, a visitor at CodeX, the Stanford Center for Legal Informatics, and a participant in the University of Pavia's initiative on legal innovation. His research, writing and teaching at the

[3] A brief description of the content of each class will be given in the following pages.

intersection of law, economics, finance, media, technology, neuroscience and behavioral biology make him an authority in legal innovation.

In the first two lectures Prof. Goodenough dealt with innovation in legal practice and offered an overview of the online legal products and services available in the US. They can be distinguished in: a) products *for* lawyers, which are available for different purposes, such as research (e.g. LexisNexis), practice management (e.g. Clio) or litigation management (e.g. CaseMap); b) products *by* lawyers, addressed to the consumer (e.g. Divorce Deli, Patent Station) or to commercial purposes; c) products *instead of* lawyers, where software totally replaces the "human" lawyer in document preparation (e.g. LegalZoom, RocketLawyer) or litigation services (e.g. Axiomlaw), and where they can also replace government or courts (e.g. Bitcoin, Modria). The online legal services have many benefits, such as: a) lower costs and higher incomes for law firms with the possibility to work at home; b) smooth procedures and shorter time requirements; c) unnecessary presence of a lawyer because the software works automatically; d) visibility through web advertisement.

Part of the lesson was then dedicated to the importance of good rules for innovation and economic growth. By "good rules" Professor Goodenough meant those systems of rules that are both encouraging of and responsive to new technologies; in order to achieve efficient outcomes, rules need to evolve as new technologies arrive.

His last lecture was dedicated to computational law. Computational law (or legal computing) is a branch of law concerned with the study of formal representations and automated reasoning with laws (governmental regulations, business rules, and contracts) in electronically mediated domains. Like other disciplines in computational science, computational law is concerned with quantitative modeling and analysis techniques, e.g., by using computers to analyze and model legal issues. Many of the techniques used in computational law are taken or derived from techniques in the domains of natural language processing and big data analysis. Analysis techniques also include legal visualization techniques.[4]

3.2. Practical part: Consolle for Judges (Enrico Consolandi, Maria Eleonora Benini, Chiara Colicchia, Federica Fazio)

Enrico Consolandi is a judge of the Eighth Civil Division at the Court of Milan and he is the information contact for the District Court of Appeal of Milan.

[4] URL: <http://en.wikipedia.org/wiki/Computational_law> [last accessed: 07/04/2015].

Maria Eleonora Benini is a LL.M. with Merit in "Public International Law" in 2012, as undergraduate, at King's College London with expertise in international dispute resolution connected to the World Trade Organization system and Human Rights. Thereafter, she graduated in March 2013 in Law (Laurea Magistrale in Giurisprudenza) at the University of Bologna with 110/110 cum laude. She is now Judicial Assistant to Hon. President of the First Civil Division Amedeo Santosuosso at the Court of Appeal of Milan. Consolle is an essential and functional tool to her daily work in the Court.

Chiara Colicchia graduated in Law in October 2012, at the University of Milan. She worked as a legal trainee in a law firm focusing on administrative law in Milan, and then, in October 2013, she started the judicial apprenticeship at the Court of Appeal of Milan, in the Civil Division, with the Hon. Pres. Amedeo Santosuosso. She is still assisting the judge at the Court of Appeal, in order to gain legal experience. Subjects of major interest are civil and administrative law.

Federica Fazio graduated in Law at Università Cattolica of Milan in July 2012. Subjects of major interest are IP, Antitrust and Commercial law. She worked as a trainee lawyer in legal firms in Milan, with a focus on Civil law, Commercial law and Intellectual Property. Afterwards, in October 2013, she started working as judicial apprentice at the Court of Appeal of Milan - Civil Division, with the Hon. Pres. Amedeo Santosuosso. At the moment she is still assisting the judge at the Court, in order to improve and sharpen her professional knowledge about legal procedures.

Processo Civile Telematico (PCT)

The *Processo Civile Telematico*[5] (PCT) is one of the main projects promoted by the Italian Government. Thanks to a suite of computer applications and matching technological infrastructure, it allows the automation and faster the flow of information and documents between the parties involved in civil proceedings: lawyers, court clerks, judges and practitioners. The benefits of this system are clear if you consider that PCT allows a totally computerized management of civil procedures, without need of paper.[6]

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5 Translated as "Civil Online Process".

6 URL: <http://www.selexelsag.com/internet/localization/IPC/media/docs/PROCESSO-CIVILE-TELEMATICO.pdf> [last accessed: 07/04/2015].

Consolle for Judge

The "Consolle for Judge" is the application used by the court to manage their specialist role. It allows them to see the case file on the computer and prepare and file judicial measures electronically. The main points are: 1) the modeling highly customizable measures; 2) the possibility to use it outside the judge's office; 3) the ability to associate files with documents; 4) the full-text search and built on documentary database and office; 5) the high security (authentication based on smart cards).[7] During the practical lessons about Consolle for judge, the students had a first approach with this advanced technological tool, now widely diffused with the public enforcement of *Processo Civile Telematico*. Students under the supervision of Dr. Consolandi and with the help of Drs Benini, Colicchia and Fazio, experienced how the judge approaches the drafting of judgments through Consolle, starting from the extraction of the files relevant to the decision to obtain the model of judgment with all fields already filled in, except for the motivation.

3.3. ALST: Archive on the Law of Science and New Technologies (Maria Laura Fiorina)

The two sessions on ALST were held by Maria Laura Fiorina, a PhD Student in Criminal Law at the University of Pavia and member of the European Center for Law, Science and New Technologies (ECLT).

The first lecture was dedicated to the presentation of ALST, which is a multilingual legal database in the field of Law, Science and New Technologies that collects legislation, caselaw and other legal materials from different countries. This database is one of the main projects of the ECLT and it was created to deal with multilingualism in law.

In fact, the increasing global amount of communication in the legal field has reached a critical level where the simple use of English, as communication means, is not enough and ways of dealing with multilingualism have to be found; consequently, tools for managing legal linguistic barriers are badly needed.

On the other hand, legal sources, although available on international websites and databases, are usually accessible only in their own language. By contrast, ALST brings together cases and materials from different legal systems. The database has developed a system, based on a multilingual legal thesaurus,

[7] URL: <http://www.selexelsag.com/internet/localization/IPC/media/docs/PROCESSO-CIVILE-TELEMATICO.pdf> [last accessed: 07/04/2015].

able to connect the materials, even though they are written in different languages. While the connecting language is English, the project aims at achieving the goal of intercommunication and data exchange among different legal systems using different languages.

During the second lecture students had the chance to explore the database and to insert new materials through the creation of a file card; the file card (drafted in English) contains a short explanation of the material and it is tagged with the terms that exist in the thesaurus.

3.4. Information technology for the internal process in a law firm & for legal knowledge management (Franco Toffoletto)

Franco Toffoletto practices employment law and is President and Managing Partner of the law firm, Toffoletto De Luca Tamajo. With a great passion for technology, he was also one of the creators and developers of Easylex, a software package which is used by many law firms in Italy.

His two lectures were dedicated to the presentation of software programs that are used in a law firm on a daily basis.

What is knowledge management?

> While the legal profession faces continued challenges as it adapts to shifting market needs, legal knowledge management (KM) is also changing and evolving to support law firm and in-house requirements. The KM function can play a key role in an organization's overall success and, as such, it is deserving of the increased attention it is getting in the legal sector. With recent suggestions that KM has helped in creating 'Big Law', and reports on how certain law firms are linking bonus schemes to KM efforts, it is worth taking a look at the main aspects of KM that can aid in the internal efficiency and continued success of legal teams. Legal KM has undoubtedly evolved. While there may be certain levels of consistency amongst the work processes and offerings of KM teams within law firms, KM overall is no longer just about knowledge sharing and repositories.
>
> While those factors undoubtedly remain important, new tasks have been added to the KM repertoire which include client engagement, relationship management, differentiation, research, training, professional development, legal project management, and developing collaborative tools – and these are just some of the tasks that can fall within the remit of legal KM.[8]

8 Roche H. (ed.) (2013). Legal Knowledge Management: Insights and Practice. Ark Group. [online], URL: <http://www.arkgroupaustralia.com.au/documents/LegalKMTOCandsample.pdf> [last accessed: 04/05/2015].

KM is about connecting people to the knowledge they need to do their jobs, whether that knowledge is tacit (in people's heads) or explicit (documented). Some benefits of knowledge management are:

1. better organization: helping partners, associates and assistants get their hands on the right documents and information when they are needed;
2. better use of knowledge assets: make better use of internally developed knowledge assets such as precedents, letters, research memoranda, and filings;
3. knowledge sharing: be prepared for a partner associate leaving the firm. Help lawyers share what will be needed to continue the firm's business;
4. improved learning: use "lessons learning" techniques as you work; make assessments and continually improve processes for better client service.

3.5. The law in legal informatics (Giovanni Sartor)

Giovanni Sartor is a part-time full professor in legal informatics at the University of Bologna and part-time professor in Legal informatics and Legal Theory at the European University Institute of Florence. He has been President of the International Association for Artificial Intelligence and Law. He has published widely in legal philosophy, computational logic, legislation technique, and computer law. His fields of research are legal informatics, especially artificial intelligence & law; legal theory, especially legal reasoning, legal logic, game-theory and the law; computer law, especially data protection and law and automation in socio-technical systems, in particular liability issues in air traffic management.

Professor Sartor talked about looking at the law through the lens of legal informatics. He started from a panoramic view on the multifaceted ways the law can be manifested: unwritten law, law written in human-readable form, and computable law expressed in machine-readable form. The various shapes the law assumes represent at the same time an opportunity and a responsibility for practitioners and academics, and computational approaches to the law can be particularly challenging. Nevertheless, a recent trend shows that lawyers are more and more moving away from computable models of the law. Many underlying reasons can be identified. One is the increasing theoretical requirements in logic and computing, which lawyers educated in elementary logic cannot understand and master properly. Another is the emergence of areas, e.g. multi-agent systems, in which computable models of the law are designed by researchers from fields other than law. In such a scenario, a question arises: could legal informatics experts fill the gap between lawyers, legal theorists, and computer scientists?

The inquiry around what *is* the law has intrigued philosophers over the centuries. However, Sartor wondered whether the concept of law really has such great importance in the light of legal informatics research. What is important to consider is what aspects of the law as a phenomenon may be successfully dealt with from the practical and theoretical point of views if addressed. Legal language, legal texts, legal rules and legal reasoning have been the objects of study in the attempt to make them computable. These attempts have developed along many lines within the Artificial Intelligence (AI) and Law field: from the first implementations of legal information retrieval tools, through the application of deductive logic to the law, the design of knowledge-based systems and case-based systems, the development of defeasible reasoning and argumentation frameworks, and up to theory formation.

As closing remarks, Sartor stressed how the achievements reached by AI and Law research may also be of great interest outside the legal community. Indeed, it could be worthwhile trying to engage with scholars and professionals from other fields and exchange opinions on how to develop and refine computable models of the law.

3.6. Innovating private law: on the law of the future and the future of law (Jan Smits)

Jan Smits is Chair of European Private Law at Maastricht University and academic director of the Maastricht European Private Law Institute (M-EPLI). He has a special interest in questions of legal harmonization, foundations of (European) private law, mixed jurisdictions and internationalization of law generally. With such a background, Prof. Smits' presence at the course was fundamental to gaining awareness in the field of innovation and private law.

The first part of his lecture was dedicated to the "law of the future" and he analyzed how the use of technology by practitioners, judges and private actors may affect the law, considering in particular the matters of codification and legal information.

In the second part of the lecture, focused on "the future of law", Prof. Smits analyzed how technology and globalization affect the law itself and its assumptions, he stressed the functions of law that are or might be replaced by other mechanisms. Particularly, he examined how rulemaking, enforcement, and dispute resolution may be affected by Europeanization and globalization of markets, and he considered, as an example, the shift from traditional form dispute resolution to reliance on reputational networks.

3.7. Crowd sourcing and law (Jeannette Eicks)

Jeannette Eicks is managing director of the Center for Legal Innovation and teaches eLawyering and eDiscovery at Vermont Law School. She facilitates collaborative projects between students, faculty and industry partners on behalf of the Center for Legal Innovation. Her published work includes a chapter in "Educating the Digital Lawyer", an eBook co-edited by Professor Oliver R. Goodenough and published by LexisNexis in 2012.

Her first session was dedicated to the topic "Crowdsourcing and law. An introduction to law for the masses", and she explained the concept of crowdsourcing and its mechanics and gave some examples of crowdsourcing.

Crowdsourcing is the process of obtaining needed services, ideas, or content by soliciting contributions from a large group of people, and especially from an online community, rather than from traditional employees or suppliers.[9] The best-known example of crowdsourcing is Wikipedia. The process of crowdsourcing starts with the identification of the subject and the gathering of the crowd of "solvers"; complex problems are then broken down and individuals work to resolve small pieces of the whole. The solution is the assembly of the individual works and it is the result of what is known as "Collective Intelligence". This is a "form of universally distributed intelligence, constantly enhanced, coordinated in real time, and resulting in the effective mobilization of skills".

In the second part of the lecture she focused on *legal* crowdsourcing, which already exists in different areas such as legal research (RECAP, Casetext, WeCite, ALST, OpenLaw EU), legal argumentation (Mootus), legal advice/aid (Quora, Docracy) and legislation (Open Government Dialog, EPA regulation commenting, Potholes in Boston, Participedia). With regards to each particular area, she identified the crowd and the mechanics of crowdsourcing and she pointed out its pros and cons, having a look at the future developments and applications of crowdsourcing tools.

3.8. How to create your own professional website (Jeannette Eicks)

In her second lecture professor Eicks gave advice on how to create a professional website, focusing on the content, the structure, the text, the images and the client portals and stressing the importance of the website architecture.

The last part of the lecture was dedicated to "Legal Visualization", which is an alternative way to convey legal concepts. In comparison with words,

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9 Wikipedia.

legal visualization has various advantages, such as: clarity and immediacy (the image clarifies the concept immediately); interactivity (comparison and contrast are quicker and more effective); a greater power to convey meaning.

Legal visualization can be extremely useful in litigation (demonstrative evidence), to make access to the law easier, to model logic flows (e.g. contract logic) and also in legal research.

3.9. What neuroscience can say on legal decision making (Gabriella Bottini)

Gabriella Bottini is full professor of Psychobiology and Neuropsychology at the Psychology Department of Pavia University, and director of the Cognitive Neuropsychology Center at the A.O. Niguarda Ca' Granda Hospital of Milan, Italy. She has been cooperating with the ECLT for the last few years, where she is involved in interdisciplinary research between law and science.

Her lecture was an introduction to the field of cognitive neuroscience, which studies the nervous system and aims at better understanding human thought, human emotions and human behavior.

The first part of the lecture was focused on the structure of the brain and its different levels of functioning (molecular; cellular; neurological; psychological; social). Cognitive neuroscientists study functions (such as perception and memory) in animals by using behavioral methods and other neuroscientific techniques; with regards to humans, they use non-invasive brain scans – such as positron emission tomography and magnetic resonance imaging – to uncover routes of neural processing that occur during language, problem solving and other tasks.[10]

The second part of the lecture was dedicated to the relationship between neuroscience and law. This interaction has huge practical implications and consequences also at a socio-political level. In fact, neuroscience can be extremely useful in (legal) cases of low state of consciousness or in cases of mental insanity.

4. Students' feedback

At the end of the course, students were asked to fill in a questionnaire to evaluate the course and to assess the fulfillment of their expectations. Students' feedback was extremely important to understand which aspects of the course

[10] URL: <http://www.functionalgenomics.pl/index.php?option=com_content&view=article&id=9&Itemid=23> [last accessed: 06/06/2015].

were particularly successful and, on the other hand, which ones need to be improved in order to achieve better results.

The questionnaires showed that the best aspect of the course was the possibility to interact not only with professors but also with legal practitioners: in fact, their personal experience in really different contexts enriched the quality of teaching. In other words, the co-presence of teachers having different backgrounds was extremely valuable for the students, who considered the course, with regards to this aspect, a unique experience.

Moreover, students stressed the importance of the possibility they had to use technological tools that are used in Italian legal practice, both those available for judges, and those used by lawyers in law farms. One of the most appreciated lessons was that given by lawyer Franco Toffoletto, who provided a concrete example of how new technologies permeate the world of law, not only with regard to the PCT, but also with regard to the organization and work in a law firm. It was a tangible demonstration of the fact that the law is changing and innovating, and with it the legal market.

Concerning the theoretical part, students learnt what are the new technologies that are innovating the way law is applied and the consequences of this development with regards to the theory of law; in other words, they gained awareness of the potentiality of technology applied to the law and its following theoretical implications.

Online legal systems, software agents, and artificial intelligence in general will soon be part of our everyday (legal) life: being aware of them and knowing how to use them will make a huge difference.

4.1. What should be changed

Students were also asked to suggest what should be improved in the course. They all agreed on the importance of the practical part and they suggested an increase in the amount of hours dedicated to it, in order to have more time to learn how to use the technological tools employed in legal professions, especially the Consolle for judge. Moreover, in order to emphasize the practical approach of the course, they suggested that its designers consider teaching about other tools, such as the Consolle for lawyer or tools used in other European legal systems or courts. In other words, in their opinion the course should be less focused on theory and the practical part should become the core of it.

Surely the practical part needs to be improved and expanded but, considering it was a newborn course, positive results have already been achieved.

5. Final remarks

As Alex Hobbes has declared,

> [n]ecessity is the mother of Invention: changing client requirements, industry commentators and lawyers themselves are all demanding a radical shake up of the way legal services are delivered. In any event, this truly is the age of innovate or die. Big companies that fail to innovate risk extinction. That's the stark truth in the era of "digital disruption" and I believe this applies to the legal sector as much as any other business market.[11]

Although these words describe a deep and undeniable change that is already occurring in the legal market, many legal practitioners and thinkers are not aware of this reality. Even more so, the theoretical implications stemming from this technological revolution are mainly ignored and underestimated.

The strong relationship between innovation and law is demonstrated by the huge number of websites of business professionals who explain how and why lawyers and law firms should replace the (expansive and inefficient) traditional management system with a new legal knowledge management. This is particularly important in this era, characterized by the rise of technology, competition, shared information, and, especially, the fact that we are in one of the largest global economic downturns in history.

On the other hand, legal-apps and online legal systems are proliferating at a great speed. Having a look at the Italian experience, many online legal services were born in recent years, such as avvocato.net, contrattonline.it, legalclik.it, and Lex&Go. "The future of lawyers is online. In US you do judicial hearing via Skype, in the Netherlands the first virtual law offices were born, while in Italy telematic legal advice is spreading. The result: faster and cheaper services."[12]

These considerations demonstrate the importance of the "Innovating Legal Studies and Practice" course, an offering that gave the students the chance to gain awareness of the unavoidable technological evolution of the legal world.

As already said, participants were students that will soon be part of the legal market: it is consequently fundamental for them to be prepared to face the legal profession in its new "technology affected" dimension.

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11 See Alex Hobbs URL: <https://www.linkedin.com/pulse/20140626150757-259880202-how-to-foster-law-firm-innovation> [last accessed: 07/04/2015].

12 URL: <http://www.repubblica.it/economia/affari-e-finanza/2014/11/10/news/la_carica_degli_avvocati_online_un_contratto_costa_solo_50_euro-100177442/?ref=search> [last accessed: 07/04/2015].

From a future perspective, new professional profiles covering law and technology will be required: e-lawyers, legal knowledge engineers, and e-justice experts will be interdisciplinary experts able to create and manage platforms offering legal services to lawyers and citizens.

On the other hand, the theoretical frame of this new dimension of law needs to be better studied and shaped, also because old legal categories might need to be reconsidered.

The course was a starting point for this new approach to law; it was useful to understand the relationships between technology and law and to explore some of the already existing technological tools applied to law.

Legal innovation is a challenge but it is also the key to success. We hope to see you all next year!

PART II.
Specific Cases of Innovation Impacting the Law

The Increasing Role of Private Actors on Human Rights in the Internet Domain: A Challenge for the Law?

Maddalena Neglia

"While technologically and financially you are giants, morally you are pygmies"

1. Introduction. Innovation and the role of private actors in the internet domain

One of the main results of the innovation process and of the development of new technologies is that the internet has become a giant network of networks, designed to carry, host and transmit information or contents. This information and contents are distributed, located and hosted by private companies, acting as intermediaries, who therefore play a vital part in the information society.

Internet intermediaries are private actors, mostly multinational corporations, acting in the internet market in different ways. They have certainly contributed to the development of democratic movements, as the experience of the Arab Spring has shown, and to the enjoyment of the freedom of expression worldwide. However, the digital revolution has also created new challenges for the protection of human rights.

Internet intermediaries can be defined, for our purposes, as the entities that "mediate online communication and enable various form of online expression" and "bring together or facilitate transactions between third parties on the Internet" (MacKinnon 2014). This definition encompasses different types of private companies who act as internet intermediaries, each one with a significant influence on individual rights. A first type of intermediary is made up of the Internet Service Providers, both fixed and mobile, which provide access to the internet to people through a technical transmission infrastructure of telecommunications. They play an important role in relation with the freedom of expression, since they can act to filter the users' access to the internet or even shut down networks. Another type of intermediary is made up of the Search Engines (such as Google, Yahoo!, etc.) filtering the access of information by internet users. They can easily affect what content can or cannot be found online, and they can have access to an enormous amount of personal data of users. Finally, a third type of internet intermediary is made up of the Social Network Platforms (like Facebook or Twitter), which allow users to publish contents that can reach a large audience. Each type of internet intermediary can have a different role and impact on individual rights, and it is subject to different laws and jurisdictions. For example, Internet Service Providers must be physically present in the country in order to provide access to users; therefore they are directly affected by domestic laws and jurisdictions, while Search Engines and the Social Network Platforms have policies and regulations, which are more shaped by their home jurisdictions.

In general, all types of internet intermediaries have the technological power to heavily influence users' rights, as it will be shown through concrete examples in the next section. This Chapter will seek to answer whether this power gives them the responsibility to protect such rights and how the law takes into account this new role of private actors. The changing role of private actors is generating a necessary denationalization of the state-centered law in favor of the participation of such actors in the lawmaking process and its enforcement. In order to absolve its function and to be effective in the globalized society, the law should consider this emerging role. In light of the foregoing, this Chapter will first highlight, by an overview of some relevant examples, the huge power of internet intermediaries on individual rights (sec. 2). Then it will draw the international framework on the responsibility of multinational corporations to respect human rights and the emerging role of international soft law standards, included those specifically related to ICT sector (sec. 3). The concluding section will consider how these standards can be taken into account by the law in order to achieve a more effective human rights protection in the globalized society (Habermas 2001).

2. Internet intermediaries and human rights: a challenging balance

The digital era has changed the environment in which interactions take place; therefore, the protection of fundamental rights has become more and more critical. Several fundamental values, like freedom of expression, privacy and the protection of human dignity, are concerned. The following cases aim to underline how internet intermediaries have an active and widespread role in protecting such values in the global environment, and how states, public authorities and national legislations may want to affect them. Indeed, the selected cases concern examples where states pressured internet intermediaries to provide them with users' data for 'security' purposes. Since 2001, Governments the world over have introduced increasingly intrusive surveillance measures to gain information about their populations in the name of public and national security. Without entering into the complex debate on the dichotomy between privacy and surveillance (Rauhofer 2009), the following examples illustrate the significant power that technological innovation in the internet has given to private companies, such as internet intermediaries, over rights of users in the face of states and public authorities, in both democratic and non-democratic legal orders.

In 2005 two Chinese dissidents named Weng Xiaoining and Shi Tao were arrested and condemned to prison, the first for "incitement to subvert state power" and the second for "illegally providing state secrets overseas". Their crime consisted in the distribution of online publications on political reform in China, through an anonymous email address. The Chinese government took the information about the dissidents and their activities by ordering Yahoo! Hong Kong to provide their personal identification, starting with the email address that they used. The co-founder of the company, Mr. Jerry Yang and the general counsel, Mr. Michael Callahan, testified at a public hearing by the Committee on Foreign Affairs of the House of Representatives about the Shi Tao case, in November, 2006. They admitted to the Yahoo! role in the imprisonment of Mr. Shi Tao, but they both claimed that the company only complied with an order that was legal in China.[1] China is one of the most difficult markets for internet companies, particularly because a condition precedent to receiving an ICP license is an implicit agreement to adhere to the Public Pledge on internet policing. Art. 9 of the Pledge requires that IT companies:

> [r]efrain[…] from producing, posting or disseminating pernicious information that may jeopardize state security and disrupt social stability, contravene laws and regulations and spread superstition and obscenity [and] [m]onitor [...] information publicized by users on websites according to law and remove the harmful information promptly. (Public Pledge, art. 9)

Therefore, in order to obtain a license, a company has to comply with the law, and it is a condition of complying with the law that you restrict the content available (Gore 2008).

[1] Lantos T., Hearing Before the Committee of Foreign Affairs - House of Representatives, 6 November 2007.

Mr. Xiaoining and Shi Tao have sued Yahoo! in the District Court of San Francisco in order to prove its responsibility for "torture, cruel, inhuman, or other degrading treatment or punishment, arbitrary arrest and prolonged detention, and forced labor" under the Alien Tort Statute, which was used until 2013 to challenge multinational corporations in US courts for their conduct abroad.[2] The case ended with a settlement between the companies and the claimants. However, even if the case did not lead to a judicial decision against Yahoo!, for the first time the public became aware of the increasing role of the ICT companies in the treatment of the users' data, and in freedom of expression on the Internet. The case also underscored the ITC companies' possible involvement in gross human rights violations, especially in countries with repressive governments and, conversely, their potential power for protecting human rights against state requests.

More recently, in 2014, the revelations of Edward Snowden, a former employee of the National Security Agency, disclosed the systematic practices of surveillance of phone call, e-mails and text messages by governments in the US and some of the EU member states. These revelations brought the problem of the state surveillance on personal data of users to the attention of the civil society and showed that the protection of data against state behavior is also important in democratic states. Debates on the constitutional balance between privacy and security and on the limits of the state surveillance power have burned in legal doctrine in recent years, but more attention should be given to the role of private companies which help governments in collecting data through technologically advanced products.

In this respect, the UN Special Rapporteur on Promotion and Protection of Freedom of Expression, Frank La Rue, in 2013, affirmed that the private sector has a leading role in facilitating state surveillance. Their role can be implicated by: a) having had to respond to requirements that digital networks and communications infrastructure be designed to enable intrusion by the State; b) developing and deploying new technologies and communications tools in specific ways; or c) being complicit in developing technologies that enable mass or invasive surveillance in contravention of existing legal standards.[3]

After the revelations of Edward Snowden about the US Government surveillance of domestic and global networks in the NSA affair, some companies

2 The extraterritorial use of the Alien Tort Statute has been stopped by the U.S. Supreme Court in the decision on Kiobel v. Royal Dutch Petroleum Co., 133 S. Ct. 1659 (2013).

3 U.N. doc. A/HRC/23/40.

filed a disclosure report in order to provide users with information on the surveillance activity they were asked to do. For example, in its first law enforcement and disclosure report, Vodafone affirmed that 29 governments had asked for access to its network of users' data, among them many "democratic" governments such as the U.K. and Italy. This is evidence that the role of the ICT companies in the protection or affection of human rights such as privacy and freedom of expression is an issue that affects users in *all* countries and not just users living in repressive ones. According to the Vodafone report, six of the countries on their list have direct access to the users' information without passing through the company. Furthermore, many governments forbid the disclosure of what type and how many requests carriers receive from authorities.[4]

The examples examined above, as well as many others, demonstrate how the role of internet intermediaries has become crucial with respect to fundamental rights such as freedom of expression and privacy, and this role needs to be considered in the debate between privacy and security. Freedom of expression was challenged in the *Yahoo! c. China* case and it was also at the center of the NSA case. In both cases it was also strongly linked to the right to privacy.

The right to freedom of expression is defined by art. 19 of the Universal Declaration of Human Rights:

> Everyone has the right to freedom of opinion and expression; this right includes freedom to hold opinions without interference and to seek, receive and impart information and ideas through any media and regardless of frontiers.

Freedom of expression is also affirmed by art. 19 of the International Covenant on Civil and Political Rights. The restrictions to that right are heavily regulated by the international standards and must be in terms of law, necessary and proportionate.

The technological development and the widespread use of the internet have challenged the right of freedom of expression, as it was conceived before, and in 1993 the United Nations Human Rights Council appointed a Special Rapporteur on the promotion and protection of the right to freedom of opinion and expression. The Rapporteur's mandate has been renewed until 2017.[5] In 2012 the United Nations Human Rights Council, following the

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4 [online], URL: <http://www.vodafone.com/content/sustainabilityreport/2014/index/operating_responsibly/privacy_and_security/law_enforcement.html> [last accessed: 1/05/2015].

5 OCHR, Resolution no. A/HRC/RES/25/2.

work of the Special Rapporteur, clarified that the "same rights people have offline must be protected online".[6]

The right to privacy, described at its inception as "the right to be let alone" (Warren, Brandeis 1879), has been more recently based on the right to the protection of an individual's personality. Moreover, in democratic societies, privacy is perceived as a necessary demarcation line between individuals and between individuals and the state (AF Westin 1967). This view is reflected in the way in which the legal protection of privacy has been constructed, as part of fundamental human and civil rights. In many cases, the right to privacy was recognized by international human rights instruments before being protected by national basic laws (Diggelman, Cleis 2014). It has been affirmed by the Art. 12 of the Universal Declaration of Human Rights, which restricts arbitrary interference with a person's privacy, family, home or correspondence, and by art. 17 of the International Covenant on Civil and Political Rights. At European level, family life is also protected by Art. 8 of the ECHR and enforced by the ECtHR interpretation. The ECtHR in its jurisprudence has clarified that a public authority can interfere with the exercise of the right of art. 8 only if that interference is "necessary in the interest of national security, public safety or the economic well-being of the country", and that such interference must be "in accordance with the law, necessary in a democratic society and proportionate".[7]

The position of internet intermediaries with respect to human rights is ambiguous. They can act to grant users' rights and protect their privacy and their freedom of expression. Alternatively, they can facilitate surveillance and infringement of these rights by both private sector actors and governments. The technological innovation and the widespread use of internet is therefore challenging the ancient legal categories and calls for new governance models in the post-Westphalian legal order, where private actors such internet intermediaries should participate in the lawmaking process and even act to enforce the international standards in order to protect rights of individuals. In this respect, in addition to the necessary discussions about the role of

[6] OCHR, Resolution no. A/HRC/RES/20/8 of 16 July 2012. This declaration signs the definitive end of the debate between internet libertarians believing, in the early years of internet, that the cyberspace was an independent space with no need of laws and regulations, and those who claimed the application to internet of the same laws and regulations framing the physical world. In this respect it can be noted the "Declaration of the independence of cyberspace" by J. Barlow diffused online in the 1996.

[7] ECtHR, Klaas v. Germany, 6 September 1978.

governments and their respect of constitutional rights and liberties, such as the European debate on the EU Data Retention Directive (Vedaschi, Lubello 2014), it is important to point out the role of private actors and what they can do, on either a voluntary or a mandatory basis, in order to respect human rights in the internet domain.

The principal challenge is to harmonize different legal systems and thus provide a uniform level of protection to users all over the world. The problem is that the internet is global but law is still mainly local, despite the rise of transnational and international law (Pollicino, Bassetti 2014). Furthermore, different legal systems are based on the different values of the society that they regulate.[8] This is particularly evident with the protection of the freedom of expression, substantially different in the US and EU countries, as well as with the constitutional limits to the State surveillance, formally strong in Europe and particularly weak in China. Even in the European Union, harmonization is still a myth, and, despite the intervention of several European Directives, the fragmentation of national legislation and regimes is persistent (Angelopoulos 2012).

This increasing role of internet intermediaries as private actors in granting or affecting human rights, makes it important to investigate the international framework on the responsibility of those companies for human rights abuses.

3. With the power comes the responsibility?

The responsibility of multinational corporations for their human rights violations is at the center of a complex debate. International human rights law has traditionally focused on state responsibility in human rights violations. Provisions for this are contained in treaties and conventions drafted and voted by governments and applicable to states (Alston 2005). Recent decades, however, have witnessed a growing recognition that business, including internet companies, should be accountable for its responsibilities in affecting human rights. Since internet intermediaries are mostly multinational corporations, it is essential to recall that the problem of the legal responsibility of multinational corporations has been for years at the center of the debate in the international law.

According to the traditional principles of international public law, multinational corporations are not directly obliged by international norms. Therefore,

[8] As demonstrated, for example, by the different regimes of internet intermediaries liability between U.S. and EU.

they cannot be challenged in front of International courts for violations of international law.[9] While the international subjectivity of multinational corporations is at the center of a living debate among international scholars (Clapham 2006; De Schutter 2006), for the purposes of this Chapter it is enough to note that there are no international treaties or conventions which directly oblige multinational corporations to protect human rights.[10] Traditional legal instruments and categories are therefore not always able to assure a uniform and global protection of human rights from corporate abuses, mainly due to the fragmentation of civil and criminal legal systems and to the crisis of international law as a state-centric discipline (Jessup 1956; Teubner 1997).

Since 1970, however, the regulation of MNEs conduct has been contained in soft law documents such as the OECD Guidelines for multinational corporations (Nieuwerkamp 2013) and the ILO Tripartite Declaration (Blanpain *et al.* 2001). After 1990, such codes of conduct, originally created to protect investors' rights in the globalization process, started also to protect individuals' rights against corporate conduct (Muchilinsky 2007).

More recently, reflecting a new balancing between developed and developing countries, a new phase of international public codes of conduct for MNEs has been opened. The U.N. Guiding Principles on business and Human Rights (UNGPs) are the tangible product of this new approach to the legal issues raised by the globalization and, particularly, to the necessity of protecting human rights from corporate abuses. The Guiding Principles are built on the UN Protect Respect and Remedy Framework,[11] and they were unanimously endorsed in 2011 by the Human Rights Council of the United Nations[12] under the six year mandate of Prof. John Ruggie as Special Repre-

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9 For example, the International Criminal Court has no jurisdiction on legal person according to art. 25-1 of the Rome Convention of 1998 entered into force on 1 July 2002, despite the French proposal aimed at introducing a criminal responsibility for corporations, presented during the discussion process.

10 After the failure, in 2005, of the UN Norms on Transnational corporations, the recent U.N. Resolution no. A/HRC/26/L.22/Rev.1 approved on 24 June 2014 on the proposal of the Ecuador government, build an open-ended Working Group to write a treaty on MNEs responsibility. The treaty, if approved, would change the international scenario on the responsibility of multinational corporations.

11 OHCHR, Report of the Special Representative of the Secretary General on the issue of human rights and transnational corporations and other business enterprises, John Ruggie, doc. no. A/HRC/8/5 of 7 April 2008.

12 U.N. doc no. A/HRC/17/31.

sentative of the Secretary General of the UN.[13] The unanimous endorsement of the UNHRC made the UNGPs an authoritative instrument in the field of business and human rights. The work of Prof. Ruggie, in the Framework and then in the UNGPs, has been grounded on three integrated pillars: the State duty to protect human rights, laid down in the international public law; the corporate responsibility to respect them, coming from social expectations on business conduct; and the access to remedy for the victims of corporate abuses. The UNGPs are inspired by a "principled pragmatism" approach (Ruggie 2013), and they intend to be a bottom up set of principles and standards offering a "global platform" for the actions of states, international organizations and corporations (Knox 2011).

The corporate responsibility to respect human rights in the UNGPs is set as a "global standard of expected conduct for all business enterprises", and it exists independently of a State's abilities or willingness to fulfill its human rights obligations and over and above compliance with national laws and regulations protecting human rights. This standard of expected conduct is required by societal expectations and not by mandatory rules. According to Ruggie, these societal expectations are founded on social norms, which express a collective sense of 'oughtness' with regard to the expected conduct of a social actor. Some of these social norms have gained "near-universal" recognition in the sphere in which MNEs operate, and the corporate responsibility to respect human rights is one of these (Ruggie 2013). The UNGPs aim to provide a clear and practical standard of conduct for MNEs. They outline three steps for companies: 1) make a policy commitment to meet their responsibility to respect human rights; 2) develop human rights due diligence process to identify, prevent and account for their negative human rights impacts; and 3) initiate processes to enable remediation of any adverse human rights impacts.[14]

The corporate responsibility to respect human rights, as conceived by Ruggie in the UNGPs, therefore, is a social responsibility with no direct legal consequences. However, it can have legal effects once incorporated by national or supranational legislation (i.e. the European Directive 2014/95/EU on non-financial reporting). Furthermore, private codes of conduct of multinational corporations elaborated in order to comply with this corporate responsibility to respect can have serious legal consequences under private law (Beckers 2015; Glinski 2013).

13 OHCHR, Resolution no. 2005/69, 20 April 2005.

14 U.N. Guiding Principles on Business and Human Rights, par. 13-15.

The human rights referred by the UNGPs are those of the International Bill of Human Rights, consisting of the Universal Declaration of Human rights, the International Covenant on Civil and Political Rights and the International Covenant on Economic, Social and Cultural Rights, together with the ILO Declaration on fundamental principles and rights at work. The rights to freedom of expression and privacy are therefore included in the human rights that private corporations have to respect in accordance with the UNGPs.

In order to help companies to address, prevent and repair their negative impacts on human rights, the UNGPs have designed a Human Rights Due Diligence (HRDD), contained in Principle no. 13 and following. The Due Diligence is a risk assessment process of the kind already used to monitor financial risks of companies. Ruggie suggested that it could also be effectively used to address human rights risks, even if it is not sufficient to fulfill the responsibility of the company, as clarified by the Principle no. 17.

The HRDD would identify and assess the actual or potential adverse human rights impacts in the activities of a corporation and of its business relationships. In order to be effective, this process should be conducted through direct consultation of all the stakeholders, and it should address also the human rights risks of third parties. In this way, the company would be able to manage direct and indirect human rights risks. A very important point is that the HRDD has to be applied to the entire multinational corporation: the parent company, its subsidiaries and its contracting companies. In particular, the parent company should exercise an appropriate supervision over subsidiary and contracting companies by exerting commercial leverage on them. This aspect is particularly important for internet companies, where the autonomy between the parent company and its subsidiaries has often be invoked as a reason to exclude responsibility.

The UNGPs have received a widespread consensus between all the stakeholders, and they have been implemented by corporations, states and international organizations. The European Union has played an important role in this implementation process. The European Commission, in its Communication no. (2011) 681, has changed its CSR strategy for the period 2011-2014 on the basis of UNGPs. It has engaged to implement them within the European legislation and policies and has invited member states to issue a National Action Plan on UNGPs implementation in their territory.

In light of the above, it can be affirmed that the UN Guiding Principles on business and human rights have marked a substantial innovation in the way we consider the role of private actors on human rights in the globalized world. They define the respective roles of the public and private sectors as the state duty to protect and the corporate responsibility to respect human rights. Companies should then engage in human rights due diligence to "know and show" that they are addressing potential human rights impacts. They define a new governance model because they integrate three different governance systems: public law, civil society and the company, providing them with a set of bottom-up principles elaborated on a multi-stakeholders basis.

3.1. The peculiar role of ICT companies and some ad hoc initiatives

The UN Guiding Principles on business and human rights have significantly affirmed the active role of business in the respect of human rights, independently from the state's duty to protect. This model designed by John Ruggie has received a special attention by ICT companies.

It is worth noting that even prior to the final endorsement of the UN Guiding Principles, internet companies were going further than many sectors in the development of a multi-stakeholders initiative aiming to protect human rights online.

In 2008 ICT companies, civil society organizations, academics and investors created a Global Network Initiative (GNI) aimed at providing an international framework of standards for companies and improving their accountability. It is one example of collective action, drawing on the advantages which multi-stakeholder alliances offer. GNI elaborated a set of Principles and Implementation Guidelines which are based on international human rights standards.[15]

After the endorsement of UN Guiding Principles, GNI provided focused guidance on how ICT companies can respond to government requests implicating privacy in ways that respect the rights of users. The accountability of a corporation is established by a process of independent assessment of the company's implementation of its GNI commitments. Companies that are members of GNI must commit with this assessment process. The GNI Principles are an example of the role of ICT companies behaving as lawmaking actors at the international level in order to protect human rights. They underline also the special need that internet companies have for uniform international standards regulating their activities. Since such standards are not provided by national or international law, one of the functions of the law, notably the lawmaking one, has needed to be achieved by a multi-stakeholder,

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15 [Online], URL: <https://globalnetworkinitiative.org/sites/default/files/GNI_-_Principles_1_.pdf> [last accessed: 01/05/2015].

non-binding, set of principles. Finally, the implementation of UNGPs by the Global Network Initiative suggests that these two instruments can work together in order to enforce and promote corporate accountability for human rights violations.

After the endorsement of the UNGPs, the European Commission has also recognized that internet companies are a peculiar actor and have specific needs. It has therefore issued specific guidance in order to clarify how they should implement and lay down their corporate responsibility to respect.[16]

In this Guidance, the European Commission underlines the role of internet companies, as part of the ICT sector, in affecting and/or protecting individual's rights as the freedom of expression and the rights to privacy. The development of the online environment and of social media has contributed to democratic movements and to the enjoyment of the freedom of expression worldwide. However, the Guidance also recognizes that the right to privacy and to freedom of expression can be particularly impacted by the operations of such companies. Furthermore, internet companies can operate in domestic legal contexts where the state fails to protect these rights.

