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Modern Intellectual Property Governance and Openness in Europe: A Long and Winding Road?

Nikos Koutras

Abstract

In the last decade a trend towards more 'openness' in terms of collaborations and access to knowledge has been observed in many different sectors and contexts. Along the spectrum of openness one can find many different varieties, such as open innovation, co-creation, open science (combined with open access and open data) and open source. Even traditionally rather 'closed' actors, such as publishing houses and the pharmaceutical industry, are gradually catching up and are trying to develop mechanisms to cope with this trend towards openness. Both public and private actors encounter challenges in combining this trend towards openness with the management of intellectual property rights (IPRs). Although a strong willingness may exist to collaborate, open up and share knowledge and data, IPRs often create boundaries and limitations towards cutting-edge collaborations and initiatives for openness and sharing. Over time, companies, universities, public research organisations, etc. have developed certain models to allow for openness while safeguarding ways to protect their IPRs. Yet the legal framework is often lagging behind and does not appear to reflect the socio-economic trend towards openness; in many jurisdictions, changes to IP legislation have rather focused on strengthening of the rights of IP owners. But this is not necessarily a problem as stakeholders tend to find workarounds in their day-to-day practice. This special issue aims to further the discussion about modern governance of IPRs in Europe and to explore different perspectives on how openness could be operationalised within the context of IP protection.

1 Overview of the Special Issue

In the last decade a trend towards more 'openness' in terms of collaborations and access to knowledge has been observed in many different sectors and contexts. Along the spectrum of openness one can find many different varieties, such as open innovation, co-creation, open science (combined with open access and open data) and open source. Even traditionally rather 'closed' actors, such as publishing houses and the pharmaceutical industry, are gradually catching up and are trying to develop mechanisms to cope with this trend towards

openness. Both public and private actors encounter challenges in combining this trend towards openness with the management of intellectual property rights (IPRs). Although a strong willingness may exist to collaborate, open up and share knowledge and data, IPRs often create boundaries and limitations towards cutting-edge collaborations and initiatives for openness and sharing. Over time, companies, universities, public research organisations, etc. have developed certain models to allow for openness while safeguarding ways to protect their IPRs. Yet the legal framework is often lagging behind and does not appear to reflect the socio-economic trend towards openness; in many jurisdictions, changes to IP legislation have rather focused on strengthening of the rights of IP owners. But this is not necessarily a problem as stakeholders tend to find workarounds in their day-to-day practice. This special issue aims to further the discussion about modern governance of IPRs in Europe and to explore different perspectives on how openness could be operationalised within the context of IP protection.

2 Structure of the Special Issue

In this respect, it is necessary to trace the historical development of the concept of copyright as a property right. The continued relevance of the rationales for copyright interests, both philosophical and pragmatic, will be assessed against digital publishing in contemporary times. Furthermore, the special issue examines the rise of open access practice and includes an analysis of the impact of the online publishing and associated revolution on commercial publishing methods. In the first article, Nikos Koutras investigates the transition from property rights to copyrights, considers justifications based on which the concept of private property was introduced and analyses how the idea of private property in land and goods was extended to creative efforts. Additionally, Koutras argues that the concept of open access supports wider distribution of information resources. Therefore, in modern times, when information and communication technologies are undergoing a 'revolution', it is imperative to go back to Plato's concept and argue that open access is an instrument with benefits of wide dissemination of information resources.

Hence, there is a need to connect the emergence of copyright protection with developments in the concept of property. The same connections can justify the development of open access in contemporary times; for instance, balancing individual rights with the social good.

Given this, intellectual efforts are produced and uploaded online with ease, nowadays. Therefore, additional issues arise in terms of online data produced and shared. In the second article, Alexandra Giannopoulou discusses data sharing. In particular, she argues that data sharing has been at the forefront of policy and legislative reforms in recent years, from open source software to open government data and from open research data to open science in general. The innovation potential that incites enhancing data access and reusability practices illustrates significant value derived from data sharing practices. Access to knowledge is considered not only a vector for scientific progress that stimulates innovation but also an indispensable tool committed to the development of a democratic society. The smart use of data has a transformative effect on the economy and on society in general.

Another field of research where an enormous amount of data is produced and disseminated, when required, is the field of medicine and its regulatory framework in terms of medical data, which has been covered in the special issue, where, in the third article, Magali Contardi argues that medical devices play an increasingly important role in healthcare worldwide by contributing substantially to the prevention, diagnosis and treatment of diseases. At the European level, enhancing competitiveness while ensuring public health and safety is one of the key objectives of the European Commission. In the pursuit of such objectives, medical devices within Europe have been regulated since 1990 by means of three directives, namely Directive 90/385/ECC concerning active implantable medical devices (AIMDD), Directive 93/42/ECC, concerning medical devices (MDD), and Directive 98/79/ECC, concerning in vitro diagnostic medical devices (IVDD). Over the past few years, the system has been subject to amendments and has been complemented by several non-binding guidance documents reflecting the consensus of stakeholders.

In the fourth article, Maria Canellopoulou-Bottis, Marinos Papadopoulos, Christos Zampakolas and Vicky Ganatsiou argue that in the post-paper world, libraries implement Web-harvesting and Web-archiving methods in several countries facing technological and legal issues that are intensified owing to the idea of 'openness' regarding access to information or openness to partnerships. The core theme of this special issue could also be seen through the prism of the 'intellectual property and contemporary issues of openness' thematic. Web harvesting and Web archiving as a technological option is usually leveraged on in the context of legal deposit systems that are set in the legal and technical frameworks of operation of major and/or national libraries, and aim at the collection, download and archiving of works that

are found available on the Internet through an automated process of tracking and pulling of works found online. In addition, Maria Canellopoulou-Bottis, Marinos Papadopoulos, Christos Zampakolas and Vicky Ganatsiou also consider that access to the Web information and works available online is subject to restrictions by regulation, especially laws pertaining to copyright, industrial property rights, data privacy, etc. on the same model as the current legal deposit material on hard copies in most libraries empowered to do the legal deposit.

The special issue also furthers the consideration in regard to Web harvesting and Web archiving. Thus, in the fifth article, Maria Canellopoulou-Bottis, Marinos Papadopoulos, Christos Zampakolas and Vicky Ganatsiou discuss the term Text and Data Mining (hereinafter, TDM). In fact, TDM determines an issue for the purpose of scientific research or for any other purpose that is included in the provisions of the new EU Directive on Copyright in the Digital Single Market (hereinafter, DSM). TDM includes Web-harvesting and Web-archiving activities. Web harvesting and archiving pertain to the processes of collecting from the Web and archiving of works that reside on the Web. Web harvesting and Web archiving are one of the most attractive applications for libraries that plan ahead for their future operation. When works retrieved from the Web are turned into archived and documented material to be found in a library, the volume of works that can be found in such libraries can far exceed the number of works harvested from the Web. The fifth article elaborates on provisions in EU Copyright law that were discussed during the proposal for a new Directive on Copyright in the DSM as well as provisions that are included in the text of art.3 and art.4 of the new Directive 2019/790/EU per TDM.

In conclusion, the special issue welcomes a more practical approach concerning intellectual property issues, which is shown in the sixth article, where Nikos Koutras investigates the interaction of public policy with the dissemination of scientific information. What is more, Koutras argues that public policy is crucial to simultaneously developing green open access as a form of social justice and social cohesion enhancement; in other words, as a tool to increase access opportunities. It is widely acknowledged that information access is imperative, while the current copyright regimes afford overly broad protection in terms of the duration, works and uses covered. Hence, the last article proposes a socio-economic framework to develop a standard concerning the balance of stakeholder interests based on green open access via public policy.

From Property Right to Copyright: A Conceptual Approach and Justifications for the Emergence of Open Access

Nikos Koutras*

Abstract

This article relies on the premise that to understand the significance of Open Access Repositories (OARs) it is necessary to know the context of the debate. Therefore, it is necessary to trace the historical development of the concept of copyright as a property right. The continued relevance of the rationales for copyright interests, both philosophical and pragmatic, will be assessed against the contemporary times of digital publishing. It follows then discussion about the rise of Open Access (OA) practice and its impact on conventional publishing methods. The present article argues about the proper equilibrium between self-interest and social good. In other words, there is a need to find a tool in order to balance individuals' interests and common will. Therefore, there is examination of the concept of property that interrelates justice (Plato), private ownership (Aristotle), labour (Locke), growth of personality (Hegel) and a bundle of rights that constitute legal relations (Hohfeld). This examination sets the context for the argument.

1 Introduction

This article relies on the premise that to understand the significance of Open Access Repositories (OARs) it is necessary to know the context of the debate. Therefore, it is necessary to trace the historical development of the concept of copyright as a property right. The continued relevance of the rationales for copyright interests, both philosophical and pragmatic, will be assessed against the contemporary times of digital publishing, followed by a discussion about the rise of Open Access (OA) practice and its impact on conventional publishing methods.

The present article argues that there is a proper equilibrium between self-interest and social good. There is thus a need to find a tool that balances individuals' interests and the common will. This requires an examination of the concept of property that interrelates justice (Plato), private ownership (Aristotle), labour (Locke) and growth of personality (Hegel). This examination sets the context for the argument. In the literature the core notion of property (*i.e.* as a concept and its subject matter) is seen to stem from Aristotle's ideas about pri-

ate property that lead to evolution, production and personal growth. Additionally, the concept of property has evolved from Plato's joint ownership theory to full liberal ownership theory and moved in the direction set by Aristotle. The concept of private property has been considered similarly by following philosophers with Aristotle's conception.

However, Plato's ideas about the concept of property for communal use is a more desirable model, which can justify the philosophy of OA. The origins of the notion of property lie in his philosophy; in accordance with his ideas, the concept of property was introduced as joint ownership in terms of social justice and, moreover, as a beneficial tool to support the growth of the whole republic – the ideal republic. He argues that there should not be private property and that, therefore, property under the 'umbrella' of joint ownership forms the appropriate factor for peace and justice. Aristotle, although a student of Plato, focuses on a more individualistic aspect; he contends that private property is more effective and will lead to improvement. It is obvious that he denies his teacher's (Plato's) rationale about joint ownership by signalling that such extreme unification is against the diversity of personal identity and against the benefit that everyone gathers through market exchange.

This leads to a discussion of Locke's philosophy, as he extends the concept of private property ownership by combining it with work. Locke claims that whatever work is produced by an individual becomes his/her property. This idea justifies the connection of ownership and creation. Specifically, in his work titled *Second Treatise on Government*,¹ Locke proposes an explanation of the right by which an individual can claim to own one part of the world when, according to the Bible, God gave the world to human beings in common. Locke argues that individuals own themselves and thus their own labour. At this point, the connection between Aristotle's and Locke's logic is evident. Locke and Aristotle agree that private property is one of numerous intricacies. However, Locke contends that there is a more individualistic rationale for property ownership than does Aristotle.