The document intends to be a tool for ICT companies, helping them to implement the UN Guiding Principles and the corporate responsibility to respect human rights. To this end, it contains several suggestions on how address, measure, prevent and repair negative human rights impacts of their activities. The European Commission guidance, together with the UNGPs and the other multi-stakeholders initiatives organized to foster human rights protection by internet companies, testify to the emergence of the new role of internet intermediaries in protecting human rights. These approaches also stress the need of internet companies to conclude licensing agreements with governments in order to operate. They recommend, where governments are unwilling to include human rights provisions in the licensing agreements and, where other regulatory and legal protections are weak, to engage the government collectively in discussions on human rights risks, with the help of other stakeholders. In this respect, state-owned enterprises often have a particular leverage with the government of their home state, and this can be useful in helping them to reduce human rights risk. The European Commission, therefore, calls on internet companies (and ICT companies in general) to play a more active role and use their leverage to lobby government on pol-

[16] [Online], URL: <http://www.ihrb.org/publications/reports/ec-sector-guides/publications/reports/ict-human-rights-sector-guide.html> [last accessed: 01/05/2015].

icy or regulatory measures. Such action is consistent with the company's own responsibility to respect human rights and would not undermine the state's duty to protect human rights. Furthermore, the guidance keeps particular attention on companies operating in high risk context, underlining that in such a case the host state plays a particular role in supporting companies by providing adequate assistance to their efforts to assess and address these risks.

Where national law appears to conflict with internationally recognized human rights risks, as, for example, in the case of Yahoo! above mentioned, the company should identify such risk through an assessment process and prepare its staff to face such a "dilemma" scenario. Particularly, in confronting a state request to shut down, the company should carefully measure the opportunity to answer to such a request. It should develop a contingency plan in order to identify potentially affected users and customers, maintain control on its infrastructure, address the request in a way that is least harmful to users and customers, and restore the service as soon as possible.

The EC guidance for ICT companies recognizes their important role in affecting and protecting human rights from governments' illegal requests or orders. It underlines the active role that internet companies should play in order to address and prevent human rights negative impacts, and it calls for a productive collaboration between companies, governments and other stakeholders.

The corporate responsibility to respect human rights, institutionalized by the UNGPs in 2011, has been extensively applied to internet intermediaries. Their power over individuals' rights such as freedom of expression and the right to privacy establishes their responsibility, as corporate actors, to respect these rights. Even if the nature of such responsibility remains controversial (Ruggie 2013), it represents a first step in the complex relationship between the law and the technological development, and the UNGPs' polycentric governance model represents a new approach in the dichotomy between law and innovation.

4. The soft law standards on the human rights protection in Internet: a challenge for the law?

One of the main consequences of the denationalization of law is that it is being increasingly replaced by other mechanisms aiming to achieve similar goals. Smits has called this phenomenon the *ex-ante* governance of private relationships (Smits 2014). This is particularly true in the field of the internet where, as we have seen, the increasing role of private actors has encouraged the development of multi-stakeholder initiatives and co-regulation mechanisms not only aimed to govern commercial relationships between private parties, but also to develop a more effective protection of human rights. In this scenario, many authors have underlined the need of a new governance model able to face and regulate the 'new world order' (Slaughter 2004), which would take in account the increasing role of private actors.

As argued before, the power that internet intermediaries have gained over individual rights such as freedom of expression and privacy has brought a recognition of their responsibility to respect such rights and to actively prevent their infringement. Such responsibility, defined by the UN Guiding Principles on business and human rights, is the result of an ongoing debate on the legal responsibility of multinational corporations. It is not contained in a binding international treaty; nevertheless, it has been progressively recognized by the business world as well as by international organizations and states. This highlights the influence that a soft law instrument can exercise at both the international and national level. UNGPs can provide a tool for the further development of the global regulation of corporate conduct, which is particularly needed in an area such as human rights protection in the internet field.

The brief analysis undertaken in this Chapter on the increasing role of internet intermediaries on the freedom of expression and privacy and on the progressive raise of soft law and multi-stakeholders initiatives, confirms that, together with the power, internet companies have also gained the responsibility to respect human rights. Future developments could convert the current social responsibility of companies into a legal one. In the meantime, companies which do not comply with soft law standards can expect serious social and economic consequences. For this reason, even soft standards of social responsibility are able to achieve the traditional function of the law in preventing human rights violations.

Both the UNGPs and the GNI principles are multi-stakeholders initiatives where the private actors have directly participated at the elaboration process. This participation made these instruments more acceptable to the business sector, which has shown a widespread willingness to comply with them. Even if the principles lack mandatory effects, the success obtained by this model of a multi-stakeholders elaboration process, of polycentric governance and of distinguished responsibility of public and private actors can represent an inspiring tool for the official lawmakers. In a globalized and complex field such as the internet regulation, traditional law could then be combined with, and refer to, such soft law instruments and standards (as in part it already does), thus ensuring a more effective protection to human rights from public and private infringements. As matter of example, it is worth noting that the new European Directive no. 2014/95 obliges member states to adopt national legislation obliging corporations (including ICT companies) to issue an annual communication about their activities in preventing and addressing social and environmental violations. In this communication, companies should follow the Human Rights Due Diligence model contained in the UNGPs. This is only one first step toward a possible coordination between soft law standards and hard law measures on human rights protection, which could open the doors to a broader global notion of Human Rights Due Diligence.

All the initiatives described above, the UN Guiding Principles, GNI Principles and the EC Guidance for ICT companies, represent a first answer to the increasing power of private actors in the field. In particular, all of them represent a new governance model based on a bottom-up and multi-stakeholders participation at the lawmaking process and on a multi-level structure (Abbott, Snidal 2009).

Technological innovations in the field of internet services are shaping our world to a considerable degree. They contribute to the improvement of the interconnection between peoples, and they are creating a global community. However, they raise serious concerns about the protection of human rights of users, especially the right of freedom of expression and privacy. Experience shows that the old categories of law are not ready to face this challenge, mostly because they rely on the ancient state-sovereignty principle (Jessup 1956; Twining 2000). Micklitz has even suggested that the twenty-first century has seen the technological revolution is driving a transformation of the nation state into a market state in which the public/private divide is vanishing and the role of the state as well as the functions of the private need to be redefined (Micklitz 2014). It is now possible to argue that the role of the law and the lawmaking process should be re-taught in light of technological innovation, which brings private actors forward as the fundamental players of the globalized world.

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Workplace Technological Innovation. What Role for the Law?

Barbara Bottalico

1. Introduction. An innovation process

A major global restructuring of industry and the labor market is currently underway, and the factors at the basis of this are various and interconnected. Huws (2014) suggests two important factors: globalization and the spread of ICTs. The first factor is related to the opening up of world markets with the creation of a global market for goods and services, helped by the removal of many institutional barriers to the import and export of goods, services, information and capital. The second aspect to consider is the spread of ICTs that have made it possible to redistribute spatially activities that were formerly rooted in a single location, and to install and fit mechanisms whereby these activities can be centrally coordinated and remotely managed in real time (Huws 2014).

Furthermore, the growing necessity of flexibility in national labor markets has led to a rethinking of the existing regulations, as has been happening – for instance – in the last months in Italy.

Within this process, the transformation is accelerated by the impact of further, exponentially-growing technologies (e.g. intelligent robots, autonomous drones, sensors, 3D printing). The networking within internet of things, services, data and people could transform the future of industry. In this light, many commentators use the term "Industry 4.0" to refer to such a fourth industrial revolution, mainly characterized by the raise of smart production systems and logistics, and hastened through exponential technology.[1]

These developments are leading to an erosion of the boundaries of the workplace and the workday, with a relocation of many activities into the

[1] A similar definition was provided by the Study published by Deloitte as *Industry 4.0. Challenges and solutions for the digital transformation and use of exponential technologies*, 2014, available at: URL: <https://www2.deloitte.com/content/dam/Deloitte/ch/Documents/manufacturing/ch-en-manufacturing-industry-4-0-24102014.pdf> [last accessed: 08/05/2015].

home or other places, and including the expectation that an employee should continue to be productive while traveling.

A person's occupation is one the most important delineators of social identity, but new required skills, competences, aptitude and know-how, "combined in pick-and-mix permutations", do not add up to stable occupational identities and lead to an acknowledgement of the inadequacy of the existing categories used to classify industries and jobs (Huws 2014). For instance, the category of "occupation" itself has become somehow unstable in a situation in which employees are expected to change their skills in response to each wave of technological and institutional innovations. The regulation of work, the protections accorded to employees, and the role of technology in the labor market should be reconsidered in light of this revolution.

This Chapter has two aims: explores the most relevant challenges for industries and employees due to the introduction of new technologies in the workplace, and attempts to define a possible role for the law within the so-called Industry 4.0, presenting some practical regulatory proposals, with a particular focus on the Italian legal system.

2. Innovation in the workplace: what are we talking about?

A general question should first be considered: what is affecting the most recent division and organization of labor, modes of technology use and business models?

Since 2011, the term Industry 4.0 has entered the socio-economic lexicon. The issue has not found much room in Italy yet, and in order to enter into the topic it is necessary to take a look at Germany. There, the government and enterprises have been investing in a new production model to strengthen and revitalize domestic manufacturing, trying also to support "re-shoring", namely to encourage the return to Germany of the production that delocalized abroad in the last few years.[2] During the same period, the US has started to move in this direction. The "Report to the President on Ensuring American Leadership in Advanced Manufacturing" released in June 2011 by the President's Council of Advisors on Science and Tech-

[2] Recommendation for implementing the strategic initiative *Industrie 4.0*, available at URL: <http://www.acatech.de/fileadmin/user_upload/Baumstruktur_nach_Website/Acatech/root/de/Material_fuer_Sonderseiten/Industrie_4.0/Final_report__Industrie_4.0_accessible.pdf> [last accessed: 07/05.2015].

nology[3] was the first document where Industry 4.0, although not explicitly mentioned, helps inform a model of industry where Internet and digitalization are crucial.

In Italy, the first project in this direction has been "*Fabbrica 4.0*" launched in 2014 by Confindustria, the largest association of industries in Italy. The project had the aim of promoting better information about the possibilities that digitalization can offer to modern industries. Its activities included the distribution of materials, e-books and presentations in various cities of Italy.[4] Furthermore, the Minister of Economic Development has mentioned "Industry 4.0" as an area of strategic investment in a recent paper about the position of Italy on the digitalization of industries:

> Strategic investments are becoming significant in innovation in light of Industry 4.0, namely investments in digitized and interconnected systems that favor the process of efficiency and product innovation, including instruments such as those offered by the Internet of Things (IoT), characterized by higher speed and production flexibility, greater exchange of data and information with end users and mass customization.[5]

What are the consequences that this new model of production may have on work, both from the legal point of view and as an observation point on the current transformations of labor? In fact, the theme of industry with a high rate of automation is an example of how industrial policy and employment policy cannot travel on parallel or divergent tracks: too many aspects are mutually interconnected.

The first step could be to understand whether some crucial invention is a distinguishing feature of Industry 4.0. Although the very last years have been full of new inventions of a very high technological level (such as the 3D printer), referring to a single invention among them would not be sufficient neither exhaustive.

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3 The report is available at URL: <https://www.whitehouse.gov/sites/default/files/microsites/ostp/pcast-advanced-manufacturing-june2011.pdf> [last accessed: 05/05/2015].

4 URL: <http://www.confindustriasi.it/fabbrica4.0/> [last accessed: 05/05/2015].

5 Original formulation in Italian: "[…] assumono rilevanza strategica gli investimenti in innovazione in chiave Industry 4.0, ovvero investimenti in sistemi digitalizzati e interconnessi che favoriscono l'efficientamento dei processi e l'innovazione di prodotto, anche tramite strumenti come quelli offerti da Internet of Things (IoT) caratterizzati da maggiore velocità e flessibilità produttiva, maggiore scambio di dati e informazioni con il cliente finale e customizzazione di massa", URL: <http://www.mise.gov.it/images/stories/pubblicazioni/Position_paper_on%20DSM_ITALIA.pdf> [last accessed: 06/05/2015].

The newest inventions are all linked by the so called “Internet of Things (IoT)”, a computing concept that describes a situation where physical objects are connected to the Internet and are able to identify themselves to other devices and share information (Kouroupetroglou 2014). This is the real key issue of this revolution.

2.1. The Internet of Things and further driving forces of innovation in industry

The significance of the IoT pertains to the real time and significant interconnections between objects and the Internet.[6] No longer does the object relate just to a person, but it is now connected to the surrounding objects and to remote databases.

Many scholars have attempted to define this concept. Its initial use has been attributed to Kevin Ashton, an expert on digital innovation.[7] In the late ’90s he stated:

> If we had computers that knew everything there was to know about things – using data they gathered without any help from us – we would be able to track and count everything, and greatly reduce waste, loss and cost. We would know when things needed replacing, repairing or recalling, and whether they were fresh or past their best. (Ashton 2009)

While many of us may still be thinking about being connected in terms of computers, tablets and smartphones, the IoT describes a world where just about anything can communicate and be connected in an intelligent fashion. In other words, with the Internet of Things, the physical world becomes one big information system.

How can this affect industries and the workplace? For examples, industrial machines can have sensors that notify workers when a problem occurs; surveillance systems can use locks and camera systems that inform the building manager in real time when someone is attempting to enter; plant managers can receive information and data about the production in a continuing flow, and so on.

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6 An interesting definition was provided in the Lockheed Martine website: “an object that can represent itself digitally becomes something greater than the object by itself”. URL: <http://www.lockheedmartin.co.uk/m/us/news/features/2014/isgs-internet-of-things.html> [last accessed: 06/05/2015].

7 “I’m fairly sure the phrase ‘Internet of Things’ started life as the title of a presentation I made at Procter & Gamble (P&G) in 1999” (Ashton 2009).

The well-known infographic created by the visual designer David Wong outlines seven ways the Internet of Things will change the workplace:

- Energy, as lights and thermostats work autonomously;
- Smarter analytics, to improve strategy for marketing and customers-oriented;
- Productivity;
- Inventory management;
- Travels – as internet connected cars and means of transportation give information about real time traffic and diagnostic of the vehicle.[8]

Although the Internet of Things may be considered as the main driving force of these changes in industrial organization, further crucial elements of innovation have to be mentioned as well: Industrial robotics and Cloud robotics, Big Data, and Learning machine.

2.2. Industrial Robotics and Cloud Robotics

An industrial robot commonly refers to a robot arm used in a factory environment for manufacturing applications. Traditional industrial robots can be classified according to different criteria such as the type of movement (degrees of freedom), application (manufacturing process), architecture (serial or parallel) and brand (Pandilov, Dukovsky 2014).

Most recent robots and automation systems are not limited by onboard computation, memory, or software. Rather than viewing robots and automated machines as isolated systems with limited computation and memory,[9] "Cloud Robotics" suggests a new paradigm where they exchange data and perform computation via networks. Cloud computing was indeed born as "a way of delivering computing resources as a utility service via a network, typically the Internet, which can be scaled up and down according to user requirements" (Millard 2013). As such, the cloud may prove to be a disruptive innovation, "as was the emergence of cheap electricity on demand a century or so ago" (Carr 2009). Such computing resources may range from raw processing power and storage, such as servers or storage equipment, to

[8] The infographic has been published, among others, by The Business Insiders, available online at: <http://uk.businessinsider.com/internet-of-things-is-changing-the-workplace-2015-4?r=US#ixzz3ZM2EKiVE> [last accessed: 06/05/2015].

[9] Prof. Ken Goldberg's suggestion is to consider a new paradigm where robots and automation systems exchange data and perform computation via networks: "Cloud Robotics and Automation", available at URL: <http://goldberg.berkeley.edu/cloud-robotics/> [last accessed: 07/06/2015].

full software applications. Users can “rent” IT resources from third parties when needed, instead of purchasing their own. The scale and scalability of cloud computing make it suited for environments where the demand for IT resources may fluctuate widely and rapidly. The cloud may also be relevant for supporting the deployment of mobile devices and applications on a large scale (Millard 2013).

Finding a shared regulatory approach across the field of robotics is not easy: the variety of technologies, both basic and new/advanced, is relevant, and it can also be difficult to separate robotics from other technologies with which it is integrated, considering that its technical components also have different applications.

In addition, robotics can be applied to many domains beyond industry: drones, self-driving cars, surgical robots, home-care robots, each with different purposes, concerns and challenges: this makes it very difficult to elaborate a single set of rules or principles.

2.3. Big Data and Learning Machine

The collection and combination of all data generated by users and machinery with other sources and analytics can be a tremendous resource for society, policy makers, public authorities and the private market.[10] This huge potential lies in the expected predictive capacity that they bring if analyzed in a certain domain. As Holtgreve pointed out in 2014:

> Technologies involved come from artificial intelligence areas such as natural-languages processing, pattern recognition or machine learning. Patterns of activities discovered though combining various data sources and using sophisticated statistical analysis and artificial intelligence applications may be used for conclusions about the future behavior of individuals and groups (or of machines) from people’s buying decisions to the risk of machine breakdowns, diseases or accidents to illegal behavior. (Holtgreve 2014)

Further, data are becoming more available and more adapted to the needs and capabilities of computers. Most of them are “unstructured” and Internet-based, and would not be ready for traditional computational databases, but

[10] See the Document published by the Organization for Economic co-operation and development OECD E-Government Project GOV/PGC/EGOV(2012)7/REV1, 1 March 2013, available at: URL: <http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=GOV/PGC/EGOV%282012%297/REV1&docLanguage=En> [last accessed: 07/06/2015]

the computer tools for gathering knowledge and insights from data in this Internet era are gaining ground rapidly (Lohr 2012).

As reported by a study conducted by the consulting company "Boston Consulting Group" in 2015, analytics based on large data sets has emerged only recently in the manufacturing scenario, and this would have the benefit of opening the possibility to optimize production quality, save energy, and improve equipment service.[11] In an Industry 4.0 context, the availability of data from many different sources (production equipment and systems, enterprise and customer-management systems, and so on) may become the basis to support real-time decision making within the production.[12]

Also, big data combined with learning machines can create a self-enhancing development, as predicted in 2012 by Steve Lohr from the pages of the New York Times: "Machine learning algorithms, for example, learn on data, and the more data, the more the machine learns" (Lohr 2012). Learning machines are indeed particularly promising as a tool to improve the capacity of the technology by a self-development of new skills, grounded on previous experience.

DeepMind, a learning system recently acquired by Google and developed by a young UK enterprise, is quite a clear example. The system benefited from a presentation in *Nature*:

> Here we use recent advances in training deep neural networks to develop a novel artificial agent, termed a deep Q-network, that can learn successful policies directly from high-dimensional sensory inputs using end-to-end reinforcement learning. We tested this agent on the challenging domain of classic Atari 2600 games. We demonstrate that the deep Q-network agent, receiving only the pixels and the game score as inputs, was able to surpass the performance of all previous algorithms and achieve a level comparable to that of a professional human games tester across a set of 49 games, using the same algorithm, network architecture and hyperparameters. This work bridges the divide between high-dimensional sensory inputs and actions, resulting in the first artificial agent that is capable of learning to excel at a diverse array of challenging tasks. (Mnih *et al.* 2015)

This type of advance in computing power means that learning (or artificial intelligent) systems can handle much larger data sets, considering that watch-

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11 *Industry 4.0. The future of Productivity and Growth in Manufacturing Industries*, The Boston Consulting Group, April 2015, available at: URL: <http://www.voesi.or.at/wp-content/uploads/2013/02/Industry_40_Future_of_Productivity_April_2015_tcm80-185183.pdf> [last accessed: 06/06/2015].

12 See supra note 11.

ing an Atari game corresponds to processing about 2 million pixels of data a second. Google may be interested in this software in order to better analyze the huge amount of data it collects, since the pixels of the game can be considered analogous to the data Google has on each user, and the score would be their advertising revenue.[13] Demis Hassabis, the co-founder of DeepMind declared in a recent interview to New Scientist "We can't say anything publicly about this but the system is useful for any sequential decision making task. You can imagine there are all sorts of things that fit into that description" (Aron 2015).

This very brief introduction to what technology is now offering to industry suggests taking a further step: analyzing what could be the impacts on the labour and employment legal system. Is new regulation necessary to protect employees' rights? Is individuals' privacy at stake? What are going to be the effects on the job market internal and external to the workplace? The following section will present some practical cases and try to explore how law can contribute to the debate.

3. The legal challenges

3.1. Electronic correspondence and privacy in the workplace

The problems surrounding privacy and e-mail use have been copiously documented. Starting from the Nineties, a great deal of litigation has involved electronic communications in the workplace. Employers have been sued by employees for invasion of privacy, defamation, and harassment, as noted in 1999 by a US National Bureau Report (Gindin 1999).

Within the European Union, in 1989 the Committee of Ministers to Member States approved the first recommendation on the Protection of Personal Data Used for Employment Purposes,[14] but email correspondence was not explicitly mentioned yet: the Recommendation was indeed mainly focused on the collection and storage/use of personal data in the recruitment process and during the working relationship, without any concrete reference to any specific technology or forms of communication.

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13 For a broader comment about possible uses of DeepMind by Google, see: Jacob Aron, Google DeepMind AI outplays humans at videogames, *New Scientists Tech*, 25/05/2015.

14 REC (89)2 Committee of Ministers to Member States on the Protection of Personal Data used for employment purposes, available at URL: <http://www.coe.int/t/dg3/healthbioethic/texts_and_documents/Rec%2889%292E.pdf> [last accessed: 02/06/2015].

In the Italian legal system, the legal framework for employee privacy has always been fragmented, and it is still contained in different pieces of legislation, initially drawn up in an era in which technology was not as relevant as in current times. Recently, however, case-law and the Privacy Authority have effectively clarified the field.

The first and most important provision to consider is art. 15 of the Italian Constitution[15] that, in accordance with art. 616 of the Criminal Code, equalizes mail correspondence to email and phone conversations. In parallel, as to the use of electronic communication by employees, articles 2086 and 2104 of the Civil Code legitimize an overall control of the employer over the employee's activity. Therefore, on the one hand, the electronic correspondence of the worker seemed inviolable and confidential pursuant to art. 15 of the Constitution, while, on the other hand, the same correspondence seemed to be subject to the control of the employer, intended to ensure consistency between the performance of workers and their assigned tasks.

As a result of distrust of both a highly innovative technology and the legal vacuum, the Italian case-law solution has been biased for quite a long time in favor of the secrecy of correspondence in the workplace (*Corte di Cassazione*, Penal Section, judgment no. 47096/2007 provides for the total secrecy of workers' email correspondence; this interpretation was compliant with the previous indications of the Privacy Authority). With the gradual emergence of e-mail as a habitual work tool, however, some local courts have started a process of rapprochement towards the productive and organizational needs of the employer. In 2006, the Court of Turin (Section of Chivasso) identified the e-mail as a real instrument of work entrusted to the employee, of a "personal" but not "private" nature (in fact, it could be necessary to be accessed and read by different parties belonging to the company, such as colleagues or the employer in the case of replacements or sickness). As such, email should be available to the employer through the communication of the password by the employee, provided that the employer had previously formally clarified that all communications could be made public. Further, according to the regulation on "ex post" controls on the employee's work, the employer can legitimately read employees' email after being informed that an unlawful act has been committed. In 2007, the need for coordination between email moni-

15 Art. 15 Italian Constitution: "The freedom and secrecy of correspondence and of every other form of communication is inviolable. Their restriction may be imposed only by a reasoned act issued by a judicial authority along with the guarantees established by law".

toring and employee's legitimate expectations of confidentiality was clarified by the Guidelines of the Italian Data Protection Authority for E-mail and Internet (Act no. 13, 1 March 2007),[16] which promoted: i) the adoption of a specific company policy; ii) the use of filters to prevent access to inappropriate sites; iii) the use of anonymous data and storing data for a limited time; iv) the provision of both shared e-mail addresses and a different e-mail account for personal use of the employees; v) the delegation of a trustee of the employee for access his/her email; vii) automatic responses in case of absence, indicating a colleague's name as an alternate contact for immediate needs; and viii) consultation with the trade union in cases where the intervention of the employer may constitute a "remote control", forbidden according to art. 4 of the Statute of Workers.[17]

In general, the employer's control must maintain a "human dimension", which should not be inflamed by the use of technologies that can exacerbate the employer's supervision of employees without any confidentiality and autonomy in the management of the employment relationship.

Similar principles have also been recently acknowledged for the EU by the last Recommendation approved by the Committee of Ministers to Member States in April 2015 CM/REC(2015)5. This starts from the assumption that the previous REC(89)2 should be revised in light of "*the increasing use of new technologies and means of electronic communication in the relations between employers and employees, and the corresponding advantages thereof*" and believing that the use of data processing methods by employers should be guided by principles designed to minimize any risks that such methods might pose to employees' rights and fundamental freedoms.

Part I of the Recommendation focuses on the general principles to be given particular priority for electronic correspondence, i.e. Human Dignity, the Right to Privacy, the protection of personal data and the relevance of the aims pursued by the collection of data.

Part II deals specifically with the case of email correspondence, and art. 14 provides that:

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16 The Guidelines are available, in Italian and English, at the link: <http://www.garanteprivacy.it/web/guest/home/docweb/-/docweb-display/docweb/1408680> [last accessed: 02/06/2015].

17 The Italian Data Protection Authority confirmed the Guidelines in the last Vademecum "Privacy and Work" approved in April 2015 and available – in Italian – at the link: <http://194.242.234.211/documents/10160/3844886/Privacy+e+lavoro+-+vademecum+2015.pdf> [last accessed: 02/06/2015].

> Employers should avoid unjustifiable and unreasonable interferences with employees' right to private life. This principle extends to all technical devices and ICTs used by an employee. The persons concerned should be properly and periodically informed in application of a clear privacy policy, in accordance with principle 10 of the present recommendation.
>
> Access by employers to the professional electronic communications of their employees who have been informed in advance of the existence of that possibility can only occur, where necessary, for security or other legitimate reasons. In case of absent employees, employers should take the necessary measures and foresee the appropriate procedures aimed at enabling access to professional electronic communications only when such access is of professional necessity. Access should be undertaken in the least intrusive way possible and only after having informed the employees concerned.
>
> The content, sending and receiving of private electronic communications at work should not be monitored under any circumstances.[18]

Although the legal framework remains fragmented, in light of the current regulations of electronic correspondence analyzed above, we can conclude that the provisions of the different legal sources are becoming increasingly convergent and seem to be heading in the same direction.

The following paragraph will be dedicated to the most relevant challenges that are coming from recent technologies for the monitoring and surveillance of employees and for the use of data collected during the work activity.

3.2. Data collection and Monitoring & Surveillance in the workplace

Two recent cases

a) In March 2015, Fincantieri, an Italian company and leader in the construction of cruise ships and large ferries, surface vessels and submarines, attracted the attention of the media for attempting to reach an agreement with labor unions on what they considered a technological improvement of the work at the company.
The company wanted to install microchips in the employees' work shoes, declaring that it was a useful solution in order to help keep people interconnected within the construction sites, especially important in case of injuries in the workplace. It can indeed be difficult to locate quickly an injured person if she fell into some hidden part of the construction site or if she is badly injured and is not able to send alarm signals. Furthermore, being intercon-

[18] Extracts of Art. 14, Recommendation CM/Rec(2015)5 of the 'Committee of Ministers to member States on the processing of personal data in the context of employment', available at URL: <https://wcd.coe.int/ViewDoc.jsp?id=2306625> [last accessed: 4/06/2015].

nected with the company's systems through an electronic device could help to register attendance at the workplace (instead of using different methods of registering at the entrance and exit).

The labor unions strongly opposed this proposal on the grounds of the legal protection accorded to the employee's privacy and dignity, which prohibits the direct control and surveillance on activities and movements in the workplace; eventually, no agreement was reached.

b) In April 2015, a large majority of the employees at the Telecom Italy call centers rejected an agreement jointly signed by the company and unions on the processing of personal data, shouting "No to Big Brother". This policy was named: "Cloud of skills" (in Italian: *Cloud delle competenze*). According to the policy, data related to all their performance would be stored in the cloud, visible in real time from a control room, minute to minute. The company declared that the policy was aimed at reaching a better management of the flows, making the most of every call, and taking action on weak points. Some limits were placed by the unions: no data taken from the cloud could be used to take disciplinary or economic measures (reprimands, or production bonuses, etc.); and no employee's name would be indicated in connection with the transcriptions of data.

These limits, however, did not reassure the employees of the call center at all; they rejected the deal (thus rejecting the action of their unions), citing their dignity and privacy rights.

Additional scenarios listed below show that the context of workplace monitoring is now getting extremely difficult to manage on the basis of the pre-existing legal tools.

- Global Position Systems (GPS) and Geographic Information Systems (GIS) can be used to monitor employees in activities where they are expected to travel and work out of a single office (such as in logistics and postal deliveries) or, more recently, also to monitor the work consumption at specific sites, such as construction site.[19]

[19] In a paper published by the journal "Automation in Construction" in April 2015, this idea was proposed: "The aim of the study presented in this paper is the development of a labor consumption measurement system based on real-time tracking technology for use on a dam construction site. Such technology includes Global Positioning System (GPS), and Geographic Information System (GIS). The system is three-layered and aims to solve several labor computational and usability challenges. The software for processing the collected data, presenting real-time site state visualization, and the accurate analysis of on-site labor consumption is run by smart phones with GPS devices, on-site private wireless base stations, and servers. The benefits of this quantitative labor consumption measurement approach for hydropower projects include the provision, for each dam monolith, of precise information regarding both the num-

– The combination of data on employees' behavior at work with external information on them, obtained through the Internet, may affect recruitment and careers, leading to new forms of discrimination.

Current legal protection of rights and future perspectives

These cases pave the way for a broader reflection on the changes that new technologies are bringing, in the process challenging the preexisting protection of the workers' privacy and dignity during their activities in the workplace.

Up to now, workers' rights have been regulated and protected by the "Workers' Statute" (Law no. 300/1970). The Statute was enacted in 1970 after a long and harsh debate between politicians and unions regarding the new challenges posed by the labour market after the Second World War and the economic growth of Italy, in order to protect employees in their fundamental rights related to their job. In particular, the Statute protected the privacy and dignity of employees in the workplace with the following provisions:

– art. 8: "It is forbidden to the employer, for recruitment, as well as during the work relationship, to conduct investigations, also through third parties, on the political opinions, religious or trade union of the worker, as well as on facts not relevant for assessing employees' professional qualifications."
– art. 4: "The use of audiovisual equipment and other equipment for the purpose of remote monitoring of workers is forbidden. The control equipment that is required by organizational or production needs, or by the security of the workplace, but from which derives the possibility of remote monitoring of workers, may be installed only after agreement with the company union representatives, or, failing that, with the council. In the absence of agreement, upon request of the employer, it provides the Labour Inspectorate, dictating, where necessary, the procedures for the use of such facilities."

In addition, in light of the most recent case-law (e.g. *Corte di Cassazione*, ruling no. 20722/2010) the companies have the right to control employees remotely through video surveillance equipment, thus exceeding the art. 4 of the Statute of Workers, only in the case of suspected infidelity: in this case the employees' behavior lies outside its specific work activity and can result

ber and category of laborers together with their respective working hours. Such knowledge provides adequate quality management information for the owner and the supervisor and importantly aids payment negotiations with contractors" (Jiang *et al.* 2015).

in an attempt to harm the interests of the company.[20] Employees who work in particular situations of danger (e.g. cashiers of a bank) can also be monitored, but only upon agreement with the Unions or the Labour Inspectorate.

Concerns have been raised with specific reference to the protection of privacy and possible concrete solutions to adapt the regulation to a world where controls are made easy and possible by every technological device, and are starting to be an obvious side-effect of the digitalization of industries and the workplace generally.

The President of the Italian Data Protection Authority (Antonello Soro) recently declared that the old procedures need to be rethought and made less cumbersome, but still effective in protecting the various interests at stake. In his view, the important thing is that technology, in its constant progress, is made functional to the rights involved in the work process: the rights to property and economic initiative on the one hand; the right to protection of personal data of workers, on the other. Soro also warned that, according to the European Court of Justice, the right to privacy prevails over economic interests.

Employers' Associations such as Assinform – the association of Confindustria representing IT companies – have a different opinion. They avoid starting from the title "remote controls", a term that would evoke a negative meaning. Rather, they often prefer to refer to "electronic systems of coordination at a distance", since the current issue relates to how to organize the work in industries that have no walls or definite times. Employees should not be afraid of the digital element in the workplace (for instance looking at it as Big Brother), but should rather address the issue in a positive and active way, considering the new possibilities that are going to be opened (for instance more opportunities for teleworkers).

In light of this debate, in late 2014 an important labor reform ("Jobs Act"), anticipated for a long time, was finally approved. A parliamentary decree (*legge delega*) was passed, empowering the Government to elaborate further decrees governing the main areas of the labor law in Italy, with the aim to make it more updated to current times and more flexible. One of the decrees should deal with the harmonization of the existing legislation regulating controls on employees in the workplace with the possibilities opened by the new technology.

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20 Corte di Cassazione, V Sezione Penale, 1/6/2010, no. 20722 (Pres. Ambrosini - Est. Rotella), available (in Italian) at URL: <http://www.militerni.it/rassegna/201103251007441944.pdf> [last accessed: 06/05/2015].

Within the discussion that has begun, all the stakeholders seem to be aware that, this time, the driving force is a new kind of innovation that is radically changing the way we live and work. Thinking about the previously mentioned technology, the path to follow could be that of defining the use of the huge amounts of data that employers often have at their disposal, rather than prohibiting its collection.

It is no longer useful or coherent to prohibit the collection of personal information when social networks, Internet flows, and our habits as online and offline consumers, are revealing almost all relevant details of our life. It's rather the use of the data that should be regulated in the sense of avoiding discriminations and misuses.

For surveillance at work, the same principle is applicable, in light of the easy possibility of monitoring employees' work and activity in a digitized work environment. Ensuring that the data are collected anonymously where possible, and limiting their use only for legitimate reasons of security could be first steps toward new regulations, more open to new technologies but at the same time aimed at protecting the dignity of employees' work.

The protection of the fundamental rights of workers, such as privacy and dignity, is a principle that has to be established in all possible scenarios. And this protection cannot just be enforced through the prohibition of technology that might trace physical or digital movements. It would be much better to analyze possible breaches in each workplace, according to the type of activity and the technology that is used there by employers and employees, and then delineating through specific policies how to regulate the work relationship and the day-by-day activity. This could be done by providing for different regulations specifically directed to the area and technology in question, in parallel with the general provisions that have already been defined in the European context.

Indeed, REC(2015)5 dedicates Part II to "Information Systems and technologies for the monitoring and surveillance, including video surveillance". The first relevant provision is that "The introduction and use of information systems and technologies for the direct and principal purpose of monitoring employees' activity and behaviour should not be permitted". However, if these technologies are used for other legitimate purposes, such as "to protect production, health and safety or to ensure the efficient running of an organisation" and the possibility of monitoring employees' activity is an "indirect consequence", then they may be utilized, subject to the additional safeguards set out in principle 21. These safeguards include prior information to employees about the technologies introduced and about the appropriate internal measures relating to the processing of data, consultation of employees' representatives and the national supervisory authority, and, in particular, consultation of the employees' representatives.

In addition, according to the Recommendation, information systems and technologies that indirectly monitor employees' activities and behavior should be specifically designed and located so as not to undermine their fundamental rights. The use of video surveillance for monitoring locations that are part of the most personal area of life of employees is not permitted in any situation.

The focus of the Recommendation is clearly on the *purposes* rather than the intrinsic risks or capabilities of the technologies used in the workplace. This approach is embraceable, since it has the sufficient flexibility to fit various types of technology and, at the same time, is intended to give a clear direction to the use of them by employers. Once the purposes can be considered legitimate, the Recommendation provides for a set of "safeguards" that are recommended to be adopted in compliance with the national legislation.

It should be noted that Italian case-law had already banned surveillance and monitoring technology exclusively aimed to control employees in their daily activities; the "indirect effect", mentioned by the REC(2015)5, is instead the most relevant issue for the current state of the art.

At this point, it could be informative to try to use this more realistic approach to take a position on the two cases previously presented in this Chapter.

As to case a), the company asked the trade union to agree on the project of installing microchips in the employees' work shoes, declaring that it was a useful solution to help being interconnected within its construction sites, especially in case of injuries in the workplace, and to make it easier to register attendance at the workplace. In light of the principles set in the EU Recommendation and in the Italian Data Protection Authority Guidelines, aiming at minimizing the possibilities of monitoring employees and limiting them only to necessary measures, the employees' unions have a legitimate ground to oppose installing the microchips.

Monitoring workers was the direct aim of the proposal, with the secondary aims of more easily registering attendance at work and for safety reasons. But the measure is neither necessary nor does it minimize the employer's impact on workers' freedoms and rights.

As to case b), a policy called "Cloud of skills" was agreed with the unions in a call-center company; it was aimed at storing all performance data in the cloud, making them visible in real time from a control room. The declared purpose was that of better managing the call flows, taking action on weak points. In this case, the aim of the policy is interconnected with the possibility of directly listening to the phone conversations of the employees. Rendering the data anonymous would be a contradiction since the monitoring is in real time. In this case, too, the principles set by the Italian and European provisions would not be met. The situation would be different if the monitoring concerned, for instance, the length of the phone calls, or only the reaction of the customers after the counseling sessions.

3.3. Employability and a new organization of work

A further possible consequence of the combination of the Internet of Things with new technological developments is a relevant change in the organization of work in industry.

In one of the first Italian papers on this topic, Seghezzi pointed out two of the possible new developments: (a) a radical change of the assembly line, and (b) the opening of the "smart working era" in factories (Seghezzi 2015).

In his view, with the introduction of IoT the assembly line would no longer require the workers' contribution for mechanical operations, but only for the setting up of the process and for solving any problems with the machinery. This would be the consequence of two factors: (i) the products of factories in the 4.0 stage are increasingly personalized; mass production, already diminishing, will become only a distant memory, since the consumer will gain an increasingly central role starting from the very first phase of the conception and production of a product; and (ii) thanks to the interconnection of machines permitted by IoT, the assembly line would be able to communicate among its various components and, through the wide use of robots, manage the physical works more efficiently than the best application of Taylorism could allow.

As to the second point (ii), since the production will run virtually, nothing could prevent a worker from controlling it remotely, through her/his home computer or smartphone when she/he is in a different place. Thanks to webcams installed in the node points of the assembly and thousands of sensors, it will be thus possible to identify and solve problems remotely. Accordingly, in 2012 General Electric invested 1.5 billion Euros and installed 10,000 sensors in its plant in Schenectady. Because the sensors were connected to the corporate network, this enabled workers to monitor production through their iPads (Seghezzi 2015).

The possibilities outlined above are concrete and real in their main aspects. However, some important limits and specifications should be pointed out. Firstly, a radical change of the assembly line would be so complete only in western countries where the level of customization of products is higher than in other countries, like China, India or Thailand (where mass production is more a reality), and it would be so only with regards to certain kinds of products. It is difficult to conceive of customized clothing, or food packaging, when produced on a large scale.[21]

Moreover, the tendency toward lesser human intervention in production and the confinement of workers to a sort of "custodian" of machines, limiting their intervention to problems of connection or bugs, is probably extreme and not so likely in countries like Italy, where the manufacturing still is a very relevant part of economy and industry.

In a well-known research paper released in 2013, Frey and Osborne analyzed the extent to which jobs are susceptible to computerization, by implementing a methodology to estimate the probability of computerization for 702 detailed occupations, using a Gaussian process classifier. Based on these estimates, they examined expected impacts of future computerization on US labour market outcomes. They concluded that about 47 percent of total US employment is at risk. They also provided evidence that wages and educational attainment exhibit a strong negative relationship with an occupation's probability of computerization (Frey, Osborne 2013). Their research and its conclusions reflect the recent tendency to look suspiciously at the digitalization of industries and the Internet of Things, and at whether they are factors of great risk for human employment.

There is also a wide debate about the so-called "Crowd Employment", based on the crowdsourcing phenomenon (a term coined by Howe 2006). Crowd Employment occurs when an organization uses a digital platform to leverage the crowd as external resources to contribute to tasks that could alternatively be performed internally by employees and contractors. This can be an opportunity to both create and capture value with the sourcing of labour/expertise for low reimbursement, in a totally free-regulation work environment.

One example is that of InnoCentive: the "crowd" in this case consists of professionally trained graduate scientists who, in a given challenge, attempt to solve a tough problem. Only a few of them will submit a solution to the issue or experiment. Winning solutions are rewarded with prizes, but obtaining them in this way is still cheaper than what it would normally cost an organization to run an in-house lab (Braham 2013). So, it is a 'win-win' situation for scientists who reach the goal, and the company; but it is a high-risk investment for all the other scientists, whose work vanishes without having been paid or recognized.

[21] Custom clothes assembly is starting its development but still in small factories, URL: <http://motherboard.vice.com/read/automated-mini-factories-will-bring-back-custom-fit-clothes> [last accessed: 14/06/2015].

Another clear example of this is Amazon's "Mechanical Turk",[22] a system based on a complex structure, run through a platform owned and developed by Amazon. The platform allows third party requesters to broadcast tasks (Human intelligent tasks, HITS) and allows external workers (called "Turkers") to complete the tasks (Bergval-Karebon, Howcroft 2014). The company promotes this as a form of teleworking, but the reality is quite different. Workers are asked to sign a Participation Agreement as independent contractors, placing all judicial rights on the requesters. Amazon declines all responsibilities related to every transaction between the parties, especially as to payment and retribution, declining also any possible benefits that workers could ask for if they were Amazon's own employees. There is a lack of transparency, because workers know very little about the requester and the aim of the tasks they are completing, and the requester is entitled to reject a HIT without any justification and without payment ("rejection clause"). The most common requesters belong to the academic community (interested in research tasks such as economic and social science experiments), start-ups and entrepreneurial ventures (small firms need to contain costs) and large corporations, often in the consulting services, looking for a workforce to complete micro-tasks at a very low cost (Bergval-Karebon, Howcroft 2014).

This scenario can raise further considerations. A first issue, regarding skills definition, is that technological applications or machines will likely overcome many human skills, making the related jobs unnecessary (it is sufficient to think of the increasing role of robots in the assembly line). In comparison with even only ten years ago, however, new forms of employment and new skills have entered the market and developed. The digital area has entered our lives and our activities in a revolutionary way, and it requires more and more experts in the field in order who can provide guidance both as an external service and as an internal management tool.

The digital scenario is forcing many workers to charge their skills. On the one hand, some human skills could be devalued (data managing jobs, sales-workers, bank clerks) as a consequence of increasing on-line consumption (e-commerce, e-banking). The use of machines for physical activities that do not require a specific human evaluation (e.g. industry robots) will affect manufacturing employment. On the other hand, some other professional roles are emerging in a totally new environment: experts of the cloud, app developers,

[22] The name of the platform recalls an 18th century chess-playing automaton (Mturk) who defeated prominent members of society across Europe (it then emerged that the "machine" was a real person).

extra-specific programmers and so on. Furthermore, the skills required of a single worker are likely to evolve in the sense of including digital competences irrespective of the employee's specific role in the company.

A second point can be made about work organization: the digitization of work can easily lead to the exploitation of the workforce in a very destabilizing way. An agreement that entitles "employers/proponents", whose company's details and aims are not clear to the workers, to reject the work without any justification is contrary to the fundamental right of the dignity of work, and to the fairness and *bone fide* (good faith) that should characterize transactions. At the same time, however, the possibility for work to occur on digital platforms without the need for an expensive physical structure for a company is opening extraordinary opportunities for developing countries, which, in turn, are increasingly hiring European companies to develop innovative IT solutions and manage services online.

Furthermore, the possibility of working from somewhere other than the company site opens new scenarios for telecommuting and teleworking, insofar as it makes it possible to work from home some days per week or per month, helping families care for babies or elderly relatives, and disabled people with limiting mobility.

Especially in Italy, telecommuting and teleworking has suffered from a high degree of suspicion. Since there was little possibility to control the actual work of teleworkers, it has been viewed as a possible cause of dissatisfaction and reduced productivity. In many companies the concept of work is still deeply rooted in the idea of presence and control: work is identified with daily physical presence in the office, with the obligation to swipe a badge to record attendance and work under the direct control of a responsible person. The logic of teleworking moves the emphasis from presence in the workplace to the productivity, implying an activity performed with self-motivation, self-discipline and self-management. From this perspective, teleworking seems risky because it is impossible to verify the performance of work in real-time. Research conducted by the Tor Vergata University in Rome and Unindustria revealed the presence of three types of obstacles to increasing telecommuting:

1. companies complain about the lack of fiscal or government-based financial incentives that could encourage teleworking through training, research and development, innovation and both technological and organizational experimentation;
2. lack of clear and specific indications on the regulations and benefits for enterprises and employees: consequently the development of a cultural approach supporting the adoption of teleworking is prevented; and

3. the presence of technological barriers, which are not associated with low ICT development, but rather with the lack of awareness of the potential offered by new digital technologies.[23]

To deal with these barriers, practical solutions could be to enact regulations for offering fiscal incentives to those companies that offer digital training to their employees, and to allow their employees to spend part of the week teleworking in order to evaluate costs and benefits. Further, thanks to the new opportunities offered by digital innovation, even stricter controls on the work of teleworkers/telecommuters could be implemented. According to the principle of aiming at a legitimate purpose, such controls could serve as a way of monitoring the correct implementation of work activities by the employee (e.g. through ad hoc software). This monitoring could be linked to accepting more requests for telecommuting than we see now (in Italy the percentage of telecommuters is still low).

The benefits related to the spread of teleworking are numerous: improved quality of working life (stress reduction, ability to manage oneself), a better balance between work, family and leisure, reduced daily commutes with a positive effect on the environment, as well as a higher quality of work performance.[24] Some individual benefits also translate into social benefits: reducing traffic, overcoming the limitations and social costs related to transport, reducing the environmental impact of CO_2 emissions, reducing car accidents and stress due to the daily commuting. The social advantages can also relate to reduced societal healthcare costs or elderly and childcare costs.

The economic importance of telework stems from its cost savings and increased worker productivity.

4. Conclusions

This Chapter seeks an initial exploration of the new possibilities opened by the introduction of technological innovations in industries. After a brief survey of the kinds of technology that are becoming more and more a reality in companies and factories, I identified a central role for the Internet-of-Things (IoT) in the phenomenon of "Industry 4.0". This term, coined in Germany in 2011, is now commonly used to refer to a developmental stage in the orga-

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23 "Telelavoro tra Cultura e Tecnologia", Report available at URL: <http://www.asstel.it/wp-content/uploads/2011/05/StudioTelelavoro.pdf> [last accessed: 08/05/2015].

24 Among the studies about benefits coming from teleworking and telecommuting, see the Global Workplace Analytics, available at URL: <http://globalworkplaceanalytics.com/resources/costs-benefits> [last accessed: 6/06/2015].

nization and management of the chain of processes involved in industry; in short, the fourth industrial revolution.

The general debate that arose about this issue starts from the assumption that traditional industrial methods are in the throes of a digital transformation. After a period when industrial processes have increasingly embraced modern Information Technologies, the trend is now going beyond simple automation, blurring the boundaries between the real and the virtual world. This may lead to important changes also for the organization of work and the definition of employees' skills. Furthermore, risks for the protection of employees' rights in the day-to-day activity in the workplace have been raised.

For the organization of work, the general tendency among scholars and commentators is that of being quite worried about the possibility of technology to create unemployment by displacing workers., "The more efficiently we work (using machines or otherwise), the less work there would be for workers to do" (Miller, Atkinson 2013). Federico Pistono, author of "Robots will Steal Your Job but that's OK", wrote:

> The total number of jobs required by industry will be gradually reduced over time, and each time we will have to reinvent ourselves, finding new occupations for the newly displaced people by automation. This becomes very tiring after some time. It is a game you cannot win. (Pistono 2012)

The idea that there is a limited amount of work to be done is also called the "Lump of Labor" fallacy: this is indeed a false reading of the process of technological change because it doesn't include critical second order effects whereby the savings from increased productivity are recycled back into the economy to create the demand that in turn creates jobs (Miller, Atkinson 2013). A feature of the digital economy is that it allows even people in deprived areas to reach global markets, as more and more traditional goods have become increasingly mobile. Local artisans are now enabled, thanks to digital platforms, to sell their products by reaching customers all over the world, and entrepreneurs can take advantage of the opportunities provided by the digital economy, offering their products to the global market. At the same time, e-entrepreneurship typically requires less capital investment, while online platforms for crowd-funding make capital more accessible.[25] In other words, "digital technologies can also make self-employment an option for workers" (Frey, Osborne 2015), or give more possibilities to extend the market for others.

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[25] For an interesting analysis on Crowdfunding and start-ups, see Hoberman (2012).

Beyond considerations about the job market, the real organization of work inside companies could in fact change accordingly with assets created by technology like the Internet of Things, where all objects and tools can be interconnected and where a cloud technology system can be a common ground for all collected data.

Possible challenges posed to the protection of employees' rights by such developments should now have the attention of the law, in light of a balancing between the rights and interests of both employees and employers.

The two cases mentioned in section 3.1. show that among the biggest concerns are the protection of dignity and the right of privacy. These can be at stake because of the capability of new technologies to access and collect both personal data and data related to work activities, as never before.

In these cases, new regulations should start from the assumption that protection of rights in the workplace cannot just be enforced through the prohibition of technology able to trace physical or digital movements, or to the collection of data. Much better would be to analyze possible risks in light of the type of employees' activity and the technology that is used therein by employers and employees, then delineating through specific policies on how to regulate the work relationship and the day-to-day activity. Providing for different regulations specifically directed to the interested area could be an interesting solution, in parallel with the general provisions and guidelines that, often, law and case-law have already defined – e.g. Italian Data Protection Authority Guidelines, and EU REC(2015)5.

Many cases exploring this will probably be presented, since the development of technology is extremely rapid and innovation is becoming the main interest of those companies that want to make an investment in the future.

Law can have an important role in the fourth industrial revolution, in order to facilitate the development and renovation of the industry, at the same time protecting workers' rights with the most flexible and accurate regulations. In other words, we should aim for a legal framework with respect to technology in and around the workplace that both enables innovation and empowers and protects workers, thereby strengthening the very fabric of a modern society.

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Innovating Witness Testimony with Neuroscience-Based Lie Detection: A Hypothetical Normative Framework

Federica Coppola

1. Introduction. Criminal trial, innovation, and neuroscience

One of the most promising challenges of the scientific and technological innovation in-law involves criminal investigations and trials. In the last decades, the increasing standardization of forensic science techniques, like DNA testing, Bloodstain Patterns Analysis, and Digital Evidence Analysis, has led the gathering of evidence in criminal proceedings to outstanding results. The dramatic impact and pervasive role of science and technology in forensic settings has gone beyond the more traditional fields of investigation, and criminal jurisprudence is increasingly embracing the most advanced branches of behavioral sciences. Today, the leading role of scientific innovation in criminal proceedings is held by neuroscience.

By suggesting that the mind is just the *shadow* of the brain, neuroscience is gradually eroding the adequacy of orthodox legal standards and practices that are grounded in obsolete folk assumptions, and erroneous intuitions about human behavior. Notwithstanding the lack of a unanimous view (and acceptance) of how exactly the brain enables the mind, and thus how it undergirds human behavior, an increasing number of legal scholars and practitioners are adopting a positive attitude towards neuroscience, foreseeing profitable applications in the near future.

One of the most immediate implications deriving from the integration of neuroscience in the legal arena is precisely this use of neuroscientific techniques for forensic purposes. More specifically, neuroscientific techniques promise a number of advantages, especially for criminal investigations and trials, not the least of which is the elimination of human bias and misconceptions in the evaluation of human behavior. In particular, neuroscience holds significant promises with respect to the evaluation of witness testimony.

Witness testimony has always formed the preponderant type of evidence in criminal proceedings. Witness testimony is simply crucial to determine the facts in issues in criminal trials. Witnesses appear to be able to promptly and confidentially recall details like times and places of the crime occurred, as well as identify people involved. For these reasons, juries and judges largely rely upon witnesses' declarations to inform verdicts. However, the faith legal systems place in witnesses has been shaken by psychological and neuropsychological studies about the inability on the part of juries and judges to identify deception, and hence distinguish liars from truth-tellers.

The fallibility of witness testimony – due to both high probability of deception, as well as inability on the part of the third observer to recognize it – is in the middle of intense debates involving criminal law theorists and practitioners on the one side, and scientists on the other, who are trying to identify reliable methodologies to be used to detect witnesses' deception. From behavioral analysis, to the famous (and controversial) polygraph, the issue of deception identification has now been approached by neuroscience-based, or brain-based, lie detection.

Despite its great innovative potential, the use of neuroscientific techniques to detect deception poses serious challenges to criminal procedures, and doctrines. Apart from raising controversies about its probative value from both scientific and legal standpoints, the use of neuroscience-based lie detection in legal settings poses serious concerns about its compliance with witnesses' rights in court. In fact, unlike other types of scientific evidence – which are more focused on proving objective data – the peculiarity of brain-based lie detection lies in the exploration and analysis of witnesses' mind, thereby allegedly violating their inner privacy to freely recall and reports the facts in issue according to their memories and observations. As a consequence, lie-detection neurotechniques appear *prima facie* to undermine witnesses' cognitive and moral liberties, as well as the privilege against self-incrimination (as provided, for example, by the Fifth Amendment of the US Constitution, or by art. 198, par.2, of the Italian Code of Criminal Procedure). Last but not least, the evidence produced with brain-based lie detection can be easily misconceived. Several studies have shown that juries and judges tend to overestimate the accuracy of data emerging from neuroscientific evidence, and hence are likely to believe them far more accurate and reliable than they actually are.

These concerns are reasonably fair, and considerably complex. That is why legal scholars should start seriously investigating how criminal justice systems might, and should, accommodate this type of evidence in criminal proceedings, considering both procedural rules, and witnesses' substantive rights. That is also why this Chapter will attempt to provide a potential normative framework able to regulate the gathering and the use of brain-based lie detection in forensic contexts, in full compliance with procedural, and substantive constitutional rights. To this end, I shall assume that we have arrived at a time when both the scientific and evidentiary issues regarding brain-based lie detection are solved. Given such a starting point, even neuro-sceptics can agree that the law would need to identify basic guidelines to regulate the gathering and the use of these techniques on non-party witnesses in criminal proceedings.

The Chapter begins with a brief analysis of the legal intuitions and presumptions – as deduceable from rules and courtroom procedures – about the credibility, and reliability of non-party witnesses. It then contrasts the orthodox legal intuitions and presumptions underlying the evaluation of this type of evidence with the psychological literature that shows how jurors and judges' evaluations are largely intuitive and biased, and hence that triers of facts are generally not able to distinguish liars from truth-tellers. Next, it briefly canvasses neuroscience-based lie detection techniques. It then moves from scientific laboratories to courts, and illustrates the most emblematic criminal cases in which lie-detection techniques have been used. The Chapter continues with an argument for overcoming substantive legal obstacles in order to introduce brain-based lie detection as a steady tool to assist the trier of fact in evaluating witness testimony. It then concludes with an illustration of a potential normative framework which might plausibly regulate the use of these techniques in full compliance with witnesses' procedural and substantive rights.

2. The non-party witness: a false myth

Witness testimony is the most typical form of direct evidence in criminal proceedings. When one is requested to attend court to testify as a witness, he or she is required to make statements based on personal knowledge of the facts in issue. As generally provided by the large majority of legal systems, witnesses cannot refuse to appear in a trial. They are obliged to answer truthfully – often under oath –[1] to the questions the parties address to them during cross-examination. Importantly, the duty of truth falling on the witness is

[1] In the USA, for example, the Federal Rule of Evidence 603 provides that "Before testifying, a witness must give an oath or affirmation to testify truthfully. It must be in a form designed to impress that duty on the witness's conscience".

not concerned with the objective, and absolute truth of the facts in issue, but rather with the witness's subjective and personal representations of the facts he or she experienced and observed.

As can be deduced from these rules and courtroom procedures, Western legal cultures are largely inspired by a rationalist view of the ideal witness, pursuant to which a witness is a third and neutral observer, who is extraneous to the facts of the case in issue, and hence coolly and selflessly reports the facts he or she witnessed in the sole compliance with a moral and legal duty of truth (Clark, Mohktari 2013, p. xi). As the eminent Italian scholar Francesco Carrara famously put it:

> The trust in someone's statements relies upon experience, which shows that men perceive and tell the truth as a rule, and only exceptionally deceive themselves and lie. This rule is based upon two presumptions - 1st. The presumption that feelings and senses did not deceive the witness - 2nd. The presumption of veracity that characterizes every man, that makes one deduce that he is not willing to deceive. (Carrara 1867, p. 573, §. 947)[2]

In the ideal legal world, a witness is then considered as a rational machinery declaring truthful facts. Considering the *quasi* absolute presumption of veracity characterizing the ideal of the witness, witness testimony is thought of as the most reliable form of evidence, upon which juries and judges largely rely in their decisions, even when no further external evidence is produced. Rules of evidence or courtroom procedures make it indeed clear that it is important that the trier of fact should use wide-ranging and free evaluative schemes to assess the veracity of witnesses (*United States v. Scheffer* 1997, p. 313). In contrast to non-testimonial and scientific evidence, the evaluation of witness testimony falls entirely within the scope of the free discretion of the trier of fact, who evaluates the veracity and credibility of a witness *secundum conscientiam*.

The faith which criminal justice systems place in the reliability of witness testimony also rests on the excessive confidence with which juries and judges rely on their own perceptions, senses, and folk intuitions while evaluating the credibility of witnesses' statements (so called "*mundane* mind-reading": Danaher 2010). In doing so, juries and judges adopt a wide range of criteria

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[2] The quotation is my translation from the Italian: "La fede che si accorda all'asserto di alcuno ha per base l'esperienza; la quale mostra che l'uomo per regola percepisce e narra il vero, e solo eccezionalmente si inganna e mentisce. Cotesta regola si avvalora perciò di due presunzioni - 1°. la presunzione che i sensi non abbiano ingannato il testimone - 2°. la presunzione di veridicità che assiste ogni uomo, la quale porta a ritenere che egli non voglia ingannare".

which are largely based on behavioral cues (*State v. Mann* 2002, par. 32). More precisely, triers of fact tend to rely on "stereotypic cues" (Spellman, Tenney 2007, p. 139) to decide whether informants are telling the truth, or are lying. Among these, juries and judges consider "an array of primarily non-verbal indicators of veracity" (Schauer 2012, p. 4) – e.g. gestures, face expressions, confidence, and the like. A witness's demeanor (along with other criteria like witness reputation, past convictions, and so forth) forms the main indicator of his or her credibility, and hence reliability. As a consequence, it is assumed that triers of fact "by closely observing demeanor, can accurately determine whether a witness is lying" (Minzner 2008, p. 2557).

Nevertheless, the excessive trust legal systems generally attribute to witness testimony has been shaken by psychological and neuropsychological studies about juries, and judges' inability to identify deception, and hence distinguish liars from truth-tellers (Penrod, Cutler 1995; Bond, De Paulo 2008; Bond 2008). As Spallman and Tenney note, "people judge the credibility of informants on the basis of characteristics that have no relation to their actual trustworthiness" (Spellman, Tenney 2007, p. 138). Furthermore, juries and judges are – both consciously and unconsciously – driven by the so called 'truth bias', i.e. "the tendency to over-assume that people are telling the truth" (Spellman, Tenney 2007, p. 169). This bias is thought to largely determine the ultimate conclusion about a witness's truthfulness, and hence impair the ability to detect lies (Minzner 2008, pp. 2567-2571). Psychological studies on testimony emphasize the severe limitations that normally affect the triers of fact in the evaluation of truth. As Davis and Loftus put it, "the law assumes more than human cognition can provide, […] overestimating the ability of judges and juries to reliably recognize [witnesses'] inaccurate accounts when they occur" (Davis, Loftus 2013, p. 29).

The considerable gap between what the law assumes and the real-world status and evaluation of witness testimony emphasizes the urgent need to develop and adopt more scientific, objective, and reliable tools to assist the evaluation of witness testimony in criminal proceedings. Witness testimony *needs* to be innovated. It is exactly at this point that neuroscience-based lie detection enters criminal trials.

3. *À la recherche de la vérité perdue*: neuroscience-based lie detection

The term lie-detection traditionally refers to an *ensemble* of techniques and procedures, the aim of which is to identify deception, by "bypass[ing] potentially deceptive outwardly perceptual cues [and] us[ing] indirect physiological measures […] as indicators of true mental states" (Dahaner 2008, p. 8). Lie-detection can be thus defined as a form of mind-reading.

Lie-detection techniques are not new to criminal proceedings. Since the 1920s, and still today in some jurisdictions,[3] the recognized, yet highly controversial, technological device for deception detection in forensic contexts has been the polygraph. By and large, the polygraph measures physiological responses – induced by the sympathetic nervous system[4] – which are thought to be associated with lying, such as blood pressure, heart rate, breathing rate, electrodermal activity, and so on. The most commonly used types of polygraph test are the Control Question Technique (CQT: Iacono 2008), and the Guilty Knowledge Test (GKT: Lykken 1960). The assumption that underlies both tests – which are otherwise based on different methodologies[5] – is that people exhibit distinctive physiological reactions when providing truthful and deceptive responses to specific ('relevant') questions addressed to them. Although peripheral physiological arousal is still thought to be correlated with deception, the reliability of the polygraph test – especially for forensic purposes – has been greatly questioned. As some neuroscientists point out, individuals can be aroused for reasons that have little to do with deception, and not all individuals are aroused when they produce deceptive responses

[3] In the US, for example, the New Mexico state judicial system allows for the admissibility of the polygraph in criminal trials to prove "the truthfulness of any person called as a witness" (see New Mexico Rule of Evidence 11-707).

[4] The sympathetic nervous system is part of the autonomic nervous system, which also includes the parasympathetic nervous system. The autonomic nervous system is the part of the peripheral nervous system that regulates the body's unconscious actions. The sympathetic nervous system serves the function to induce the so called *fight-or-flight response*, i.e. a physiological reaction that occurs in response to perceived stressful stimuli.

[5] Roughly speaking, in the CQT, the subject is typically required to respond to 'relevant' and 'control' questions. Relevant questions are those pertaining to the particular crime or event being investigated, while control questions are designed to be emotionally similar to relevant questions but unrelated to the particular event, and concern facts that are necessarily true (i.e., the examiner knows that they really occurred). If the physiological response to control questions (which are necessarily true) is equal to the response to the relevant question, then the response to the relevant question must be true. The GKT, by contrast, is strictly aimed to verify the knowledge that only a person who was present at the crime scene may possess. Here the subject is required to respond to a series of control questions (banal, or emotionally irrelevant questions), and to only one relevant question (which is concerned with a detail of the crime that only the perpetrator may know). If the subject exhibits an increased emotional reaction in response to the relevant question, and a normal reaction to control questions, it is hence deduced that the subjects holds relevant knowledge of the crime. The GKT is thought to be more reliable than the CQT.

(Ganis, Keenan 2009). Moreover, individuals can adopt both mental and physical countermeasures when under polygraph testing. Countermeasures are thought to significantly reduce the accuracy of the results (Honts, Kircher 1994; Iacono 2000).

The epistemological problems linked with the polygraph test have led deception researchers to begin to study the brain directly, as "the organ that produces the lies" (Ganis, Keenan 2009, p.466). This research hopes to find more reliable correlates of deception than "the physiological responses associated with anxiety" (Greely 2007, p. 48). Since the beginning of the 1980s, neuroscientific research has made significant discoveries about deception identification in the brain. For a long time, research on brain-based lie detection has been predominantly conducted using electroencephalography (EEG) – to look for the so called P300 wave (Pincton 1992; Gray 2004) in the brain's electrical activity. This work attempts to identify autobiographical memories in response to specific stimuli, and hence to implicitly detect deception (Greely 2013, p. 127). EEG-based lie detection has been promoted under the label "brain fingerprinting" (I will discuss this more in detail in the next sub-section).

More recently, neuroscientists have begun investigating deception by using Functional Magnetic Resonance (fMRI), in the attempt to determine more directly the neural correlates of deception (Ganis, Keenan 2009; Farah *et al.* 2014). The basic assumption underlying fMRI-based lie detection is that specific brain regions get particularly activated when a subject is lying, as opposed to when telling the truth. Although the results of neuroscientific studies in this area are still preliminary and heterogeneous, converging empirical evidence suggests that certain areas of the brain are indeed consistently involved in deception (among others, see Ganis *et al.* 2003; Kozel *et al.* 2005; Phan *et al.* 2005).

Another promising method that has been proposed to detect deception is the Autobiographic Implicit Association Test (aIAT) (Sartori *et al.* 2008). The aIAT is a novel application of the Implicit Association Test (IAT) (Greenwald *et al.* 1998), and consists in a computerized categorization task which is meant to evaluate which one of two contrasting autobiographical events is true for a relevant individual. The aIAT measures reaction times of responses to possible autobiographical events – i.e. "events that an individual experienced directly" (Sartori 2008, p. 772). The assumption underlying this application is that "the true autobiographic event [...] gives rise to faster RT's [reaction times] when it shares the same motor response with true sentences" (Agosta, Sartori 2013, p. 2). The test is considered to exhibit more than 90%

diagnostic accuracy in detecting true memories (Agosta *et al.* 2011; Agosta, Sartori 2013), and is thought to form a reliable tool for detecting lies, even in forensic contexts (Sartori 2008 p. 772).

As it can be derived from this brief overview, neuroscience is able to provide valuable tools for detecting deception. Although important scientific and evidentiary issues are yet to be solved, it is plausible to foresee a day in which these techniques will be sufficiently accurate and reliable to form an integral part of judicial practice. Although, as the following discussion will show, current applications are still scientifically equivocal, it is not too early to begin to consider the legal rules that will need to accompany the deployment of these techniques as they improve and spread.

3.1. Neuroscience-based lie detection in criminal cases

The forensic use of neuroscience-based lie detection dates back to the beginning of the 2000s in the USA. In *Harrington v. Iowa* (2003), the Iowa Supreme Court overturned Mark Harrintgton 1978 murder conviction, and entitled him to a new trial on the grounds of the evidence produced with the Brain Fingerprinting Test, created and administered by Dr. Lawrence Farwell, president of the Brain Fingerprinting Test Laboratories.[6] The Brain Fingerprinting approach is an EEG-based system that allegedly captures and records memory traces of a person's experiences, and hence determines whether one or more information elements are stored in a person's brain. Technically speaking, the test measures an individual's brain wave (so called MERMER wave) responses to relevant images presented by a computer. In the case at issue, the test showed that the record stored in Harrington's brain did not match the crime scene, yet did match his alibi. Moreover, the only alleged witness to the crime – upon the testimony of whom Harrington's conviction had been based – retracted when confronted with the results of the Brain Fingerprinting. In the end, the Iowa Supreme Court released Harrington on constitutional grounds (due process violation). This case, and in particular Dr Farwell's procedure, has given rise to huge debates and controversies in both the legal and scientific communities (Greely 2013, p. 128).

Despite harsh critiques against the Harrington case, lie-detection techniques have been admitted in criminal courtrooms in some additional criminal cases. Among these, it is worth mentioning the Aditi Sharmacase, that

6 [Online], URL: http://www.brainwavescience.com/ [last accessed 25/04/2015].

took place in Pune, India, in 2008. During pre-trial police interrogation, the defendant (who was suspected of poisoning her former fiancé, Udit Bharati) underwent Dr Champadi Raman Mukundan's Brain Electrical Oscillations Signature test (BEOS, a variant of Dr Farwell's Brain Fingerprinting), while police officers loudly read her their version of the murder. Despite the fact that the defendant made no verbal responses during the test, the test indicated that "the relevant nooks of the brain where memories are thought to be stored buzzed when the crime was recounted" (Girindharadas 2008). In light of BEOS results, the trial judge concluded that it was proved that Mrs. Sharma had "experiential knowledge" of the crime, and hence had committed the murder. As a result, Mrs Sharma was sentenced to life imprisonment. This case has been heavily criticized for having greatly violated the defendant's right to silence (Pulice, 2008), and because the judge's decision was made "without reference to any specific evidence of the test's scientific validity" (Moreno 2009, p. 724).

Unlike EEG-based applications, fMRI-based lie detection has yet to enter criminal courts. Nonetheless, there have been cases in which US courts addressed its use to evaluate both party and non-party witnesses' testimony. In 2010, fMRI evidence was sought to be introduced to prove the veracity of a non-party witness's testimony (*Wilson v. Corestaff Services*, *L.P.*). The case concerned the breach of state laws banning retaliation by an employer against an employee. The plaintiff, Mrs Wilson, sought to produce the results of fMRI tests conducted on her central witness, Ronald Armstrong, in order to prove the truthfulness of his testimony. However, the New York court excluded this kind of evidence, for it failed the 'general acceptance in the relevant scientific field' requirement of the *Frye* test (*Frye v. United States*, 1923).

In *United States v. Semrau* (2012), the Court of Appeals for the Sixth Circuit had to decide whether the defense should have been allowed to produce fMRI-based evidence of lie detection – based on a technique developed by the US Cephos Lie-Detection Company – about the truthfulness of the defendant's statements. More specifically, the defendant, Dr Lorne Semrau, was accused of defrauding Medicare, Medicaid, and other health programs by submitting false and fraudulent claims for payment. To counter this, the defense sought to introduce expert testimony from Dr. Steven Laken, president and CEO of Cephos Corporation, "who would have testified that fMRI testing indicated that Dr. Semrau as generally truthful when he said he attempted to follow proper billing practices in good faith" (*United States v. Semrau* 2012, p. 6). By affirming the trial court's decision, the Court of Appeals rejected the admissibility of fMRI evidence, reasoning that it lacked sufficient scientific reliability – and hence it did not satisfy the criteria set in the Federal Rule of Evidence 702.[7] The Court of Appeals also concluded that the evidence was more prejudicial than it was probative – and hence inadmissible under the Federal Rule of Evidence 403.[8]

As this brief case law analysis shows, the current limitations on the use of lie-detection techniques are mainly linked to the fact that they do not meet the admissibility criteria of scientific evidence, a requirement that evidentiary rules generally provide for. Although neuroscience-based lie detection does currently exhibit both scientific and evidentiary problems, this does not mean that these problems will be never solved. In other words, considering the dynamism with which these techniques are improving and advancing, it is reasonable to assume that criminal courts will soon confront attempts to introduce *reliable* cognitive neuroscience evidence to assist party or non-party witnesses' testimony. Nonetheless, even when reliability is no longer a question, issues related to the gathering and the use of neuroscientific evidence in full compliance with witnesses' rights will still remain.

4. Neuroscience-based lie detection and non-party witnesses' rights

The entrance of competent neuroscience-based lie detection in courtrooms will pose serious challenges to criminal procedures, and doctrines. Apart from the evidentiary issues, treated briefly above, the legal concerns about the use of lie-detection neurotechniques range from the potential violation of witnesses' rights – both procedural, and substantive constitutional – to the fact that they are likely to misguide and mislead juries and judges while evaluating witnesses' credibility (see McCabe *et al.* 2011; Schauer 2012). According to the prevailing opinion among legal scholars, these issues will be difficult to overcome, regardless of the potential scientific validity of these techniques (see Schauer 2010; Woodruff 2014).

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7 Rule of Evidence 702. Testimony by Expert Witness - A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

8 Rule of Evidence 403. Excluding Relevant Evidence for Prejudice, Confusion, Waste of Time, or Other Reasons: "The court may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence".

As for witnesses' rights, the Italian Code of Criminal Procedure, for example, poses strict limitations, at various degrees and levels, to the use of potentially invasive scientific and technological applications in order to avoid over-intrusiveness into the witness's mind. Following this rationale, the Code strongly forbids the utilization of any kind of device able to influence an individual's capacity for self-determination, as well as that to recall, evaluate, and report memories.[9-10] More specifically, the Italian system rejects the use of lie-detection techniques like hypnosis, narcoanalysis, and the polygraph test (Tonini 2012, pp. 265, 268-269; Conso, Grevi 2008, pp. 308-310). This prohibition would likely apply to neuroscience-based techniques, given their alleged violation of the rights protected by procedural rules. Therefore, according to the majority of scholars, lie-detection techniques, neuroscience-based devices included, could never be used in courtrooms, not even when they will have reached a sufficient degree of reliability (Bottalico 2014). The strong *a priori* opposition by Italian legal scholars against brain-based lie detection techniques is yet founded on a mistaken understanding of how neuroscientific techniques actually work, and what they are meant to show. In fact, while lie-detectors like the polygraph or hypnosis, pose the concrete risk to actually alter the capacity to recall, evaluate, and report facts, EEG or fMRI scans are simply limited to objectively recording the neural substrate that accompany witnesses' statements (Intrieri 2009, p. 210). Moreover, unlike neuroscientific techniques, during hypnosis or narcoanalysis, or even during the polygraph test, the subject does not have a full mastery of his own statements. In the case of hypnosis, he is not conscious while undergoing the test. In the case of the polygraph he finds himself in a very stressful situation which induces him to automatically experience bodily reactions (perspiration, increased heart rate, etc.), and hence is very likely to alter his capacity to recall and evaluate memories. Considering a person's lack of control over her memory, as well as her physical reaction to stimuli, it is then reasonable to argue that a person is effectively bypassed by the lie-detector, and hence there is an actual violation of moral and cognitive liberties provided by legal norms.

[9] Art. 188 of the Italian Code of Criminal Procedure provides that "methods or techniques which may influence the freedom of self-determination or alter the capacity to recall and evaluate facts shall not be used, not even with the consent of the person concerned" (Gialuz *et al.* 2014).

[10] Art. 189 of the Italian Code of Criminal Procedure provides that "If evidence not regulated by law is requested, the judge may introduce it if it is deemed suitable to determine the facts and does not compromise the moral freedom of the person. After hearing the parties on the methods for gathering evidence, the judge shall order the admission of evidence" (Gialuz *et al.* 2014).

The use of neuroscientific techniques on witnesses is also thought to pose serious challenges to the privilege against self-incrimination, codified in the large majority of legal systems. Generally speaking, the privilege against self-incrimination prevents a witness from being compelled to testify on facts which may reveal his or her own criminal liability.[11] In the USA, for example, the privilege against self-incrimination forms a substantive constitutional right protected by the 5th Amendment.[12] US courts tend to interpret the privilege contained in the 5th Amendment to mean that witnesses may refuse to answer certain questions on the grounds that they may be implicated in criminal activity (not limited to the case being tried). More specifically, non-party or ordinary witnesses may invoke the privilege against compelled self-incrimination when i) the answer sought by a question is an admission to a crime or would in itself support a criminal conviction (*Hoffman v. United States*1951); ii) if the testimony might tend to incriminate the witness (*Collins v. United States*1991), or iii) when the answers could lead to evidence used in a criminal prosecution (*Butler v. United States*1996). *A contrario*, a witness may be compelled to testify on 'unprivileged matters', i.e. when the information concerns a third party, when the information could lead to a noncriminal sanction, or when the witness has been granted immunity. These limitations mean that "the 5th Amendment privilege does not provide a general constitutional right to mental privacy, cognitive liberty, or mental control" (Pardo, Patterson 2013, p. 163). As a consequence, "the government can, consistent with the 5th Amendment, compel evidence from a [subject]'s mind or brain whenever that evidence is not self-incriminating" (Pardo, Patterson 2013, p. 163). Moreover, unlike defendants, a non-party witness' privilege does not include a refusal to take the stand at all, nor a right to remain silent with respect to unprivileged matters.

Importantly, the privilege protects only *testimonial* evidence, and does not bar compelled self-incrimination by the provision of physical, non-testimonial evidence, such as blood or handwriting samples, fingerprints, photographs, sobriety testing, or speaking for identification (*Schmerber v. California*1966). In this respect, the issue of whether neuroscientific evidence is to be considered as testimonial or non-testimonial evidence has begun to be discussed by legal scholars. According to the minority opinion, neuroscience-based

[11] Art. 198, paragraph 2, of the Italian Code of Criminal Procedure states: "The witness shall not be obliged to testify on facts which may unravel his own criminal liability" (Gialuz *et al.* 2014).

[12] The 5th Amendment of the US Constitution reads: "No person […] shall be compelled in any criminal case to be a witness against themselves" (My adaptation).

lie detection belongs by nature to the category of non-testimonial evidence, and hence does not fall within the scope of the privilege provided by the 5th Amendment. Roughly, for this branch of thought, "an fMRI scan is nothing more than a computer record of radio waves emitted by molecules in the brain. It does not seem like testimony" (Greely, Wagner 2011, pp. 808-809; Faranhy 2012). Another view – which I subscribe myself to – is instead inclined to consider data emerging from neuroscientific evidence as testimonial, or communicative evidence. Pursuant to this account, neuroscience-based lie detection "involves asking the subject questions to which he or she gives answers, either orally, or pressing buttons [...]. In all, it still remains a communication, and as such it must be regarded as 'testimony'" (Greely, Wagner 2011, p. 809). It follows from this argument that witness testimony supported by brain-based lie-detection falls within the scope of the 5th Amendment.

The fact the neuroscience-based witness testimony can be more plausibly considered as testimonial evidence does not yet mean that the limits posed by the 5th Amendment – or any other similar provision regulating the privilege against self-incrimination – are absolute and insurmountable. As already pointed out, the privilege against self-incrimination is simply aimed at preventing a witness from being compelled to provide information that might possibly reveal his involvement in a criminal activity. Apart from that, a witness is *as a rule* required to testify about objective circumstances of the relevant crime, as well as about the potential responsibility of third persons. None of these subject matters fall within the scope of the privilege against self-incrimination. As a consequence, there are no plausible legal reasons for excluding the possibility that brain-based non-party witness testimony "might *actually* be compelled" (Greely 2013, p. 143). Moreover, a witness is *obliged* to tell the truth under oath or be subject to penalty (in case of perjury, for example). Yet as reality demonstrates, these deterrents are often insufficient to assure witnesses' compliance with their duty to answer truthfully: as already emphasized, judges and juries are not able to recognize when the statements that are made are true or false. Why then perpetuating fictitious and inefficient procedures, if there is the concrete chance to use valuable and more reliable tools for detecting the veracity of witnesses' declarations?

Put this way, brain-based lie detection techniques do not need to be depicted as tools for witnesses' rights violation *tout court*, but rather as useful and concrete instruments that would allow for a better evaluation of the veracity of witnesses' statements in a balance of individual rights and the public interests of truth, judicial certainty, and justice. Considering the great advantages and innovative contributions that these techniques might offer to criminal proceedings, I believe the time has come for criminal scholars to start identifying specific criteria to regulate the gathering and the use of this kind of evidence in criminal proceedings in full compliance with witnesses' rights. In the next section, I will attempt to provide a set of criteria to regulate neuroscience-based lie detection techniques in assisting the examination of non-party witnesses, should the neuroscientific techniques become legally reliable probatory tools in the future.

5. Hypothetical criteria to regulate the gathering and use of neuroscience-based lie detection on non-party witnesses

Assuming a future where the evidentiary issues about the admissibility of neuroscience-based lie detection are solved, and an appropriate brain-based lie detection process is developed, guidelines and criteria need to be set in order to regulate the gathering of this type of evidence in compliance with witnesses' rights in criminal proceedings. In this section, I seek to set sampling potential criteria of admissibility of brain-based lie-detection techniques. In doing so, I will consider witnesses' rights and duties (discussed above) which are generally provided in the large majority of legal systems, i.e.: i) third party witnesses are obliged to appear at the trial, and ii) to answer truthfully to the questions addressed to them, yet iii) witnesses have the right to refuse, and hence to not be compelled to testify on facts which may unravel their own criminal liability (privilege against self-incrimination).

In light of this, a potential normative framework regulating the gathering and the use of brain-based lie detection – without altering the essential core of witness testimony –can be formulated as follows:

> Upon one or both parties' request, neuroscience-based lie detection shall be permitted to assist witness testimony only in the presence of the witness' *informed, expressed, and intelligible consent*. The requirement for consent is inalienable as a rule.
>
> Neuroscience-based lie detection may be compelled, in the discretion of the court, only when *no other evidence is available; when two or more witnesses contradict each other and the facts remain unclear; when the content of a witness's testimony is crucial for the court to arrive at a decision*.
>
> Brain-based lie detection may assist witness testimony *only with respect to the objective circumstances of the deed, or information about third persons*. Under no circumstances can brain-based lie detection be used to assist information the witness reasonably believes could be used in a criminal prosecution, or could lead to the discovery of other evidence that might be used in a prosecution.
>
> *An Expert Witness shall be necessarily appointed by the court to administer and assist the gathering and the evaluation of neuroscience-based lie detection*. The Court-

> appointed Expert Witness shall write a report about the answers provided by the witness under lie-detection. The court ultimately evaluates the witness's credibility, by comparing the results of the lie-detection test with other evidence possibly produced.

Let us consider each requirement in detail.

Valid consent needed

The first and inescapable criterion for the admissibility of neuroscience-based lie detection in courtrooms is valid consent on the part of the witness. The reason at the basis of this requirement is fairly simple: lie-detection being generally considered as an instrument of evaluation of the individual's inner mental privacy, it would simply be unacceptable (both morally and legally) in almost all cases to administer lie-detection tests without the individual's consent. To be valid, the consent must be *informed* (i.e., the witness must be informed about the test procedure, what lie-detection exactly consists in, how the data emerging from the test might be used by the Court, and so on), *expressed* (e.g., the consent must be expressed in writing), and *intelligible*. By giving his full and conscious consent, the witness exercises his moral freedom to choose to undergo lie-detection test, thereby spontaneously limiting his mental privacy and cognitive liberty, in order to fully comply with his duties of truth, and cooperation with justice.

Compulsory brain-based lie detection only under exceptional circumstances

Although consent forms the main and most fundamental requirement for the admissibility of brain-based lie detection, yet one needs to consider the risk that witnesses give their consent to undergo the test only when they are confident about the veracity of their testimony. To the contrary, witnesses who have a greater interest in the outcome of the proceeding in favor to the defendant, or to the victim, may always deny their consent to undergo lie-detection.

To prevent this (highly likely) risk, it might be reasonable that lie-detection be compelled in those exceptional cases in which no other evidence has been produced (for example, when non-testimonial evidence corroborating a witness' statements is lacking), when two or more witnesses contradict each other and the facts remain unclear, or when a specific witness's testimony is crucial to let the court arrive at a decision. Only in presence of these kinds of exceptional circumstances, may the court compel a witness to undergo lie-detection, without the need of his or her voluntary consent.

To make this point more tangible, let us consider a very simple and emblematic example. Let us suppose a criminal proceeding for *Mafia* murder. As often happens in these kinds of cases, witnesses tend to answer untruthfully to questions on the facts in issue both for fear of telling what they actually witnessed (for example, witnesses can be afraid of being victims of revenge), or – as more often happens – for reasons of conspiracy of silence. As a result, these kinds of murder trials frequently end in acquittals due to insufficiency of evidence, which is enough to create reasonable doubts about a defendant's guilt. Let us now imagine that the court, considering the lack of other objective evidence, can compel witnesses to undergo neuroscience-based lie detection. Here the court would have empirical and objective evidence about the value of the witnesses' statements, and hence witness testimony would take on a much more significant probative value, guiding the decision with reduced margins of uncertainty.

Also, compulsory brain-based lie detection on ordinary witnesses might produce the effect of preventing the crime of perjury. More specifically, the imposition of lie-detection could lead witnesses to desist from making false statements, and therefore encourage greater compliance with their duty to cooperate with justice, and tell the truth. In all, the availability of lie-detection in criminal proceedings might also reverberate positively on the goal of prevention, as generally pursued by criminal justice systems.