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1. J. Locke, *Second Treatise of Government and a Letter Concerning Toleration* (Oxford University Press, 2016).

Further on, according to Hegel's views, the concept of property is used to comprehend it as a phase in the development of human kind and the growth of individual personality; thus, he extends the appropriate environment or surroundings of private property following Aristotle's and Locke's logic or reasoning. This chronological order provides an effective flow of thought that enables me to propose justifications for the emergence of OA as additional support to current copyright regimes.

From Aristotle's philosophy to modern times there are differences regarding traits of property and its ownership, as, one by one, philosophers added new features to their theories. Plato's argumentation about joint ownership was neglected. However, Plato's philosophy on property enables us to draw on his notions about communal property or joint ownership and its significance within OA. The argument of this article is based on Plato's logic, partly because later philosophers also implicitly support his ideas regarding communal use of property, as they highlight several unique aspects of community as a whole.²

The OA practice supports wider distribution of information resources. Therefore, when information and communication technologies are undergoing a 'revolution', it is imperative to go back to Plato's concept and argue that OA determines an instrument with benefits towards wide dissemination of information resources. Hence, there is a need to connect the emergence of copyright protection with developments in the concept of property. The same connections can justify the development of OA in contemporary times, as, for instance, balancing individual rights with the social good. The last part discusses OA in terms of an appropriate shift of existing copyright protection in the digital age, which leads to distribution of information and information accessibility. Also considered here is the question of whether open access could be an efficient way of enhancing the relationship between individuals' interests and the common will.

In the following section, the first subsection deals with the conceptualisation of property based on Plato's and Aristotle's views about property. This discussion traces the transition from public or communal property (Plato's perspective) to the understanding of property as an individual ownership right and the change in the understanding of private property that encourages personal developments (Aristotle's perspective). This helps to associate basic elements in the ideas of previous philosophers with the views of modern philosophers concerning the concept of property. The argument advances further in part two with a discussion that relies on modern philosophers' ideas (e.g., Locke and Hegel) about property as they argue about the connection between

ownership and the input of labour in order to possess actual property.

2 Conceptual Framework of Property

2.1 Plato's Notions of Property

Plato's ideas about property were related to his ideas about family, society and the republic. They also contain the origins of notions of patents. His ideas are explained below. In the period around 500 B.C. in Ancient Greece, some form of patent rights was recognised. For example, in the Greek city of Sybaris, patents were granted for the creation of unique culinary dishes.³ Encouragement was provided to those who introduced refinements in luxury; profits accruing from such endeavours were secured to the inventor by a patent for the period of one year.⁴ This kind of protection for one year illustrates that creative endeavours were encouraged in a manner that protected the whole market from monopolies. At the same time, one or more persons could enjoy an economic advantage in relation to their creative efforts. In this context, Plato's ideas are useful to describe an ideal republic in which only philosophers ought to keep private property in terms of justice.⁵ For the rest, he suggests that there should be joint ownership.⁶ The shape of Plato's ideal republic requires justice as its main purpose.⁷

Plato contends that owning private property leads to greed and lust. He claims that children should be taken from their biological parents and redistributed by the state to other parents; that is how he supports his arguments concerning private property and the right to 'own' a child.⁸ In other words, Plato does not believe in private property as such; he believes that, eventually, no one should own anything, except for the philosophers.⁹ Therefore, some scholars call Plato a proto-socialist or a proto-communist. In response, it can be said that this view of property was applied by Plato only to the guardian class and the auxiliaries for the purpose of focusing their attention on the ever-important matter of the state. It should not overshadow the fact that this was the first time that someone initiated a discussion about the

2. This mutual philosophical consideration can be described as follows: Aristotle highlights individualism and self-interest, Locke proposes that property rights are individuals' natural rights and Hegel emphasises that all types of individuals' rights lie in property.

3. A. Rich, *A Dictionary of Roman and Greek Antiquities* (Nabu Press, 2010).
4. W. Smith, *A Concise Dictionary of Greek and Roman Antiquities* (Nabu Press, 2010).
5. C.H. Kahn, *Plato and the Socratic Dialogue: The Philosophical Use of a Literary Form* (Cambridge University Press, 1998).
6. M.S. Kochin, *Gender and Rhetoric in Plato's Political Thought* (Cambridge University Press, 2002).
7. L.H. Craig, *The War Lover: A Study of Plato's Republic* (University of Toronto Press, 1996); S. Rosen, *Plato's Republic: A Study* (Yale University Press, 2005); J. Lear, 'Allegory and Myth in Plato's Republic', in G. Santas (ed.), *The Blackwell Guide to Plato's Republic* (Blackwell Publishing Ltd, 2006) 25.
8. C.H. Zuckert, *Plato's Philosophers: The Coherence of the Dialogues* (University Of Chicago Press, 1st ed., 2009).
9. C. Zoller, 'Interpreting Plato's Dialogues (Review)', 45(3) *Journal of the History of Philosophy* 486 (2007).

importance of private property, its content and how it was going to be used, as well as to explicate the main purposes for private ownership of property.¹⁰

Plato's ideas about private property are fundamentally affiliated with the concept of family, particularly with 'children', as he argues that having a child leads to greed and lust. However, as children grow into adults and, consequently, become active members of society, Plato's views about private property are, ultimately, not productive and are less humanitarian. Plato influenced his student, Aristotle, just as Socrates influenced Plato. However, each man's influence eventually moved in different directions. Plato believes that concepts such as property have a universal form – an ideal form – that led to his idealistic philosophy and ideal republic. Conversely, Aristotle believes that universal forms are not appropriately connected to each other and that thus each instance of an object has to be examined by itself. In the light of this logic, Plato is more interested in justifying communism of the elites based on joint ownership, whereas Aristotle is more interested in justifying a political order based on private property from an individual standpoint – something that is relevant to me and leads me to examine Aristotle's views on the concept of property.

2.2 Aristotle's Philosophy and His Concept of Property

Aristotle's views are particularly crucial because the entire structure of his thought had a great and even dominant influence on the economic and social thought of the Western world. Although Aristotle, in the Greek tradition, scorns moneymaking and is scarcely a partisan of laissez-faire, he sets forth a trenchant argument in favour of private property.¹¹ Perhaps influenced by the private property arguments of another Greek philosopher, Democritus, Aristotle strongly attacks the concept of communism among the ruling class, as called for by Plato.¹² He denounces Plato's goal of the perfect unity of the state through communism by pointing out that the idea of such extreme unity militates against the diversity of mankind and against the reciprocal advantage that everyone reaps through market exchange.¹³

First, private property is more highly productive and will, therefore, lead to progress. According to Aristotle's view, goods owned in common by many people will receive little attention, since people will be guided main-

ly by their own self-interest.¹⁴ In contrast, people will devote the greatest interest and care to their own property. Aristotle connects creation and production with progress, and this connection provides a justification for the need to extend Plato's idea of private property in goods to creative endeavours.

Second, Aristotle responds to one of Plato's arguments for property: that it is conducive to social peace as no one will be envious, or try to grab the property, of another. Aristotle argues that property will lead to continuing and intense conflict, as each will complain that he has worked harder and obtained less than others who have done little and taken more from the common store. Further, Aristotle declares that not all crimes or revolutions are powered by economic motives. As Aristotle trenchantly puts it, 'men do not become tyrants in order that they may not suffer cold'.¹⁵ Aristotle's statements make it evident that in his view creators have to be rewarded and protected in regards to their work and contribution to the whole society. In light of this rationale, it is imperative to create an appropriate form of property to protect intellectual creations. Plato's concept of property has distinct negative aspects and easily causes injustice and conflict regarding creators' profits.¹⁶ Thus, Aristotle's arguments help justify the need to transform Plato's idea of property and expand its focus on goods to include creative efforts.

Aristotle provides a third argument against Plato's concept of property. He says that private property is plainly embedded in man's essence. His admiration of personality or individuality, money and property is interconnected with a natural love of exclusive ownership. Fourth, Aristotle specifies that private property has existed always and everywhere.¹⁷ To enforce communal property on society would be to disregard the record of human experience and to leap into the new and untried. Abolishing private property would probably create more problems than it would solve. Eventually, Aristotle weaves together his economic and moral theories by providing the brilliant insight that only private property furnishes people with the opportunity to act morally; for example, to practice the virtues of welfare and charity. The compulsion of communal property would destroy that opportunity. To sum up, according to Aristotle, the concept of private property constitutes a means of wealth, production and justice and should thus be protected. Although critical of moneymaking,¹⁸ Aristotle

10. G.A. Press, 'Methods of Interpreting Plato and His Dialogues (Review)', 34(1) *Journal of the History of Philosophy* 135 (1996).
11. E. Brady, 'Aristotle, Adam Smith and the Virtue of Propriety', 8(1) *Journal of Scottish Philosophy* 79 (2010); M.J. Calkins and P.H. Werhane, 'Adam Smith, Aristotle, and the Virtues of Commerce', 32(1) *The Journal of Value Inquiry* 43 (1998).
12. H.W. Spiegel, *The Growth of Economic Thought* (Duke University Press, 1991); J. Brunschwig, *A Guide to Greek Thought: Major Figures and Trends* (Harvard University Press, 2003); L. Nolan, *Primary and Secondary Qualities: The Historical and Ongoing Debate* (Oxford University Press, 2011).
13. A.D. Bloom, *The Republic of Plato* (Basic Books, 1991); R. Mayhew, *Aristotle's Criticism of Plato's Republic* (Rowman & Littlefield Publishers, 1997).

14. C. Ash, 'Social-Self-Interest', 71(2) *Annals of Public and Cooperative Economics* 261 (2000); I. Maitland, 'The Human Face of Self-Interest', 38(1/2) *Journal of Business Ethics* 3 (2002); S. Besson and J.L. Martí, *Deliberative Democracy and Its Discontents* (Ashgate Publishing, Ltd., 2006); H.O. Rocha and S. Ghoshal, 'Beyond Self-Interest Revisited', 43(3) *Journal of Management Studies* 585 (2006); C. De Dreu and A. Nauta, 'Self-Interest and Other-Oriented Behavior in Organizational Behavior: Implications for Job Performance, Prosocial Behavior, and Personal Initiative', 94(4) *Journal of Applied Psychology* 913 (2009).
15. Aristotle, *Politics* (Digireads.com Publishing, 2004) 25.
16. H.-H. Hoppe, *The Ethics and Economics of Private Property* (2004).
17. M.N. Rothbard, *Aristotle on Private Property and Money* (2009).
18. S. Meikle, 'Aristotle's Economic Thought' (1997), available at: <https://ideas.repec.org>; H.C. Mansfield Jr., 'Marx on Aristotle: Freedom, Money, and Politics', 34(2) *The Review of Metaphysics* 351 (1980);

still opposes any limitation on an individual's accumulation of private property. Instead, in his view, education should teach people to voluntarily curb their rampant desires and thus lead them to limit their own accumulation of wealth. Despite his cogent defence of private property and opposition to coerced limits on wealth, the aristocrat, Aristotle, is fully as scornful of labour and trade as his predecessors.