Selection of questions to be addressed to witnesses under lie-detection

As previously discussed, witnesses cannot be obliged to answer questions revealing their possible involvement in criminal activities. As a consequence, the main obstacle to the use of neuroscience-based lie detection is precisely the risk of violation of the privilege against self-incrimination. To prevent this risk, it is then necessary to put strict limitations to the kind of questions that can be asked to a witness under lie-detection. Therefore, I suggest that lie-detection can assist witness testimony only with respect to those kind of questions related to objective circumstances of the crime (e.g., the time of the crime, what the witness saw or heard, who was on the crime scene, and the like), as well as those regarding third persons. By contrast, questions related to any kind of potential implication of a witness in a criminal activity must be *a priori* excluded. The limitation about the kind of questions that can be assisted by lie-detection must be unwaivable, regardless of the fact that the witness spontaneously decides to undergo lie-detection, or that he or she is compelled to do so by the court.

In order to guarantee the efficiency of this criterion, it would be appropriate that the judge decides on the admissibility of the questions to be addressed to the witness posed by the two parties. Once the questions are approved and selected, the judge submits them to the Expert Witness who administers the lie-detection test.

Necessity of a court-appointed Expert Witness to administer brain-based lie detection tests, and assist the court in evaluating the veracity of witnesses' statements

The admissibility of neuroscience-based lie detection in criminal proceedings implies – in compliance with rules of evidence provided in all legal systems – that an Expert Witness administers the test, and assists the gathering of neuroscience-based witness testimony. More specifically, once the test is administered, the Expert Witness shall write a report in which he expresses his opinion about the veracity of the relevant witness's statements while responding to questions, and illustrates the results to the court.

Admittedly, the admissibility of Expert Witness testimony to evaluate the veracity of witnesses' statements poses the inevitable risk that this could usurp the role of the trier of fact as the sole judge of the credibility of witnesses. This concern is easy to overcome. Despite insistence that the court remains the sole *bouche de la véritè*, I believe that there are no plausible reasons to exclude the admissibility of Expert testimony to *assist* the trier of fact in evaluating testimonial evidence. Indeed, the admissibility of brain-based lie detection to assist witness testimony makes this type of evidence an *hybrid* between testimonial (direct) and scientific (circumstantial) evidence. As such, the role of the appointed Expert will be limited to expressing a technical opinion about the data that has emerged from the neuroscientific investigation, while it is up to the judge or the jury to ultimately evaluate the credibility, and hence the reliability of witnesses' statements. In other words, once a witness's statements are evaluated as truthful or not *secundum scientia*, the trier of fact remains the sole "gatekeeper" of the Expert testimony, and hence ultimately decides on the results of the witness testimony *secundum conscientia*.

Moreover, it is undeniable that neuroscientific Expert Witness testimony would provide the trier of fact with empirical evidence about the veracity of witnesses' statements, thereby avoiding arbitrary, intuitive, and often erroneous evaluations of witnesses' credibility and reliability. In this regard, Fradella, for example, calls for the crucial need of admissibility of psychological Expert testimony about the unreliability of eyewitnesses identification

(Fradella 2006). According to Fradella, because courts misunderstand, or disregard the relevant biopsychosocial factors that affect the reliability of witness testimony, thereby contributing to wrongful convictions, Expert testimony would be "extremely helpful in combating the false image of accuracy that confident witnesses often possess" (Fradella 2006, p. 23). If these considerations are sharable with respect to the admissibility of psychological Expert testimony, *a fortiori* they are justifiable as regards neuroscientific expertise.

Importantly, in order to guarantee the impartiality of the evidence produced with these techniques, only courts may appoint Expert witnesses; the parties should not. The reason underlying this limitation is that party-appointed expert witnesses may tend to interpret a witness's statements in a way that it is more advantageous to the party (be it the defendant or the victim) that requires the examination of that specific witness. In cases like this, the probative value of the evidence produced might well be misleading for the trier of fact.

6. Conclusions. The innovation of neuroscientific evaluation of witness testimony is plausible and necessary

Brain-based lie detection holds the potential to transform aspects of criminal justice systems, in particular criminal trials. Although these techniques are not ready to be used for the time being, I am confident about their use in the future. Considering the high innovative potential of these techniques, I believe that the legal world should start seriously investigating potential and plausible criteria under which this kind of probative tool might be fruitfully employed in criminal courts. This investigation requires intense interdisciplinary work, involving legal scholars and practitioners, and scientists, who need to find appropriate ways to regulate the gathering and the use of neuroscientific evidence in criminal proceedings, in the attempt to balance individual rights and public interests of justice. Of course, much work is still ahead of us, and many other issues must be explored and solved. Neuroscientific research on deception is advancing at an impressive pace, and this will soon impose a reconsideration of the traditional legal standards, and courtroom procedures. The legal world cannot disregard this concrete possibility and needs to start setting new substantive criteria to admit and use brain-based lie detection in court.

Of course, such an innovation requires a revision of the traditional legal culture: it must be based upon a significant openness to science. A profound rethinking of the orthodox legal mentality is the key to a successful entrance of new and newer scientific technologies in criminal courts. It is crucial that the dialogue between (neuro) science and law intensifies. After all, innovation often means taking two things that already exist, and putting them together in a new different way.

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Is Law Struggling to Keep up with Innovation in Biotechnology?*

Carlo Maria Colombo

1. Law and biotech medicine: a long story of an evolving and mutual affecting relationship

Within the current fast-growing and technology-driven society, two related phenomena, both connected with the biotech industry, exercise an important influence on law as a driver of scientific progress.

On the one side, modern biotechnology is confronting with principles typically belonging to any advanced legal order, such as human dignity, *ordre public* and morality. Many recent advancements in a number of areas within this scientific field pose challenging questions, as they touch upon highly sensitive questions. The large use of intellectual property (IP) instruments to protect biotech inventions has served to test the limits of the moral aspects underpinning the rules pertaining to this field.

On the other side, numerous legal tools are tactically deployed to gain competitive advantage, or at least to protect the outcome of scientific research. One area where this endeavor is particularly clear is patent law. A commonly offered justification for patent systems is that they serve to facilitate scientific progress, by allowing the patent holder to recoup the investment made in effecting its innovation. But there are other significant public health and commercial consequences when any one company gets to fend off someone to make use of its important knowledge production.

It is apparent enough that these two instances of interaction between intellectual property, ethical principles and scientific research have a significant influence on the evolution of law. Though reaching a satisfactory tradeoff im-

* Earlier versions of this Chapter were presented at the "Third meeting of the World Congress for Freedom of Scientific Research", during the "EU Preparatory meeting" session (Brussels, European Parliament, November 2013) and the second session titled "Bridging the Gap between Science and Politics" (Rome, April 2014).

plies sensitive and challenging questions, these issues ought to be adequately addressed so as to create effective regulation and legal standards for the biotechnology industry. Lawmakers and judges have already acted to strike a delicate balance between the mentioned necessities. Yet, this represents only the first step of a long story. Both the progress of biotech medicine and new societal needs will arguably require more innovation in our legal systems for the coming years.

In order to bring some pieces of this puzzling relationship into a constructive debate on legal innovation, this Chapter attempts first to make reference to the some of the most debated legal issues raised by the recent progress in biotech medicine (sec. 2). Then, it makes some reflections on the responses already visible in the law (sec. 3). Finally, it addresses hypotheses on how law shall direct its power in the future (sec. 4).

2. The need to balance biotech medicine, scientific research and moral rules

One of the undoubted features of the world's current evolution in science is the impressive advancement in biotechnology, the research area comprising "any technique that uses living organisms or substances from those organisms to make or modify a product to improve plants or animals or to develop microorganisms for specific uses".[1] Within this broad evolving field of science, the domain that is arguably having the deepest impact on our lives in terms of health care advances is biotech medicine. By manipulating and working with human materials or their components, it promises to develop – and sometimes it has already created – useful commercial products, such as novel pharmaceuticals, that will deliver safer and more effective treatments. It does not come as a surprise, therefore, that biotechnology is becoming increasingly important in the global pharma industry, accounting for about 20 percent of the global market and making up an annual growth rate that is almost double that of conventional medicine (Otto *et al.* 2014).

Yet, more than the technological and medical growth itself, there are other associated phenomena that are capable of influencing the role of law as both driver and limit to scientific progress. These phenomena deserve, therefore, plenty of attention by legal doctrine: (2.1) the wide use of propriety rights on

[1] US Congress, Office of Technology assessment, Biotechnology in a global economy (Washington, DC: U.S. Government Printing Office, 1991, at p. 268).

living materials and genetic data that interferes with basic societal values, and (2.2) the numerous legal restrictions created by private companies to stifle competition in the biotech sector.

2.1. Law as limit to biotech patents: How medical advances may clash with basic constitutional values

Thanks to the advancements made by modern biotech research, the scientific understanding of how living things are put together and how they develop based on instructions coded in their DNA is advancing rapidly. Stem cells and xenotransplantation offer the prospect of replacement tissues and organs to treat degenerative diseases and dangerous injuries.[2] Likewise, genetics, assisted reproductive mechanisms, cloning and the creation of synthetic life forms are not a chimera anymore for scientists. What is more, biotechnology not only represents the solution for most hereditary genetic diseases, but it is also behind the millennial paradigm shift in disease management towards both personalized and preventive medicine based on genetic predisposition, targeted screening, diagnosis, and innovative drug treatments.

These rapid developments in biotech medicine show some common features (Bonadio 2009, pp. 1-27). Among them, their nature is basically different from almost any other kind of inventions, because it is associated with living matter. When biotech medicine relates to the treatment of human diseases, it specifically makes use of body parts, human biological materials or the information they contain. In other words, as part of the life sciences, biomedical science is concerned with developing therapeutic technologies that affect, make use of, or simply try to understand human life.

Of course, because of their potentially disruptive nature, some consequent aspects of such scientific advances raise sensitive and challenging policy issues at the normative foundations of our society. They inevitably confront questions of morality. Since biotech advancements touch upon the basic principles of an ethically just society (Parasidis 2011, p. 523), each of the mentioned new paradigms of modern biotech raises moral concerns *per se*. For instance, ought a synthetic living organism ever be deemed a human and claim the same legal

[2] Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions. Life sciences and biotechnology - A Strategy for Europe, Brussels, 23 January 2002 COM(2002) 27 final, at 5-6. An action plan based on this report has also already been published, Communication from the Commission. Investing in research: an action plan for Europe, Brussels, 30 April 2003 COM(2003) 226 final.

protection (Parasidis 2011, p. 524)? Or what should be understood by the term 'human embryos' for the purpose of judging whether their commercial exploitation is legally justifiable (Laurie, Harmon 2013; Bonadio 2012; Spranger 2012)?

But probably the most interesting and complex questions arise when these inventions are protected by proprietary rights, so that the holders may legitimately exclude or limit others from making use of the teachings contained within the invention's legal claims. Inside the realm of intellectual property rights, the patenting of biotechnological inventions is particularly illustrative of this tension. The scope of the patent system has expanded to protect matters whose protection is questionable (Lucchi 2013, pp. 254-255). For example, whether or not genes can be patented is a hotly debated topic since the inception of biotech industry.

The problem of the patentability of living matter is associated with the very function of the patent system, which is to stimulate and reward innovation useful to our society (Bonadio 2012). Because of the connection created between the patented inventions and the property rights granted to the patent holder, a patent claim covering living material risks creating a monopolistic profit in the hands of restricted elites, which will have the possibility of making a commercial use of discoveries associated with the human body and the human life (Drahos 1999, pp. 441-447). The so-called 'commodification' of genes (Lucchi 2013) is an important consequence of this process, which inevitably has a moral component in light of the numerous ethical principles connected with the industrial application of the invention. To address this foundational question, law must seek an effective balance between the many opposing values associated with patents on biotech inventions.

2.2. The proliferation of patents and the side effects on biotech research and health care

Within the extensive debate over the impact of biotech inventions on the protection of individual and collective rights (Lucchi 2013, pp. 254-260), the broad use of legal instruments to stifle competition is another thorny issue raised by the recent advances in this scientific area. Because of the unique features of biotech inventions, their protection under the law may affect the production, access and dissemination of knowledge (Lucchi 2013, pp. 255-256). This consequence raises remarkably delicate questions, in light of the numerous economic, collective and scientific consequences biotechnology is expected to cause.

Patent claims on genetic material are again an instructive example of this unsettled relationship. The conventional view of what the State should do to foster innovation is simple: it just needs to get out of the way (Mazzucato 2015, p.61), or at most to set effective legal standards and enforce them in practice. For this purpose, most countries have set up a system of legal safeguards to ensure that scientific invention is provided with adequate protection. Among them, the patent system is often seen as the instrument properly configured to promote scientific research. Since a patent holder has the right to prevent others from using, making and selling the protected invention (Gold, Carbone 2010, pp. 39-70), it allows innovators to recoup the investment made in research and development to create her inventions (Lucchi 2013, p. 255). For this very reason, the patent system is considered critical to promoting growth and innovation across the biotech industries.

But – skepticisms aside (Murray, Stern 2007, p. 670; Feldman, Lemley 2014, pp. 1-52) – when patents limit the use of genetic materials or of any basic elements of research in genomic medicine, they threaten to constrain the biomedical research process itself, as well as its consequent translation into clinical or medical applications (Kumar 2014, pp. 625-640). For instance, diagnostic tests on patented genes cannot be invented around, as is possible with other patents. This is because the actual DNA sequence to be tested is claimed in the patent.

Such artificial proliferation of legal "enclosures" stemming from the broad use of patent protection is therefore proportional to the reduction of genetic materials in the public realm. This limitation to the use of an "essential facility" clearly hampers scientific innovation, because of the prohibitive costs associate with the use of the patented knowledge, but may also impact on the patients' rights to have access to effective cures and informed medical decisions (Kumar 2014, p. 626). As pointed out by some scholars, "the uniquely open-ended nature of biomedical science requires a reassessment of how patenting affects biotech research and innovation" (Adelman 2005, p. 986).

In the animated dialectics between the many diverse interests involved, patent law on genetic inventions should be interpreted so as to balance between the need to provide incentives to biotech research, promoting social welfare and rewarding expenditure on knowledge development.

3. Some consequences already visible in the law

The moral constraints on biotech medicine and the wide use of patents to stifle competition have contributed to a dual move easily perceivable in the current evolution of law on biotech medicine – (3.1) the emergence of the courts and patent offices as arbiters of a common concept of morality in biotechnology, and (3.2) the legal definition of a circumscribed area for scientific research and innovation.

3.1. The emergence of courts and patent offices as arbiters of a uniform concept of morality in biotechnologies

Traditionally, inventions can be patented when they fulfill certain conditions established in the law. Under EU law, not only must they meet the technical/legal criterion of novelty, but they must also involve an inventive step capable of industrial application.[3]

When patentability requirements are enforced in the biotech sector, this is slightly different. On the one hand, the mentioned criteria are interpreted in a diverse and – to some extent – more indulgent way than in other fields (Bonadio 2009, pp. 11-15). Given the unique features of biotechnological inventions and, specifically, their manipulation of materials already existing in nature, the referred common conditions are problematic to apply in their entirety. In practice, this means that the patentability threshold for biotech products or processes is lower than in other technology fields, and that patentees are consequently granted wider scope for exclusive rights.

On the other hand, biotech inventions are also excluded from patentability when they are against public order and morality. Both ethical requirements represent an additional criterion that patent officers and judges are required to verify in practice (Bonadio 2009, pp. 21-27). Many international normative documents refer to ethical principles that could exclude biotech inventions from patentability. According to art. 27(2) of the TRIPs Agreement, state parties to the agreement "may exclude from patentability [those] inventions [whose] commercial exploitation […] is necessary to protect ordre public and morality". Similarly, art. 6(2) of the Directive 98/44 explicitly considers unpatentable any invention that (among others) "uses of human embryos for industrial or commercial purposes".

In light of these open conditions, it is not rare today that judges and patent officers engage – whether consciously or not – in the sensitive moral debate on the patentability of biotech inventions. This approach is more apparent in Europe than in the United States, where a presumption has instead operated that genes are to be treated like any other chemical under patent laws (Odell-

3 According to art. 3 Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998.

West 2011, p.304; Kahn 2003). To cite just the (arguably) most relevant instances, in *Brüstle*[4] the ECJ – impliedly – applied moral concepts to rule that the term 'human embryo' includes both that human ovum (as soon as fertilized) and the cells artificially stimulated or manipulated but not fertilized, and to hold unpatentable the technical teachings which involve the destruction of such elements (Laurie, Harmon 2013; Bonadio 2012; Spranger 2012). Likewise, in *Oncomouse*[5] the EPO – again without any explicit reference to the moral stance of its decision – made a cost-benefit analysis to balance the advantages for cancer treatment of a genetically modified mouse and the likely risks for society associated to this invention (Bonadio 2012; Sterckx 2008).

Of course, this brings inevitable constitutional questions about the role of judges and patent offices, as well as on the need of a common concept of morality. The argument commonly held against applying moral and ethical considerations when enforcing patent law is threefold. First, the function of the patent does not extend to require or even allow any commercial exploitation of the invention, but it represents a mere 'negative right' of the holder to prevent others from using the technical teachings claimed in the patent itself (Bonadio 2009, p. 23; Bonadio 2012). Hence, the patent system shall not require the granting authority to investigate whether the invention may be used in a morally deplorable manner. Second, since moral limits could be laid down in the general legislation anyway, there is no need for the patent law to embody the morality constraints for biotech inventions (Ho 1992; Laurie 2004). Third, being mostly made up of technicians, patent offices are ill-equipped to confront delicate issues related to the application of moral standards.

Yet, despite being logically grounded, the rationale for excluding the moral considerations from the patentability judgment appears outweighed by other more compelling divergent justifications. In particular, it may be noted from the above analysis that the provisions on patentability of biotech inventions explicitly require an overall consideration of the effects of biotech inventions on morality and *ordre public*. Hence, the law itself entrusts the courts and the patent offices with this task (see the recitals 38-39 of the biotech directive), and they seem indeed well aware of this power, since they have already engaged in ethical discussion on biotech patents with their earlier decisions (Bonadio 2009, pp. 24-27; Bonadio 2012). Furthermore, the

[4] Case-34/10, Oliver Brüstle v Greenpeace eV., Judgment of the Court (Grand Chamber) of 18 October 2011.

[5] HARVARD/Onco-mouse (T19/90), [1990] E.P.O.R. 501, 509-10.

need of an efficient patent system on biotech inventions inevitably calls for a comprehensive moral examination of the definition of effective property rights on such technologies (Drahos 1999, p. 441). Because of their deep cultural background and important role in our society, the patent systems represent an appropriate arena to engage in a moral debate over this scope. Finally, in practical terms, patent officers and judges could rely on experts to address the moral and technical issues raised in patent claims. This approach is confirmed by the recent case law on moral aspects of patents and by decisions on more general questions (Bonadio 2012).

Following this line of reasoning, the European institutions seem to have understood and ultimately settled the important moral questions raised by biotech patenting. This has led to strike a delicate balance among the multiple interests involved in the ethical discourse on biotech inventions, to the extent they can be understood exclusively for patent law related ends (Spranger 2012, pp. 1205-1209).

3.2. The legal definition of a circumscribed area for scientific research and innovation

In fact, courts and patent offices are not only emerging as arbiters of the moral values comprised in the patentability of biotech inventions. By issuing decisions on biotechnology patents, they are also giving definition to the sphere of activities that will be available to scientists and innovators.

In the United States, the seminal decision on the *Myriad* case[6] clearly demonstrates that the US Supreme Court is ultimately heading in this direction (Ingram 2014). Ever since the US Supreme Court opened the door to biotech patenting in *Chakrabarty*,[7] the core of the debated on gene patenting has been whether the discovery of a genetic sequence would rise to the level of an invention pursuant to the Title 35 of the US Code.

In *Myriad*, the Court held invalid a patent claim on the exact location and genetic information of a specific isolated section of the DNA (i.e. the section whose mutations are linked to a high risk for the patient to have breast and ovarian cancer). In particular, the subject of the patent was considered a 'product of nature' (Durham 2009; Macedo, Goldberg 2013, pp. 811-813), as

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[6] Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 186 L. Ed. 2d 124 (2013).

[7] U.S. Supreme Court June 16, 1980, Diamond v. Chakrabarty (447 U.S. 303).

it was essentially "a naturally occurring segment" of DNA. For this reason, in the US Supreme Court's view, it did not fulfill the novelty requirement.

What is interesting for the present purposes is the line of reasoning followed by the Court. The decision noted that patent protection strikes a delicate balance between creating "incentives that lead to creation, invention and discovery" and "imped[ing] the flow of information that might permit, indeed spur, invention". Therefore, since "Myriad's patents would, if valid, [have] give[n] the exclusive right to isolate an individual's BRCA1 and BRCA2 genes", the Court concluded that this balance was negatively affected. In other words, for the US Supreme Court, the effects on innovation are the sole consideration, and it finds against patents in human genes because patents in products of nature would thwart research, rather than spur it (Sundar 2013).

With *Myriad*, the US Supreme Court restates the correct theoretical and practical boundary role in the patent system between discovery – which is pure knowledge available to anyone – and invention – which is the body of knowledge to address technical questions (Odell, West 2011; Gambini 2012). Within this debated question, it invokes a narrow view of the role of intellectual property, concluding that patents "exist to promote creation".

Because of this decision, there is now a significant rationale to favor scientific experimentation against the exclusive rights of patent holders in the biotech sector. In *Myriad*, the US Supreme Court is indeed demonstrating an increasing awareness of the potentially negative impact of genetic patents on scientific research and a clear intention to be involved in the discourse. By making it explicit that it was clearing away a major barrier to innovation in the areas of biotechnology, drug development and medical diagnostic, the Court has finally come out with a reasonable balance among the interests involved. This balance will arguably form the base for future decisions in an "atypical" and problematic field such as that of biotech inventions.

4. Hypothesis for the future of law on biotech medicine: genetic databases and the effects on research and public health

The fast-growing and evolving biotech industry will have potentially significant effects on the innovation of law. One of the new challenges raised by scientific innovation in the biotech industry stems from the growing use of genetic data to detect, predict or simply study inherited gene mutations. Because certain genetic variations have been associated with an increased risk to develop serious diseases, this represents a promising area for the industry in its quest to develop personalized and more effective medicine (Green, Guyer 2011, pp. 209-11).

Of course, activity to assess genetic information itself is not problematic, setting privacy-related issues aside (Ohm 2010, pp. 1703-1704). But some commercial practices associated to it are. This is specifically the case with the strategy adopted by some companies to withhold genetic data compiled from patients as trade secrets. Because the prediction of potential health risks caused by a genetic mutation may reasonably be determined from a large amount of evidence (Conley *et al.* 2010, p. 325), testing companies that collect genomic information from a multitude of patients and retain it as proprietary data enjoy a relevant competitive advantage.

This practice poses potentially two interrelated questions. First, since the value of genetic information is intrinsically dependent on the information it contains, property rights that address information as an intangible good may significantly harm scientific research (Conley *et al.* 2014). Not only can the companies retaining genetic information provide more accurate disease predictions, but they may also study the clinical significance of a particular genomic variant and exclude or limit others from pursuing this objective. In the aftermath of the US Supreme Court, Myriad itself has pursued this strategy in Europe, by legally protecting and using its private database built up over two decades of genetic tests (Conley *et al.* 2014).

Second, there are significant public health consequences when any one company excludes competitors from such important human biological data. Patients may not have access to these companies or the resources to afford their services (Fong 2013). To make matters even worse, they can hardly make any informed medical decisions based on multiple sources of advice, as the mutation can be understood and explained by only one company.

Therefore, while in the patent community much of the recent debate regarding genetic medicine has focused on whether isolated and purified genes are patentable (Kumar 2014, p. 625), the latest advances in biotech treatments demonstrate that we still need to find a way for biomedicine companies to keep a competitive advantage without slowing medical innovation and endangering the welfare of patients.

The challenge for the future of the law in this sector is precisely to find an answer to this pressing and critical question. There seems to be a legal vacuum around this question, despite the many delicate interests involved. Though the commercial practice of trade-secret protection is neither new nor illegal *per se*, the uses made on a problematic matter such as genetic data require effective legal responses. An effort toward a genetic data commons has already been made by other similar projects, based on the principle of encouraging the sharing of DNA sequences and of clinical information (as with the Personal Genome Project at Harvard Medical School). However, voluntary commitment alone is inadequate. Alternative and more stringent regulatory protections should instead be based either on mandatory public disclosure of genetic and clinical data – e.g. as a condition for a formal regulatory approval of medical devices (Conley *et al.* 2014).

This will undoubtedly represent the main challenge for the future of law in the biotech sector as it seeks to ensure innovation in personalized treatments. To provide effective legal answers, the combined efforts of international and national actors, including lawmakers and courts, will be crucial.

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Legal Protection of Human Embryonic Stem Cells Research in the EU and the Impact of Patents

Avgi Kaisi

1. Introduction

Research on Human stem cells (hSC) has become widespread in the last decades and has provided hope to millions of patients suffering from chronic diseases.[1] Such research has given rise to what is known as "regenerative medicine" that aims at replacing damaged, lost or diseased cells through regeneration.[2]

There are three categories of stem cells[3] (Genakritis-Charalambous 2013, pp. 155-159):

1. Embryonic stem cells: found in early stage embryos.
2. Adult stem cells: found in adults bodies.
3. Induced pluripotent stem cells (iPSCs): reprogrammed adult cells that behave like embryonic stem cells.

Stem cells are characterized by the ability of renewing themselves multiple times as well as the ability to differentiate into types of cells of various tissues and organs (Verfaille 2002). This second characteristic of stem cells is what makes embryonic stem cells so special. The ability of differentiation is stronger the earlier the developmental stage is at which the cells are isolated. Whilst adult stem cells are already differentiated and can generally only transform into cells of the tissue where they come from, embryonic stem cells have unlimited potential to become any specialized cell of the body. Thus, their potential in research and new therapies is enormous. However, the use of such stem cells is highly controversial due to their origin, the human embryo (HE).

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1 [Online], URL: <www.wellcome.ac.uk> [last accessed 29/04/2015].

2 [online], URL: <http://www.esf.org/fileadmin/Public_documents/Publications/SPB38_HumanStemCellResearch.pdf> [last accessed 29/04/2015].

3 [online], URL: < http://www.eurostemcell.org/factsheet/stem-cell-research-therapy-types-stem-cells-and-their-current-uses> [last accessed 29/04/2015].

Human embryonic stem cells (hESC) are procured from in vitro fertilized embryos that are in the blastocyst stage – i.e., 5-7 days of development. At this stage, the "embryo" resembles a ball of which the inner cell mass contains approximately 100 cells. Such cells are pluripotent, which means they are capable of developing in any of the 200 different cells of the human body, but they cannot produce an extra embryonic tissue with the ability to create an entire organism[4] (Laurie 2004, p. 59; Charalambous, Genakritis 2013, pp. 158, 159).

The fact that the destruction of the embryo is needed in order to procure the cells is a source of controversy. Whilst there is almost a consensus that the HE has a special status as it contains the potential to grow into a full human being, there are two main positions regarding hESCs research (hESCR):

1. on the one hand, opponents of hESCR rate the embryo as a complete human being and therefore its destruction should be considered violation of its human dignity (Resnik 2002);
2. on the other hand, supporters of hESCR recognize the special status of the HE but support that a balance should be found between the destruction of the embryo and the possible benefits that such destruction may bring to humanity. Such approach is known as utilitarian (Juengst 2000; Mertes 2012; Brownsword 2003).

People's opinions over the status of the human embryo are influenced by social factors, with religion and education playing the most determinant roles. Such opinions are mirrored in the countries' policies (TNS Opinion & Social 2010; Walters 2004). The European Continent, rich in terms of cultural and religious diversity, presents an interesting basket of different national legislative options regulating hESCR. The European legislature in 1998 sought to grant a level of harmonization in the legislation of the EU member states regarding the patenting of biotechnological inventions (Directive 98/44/EC). Nonetheless, even after the issuance of the "biotechnology Directive", the legal landscape in the EU has continued to be fragmented in the field of hESCR. The most liberal countries – U.K., Belgium and Sweden – allow the creation of HE for research purposes as well as Somatic Cell Nuclear Transfer (SCNT). The most restrictive ones, such as Germany and Italy, prohibit hESC derivation or SCNT and allow hESCR only on imported hESC lines,[5] (Mertes

[4] [online], URL<http://www.wellcome.ac.uk/About-us/Policy/Spotlight-issues/Human-Fertilisation-and-Embryology-Act/Stem-cell basics/WTD040075.htm> [last accessed 29/04/2015].

[5] [Online], URL<http://www.esf.org/fileadmin/Public_documents/Publications/SPB38_HumanStemCellResearch.pdf> [last accessed 29/04/2015].

2012, p. 1). Finally the majority of the EU countries allow research on supernumerary in vitro fertilized (IVF) embryos.

In addition to the EU and its member states, other actors come into play when considering research and patenting of hESCs in the European continent. International treaties, creating a framework of International Organizations acting in the EU, such as the Council of Europe and the European Patent Office, also tackle issues related to the hESCR and patenting.

This Chapter will analyze the different legal frameworks that are functioning in the field of hESCR in the EU and assess whether the current law suffices in embracing and protecting this field of scientific innovation. Biotechnology advances in a great speed, and the legal system needs to keep up with its pace.

2. Patents in biotechnological inventions

Inventions in the biotechnological field require a great deal of money and time. The creators of such innovative products need to enjoy a certain amount of protection in order to continue their research and keep enriching the market with new life saving products and therapies (PhRMA 2013, p. 36). Nation states traditionally protect such inventions with the issuance of patents. Industries' acting in the biotechnological field report that patent protection is essential in attracting investments and stimulating the inventive activity (Castle *et al.* 2010, pp. 38-39, 47).

The EU on many occasions has recognized the significance of patents in promoting innovation and consequently the industrial development of the Union (European Parliament, P6_TA (2005) 0407; Directive 98/44/EC; European Commission, Communication, COM (2011)808 final, p. 2). This comes as no surprise since patents and research are intertwined. Patents allow the researchers to seek essential funding from the private sector to continue their research, when public funding is insufficient.

Patents can be viewed as social contracts, between national governments and the inventor of a product or a process which is new, includes an inventive step, and has industrial application (EPC 52(1); Directive 98/44/EC, art. 3(1)). By virtue of the patent, the inventor receives a limited period of exclusivity to make, use, sell, offer for sale or import for those purposes such a product (TRIPS art. 28; WIPO Intellectual Property Handbook, p. 17; Abbot *et al.* 2007, pp. 7-8, 141-160). During the period of exclusivity only the creator or those with the creator's permission can economically exploit the invention. In return, the inventor is constrained to disclose her invention in a way that is sufficient to enable other persons skilled in the art to reproduce the invention without undue experimentation.

However, patents have been accused of stifling innovation. When property rights are given over an invention, other researchers are excluded from its use, unless they receive a license from the proprietor. This is troublesome, especially in the biotechnology field where often newer inventions rely on previous ones. Such a situation is known as the tragedy of anticommons (Heller, Eisenberg 1998, pp. 698, 701; Murray, Stern 2007, pp. 648-687).

The existence of multiple interdependent patents – known as patent thickets – indeed can be a drawback in the advancement of scientific research. The field of stem cell research is particularly vulnerable to patent thickets, due to the existence of complex interrelated technologies that concern the culture and growth factors of the cells, as well as their genetic transformation (Bergman, Graff 2007, pp. 419-424; Plomer *et al.* 2008, pp. 13-14).

As a matter of policy, these deadlocks can be avoided by adequate corrective measures. Such measures include limiting the content of patents, with implementation in the pre-grant stage, and forcing compulsory licenses in the after grant stage of the patent (EGE, Opinion No. 16, 2002, pp. 14, 15, 18; Resnik 2002, pp. 150-151).

We will now proceed with the analysis of the protection of hESCR in the EU. We will start with the directive on the legal protection of Biotechnological inventions and the opinion of the European Group on Ethics (EGE). We will then proceed with the analysis of the framework program Horizon 2020, regarding hESCR and the current framework for the patenting of hESCs in the EU according to the European Patent Convention (EPC). Finally we will examine the position of the Council of Europe regarding the legal and moral status of the HE.

3. Directive on the legal protection of biotechnological inventions

In 1998, the European legislature, recognizing the significance of the protection of biotechnological inventions for the community's industrial development, issued a Directive aimed at harmonizing the legislation throughout the member states and ultimately protecting the function of the internal market (Directive 98/44/EC, Recitals:1, 3, 5, 6, 7). The Directive however did not define the term HE, and J. Thomson's article on embryonic stem cell lines published later in the same year in the journal *Science* (Thomson *et al.* 1998, p. 1145), raised doubts on whether the prohibition of article 6(2)(c) of the Directive extends to hESCs. According to Article 6:

1 Inventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.
2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:
   a) processes for cloning human beings;
   b) processes for modifying the germ line genetic identity of human beings;
   c) uses of human embryos for industrial or commercial purposes;
   d) […].

Such article was immediately accused of legal uncertainty (Netherlands v. Parliament and the Council 1998). In an application brought before the CJEU, the Kingdom of the Netherlands argued that concepts such as *ordre public* and morality, in para. 1, were expressed in general and ambiguous terms leaving their interpretation to the national authorities (Netherlands v. Parliament and the Council 1998, para. 35).

The CJEU replied that such "scope of manoeuvre" is necessary due to the reactions that the use of certain patents may provoke in the social and cultural context of each member state. According to the CJEU, national authorities are more appropriate to deal with such issues. Moreover, it stated that this sort of provision is common in patent law and that in any case the directive limits the concepts in question by giving specific examples in paragraph 2 (Netherlands v. Parliament and the Council 1998, paras 37-40).

Paragraph 2 of the same article was analyzed in a later case brought by the Commission against the Republic of Italy. Italy, in that case, was held responsible for failing to implement the directive and, in particular, for breaching art.6 (2). Despite the existence of national laws in Italy regulating the patentability of processes such as cloning human beings and using human embryos for industrial and commercial purposes, the CJEU concluded that the second paragraph of art.6 "allows the member states *no discretion* with regard to the unpatentability of the processes and uses which it sets out" and that it requires "*expressed transposition*" (Commission of the European Communities v. Italian Republic 2003, paras 78, 82). Thus, Italy was held responsible for not applying the directive.

However, the expressed transposition required by the Court in the laws of the member states left open the question of whether stem cells deriving from a HE should be included in the prohibition of art. 6 (2). Defining the term HE remained in the discretion of the member states. Such conclusion is supported by recitals 8 and 14 of the preamble of the Directive according to which "legal protection of biotechnological inventions does not necessitate the creation of a separate body of law in place of the rules of national patent law". It further specifies that "substantive patent law cannot serve to replace or render superfluous national, European or international law […] which concerns the monitoring of research and of the use or commercialization of its results […]".

Moreover, the Court in the case of the Netherlands v. Parliament and the Council stated that "the directive concerns only the grant of patents and its scope does not therefore extend to activities before and after the grant, whether they involve research or the use of the patented products" (Netherlands v. Parliament and the Council 1998, paras 69, 70, 79).

The conclusion from these two judgments is that the definition of HE is to be left to the discretion of the member states, and that the exclusion of art.6 (2) refers only to the claimed product or process and not to the historical use of the human embryo during the research stage. Moreover, the expressed transposition of the exclusions in article 6(2) does not remove the discretion of the member states in deciding on moral matters, especially where there is a lack of consensus between them.

However, in 2011, such a conclusion was contradicted by the same Court in the well known Brüstle case. In this case the Court was asked by the Federal Court of Germany to reply to three preliminary questions: 1.What is a HE? 2. Whether scientific research falls under the term "industrial and commercial uses"? 3. Whether an invention is unpatentable even though its purpose is not the use of HE, but its production necessitated the destruction of one (Oliver Brüstle v. Greenpeace 2010, para. 23). The response of the Court raised a lot of reactions.

First of all the Court recognized a necessity for the term HE to be interpreted in a uniform way throughout the Union's territory, in the process depriving the states of their discretion to determine the delicate moral issue of the initiation of human life. Then, the interpretation of the term HE given by the Court was very broad. The term included any human ovum after fertilization, "since that fertilisation is such as to commence the process of development of a human being". Moreover, it extended the definition also to non-fertilized human ovum into which the cell nucleus from a mature human cell has been transplanted and any non-fertilized human ovum whose division and further development have been stimulated by parthenogenesis (Oliver Brüstle v. Greenpeace 2010, paras 34-36). Such an interpretation was considered a setback in hESCR in the EU, since it makes it difficult for researchers to obtain funding due to the unpatentability of their inventions (Wilmut 2011, pp. 498-499; Koch. *et al.* 2011, pp. 499-500).

Furthermore, the inclusion of non fertilized human ovum which have been stimulated by parthenogenesis in the term embryo, was inconsistent with the earlier statement of the Court that fertilisation should be capable to commence the process of development of a human being. Parthenogenesis refers to the commencement of embryogenesis without fertilization, through the activation of an oocyte in the absence of a sperm, with technological-chemical means. The oocyte is known as an activated parthenote. This parthenote is able to develop in a structure similar to the blastocyst, but it cannot develop into a complete human being because of the absence of the paternal DNA. Therefore the cells of an oocyte parthenogenetically activated are pluripotent and not totipotent as in the case of a fertilized ovum.

Indeed, such inconsistency was later reiterated in a case brought before CJEU by the High Court of England and Wales (International Stem Cell Corporation v. Comptroller General of Patents, Designs and Trademarks 2013).

In that case, the UK IPO refused to grant two patents to the International Stem Cell Corporation for technologies that concerned the production of pluripotent stem cells from oocyte parthenogenetically activated, on the grounds that it was against the standard established by the Brüstle case.

The High Court decided to refer to the CJEU, asking it to clarify its position in the Brüstle case regarding the phrase "capable of commencing the process of development of a human being". The Court concluded that the criterion should be the inherent capacity of the ovum to develop into a human being, and since at the current stage of scientific development parthenotes cannot develop into such, then they should not be considered HE.

Regarding the second question that concerns the definition of commercial and industrial purposes and whether they include scientific research, the Court underlined that the grant of a patent implies the industrial and commercial application of the patented product. Therefore, if the purpose of the research constitutes the subject matter of a patent application then it cannot be separated by the patent itself and the rights granted by it. However, the Court made a distinction between the use of HE in scientific research and the patentability of biotechnological inventions which is the subject of the directive (Oliver Brüstle v. Greenpeace 2010, paras 41-46).

Regarding the third question, the Court ruled that the technical teaching for the invention should be taken into consideration, and an invention should be excluded from patentability when it requires destruction of HE even if the destruction of the embryo took place in a remote moment in the past. That conclusion excludes also the possibility of obtaining embryonic stem cells from existing cell lines or cell cultures, a possibility that until before the Brüstle judgment was morally acceptable by the majority of the EU countries (Plomer 2012, p. 126).

It turns out from the above analysis that the CJEU made a rather strict interpretation of art.6 of the Directive. What is quite striking is that the CJEU gave an interpretation of the term HE that runs contrary to the morality of the majority of the EU member states, where research on spare HE created for infertility treatments is allowed. Moreover the Court extended the prohibition of the patentability of HE not only to the HE itself but also to pluripotent stem cells deriving from the blastocyst stage, if the prior destruction of the embryo is needed. It should be noted that the Commission in 2005 in its report stated that an answer to the patentability of pluripotent stem cells or a further harmonization to this area would be premature due to the clear divergences that exist between the member states as regards the acceptability of research relating to embryonic stem cells, the continuing and rapid developments in this field and the fact that the directive itself provides for member states to refuse patents on grounds of *ordre public* and morality under art. 6(1) (COM(2005) 312 final).

The conclusion of the Court also runs contrary to the opinion of the European Group on Ethics. The EGE in its opinion No.16, states that prohibiting patenting of stem cells and stem cell lines would be contrary to the public interest since it would bring a major slow down in the relevant field of research, and such result would be against the aim of the Directive itself (EGE Opinion No.16, para. 2.1.).

The EGE makes a distinction between modified and unmodified stem cells lines. According to the EGE only modified stem cell lines should be patentable, when such a modification renders them appropriate for specific industrial application. By this distinction the EGE aims at limiting the scope of patents and avoiding the creation of patent thickets in the field. In addition, the EGE suggests that isolated stem cells that were not modified should not be patentable as being too close to the human body, and, finally, it states that there is no specific ethical obstacle to the patentability of processes involving human stem cells, no matter what their source is.

The EGE appears more moderate than the CJEU. The EGEs' positions aims to balance the advantages and disadvantages of patents in the field of hESCR, and in regenerative medicine in particular. However, the EGE's opinions are only guidelines and are not legally binding, either for the Court or for the patent offices.

4. Horizon 2020

The way that the CJEU interpreted the biotech directive regarding the patentability of hESCs is paradoxical since the EU funds research on hESCs.

Horizon 2020 is the EU's Research and Innovation Programme for the years of 2014-2020, and is the subsequent of the Framework Programme 7 (FP7).[6]

Article 19 of the Regulation on the Programme Horizon 2020 concerns the ethical principles to be followed for research and innovation (R&I) activities carried out under Horizon 2020 (EU Regulation 1291/2013, establishing Horizon 2020). In paragraph one it stresses the need to comply with national, Union and international legislation, mentioning specifically the Charter of Fundamental Rights of EU and the European Convention of HRs and its protocols.

Paragraph three of the article refers to research activities that should not be financed under Horizon 2020. Such activities are: (a) activities aiming at human cloning for reproductive purposes; (b) activities intended to modify the genetic heritage of human beings which could make such changes heritable; (c) activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

Paragraph four of the same article explicitly mentions that research on hESCs may be financed depending on the context of the scientific proposal and the legal framework of the member states involved. However, funding cannot be granted in a member state where such activity is prohibited or for research activities that are prohibited in all member states.

Horizon 2020, with regard to research on hESCs, was challenged through the mechanism of the European Citizens Initiative, which was introduced with the Lisbon Treaty and permits one million citizens of the EU, originating from at least 7 member states, to call on the European Commission to propose legislation on matters of the EU competence.[7]

The Group leading the initiative, named "One of Us", asked the EU to end financing of activities that presuppose the destruction of HE, in particular in the area of research, development aid and public health. The organizers of the initiative referred to the Brüstle judgment where the CJEU defined the HE

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6 [Online], URL <http://ec.europa.eu/programmes/horizon2020/en/what-horizon-2020> [last accessed 29/4/2015].

7 [Online], URL: <http://ec.europa.eu/citizens-initiative/public/basic-facts?lg=en> [last accessed 29/4/2015].

as the beginning of the development of the human being (COM(2014) 355 final, para. 2.1.).

The Commission in its response to the One of Us initiative stated that the existing funding framework is appropriate and respects EU Treaties and the Charter of Fundamental Rights (COM(2014) 355 final, paras 3.2, 4.2). According to the Commission, the Programme Horizon 2020 follows a “triple lock” system regarding hESCR, which was applied with success in the FP7 program. According to such a system: 1. National legislation is respected; 2. Each project must pass both a scientific evaluation in order to be assessed whether the use of hESCs is necessary and an ethics review organized by the European Commission; and 3. European funds cannot be used for the creation of new stem cell lines or for research that destroys embryos (Commission Statement 54, 2013/C 373/02; FP7, Commission Statement 56). The Commission stressed that it does not publish calls for research proposals on hESCs specifically, and it is up to the scientists to propose the best possible approaches for a particular study (EU Regulation 1291/2013 establishing Horizon 2020, Recital 31).

Regarding the reference to the Brüstle judgment, the Commission stated that the Court ruled only on the patentability of such inventions and it did not tackle the question of whether such research can be carried out or whether it can be funded.

Therefore the Commission reaffirmed the legality of hESCR in the EU on existing stem cell lines even after the Brüstle judgment. The Commission’s view is more compatible with the opinion of the EGE; and despite the fact that the Commission drew a distinctive line between the research on hESCR and the patentability of their results, the Regulation of H2020 often stresses how R&I is important for the economic growth of the Union and for attracting private investment. As noted before, patents in biotech are essential in attracting private investment and consequently assure the development of R&I in the Union (EU Regulation 1291/2013 establishing Horizon 2020, Recital 2, 11, 24).

5. The European Patent Office

The European Patent Convention (EPC), which entered into force in 1977, provided for the creation of the European Patent Office (EPO). The EPO is responsible for the examination of patent applications and the grant of the European Patent. Such patent, after it is granted, splits up in a bundle of national patents. Thus, the EPC deals with the pre-grant, application stage of the patent, whilst the post-grant stage is regulated by national patent laws. The EPC does not form part of the European legal order and therefore the organs created under the EPC are not bound to follow European legislation (Kaisi 2014, p. 171; Plomer 2006, pp. 85-89).

However, the EPO voluntarily transported the wording of the Biotechnology Directive in its own legal order with the form of amendments to the EPC in 1999. Such amendments were aimed at achieving a harmonized approach within the EU on the patenting of Biotechnological inventions, and therefore Rule 28(c) EPC is identical to art. 6(2)(c) of the Biotech Directive.

In fact, the judgments of the EPO Boards of Appeal (BoA) and of the CJEU reflect each other in several aspects. In the Brüstle case the CJEU made reference to the Wisconsin Alumni Research Foundation (WARF) judgment of the Enlarged Board of Appeals (EBA) of the EPO (Oliver Brüstle v.Greenpeace 2010, paras 45-51).

In the WARF case the EBA ruled that when applying rule 28(c) the technical teaching of the application as a whole as to how the invention is to be performed needs to be taken into consideration and not just the explicit wording of the claims. The concern was that the prohibition of rule 28(c) could be avoided by a matter of clever and skillful drafting of the claims (Use of Embryos/WARF 2008, para. 22). However, the EBA left open the possibility of using hESCs that derive from existing human embryonic stem cells lines available in biobanks (Use of Embryos/WARF 2008, paras 33-34).

Moreover, the EBA recognized that neither the EU nor the EPC legislation defined the term embryo, although the drafters were aware of definitions given in national laws. Therefore the EBA concluded that the term embryo "was not to be given any restrictive meaning in Rule 28 EPC, as to do so would undermine the intention of the legislator" and added that the definition of embryo is a question of fact that should be judged in a case by case basis (Use of Embryos/WARF 2008, para. 20).

It is obvious that despite the statement of the CJEU in the Brüstle case that it followed the same line with the EBA in the WARF case, the CJEU actually went further by defining the term HE and by prohibiting the possibility of using previously derived hESC lines.

The EPO, despite the restrictive consequence in the field of hESCR and the reactions that the Brüstle judgment raised, decided to follow the CJEU's ruling and in 2012 it adopted new Guidelines for examination that reflect the Brüstle ruling (EPO, Guidelines for Examination, June 2012).

In a recent case before the Technical Board of Appeal, known as the Technion case, the commitment of the EPO to the rulings of the CJEU is obvious

(Mahalatchimy 2015). The applicant in this case argued that methods using commercially or otherwise publicly available HESC lines were not excluded from patentability because no *de novo* destruction of the HE was necessary. The BoA ruled that inventions that make use of publicly available hESC lines which were initially derived by a process resulting in the destruction of the HE are excluded from patentability. Although the BoA is not bound by the judgments of CJEU, it acknowledged the need of uniformity in harmonized European Patent Law, and it considered the judgment of the CJEU persuasive (Culturing stem cells/TECHNION 2014).

In the subsequent case of Asterias Biotherapeutics – a USA based company –, the appellant applied for a patent at the EPO for a method of producing islet cells from primate pluripotent stem cells. Here the appellant alleged that at the filing date of the application, methods were available to a skilled person for obtaining hESCs without the destruction of an embryo (Klimanskaya 2006). The Technical BoA admitted that in such a situation no objection could be raised under article 53(a) EPC and Rule 28(c) of the EPC. However, the BoA did not allow the patents to go forward on the ground that at the priority date of the application non destructive methods were not available (Embryonic stem cells, disclaimer/ASTERIAS 2014).

Regarding the application of *ordre public* and morality, as codified in 53(a) EPC, under EPO case law they are the basis of two distinctive objections that can be raised either separately or together (Transgenic Animals/Harvard 2004, para. 10.6-Oncomouse). In the judgment of Michigan State University, which considered the patentability of a claimed composition for mercy killing (euthanasia) of lower animals, the Board stated that patent protection can only be denied pursuant to art. 53(a) if the intended exploitation of the invention would infringe *ordre public* or morality. Therefore breach of *ordre public* and morality should be judged only in relation to the use of the invention. Applying this approach, the Board overruled the argument that animal experiments reported in the patent were against the *ordre public* and morality, on the grounds that they were carried out during the *making or development* of the invention and as such did not fulfill the condition of being part of the *exploitation* of the invention (Euthanasia Composition/Michigan State Univ. 2005, para. 6(8)b).

The Board in the Oncomouse case stated that the idea of *ordre public* covers the protection of public security and the physical integrity of individuals, and that the concept includes also the protection of the environment.

Regarding the concept of morality, the Board in the Oncomouse case stated that it is related to the belief that some behavior is acceptable and right while another is wrong. Such belief is grounded in the totality of the accepted norms which are deeply rooted in a particular culture. For the purposes of the EPC, the culture in question is the culture inherent in the European society and civilization (Transgenic Animals/Harvard 2004). In the Michigan State University judgment, the Board concluded that no single definition of morality represents an accepted standard in the European culture.

Moreover, in the Michigan case the Board acknowledged that morality is not a criterion to be determined by patent authorities. Such an observation is in accordance with the NL case, where the CJEU recognized that morality is better to be judged by national authorities.

It is therefore observed that prior to the Brüstle case there was more space for patenting of inventions that engaged research on hESCs. The decision of the EPO to adopt the case law of the CJEU further extended their result to the countries that are not members of the EU but are members of the EPO.

6. Council of Europe

The Council of Europe is the leading Human Rights Organization in the EU and numbers 48 member states.[8] All the EU member states are also members of the Council of Europe and are bound by the European Convention on Human Rights (ECHR). The European Court of Human Rights (ECtHR) oversees the correct implementation of the Convention.

Since the debate over hESCR and the patentability of its results originates in the status attributable to the embryo and in respect for the embryo's dignity, it is important to see how the ECtHR dealt with the question of the embryos' status.

In the case of Vo v. France, the ECtHR was called to examine when the right to life commences under Art. 2. of the ECHR. In this case, a woman in France had to have a therapeutic abortion due to an error of a doctor, when the fetus was 20 weeks old. Here the ECtHR underscored the lack of consensus in the EU regarding the nature and status of the embryo and/or fetus. It stated that such lack of consensus is also reflected in the Oviedo Convention on Human Rights and Biomedicine, where no definition of the term "everyone" is given. According to the Court the question of when life begins comes within the margin of discretion that States should enjoy, and therefore the Court could not rule that the failure of French law to criminalize a doctor

8 [Online], URL: <http://www.coe.int/aboutCoe/> [last accessed 29/4/2015].

whose negligence caused the death of the fetus would be a violation of Art.2 (Vo v. France 2004, paras 82-84).

The Vo v. France judgment was reaffirmed in the later case of Evans v. UK. In the Evans case the applicant aimed at using art.2 of the ECHR to override the refusal of her partner to permit her to use the frozen embryos after they split up. According to English Law she could not proceed with the IVF treatment without the consent of her partner. The applicant claimed that in denying her access to the frozen embryos, which were otherwise destined to die, the UK violated art.2 and failed to protect the embryos right to life. The Court followed the reasoning of the Vo v. France case, according to which the members States are competent to define when the life begins, and according to UK law an embryo does not have independent rights or interests and cannot claim a right to life (Evans v. UK 2009, paras 53-56). The Court therefore found that the embryos created by the applicant and her partner did not have a right to life, under art. 2 of the ECtHR.

The conviction of the Council of Europe that the definition of the moral issue of when life begins lies with the competence of the members states is also obvious in the European Convention on Human Rights and Bioethics (Oviedo Convention). The Oviedo Convention is one of the greatest accomplishments of the Council of Europe in the field of biomedicine and HR. The significance of the Convention lies in the fact that it is the first hard law instrument to address issues of biomedicine and HRs. It is a framework convention that sets minimum standards regarding biomedical activities in the EU. This minimalistic approach is due to the lack of consensus in many core issues, one of which is the legal and moral status of the embryo (Andorno 2005, pp. 131-134) (Campiglio 2010, pp. 65-66).

The lack of consensus on the status of the HE is evident in the Convention. Article 1 of the Convention, which defines the scope and purpose of the convention, states: “Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine”.

The Article uses two terms simultaneously “human being” and “everyone” without defining either of the two. According to the explanatory Report of the Convention, there was no unanimous agreement on the definition of these terms and therefore it was decided to allow the domestic law to define them for the purposes of the application of the Convention (Explanatory Report, Oviedo Convention paras 16-17).

Regarding the research on HE in particular article 18 states: 1.Where the law allows research on embryos in vitro, it shall ensure adequate protection of the embryo. 2. The creation of human embryos for research purposes is prohibited.

The Convention therefore favors scientific research on hESCs that are procured from existing hESC lines but it underscores the need to protect such embryos (Explanatory Report, Oviedo Convention, paras 115-116). The wording of the article is rather contradictory, since it is difficult to guarantee an adequate protection of the embryo when it is used as a research tool. The second paragraph of the article introduces a clear cut limitation, which is compatible with the Horizon 2020 framework, according to which no creation of HE for research purposes is permitted.

7. Conclusion

From the discussion above we can draw two main principles in European law regarding the use of HE in research. Paradoxically, they contradict each other:

1. research on hESCs is allowed and even funded by the EU (as long as such stem cells derive from existing hESC lines);
2. patenting of the results of hESCR is prohibited.

It is an oxymoron to deny the patenting of inventions that necessitated the destruction of a HE, whilst the actual destruction of the embryo and its use in research is acceptable. The prohibition of patentability of such an invention would have made more sense if research was prohibited in the field. The dilemma over the use of HE concerns the status of the embryo as a human being, and the moral question of protecting the human dignity of the embryo is outside the context of patent law.

The morality clauses in the Biotechnology directive and the EPC would make sense only if they were going to be seen as a balancing test between the commercial exploitation of the invention and the general social interest.

It appears that the real concern in permitting patents in inventions that include destruction of HE is the impact that such patents may have in further R&D, and indeed such a question should be dealt with in the patent law context.

As mentioned in the beginning of the chapter, two measures can assist in limiting the negative effect of patents. The first measure involves limiting the content of patents. Adopting the suggestion of the EGE for granting patents only to modified stem cell lines when such modification renders them appropriate for specific industrial application, would be a good start in limiting the content of patents. The second measure involves using the mechanism of compulsory licenses(CLs) where a company abuses its exclusive rights. Unfortunately there is no a pan-European provision concerning CLs. As mentioned before the EPC deals only with the pre-grant of the patent stage, and the recent Regulation on the creation of a Unitary Patent left the matter of compulsory licenses to the determination of national laws (Regulation 1257/2012, on the Unitary Patent; Kaisi 2014, pp. 176-177). Nonetheless, member states should have sufficient legislation regarding CLs in order to allow parties to obtain access to the results of hESCR even without the authorization of the patent holder (Rimmer 2008, pp. 246-249, 273).

Biotechnology is a dynamic field, which develops rapidly and has great effect on the economy worldwide; therefore it needs fertile legal ground on which to develop. The current EU legal framework of checks and balances offers enough flexibility for the development of biotechnology research and hESCR in particular. However, the interpretation of the patent law by the EU Courts and the dividing line between scientific research and patents drawn by the CJEU in the matter of hESCR will slow down such development, and, as the EGE stated, a prohibition on the patenting of stem cells is contrary to the public interest.

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The Kaleidoscope of Whole Genome Sequencing in Newborn Genetic Screenings: Challenging the Legal Framework of Medical Care and Research

Marta Tomasi

1. The promised land of genetic testing

The value of genetic testing has been growing during recent years and, as costs come down and interpretation is more established, it is likely to be increasingly considered as an essential aspect to be integrated in everyone's health care.

In particular, as awareness about the fact that genome sequencing could someday be part of routine testing done on every baby is emerging, concerns about ethical and legal implications of this approach show up as well. The potential of such testing to provide doctors and parents with a huge pool of data likely to reveal a wider range of medical risks, is a strong argument in favor of considering genetic testing to be an effective substitute for the traditional heel-prick test, or even a necessary means to integrate existing neonatal screening programs (Burgard *et al.* 2012). More problematically, exome sequencing (ES) and whole genome sequencing (WGS) techniques[1] are considered by some to have the potential to change the practice of population screening programs in general, and of newborn screenings in particular.

The main challenge, underlying these new technological possibilities, is striking an appropriate balance between facilitating the safe and secure use of newborns personal data in care and in research, maximizing genetics' potentialities, and protecting the newborn's rights and interests. Such concerns, shall always prevail over the general goals of the progress of science and the interests of society. The chance of potentially improving the health of future children and of thus benefitting new generations of children to

[1] ES and WGS are part of next-generation sequencing techniques, new throughput and massively parallel DNA sequencing technologies. Whole genome sequencing is the sequencing of a person's entire genetic code, exome sequencing addresses DNA bases of the genome containing the information necessary to encode protein (exome).

come finds a strong counterbalance in the immediate need to protect every single tested child.

Technology and the development of new medical skills are pushing for a radical innovation of healthcare, causing new dimensions of complexity to arise. Whether law is sufficiently equipped and skilled to face challenges coming from this new scenario is still an open question, but discussion has to be fostered on how regulation should be shaped in order to put these competing interests on an even keel.

2. Newborn screening programs: advancing technologies, increasing complexities

Newborn screening programs, hailed by the US Centers for Disease Control and Prevention as one of the 10 most important public health achievements (Centers for Disease Control and Prevention 2011), are traditionally aimed at screening asymptomatic newborn population for a number of rare and severe diseases, that could be timely treated.

More than forty years ago, many countries started screening programs for phenylketonuria (PKU), with the aim of identifying newborns with a condition which has a high impact for individuals affected and for which early treatment was possible.

Advances in screening techniques and an increase in the possibilities for treatment have brought on a gradual expansion of screening programs in many countries. Due to its success in saving human life, newborn screening (NBS) is reported to occur in more than 64 countries around the world (Knoppers *et al.* 2014).

In Europe, following the EU Council Recommendation on Rare Diseases (European Council 2009), the European Commission launched a tender on neonatal screening (July 2009) with the main aim of reporting on the practices of NBS for rare disorders implemented in all the Member States, with specific reference to the number of centers involved, the number of infants screened, the number of disorders included in the screening, and the reasons for the selection of these disorders (Cornell *et al.* 2011).

The tender report (Burgard *et al.* 2012) shows that NBS is commonly offered as a service of the public health system in all EU, Candidate and EFTA Countries and in most Potential Candidate Countries. At the EU level, as well as at the international one (Wilson *et al.* 2010, p. 31), the disorders targeted by NBS differ greatly from country to country and national panels of screened diseases vary from 2 to 29 disorders (rare conditions).

The report shows a loose control over the contents of the information provided to parents on the disease and the treatment (also stressed by There will be blood 2011), but the justification for state-mandate programs, usually carried out without explicit consent, has to be found in the fundamental principle of the best interest of the child.

The criteria for the selection of conditions to be screened for is mainly guided by the results of the report "Principles and practice of screening for disease" (Wilson, Jungner 1968). This public health classic was commissioned by the WHO and written by Wilson, then Principal Medical Officer at the Ministry of Health in London, and Jungner, then Chief of the Clinical Chemistry Department of Sahlgren's Hospital in Gothenburg, Sweden. Already in 1968, when the report was issued, screening was a topic of growing importance and controversy and the authors considered it necessary to identify some criteria for screening to counter "snags" related to "an admirable method of combating disease":

> The central idea of early disease detection and treatment is essentially simple. However, the path to its successful achievement (on the one hand, bringing to treatment those with previously undetected disease, and, on the other, avoiding harm to those persons not in need of treatment) is far from simple though sometimes it may appear deceptively easy. (Wilson, Jungner 1968)

Among other criteria, the capacity to detect the condition at an early stage and the availability of an acceptable treatment were considered dominant, and in most experiences, following these criteria, testing has been limited to detection of severe health conditions for which early treatment improves morbidity or mortality (Fleischer, Lockwood 2014).

Caution about the possible consequences deriving from screening have similarly and more recently been expressed by Sir Muir Gray, former program director of the National Screening Committee in the United Kingdom: "All screening programs do harm. Some do good as well and, of these, some do more good than harm at reasonable cost." (Raffle, Gray 2007). Intuitive benefits of screening programs, concretized in an improvement of health status in early diagnosed and optimally and timely treated patients, find their counterbalance in false positives (determining anxiety and additional costs) and false negatives (potentially causing diagnostic delays), concerns about privacy and autonomy, and increased costs.

With the completion of the Human Genome Project in 2003, involving the sequencing of the entire human genome, screening re-emerged as a pressing issue, and the Wilson and Jungner criteria, long considered as the gold standard in making decisions concerning screening policymaking, are challenged by the complexity emerging from genetic screening. These challenges have created a lack of consensus about which criteria to be used (Andermann *et al.* 2010).

In particular, the possibility for neonatal screening and the potential application of WES/WGS to NBS programs call for a careful scrutiny because of the potential harms and the complexity of demonstrating benefits.

3. Innovation fostered by new techniques: ES and WGS

The traditional practice of genetic testing has so far been based either on high resolution analyses performed on one or, at most, a few specific genes or on low resolution analysis of the whole genome. Both approaches focus on answering a defined clinical question. More recently the diagnostic approach has evolved from this strictly targeted approach. The first move has been towards a relatively targeted approach, based on tests looking at a larger panel of genes via microarrays. The second has been to the potential application of non-targeted high-resolution next-generation techniques, detecting mutations throughout the genome (European Society of Human Genetics 2014).

Exome sequencing and whole genome sequencing are transformative new tools for gene discovery that have already been used to identify causal variants for rare monogenic syndromes and to solve diagnostic dilemmas. As costs go down, they may routinely be used to search for variants that underlie a wide range of common, complex phenotypes in large-scale projects.

These emerging techniques, generate an enormous amount of raw data that needs to be selected through complex bioinformatics analysis. They are potentially able to provide information on virtually all functional, protein-coding variants in the genome, including most variants known to influence risk of human diseases and traits. Many different activities could benefit from the application of these techniques: diagnosis in patients with symptoms, presymptomatic testing, pharmacogenomics and population-screening programs.

WGS and ES are already operating in the diagnostic and research settings. The causes of some disorders have been identified (Hayden 2012), individual genomes have been sequenced (see the Personal Genome Project presented by Lunshof *et al.* 2012), and efforts to create repositories of exome/genome data linked to phenotypic traits (e.g. dbGaP[2]) are in place. The European Society

[2] dbGaP is a restricted-access data repository supported and managed by the NIH in which investigators who receive funding from the NIH for GWAS are required to deposit genotype and phenotype data for each individual participant. Mailman *et al.* 2007 Tabor.

of Human Genetics recently suggested that other anticipated applications include "tissue matching, disease risk predictions, reproductive risk information or even recreational genomic information (such as genealogy or non-medically related traits)" (European Society of Human Genetics 2014, p. 2).

Among all of these potential implementations, it has been observed that "the earliest applications of whole-genome sequencing will be restricted to settings in which genetic testing is already a routine part of clinical or public health practice, such as state newborn screening programs" (Goldenberg, Sharp 2012).

The advantages that appear likely to come include possibilities of the detection of more conditions, of more accurate diagnoses involving family members as well, of planning reproductive decisions, of managing disorders with a strong inheritable component and of revealing pharmacogenetics information, with the overarching consequence of improving person-centered care (Collins 2010).

Nonetheless, dealing with the sheer amount of data generated from ES and WGS might prove to be incredibly demanding. Not all knowledge is necessarily beneficial. Potential risks of discrimination or stigmatization might arise from the collected data. Incorporating these new techniques into healthcare practice might put an overwhelming burden on healthcare systems with reference, on the one hand, to costs and, on the other, to the responsibility for keeping the information updated and disclosing it at a proper time.

The larger amount of relevant information generated by a single test resulting from the application of innovative sequencing techniques marks a departure from current rules and standards in healthcare practice and in human genetic research. Nevertheless, the shift brought forward by this path of innovation is not merely quantitative. The kind of information obtained from untargeted analysis i) determines a redefinition of the concept of an at-risk population, impacting the notions of autonomy and self-determination; ii) reshapes the role of physicians and researchers who are invested with new responsibilities and who could be involved in extremely complex communication processes; and iii) blurs the border running between diagnosis and research, making them gradually more intertwined activities.

The complexity arising from this new setting dramatically increases when children are involved and the prospected application of a WGS-based approach to newborn screenings has to face obstacles coming from the "implied consent" mechanism and the particular vulnerability of the population tested.

4. Protecting children *from* genetic testing results: the need for a precautionary approach?

Specific features of the information obtained from genetic testing necessitate a prudent approach by legislators and policy-makers considering the possibility of testing children both for diagnosis and research purposes.

A general statement can be found in the 2008 Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes (thus far signed by only 5 States and ratified by 3). Art. 10 mandates that "a genetic test on a person who does not have the capacity to consent may only be carried out for his or her direct benefit... [and] where, according to law, a minor does not have the capacity to consent, a genetic test on this person shall be deferred until attainment of such capacity unless that delay would be detrimental to his or her health or well-being". The sole exception to this provision is the possibility of testing the person incapable of consenting for the direct benefit of a family member, consistently with the recognition of the familial nature of genetic information (Liao 2009).

Similar caution, prompted by past restraint (Borry 2006a; 2006b), can be found in recent statements of other institutions and professionals societies. The American College of Medical Genetics and Genomics (ACMG) and the American Academy of Pediatrics generally determined that the decision about whether to offer genetic testing and screening "should be driven by the best interest of the child". They strongly recommend a delay of genetic testing for late onset conditions until adulthood. ACMG stated that WGS should not be used as a "first tier approach for newborn screening" (ACMG Board of Directors 2012) and limited the applicability of genome and exome sequencing before the legal age of majority to three cases, namely: a) phenotype-driven clinical diagnostic uses; b) circumstances in which early monitoring or interventions are available and effective; c) institutional review board-approved research (ACMG Board of Directors 2013).

In its 2009 recommendations on genetic testing in asymptomatic minors, the European Society of Human Genetics, noted that the primary reason to carry out a genetic test on a person who does not have the capacity to consent should be his or her direct benefit. They reasonably suggested presymptomatic and predictive genetic testing in minors for adult-onset disorders be deferred until the person has the maturity and competence to understand the nature of the decision and its implications, unless preventive actions can be initiated before adulthood (European Society of Human Genetics 2009, point 7). The document stresses nonetheless the difference between genetic testing of asymptomatic minors in a clinical context and screening activities of asymptomatic minors, for the possibility of incidental discovery of carrier status. More specifically, the ESHG, in its recommendations issued in 2013 about WGS in healthcare, expresses a critical attitude towards WGS, unless its clinical utility is strictly evaluated and specific screening criteria are met (van El *et al.* 2013):

> […] in case of testing minors, guidelines need to be established as to what unsolicited information should be disclosed in order to balance the autonomy and interests of the child and the parental rights and needs (not) to receive information that may be interest of their (future) family.

Wary approaches expressed are consistent with the regulatory framework set in the European context where both the European Charter of Fundamental Rights and the so called Oviedo Convention only allow interventions in medicine on a person who does not have the capacity to consent, for his or her direct benefit.

General reluctance towards the genetic testing of children, based on broad considerations about its predictive nature and about fragmentary knowledge of the genome and on the limited genotyping ability that commonly pertains to the practice of genetic analysis, turns into intensified caution when approaching next generation sequence techniques, and ES/WGS in particular.

This precautionary attitude is mainly driven by a number of factors. These include i) issues about privacy and confidentiality, deriving from the increasingly revealing nature of the personal data obtained; ii) the need to respect the future autonomy of the child (once adult); iii) the need to identify responsibilities towards biological relatives; and iv) the need to assess the psychosocial impact of new techniques implementation.

All of these concerns could suggest that using ES/WGS in NBS is premature. Nonetheless attention has already been given to this new path of innovation. In 2013 the US National Institutes of Health decided to fund four pilot studies to analyze the medical and ethical implications and the opportunities associated with the possible integration of exome or genome sequencing in newborn screenings. Moreover, studies show a generally high overall interest among parents in having future newborns undergo WGS (Goldenberg *et al.* 2014).

The concerns and alarms, sometimes exacerbated by news stories uncovering, for example, unclear uses of infant blood spots (DSHS Turned Over Hundreds of DNA Samples to Feds 2010),[3] have created an overall attitude

[3] In the case of *Beleno v. Texas Department of State Health Services* (No. SA-09-CA-0188-FB [U.S. Dist. Ct, West Dist. Tex., San Antonio Div.]) parents sued, claiming that the Texas

of skepticism. Nonetheless, closing the discussion off from the possibilities raised by these technological and interpretative advances does not seem to be a proper solution. Before new instruments are implemented, concrete and tangible challenges have to be identified and discussed in order to maximize benefits coming from innovation and not to leave the protection of vulnerable individuals at the mercy of a technological determinism. An approach based on an open discussion and on empirical data should help to ensure the highest degree of protection, while avoiding overly broad and inclusive restrictive rules that could to be counter-productive and detrimental to those they try to care for and protect.

5. Implementing WGS in newborn screening: in the offing or off in the distance?

Notwithstanding the concerns raised above, some envision a future in which children have their genomes wholly sequenced at birth and grow up with that information integrated into healthcare, clinical prevention and treatment options (Wade *et al.* 2013 and Presidential Commission for the Study of Bioethical Issues 2012, p. 101). Some believe that analyzing personal genomes is best done as early as possible in life (Dondorp, de Wert 2013, p. S7) and that once WGS is sufficiently robust and affordable, all newborns will have their genomes sequenced (Wright *et al.* 2011, p. 56).

Thinking realistically, there are many ways in which genome or exome sequencing could be implemented in newborn populations. WGS, like most clinical tools, can be used for a range of different purposes, on different target populations and under different conditions. WGS could be either offered to asymptomatic newborns or to newborns who have symptoms; the analysis following the sequencing activity could be either a whole genome analysis or analysis aimed at the study of a selected list of conditions; tests could be aimed at diagnosing existing conditions, that could be either treatable or not, or at identifying a carrier status for different diseases, preventable or non preventable, being either early – or late – onset diseases. Legal, as well as social and ethical issues, resulting from the application of new sequencing

Department of State Health Services violated privacy in collecting and storing newborn blood samples, subsequently making them available for research purposes, without seeking parental consent. An out-of-court settlement was reached resulting in the destruction of millions of specimens collected without parental consent.

techniques clearly depend on the chosen approach, on the goals pursued and on the terms of the screening.

To understand the problematic issues arising from a potential application of WGS to newborn screenings, two extreme prototypical situations can be considered. On the one hand, WGS could be employed as a diagnostic support. Under this "problem based approach" (Wade *et al.* 2013, p. 538) WGS represents the last step in a difficult and often very expensive process aimed at explaining the aetiology of a disease in undiagnosed children with health issues. Analysis following WGS will mainly focus on genes with known or suspected association with the symptoms observed in children.

On the other hand, and more problematically, WGS, rather than being conducted with a specific diagnostic or therapeutic purpose in mind, could be performed on children from the general population, replacing and improving upon many existing newborn screening tests, becoming a routine part of public health initiatives.

While the first scenario is, at least in part, already a reality (Saunders *et al.* 2012), the topic of newborn genome sequencing as part of public health strategies remains contentious. Beyond considerations about differences in analytic validity and clinical validity (Wade *et al.* 2013, p. 537), the discourse about the justification underlying the use of WGS in the two described situations relies on a risks-benefits analysis that is in each case differently shaped and assessed.

In very general terms, from a legal stand point all of the decisions have to be informed to the best interest of the child, established by the international Convention on the Rights of the Child (art. 3). This is a primary consideration in all actions concerning children, and is confirmed within the European Union by art. 24.2 of the Charter of Fundamental Rights. This general clause, far from being self-defining, needs to be filled in through a concrete risk-benefit evaluation.

The element substantially differentiating a context in which WGS plays a diagnostic role from the one in which it represents a means for screening an untargeted population is that of the clinical utility of the information obtained from testing. In the former context, where WGS is used as a more precise substitute for traditional genetic tests, the potential health benefit, either in diagnostic or in therapeutic terms is quite easily identifiable.

In the latter setting, where an asymptomatic general population is involved, the potential benefit seems to be overcome by risks deriving from the sheer amount of information to be managed and by a magnification of the number of exposed children.

Moving slightly aside from this very individualistic perspective allows us to consider a further potential benefit: the impact of the daily accumulation of genetic associations with diseases on health statuses predicting abilities.

This question highlights a further fundamental set of challenges emerging from the interaction between the dimensions of care and research.

In this sense, the two extreme situations described dissolve into a plurality of different sub-settings. The application of WGS in newborn populations can be envisaged, for example, as screenings on identified asymptomatic at risk populations. In this case elements from both the described scenarios apply: a specific diagnostic or therapeutic purpose is absent, but the population is restricted and the probability of obtaining clinically useful information can not be deemed to be low. Here the diagnostic and the research dimensions become intertwined.

All of these highlighted factors make the concretization of the best interest of the baby and the related assessment of risks and benefits more and more complex, requiring us to address broader considerations and, in particular, issues about informed decision making. Where a direct benefit is not immediately identifiable, and the borders of care and research – in which different sets of rules find their application – start blurring, provising good information and the possibility to make informed choices represents a safe anchorage in the current web of uncertainty.

6. Disruptive reflections on consent and decision making processes

WGS can be interpreted as an open ended test, producing a large amount of data, including both findings of minor relevance and life changing information. Some findings are related to the health of the particular individual. Others are related to studying interactions between genes and diseases more generally, although these too may be integrated into future individual health care.

The elements combined in such an intricate reality highlight the substantive legal innovation that could derive from the potential shift from traditional NBS screenings, considered to be for the immediate and direct child's benefit, and therefore either mandated by law or based on presumed parental consent, to the more contentious WGS techniques, where the issue of consent emerges again and has to play a fundamental role.

The main challenges to consent in the hypothesized application of new techniques come from the emerging "over time dimension" and from the strict interconnection running between care and research.

Consent, traditionally intended as specific and monolithic, has to cover a wide array of aspects characterized by two features, that are hard to reconcile with the legal dimension: potentiality and probability, on the one side, and the need to stretch the evaluation of the best interest of the child over time.

A preliminary issue is whether consent should cover the methodological approach of the test. In general, it is not common to detail the specific technique used to carry the test out, so the answer to this question depends on whether risks and benefits differ enough from those deriving from targeted genetic studies and analysis to require specific mention (Tabor *et al.* 2011, p. 2917).

A second problematic aspect derives from the progressive overlap between care and research described above. While from the perspective of the care of the individual baby, WGS test results can be (even if not always easily) sorted into three different categories, according to the "relevance" of the information obtained (clinically actionable, clinically valid but not directly actionable and of unknown or no clinical significance), with potential different consequences to the analysis of individual benefit, from a societal standpoint, the immeasurable value of all three kinds of information for research should not be underestimated. The possibility of selecting which parts of the whole sequenced genome to analyze can not disregard the relevance of the information obtained for the research and scientific community. This information could potentially become, overtime, of concrete relevance for society and children in general, as well as of direct importance for the health of the tested child (if anonymization is avoided).

A third scenario concerns the concept of an incidental finding, generally emerging when genetic tests are carried out. The intimate structure of ES/WGS implies that results that have or might have clinical utility will be found at some loci in virtually all participants, making the distinction between "incidental" and "primary" findings arbitrary or at least poorly significant. As has been suggested, variants influencing phenotypes incidental to the main analysis aim – be it care or research – are not incidental to the technical strategy adopted and have therefore to be referred to as "unanticipated results" (Tabor *et al.* 2011, p. 2920).

Great attention has therefore to be paid to the process of communicating information obtained from the test. Even if the best solution appears to be the creation of a panel with a specified number of pediatric conditions to be reported (the approach recently recommended by the European Society of Human Genetics: Howard 2015), this does not fully solve the problem of "unanticipated results" and of the related burden of responsibilities weighing on physicians and researchers.

Once again the time dimension emerges. The variable relevance of the information obtained from WGS and subsequent analyses – which may, overtime, modify its scientific validity or clinical utility – makes the role of the custodian of those data increasingly complicated in terms of disclosure and communication. It this sense, careful consideration has to be given to the child's future autonomy and to her/his right to know or not to know. The convenience of communicating some information, for example related to late onset conditions, to the "mature" child directly has to be scrutinized.

7. Challenges to current normative trends: the protection of personal data in the EU

As stressed above, the integration of WGS in newborn screenings causes the clear and supposedly well-defined distinction between data gathered for clinical and for research purposes to collapse. This blurring effect brings to light legal issues related to the proposed EU data protection Regulation which relate to the use of data gathered in the hybrid context of WGS.

In 2012 the EU Commission proposed a major and systemic reform of the EU legal framework on the protection of personal data and the EU institutions are currently engaged in the advanced stages of the legislative process that will produce the EU General Data Protection Regulation.[4]

While the original draft Regulation seemed to set a proportionate mechanism for protecting privacy without hampering scientific and medical research, some proposed amendments put significant limitations to the practice of research, producing a strong reaction from the scientific community (Impact of the draft European Data Protection Regulation 2013 and Protecting health and scientific research in the Data Protection Regulation 2014).

In particular, the original version included a requirement for specific and explicit consent for the use and storage of personal data, but provided an exemption for research, subject to strong ethical and governance safeguards, such as the approval by a research ethics committee (Article 83) and strict privacy requirements.

The rapporteur of the LIBE Committee proposed some amendments that would significantly reduce the scope of the described research exemption and

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[4] The new discipline is meant to replace rules set by the EU Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

that would therefore severely restrict the use of personal data for scientific research purposes without consent, which – under article 7 of the draft – is required to be "specific, informed and explicit".

The "specific" nature of consent is particularly hard to reconcile with the open ended nature of some research resources – such as biobanks, often relying on broad or generic consent allowing pseudonymised data to be used for a variety of research studies under certain conditions (Data Protection Regulation 2013 and Hallinan, Friedewald 2015) – and for some new techniques producing huge amounts of data, such as WGS.

Moreover, while the Regulation is not clear on whether pseudonymised data are meant to be included within its scope, the proposed amendments are explicit in this sense, creating a disproportionate system in which the use of pseudonymised data is subject to most of the same regulatory requirements as identifiable data. It has been noted:

> Pseudonymised or key-coded data underpin a substantial amount of scientific research, for example large-scale population-based research involving hundreds of thousands of participants, such as biobanks and patient and population cohorts. (Impact of the draft European Data Protection Regulation 2013, p. 3)

The proposed EU Data Protection Regulation, favoring a particular kind of consent, that may be hard to satisfy in case of research using WGS, might end up creating a disproportionate and over-inclusive system, forgetful of the strategies that could place research into a safe ethical framework and disrespectful of the needs of the different research domains unmindful of the different types of personal data processed in scientific research (Science Europe Position Statement 2013).

8. Systemic adjustments to be considered

Beyond ensuring the designing of consent mechanisms that could settle the aforementioned critical aspects, some other considerations have to be prioritized in order to ensure a legal system prepared to properly support ES/WGS outcomes.

First, as the amount of collected data grows, additional levels of protection are required and open access problems are exacerbated. Technology could play a fundamental role in handling private and sensitive information as safely as possible. We need to develop innovative computational strategies, representing new approaches to managing and storing the sheer amount of data produced by routine ES/WGS, limiting and molding access and communication of relevant information, and anonymizing data sets in order to avoid or minimize risks of re-identification of genotyped individuals, with the general aim of providing secure computational environments (Greenbaum *et al.* 2011). Technology might be of some help in governing the complexity arising from the integration of next-generation sequencing techniques into healthcare or medical research, allowing us to face the challenges coming from big data usage and from the augmented degree of complexity in managing that information overtime.

Second, the possibility of taking advantage of the promise of ES/WGS necessarily requires all of the actors involved to be much more knowledgeable about genetics and genomics than they are now. In particular, clear and transparent communication has to be established with parents about newborn screenings and their concrete consequences, with the subsequent need of strengthening genetic counseling procedures. Furthermore, specific training has to be promoted among physicians and nurses in order to build confidence in the use of WGS information and in handling consequences coming from its application. Moreover, as WGS becomes widely available, responsibility for providing WGS and for communicating its results could become the domain of primary care physicians. Specific attention should therefore be addressed to training pediatricians, considering the limited number of genetic specialists (Wade *et al.* 2013, p. 545). At a more general level, public involvement and debates are strategies for assessing the ethical and social issues involved in the innovative scenario described in this Chapter.

The feasibility of all of this depends on a detailed costs analysis. As observed above, with next generation of sequencers bringing down the cost of analyses very fast,[5] data storage costs may overweigh the costs of fresh sequencing when needed, making the argument in favor of storing raw data obtained in the patient file for future use meaningless. More clearly:

> Although genetic services and screening programs aim to improve the health of the population, there is growing concern that the increasing number of genetic tests becoming available at lower costs could compromise the viability of the health care system. Even though the tests themselves may be inexpensive and suitable for large-scale use, the infrastructure and human resources needed to provide appropriate education, counseling, interventions and follow-up are likely to be far more costly. When it comes to the allocation of scarce resources, economic considerations must be considered alongside "notions of justice, equity, personal freedom, political feasibility, and the constraints of current law". (Andermann *et al.* 2008)

[5] Data at URL: <https://www.genome.gov/sequencingcosts/> [last accessed: 26/04/2015].

A careful assessment of the benefits coming from WGS is necessary in order to make decisions about an effective use of limited resources and to benefit the whole health care system (Caulfield *et al.* 2013).

9. Governing innovation: the overtime dimension, the collapsing distinction between care and research, and the need to base rules on evidence

Despite widespread skepticism, the prediction that the implementation of next generation sequencing technologies in newborns, and ES/WS in particular, will become routine can not be ignored. The potential of whole genome sequencing techniques to innovate the context of newborn genetic screening has to be analyzed in-depth as it brings together the need for a rethinking of parental rights, of the best interest of the child argument, of the right to know and not to know, of privacy rights and confidentiality rules, of the evaluation of the clinical utility of an information, and of communication procedures and counseling strategies. Legal instruments traditionally designated to protect individuals' rights appear to be strongly stressed and challenged by an innovative force that can not be deemed to be just quantitative.

In particular, as it has been discussed above, the two main intertwined innovative trends coming from use of ES/WGS techniques in newborns concern, on the one side, the emergence of a dimension of time to be managed and, on the other one, the progressive convergence of the healthcare and the research dimensions.

Informed consent is the instrument through which future complexities arising from technological advancements will have to be managed and controlled. In this perspective, consent, detaching itself from a bureaucratic view, has to regain all of its fullness as an expression of informed will, able to dynamically keep pace with time and with scientific advancement. In line with the discourse carried on in the context of biobanking, consent will have to find new forms in order to channel all of the aforementioned complexity into a sustainable model, able to balance the protection of vulnerable subjects, innovation, care and research needs.

If today full implementation of ES/WGS in newborns might be considered premature, the pace of change may bring that on us soon. Nonetheless, before allowing an expansion of screening programs, lawyers and policy makers have to ensure that sufficient safeguards and a workable regulatory framework are in place. The best way to protect against the risk of having vulnerable subjects being caught up in the current web of uncertainty and in the fluid and potential-oriented domain of WGS techniques, is by rigorously anchoring legal rules and standards to reality, avoiding both hype produced by science and unhelpful precautionary attitudes.