Aristotle created great trouble for the future by morally condemning the lending of money and decrying the charging of interest as 'unnatural'.¹⁹ Since money cannot be used directly and is employed only to facilitate exchanges, it is 'barren' and cannot itself increase wealth. Therefore, the charging of interest, which Aristotle thought to imply a direct productivity of money, was in his view contrary to nature and thus strongly condemnable.

Yet the classical philosophy of Aristotle was, in due course, followed by the development of liberal philosophy. Locke was one of the foremost liberal thinkers of his time, and his ideas on property inform our contemporary understanding. It follows examination of Aristotle's conception as regards private property in the context of Locke's ideas about property. It is instructive that when Locke's political theory was first published in 1689, the impressive authority of Aristotle stood ready to defeat it. When it was confirmed that the renowned author of *An Essay Concerning Human Understanding* had also written the anonymously published *Two Treatises of Government*, Locke was broadly taken to show a distinctive kind of political theory based on individual rights and social contract; this type of account of politics has in many ways rested on Aristotle.

3 From Lands and Goods to Creative Efforts

3.1 Locke's Philosophy on Property

An analysis of Locke's philosophy will help to highlight the importance of work in relation to property ownership. To begin with, it should be noted that both Locke and Aristotle acknowledge that the issue of private property is fraught with intricacies. Though both philosophers sketch disparate interpretations on how land should be distributed among people, Locke puts forward a more individualistic notion of property ownership than does Aristotle. Specifically, in his *Second Treatise on Government*,²⁰ Locke provides an answer to the question, By what right can an individual claim to own one part of the world when, according to the Bible,

S. Zarlenga, 'The Lost Science of Money', 16(5) *European Business Review* (2004).

19. I. van Staveren, *The Values of Economics: An Aristotelian Perspective* (Routledge, 2013); R. Kraut and S. Skultety, *Aristotle's Politics: Critical Essays* (Rowman & Littlefield, 2005).

20. J. Locke, *Two Treatises of Government* (2013); J. Locke, *Second Treatise of Government: An Essay Concerning the True Original, Extent and End of Civil Government* (John Wiley & Sons, 2014).

God gave the world to human beings in common? In this work, Locke argues that individuals own themselves and thus their own labour. Accordingly, he argues that individual property rights are natural rights. It is evident that this idea is similar to Aristotle's, which did not support Plato's idea concerning joint ownership.

Following this argument, it is plausible that when individual labours and the outcome of this work is the creation of tangible objects, those objects become his property. Political philosopher Robert Nozick calls this idea the Lockean proviso. Further, according to Locke, the labourer has to hold a natural property right in the resource itself as the exclusive ownership was immediately appropriate for production. In addition, in the context of the connection of right on property with production, Locke clarifies that, in accordance with his philosophy, the concept of property illustrates exclusive rights on abstracts, especially creative endeavours, as he interconnects ownership with production.

Locke's theory on property can be examined as an expansion of Aristotle's main argument regarding private property. Locke argues that individuals can acquire full property rights over moveable and non-moveable parts of earth in a state of nature. The terms 'moveable' and 'non-moveable' are, in other words, 'tangible' and 'intangible' abstracts comprising notions, ideas, innovations, thoughts and, in general, intellectual creations. In regard to Locke and his contribution to theories of property, he expands on Aristotle's concept by stating that everyone owns a property, to which nobody else has any right. Admittedly, Aristotle's argument differs from Locke's in that Aristotle opined that those with private property should share it. Locke disputed this idea, arguing that one should only acquire as much property as is appropriate; he or she should not gather endlessly. Hence, Locke is Aristotle's successor concerning the development of the concept of property and offers the original point for justifying moving from private property in goods to property in creative endeavours. Locke's philosophy on property is followed by Hegel's theory, which can also be considered a further successor, as Hegel developed these ideas about property and made them into a natural right. Hegel's philosophy of property is discussed in the following subsection.

3.2 Hegel's Philosophy of Property

There are several approaches and varied definitions of property from a philosophical perspective; regardless of these differences, the element common to the concept of property is that it is treated as a means rather than as an end. In most theories of property, it is regarded as a means to the good life – as a term for gaining freedom or as a term for the recognition of a human being.²¹ Hegel follows Locke's rationale regarding the relationship between the individual and property; he argues that property is the embodiment of personality. Further, his

21. M.J. Radin, *Reinterpreting Property* (University of Chicago Press, 1993); D. Resnik, 'A Pluralistic Account of Intellectual Property', 46(4) *Journal of Business Ethics* 319 (2003); C. May, *The Global Political Economy of Intellectual Property Rights: The New Enclosures?* (Routledge, 2013).

view can be seen as extending Locke's notions regarding private property, in as much as in claiming that property is the embodiment of personality, he transforms it into a natural right.

Simultaneously, he argues that the basis of individual rights lies in property. Property is not merely material acquisition, as it is central to an individual's assertion of identity and personality, and thus Hegel follows the same logic as Locke. What is more, Hegel says that property comprises both material and non-material aspects – in other words, tangible and intangible abstracts. Since Aristotle introduced private ownership as an aspect of self-interest, it encouraged philosophers like Locke and Hegel to further develop this issue and argue that property rights are natural rights and embodiments for personal growth, respectively. Suffice it to say that individuals' notions and self-interests are inherently distinguished from intellectual creation. From this mutual philosophical consideration, intellectual creation should be secured and protected as an additional instrument that accomplishes the move from property in goods to personal creations.

According to Hegel, property is an expression of ourselves and the 'location' where an individual can claim rights and state that 'this is mine' – a claim that others respect.²² The system of private property establishes individuality via contract and exchange. Based on this point, Hegel justifies the inevitable links among property, growth of personality and profits that stem from the aspect of self-interest. Contract demonstrates ownership through institutionalised patterns of mutual respect of individual rights and commitments. Economic life governed by free exchange of goods is based on an institutionalised notion of the individual as having some claim to recognition as a right-bearing person. If an exchange market is to operate effectively, economic actors have to identify universal standards by which a person can claim to own property. Established patterns of mutual recognition in the modern economic sphere are embodied in economic actors and depict a 'common will'.²³

As a result, the individual has no social traits and thus no reference to the social environment. This means that individuals have no private/personal life with features

to be integrated into society, such as a marriage and/or family with/without children, and thus no social reference.²⁴ Therefore, rights demonstrated by Hegel's idea of private property are abstract rights and engage individuals as universal subjects without specific features.²⁵ In addition, morality is called by Hegel the system of mutual recognition and abstract right. Hegel tries to merge various features of his philosophy and social views into a general declaration about the nature of modernity.²⁶ He traces a contemporary conception of individuality and of the individual as the agent of rights to modern social, economic and political institutions. To Hegel, morality is the subjective part of the mutual social commitments that are politically institutionalised in contracts and economic markets. Therefore, individuals experience mutual commitments as a moral obligation to respect abstract rights as ideals or a vision of good based on mutual recognition of abstract rights.

From the perspective of freedom and in accordance with Hegel's philosophy, where emphasis is placed on human needs, property is the first component of freedom and, therefore, is in itself a substantive end. Following this notion, Hegel highlights that if possession, as power over things, is simply pursued to satisfy self-interest, then possession is the means of satisfying these sorts of needs. However, according to Hegel, satisfaction of human needs is the aspect of mediation regarding recognition of the subject as a free agent. In this manner, power over things appears as a means for the growth of individual personality. Therefore, this justification represents the importance of an effective interconnection among self-interest, property and personal progress or individual advancement.

Accordingly, Hegel claims that property is the manifestation of the individual's effort to deploy his or her powers and come to self-consciousness by the appropriation of his or her environment.²⁷ Consequently, Hegel's task is not to provide a justification for property, but rather to comprehend and understand it as a phase in the production of the human mind. It is also the case that any effort to justify property in the context of Plato's ideas regarding joint ownership will not be suitable for Hegel, as he ignores the role that property plays in the growth of self-awareness among individuals. So long as property is the manifestation of one's will, it is appropriate to make clear that the substantial relationship between the willing subject and what should be individual's property is a procedure that should rely on self-determination.

22. D. Knowles, 'Hegel on Property and Personality', 33(130) *The Philosophical Quarterly* 45 (1983); M. Salter, 'Justifying Private Property Rights: A Message from Hegel's Jurisprudential Writings', 7(3) *Legal Studies* 245 (1987); H.-C. Schmidt am Busch, 'Personal Respect, Private Property, and Market Economy: What Critical Theory Can Learn from Hegel', 11(5) *Ethical Theory and Moral Practice* 573 (2008); A. Chitty, 'Recognition and Property in Hegel and the Early Marx', 16(4) *Ethical Theory and Moral Practice* 685 (2013).
23. J.R. Hollingsworth and R. Boyer, *Contemporary Capitalism: The Embeddedness of Institutions* (Cambridge University Press, 1997); C. Knill and D. Lehmkuhl, 'Private Actors and the State: Internationalization and Changing Patterns of Governance', 15(1) *Governance* 41 (2002); K. Nicolaidis and G. Shaffer, 'Transnational Mutual Recognition Regimes: Governance without Global Government', 68(3/4) *Law and Contemporary Problems* 263 (2005); W. Zhang et al., 'Local Gabor Binary Patterns Based on Mutual Information for Face Recognition', 7(4) *International Journal of Image and Graphics* 777 (2007); C. Shan, S. Gong & P.W. McOwan, 'Facial Expression Recognition Based on Local Binary Patterns: A Comprehensive Study', 27(6) *Image and Vision Computing* 803 (2009).

24. A. Honneth, *The Pathologies of Individual Freedom: Hegel's Social Theory* (Princeton University Press, 2010).
25. G.W.F. Hegel, *Hegel: Elements of the Philosophy of Right* (Cambridge University Press, 1991); R. Cropanzano et al., 'Self-Enhancement Biases, Laboratory Experiments, George Wilhelm Friedrich Hegel, and the Increasingly Crowded World of Organizational Justice', 58(2) *Journal of Vocational Behavior* 260 (2001).
26. F. Hegel, *The Philosophy of Right* (Hackett Publishing, 2015).
27. R. Teichgraber, 'Hegel on Property and Poverty', 38(1) *Journal of the History of Ideas* 47 (1977), at 47; *A Theory of Property* (Cambridge University Press, 1990); J.L. Schroeder, 'Unnatural Rights: Hegel and Intellectual Property', 60 *University of Miami Law Review* 453 (2005), at 453-456; May, above n 21, at 45-47.

Given Hegel's conceptualisation, it could be argued that intellectual property (IP) demonstrates individuals' ways of thinking and that it is thus necessary to clarify that when someone participates in a process where notions or thoughts develop in accordance with subliminal willingness. Hence, Hegel's ideas regarding comprehension of property can be considered a phase in the evolutionary process of the human mind.

From the foregoing discussion, it is evident that Plato, Aristotle, Locke and Hegel have developed the concept of property from communal property to individual ownership. Simultaneously, the justifications for ownership have expanded the concept of property from physical to intellectual goods. Thus, the concept of private property as a natural right gradually lends itself to the growth of notions regarding the elements of such a right.

3.3 The Extension of Property to Intellectual Efforts: Justifications

An important form of property in contemporary society is IP, which refers to original expressions of thought and new applications of ideas.²⁸ The efforts to recognise and protect IP and the relevant markets in such IP have developed considerably over the course of this century. If anything, the effects of ongoing information and technology (IT) advancements point to the influence of intellectual creations and the corresponding desire to protect the economic and intellectual aspects of the same.²⁹ Thus, in many ways, IP is justified as a kind of property. This comprises a vast area of specialist knowledge, and several salient issues could be identified. The following discussion is not meant to be an exhaustive analysis of all the relevant issues in this regard. Under this technological growth and progress, another aspect of property that should be considered is related to actual profits, as the concept of creation can be associated with such profits.³⁰

A notable scholar in the area of IP theories is Robert Merges, who claims that property does have a future. In addition, he states that if property demonstrates a proper respect both for individual proprietors and the social needs, it can contribute beneficially to a well-organised sociopolitical framework.³¹ As long as modern society's profitable resources come to be intangible, this capacity will gradually be served by the crucial part of property we call IP.³² Accordingly, Merges clearly sets out the basic features of a workable justification of IP, which are as follows: (a) properties' creative labour in accordance

with creative work is recognised and rewarded with true legitimate rights, and hence work from hourly wages is converted into a freestanding economic asset whenever possible; (b) grant of real rights, though not absolute rights, and within this element the creator's contribution is acknowledged by granting IP rights, but society's contribution to creative work is also acknowledged; and (c) accommodation of consumers' and users' necessities by facilitating and encouraging cost-effective and easy IP permission and licensing tools, combined with plain methods that allow binding dedication of rights to the public benefit. This last element of Merges's justification for IP serves as additional justification for OA practice.

In the contemporary discourse of IP, the economic aspects of IP outweigh all other considerations. Therefore, it is imperative that the economic justifications of IP be addressed. This analysis could provide an additional factor in determining reasons for which the notion of property may be extended to creative endeavours. Not surprisingly, economists explore ways of allocating scarce resources efficiently to unlimited wants and realise that IP rights are a plausible way of dealing efficiently with scarcity.³³ Another significant justification is that of utilitarianism; proponents argue that technological inventions are utilitarian works and, therefore, the principal economic theory applied is about utilitarianism. Moreover, utilitarian theorists generally endorse the creation of IP rights as an appropriate instrument to foster innovation.³⁴ Hence, it is acknowledged that freedom of expression and creation and dissemination of information – and its protection – ought to coexist to support effective outcomes, such as innovation. This justification illustrates the importance of creators' rights and a recognition that such efforts enhance social evolution; thus, creative efforts should be protected and shared.³⁵

However, a host of authors who have pursued economic analyses of IP have relied on the 'Kaldor-Hicks' criterion that advises lawmakers to develop a system of regulations that maximises aggregate welfare measured by end users' ability and willingness to pay for the goods and services in relation to information. Thus, three different economic justifications dominate the literature. First, incentive theory is the most common; it claims that the optimal doctrine is the one that maximises the difference between a) the current discounted value to end users of the intellectual products whose creation is

28. M.A. Lemley, 'Property, Intellectual Property, and Free Riding', 83 *Texas Law Review* 1031 (2004).

29. N. Kumar, 'Intellectual Property Rights, Technology and Economic Development: Experiences of Asian Countries', 38(3) *Economic and Political Weekly* 209 (2003); L. Yang and K.E. Maskus, 'Intellectual Property Rights, Technology Transfer and Exports in Developing Countries', 90(2) *Journal of Development Economics* 231 (2009).

30. E. Arezzo, 'Struggling around the Natural Divide: The Protection of Tangible and Intangible Indigenous Property', 25 *Cardozo Arts & Entertainment Law Journal* 367 (2007).

31. R.P. Merges, *Justifying Intellectual Property* (Harvard University Press, 2011).

32. I. Mgbeoji, 'Justifying Intellectual Property', 50 *Osgoode Hall Law Journal* 291 (2012).

33. M.P. Pugatch, *The International Political Economy of Intellectual Property Rights* (Edward Elgar Publishing, 2004); M.P. Pugatch, *The Intellectual Property Debate: Perspectives from Law, Economics and Political Economy* (Edward Elgar Publishing, 2006).

34. P.S. Menell, 'Intellectual Property and the Property Rights Movement', 30 *Regulation* 36 (2007); P.S. Menell, 'The Property Rights Movement's Embrace of Intellectual Property: True Love or Doomed Relationship?', *UC Berkeley Public Law Research Paper No. 965083* (2007).

35. R. Landry, N. Amara & M. Lamari, 'Does Social Capital Determine Innovation? To What Extent?', 69(7) *Technological Forecasting and Social Change* 681 (2002); D. Lane et al., *Complexity Perspectives in Innovation and Social Change* (Springer Science & Business Media, 2009); S.J. Guastello, *Chaos, Catastrophe, and Human Affairs: Applications of Nonlinear Dynamics to Work, Organizations, and Social Evolution* (Psychology Press, 2013).

induced by holding out to creators and inventors the carrot of monopoly power, and b) the ensemble detriments generated by such a system of incentives. In other words, this theory urges governmental lawmakers to establish or further develop IP protection when doing so would help end users by stimulating creative efforts more than it would hurt them by constricting their access to intellectual products or raising their taxes.

The second is the economic justification, which is based on patent regimes that reduce rental dissemination. Accordingly, its objective is to eliminate or reduce the tendency of IP rights to advance duplicative or uncoordinated inventive activity. Economic waste of this sort can occur at three stages in the inventive process.

Third, it is indispensable to realise that copyright and patent systems play crucial roles in letting potential producers of intellectual products know what end users want; hence, they channel productive outcomes in directions most likely to enhance end users' welfare. Based on this rationale, sales and licences will ensure that goods get into the hands of people who need them and can pay for them. Only under specific circumstances in which transaction costs would prevent such voluntary exchanges should the holders of IP rights be denied total scrutiny in relation to the uses of their works.

This overview of the economic rationales of IP rights needs to be related to the wider issue of whether the products of creative efforts can even be characterised as property. At this point, it is logical for me to ask how the concept of property ownership has informed the development of notions of IP. IP refers to the rights associated with the expression of an idea, or to other abstract objects.³⁶ In other words, IP indicates 'goods' created from our mind. Well-known types of IP rights comprise patents, trademarks and copyrights. In general, IP law supports exclusive rights to the appropriator over the use of IP and its aforementioned 'goods'. Below it is argued that the notion of IP rights was originally created to protect inventors and scientists, aiming to simultaneously protect creative procedures and benefit society. However, by amplifying the 'shield' of protection, this concept caused the opposite result. A few alternative initiatives to protect IP with less emphasis on trade emerged in the early nineties as a response to the progressively high level of capitalisation of IP rights.

4 The Historical Growth of Copyright as Property Right

In this part, the growth of copyright as property right is traced by examining the historical evolution of copyright from being considered property of goods to being considered property of creative endeavours with legal protection. It follows the connection of the Renaissance

developments with the creation of the printing press and explains how these resulted in the necessity for conceptualising IP and then protecting it through laws. Additionally, the Renaissance period was distinguished by a great revolution regarding intellectual creations, and, therefore, the concept of legitimate protection from relevant works emerged. This revolution laid the basis for the growth of the printing press industry. Consistently with the argument made in this article, this growth will lend further support to the claim that it is necessary to reform the concept of copyright to property right.

The following discussion is divided into six parts. The first part discusses the importance of the Renaissance and the rapid growth of intellectual creations, which indicated the end of medievalism and the beginning of the new age that would eventually introduce the law and economy of copyright. The second part looks at printing and publishing in Europe during the fifteenth century, when two advances illustrate a stage in the growth of copyright. In the third part, Speyer's monopoly,³⁷ which was introduced in Venice, and the English printing culture are considered as two issues that stand out during the Renaissance period. The fourth part analyses the Statute of Anne, the first official copyright regime, which signifies the introduction, for the first time, of an intellectual protection regime that translates the concept of copyright into a property right. The fifth part considers the significance of the *Berne Convention* as an international agreement governing copyright. The last part examines the significance of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement administered by the World Trade Organization (WTO). The TRIPS Agreement introduced IP law into the international trading system for the first time and remains the most comprehensive international agreement on IP.³⁸ It provides the background for the discussion in subsequent chapters.

4.1 Renaissance Period

In the middle of the fourteenth century, Black Death, one of the most devastating pandemics in human history, swept through Europe, killing one-third of the population.³⁹ Every institution of the medieval world was disconcerted, setting peasants free from feudal commit-

36. D.E. Bouchoux, *Intellectual Property: The Law of Trademarks, Copyrights, Patents, and Trade Secrets* (Cengage Learning, 2012).

37. C.L.C.E. Witcombe, *Copyright in the Renaissance: Prints and the Privilegio in Sixteenth-Century Venice and Rome* (BRILL, 2004); C. Geiger, *Criminal Enforcement of Intellectual Property: A Handbook of Contemporary Research* (Edward Elgar Publishing, 2012).

38. C.M. Correa, *Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options* (Zed Books, 2000); F.M. Abbott, 'The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO', 5 *Journal of International Economic Law* 469 (2002); D. Matthews, *Globalising Intellectual Property Rights: The TRIPS Agreement* (Routledge, 2003); C. Deere, *The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries* (Oxford University Press, 2008).