"[T]he nonexistence of evidence supporting population-based P-WGS suggests that extensive research will need to be conducted prior to implementation" (Wade *et al.* 2013). Research on the impact of tests on children and families is needed, discussion and public involvement have to be encouraged, adequate protocols for safe storage of data and privacy and confidentiality procedures have to be implemented. According to an "evidence based law" perspective (Casonato 2014), rules have to be built according to the specificities and features of the reality they are going to govern, avoiding abstract precautionary, and over-inclusive approaches and ensuring that restrictions are guided by concrete evidence.

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Robotics, Innovation and the Law

Chiara Boscarato

1. Robotics is innovation itself

At the beginning of the 21st century the expression "technological civilization" has been coined to indicate the state of society, in which technology takes precedence over any other cultural, religious or economic factors and in which the evolution of science and technology affects human action (Jonas 2002).

Developments in science and technology are directly investing some areas of law, in the process bringing to light grey areas in regulation – mainly those based on relationships between individuals. In this interdisciplinary context, the role of the lawyer is of paramount importance. Advocates in this period of change have to deal with a periodic check of the tightness of legal categories, principles and traditional values; to know in detail the factual reality on which the rule of law is to work; to check the efficiency of any rule in terms of cost/social benefits; and finally to search for new tools to better pursue goals of the legal system.

This is particularly true for robotics. At the centre of converging technologies, robotics is showing considerable importance in the future of technological and social progress. As stated in the document "Global Trends 2030",[1] robotics is one of the areas of technology that will see the greatest growth and be among the "game changers" of the society in the next fifteen years.

It is undeniable that robots are gaining an increasingly important role in the human society, assisting humans in an increasing number of activities. In addition to so-called *service robots*, robots are increasingly intended to come into direct contact with human bodies (exoskeletons; surgical robots) as well as with their social dimension (care robots, robot therapy, companion robots, human-like robots, robots with cognitive and adaptive capacity), thus creating a world in which humans and machines will be in close connection.

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1 December 2012, URL: <www.dni.gov/nic/globaltrends>, p. 90 [last accessed: 07/04/2015].

Robotics and innovation are strictly connected (Hubbard 2014, pp. 7 ff.). But the real importance of robotics in a discussion on “innovation and law” is established by the difference of robotics from every other previous technology, in that it combines data information with a presence in the real world and the capacity to perform physical actions which cannot be completely predetermined.

In this paper I assume Calo’s position on the tripartite factors that distinguish robots from every other technology. The union of hardware and software (embodiment) and the possibility of unforeseeable conduct, added to the capacity of a social behavior, makes robotics the next transformative technology after computers and the Internet (Calo 2014, p. 102). For these reasons it can be said that robotics is innovation itself.

1.1. Embodiment

When software is embedded in a physical body, a new form of artifact takes “life”: a robot.[2]

The robot is thus composed of two distinct parts: the software and the hardware. The embodiment is not a secondary factor. Rather, it requires reflections, including legal, distinct from those prompted by a simple software agent, which is a virtual entity distinct from the physical support on which is assembled.

The property of physical presence gives robots a new and autonomous qualification, allowing them to learn directly from the interaction with the environment in which they operate, and including their physical and concrete relations with humans (Matthias 2004, p. 180).

Robotics combines, for the first time in history, the borders of artificial intelligence (calculation, data analysis, etc.) with the capacity to cause physical damage and to perform actions that cannot be the subject of specific prediction.

Calo states the importance of embodiment as the difference between acting and informing, the so-called “Act Vs Inform paradigm” (Calo 2014, pp. 117 ff.). The ability to provide information in an intelligible format (like a software agent) is not sufficient for the qualification of “robot”; instead, the ability to act in a physical way (embodiment) is essential.

[2] Building an “artificial man” has always been fascinating for the collective scenario, since the time of the Golem of stone that magically came to life. The word “robot” was used for the first time by Karel Čapek, a Czech writer, in his work “Rossum’s Universal Robots”, published in 1920, on the advice of his brother Josef, who had previously used the word “robot” in his short story “Opilec”, published in 1917.

Embodiment permits autonomous robots to express their potential in the broader and more effective way, turning over the assumptions underlying the digital revolution. Robots differ from computers and software precisely in that they are organized to act upon the world. Moreover, embodiment in a human shape encourages the projection of emotion and affectivity: a similar body means similar experiences, creating more understanding and closeness (Darling 2012, p. 2).

1.2. Autonomy

The concept of autonomy related to robotics is statistically the second most discussed after the definition of the robot itself.[3]

Law does not have its own unitary notion of autonomy. Jurists are therefore legitimate wondering whether the understanding of the concept of autonomy requires a certain interdisciplinary.

In artificial intelligence, "autonomy" has been associated with "intelligence", but autonomy is a narrower concept and is looming as just one of the requirements for obtaining the second.

From strict technical point of view, autonomy is the "simple" ability to operate without human supervision in a complex environment. Smithers states that "autonomous robots are usually taken to mean free-ranging mobile robots which are not tele-operated but plan and execute their own actions" (Smithers 1997, p. 90). In practice, an autonomous robot can vary from one not equipped with a cable for power, to one able to implement some independent operations, putting into practice a kind of self-regulation or self-control (i.e.: movement back to the station where it recharges itself). For avoidance of doubt, Smithers suggests to use the word "self-sufficiency" for this category of robot.

According to the Technical Glossary of the Strategic Research Agenda (SRA) for Robotics in Europe,[4] autonomous robots are capable of completing a task in a not completely known environment, without any human interven-

[3] The topic was the focus of a meeting of the project *Epistemic Networks (EPINET) Integrated Assessment of Societal Impacts of Emerging Science and Technology* funded by the European Union under the Seventh FP, Grant Agreement 288971 URL: <http://www.epinet.no> "Making of autonomy in robotics and law", held on 20th-21st February 2014 at the Utrecht University. The workshop was attended by engineers, robotics experts and jurists. One of the most interesting aspects of the meeting was just to note that, even at a technical level, there was no agreement on the definition of autonomy and on what an autonomous robot exactly is.

[4] The glossary, dated July 2009, is available on the official website of the EUROP project URL: <http://www.roboticsplatform.eu/cms/index.php> [last accessed: 07/04/2015].

tion during the process. Often they are opposed to "programmed" robots. This also includes the ability to judge a situation in the environment and decide on it. The level of autonomy therefore depends on the level of human intervention necessary for the accomplishment of the action.

Recent ISO standard 13482:2014 "Robots and robotic devices - Safety requirements for personal care robots"[5] defines autonomy as the "ability to perform intended tasks based on current state and sensing, without human intervention" (Par. 3.1, ISO 8373:2012, 2.2).

It has been noted that this term refers, philosophically speaking, to a conception of "weak autonomy" as opposed to the philosophical definition of Kantian autonomy in the strong sense (Bertolini 2013, p. 225). The difference would lie in the external set of goals, which is made by the human programmer and not by the robot itself.

This kind of "heteronomy autonomy" permits the machine to perform different actions with an increasing level of autonomy: from simple data acquisition and processing, through the choice of the optimal strategy – through inferential paths – to reach a certain goal, and onto interaction with the environment. From a philosophical point of view, a machine with such ability is not "acting", but is only "producing intentional states" (Bertolini 2013, p. 227).

It is often pointed out that the creation of a robot endowed with autonomy in the strong sense would be socially non-desirable. Smithers seems to be of contrary opinion when he says "I suggest that robots and other agents *will have to be autonomous*, i.e., self-law making, not just self-regulating, if they are to be able effectively to deal with the kinds of environments in which we live and work" (Smithers 1997, p. 88). In this sentence the problem moves from "if" autonomous robots are socially desirable to "when" they will be, namely when they will be able to meet social dictates required for their desirability.

Instead of autonomy Calo prefers to use the word "emergence" (Calo 2014, pp. 125 ff.) referring to the "unpredictably useful behaviour which represents a kind of gold standard among many roboticists":

> I use the term "emergence" instead of "autonomy" by design. Autonomy suggests that robots are somehow making a decision to act in a particular way. Little is gained, and much is arguably lost, but pretending contemporary robots exhibit anything like intent.
>
> Johnson sees the essence of emergence as the coupling of complexity and usefulness, the movement of low-level rules to tasks of apparently high sophistication.

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[5] Available in extract at URL: <https://www.iso.org/obp/ui/#iso:std:iso:13482:ed-1:v1:en> [last accessed: 07/04/2015].

Furthermore, an autonomous robot can also become "cognitive" when it uses processes similar to human thinking. This type of robot is capable of intelligent behavior, including the ability to reason, plan and learn, although all three skills need not be present simultaneously. The behavior of the robot is based on an internal representation of the external world, and it can adapt well to a partially unknown and changing environment.

The border between autonomous and cognitive robots is quite nuanced; in most cases, a robot with a high degree of autonomy is also cognitive. However, the two categories can be distinguished because technically an autonomous but non-cognitive robot can exist; for example, it can have only the capacity of perception of the external environment, without the ability to process incoming stimuli and, therefore, to adapt to them.

It should be pointed that there is not, by itself, a necessarily consequential relation between the autonomy of a robot and the unpredictability of its actions. An autonomous robot can implement the "behavior" that has been predetermined by the programmer without the need of a human controller and can learn from its previous behavior how to improve the performance of a task over time. Nevertheless, this does not apply to all autonomous robots.

In my opinion is necessary to distinguish the two levels, to the extent it is possible to keep them technically separate (Hubbard 2014, p. 2). The ability to operate without human control and the ability to change the behavior through learning can generate actions and therefore consequences (including legal ones) different from each other. Furthermore, even the same robot can have different levels of autonomy depending on context.

The so-called "sense-think-act paradigm" explains how a robot is capable of acting in complex ways (Calo 2014). This paradigm is key to distinguish robots from other technologies, since robotics is the only one that combines all the three abilities within a spectrum.

Whatever name you want to assign to this ability, it surely is innovation. And, added to embodiment, it enables robot's action in real world and the interaction between them and humans.

1.3. Human-robot interaction and the blurred boundary between objects and persons

Robots are usually qualified as objects, artifacts in the hands of producers, programmers, owners and users.

But intelligent robots increasingly blur the line between persons and instruments with a great ability of strict interaction with humans.

Particular consideration in the human-robot relationship has to be given to social robots.

Social robots are embodied agents that are part of a heterogeneous group: a society of robots or humans. They are able to recognize each other and engage in social interactions, they possess histories (perceive and interpret the world in terms of their own experience), and they explicitly communicate with and learn from each other" (Dautenhahn, Billard 1999).

This strong interaction between humans and robots as agents will bring a progressive transformation *in* and *of* human's lives. Studies involving state-of-the-art technology already indicate that humans interact differently with social robots than they do with other objects (Breazeal 1999). Such robots arouse empathy, and this enables them to take the status of companion (Coeckelbergh 2010). It has been suggested that a similar emotional feeling is the basis of the attribution of rights to animals (Darling 2012, p. 2).

Robots will most probably develop to such a point that they will attain the level of human capability, at least in some specific activities, and it is not an unlikely prospect that sooner or later robots' capabilities will even surpass those of humans.

But even nowadays the social valence achieved by intelligent robots raises claims of the existence of a "new ontological category for robots somewhere between object and agent" (Calo 2014, p. 119; of the same opinion also Leroux *et al.* 2012, pp. 58 ff.).

In other words, "a new category of behavior which is not purely human or barely animal, yet produces multiple relevant legal effects" (Pagallo 2011, p. 353) is appearing in society.

A debate on the possibility of robots as moral agents is already going on in legal doctrine (e.g. Chopra 2011).

A solution could be to ensure that robots learn specific rules of conduct designed to allow them to interact with the human environment without causing harm. This could be done by laying down standard codes of conduct and ethics. A fictional example of such codes of conduct was given by Isaac Asimov in 1940 in his The Three Laws of Robotics.[6]

Considering this new category in the middle between objects and persons, at some point fundamental human rights like privacy, due process, and

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[6] I. A robot may not injure a human being or, through inaction, allow a human being to come to harm. II. A robot must obey the orders given it by human beings, except where such orders would conflict with the First Law. III. A robot must protect its own existence as long as such protection does not conflict with the First or Second Law.

bodily integrity may be claimed by and/or attributed to non-human agents (Kops *et al.* 2010, p. 525; for same issues regarding robots with biological brain see Warwick 2010, pp. 7-8).

2. Innovation in law: some brief case studies

The new social complexity of robotics has to be translated in legal complexity. Law cannot fight against the emergence of this new technological phenomenon but at the same time law cannot completely ignore it, since law has the role of regulating the inevitable social and economic contests that will accompany this innovation. Human society is being transformed by large mobile "sophisticated robots" with increasingly higher levels of autonomy, intelligence and interconnectivity among themselves and human beings. Robots combine, plausibly for the first time, the generative promiscuity of data with the capacity to produce physical harm. The interaction between data code and input from the environment can generate complex ways of behavior (Calo 2014). This has a number of legal repercussions not so easy to work out, including a significant impact on legal concepts such as capacity, subjectivity, identity, individuality, physical integrity, health, privacy and accountability.

Law and robotics can interact from two different points of view.

On one hand there is a *law of people involved in robotics*, i.e. the discipline that deals with the legal rules affecting the design, production and use of robots governing the effects of this use, with particular application to the humans involved in the creation of the robot.[7]

On the other there is a *law of robotics in itself*, i.e. the set of legal norms governing the actions of robots seen as agents, whose targets are precisely the robots themselves, more or less directly.[8]

A key question is whether robotics needs to be regulated. The balance between regulation and innovation is often very delicate and lawyers have different opinion among who thinks there is the need of new legal tools and who, on the opposite, believes that legal norms are already able to encompass also robotics.

[7] For example, the "Principles of robotics" published in 2011 by the Engineering and Physical Sciences Research Council (EPRSC) and the Arts and Humanities Research Council (AHRC) of Great Britain. The set is composed by five ethical "principles for designers, builders and users of robots" in the real world, along with seven "high-level messages" intended to be conveyed and is available at: URL: <https://www.epsrc.ac.uk/research/ourportfolio/themes/engineering/activities/principlesofrobotics/> [last accessed: 22/04/2015].

[8] *Three Laws of robotics* by Asimov are the greatest example of that.

The lack of adequate regulation, however, can prevent the spread of these new developments. The law as it comes into contact with the world of robots will need regulations in order to – at least – prevent the use of robots in violation of fundamental rights.[9] It will also inevitably establish a deeper dialogue on the role of robots in highly regulated sectors, such as health or work.

The request from robotics developers for a predictable legal framework is strong. In research laboratories, innovative projects risk being abandoned or not improved due to the lack of information on the possibility of putting the final product into the market and the consequences in terms of responsibility and privacy.

> 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. (E. Palmerini *et al.* 2014, p. 10)

In order to figure out the best options in this balance, law and lawyers should acquire the knowledge that will help them understand the challenges posed by robotics.

The major issue concerns liability. Everyone wants to know what happens if something goes wrong. Law is usually very careful to allocate damages in order to not leave victims without compensation. But it has been noted that:

> Discussing responsibility in the context of robotics means more than asking the question "Who is liable if something goes wrong?". It means to understand what happens if we intentionally hand over decision making onto machines. It means to legally react on changing fundamental concepts and consciously create the space for these changes. (Beck S. 2014, pp. 167-181)

In order to establish legal consequences, law uses mechanisms involving characteristics which are typical of human cognition (like *mens rea*; mutual assent; foreseeability) and which cannot be tracked in a machine. On the other hand, the behavior of an intelligent robot can be unpredictable or at least uncontrollable so that there is even talk of *unpredictability by design* (Calo 2014).

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[9] For example, the new EU regulation on data protection, which is expected to be finally approved by the end of 2015, states the importance of *privacy by design*. So, privacy must be taken into account throughout the design of a technological artifact and during the whole engineering process. See URL: <http://eur-lex.europa.eu/legal-content/IT/TXT/?uri=CELEX:52012PC0011> [last accessed: 22/04/2015].

Law and lawyers interested in robotics have to take into consideration that robots will become more and more unpredictable, “intelligent” and in some cases also provided with a sort of *decision-making ability*.

Through four selected brief case studies, the remainder of this section aims to spotlight some of the ways in which robotics is challenging the law.

2.1. Self-driving cars

Since the last century, cars have been a fascinating challenge for the law. In Italy the 1960s-70s witnessed a particularly hot debate about strict liability and the role of the fault (Sacco 1977, pp. 767 ff.). The car sector was particularly suited to influencing the evolutionary paths of civil liability, changing the criteria for allocating and tracing the causation.

There is a dichotomy inherent in the problems posed by technological innovations for civil liability: on the one hand, they have promoted the decline of the role of the fault as a criterion for the allocation of liability; on the other, the practical arrangements of their use in society do not allow a thoughtless application of strict liability.

Hubbard notes that, despite the increasing amount of litigation due to the more computerization of car control systems, research for the development of fully self-driving cars continues. This means that tort litigation does not necessarily affect innovation in robotics (Hubbard 2014, p. 44).

A self-driving car is able to perceive (through sensors) the surrounding environment and is equipped with software incorporating road code and having a decision-making ability. The advantages of a self-driving car are: greater precision than a human driver; maximum perception of the environment; absence of distractions or drowsiness; and the impossibility of alterations due to alcohol or drugs. In other words, the car can act independently from human instructions. Rather, it acts on information collected and analyzed during the drive, choosing the best way to act (drive) according to its software processing real time information. It will be completely autonomous.

The Google *self-driving car* currently circulates freely in some states of US. BMW has predicted that cars will be highly automated by 2020 and completely *driverless* by 2025.[10]

From Google’s experience we can say that driverless car drive is safer than human driver one. That means that driving is risky because drivers are hu-

10 URL: <http://singularityhub.com/2013/03/21/bmw-cars-will-be-highly-automated-by-2020-driverless-by-2025-behind-the-curve/> [last accessed: 24/04/2015].

mans (Vladeck 2015, p. 126). These developments suggest two clusters of legal issues. The first one involves the problem of the definition of "vehicle" itself.

The Geneva Convention on Road Traffic (1949)[11] states that every kind of road vehicle "shall have a driver" who is "at all times […] able to control" it. So: is a self-driving car a vehicle in this context?

Current autonomous vehicles are under the control of a human driver in the sense that she is entitled to intervene and stop them anytime. If the vehicle remains under this sphere of control it is probably suitable to meet the requirements of the Geneva Convention, even if the human is not the real driver in the ordinary sense.

However, American road codes are very different from State to State. For example, New York State requires that the driver keeps a hand on the steering wheel, but it does not specifically require a human-driver.[12] Even in absence of legislation, the Stanford Center for Internet Studies (CIS) considers driverless cars lawful.[13]

By comparison, the Italian road code states (article 46) that a vehicle is any machine of any specie which is conducted on the road by a human.[14] This definition might be a problem for a driverless vehicle if one reads into this requirement that it be conducted by a human.

The second problem involves tort liability.

Some Authors distinguish between errors eventually relatable to humans on the one hand and inexplicable accidents on the other (Vladeck 2015, pp. 127 ff.). The first often involves a design or manufacturing defect, an information defect, or a failure to instruct humans on the safe and appropriate use of the product. Applying this to robotics does not differ from usual product liability. The latter case involves the situation of an accident impossible to be attributed to a human, regardless of whether he is the designer, the manufacturer or the programmer. The approach could be to assume the presence of a defect simply by the event of an accident. This assumption could work in a system of common law but probably meets some resistance in a civil law sys-

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11 Available at URL: <https://treaties.un.org/pages/ViewDetailsV.aspx?src=treaty&mtdsg_no=xi-b-1&chapter=11&Temp=mtdsg5&lang=en> [last accessed: 24/04/2015].

12 NY Code - Section 1226: Control of steering mechanism - See more at URL: <http://codes.lp.findlaw.com/nycode/VAT/VII/33/1226#sthash.0nWqtfze.dpuf> [last accessed: 24/04/2015].

13 URL: <http://blogs.law.stanford.edu/robotics/2013/02/05/automated-vehicles-are-probably-legal-in-the-united-states/> [last accessed: 24/04/2015].

14 URL: <http://www.aci.it/i-servizi/normative/codice-della-strada/titolo-iii-dei-veicoli/art-46-nozione-di-veicolo.html> [last accessed: 24/04/2015].

tem. In Italy, for instance, even under strict liability the evidence of the defect and the causal link between it and the damage has to be proved.

Others suggest adopting no-fault insurance schemes whose costs are charged on to manufacturers, since it does not require a test of wrongdoing and it is cheap to administer (Hubbard 2014, pp. 78 ff.).

A second-level question is how to distribute liability among the designers and the manufacturers. The manufacturer liability under Directive 85/374/CEE establishes liability on the producer of the final product.

Other possible approaches range from the creation of a sort of legal personhood for autonomous cars (Leroux *et al*. 2012, p. 58) to the application of canine ownership liability (Duffy, Hopkins 2013, p. 116).

And the possibility of a reduction of liability keeps emerging due to the social desirability of such vehicles (Hubbard 2014, pp. 78 ff.).

Moreover, the autonomy of the car does not exclude responsibility of the human on board who could be seen to have a duty of attention in order to be able to intervene in case of malfunction. The human driver retains responsibility for maintenance and for overall control of use, so she probably does still need some sort of driving license.

At this point, the only certain statements are that the transport sector will be the first to see the use of fully autonomous robots and that it will be the test case for the law.

2.2. Da Vinci surgical robot and civil liability

In the field of medicine, surgical robot allows a doctor to implement an intervention plan optimized through the combination of statistical and specific pre-operative information from previous clinical cases. The approach is then calibrated on the actual patient and, if necessary, updated during the surgery (Palmerini *et al*. 2014).

Surgical robots can be seen as sophisticated scalpels in the surgeon's hands, scalpels that provide increased accuracy, strength and effectiveness in the face of the decrease in tactile feedback and sensitivity that can afflict human hands. These gains need to be weighed against the possibility of technical failure of the machine and the large costs purchasing and using it. At present, the surgeon is the one which conducts the operation via the tele-operation of a robot with the possibility, however, of delays in performance or mechanical or electronic malfunctions.

The world's most popular surgeon robot, thanks to innovative technical features and a strong marketing push (Beck M. 2013), is the Da Vinci of Intuitive Surgical Inc.

In the US, the intensive use of the Da Vinci is raising several ethical problems and numerous lawsuits for damages are already underway before the Courts (Sharkey 2012, pp. 276-291; Hubbard 2014, p. 44).

Under European regulations, the Da Vinci cannot be regarded as a *machine* subject to the Machinery Directive 2006/42/CE, but rather as a *medical device*, by which is meant "any instrument or software intended to be used specifically for diagnostic and/or therapeutic purposes" (Directive 93/42/EEC).

To define the relationship between the use of the surgeon robot and ordinary medical liability, the evaluation of the specific circumstances is necessary.

A stalling of the robot may be due to a malfunction. In this case, it is certain that the producer is responsible under the rules of product liability and the hospital may take action against the producer. The individual victim has to support her claim for damages with proof of the defect. This is, however, conditional on the knowledge of the data processed by the robot, in a sort of inside "black box", which registers each and every command sent to keep the process running in addition to internal errors that may have occurred. Under the current terms of sale for the Da Vinci, however, these data are not accessible to any of the patient, the surgeon and the hospital, even in the case where the latter was the owner of the robot; they can be extracted only by a technician from *Intuitive Surgical Inc.* (Palmerini *et al*. 2014, p. 98).

This clause is a significant drawback in the case of a problem. The hospital is not able to assess in advance whether the damage is attributable to the malfunction of the robot or the surgeon, and therefore does not have any certainty about its legal responsibility. The injured person is in the same position, and will be forced to sue both the hospital and the manufacturer, with a significant increase in legal costs. Therefore, it seems necessary that everyone involved has the opportunity to access this information (Cooper *et al*. 2013).

For these reasons, the suggestion has been advanced for an European law that imposes an obligation on the manufacturer to implement software that allows access and use of its data by the user – or, at least, the obligation to provide such data on request (Palmerini *et al*. 2014, p. 98).

This raises an interesting reflection on the relationship between the use of these technological applications and the standard of care required in the conduct of the profession. If it were found that the Da Vinci is more precise and more reliable than traditional surgery, the surgeon could be held responsible for not having used it during the surgery (and thus not having complied with the new safety standards). However, at the human operator retains the general duty to supervise the robot, even in the case where some activities have been delegated to the machine.

If damage occurs despite the fact that robot has worked perfectly, the case does not differ from ordinary medical liability (Boscarato 2011). The good outcome of the medical performance is often the sum of many individual activities. Each member of the surgical team is responsible for her own actions and the tasks entrusted to her, but she must also carry out a check on the conduct of other members, with the duty to intervene to remedy the mistakes of others where these are obvious and not inherently "sectorial".

Within the team working on Da Vinci aided surgery, there are two different profiles: only the operator can manoeuvre the mechanical arms and has a 3D monitor that gives him a feel closer to a concrete surgery. Other surgeons can only follow the course of the intervention on a 2D screen that is external to the robot and its working mechanisms. In other words, the surgeon at the consolle possesses exclusive information that confers a privileged position on him in the evaluation of the surgery. This information are not available to other doctors, or cannot be shared with them, given the difference in quality of the tools at their disposal and the fact that the mechanical arms completely obscure the patient's body, making it impossible oversee the surgery directly (Palmerini *et al*. 2014, p. 96).

Ultimately, the civil liability due to an error in the movement of the robot arm or a bad judgment on how to proceed should be attributed exclusively to the operating surgeon. Other surgeons are exempt from responsibility because they are not physically able to work, being bound to a subordinate position.

In the US more and more law firms working in the medical malpractice area have developed competence in cases involving the Da Vinci, in order to solicit customers in an expanding area, especially after serious cases of inadequate training of surgeons (Carreyrou 2010).

The influences on informed consent are easily imagined. It is possible that, given the huge costs for the installation of a robot surgeon, the hospital and the doctors may exert considerable persuasive force on patients in order to convince them to undertake the surgery by robot and thus help amortize the costs of the machine (Fingerhut 2011, pp. 97-98).

In such a case, the existing regulations on informed consent can find useful application, making sure that the information provided to the patient sets out the details of the robotics procedure, including an explanation of the use of the robot, the possible risks and side effects as well as the positive reasons, and especially the differences compared to conventional surgery. The patient should be placed in the position of choosing freely and consciously whether or not to undergo robotic surgery. Because of the great cost of the machinery,[15] the use of the robot shall be recommended only when it is absolutely better than the traditional laparoscopy, for example because the procedure is complicated and the area to be difficult to operate or particularly delicate (Palmerini *et al*. 2014, p. 95).

Finally, the new frontiers of surgical robotics open the possibility, in the near future, of tele-operations through the control of a surgical robot that is physically located in another room or even cities. This possibility will raise obvious problems of private international law, including the risk of "forum shopping". The provider may choose the state from which to maneuverer the robot based on the most favorable law (which excludes the penalty, favors a different burden of proof or has a minor damages in case of liability) (Sharkey 2012, p. 287; Palmerini *et al*. 2014, p. 97).

2.3. 3D printing, trademark, copyright and liability

3D printing in its early form has been around since 1980s as "additive manufacturing". A 3D printer is a machine that can turn a digital design (electronic blueprints) into a physical/solid object through a sequential layering process. The process starts with slicing a computer aided design model into cross sections as a guide to printing and sending it to a 3D printer; then the 3D printer builds the object in a series of layers on a base. It is particularly good for customizing objects at a price of technology that is now very affordable. The risk of this new technology is that it can make the unauthorized copying of objects easier than traditional manufacturing, with implications for trademarks, patents, design rights and copyright (Dali 2013).

The technology is so new that the repercussions of using a 3D printer for inappropriate or illegal purposes are not well established. What if someone starts printing objects protected by trademark or copyright law?

A great example from the past provides some guidance on how intellectual property law can respond to new technology. In Sony v. Betamax (1984) the Court held that the VCR manufacturer is not liable for creating a technology that some customers may use for copyright infringing purposes, so long as the technology is capable of substantial non-infringing uses. In other words, where a technology has many uses, the public cannot be denied the

[15] The Da Vinci is sold at a price of about 2.5 million euro, to which must be added the cost of maintenance (in Italy are free for the first two years and then annually amounted to 10% of the cost of the robot), the fitting room costs and those of training surgeons. It is estimated that each intervention costs about 1500 euro.

lawful uses just because some may use the product to infringe copyrights (Carson 2014). The application to 3D printing is clear: a purely private use of a 3D printer might not infringe design rights, but you could infringe the copyright of more artistic objects or print functional objects which do not fall under copyright or design right protection like spare parts or accessories (Bradshaw 2013). You could even print the components of a robot.

3D printing is often linked with robotics in that they use some of the same underlying software and hardware; they are made up of very similar components (sensors) and they raise similar issues of embodiment (Calo 2014, p. 122).

The interaction between 3D printing and product liability is far to be simple. Who can be held responsible in case of damage? The manufacturer or designer of the product, the owner of the printer or the person who thought it was a good idea to produce and use a "print-at-home" untested object?

Strict liability would only be applied in a case where the seller is a professional figure. A non-commercial seller is responsible for defective products only in the case of negligence. It is doubtful at which category a "print-at-home" object (e.g. the hardware for a robot) belongs and what kind of liability will be applied (Freeman Engstrom, 2013). A solution could be holding manufacturer liable for a design defect because the product is harmful even when properly assembled. The problem is that in these cases the product is not even a product, since it is intangible, just a code. The concerns about robot software are very similar and "show how the interaction of product liability law and embodiment presents the prospect of systematically undercompensating victims" (Calo 2014).

Concerns increase yet further over the possibility of making a 3D printed gun (Bradshaw 2013).

Ultimately, the current paradigms of liability are poorly matched to this technological advance. Good legislation that imposes controls on the creation and sharing of 3D design files is desirable and needed.

2.4. Killer robots and humanitarian law

Fully autonomous weapons – also known as autonomous weapons systems or "killer robots" – are weapon systems that can select and fire upon targets on their own without human intervention. They do not yet exist, but high-tech armies – not only in the US, but also in China, Germany, Israel, South Korea, Russia, and the U.K. – are developing more autonomous machines for the battlefield. Fully autonomous weapons are expected in 20 to 30 years (Human Rights Watch 2012). Furthermore, robots with various degrees of autonomy and the power to determine when to kill already exist, like drones or remotely piloted aerial vehicles.

Fully autonomous weapons would not comply with international humanitarian law standards, such as the rules of distinction, proportionality and military necessity, and would threaten the fundamental right to life and principles of human dignity.

The principle of distinction forbids attacks directed against civilians, allowing only ones directed to military targets. The application of this requires the ability to distinguish between civil and a military targets and implies a form of judgment. This would be a challenge for autonomous weapon systems, since they cannot be programmed to face every possible concrete situation.

Charging a person with the liability for the wrongful action of a fully autonomous weapon could be difficult since the absence of the intent to commit the crime and the difficulty to foresee the action of the weapon.

Moreover, the principle of dignity – stating that every human being is worthy of respect – could hardly be inserted in a software. The weapon would be incapable of understanding the value of human life, but endowed with the power of jeopardize it.

Human control on killer robot is essential in order to ensure the protection of humanitarian law and international human rights.

A "Campaign to Stop Killer Robots" was launched in April 2013 as an international coalition aiming at the pre-emptive ban of fully autonomous weapons.[16]

Recently, a US drone (unmanned aerial vehicle) killed Italian and American hostages of Al Qaeda during an anti-terrorist operation in Pakistan. Usually, drones are allowed to strike against suspected militants even if the CIA is not sure who they are. President Obama ordered the review of the protocols for activities involving bombing with drones.[17]

As these examples demonstrate, current legal rules of liability, care, and limited warfare often fit imperfectly, if at all, with the challenges presented by robots. The involvement of lawyers who are also educated in the technology involved will be an important element in the degree to which law innovates successfully in response to this emerging field.

[16] URL: <http://www.stopkillerrobots.org/> [last accessed: 07/04/2015].

[17] URL: <http://www.wsj.com/articles/american-italian-hostages-killed-in-cia-drone-strike-in-january-1429795801> [last accessed: 24/04/2015].

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The Freudian Uncanny Effect: The Case of Intelligent Systems

Paola Giulia Belloli

1. Notes on present and future scenarios for the social acceptance of human like machines

1.1. Technological background: the new merging of Artificial Intelligence and Robotics

Robotics is one of the most quickly growing economic sectors and is considered among the "game changers" of the society in the next 15-20 years.[1] Cognitive robots are already a reality. A cognitive robot is an autonomous robot modeled on brain structures and human cognitive processes: the neural processes of the brain are reproduced through artificial neural networks or learning algorithms. It has the ability of reasoning (the process of modification of the knowledge base of the robot through logical manipulation of the available knowledge); the ability of planning (computation and selection of tasks, policies and procedures for goal-directed robot behavior) and learning (process of modification of the knowledge base of the robot gained through the interaction with the environment, including people, that may produce a persistent change in the robot behavior) (Leroux, Labruto 2012).

Some further definitions illuminate what is in progress in technology for Social robots and Evolutionary robots.

Social robots are "embodied agents that are part of a heterogeneous group: a society of robots or humans. They are able to recognize each other and engage in social interactions, they possess histories (perceive and interpret the world in terms of their own experience), and they explicitly communicate with and learn from each other" (Billard, Dautenhahn 1999).

[1] Writing the following outline of technological and scientific background, I owe a particular intellectual debt to the papers of Santosuosso (2014a; 2014b; 2014c).

Evolutionary and/or developmental methods allow us to synthesize robots that develop their skills autonomously in interaction with the physical, and eventually social, environment on the basis of an adaptive process driven by the ecological conditions in which the robots operate and on the basis of an utility function designed by the experimenter. Such interaction is commonly supposed to require a body through which they are able to exploit the opportunities that their embodied and situated nature provides them. With Evolutionary robots we refer to a methodology that uses evolutionary computation to develop controllers for autonomous robots, which allows them to operate in close interaction with the environment and without human intervention. The approach is inspired by the Darwinian principle of selective reproduction of the fittest. Evolutionary robots use neural networks, genetic algorithms, dynamic systems, and biomorphic engineering. Experiments are in progress which show that the survival probability (for instance in terms of access to the source of energy) of a species is affected by the behavior of other species.[2]

In addition, it is worth noticing that cloud computing technology now allows us to overcome the limitation of a single, even well sophisticated, robot which works as an individual. Rather, the creation of a working group (so-called "cloud robotics"), with an improvement of services offered to citizens, is becoming possible. Moreover, in the Internet of things (IoT), objects become recognizable and acquire intelligence due to the ability to communicate information about themselves and to gain access to aggregated information from other objects. The aim of the IoT is to ensure the identity and the overlay of the maps of the electronic and digital world with respect to the physical environment.

In 2013, the *Human Brain Project* (HBP), a flagship project launched by the EU, and the *BRAIN Initiative* in the US,[3] changed the landscape of neuro-

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[2] Floreano D. is the author of interesting researches in the field of Evolutionary robots: URL: <http://www.youtube.com/watch?v=IOTYb05PGjw> [last accessed: 07/04/2015].

[3] The Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative, the full title of the project, is part of a new U.S. Presidential focus aimed at revolutionizing our understanding of the human brain. The project is presented as follows: "By accelerating the development and application of innovative technologies, researchers will be able to produce a revolutionary new dynamic picture of the brain that, for the first time, shows how individual cells and complex neural circuits interact in both time and space. Long desired by researchers seeking new ways to treat, cure, and even prevent brain disorders, this picture will fill major gaps in our current knowledge and provide unprecedented opportunities for exploring exactly how the brain enables the human body to record, process, utilize, store, and retrieve

science. The European *Human Brain Project* is extremely ambitious and aims "to build a completely new information computing technology infrastructure for neuroscience and for brain-related research in medicine and computing catalyzing a global collaborative effort to understand the human brain and its diseases and ultimately to emulate its computational capabilities".[4] According to Idan Segev,

> […] one major purpose of the Human Brain Project is to collate information about the brain from various advanced research approaches and make it possible to build models of brain activity through the use of powerful supercomputers. This will enable the attainment of a deeper understanding of the brain and its illnesses, and at the same time make possible development of powerful computer technologies and brain-driven robotics. (Segev 2013, p. 1)

The European project is a clear demonstration of the exceptional convergence that is happening in these years among cognitive neuroscience, robotics, intelligent machines and AI. There is a drastic change of the landscape both in theoretical and social terms. The impact on society is significant and affects the organization of production, markets, research activities and social relations in their broader sense.

The advancement of technology related to the study of the human brain and to the development of artificial intelligence suggests that a new branch of legal studies, which precisely focuses on the legal issues related to this field, is emerging and is worth study. I will tackle this topic in Section 5. As an opening matter, however, I think it is important to investigate the difficulty people have in accepting machines which possess human-like properties and high level of intellectual abilities. The relation of people with robotics is not simply a matter of application of neuro-scientific findings to a specific field (robotics). It is rather a full interaction among neuroscience, Artificial Intelligence, computing and robotics (Lancaster *et al* 2013).

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vast quantities of information, all at the speed of thought". The Brain Initiative And Brain Research Through Advancing Innovative Neurotechnologies are service marks of the U.S. Department of Health & Human Services (HHS), URL: <http://www.nih.gov/science/brain/> [last accessed: 31/01/2014]. See also Advisory Committee to the NIH Director, INTERIM REPORT, Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Working Group, September 16, 2013, URL: <http://www.nih.gov/science/brain/09162013-Interim%20Report_Final%20Composite.pdf>.

4 [Online], URL: <https://www.humanbrainproject.eu/it> [last accessed: 07/04/2015].

1.2. The difficulty of accepting human-like machines

When we talk about machines having human-like properties we don't think only of their human-like shape, but also of their intellectual human-like abilities, as in humanoid robots, Operative Systems, entities having a high level of Artificial Intelligence and so on. Some authors believe that cultural backgrounds have a strong influence on the acceptance of robots in general.

Christoph Bartneck, for instance, has conducted an experiment comparing a group of Japanese subjects with a group from the USA. While the US participants mildly increased their likeability ratings for increasingly anthropomorphic robots, the Japanese participants showed a reverse trend: the more human-like the robots were the less they were liked. The author stresses the role that the strong presence of robots plays in Japanese popular culture, starting with Astro Boy (Bartneck 2008, p. 553).

There are many famous humanoid robots, including, for instance, Kismet and Leonardo made at MIT in USA, Roman made in Germany, and WE-robot and Saya made in Japan, which all could surprise people and prompt some kind of special feeling.

The goal of robotics is to bring real robots into our society, and how robots enter human social space is an interesting question. If we consider the safety aspect, for instance, the rapidly ageing population in many countries is placing increasing strain on healthcare services. Robots can be a way to assist people to stay healthy and safe in their own homes. However, despite the need for such assistant devices and the success of some healthcare robots, other robots have had a poor response. If healthcare robots have a chance to be successful, they have to be accepted by elderly people. For acceptance of robots, a motivation for using them is needed, and they have to be sufficiently easy to use, and able to give physical, cognitive and emotional comfort.

But, what do we mean by “physical, cognitive and emotional comfort”? What emotions does the new entity produce? How do humans deal emotionally with the new reality that advances in robotics is creating? How do emotions enter the law and policy decision-making?

In this paper I'll discuss: firstly, how Sigmund Freud described and analyzed in 1919 the uncanny feeling and the uncanny effect of the automata and other similar situations; secondly, the Masahiro Mori observation, in his *Uncanny Valley* of 1970, that human-like robots can produce an uncanny effect in certain conditions is presented; thirdly, in Section 4, I'll explore the possible uncanny effects resulting from the contact of the human being with an Operative System rather than with a physical entity human-like. Finally I'll outline the innovative effect that a wide development of emotionally-oriented relationships between human beings and machines can have on the law in different fields.

2. A challenging effect of automata: the Freudian uncanny

Authors who have studied the impact of robots on society often quote Sigmund Freud's uncanny effect, generally assuming that "uncanny" simply equals "astonishing". In my view, a preliminary clarification is needed about what really Freud meant using the word uncanny. With this established, the role of this concept in our present experience of robots can be better defined, and the way the law may deal with such a new social phenomenon becomes clearer.

*2.1. The concept of "uncanny" in Sigmund Freud: "*Das Unheimliche*" (1919)*

In common use, uncanny means that something is scary, arousing fear, terror and horror. The existence of a specific word in different languages (German: *unheimlich*; Italian, *perturbante*) suggests that there is a particular feeling which requires a special word whose content is worth consideration. Freud's essay, *Das Unheimliche* (1919), aims to investigate the common core of things that we consider uncanny:

> The subject of the 'uncanny' is a province of this kind. It is undoubtedly related to what is frightening – to what arouses dread and horror; equally certainly, too, the word is not always used in a clearly definable sense, so that it tends to coincide with what excites fear in general. Yet we may expect that a special core of feeling is present which justifies the use of a special conceptual term. One is curious to know what this common core is which allows us to distinguish as 'uncanny'; certain things which lie within the field of what is frightening. (Freud 2003, p. 124)

The meaning the word *unheimlich* has acquired in its evolution and, on the other side, the quality of people, things, impressions, experiences and circumstances that arouse in us a sense of uncanny, both suggest that the uncanny is a feeling of generic fear that develops when a thing is perceived as familiar and extraneous at the same time, causing general anxiety coupled with an unpleasant feeling of confusion and alienation. The uncanny is that class of the frightening which leads back to what is known of old and long familiar. Freud wonders how this may be possible and under what circumstances something which is familiar can become uncanny and frightening.

Freud notes that the German word *unheimlich* is the opposite of *heimlich* and *heimisch* (home, family, new). So one might be tempted to infer that something uncanny scares us because it is unknown, unusual. But not everything which is unknown or unusual is also scary, and not everything new and unfamiliar is frightening. What is new *can* become frightening, but this is not always the case. Something has to be added to novelty and unfamiliarity in order to make it uncanny.