39. M. Dols, 'The Black Death in the Middle East'; D. Raoult et al., 'Molecular Identification by "Suicide PCR" of *Yersinia Pestis* as the Agent of Medieval Black Death', 97(23) *Proceedings of the National Academy of Sciences* 12800 (2000); P. Ziegler, *The Black Death* (Faber & Faber, 2013).

ments.⁴⁰ It was almost a century after the eruption of the Black Death that innovation in printing processes appeared, which, more than any other event, pointed to the end of medievalism and played a crucial role in the growth of the Renaissance. Moreover, it was the sign of the beginning of the new age that would finally introduce the law and economy of copyright.⁴¹

In 1439, Johannes Gutenberg, a German blacksmith, goldsmith, publisher and printer, introduced printing to Europe.⁴² His invention was a mechanical moveable type of printing, which shifted society as a whole and illustrates why it is regarded as the most crucial event of the modern period.⁴³ Notions, considerations and discussions stimulated minds across Europe and a trend of publishing came into being. The literate people of any class could publish pamphlets and even books in their own language.⁴⁴ It is worth noting that the first books printed in Europe were block books, with each page cut from a single block of wood, and usually these books were produced in two colours.⁴⁵ Additionally, the procedure of cutting letters into the wood was labour intensive, and so books were only a few pages thick.⁴⁶

As years passed by, another German goldsmith, Johannes Gutenberg, invented a more convenient process of printing by creating punches and casting styles of letters that permitted book printing within a more effective moveable form. Imitations of Gutenberg's printing press spread rapidly through Europe, and by the end of the century the publishing industry across Europe printed prolifically. The first printed European creation in moveable form is a papal indulgence of 1454

that was created in Mainz.⁴⁷ In the 1460s, German printers established workshops in Venice, Rome and Basel, which were under German dominance at the time.⁴⁸ Setting up workshops for printing books was a costly enterprise, requiring appropriate instruments and technology. The following subsection examines the main features of intellectual protection during the Renaissance period.

4.2 The Contrast of Contents

At that time, the trends were associated with growth, but in different 'clothes' compared with the period after the Renaissance. This comparison highlights the process of how copyright transformed into a property right. The contemporary world is distinguished by the continuous technological developments that comprise the basic feature of modern times.⁴⁹ The primary characteristic of the Renaissance was the growing volume of intellectual creations. Consequently, monopolies, relevant privileges and the necessity of creators' protections gradually emerged. In contemporary times, creators have sought to protect their online creations by using several digital licences.⁵⁰

Moreover, the Renaissance period was characterised by a growth of interest in classical learning and values, the decline of feudal regimes, development of commerce and the application of inventions with effective potential, such as paper and printing. Throughout the Renaissance, creators needed protection for their creations, but there was no particular 'redress' or legitimate regime for intellectual protection.

The Statute of Monopolies (1623), which clarifies how monopolies are a crucial element in the relationship between governments and publishers by excluding creators' roles and rights, played a critical role in the examined evolution. This statute was an Act of the English Parliament and illustrates the first statutory expression of English patent law.⁵¹ Chris Dent argues that the Statute of Monopolies was a milestone in the history of patents, with ongoing importance.⁵² Further, it is worth noting that the monarch issued the patents involved to

40. E. Brown, 'The Tyranny of a Construct: Feudalism and Historians of Medieval Europe', 79(4) *The American Historical Review* 1063 (1974); B. Stein, 'Politics, Peasants and the Deconstruction of Feudalism in Medieval India', 12(2/3) *The Journal of Peasant Studies* 54 (1985); J. Bean, *From Lord to Patron: Lordship in Late Medieval England* (Manchester University Press, 1989); J.L. Forgeng and J.L. Singman, *Daily Life in Medieval Europe* (Greenwood Publishing Group, 1999); F. Oakley, *Politics and Eternity: Studies in the History of Medieval and Early Modern Political Thought* (BRILL, 1999); J. Canning, *A History of Medieval Political Thought: 300-1450* (Routledge, 2014).
41. W.M. Landes and R.A. Posner, *The Economic Structure of Intellectual Property Law* (Harvard University Press, 2009); R. Bowker, *Copyright: Its History and Its Law* (2012).
42. E.L. Eisenstein, *The Printing Revolution in Early Modern Europe* (Cambridge University Press, 2005); J. Kostylo, 'From Gunpowder to Print: The Common Origins of Copyright and Patent', in *Privilege and Property: Essays on the History of Copyright* (Open Book Publishers, 2010).
43. A. Briggs and P. Burke, *Social History of the Media: From Gutenberg to the Internet* (Polity, 2010); C. Reed, *Gutenberg in Shanghai: Chinese Print Capitalism, 1876-1937* (UBC Press, 2011); M. McLuhan et al., *The Gutenberg Galaxy: The Making of Typographic Man* (University of Toronto Press, 2011).
44. C. Suhr, 'Publishing for the Masses: Early Modern English Witchcraft Pamphlets', 113(1) *Neuphilologische Mitteilungen* 118 (2012).
45. R. Chartier, *The Order of Books: Readers, Authors, and Libraries in Europe Between the Fourteenth and Eighteenth Centuries* (Stanford University Press, 1994); E. Buringh and J.L. Van Zanden, 'Charting the "Rise of the West": Manuscripts and Printed Books in Europe, A Long-Term Perspective from the Sixth through Eighteenth Centuries', 69(02) *The Journal of Economic History* 409 (2009).
46. L. Febvre and H.-J. Martin, *The Coming of the Book: The Impact of Printing 1450-1800* (Verso, 1997).

47. V. Gillespie and S. Powell, *A Companion to the Early Printed Book in Britain, 1476-1558* (Boydell & Brewer Ltd, 2014).
48. P. Benedict, *Graphic History: The Wars, Massacres and Troubles of Tortorel and Perrissin* (Librairie Droz, 2007).
49. D. Landes, *The Unbound Prometheus: Technological Change and Industrial Development in Western Europe from 1750 to the Present* (Cambridge University Press, 2003); M. Givoni, 'Development and Impact of the Modern High-Speed Train: A Review', 26(5) *Transport Reviews* 593 (2006).
50. Q. Liu, R. Safavi-Naini & N.P. Sheppard, 'Digital Rights Management for Content Distribution', 21 *Proceedings of the Australasian Information Security Workshop Conference on ACSW Frontiers* 49 (2003); V. Rosset, C.V. Filippin & C.M. Westphal, 'A DRM Architecture to Distribute and Protect Digital Contents Using Digital Licenses', in *Advanced Industrial Conference on Telecommunications/Service Assurance with Partial and Intermittent Resources Conference/E-Learning on Telecommunications Workshop (AICT/SAPIR/ELETE'05)* (2005) 422.
51. A. Pottage and B. Sherman, *Figures of Invention: A History of Modern Patent Law* (Oxford University Press, 2010).
52. C. Dent, 'Generally Inconvenient: The 1624 Statute of Monopolies as Political Compromise', 33 *Melbourne University Law Review* 415 (2009).

grant monopolies over specific enterprises to skilled individuals with new techniques. However, earlier English patent law was based on custom and common law, not on statute.⁵³ Moreover, the Crown granted patents as a form of economic protection to ensure high industrial production; it was in response to this state of affairs that this statute emerged.

The issue was that these patents were the Crown's 'presents' or gifts, with no judicial review, oversight or consideration; consequently, no actual law developed around patents.⁵⁴ This practice came from guilds – groups that were manipulated by the Crown and in turn held monopolies over specific industries.⁵⁵ Unlike the context of the current copyright and patent system, where privileges stem from creations, in the earlier period privileges were accepted as gifts from those who were ruling and were for the exclusive benefit of those who had governmental connections. Accordingly, Kostylo claims that: '[I]n contrast to modern copyright and patent, early privileges were conceived as a form of municipal favour (*gratiae*) and an exception to the law (*priva lex*) rather than the recognition of the author's inherent rights'.⁵⁶ In addition, she points out, these privileges took various shapes, such as exclusive monopolies granting the creators the right to take advantage of their work or engage in other productive activity, and printing privileges bestowed on publishers or authors exclusive rights to print and sell a work. Hence, both privileges were granted in terms of manipulation rather than as the acknowledgement of the creator's production and affiliated IP rights. Moreover, these types of privileges would later be determined as patents for inventions and proto-copyrights, respectively.⁵⁷

Thus, in the context of legitimacy, printing privileges and grants for automated inventions were practically identical. Further, according to Karjala, if patents are to be restricted in the current century to tangible objects and their operation by industrial procedures, it is to become progressively irrelevant as we steadily approach an information-as-product economy.⁵⁸ Considering that the history of patents begins not with inventions but

with royal grants of industrial monopolies in the Renaissance period, such as those granted by the English Crown, the origin of the idea that IP is a legal right is significant. Advocates claim that this radical change from monopoly privilege to legal property emerged solely in response to institutional and economic demands.⁵⁹ Such history is relevant, as the concepts of copyright and patent were not very distinct.

Going back to Kostylo's argument about the lack of differentiation between copyright and patents, there are at least two explanations: legal and cultural. In legal terms, primary printing privileges for mechanical inventions had not produced a separate bureaucratic framework and continued to rely on the same system of discretionary privileges. A notable effort that shows the first attempt to differentiate these concepts was the 1710 enactment of the Statute of Anne, which introduced a legitimate framework for intellectual protection.⁶⁰ The following section considers its significance as the first official regime for copyright law.

4.3 Early Printing and Publishing in Europe

Early printers were also publishers themselves, but by the sixteenth century there was a considerable increase in the number of printers. However, other individuals, who undertook the majority of costs and commercial risks, supported them financially.⁶¹ Many title pages of books from that time claim at the bottom that the work was printed by xxx for xxx (publisher or bookseller of the book). Occasionally, the publisher or bookseller was responsible for covering the costs of part of the supplies and equipment in the print shop and was usually sharing the income from the print run with the printer.⁶² It is worth mentioning that several books were published under the auspices of a significant patron, such as the Pope, a monarch or a wealthy cardinal, signifying that the financial aspect of the printing process was of paramount importance. For example, Aldus Manutius was an Italian humanist who became a printer and publisher when he founded the Aldine Press at Venice.⁶³ He made significant contributions to the enterprise of publishing, including inventing the italic form, introducing the use of the modern semicolon and the contemporary appearance of the comma and introducing inexpensive books in small formats. Additionally, and in relation to the costs of the printing process, it should be mentioned that Aldus Manutius issued various books with papal

53. C. MacLeod, *Inventing the Industrial Revolution: The English Patent System, 1660-1800* (Cambridge University Press, 2002); A.L. Durham, *Patent Law Essentials: A Concise Guide* (Praeger, 4th ed., 2013).

54. T. Nachbar, 'Monopoly, Mercantilism, and the Politics of Regulation', 91(6) *Virginia Law Review* 1313 (2005).

55. A. Kieser, 'Organizational, Institutional, and Societal Evolution: Medieval Craft Guilds and the Genesis of Formal Organizations', 34(4) *Administrative Science Quarterly* 540 (1989); S. Epstein, *Wage Labor and Guilds in Medieval Europe* (UNC Press Books, 1991); G. Richardson, 'Guilds, Laws, and Markets for Manufactured Merchandise in Late-Medieval England', 41(1) *Explorations in Economic History* 1 (2004).

56. J. Kostylo, *Commentary on Johannes of Speyer's Venetian Monopoly (1469)* (2008) Primary Sources on Copyright (1450-1900).

57. S. Bottomley, *The British Patent System during the Industrial Revolution 1700-1852: From Privilege to Property* (Cambridge University Press, 2014).

58. E.C. Walterscheid, 'Defining the Patent and Copyright Term: Term Limits and the Intellectual Property Clause', 7 *Journal of Intellectual Property Law* 315 (1999); D. Karjala, 'Distinguishing Patent and Copyright Subject Matter', 35 *Connecticut Law Review* 439 (2002); C. Long, 'Information Costs in Patent and Copyright', 90(2) *Virginia Law Review* 465 (2004).

59. A. Mossoff, 'Rethinking the Development of Patents: An Intellectual History, 1550-1800' (2006).

60. S. Elias and R. Stim, *Patent, Copyright & Trademark* (Nolo, 2004).

61. J. Pasley, *The Tyranny of Printers: Newspaper Politics in the Early American Republic* (University of Virginia Press, 2002); A. Pettegree, *The Book in the Renaissance* (Yale University Press, 2010).

62. A. Fyfe, 'Information Revolution: William Chambers, the Publishing Pioneer', 30(4) *Endeavour* 120 (2006); J. Curran and J. Seaton, *Power Without Responsibility: Press, Broadcasting and the Internet in Britain* (Routledge, 2009); N. Goff, 'Direct-Response Bookselling: How It Died, Why It Is Alive Again, and Why It Will Become Even More Important in the Future', 27(3) *Publishing Research Quarterly* 259 (2011).

63. N. Barker, *Aldus Manutius and the Development of Greek Script & Type in the Fifteenth Century* (Fordham University Press, 1992); E. Lup-ton, *Thinking with Type* (Chronicle Books, 2014).

financial support.⁶⁴ According to Sider, most printing projects were meant to make a profit, but not necessarily constantly regardless of total costs.

Moreover, many early printers had serious difficulties publishing, as printing was a capital-intensive and highly competitive business.⁶⁵ It is to be expected that the publishers wanted to secure their investment and gains. Therefore, before printing a particular text, the printer would request permission from governments for an exclusive monopoly on printing that text. It is not surprising that privileges, monopolies and relevant revenues associated with intellectual creations and relevant efforts arose.⁶⁶ However, it is obvious that the author's role was not so important in relation to the management of his works and potential agreements with publishers. Indeed, the author's role was relegated to the bottom in the hierarchy of interests in the context of trade, and the bilateral agreements between the publishers and the rulers highlight the emerging disadvantage of the author's role. According to Kretschmer, the rhetoric of author's rights has been broadly pushed by third parties (*i.e.* investors in creativity, rather than creators), who also turn out to be the chief beneficiaries of the extended protection. He argues, furthermore, that ever since the beginning the printing press environment has been extremely blurred, still showing traces of feudal features.⁶⁷ In early times, the creators were mostly men, and therefore the pronoun *he* is used for reference.

The following subsection examines the relationship between Speyer, the publisher and the Venetian Government that granted exclusive privileges for printing in Venice. Hence, the concept of copyright developed from the exclusive privilege of printing rather than from a desire to protect the author's creation.

4.4 Speyer's Monopoly and the English Printing Culture

During the fifteenth century, the home of the first printing privileges was Venice. The very first publicly claimed copyright was decided by the rulers of Venice on 18 September 1469, shortly after the German Master Johannes of Speyer opened a printing shop there and started printing with the support of the rulers of the

Venetian Republic. This was the earliest European initiative where Speyer was granted an exclusive monopoly on printing in Venetian territories. Johannes Speyer was indeed bestowed with much more than merely a right to copy. He was given a five-year monopoly to print. In contemporary terms, this was a formal paradigm 'infant' industry protection.⁶⁸ The practice of granting exclusive privileges to print in a particular city, to print a particular text or to print a particular category of texts spread instantly from Venice throughout the Italian states, and from there to France and England.⁶⁹

Even though this monopoly has been addressed as the first acknowledged patent, setting in motion a long tradition of granting printing privileges in Europe, Speyer's monopoly does not seem to be something new or outstanding in the economic life and legal tradition of Venice. This is because Venetians may not have been the first to introduce printing into Italy, though they rapidly determined the significance of this new craft.⁷⁰ Thenceforth, in the thirteenth century the Venetian people led Europe in their endeavours by granting monopoly rights to immigrants who brought new skills and qualifications to the city.

Certainly, during the fifteenth and sixteenth centuries the Venetian Government received over a thousand applications from specialists in diverse areas, among whom were the makers of soap, gunpowder, saltpetre and glass, tanners, miners and civil engineers.⁷¹ These applications cover every possible subject, from machines and tools for draining the marshes to poisons and windmills. Significantly, this new craft of printing flourished outside the guild structure and, consequently, in the absence of any administrative framework controlling and supervising this sort of commerce. As for the guilds, the rest of society usually judged these institutions as 'rivals' of the public good and not as laudable patterns for organising society on corporate lines.⁷² It is evident that printing and publishing commerce was not organised into a closed form until 1549. Hence, for the first eighty years of printing in Venice, relevant privileges continued to be granted occasionally and on an ad hoc basis. In this manner, distinction between commercial monopolies and proto-copyrights did not exist in early modern Venice.

64. H.-J. Martin, *The History and Power of Writing* (University of Chicago Press, 1995).

65. S. Sider, *Handbook to Life in Renaissance Europe* (Oxford University Press, 2007); B.R. Costas, *Print Culture and Peripheries in Early Modern Europe: A Contribution to the History of Printing and the Book Trade in Small European and Spanish Cities* (BRILL, 2012); A. Milward and B. Saul, *The Economic Development of Continental Europe 1780-1870* (Routledge, 2013).

66. K. Maskus, *Intellectual Property Rights in the Global Economy* (Peterson Institute, 2000); P. Romer, 'When Should We Use Intellectual Property Rights?', 92(2) *The American Economic Review* 213 (2002); K. Idris, *Intellectual Property: A Power Tool for Economic Growth* (WIPO, 2003); E. Gresser, *U.S. Share of World Intellectual Property Revenue – 39 Percent* (2013).

67. M. Kretschmer, 'Intellectual Property in Music: A Historical Analysis of Rhetoric and Institutional Practices', 6(2) *Studies in Cultures, Organizations and Societies* 197 (2000); M. Kretschmer, L. Bently and R. Deazley, 'The History of Copyright History: Notes from an Emerging Discipline', in *Privilege and Property: Essays on the History of Copyright* (Open Book Publishers, 2010) 1.

68. G. Grossman and H. Horn, 'Infant-Industry Protection Reconsidered: The Case of Informational Barriers to Entry' (Working Paper 2159, National Bureau of Economic Research, February 1987); K. Head, 'Infant Industry Protection in the Steel Rail Industry', 37(3/4) *Journal of International Economics* 141 (1994); M. Shafaeddin, 'What Did Frederick List Actually Say? Some Clarifications on the Infant Industry Argument' (UNCTAD Discussion Paper 149, United Nations Conference on Trade and Development, 2000).

69. C. Hesse, 'The Rise of Intellectual Property, 700 B.C.-A.D. 2000: An Idea in the Balance', 131(2) *Daedalus* 26 (2002).

70. J. Kostylo, 'Sinking and Shrinking City: Cosmopolitanism, Historical Memory and Social Change in Venice' in *Post-Cosmopolitan Cities: Explorations of Urban Coexistence* (Berghahn Books, 2012) 170.

71. J. Weatherford, *The History of Money* (Crown Publishing Group, 2009).

72. J. Beinun, *Workers and Peasants in the Modern Middle East* (Cambridge University Press, 2001); J. Lucassen, T. De Moor & J.L. van Zanden, *The Return of the Guilds* (Cambridge University Press, 2008).

In sum, the practice of granting industrial privileges in early modern Italy constituted a crucial field in which new ways and methods arose concerning authorship and property. These developments formed the social and philosophical vocabulary of IP that foreshadowed its legal outline and adjustment as part of copyright tradition in the longer term. Let us now turn to England, a country with a long history concerning copyright and its growth. As England was also influenced by the rapid growth of intellectual creations in the Renaissance period, it acquired a well-established literary and printing culture.

First, in the sixteenth century the society of England was affiliated with Aristotle's views regarding property and the significance of individual evolution, and thus society was individualistic.⁷³ Second, England has a long history of literary and printing culture, in which the concept of authorship could have been constructed. In addition, and as mentioned before, it is well known that printing had a revolutionary influence in Europe. England adopted the moveable sort of printing press from Germany during the Renaissance and instantly improved its publishing industry.⁷⁴ Third, in terms of copyright protection, England has the longest legal tradition of copyright protection and was the first country to demonstrate a common law tradition of authors' rights.⁷⁵

4.5 The Statute of Anne 1710

Ronan Deazley claims that there were no fewer than thirteen failed efforts between 1695 and 1704 to accord a framework of statutory regulation for printing.⁷⁶ Eventually, the Worshipful Company of Stationers and Newspaper Makers, usually known as the Stationer's Company,⁷⁷ agreed to the Statute of Anne, which was enacted in the spring of 1710. Accordingly, there are advocates who argue that the passing of the Statute of Anne in 1710 is the seminal moment in copyright history.⁷⁸ It is evident that, for the first time, regulations identified an author's – not the bookseller's – right to administer the reproduction of books. Further, the author's copyright as the exclusive right to administer the reproduction of books, according to the Statute of Anne, was valid for fourteen years since publication and could be renewed by the author for an additional seven

years.⁷⁹ By acknowledging the author's right to property in books and other printed material, the Statute of Anne set the foundation for the contemporary structure of copyright law.