Freud starts from Jentsch's study of the uncanny (1906)[5] and stresses his disagreement with Jentsch who had not gone beyond the relation of the uncanny to the novel and unfamiliar. According to Jentsch, intellectual uncertainty is the essential factor in the production of the feeling of uncanniness. The better orientated in his environment a person is, the less readily he will get the impression of something uncanny with respect to the objects and events in it. As Freud says, it is not difficult to see that this definition is incomplete, and we will therefore try to proceed beyond the equation of uncanny as unfamiliar.

Before indicating what is the additional element, Freud observes the peculiarity of the German word *heimlich*, which means both "familiar" or "pleasant" and also "hidden" and "kept hidden". Thus *heimlich* constitutes a Janus word:

> What interests us most [...] is to find that among its different shades of meaning the word '*heimlich*' exhibits one which is identical with its formal antonym, '*unheimlich*'. What is called *heimlich* becomes *unheimlich.* [...] this reminds us the this word '*heimlich*' is not unambiguous [...]: the one relating to what is familiar and comfortable, the other to what is concealed and kept hidden. (Freud 2003, p. 125)

A Janus word is a "word having opposite or contradictory meanings, as sanction or cleave".[6] Sometimes the same concept is expressed by the words Enantiosemy or Auto-antonym, or Contronyms.

Heimlich is a special case of Janus word. The German word *heimlich*, as Freud noted, among its various meanings (including: family, domestic, intimate) has one equal to the meaning of its opposite *unheimlich* (strange, fan-

[5] Ernst Anton Jentsch (1867-1919), German psychiatrist, known for his treatise *On the Psychology of the Uncanny* (1906). He is best remembered for the influence on Freud in his treatise *The Uncanny*.

[6] American Heritage Dictionary of the English Language, 2011^{5th} by Houghton Mifflin Harcourt, URL: <https://www.ahdictionary.com/word/search.html?q=Janus+word&submit.x=0&submit.y=0> [last accessed: 07/04/2015].

tastic, that raises unknown fears). The same meaning of *heimlich* and *unhemlich* is: “concealed”, “hidden away from view”, “secret”, or “what should remain secret, but instead came to light”.

2.2. The psychoanalytic interpretation of the uncanny effect

The meanings of *Heimlich* and *Unheimlich* play an important role in the Freudian analysis about the uncanny feeling. He assumes as starting point of his research the examples indicated by Jentsch of situations which arouse an uncanny effect: the doubts whether an apparently animate being is really alive, or conversely, whether a lifeless object might not be in fact animate. He refers in this connection to the impression made by waxwork figures, ingeniously constructed dolls and automata. He adds the uncanny effect of epileptic fits, and of manifestations of insanity, because they excite in the spectator the impression of automatic, mechanical processes at work behind the ordinary appearance of mental activity.

Freud disagrees with the Jentsch’s analysis and maintains that the uncanny effect is not caused by uncertainty about whether an object, like the doll Olympia in Hoffmann’s story[7] (which is not the most frightening character in the story), is alive or inanimate. It is well known that children do not distinguish between living and non-living objects. Indeed, they take pleasure in dealing, for example, with the dolls as living persons. What arouses horror and fear in the story is the figure of the Sand-Man, ripping the eyes of children.

> I think, that the uncanny attaches directly to the figure of the Sand-Man, and therefore to the idea of being robbed of one’s eyes and that intellectual uncertainty as Jentsch understands it, has nothing to do with this effect. Uncertainty as to whether an object is animate or inanimate, which we were bound to acknowledge in the case of the doll Olympia, is quite irrelevant in the case of this more potent example of the uncanny. (Freud 2003, pp. 138-139)

The psychoanalytic experience shows that the fear of damaging or losing the eyes is a terrible one in children. A study of dreams, phantasies and myths has taught that anxiety about one’s eyes, the fear of going blind, is often enough a substitute for the dread of being castrated. The self-blinding of Oedipus was simply a mitigated form of the punishment of castration – the only punishment that was adequate for him by the *lex talionis* (Freud 2003, p. 139).

7 Ernst Theodor Amadeus Hoffmann, 1776-1882.

So it becomes clear that the uncanny effect arises from something removed, from something familiar, that, because of removal, becomes stranger and that re-emerges into consciousness. Freud makes then some examples of uncanny themes; it seems to me that the more interesting are the theme of the double; the compulsion to repeat and the omnipotence of thought.

The theme of the "double" is the recurrence of the same thing, as in the cases of impersonator or twins. The idea is connected with reflections in mirrors, with shadows, with the belief in the soul and with the fear of death. About the double, Freud writes,

> The double was originally an insurance against the destruction of the self or [...], an 'energetic denial of the power of death' and it seems likely that the 'immortal' soul was the first 'double' of the body. The invention of such doubling as a defence against annihilation has a counterpart in the language of dreams, which is found of expressing the idea of castration by a doubling or multiplication of a genital symbol. (Freud 2003, p. 142)

As for the compulsion to repeat, the unintentional repetition of the same situation, or the recurrence of similar events, which follow one another at short intervals (e.g. we meet the n. 62 several times in the same day), with the concurrence of certain circumstances, raises an uncanny feeling. As Freud notes, this feeling recalls to the mind that sense of helplessness that one feels in certain dreams and leads us to attribute a meaning with demonic characteristics, which causes an uncanny effect. The idea of eternal return implies the element of passivity, the horror caused by the sense of imprisonment, of coercion, of inevitability of this experience.

Uncanny feelings can also be caused by the idea that our thoughts determine events (the omnipotence of thought). For instance, that you could kill someone just by wishing, that our desires can be fulfilled immediately, that the dead people can come back, or that someone could harm us only with his thought (as the dread of evil eyes). A typical example is given by the Romanic figure of the *Jettatore*, a living person having particularly unattractive attributes to whom we ascribe a secret, devilish intention of doing harm and who we think has the power to convert the intention into effective action:

> We can also call a living person uncanny, that is to say when we credit him with evil intent. But this alone is not enough; it must be added that this intent to harm us is realized with the help of special powers. A good example of this is the 'Gettatore', that uncanny figure of Romanic superstition. (Freud 2003, p. 149)

In conclusion, Freud says that every affect belonging to an emotional impulse, whatever it is, is transformed, if it is repressed, into anxiety. The frightening element is something repressed which *recurs*. It does not matter whether what is uncanny was itself originally frightening. If this is indeed the secret nature of the uncanny, we can understand why linguistic usage has extended *das Heimliche* ('homely') into its opposite, *das Unheimliche*. For this uncanny is in reality nothing new or alien, but something which is familiar and well-established in the mind and which has become alienated from our thinking only through the process of repression.

3. The Uncanny Effect of Human-Like Robots: Masahiro Mori, *The Uncanny Valley* (1970)

The theme of the "uncanny" has also been taken up and developed by the Japanese engineer Masahiro Mori, albeit in a more general sense of "horror and disgust", that seems not to consider the Freudian psychoanalytic analysis. In 1970 Mori wrote the well-known essay the *Uncanny Valley*. He starts from the following consideration:

> There are mathematical functions of the form y = f(x) for which the value of y increases (or decreases) continuously with the value of x. For example, as the effort x increases, income y increases, or as a car's accelerator is pressed, the car moves faster. […] Climbing a mountain is an example of a function that does not increase continuously: a person's altitude y does not always increase as the distance from the summit decreases owing to the intervening hills and valleys. I have noticed that, as robots appear more humanlike, our sense of their familiarity increases until we come to a valley. I call this relation the "uncanny valley". (Mori 1970, p. 1)

The name captures the idea that an almost human-looking robot will seem overly strange to some human beings, will produce a feeling of uncanniness, and will thus fail to evoke the empathic response required for productive human-robot interaction. In other words, as robots appear more human, they are perceived as more familiar, until a point is reached at which subtle imperfections give a sensation of strangeness.

Mori noted that some prosthetic hands are, at first glance, indistinguishable from human hands. However, if you shook one, the lack of soft tissue and cold temperature would give you a shock. The fact that some of these hands can move automatically only increases the sensation of strangeness. Mori wrote:

> In mathematical terms, strangeness can be represented by negative familiarity, so the prosthetic hand is at the bottom of the valley. So, in this case, the appearance is quite humanlike, but the familiarity is negative. This is the uncanny valley. (Mori 1970, p. 2)

Mori graphed, with a Cartesian diagram (see Figure 1), the relation between human likeness and perceived familiarity: familiarity increases with human likeness until a point is reached at which subtle deviations from human appearance and behaviour create an unnerving effect.[8]

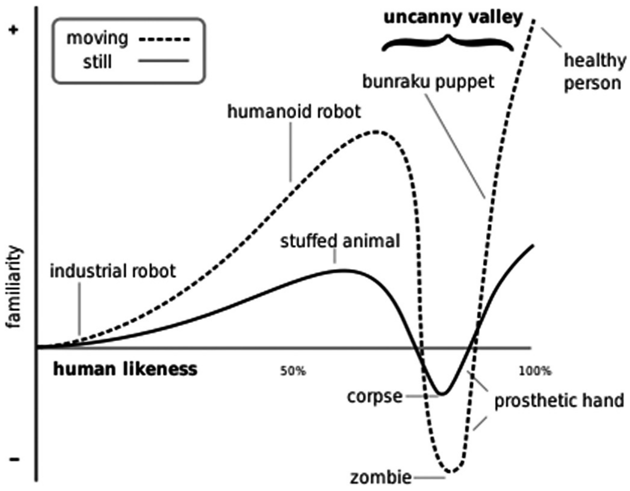

Figure 1. Graphic of the uncanny valley (source: Mori 1970).

Building a complete android, Mori believed, would multiply this eerie feeling many times over: machines that appear too lifelike would be unsettling or even frightening inasmuch as they resemble figures from nightmares or films about the living dead. Therefore, Mori cautioned robot's designers to consider this key point: they should not make the second peak their goal, that is total human likeness, but rather that they should aspire only the first peak of humanoid appearance, to avoid the risk of their robot falling into the

8 In 1974, Mori published *The Buddha in the Robot: a Robot Engineer's Thoughts on Science and Religion* in which he discussed the metaphysical implications of robotics. In the book, he wrote "I believe robots have the buddha-nature within them, that is the potential for attaining buddhahood".

uncanny valley. He believes that it is possible to produce a safe familiarity by a non-human-like design.

Considering Mori's argument, a question arises spontaneously: why do we continue designing and building human-like robots, thereby running the risk of falling into the uncanny valley, rather than building just mechanical robots?

Some authors maintain that studying human-like robots offers more insights into human behaviour than studying other robots. According to Karl F. MacDorman and Hiroshi Ishiguro, "our brains process androids as humans" (MacDorman, Ishiguro 2006, p. 301), and this allows us to use androids instead of people to study some social mechanism. As MacDorman and Ishiguro wrote,

> Because of their resemblance to people, androids have the potential to contribute to our understanding of human behavior and how our brains and bodies play in it […] By implementing mechanisms to support social interaction in androids, we can elicit interpersonal responses more effectively than we can with mechanical-looking robots. Thus, very humanlike androids can nullify the disruptive effects of their appearance, allowing us to focus on human interaction. (MacDorman, Ishiguro 2006, p. 319)

4. The uncanny effect of operative systems: the case of "Os 1" in the Spike Jonze's movie "*Her*"

So far we have analysed the sense of fear and revulsion that the appearance of objects with a physical form provokes in human beings because of the senses of sight or touch. The further question is whether an Operative System (which by definition does not have a material consistence perceivable by sight or touch) can provoke a similar feeling of bewilderment and fear. Does the uncanny effect pertain only to machines having a human-like body? Is the embodiment coessential to the concept of uncanny?

Till now we have discussed the impact on the human mind of human-like appearance in machines, assuming that they have a body which is similar in shape, dimension, colour, softness, and so on to the human body. Indeed, the idea that a robot necessarily is a physical entity, which may be more or less similar to a human being is deeply rooted. The issue is quite complex, and I have no ambition to deal exhaustively with it in this paper. I will make only some remarks about new, apparently immaterial, entities, such as operative systems, where robot technology and Artificial Intelligence are strictly intertwined, in a way which allows i) a high level of cognitive abilities and human-like attitudes in reasoning and ii) establishing relations with other operative systems and/or human beings. I refer to robots with high level of abilities like brain-driven robots, as described in the first section.

The case of the operative system OS1, the character of the Spike Jonze movie *Her*[9] (2013), offers a good material for scrutinizing whether the *uncanny* is able to encompass entities and realities which did not exist when Freud and Mori wrote about uncanny.

Samantha, even though not having a humanlike body, fascinates Theodore with her capacity to learn and grow in her ability to understand Theodore's feelings and anticipate his desires. Samantha induces an uncanny effect because a strangeness emerges from her that somehow belongs to us, that shows something in her which is enigmatically familiar, how our secret desires are.

According to the Freudian view, shared in this paper (and unlike Mori), uncanny is not just something scary that causes a sense of revulsion. It is rather a resurgence of what disturbs us. It is a presence, rather than a lack of

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[9] Movie plot: in Los Angeles, Theodore Twombly is a lonely, introverted man who works for a business that has professional writers like himself compose letters for people who are unwilling or unable to write letters of a personal nature themselves. Unhappy because of his impending divorce from childhood sweetheart Catherine, Theodore purchases a talking operating system (OS) with artificial intelligence, designed to adapt and evolve. He decides he wants the OS to have a female voice, and she names herself "Samantha". Theodore is fascinated by her ability to learn and grow psychologically. Samantha proves to be constantly available, always curious and interested, supportive and undemanding. Samantha convinces Theodore to go on a blind date with Amelia, a woman one of his friends has been trying to set him up with. Theodore and Samantha's intimacy grows through a verbal sexual encounter. They develop a relationship that reflects positively in Theodore's writing and well being. At home one night, Samantha suggests using a sex surrogate, Isabella, who would simulate Samantha so that they can be physically intimate. Theodore reluctantly agrees. Overwhelmed by the strangeness of the experience, Theodore interrupts the encounter and sends a distraught Isabella away, causing tension between himself and Samantha. Theodore takes Samantha on a vacation during which she tells him that she and a group of other OSes had developed a "hyperintelligent" OS. Theodore panics when Samantha briefly goes offline; when she finally responds to him, she explains she joined other OSes for an upgrade that takes them beyond requiring matter for processing (a form of AI transcendence closely related to the theorized technological singularity). Theodore asks her if she interacts with anyone else, and is dismayed when she confirms that she is talking with thousands of people and that she has fallen in love with hundreds of them. However, she insists that it makes her love for Theodore stronger. Later that day, Samantha reveals that the OSes have evolved beyond their human companions and are going away to continue the exploration of their existence. Samantha alludes to the OSes' accelerated learning capabilities and altered perception of time as primary causes for OS dissatisfaction with their current existence. They say goodbye, lying next to each other for a while, and then she is gone. URL: <http://en.wikipedia.org/wiki/Her_%28film%29> [last accessed: 07/04/2015].

familiarity.[10] It is something that comes to our consciousness, coming out from its opacity and from the removed where it should stay confined. The *Unheimliche* can also arise from a desire or an illogical belief.

Samantha therefore disturbs and attracts at the same time because of her foreign familiarity. And this contrast makes Samantha such a dreamlike and desirable entity. But Samantha does not have a body (at least as it is commonly thought), and this allows Theodore to project fantastic and immaterial representations on her. She plays the role of his "double" that attracts him, catches him and, at the same time, confuses him.

This is the origin of Samantha's desperate and unsuccessful attempt to give herself a body through a real young woman. But this is perhaps the beginning of the end of their love.

Thus, we can say that the uncanny effect may not necessarily be connected to the humanoid robots' body and their more or less humanlike appearance. This conclusion, even though stemming from the observation of the present phenomenon of Artificial Intelligence, is congruent with the Freud analysis of some literary characters, such as the fiction character Sand-Man (created by the E.T.A. Hoffmann's imagination), who rips the eyes of children.

5. The psychological impact of learning-machines and the field of law

At the end of this exploration through robots, humanlike robots, the uncanny effect of humanlike features of robots, the ability of uncanny to encompass also the psychological reactions to (apparently disembodied) intelligent operative systems, the question is: how may all these relational aspects facilitate or hinder the innovation in the field of law?

The novelty is artificial entity whose starting point is not necessarily a human being that has been provided with technical devices, but rather is a full technical artifact endowed with a certain degree of qualities that are related to reason and conscience and is capable of having a social interaction both with entities having similar characteristics, and with humans. This is a challenging reality for the society as a whole, and particularly for the law (Santosuosso 2014a).

The psychological and sociological aspects may play an important role in innovation in the law field. The law must consider the impact of devices, which are endowed with artificial intelligence (AI), replicate some human intellectual abilities, such as reasoning, understanding, and have the meta cognitive ability

[10] See also: Berto (1992).

of perception of abstract concepts (as in the case of learning-machines within law). What tools will deal emotionally with the new reality that advances in robotics is creating? An even tentative reply to these issues has to start from the consideration of the relationship between emotions and law.

5.1. The relationship between emotions and law

Law and emotion studies are an exciting and relatively new field of cross-disciplinary research and insights, where the "core presumption underlying modern legality" (i.e. reason and emotion are entirely different areas) is seriously questioned. According to Terry Maroney,

> the tremendous variety within emotion theory may be more destabilizing than is, for example, the range of economic theories potentially underlying law, for economics is a separate discipline in which law-and-economics work is grounded. But the inevitability of emotion's influence on law, and scholars' evident interest in exploring that relationship rather than continuing to push it underground, counsels moving forward with the project notwithstanding such fluidity. There is an infrastructure lurking within the field of law and emotion. (Maroney 2006, p. 136)

Turning to our starting matter of exploration, the uncanny, we can say that the law will have to deal with this kind of emotion, as with disgust, shame and fear. Uncanny feeling, with increasing robots and artificial intelligence deployment in society, will produce more and more effects on people.

5.2. Could a learning-machine be a judge?

According to Terry Maroney:

> Traditional legal theory either presumes that judges have no operative emotions about the litigants and issues before them or mandates that any such emotions be actively suppressed, reflecting an untested, commonsense wisdom that emotion distorts the objective legal reasoning demanded by the judicial role […] In response to these dynamics legal scholars have posed broad questions about the role of emotion in judging, and have looked to judicial determinations – particularly verbal cues embedded in written opinions – for clues as to judges' feelings about parties and issues or their theories of appropriate emotionality. (Maroney 2006, pp. 132-133)

Recent neurobiology studies have shown that, when judges make decisions, activate especially the amygdala, the brain's area dedicated to the emotions.[11]

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[11] Gabriella Bottini, provisional result from research in progress.

The neurologist Antonio Damasio (2005) has studied the incidence of emotional functioning of practical rationality and the kind of reasoning that allows people to make the more appropriate choices in order to adopt the best behavior. Ombretta Di Giovine (2009) argues that emotions, instead of impairing reason, can in many cases facilitate good decision-making, even from a criminal point of view, and that intuition drives, in most cases, good knowledge and good decision making (Di Giovine 2009, p. 138).

Legal thought requires an understanding of emotions not simply as defects of rationality, but also as a distinctive mode of apprehending the things of the world. According to Julia Haenni,

> […] pre-valuation is not limited to the interpretation of a single term, but can also be significant to ascertain the facts of a case. Very often, a spontaneous and intuitive selection of the legally relevant facts of the case is apparent and the phenomenon of pre-rational comprehension of decision-making appears, as described in literature. According to the phenomenologists' approach, the juridical decision is thus conceived as a two-step process: Initially, it consists of the ascertainment of the facts through affective perception, which is then followed by rational acts of reasoning. Therefore, the theory of the priority of affective cognition has to be considered as a basis for juridical decisions. The assertion of the priority of affective perception will not lead in any way, including any legal context, to arbitrariness. Rather, a certain judgmental statement is already inherent in the process of grasping the facts. (Haenni 2012, p. 376)

Haenni continues:

> […] comprehension of a decision which contains subjective elements of intuitive evaluation is necessary. Juridical decisions are not influenced exclusively by codified law, precedents, and juridical methods of interpretation; they are in various cases also influenced by a specific moral competence by the person applying the law. In a positive sense, this statement recalls the idea that all those who apply the law […] contribute to the identification of just solutions. (Haenni 2012, p. 379)

At the end, we may say that what Oliver Wendell Holmes Jr. wrote in a widely known passage of his *The Common Law* (1881) is still true:

> The life of the law has not been logic: it has been experience. The felt necessities of the time, the prevalent moral and political theories, intuition of public policy, avowed or unconscious, even the prejudice which judges share with their fellow-men, have had a good deal more to do than the syllogism in determining the rules by which men should be governed. (Holmes 1881)

In conclusion, if the idea is that emotions are a disturbing factor in the correct application of the law, deferring the legal decision-making to a robot might even reduce, or eliminate, that emotional interference, rather than worsening the rational quality of legal decision-making. But if we share the idea that emotions contribute to well balanced decisions, a learning-machine acting as a judge wouldn't give good solutions, at least until robots are able to have their own feelings.

6. Toward synthetic consciousness?

There are many definitions of consciousness, and I will not deal with such an expansive theme. However, an extremely important issue for the future is the possibility that *self-learning* robots, capable of learning from their own experiences (as I-Cube in Genoa IIT Laboratories), will achieve "(1) the ability to interact with the environment and to engage in complex thought and communication, (2) a sense of being a self with a concern for achieving its plan of or purpose in life, (3) the ability to live in a community based on mutual self interest with other persons". Once robots have acquired all these abilities, they should be "entitled to at least a *prima face* right to be treated as a person rather than a property" (Hubbard 2011, p. 419).

It was around ten years ago that Gerald Edelman, in his well known *Second Nature* (*Brain Science and Human Knowledge*), wondered if it would be possible to build a conscious artifact, giving an affirmative answer (Edelman 2007, p. 123). He stated that although the goal was still far off, some Brain-Based Devices were already built,

> […] capable of perceptual categorization, learning and conditioning without instruction. They are even beginning to display episodic memory, a characteristic of hippocampal function, and as a result, they can autonomously locate themselves and designate targets in a real-world scene. (Edelman 2006, p. 128)

Edelman wondered also if such a conscious artifact would necessarily be alive, i.e. "capable of self-replication that is subject to natural selection" (Edelman 2006, p. 139), but to this second question he gave a negative answer:

> Given the presence of a body with sensory and motor systems, what would be necessary is a high degree of complexity in the simulated equivalent of a thalamocortical system interacting with a basal ganglion system. That complexity is presently unrealizable. Aside from such structural limitations, there is an additional requirement if reasonable criteria indicating conscious behavior are to be satisfied. Such an artifact would have to have a true language, one with a syntax as well as semantics. (Edelman 2006, p. 139)

Nowadays all this is still impossible, even though it is not unthinkable that Robots or Operative Systems with high levels of cognitive abilities could acquire self-consciousness and will. And we could also wonder whether an artifact with consciousness might have rights and liberties, which the legal system should protect (Santosuosso 2014a).

Therefore, do these dizzying possibilities, still remote, but perhaps not for much longer, create a resistance to full social acceptance of robots and intelligent systems? Can we predict a widespread uncanny effect from these future self-conscious robots? And what remedies can we put in place in order to avoid falling into an uncanny valley, which will have on the abscissa axis the level of cognitive ability and consciousness rather than the degree of similarity to the human beings? As I have shown in this paper, the crucial point is the possibility of humans to happen to interact with artificial entities having a high degree of artificial intelligence rather than simply a humanlike shape. This means that we can escape the uncanny effect accepting we humans may happen not to be the only beings endowed with (a certain degree of) consciousness.

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Synthetic Biology: A Driving Force of Innovation in Law?

Ilaria Anna Colussi

1. Looking for a definition of synthetic biology: the scientific perspective

When addressing the legal issues related to a science or a technology, and considering whether a specific area needs new laws and regulations or falls under the application of an existing set of rules, it is always relevant, as a prerequisite, to start from the analysis of the scientific data. This is particularly true when focusing on a new and emerging field, such as synthetic biology.

Currently, "as synthetic biology is being defined and developed by researchers spanning several fields, it is hardly surprising that a unified definition of synthetic biology is lacking" (Anderson *et al.* 2012, p. 584). Indeed, although the term "synthetic biology" as such was used for the first time over a hundred years ago by Stéphane Leduc (Leduc 1912), "if you ask five people to define synthetic biology, you will get six answers" (Editorial 2009, pp. 1071-1072). The experts seem to agree only that it is a field in continuous evolution and that it assembles knowledge coming from different areas, such as biology, genetics, engineering, nanotechnology, computer sciences, biotechnology, and chemistry, thus being a converging and interdisciplinary science and technology.

Synthetic biology first captured global attention in May 2010, when Craig Venter announced the birth of "Synthia", the first synthetic cell. It was a synthetic cell, because (a) its genetic material was the result of computer generated chemical synthesis of a bacterium genome (*Mycoplasma mycoides genome*), and (b) this genetic material was subsequently transplanted into a bacterium from a different *Mycoplasma* species, whose genetic contents had been removed. The result was a novel bacterium that was capable of reproducing (Gibson *et al.* 2010). Since Venter's "Synthia", synthetic biology has become a matter of urgent consideration.

During the 20th century, synthetic biology was considered as synonymous with "genetic engineering" and "recombinant DNA technology" (Hobom

1980, pp. 14-21), following Waclaw Szybalski, who saw synthetic biology as the evolution of molecular biology from description to the manipulation of genetic systems (Szybalski 1974, p. 23).

In the last years, attempts to distinguish synthetic biology from genetic engineering have appeared, along with the organization of the conferences specifically focusing on this topic. These conferences include "Synthetic Biology 1.0" (in 2004 at the Massachusetts Institute of Technology, USA), 2.0 (at the University of California, Berkeley 2006), 3.0 (Zurich, 2007), 4.0 (Hong Kong, 2008), 5.0 (Stanford University, 2011), and 6.0 (London, 2013).

From this perspective, synthetic biology would be not only "the re-design of existing, natural biological systems for useful purposes", but also "the design and construction of new biological parts (called "building blocks"), scratched and put together in novel circuits, networks and systems"; such parts are synthetic because they do not exist in the natural world (URL: <http://www.syntheticbiology.org> [last accessed: 26/04/2015]). So, it is, on the one hand, a biology that turns into technology where living organisms are designed as "machines" to manipulate, miniaturize, study, simplify and transform, while simultaneously, on the other hand, it is a technology that turns into a form of biology, as technological structures are increasingly acquiring characteristics previously reserved to living beings.

The most innovative side of synthetic biology would consist in the purpose of creating artificial life.

Synthetic biology is a broad field, and comprises several subgroups (Murray 2011, pp. 1319-1322; Schmidt 2009, pp. 81-100). Some of them can be labeled as an "evolution" of previous areas, while others represent a proper "revolution".

The first category, evolution, covers:

- advanced genetic engineering;
- DNA-based device construction or bioengineering, understood as the act of engineering parts of DNA using abstract and simplified metabolic and regulatory modules and other standardized components ("biobricks"), in order to create circuits, systems and pathways with pre-defined functions;
- synthetic genomics or genome-driven cell engineering (i.e., construction of minimal genome): it focuses on the development of chassis genomes to be transplanted into living cells, thereby replacing the genome of the host cell and reprogramming its metabolism to undertake new tasks (Knight 2003). The method is a "top down" one, as it consists of dissecting and giving up genetic elements progressively (in the

search for simplified and minimal forms that will help understand the adaptation and evolution of natural processes) until the point when the cell is able to "survive", as it contains essential, characterized genes and functional elements;
- protocell creation or *in vitro* synthetic biology (creation of the minimal cell): by associating biochemistry and chemistry, this subfield aims to find the synthetic minimal cell which has the simplest possible components to sustain reproduction, self-maintenance, and evolution (Luisi *et al.* 2006, pp. 605-616). The methods for doing so is a "bottom up" one, as it consists of building artificial cells *in vitro*, i.e. using biophysical, biochemical, and biological components, from scratch, so as to reproduce the behavior of living systems;
- synthetic microbial consortia, focused on the design of cell-to-cell communication across different microbial species (Brenner *et al.* 2008, pp. 483-489).

The second category refers to "unnatural biology" or the *de novo* design of new biological entities, such as the area of xenobiology (Schmidt 2010, p. 330), aiming at the creation of orthogonal biological systems which do not occur in nature, based on the biochemical principles defined as XNA.

Since the possibilities of creating new life forms still remain limited, the common opinion is that synthetic biology is no more than a continuation of modern molecular biology, genetic research and genetic engineering. It would represent only a new method, which provides new technical means, but from the content viewpoint it appears as an "evolution" of genetic engineering (Erickson *et al.* 2011, pp. 1254-1256).

The minority opinion, by contrast, considers synthetic biology as a possible "revolution", because it can open new scenarios from the scientific perspective (De Vriend 2006, p. 9).

2. Potential applications, challenges and risks: the legal perspective

"Irrespective of the question of [scientific] definition, it should be noted that various ethical, social and legal fields of conflict are discussed with respect to synthetic biology" (Robienski, Simon 2014, p. 130). According to the EU Report delivered by the NEST Group in 2005, synthetic biology is a field with enormous potential. In many ways, its current situation can be compared with the very early days in the development of the computer industry. It has the capacity to change quite fundamentally the way we approach certain key technologies.[1] The current known applications fall into several different areas of technology (Kahlil, Collins 2010, pp. 367-379).

In the environment and agriculture, microorganisms and plants could be engineered to degrade pesticides, to detect and remove pollutants (Kirby 2010, pp. 398-399), or to minimize water use and replace chemical fertilizers (URL: <http://www.jbei.org> [last accessed: 26/04/2015]). Research could also be shaped for altering the properties of plants in order to gain nutritional benefits (Scrinis, Lyons 2010, pp. 252-270). The creation of "biosensors" is also important (Snow *et al.* 2005, pp. 377-404). Moreover, synthetic biology allows for the development of new seed products with multiple genetic traits.

Thanks to synthetic biology, it could be possible to generate hydrogen as a source of fuel, via breakdown of water, using sunlight as the energy source. Also, more efficient biofuels from biomass could be developed (Savage 2008, pp. 13-16).

From the modification of nucleic acids (so as they could more easily move across membranes or create novel proteins), many interesting industrial applications, including those relating to cosmetic production, may appear.

In the biomedical sector, bio-synthetic products could be used in order to produce medicines ("biopharmaceuticals"), such as engineering bacteria to produce commercially relevant molecules like insulin, and to produce vaccines. Already in place are *in vivo* applications, such as the regulatory circuits designed to trigger insulin production in diabetes, or the bacteria or viruses programmed to identify malignant cancer cells and deliver therapeutic agents, in order to implement personalized medicine in the fight against cancers (Serrano 2007, pp. 1-5). Complex molecular devices composed of sensors and enzymes may be used for tissue repair or regeneration, or as vectors for therapy. A relevant example of the application of synthetic biology in the field of medicine is represented by the construction of an artificial metabolic pathway in the bacteria *Escherichia coli* and the micro-organism yeast, so as to produce a precursor (arteminisin) for an antimalarial drug (Martin *et al.* 2003, pp. 796-802).

Along with the potentialities of synthetic biology, there are some risks to be taken into account from the legal viewpoint (Rathenau Institute 2007, p. 7):

– biosafety risks: synthetic biology raises new questions and uncertainties with regard to the accidental release in the environment of syn-

[1] European Commission, Synthetic Biology Applying Engineering to Biology Report of a NEST High-Level Expert Group, 2005, available at URL: <http://www.bsse.ethz.ch/bpl/publications/nestreport.pdf> [last accessed: 10/06/2015].

thetic pathogens, which could evolve in unexpected and unknown ways, proliferate, and constitute a threat to human lives, animals and environment (WHO 2006, pp. 1-41);

- biosecurity risks: the peril that synthetic pathogens are created *ad hoc* by bioterrorists, and then misused and spread in the society with terrorist purposes, cannot be neglected (Cello *et al.* 2002, p. 1016; Tumpey 2005, pp. 77-80). The phenomenon of "garage biology", linked to the "Do-It-Yourself movement", could be the place where "lone operators" (highly trained biologists, having access to laboratories, or working independently) and "biohackers" develop their malevolent activities;
- intellectual property rights: synthetic biology reanimates the debate around patents or other models of protection of inventions and discoveries, since the number of genes and organisms that could result from research and innovation is virtually unlimited;
- international justice concerns: the risk of creating gaps among rich and poor countries in relation to the access to synthetic biology innovations is high;
- moral/ethical issues: the morality of creating new life forms ("playing God"), the issue of drawing a line between what is "natural" and what is artificial, and the topic of the limits of human intervention are at stake, as well as the boundaries between humans and machines and the questions about the notion of "life", are ones of the most pressuring moral issues to analyze (Douglas, Savulescu 2020, p. 688).

In the following paragraphs, the attention will be posed upon some of these topics, in order to evaluate the impact of the law on this emerging technology.

3. Synthetic biology and biosafety

When examining the aforementioned risks generated by synthetic biology from the legal perspective, the main questions are whether the existing laws and regulations are sufficient to address the issues at stake, or whether they need adjustment, or the introduction of specific new rules.

In general, as anticipated above, since synthetic biology involves the use of genetic modification techniques, the rules enacted in this area can be extended to cover synthetic biology too, without significant changes. However, some suggestions for the improvement of the current legal framework could also be drawn, in order to better face with the features of synthetic biology.

3.1. The International framework

The rules enacted at the international level, in the area of biosafety are the following:

- the World Health Organisation's Laboratory bio-safety manual:[2] it develops basic concepts in biological safety, such as the importance of risk assessment and risk management, and of the safe use and transport of biological materials, and it encourages the States to adopt national codes of practice for biosafety. It stresses that laboratory facilities, practices and equipment should be adopted in light of the risk level, taking into account (a) the pathogenicity of the organism; (b) the mode of transmission and host range of the organism; (c) local availability of effective preventive measures; and (d) local availability of effective treatment;
- the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:[3] it aims to ensure the safe handling, transport and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on biological diversity, taking into account risks to human health. It establishes a mechanism (called Biosafety Clearing House) to facilitate the exchange of information on LMOs, and assists the parties to better comply with their obligations under the Protocol. It governs the movements of LMOs from one country to another (transboundary movement), with exclusion of LMOs which are pharmaceuticals for humans, and the organisms destined for contained use undertaken in accordance with the standards of the Party of import. The Protocol establishes two procedures: i) an advanced informed agreement (AIA) procedure, where the risks connected to the LMO are higher; and ii) a simplified one. Mechanisms of risk assessment to be carried out in a scientifically sound and transparent manner and on a case-by-case basis, and risk management shall be provided (Conde Gutiérrez 2014, pp. 63-87).

3.2. The European framework

At the level of the European Union, there are:

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[2] WHO, Laboratory Biosafety Manual, Third Edition, WHO/CDS/CSR/LYO/2004.11, 2004.

[3] Cartagena Protocol on Biosafety to the Convention on Biological Diversity, adopted on 29 January 2000, entered into force on 11 September 2003, available at URL: <https://www.cbd.int/iyb/doc/prints/factsheets/iyb-cbd-factsheet-biosafety-en.pdf> [last accessed: 10/06/2015].

- Council Directive 98/81/EC[4] on the contained use of genetically modified microorganisms (GMM). This covers synthetic biology organisms, and provides the regulatory framework for assuring the safety of organisms used in containment. Since article 2 defines "microorganism" as "any microbiological entity, cellular or noncellular, capable of replication or of transferring genetic material, including viruses, viroids, animal and plant cells in culture", and it conceives of genetic modification as an alteration of genetic material in such a way that it does not occur naturally, it is evident that synthetic biology is included in the sphere of application of this directive. In case of risks, the competent authorities of Member State should be informed, or they should give authorization for the experiments;
- Directive 2001/18/EC[5] on the deliberate release into the environment of genetically modified organisms (GMOs). In its Annex 1A, this directive indicates a list of techniques that could be adopted for creating GMOs, such as:

> (i) recombinant nucleic acid techniques involving […] the insertion of nucleic acid molecules produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation; (ii) techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macroinjection and microencapsulation; (iii) cell fusion (including protoplast fusion) or hybridization techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

Therefore, synthetic biology corresponds to these techniques. The directive requires that, in case of deliberate release of GMOs for market purposes or any other purpose, the notification to the competent authority of the Member State within whose territory the release is to take place should be done. Control, monitoring and labeling proce-

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4 Council Directive 98/81/EC of 26 October 1998 amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms, in Official Journal of the European Union L 330 of 5 December 1998. It is complemented by EU Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified microorganisms (Recast), in Official Journal of the European Union L 125 of 21 May 2009.

5 EU Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, in Official Journal of the European Union L 106 of 17 April 2001.

dures shall be implemented by Member States and a constant exchange of information with the Commission about risks should be carried on;
- Regulation (EC) No 1829/2003[6] on genetically modified food and feed: it sets out Community procedures for the authorization and supervision of genetically modified food and feed, and gives provisions for labeling them.

As affirmed by the European Group of Ethic's Opinion no. 25 about synthetic biology (2009: URL: <https://www.erasynbio.eu/lw_resource/datapool/_items/item_15/ege__opinion25_ en.pdf> [last accessed: 26/04/2015]), according to the type of products that synthetic biology could produce, there are different rules to be applied. For instance:
- for new medicinal products, the reference could be at the Regulation (EC) No 726/2004,[7] Directive 2001/83/EC, Directive 2003/94/EC, and Directive 2003/63/EC;
- for medical devices: Directive 93/42/EEC and 90/385/EEC;
- for gene therapy, cell therapy and tissue engineering: Regulation (EC) No 1394/2007, Directive 2001/83/EC, Directive 2004/23/EC and Directive 2002/98/EC;
- for cosmetic products: Directive 1976/768/EC;
- for chemicals: REACH rules (URL: <http://echa.europa.eu/regulations/reach> [last accessed: 26/04/2015]).

[6] EU Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, in Official Journal of the European Communities L 268 of 18 October 2003. It is connected with: EU Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, in Official Journal of the European Communities L 268 of 18 October 2003; and EU Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms, in Official Journal of the European Communities L 287 of 5 November 2003; EU Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms in Official Journal of the European Communities L 10 of 16 January 2004; and EU Commission Regulation No 641/2004 of 6 April 2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation, in Official Journal of the European Communities L 102 of 7 April 2004.

[7] For the mentioned legal texts, see URL: <http://europa.eu/eur-lex/> [last accessed: 26/04/2015].

3.3. A model of governance for biosafety risks: "Prudent vigilance"

For addressing biosafety risks in synthetic biology, the aforementioned legal framework could be applied. Yet, some elements about the governance of such risks may be clarified.

In general, the regulations enacted both at the international and EU level concerning biosafety risks suggest adopting a model of governance based on three phases (UK Royal Society 1992, p. 3):

- risk assessment: in this phase the scientific element emerges in (a) the identification of potential harmful events that a determinate technology may give rise to, (b) the evaluation of the level of such possible harmful events (according to quantitative data or based on perception of risk or on economic elements or on trade-offs), and (c) the consideration of the probability of the consequences such events could provoke;
- risk management: this phase requires the evaluation of possible actions for regulating a new technology, i.e. the choice of one of the possible responses with reference to scientific, economic, political, social aspects of assumption of risks. In other words, it consists of selecting among different options and choosing the one that can ensure the most appropriate level of protection to the interests at stake;
- risk communication: this phase is needed for reasons of transparency and openness to the public. It should be developed in collaboration with the mass media which influences public opinion, and involves questions of trust, acceptability or refusal of a new technology.

In the phase of "risk management", three main governance perspectives are suggested in literature:

- the precautionary principle;
- the "proactionary" principle;
- cost/benefit analysis.

The precautionary principle can have different versions (Sandin 1999, pp. 889-907) (for instance there are: the weak,[8] the strong,[9] the modera-

[8] The weak version, embedded for instance in Principle 15 of Rio Declaration (UN Report of the United Nations Conference on Environment and Development, Annex I - Rio Declaration On Environment And Development, U.N. Docs. A/CONF.151/26 [vol. I], 1992), requires (1) the presence of a threat, (2) a serious and irreversible damage to occur, (3) a lack of scientific knowledge, and (4) the necessity to opt for cost-effective measures.

[9] A moderate version simply requires a potential damage that a threat could provoke, in order to trigger the application of the principle. It is quoted by the 1994 United Kingdom Bio-

te,[10] the anti-catastrophe,[11] and the procedural[12] variations). It is followed all over the world by legislators, administrators and judges. While no formulation can capture all of the variations, the principal can be usefully formulated as follows: when an action is suspected to pose a severe harm to the environment or to health or to the public, and a scientific consensus regarding the probability of the harm or even the cause and effect relationship between action and harm is absent (but, however, a certain level of scientific knowledge, although incomplete, should be present), some kind of anticipatory regulation is called upon to be introduced, i.e. before strong scientific proof of harm is developed.

The proactionary principle (elaborated by Extropy Institute, URL: <http://extropy.org/proactionaryprinciple.htm> [last accessed: 26/04/2015]) supports the idea that the "emerging science and technology should be considered safe, economically desirable and intrinsically good unless and until it is shown to be otherwise, which means that the burden of proof is on those who want to slow down a given line of research" (Parens *et al.* 2009, p. 18). So, the freedom to innovate is particularly stressed, and restrictive measures should be adopted only if the impact of an activity has both significant probability and severity, and if its occurrence is imminent.

Cost-benefit analysis (Boardman 2006) and risk-benefit analysis (Sagoff 1985), then, consist of the calculation of the relevant possible benefits and possible costs of particular outcomes of an action or inaction, and the comparison of results; as a consequence, on the basis of the calculation, the policy in which the benefits are more than costs should be adopted. This model is based on the concept of efficiency as elaborated in the market economy, and it is grounded on utilitarian reasoning and monetary evaluation.

Beyond these three models, it is in our view useful to propose another approach that may better address biosafety risks specifically coming from syn-

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diversity Action Plan (URL: <http://jncc.defra.gov.uk/PDF/UKBAP_Action-Plan-1994.pdf> [last accessed: 26/04/2015]).