Atkinson and Fitzgerald claim: '[T]he Act also resolved long-standing antagonism between publishers and parliamentarians, many of whom wanted to drive a dagger through the heart of the booksellers' monopoly'.⁸⁰ The Statute of Anne was an agreement that stemmed from the publishers' willingness to regulate a chaotic market and politicians' willingness to strike at monopoly. Additionally, it is necessary to mention that the regulations, which were affiliated with the Statute of Anne, could not be described as friendly to booksellers. However, the most important transformation brought about by this Statute is in relation to what it does not legislate. It makes no provision whatsoever for the state arrangement of what could or could not be published. Additionally, the Statute of Anne argues about liberties that offending printers and booksellers have taken with authors and owners of intellectual creations who have realised that their books, inventions or writings were printed without their acquiescence. Deazley claims that: '[T]he basic plank of the Statute of Anne was then, and remains, a social quid pro quo. To encourage "learned men to compose and write useful books" the State would provide a guaranteed, if finite, right to print and reprint those works'.⁸¹ I find support in this conclusion to contend that with the Statute of Anne a critical opportunity or bargain emerged involving authors, booksellers and the public. Deazley's statement correctly reflects the significance of the Statute of Anne as the first attempt at an effective equilibrium among the stakeholders of IP.

The scope of licensing under this statute was to regulate what might be said in print to control the publishers in the interests of good order. The primary aim of the Statute of Anne was to inspire further study and speech and to empower debates in the public sphere. Therefore, by entrusting the copyright of a printed work to the creator or author rather than the publisher or bookseller, the author is made responsible for the publishing and reproduction of his/her book; thus, the Statute reformulates the concept of copyright as a property right. That is, copyright, rather than being an advantage, benefit or 'gift' to authors, is the natural consequence that stems from their intellectual creativity. Hence, the Statute grants a legal framework to the public sphere, supporting a regime in which authors are invited to bring their intellectual creations or writings into the public forum. The rationale is that these are the

73. S.-H. Mun, *Culture-Related Aspects of Intellectual Property Rights: A Cross-Cultural Analysis of Copyright* (ProQuest, 2008).

74. British Academy, B.H. Harrison & M.H.C. Gray, *The Oxford Dictionary of National Biography: In Association with the British Academy: From the Earliest Times to the Year 2000* (Oxford University Press, 2004).

75. A. Barron, 'Copyright', 23(2/3) *Theory, Culture & Society* 278 (2006).

76. R. Deazley, *On the Origin of the Right to Copy: Charting the Movement of Copyright Law in Eighteenth Century Britain* (Hart Publishing, 2004).

77. *Ibid.*; M. Rose, 'The Public Sphere and the Emergence of Copyright: Areopagitica, the Stationers' Company, and the Statute of Anne' in *Privilege and Property: Essays on the History of Copyright* (Cambridge: Open Book Publishers, 2010) 67.

78. M. Rose, *Authors and Owners: The Invention of Copyright* (Harvard University Press, 1995); P. Geller, 'Copyright History and the Future: What's Culture Got to Do with It', 47 *Journal of the Copyright Society of the USA* 209 (2000).

79. L. Bently, U. Suthersanen & P. Torremans (eds.), *Global Copyright: Three Hundred Years Since the Statute of Anne, from 1709 to Cyberspace* (Edward Elgar Publishing, 1st ed., 2010).

80. B. Benedict and B. Fitzgerald, 'The Nineteenth Century: Liberty and Literary Property', in *A Short History of Copyright* (Springer International Publishing, 2014) 37.

81. R. Deazley, *Rethinking Copyright: History, Theory, Language* (Edward Elgar Publishing, 2006) 13-14.

creations that stem from their authority, their learning and their considerations.

The old regime of licensing that strengthened the Stationer's Company was an opportunity for mutually beneficial discussions between the booksellers and the state. Accordingly, some proponents claim that the Statute of Anne offered a triple-path opportunity among creators/authors, booksellers and the reading community.⁸² Specifically, authors were granted legal recognition and definite monopoly rights, booksellers were granted the chance to purchase and take advantage of these monopoly rights and the reading community was certain that after the end of the restricted term of protection the works would become free and open to everyone. By designating limitations, the Statute of Anne produced the literary commons, which is now known as public domain, and offered more social aspects in conjunction with intellectual creations.⁸³ In other words, authors and booksellers began to enjoy mutual benefits.

4.6 From 'Privilege' to Berne Convention

As a cumulative consequence of the invention of the printing press by Gutenberg in 1436 and in conjunction with Speyer's monopoly and the Statute of Anne, the amount of publishing and copying worldwide developed considerably.⁸⁴ Before the emergence of the printing press, booksellers used to copy authors' manuscripts by hand.⁸⁵ After the introduction of printing, booksellers were able to copy authors' manuscripts at a much faster rate. Therefore, profits from the sale of books helped booksellers to recover the costs incurred on authors' manuscripts and the process of printing.

Because of the ease of printing, printing presses led to 'piracy'; there were 'pirate' booksellers who copied books already published by the 'lawful' booksellers. In addition, these 'pirate' booksellers could sell copied books at lower prices. This was because they were able to avoid paying for authors' manuscripts.⁸⁶ It is reason-

able to expect that neither the 'lawful' booksellers nor the authors had any legal recourse against these 'pirate' booksellers. And it is obvious that from this point on the necessity of protection of the interests of the authors and publishers emerged. This necessity first emanated from the booksellers, whose economic interest was endangered by the 'pirate' booksellers. The booksellers successfully lobbied their respective sovereigns for protection in the form of an exclusive right, better known as a 'privilege'.⁸⁷ The privilege granted legitimate booksellers the exclusive right to print and sell specific authors' manuscripts for a limited time. In essence, the government bestowed upon the printer a limited monopoly. The sovereigns also benefited from this arrangement, because they could decide which booksellers would receive a privilege and which manuscripts were suitable for printing.⁸⁸ The sovereign censored manuscripts that it believed would threaten the public order.⁸⁹ The use of these privileges came to an end about two hundred years after they were introduced.⁹⁰ There are three reasons or justifications for their demise: (a) Printers began to abuse their monopoly power, thereby angering their sovereigns in the process. In England, for instance, such abuses were one factor in the House of Commons' refusal to renew privileges.⁹¹ (b) As governments became more mature, the need for censorship began to diminish. (c) The authors became more active in arguing for protection of their own rights.⁹²

The new system of protection that filled the vacuum left by the privilege system was a statutory form of protection that focused, for the first time, on the rights of the authors.⁹³ With the Statute of Anne, the first statutory copyright for the protection of authors spread throughout Europe and the United States. However, a great number of authors' works crossed national boundaries and, as authors were unprotected in foreign countries, 'pirates' easily targeted their literary works.⁹⁴ The authors from different countries acted to force governments to protect their works under an international

82. R. Deazley, 'Commentary on the Statute of Anne 1710', available at: www.copyrighthistory.org; M. Rose, 'Public Sphere and the Emergence of Copyright: Areopagitica, the Stationers' Company, and the Statute of Anne', 12 *Tulane Journal of Technology and Intellectual Property* 123 (2009).
83. L.R. Patterson, 'Understanding the Copyright Clause', 47 *Journal of the Copyright Society of the USA* 365 (2000); S. Morris and H.S. Shin, 'Social Value of Public Information', 92(5) *The American Economic Review* 1521 (2002); J. Boyle, 'The Second Enclosure Movement and the Construction of the Public Domain', 66(1/2) *Law and Contemporary Problems* 33 (2003); L.R. Goldberg et al., 'The International Personality Item Pool and the Future of Public-Domain Personality Measures', 40(1) *Journal of Research in Personality* 84 (2006); L.A. Fennell, 'Commons, Anticommons, Semicommons', in K. Ayotte and H.E. Smith (eds.), *Research Handbook on the Economics of Property Law* (2010).
84. I. Wallerstein, *The Modern World-System I: Capitalist Agriculture and the Origins of the European World-Economy in the Sixteenth Century, with a New Prologue* (University of California Press, 2011).
85. R. Rouse and M. Rouse, *Manuscripts and Their Makers: Commercial Book Producers in Medieval Paris, 1200-1500*, Vol. 1 (2000) 328; L. Mayer, *Worlds Made Flesh: Chronicle Histories and Medieval Manuscript Culture* (Routledge, 2004).
86. M. Everton, "'The Would-Be-Author and the Real Bookseller": Thomas Paine and Eighteenth-Century Printing Ethics', 40(1) *Early American Literature* 79 (2005); A. Johns, *Piracy: The Intellectual Property Wars from Gutenberg to Gates* (University of Chicago Press, 2010); W. Slaut-

- er, 'Upright Piracy: Understanding the Lack of Copyright for Journalism in Eighteenth-Century Britain', 16(1) *Book History* 34 (2013).
87. S. Yamada, 'Pirate' Publishing: The Battle over Perpetual Copyright in Eighteenth-Century Britain (Shoji Yamada, 2012).
88. M. Biagioli and P. Galison, *Scientific Authorship: Credit and Intellectual Property in Science* (Routledge, 2014).
89. B. Müller, 'Censorship and Cultural Regulation: Mapping the Territory', 22(1) *Critical Studies* 1 (2003); R. Birn, 'Book Censorship in Eighteenth-Century France and Rousseau's Response' (2005) 1 223; Anastasia Castillo, *GRIN - Banned Books: Censorship in Eighteenth-Century England* (2009).
90. K. Shao, 'Monopoly or Reward: The Origin of Copyright and Authorship in England, France and China and a New Criticism of Intellectual Property', 41 *Hong Kong Law Journal* 731 (2011).
91. A. O'Brien and M. Bosc (eds.), *House of Commons Procedure and Practice, Second Edition 2009* (Yvon Blais, 2009).
92. N.J. Karolides, M. Bald and D.B. Sova, *120 Banned Books: Censorship Histories of World Literature* (Checkmark Books, 2nd ed., 2011).
93. S. Ricketson, *International Copyright and Neighbouring Rights: The Berne Convention and Beyond/Sam Ricketson and Jane Ginsburg* (Oxford University Press, 2nd ed., 2006).
94. C. Bold, *The Oxford History of Popular Print Culture* (Oxford University Press, 2011).

system and not just via domestic regimes.⁹⁵ As the magnitude of piracy expanded, the scope of relevant activity regarding copyright protection from an international perspective also developed. More countries pursued the aim of settling copyright relations based on treaty.⁹⁶

Material reciprocity was the core concept of the first international copyright treaties.⁹⁷ In accordance with this concept, country one would grant country two's authors the same protection as country two would grant country one's authors.⁹⁸ However, this regime was ineffective and complicated,⁹⁹ and a number of countries maintained piracy as the focal theme of their international copyright relations. They declined to enter into any treaties, or if they did enter into such treaties they failed to abide by the terms.