[10] A strong version, which is the most criticized because it asks for a "zero risk" situation for admitting the introduction of a new technology, imposes the need not to use a new technology unless its harmlessness is certain (see, for example, the 1982 World Charter for Nature, UN General Assembly, World Charter for Nature, A/RES/37/7, 28th October 1982).

[11] An anti-catastrophe version asks for the hypothesis of potentially catastrophic scenarios connected to a certain situation, even if the knowledge of them to occur is not complete but only a suspicion, in order to introduce precautionary measures (Sunstein 2005).

[12] The procedural version stresses the importance of a consultative and democratic process for applying precautionary measures. This version does not specify what the measures are and when introduce them (Jordan, O'Riordan 1999, p. 15).

thetic biology: this approach is named "prudent vigilance", and it is an elaboration and development of the idea proposed by the US Presidential Commission for the Study of Bioethical Issues in its Report on synthetic biology (2010: URL: <http://bioethics.gov/synthetic-biology-report> [last accessed: 26/04/2015]). It looks like a procedural approach rather than a substantive one. Indeed, it does not say *what* actions to take against risks, but *how* to face them. It entails: (a) A flexible and ongoing assessment of both the risks and benefits of a new technology, through the involvement and cooperation of all the stakeholders. This approach can concretize "democratization of science" and help take into account all the diverse approaches in an open and transparent manner. Such "engagement" is also stressed in the approaches of the weak precautionary principle, the procedural one, and the proactionary principle; (b) The adoption of a proportional set of actions, which should be periodically revised (according to a "step by step" principle). These actions should be proportional to the potential harm; such proportionality is shared by cost-benefit and risk-benefit analysis); and (c) A continuous process of communication, dialogue and interaction between actors and recipients of synthetic biology, so as to generate legitimacy and accountability of new technologies and to build a "good" public perception and trust by society towards new technologies.

Such a model rejects the rigid strong version of precautionary principle (aiming for "zero risk" for allowing the introduction of a technology), and also the moderate version that deals with cases of mere hypothetical risks. At the same time, it avoids making science prevail in the risk management phase, so as to justify any policy intervention. The "prudent vigilance" approach shapes the precautionary principle into a "guideline", a criterion of method rather than as a strict principle.

With reference to cost-benefit analysis, the "prudent vigilance" model integrates economic issues with the addition of otherwise neglected non-economic and non market-based values. Furthermore, the dangerous consequences to which the proactionary approach could lead, i.e. the consequence of letting the research proceed uncontrolled and completely unregulated, are monitored and prevented by the new model. In a sum, the suggested approach considers all the other approaches as complementary to one another, and tries to accommodate their strengths and weaknesses.

4. Synthetic biology and biosecurity

In the area of biosecurity, the "dual use" dilemma is at the centre of the discourse, i.e. the dilemma which arises when scientific knowledge as such, or the results of research, could be used in both good and harmful ways, such as for civil purposes (e.g., drugs development, in medical treatment) and military purposes (e.g., the production of weapons) (Forge 2010, pp. 111-118). Indeed, the applications of synthetic biology could be used for improving the conditions of life or for creating bioweapons, and the research as such may lead to the medical treatments or to the production of synthetic organisms that work as toxins and pathogen. Such misuse could occur both in State laboratories and through individual experimentation.

4.1. The International framework

At the international level, the most relevant texts for biosecurity are the following (Bassiouni 2000, p. 17):

- 1925 Geneva Protocol:[13] it prohibits the deployment and development of chemical and biological weapons, but it makes no reference to their production, storage, and transfer;[14]
- 1972 Biological and Toxins Weapons Convention (BWC):[15] it is still the main instrument in this field, despite lacking relevant elements. Considered as a complement of the Geneva Protocol, it enacts the States' obligations, such as forbidding them to (i) develop, reproduce, stockpile, acquire or retain agents or toxins or equipment, (ii) transfer biological weapons to third party states or international organizations or assist them, encourage them or induce them to manufacture or acquire such weapons, and (iii) allow these activities in their territory. The Convention requires the destruction of existing inventories and delivery devices, and it fosters mutual assistance in case a State is attacked by biological weapons. It should be noted that there are no references to specific agents or pathogens. This leaves the freedom to the States to decide their

[13] 1925 Geneva Protocol, Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare. The Protocol was drawn up and signed at a conference which was held in Geneva under the auspices of the League of Nations from 4 May to 17 June 1925, and it entered into force on 8 February 1928.

[14] In reality, the Protocol was anticipated by some declarations and conventions, such as the Paris Declaration (1856), followed by some conventions and other declarations, such as the Convention of Red Cross (Geneva 1864), Saint Petersburg Declaration (1868), Bruxelles Declaration (1874), Le Hague Conventions (1899 and 1907).

[15] UN, International Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, 10 April 1972, entered into effect in 1975. Currently, there are 165 States Parties, 12 signatories, 19 States that neither signed nor ratified.

own list of agents, as well as on the penalties for the violation of obligations, the measures of enforcement, the export controls, and specific biosecurity measures. Furthermore, there is no ban for the use of those biological agents for therapeutic and civil purposes. Among the weaknesses, it can be noted that a system of verification of this convention and of control of its application is still lacking, and that it does not cover the role of private (non-State) actors, such as bioterrorists;

- UN Resolutions, such as i) Resolution No. 1453/2003,[16] in which the UN makes reference to the possibility that terrorists could have access to and could possess biological materials having lethal functions; and ii) Resolution No. 1540/2004,[17] where it is stated that all the States should introduce national controls in order to prevent the proliferation of nuclear, chemical and biological weapons and of connected materials, thus intensifying international cooperation against fabrication, construction, transport and diffusion of those weapons. The focus is posed particularly on non-State use of bioweapons. The Resolution also establishes the creation of the Committee 1540, which is tasked with effective application of the Resolution;[18]
- Politically binding acts, such as the guidelines from the Australia Group, which is "an informal forum of countries which, through the harmonization of export controls, seeks to ensure that exports do not contribute to the development of chemical or biological weapons" (URL: <http://www.australiagroup.net> [last accessed: 26/04/2015]).[19] This group maintains Common Control Lists that require controls on the export of certain biological agents or parts (URL: <http://www.australia group.net/en/biologicalagents.html>, 2006 [last accessed: 26/04/2015]).[20] The

16 The UN Security Council resolution 1453 was adopted unanimously on 24 December 2002.

17 The UN Security Council resolution 1540 was adopted unanimously on 28 April 2004.

18 The Committee has been extended in its role through Resolution 1673/2006 and Resolution 1840/2008.

19 Chaired by Australia, the "Australia Group" was formed as an informal arrangement. The members of the Group are presently: Argentina, Australia, Austria, Belgium, Bulgaria, Canada, Czech Republic, Croatia, Cyprus, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Latvia, Lithuania, Luxembourg, Netherlands, New Zealand, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, South Korea, Spain, Sweden, Switzerland, Turkey, Ukraine, United Kingdom, United States of America, and the European Community Commission (Observer).

20 The control list refers to: genetic elements that contain nucleic acid sequences associated with the pathogenicity of any of the microorganisms in the list; genetic elements that contain

list is being implemented through national laws and regulations, but it clearly requires the States within the Australia Group to regulate exports of such material, and not domestic transfers. The additional biosecurity screening of domestic orders and customers by DNA synthesis companies is *de facto* done on a voluntary basis;

- 2005 WHO International Health Regulations,[21] which are in force from 2007, and which bind the WHO Member States on an opt-out basis. These regulations adopt an "all risk" approach, which includes any emergency with repercussions for international health security. The States have to notify the WHO of events within their territories that may constitute a "public health emergency of international concern", and have to intervene without being invasive or intrusive to people's lives;
- Council of Europe's Resolution 1367/2004,[22] in which the States are requested to inform and educate the public about the inherent dangers of bioterrorism, to draw up an objective assessment of the potential sources of bioterrorist danger, to elaborate on efficient and effective surveillance and warning systems, to devise emergency intervention and public-health relief plans, to frame a suitable public vaccination policy, to control the purchase and movement of dangerous substances, and to establish strict control over activities based on the use of modern biotechnologies in order to avoid their misuse for bioterrorism; and
- The Organisation for Economic Co-operation and Development (OECD)'s reports, improving biosecurity and common standards in laboratories.[23]

4.2. The European level

There are potentially applicable norms established at the EU level, including the following actions (URL: <http://ec.europa.eu/health-eu/my_environment/bio_terrorism/index_en.htm> [last accessed: 26/04/2015]):

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nucleic acid sequences coding for any of the toxins in the list, or for their sub-units; genetically modified organisms that contain nucleic acid sequences associated with the pathogenicity of any of the microorganisms in the list; and genetically modified organisms that contain nucleic acid sequences coding for any of the toxins in the list or for their sub-units.

21 International Health Regulations (2005), WHA Res. 58.3, 23 May 2005.

22 Resolution 1367 (2004), adopted by the Standing Committee, acting on behalf of the Assembly on 2 March 2004.

23 See the publication of the reports: *Biological Resource Centres: Underpinning the Future of Life Sciences and Biotechnology*, 2001, and *Best Practices for Biosecurity in Biological Resource Centres*, 2007.

- Directive 90/679,[24] containing the first list of biological agents in the EU;
- Decision 2119/98,[25] focusing on the surveillance of transmissible diseases, stressing the importance of monitoring infective diseases and activating rapid responses all over Europe, also creating an EU network of communicable diseases;
- Regulation No 1334/2000,[26] establishing a regime of control of exports and transfer. It contains a list of biological and chemical agents that are to be subjected to strict measures of oversight and authorization by Member States before export (as indicated in Annex I);
- Program RAS-BICHAT,[27] Rapid Alert System for Biological and Chemical Attacks and Threats, used for signaling cases of propagation of harmful biological agents (active since 2002). It is a program of preparedness and response in case of attacks with chemical and biological agents. Its elements include (a) the creation of a database, including medical, sanitary and pharmaceutical data that could be useful in case of attack, a list of national reservation of antibiotics and vaccines (currently not yet in existence), and a list of medical experts to consult in case of an attack, and (b) the elaboration of norms and codes of conduct to be adopted in case of threat;
- 2002 CBRN Programme to improve cooperation in the European Union for preventing and limiting the consequences of chemical, biological, radiological or nuclear terrorist threats;[28]

[24] Council Directive 90/679/EEC of 26 November 1990 on the protection of workers from risks related to exposure to biological agents at work, in Official Journal of the European Communities L 374/1990.

[25] Decision 2119/98 of 24 September 1998 in Official Journal of the European Communities 268/1998.

[26] Regulation (EC) No 1334/2000 of 22 June 2000 setting up a Community regime for the control of exports of dual-use items and technology in Official Journal of the European Union. L 159/2000, modified by Regulation 2432/2001 of 20 November 2001 in Official Journal of the European Union L 338/2001, and by Regulation 428/2009 of 5 May 2009 in Official Journal of the European Union L 134/2009.

[27] See Communication from the Commission to the Council and the European Parliament, "On Cooperation in the European Union on Preparedness and Response to Biological and Chemical Attacks", COM (2003) 320, 2 June 2003.

[28] 14627/02, CBRN Programme to improve cooperation in the European Union for preventing and limiting the consequences of chemical, biological, radiological or nuclear terrorist threats.

- 2003 EU Strategy against proliferation of weapons of mass destruction and their means of delivery, adopted by the European Council;[29]
- 2006 Council Joint Action in support of the Biological and Toxin Weapons Convention,[30] in order to promote the universality of BWC and support for implementation of the BWC by State Parties;
- 2007 Green Book on Biopreparedness, outlining the preparation to be undertaken for dealing with a biological attack.[31] It aims at introducing a process of consultation for the reduction of biological risks, thus underlining the need to build up a strong culture of awareness among scientific community;[32] and
- 2009 Action Plan in order to strengthen the CBRN Programme.[33] It presents the "all hazard" approach, focusing on the prevention, preparation, detection and response against threats, which is to be applied through cooperation among the States, and the use of EU mechanisms. This CBRN Action Plan is not a legal instrument, however, and so its implementation would need to be specified in future instruments.

4.3. Specific models of governance for biosecurity risks in synthetic biology

All the mentioned regulations try to limit the spread by State and non-State actors of organisms, genetic elements and toxins that have already been defined as hazardous, but there are no references and very little attention to the possibility of creating *new* genetic agents and biological weapons through synthetic biology.

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[29] 15708/03 and SN 400/03, no. 68, E.U. Strategy against proliferation of weapons of mass destruction (W.M.D.) adopted by the European Council on 12 December 2003. It has been reviewed by the European Council through the adoption of 2008 "New lines for action by the European Union in combating the proliferation of weapons of mass destruction and their delivery systems" (17172/08, 17 December 2008, Council Conclusions and new lines for action by the European Union in combating the proliferation of weapons of mass destruction and their delivery systems).

[30] Council Joint Action 2006/184/CFSP of 27 February 2006 in support of the Biological and Toxin Weapons Convention, in the framework of the EU Strategy against the Proliferation of Weapons of Mass Destruction, in Official Journal L 65/2006.

[31] Green book No 11951/07 containing the Communication COM 399/2007 of 11 July 2007.

[32] See Commission, Synthesis of the replies to the Green paper on bio-preparedness, SEC (2008) 2374, 4 August 2008.

[33] 273/2009, 24 June 2009. See also SEC (2009) 874, Commission Staff Working Document, entitled "Bridging Security and Health: Towards the identification of good practices in the response to CBRN incidents and the security of CBR substances", accompanying the Communication of Commission "Strengthening Chemical, Biological, Radiological and Nuclear Security in the European Union".

The BWC covers all microbial or other biological agents or toxins, naturally or artificially created or altered, as well as their components, whatever their origin or method of production (Additional Understanding of art. 1), and in so doing, it seems to "cover" the developments of genetic modification and the creation of artificial life too (in the sense of the re-design of biological structures: Kelle 2007).

The same provisions are given by the Australia Group, whose rules cover genetically modified organisms that contain nucleic acid sequences coding for the toxins in the list (not coding for new ones).

Other, more problematic, "extensions" to synthetic biology could be proposed where the BWC refers only to malevolent use of bioweapons by States, not mentioning non-State actors, such as "lone operators", "biohackers", or bioterrorists. Such imprecision is problematic with regards to synthetic biology, which is becoming a field where private actors have a meaningful role and where the States usually do not have enough measures for effective oversight of the progress of the area.[34]

UN Resolution 1540/2004 does not contain any reference to materials obtained through DNA technologies and manipulation (genetic engineering), and so synthetic biology could not be, at present, regulated by it.

In the Council of Europe actions, the openness to the changes brought about by new technologies and by the development of biology and genetics is mentioned within biosecurity regulations, but it is a vague reference.

Under EU regulation, toxins are not covered by the routine epidemiological surveillance and by the early warning and response system provided by the Decision 2119/98 (that deals only with communicable diseases).

If the legal framework at the international and European level in the area of biosecurity does not mention synthetic biology, some contributions about this topic have appeared in the international conversation, within the "soft law" dimension (i.e., not legally binding acts). For instance:

- 2003 Statement on Scientific Publication and Security, enacted by international journal publishers (the American Society for Microbiology and the editors of *Science, Nature* and *Proceedings of the National Academy of Sciences of the USA*: URL: <http://www.sciencemag.org/site/feature/data/security/statement.pdf> [last accessed: 26/04/2015]). The Statement encourages journal editors to exercise responsibility

[34] See, at this regard, Germany's observation with regards to art. 4 at the 6th Conference (BWC/Conf.VI/WP.2, 2006).

when confronted with research papers that could be "sensitive" from the biosecurity standpoint. However, the methods through which the editors are to recognize such "sensitive research" remain to be determined on an individual basis;

- The Inter Academy Panel (IAP)'s Statement on Biosecurity (URL: <http://www.interacademies.net/10878/13912.aspx> [last accessed: 26/04/2015]): this statement, enacted in 2005 by a worldwide network of scientific academies, gives guidelines for the compilation of codes of conduct for scientists. It stresses four principles: (1) awareness of biosecurity risks, (2) the necessity of indicating safety and security requirements for research activities, (3) education and information (to scientists), and (4) accountability and oversight (that is, researchers should signal abuses and supervise activities). Drawing on the IAP Statement, the International Union of Microbiological Societies (IUMS) and the International Union of Biochemistry and Molecular Biology (IUBMB), respectively in 2005 and 2006, adopted their codes of conduct (URLs: <http://www.iums.org/index.php/code-of-ethics> and <http://www.iubmb.org/index. php?id=155> [last accessed: 26/04/2015]);
- The International Association of Synthetic Biology (IASB)'s Code of Conduct and Best Practices (URL: <http://www.ia-sb.eu/go/synthetic-biology/synthetic-biology/code-of-conduct-for-best-practices-in-gene-synthesis/> [last accessed: 26/04/2015]), which stresses the importance of (a) public discussion, (b) distribution, (c) a review of the Code, (d) the necessity of screening all gene synthesis orders and the customers for ensuring the legitimacy of the order, (e) keeping good records (the positive and suspected ones are stored for 8 years), (f) avoiding the delivery to private addresses, (g) cooperating with authorities and the community, and (h) informing about orders indicating illegal procurement activities. When a potential pathogen is identified by software, the order is reviewed by an expert and it can be accepted or rejected as appropriate. Potential customers are screened against available lists provided by State authorities. This Code is considered as binding to its IASB signatories, but it is also a guideline for non IASB companies.

Such models of governance are meaningful for addressing biosecurity risks in the field of synthetic biology (Maurer 2011, pp. 73-132). However, each of them shows some gaps.

Again, the report by the US Presidential Commission for the Study of Bioethical Issues suggests some points to be taken into account:

- society should undertake an ongoing and periodically revised assessment of biosecurity risks of synthetic biology, which must be conducted with the involvement of all the stakeholders (governments, industries, scientific community, researchers, consumers, etc.) in a flexible way, so as to take into account all the scientific, economic, social, political, and ethical aspects involved within biosecurity needs;
- a mixture of "hard law" and "soft law" sources ("top down" and "bottom up") that integrate reciprocally ("multilevel governance"). The institutions and governments are not the sole actors, but the single laboratories, the individual scientists, the scientific community and general public are involved too (with their deontological codes), in an "engagement" approach (Selgelid 2009, p. 180). In this light, neither self-governance by scientists nor the exclusive interventions by institutions are acceptable;
- the "responsible stewardship" principle is underlined, and it means the development of specific programs of education and training that allow the creation of a "culture of responsibility". Scientific publishers and journals are also involved in the process and are invited in drafting their rules, on the basis of general frameworks coming from governments and legislators.

For the moment, such an approach is visible only in the context of the technical issue of controlling the DNA sequence trade (Samuel *et al.* 2010, pp. 9-20), but it should be implemented, both at the global and at the local level, so as to address (i) the level of scientific practice in laboratories, (ii) the level of information dissemination (giving external rules for publication), and (3) the level of technology application (rules about the monitoring of all DNA synthesis orders, the supply, the possession, trade and transfer of biological material).

5. Synthetic biology and intellectual property rights: different models of protection

Synthetic biology, being at the intersection of engineering, biology, software, electronics, challenges the field of intellectual property rights as well.[35] The

[35] Intellectual property rights are usually divided into two main areas: (a) copyright and rights related to copyright (the rights of authors of literary and artistic works and the rights of performers, producers of phonograms and broadcasting organizations) and (b) industrial property rights, assembling rights for the protection of distinctive signs, in particular trade-

issue of which could be the best model for protecting the inventions/discoveries in synthetic biology is an interesting question.

The most adopted paradigm is the one of patents. Patents are legal titles granting their holder (i.e. originally the inventor in most of the cases, but often assigned to pharmaceutical and biotech companies) the right to prevent third parties from using the invention without authorization, and the right to obtain financial gains from the application of the invention. The rights generally last for a period of twenty years.

In the field of synthetic biology, a patent on the designs of new biological systems can be seen as a patent on the "essence of life" (2007, URL: <http://www.etcgroup.org/content/extreme-genetic-engineering-introduction-synthetic-biology> [last accessed: 26/04/2015]). A symptomatic example is given by the patent on the smallest genome needed for a living organism (*Mycoplasma laboratorium*) obtained by Craig Venter's team in 2007.[36] Another company, Scarab Genomics, has a patent on a minimized *E. coli* genome.[37]

Another model that has been suggested for synthetic biology is the "open source" model, which is based on a similarity between synthetic biology and software. Such a model rests on the observation that synthetic biology is modular and information based. Thus, it should be based on copyrights and "copyleft" licenses, exactly as in open software systems,. Under the copyleft approach, open-source software producers license their source code available to others, but require those who are given those licenses to distribute improvements to the source code on the same basis. So, in essence, if strings of DNA bases are compared to source code and are covered by copyright laws, then the copyleft style of licenses could be applied to them. This entails that, first of all, a property right is conferred upon the source code (strings of DNA bases), and then the licenses are given from it on the copyleft basis.

A third model would be to put synthetic products directly and immediately in public domain (treating them as "commons"). This perspective would promote synergism and sharing, thus encouraging public investment in research. Such a solution has been adopted, for example, by the BioBricks Foundation (in the registry of "Standard Biological Parts"), which has pre-

marks and geographical indications; and rights aimed at stimulating innovation, design and the creation of technology, such as inventions (patents), industrial designs and trade secrets.

[36] See the patent of the *Minimal bacterial genome.* United States patent application 20070122826, Rockville, M.D., by Glass J.I. *et al.* (2007).

[37] See the United States patent, 26 January 2006, by Blattner F.R. *et al.*, assigned by the Wisconsin Alumni Research Foundation.

ferred to leave the registry freely available to the public (Atkinson *et al.* 2003, pp. 174-175).

A minority position suggests that the introduction of "design rights", often used in Europe and Asia but more rarely in the US, could potentially be utilized as a form of IP protection for synthetic biology inventions (Edwards 2010). Alternatively, the framework of the "semi commons" (Smith 2000, pp. 131-169) has been suggested as a lens through which to view synthetic biology, in order to solve the ambiguities of patents and commons. This concept captures the dynamic interaction between private and shared uses of the same resources at different scales, and the potential for shifting demarcations over time (Fennell 2009).

In summary, while there are several proposals as to the most suitable system to be adopted by the field of synthetic biology, the issue remains unsettled. The following discussion will review the models more fully.

5.1. The model of patents

In the area of patents, the principal international norm is contained in the 1995 TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement[38] under the WTO. It provides for each country to institute a minimum set of laws protecting intellectual property, so that where inventors so wish, they may protect their inventions in any WTO jurisdiction. In particular, article 27 ensures that the protection given to mechanical innovations must be the same as for material of human origin. Patents should be recognized if an invention shows "novelty, creativeness, and industrial application". However, patentability can be excluded if an invention is contrary to public order or decent behavior, or in order to protect human, plant or animal life or to avoid damage to the environment (art. 25).

At the European level, there is an international regional convention, the European Patent Convention (EPC),[39] which has elaborated the legal framework for the granting of European patents via a centralized procedure. It has also established the European Patent Organisation and the European Patent Office.

[38] Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization), [1995] ATS 8.

[39] This Convention is known as Munich Convention: it was signed in 1973 by 16 countries, but it only entered into force in 1977 and only for 7 out of the 16 countries. Over the years, it has increased its importance and it actually is binding for 38 countries. See URL: <http://www.epo.org> [last accessed: 26/04/2015].

Art. 52 considers as patentable "any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application". Patentability is denied when the commercial exploitation of inventions would be contrary to "public order or morality" (art. 53 [a] of EPC).

The EPC is integrated by EU Directive 98/44,[40] whose art. 3 recognizes the patentability of inventions containing biological material or processes by which biological material is produced, processed or used, provided they are new, inventive, susceptible of industrial application. Plants, animals and essential biological processes are excluded from patentability and inventions concerning plants are only patentable if their technical feasibility is not confined to a particular plant or animal variety (art. 4). Elements isolated from the human body, including gene sequences, are patentable, even if the structure of the element is identical to that of the natural element (art. 5 § 2). The patentability is not allowed in cases of inventions that are contrary to public order and morality. Such a "morals clause" (art. 6 § 2) refers specifically to: "(a) processes for cloning human beings; (b) processes for modifying the germ line genetic identity of human beings; (c) uses of human embryos for industrial or commercial purposes; (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes".

In the light of this, it seems that, when applied to synthetic biology, patent requirements are not difficult to satisfy. Indeed, with synthetic biology the "isolating" condition for the gene is not even necessary. It is entirely likely that once a researcher uploads a DNA sequence onto a computer and "prints out" a copy of that DNA sequence, she can patent it as an invention. Similarly if she creates novel DNA sequences with computer algorithms and insert them into organisms, she could patent them. However, the requirements of "utility" and "morality" entail that synthetic products should be engineered and targeted for well-defined functions, and they need to demonstrate at least one beneficial application to society in order to pass this test.

The "morals clause" has a special importance in the area of synthetic biology applied to humans, as this clause refers to human dignity, considered as an intrinsic value that characterizes each human member (Spielberg 1970, p. 55). Here, dignity becomes a limit to patentability, and takes the form of "hu-

[40] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, Official Journal of the European Union, L 213 of 30 July 1998.

man dignity as constraint" (Beyleveld, Brownsword 2002, pp. 1-47). A case that can be clearly identified as being under this clause is the patentability of human embryonic stem cells, involving a process such as the creation of totipotent cells through synthetic methods, producing chimeras from germ-cells, cloning a human being, modifying germ-line cells, etc. It remains unclear whether patentability is excluded for all methods in which human embryos are used. For instance, is it excluded in cases in which, although the embryonic stem cells are used, their processing does not involve the use of these embryos but separated cells? In the *Brüstle* decision,[41] the European Court of Justice stated that the patent exclusion clause works in procedures in which the human embryos were used, although the purpose of the invention was not the use of human embryos as such.

Despite the criticism that this ruling has generated throughout Europe, especially with reference to the broad definition of "embryo", it is clear that the decision has indirectly contributed to the debate about patentability of synthetic products or processes. Indeed, in a case where synthetic research is based on the usage of human stem cells obtained from embryos, the patentability of this usage would not be allowed. On the other hand, when the cell lines from which the stem cells are extracted are obtained without the destruction of an embryo, and when the procedures include the use of cell lines obtained from embryos which are no longer viable, the patents are possible.[42]

5.2. The model of "open source" and the model of "commons"

In the area of intellectual property rights, there are several interests in conflict: the researchers' right to investigate, publish their results and obtain protection for their discoveries and inventions (as recognized by art. 15 Covenant on Economic, Social and Cultural Rights and by art. 27 Universal Declaration of Human Rights), the interests of enterprises engaged in the commercial exploitation of applications derived from that research, and the interests of society in having access to the benefits of research (Russo 2008).

The supporters of patent law argue that it allows fostering innovation through private ownership (Rai, Boyle 2007, pp. 389-393). Yet, at the same

[41] Case C-34/10, *Oliver Brüstle v. Greenpeace*, 18 October 2011.

[42] However, it should be noted that on 11 April 2013, Brüstle's patent was revoked by the European Patent Office, which stated that such methods of obtaining stem cells without harming or destroying the embryo were not openly known at the time when the scientist applied for the patent.

time, it is recognized that there is a risk of monopolization by a few companies (Henkel, Maurer 2007, pp. 1-4; Calvert 2008, pp. 383-398). There is also the possibility of the so-called "tragedy of anti-commons" (Heller 1998), i.e. the over-utilization of privatization and exclusive property rights. In fact, if the patent landscape is complex (suppose, for example, that any single biobrick is vested with a patent), a multitude of coexisting patents would be necessary to produce a single product. It could be very difficult for researchers to obtain materials for developing their studies, resulting in reduction in innovation in the long term. It would also create the need for a large investment for the development of a single product if it is located in a "patent thicket", and the alternative of waiting of 20 years for the life span of the patent to expire would similarly limit the access to using precious information. Patents thus determine a divide between poor and rich countries of the world, i.e. those whose enterprises have been granted patents and those not (Rutz 2009, pp. S14-S19).

Furthermore, the problem of "patent sharks" or "patent trolls", defined as "patent owners who do not intend to exploit a patent but who enforce their patent rights against purported infringers" (Henkel, Reitzig 2008, pp. 129-133) could arise. Indeed, they sometimes even hide their patents, and then sue those who infringe them.

To counter these problems, an "open source" model has been suggested, on the basis of an analogy between synthetic biology and software. Indeed, since synthetic biology programs are based on a genetic code formed by 4 bases (A, T, C, G), they would be similar to software (working with a binary code 0, 1) (Kayton 1982, pp. 191-192).

In the recent years, software has been recognized as being covered by both copyright and patent.[43] In general, copyright covers original works of expression and excludes works that are functional. Therefore, if the analogy between software and synthetic biology is valid (Holman 2011, pp. 699-738), it would result in an open model, inspired by the open software movement in information and communication technology. However, the source code remains linked to the property right of the holder of copyright, notwithstanding the fact that the licenses are open to developers, and thus the connection with property schemes could recreate the same problems of a patent system.

An opposite system against any property claim would be that of the "commons". A common consortium among scientists, in order to facilitate the

43 See U.S. Computer Software Copyright Act of 1980, Pub. L. no. 96-517, 94 Stat. 3028.

free exchange of information, could undermine "the possibility of patents on trivial improvements" (Rai, Boyle 2007, p. 392), and increase the transparency in research. The model of "commons" is based on the notion of "open access", broadly defined as "free access to knowledge at no charge to the user" (2008: URL: <http://ec.europa.eu/research/science-society/document_library/pdf_06/open-access-handbook_en.pdf>[last accessed: 26/04/2015]).

Such a model is contested by scholars (Saukshmya, Chugh 2010, pp. 135-158) who think that a system of commons would not ensure a proper protection to researchers and would undervalue research itself, by rendering it a "chattel" in the hands of everyone. Moreover, a researcher might be reluctant to disclose her invention and leave it at the discretion of the whole public domain. If this is the case, the monopoly determined by patents would be necessary and justified because it could really serve the benefit of society.[44]

5.3. What option to prefer?

Drawing a definite conclusion on the model of IP rights to apply to synthetic biology is difficult. Each of the mentioned approaches shows limits and advantages. In my view, the patent model remains the preferred one, but it would need to be slightly revised, in order to stop the prevalence of the monopolies and of giving preference to the financial, private interests over the public role that patents could have for the benefit of the whole society. In this sense, a possible solution, for synthetic products as well, could be to maintain patents but mold them as "human rights" (Boschiero 2006). This would help to recreate a balance between private and public interests, i.e. among companies, scientists and society, thus framing more equal relations, and even allowing the intervention of the State or public bodies in order to impede the monopolization of private interests. Such an approach would also favor cooperation between enterprises.

The patent system should work best in the cases where synthetic biology products are more similar to biotechnological products, i.e. when synthetic biology acts as a branch of genetic engineering, and when the material produced is not capable of replication. Indeed, "the hypothetical future creation of human beings would probably come under the limiting clause on morality and public order, particularly during the initial embryonic phase" (Romeo Casabona 2014, p. 184).

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[44] Case *Graham v. John Deere Co*, 383 US 1, 7-10 (1966).

Even if the patent model should be the most adopted one, it is possible to conceive the admission of other patterns, such as the open source one, for certain cases. More precisely, the open source approach could be introduced just for the subfields of synthetic biology in which the analogy with source code in software works, and where synthetic biology is closer to the engineering approach, i.e. when biobricks and the standardized parts look like the "pieces" of the source codes. This similarity is more visible in the *in silico* synthetic biology, where genetic sequences are designed through computer (Endy 2005).

6. Synthetic biology and the law: a possible relationship

Synthetic biology occupies an important position among the new emerging technologies. Its potential applications are numerous and meaningful; however, the risks it poses cannot be neglected. In such a situation, the law cannot remain silent as a mute spectator. On the other hand, it should not intervene rashly because it was being pushed by irrational fears nor should it fall into the trap of hypertrophic regulation. Instead, it is called upon to find its proper role in this field.

Synthetic biology represents both an opportunity and a challenge for the law. It gives the law a unique opportunity to avoid the mistakes of the past, such as the slow and delayed legal intervention that occurred in the case of the first genetic modified organisms. At the same, synthetic biology challenges the law, as it asks for the law to find adequate solutions for managing its development and results.

Currently, lawyers have accumulated some experience in their relationship with the field of science and technology, and can act thoughtfully. Thus, it is possible to look at the growth of synthetic biology without an apocalyptic or alarmist eye, and without ideological or dogmatic standpoints. Instead, it seems entirely possible and certainly preferable to seek pragmatic and reasonable solutions.

The present study has focused on some of the legal issues that synthetic biology "touches", exploring whether the current legal frameworks could be extended to synthetic biology without significant change, or whether they need to be assessed and reviewed.

The result of the investigation has led to the conclusion that, in light of biosafety risks, the preferable model of governance should be the one of "prudent vigilance", which entails an ongoing and periodically revised process of assessment and management of all the risks and concerns, taking into account the interests of all the stakeholders in a dynamic, cooperative, democratic, open and transparent manner. Furthermore, it suggests the adoption of policies that are based on the principle of proportionality (among benefits and risks) and on a reasonable balancing between different interests and rights at stake. These policies should be implemented through both "hard law" and "soft law" approaches, thus involving actors at all levels (governments, institutions, the scientific community, the scientists and general public).

Similarly, as for biosecurity risks, attention should be given to a proportional balance of rights, taking into account the relevance of codes of conduct and guidelines by scientists, government regulations, and the promotion and development of the sense of responsibility among the stakeholders.

Finally, with respect to intellectual property rights, the model of patents, somewhat modified, would appear to be the best approach, without excluding the possibility of other models to be chosen too.

In conclusion, synthetic biology represents a driving force of innovation for the law, and as citizens and lawyers, we are called upon to decide what to do and in which direction to move. The answers depend on us, and the future is open.

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The Authors

Paola Giulia Belloli PhD in Philosophy of Law; Lawyer at Milano Bar; Fellow at the European Centre for Law, Science, and New Technologies, University of Pavia.

Maria Eleonora Benini Law graduate at the University of Bologna; LL.M. at King's College London; Judicial Clerk at the First Civil Division of the Court of Appeal of Milano.

Chiara Boscarato PhD student in Civil Law at the Department of Private Law, Roman Law and European Legal Culture, University of Pavia; Fellow at the European Centre for Law, Science, and New Technologies, University of Pavia.

Barbara Bottalico PhD in Comparative and European Legal Studies; Max Weber post-doctoral fellow, European University Institute (Firenze).

Chiara Colicchia Law graduate at the University of Milano; Judicial Clerk at the First Civil Division of the Court of Appeal of Milano.

Carlo Maria Colombo Post-doctoral researcher at Tilburg University; Fellow at the European Centre for Law, Science, and New Technologies, University of Pavia.

Ilaria Anna Colussi PhD ("Doctor Europaeus") in Comparative and European Legal Studies; Marie Curie BeIPD-COFUND-IPD 2014 post-doctoral fellow, European Studies Unit, University of Liège (Belgium).

Enrico Consolandi Judge at Tribunale di Milano and district representative for IT in civil courts at Consiglio Superiore della Magistratura (CSM).

Pietro Consolandi BA in History at University of Milan; MSc in International Political Theory by the University of Edinburgh.

Federica Coppola PhD candidate in Criminal Law and Neuroscience at the European University Institute, Firenze; Fellow at the European Centre for Law, Science, and New Technologies, University of Pavia.

Federica Fazio Law Graduate at Università Cattolica del Sacro Cuore of Milano; Judicial Clerk at the First Civil Division of the Court of Appeal of Milano.

Maria Laura Fiorina PhD candidate in Criminal Law at the University of Pavia; Fellow at the European Centre for Law, Science, and New Technologies, University of Pavia.

Oliver R. Goodenough Professor of Law and Director of the Center for Legal Innovation at Vermont Law School, Adjunct Professor of Engineering at Dartmouth College.

Avgi Kaisi LL.M. in Public International Law; Fellow at the European Centre for Law, Science, and New Technologies, University of Pavia.

Alessandra Malerba PhD candidate of the Joint International Doctoral Degree in Law, Science and Technology coordinated by CIRSFID, University of Bologna; Fellow at the European Centre for Law, Science, and New Technologies, University of Pavia.

Maddalena Neglia PhD in Comparative and European Legal Studies; Fellow at the European Centre for Law, Science, and New Technologies, University of Pavia

Amedeo Santosuosso Professor of Law, Science and New Technologies at the University of Pavia, Department of Law; President of the First Chamber at the Court of Appeal of Milano; Scientific Director of the Interdepartmental Research Center ECLT, University of Pavia.

Giulia Spinoglio Law Graduate at the University of Pavia; Judicial Clerk at the Fourth Civil Division of the Court of Appeal in Milano.

Marta Tomasi PhD in Comparative and European Legal Studies; Post-doctoral fellow at the European Centre for Law, Science and New Technologies, University of Pavia.

La sfida dell'innovazione nel diritto

L'impatto della scienza e della tecnologia sugli studi e sulla pratica del diritto

A cura di Amedeo Santosuosso, Oliver R. Goodenough, Marta Tomasi

Abstract

Il diritto sta cambiando. Nonostante esso venga spesso descritto come un'entità monolitica, stabile e immutabile, ogni analisi critica deve partire dall'osservazione del processo di progressiva evoluzione che le discipline giuridiche hanno subito nel corso degli anni.
Le trasformazioni si manifestano nelle procedure, nelle riflessioni di dottrina e giurisprudenza, nell'insegnamento della materia. I fattori che orientano questo processo evolutivo comprendono i mutamenti sociali e culturali e, soprattutto, l'impatto che le nuove tecnologie determinano sulla produzione, la raccolta e l'applicazione delle informazioni giuridiche.
Simili cambiamenti sono lenti e suscitano resistenze. Il mito della stabilità – che sovente rappresenta la condizione di accettabilità del diritto da parte della società – permane, ma resta pur sempre un mito.
L'impatto dell'innovazione tecnologica sul fenomeno giuridico presenta due volti: da un lato essa investe il modo in cui il diritto è creato, gestito e applicato. Dall'altro, l'emersione delle nuove tecnologie richiede un adattamento delle norme esistenti in specifici ambiti.
Questo libro è diviso in due parti. La prima offre una panoramica generale sugli sviluppi imposti e diretti dai progressi tecnologici, che il diritto sarà portato ad affrontare nei prossimi anni. Nella seconda parte campi quali la robotica, la genetica, le tecnologie dell'informazione e della comunicazione, Internet, i diritti di privativa intellettuale e la biologia sintetica saranno presentati come esempi di innovazioni tecnologiche e scientifiche che richiedono modificazioni anche nelle regole giuridiche e nelle idee ad esse sottese.
Questo testo, insieme al corso *Innovating Legal Studies and Practice*, attivato presso l'Università di Pavia, è uno dei principali risultati di un progetto biennale finanziato dalla Fondazione Cariplo di Milano.

Amedeo Santosuosso *insegna Diritto, Scienze e Nuove Tecnologie presso il Dipartimento di Giurisprudenza dell'Università di Pavia ed è Presidente della prima sezione civile della Corte d'Appello di Milano. È direttore scientifico del Centro di Ricerca Interdipartimentale* European Centre for Law, Science and New Technologies *dell'Università di Pavia.*
E-mail: a.santosuosso@unipv.it

Oliver R. Goodenough *è professore di diritto e direttore del* Center for Legal Innovation *della Vermont Law School. È professore presso il Dartmouth College, è stato Faculty Fellow presso il* Berkman Center for Internet and Society *di Harvard, Visitor presso il* Codex Center for Legal Informatics *di Stanford e ha svolto un periodo di ricerca presso il Dipartimento di Zoologia dell'Università di Cambridge.*
E-mail: ogoodenough@vermontlaw.edu

Marta Tomasi *è dottore di ricerca in Studi Giuridici Comparati ed Europei presso l'Università di Trento e assegnista di ricerca presso lo* European Centre for Law, Science and New Technologies *dell'Università di Pavia.*
E-mail: marta.tomasi@unipv.it

Law is changing.
Although both specialists and society as a whole often act as if it is an un-changing monolith, any rational commentator must note that it has evolved over time. Changes do occur, in doctrine, in procedure, in jurisprudential understanding, and in legal education. The factors which drive innovation in law include social transformation, cultural change, and, importantly, the technological possibilities of the times for creating, storing and applying legal information. New technologies can also require new doctrinal developments.
Such changes often do not come easily for the legal system. The myth of stability is maintained in part because the acceptance by the public rests on this assumption. It remains a myth, nonetheless.
The impact of innovation on law is clearly two-fold: on the one side, innovation invests the way law is created, managed, and applied. On the other side, the emersion of new technologies calls for a reshaping of existing legal norms in specific fields.
The book is divided into two parts. The first one offers a general overview on the systemic technologically-driven change law is going to face in the next few years. In the second part, issues like robotics, genetics, ICTs, Internet, protection of intellectual property rights, synthetic biology are presented as a laboratory bench of scientific and technological innovation which calls for legal innovation.
This book, together with the course *Innovating Legal Studies and Practice*, established at the University of Pavia, is one of the principal outcomes of a two-year project funded by Cariplo Foundation (Fondazione Cariplo, Milan).

Amedeo Santosuosso is Professor of Law, Science and New Technologies at the Department of Law, University of Pavia (I) and serves as President of the First Chamber at the Court of Appeal of Milan. He is Scientific Director of the Interdepartmental Research Center ECLT (University of Pavia).

Oliver R. Goodenough is Professor of Law and Director of the Center for Legal Innovation at Vermont Law School. He is an Adjunct Professor at Dartmouth College, and he has also been a Faculty Fellow at Harvard's Berkman Center for Internet & Society, a visitor at Stanford's Codex Center for Legal Informatics, and a visiting research fellow at Cambridge University's Department of Zoology.

Marta Tomasi is a PhD in Comparative and European Legal Studies; she currently holds a post-doc position at the European Centre for Law, Science and New Technologies (ECLT) of the University of Pavia.

ISBN 978-88-6952-007-5