The first attempt to protect foreign authors via the national treatment regime came from the decree of 1852.¹⁰⁰ According to this treatment, country one granted authors from country two the same protection that country one granted its own authors. Thus, a national treatment framework is much easier to manage than a reciprocity framework, as courts need only interpret their own domestic copyright law.¹⁰¹ Therefore, any advances in domestic authors' rights in country one would automatically accrue to authors from country two.

Following the decree of 1852, a trend arose in Europe for better international protection of the authors' rights. The extension of copyright protection demonstrated additional support to authors' rights. As authors' rights triggered even more attention in domestic legislation, authors became an effective political group. Since the beginning of the movement, in the context of international copyright protection, two explicit principles competed for supremacy. First, the non-discrimination principle of domestic treatment preserves the probity of national regulations and ensures that foreign authors will be homogenised with local authors. Second, multilateral patterns ensure international consistency and thus increase the distribution of works of authorship globally.

In 1858, the first international Congress of Authors and Artists met in Brussels; the work of this group laid the

groundwork for the drafting and signing of the *Berne Convention*.¹⁰² In addition, the decisions issued by the Congress impelled the gradual elimination of formalities, national treatment and domestic regulations. Thus, in accordance with the first draft of the *Berne Convention*, national forms were to work in cooperation with international forms, but the latter were to be applied via domestic regulations. Although the convention did not achieve every goal outlined at the first Congress in 1858, it illustrated the taking of a great step regarding international copyright protection. And despite the diverging views expressed by the participating countries, the last draft of the *Berne Convention* (1886) laid the groundwork for later developments concerning universality of an appropriate international copyright regime, which was introduced in earlier drafts. Therefore, the adoption by members of the WTO of the TRIPS Agreement further extended the *Berne Convention's* minimum standards to countries beyond the Berne Union. Therefore, the TRIPS Agreement is addressed in the following subsection.

4.7 From Berne Convention to TRIPS Agreement

The broadly differing patterns of protection and enforcement of IP rights, as well as the absence of a universal regime of regulations and disciplines to deal with the international trade in products, became a critical trend in the international trade relations.¹⁰³ Eventually, the TRIPS Agreement was negotiated. It comprised an integral part of the multilateral trade negotiations under the Uruguay Round of the General Agreement on Tariffs and Trade (GATT).¹⁰⁴ It covers copyright and related rights (*i.e.*, the rights of performers, producers of sound recordings and broadcasting organisations); trademarks, including service marks; geographical indications, including appellations of origin; industrial designs; patents, including the protection of new varieties of plants; the layout designs of integrated circuits; and undisclosed information, including trade secrets and test data. A significant trait of the TRIPS Agreement concerns the extension of multilateral GATT dispute settlement as an appropriate regime for IP protection. This permits application of trade approvals by comprising, for instance, the suspension of concessions or other obligations.¹⁰⁵

Sell and Prakash argue that, while the TRIPS Agreement represents the first comprehensive and enforceable

95. J. Ederington, 'International Coordination of Trade and Domestic Policies', 91(5) *The American Economic Review* 1580 (2001).

96. J. Jackson, *The Jurisprudence of GATT and the WTO: Insights on Treaty Law and Economic Relations* (Cambridge University Press, 2000).

97. V. Curzon, 'Non-Discrimination and the Rise of "Material" Reciprocity', 12(4) *World Economy* 481 (1989); K.A. Elliott and T. O. Bayard, 'Reciprocity and Retaliation in U.S. Trade Policy' (Peterson Institute Press, 1994); E. Fehr and S. Gächter, 'Fairness and Retaliation: The Economics of Reciprocity', 14(3) *The Journal of Economic Perspectives* 159 (2000); H. Gintis, *Moral Sentiments and Material Interests: The Foundations of Cooperation in Economic Life* (MIT Press, 2005).

98. P. Yu, 'Currents and Crosscurrents in the International Intellectual Property Regime', 38 *Loyola of Los Angeles Law Review* 323 (2004).

99. B. Cammaerts, 'The Hegemonic Copyright-Regime vs. the Sharing Copyright Users of Music?', 33(3) *Media, Culture and Society* 491 (2011).

100. G. Gutu, 'Interpretative Dimensions on Object of Public Property', 6(1) *Contemporary Legal Institutions* 163 (2014).

101. M.A. Leaffer, *Understanding Copyright Law* (LexisNexis, 2010).

102. J. Ginsburg, 'International Copyright: From a Bundle of National Copyright Laws to a Supranational Code', 47 *Journal of the Copyright Society of the USA* 265 (2000).

103. D. Harris, 'TRIPS' Rebound: An Historical Analysis of How the TRIPS Agreement Can Ricochet Back against the United States', 25(1) *Northwestern Journal of International Law & Business* 99 (2004).

104. P. McCalman, 'Who Enjoys "TRIPS" Abroad? An Empirical Analysis of Intellectual Property Rights in the Uruguay Round', 38(2) *Canadian Journal of Economics/Revue Canadienne D'économique* 574 (2005).

105. S. Babovic and K.M. Wasan, 'Impact of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement on India as a Supplier of Generic Antiretrovirals', 100(3) *Journal of Pharmaceutical Sciences* 816 (2011); G.D. Vita, 'The TRIPS Agreement and Technological Innovation', 35(6) *Journal of Policy Modeling* 964 (2013).

global agreement on IP rights, it has been the subject of much criticism since its inception.¹⁰⁶ The standard argument in support of TRIPS arises from the recognition of the modern importance of the knowledge economy and private IP as a crucial element of international commerce.¹⁰⁷ According to Matthews, disputes regarding IP protection constitute significant non-tariff obstacles to commerce; thus, TRIPS is a consequence of the necessity of a robust multilateral scheme to substitute what was an ineffective patchwork of pre-existing IP conventions.¹⁰⁸ For the first time since GATT was launched in 1947, the Uruguay round of multilateral trade negotiations constituted an effort to harmonise international IP rights protection. By the end of these negotiations, participating states signed the TRIPS Agreement to regulate and protect trade-related aspects of IP rights. Additionally, the TRIPS Agreement brought IP into the trade regime overseen by the WTO and put in place a global minimum standard of intellectual protection that WTO members must follow. This covers copyrights, trademarks, industrial designs, geographical indications, patents, integrated circuit designs, trade secrets and anti-competitive contract restrictions. Suffice it to say that by globalising IP rights via the TRIPS Agreement, obstacles to trade were overcome.

Various wider benefits to society are said to accrue from the imposition of temporary monopolies and other limitations that result from private IP rights.¹⁰⁹ By instituting legal protection, the disclosure of new knowledge and creativity is encouraged, and the significant costs associated with the creative process (such as with research and development) can be recouped and remuneration earned. Innovation is thus both rewarded and further promoted. Not only should the scope and reliability offered by a global intellectual property rights (IPR) regime stimulate domestic innovation, but the security offered to patent holders in the developed world and others can also encourage foreign direct

investment, technology transfer and licensing, and the diffusion of knowledge to the developing world.

What is more, the TRIPS Agreement represents a significant advance from previous agreements concerning IP rights in terms of monitoring, enforcement and dispute settlement capabilities. In addition, a TRIPS Council reviews domestic legislation and application of the accord. Therefore, its supporters see the TRIPS Agreement as representing an enforceable global regime of IP protection that plays an essential role in the contemporary global information society. The rewarding and encouraging of innovation spurs economic growth and enables technological evolution.

Since the TRIPS Agreement came into force, it has attracted increasing criticism from developing countries, academics and non-governmental organisations. Some of this criticism is against the WTO as a whole, but many advocates also regard the TRIPS Agreement as ineffectual policy. The TRIPS Agreement's wealth concentration effects (moving money from people in developing countries to copyright and patent owners in developed countries) and its imposition of artificial scarcity on the citizens of countries that would otherwise have had weaker IP laws are common bases for such criticisms.

For example, Drahos claims that: '[I]t was an accepted part of international commercial morality that states would design domestic intellectual property law to suit their own economic circumstances. States made sure that existing international intellectual property agreements gave them plenty of latitude to do so.'¹¹⁰ Further, Archibugi and Filippetti contend that the importance of TRIPS in the process of generation and diffusion of knowledge and innovation has been overestimated by both their supporters and their detractors.¹¹¹ Claude Henry and Joseph E. Stiglitz argue that the modern IP global framework may impede both innovation and distribution and suggest reforms to empower the global dissemination of innovation and sustainable deployment.¹¹² This article argues that OA practice is justified as a means of widening access to knowledge; the next part introduces the issues that will be developed further in the following chapters.

106. S. Sell and A. Prakash, 'Using Ideas Strategically: The Contest between Business and NGO Networks in Intellectual Property Rights', 48(1) *International Studies Quarterly* 143 (2004).

107. P. Van den Bossche, *The Law and Policy of the World Trade Organization: Text, Cases and Materials* (Cambridge University Press, 2008); B. Hoekman and M. Kostecki, *The Political Economy of the World Trading System* (Oxford University Press, 2009); A. Narlikar, M. Daunton & R.M. Stern, *The Oxford Handbook on The World Trade Organization* (Oxford University Press, 2012).

108. D. Matthews, 'WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the Trips Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?', 7 *Journal of International Economic Law* 73 (2004); D. Matthews, 'TRIPS Flexibilities and Access to Medicines in Developing Countries: The Problem with Technical Assistance and Free Trade Agreements', *European Intellectual Property Review* (2005); D. Matthews, 'From the August 30, 2003 WTO Decision to the December 6, 2005 Agreement on an Amendment to TRIPS: Improving Access to Medicines in Developing Countries?', *Intellectual Property Quarterly* (2006).

109. D. Lee, 'Understanding the WTO Dispute Settlement Process', *Trade Politics* (Psychology Press, 2004); J.L. Goldstein, D. Rivers & M. Tomz, 'Institutions in International Relations: Understanding the Effects of the GATT and the WTO on World Trade', 61 *International Organization* 37 (2007).

110. P. Drahos and J. Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* (Earthscan, 2002) 38; D. Klein, *The Strategic Management of Intellectual Capital* (Routledge, 2009).

111. D. Archibugi and A. Filippetti, 'The Globalisation of Intellectual Property Rights: Four Learned Lessons and Four Theses', 1(2) *Global Policy* 137 (2010).

112. C. Henry and J. Stiglitz, 'Intellectual Property, Dissemination of Innovation and Sustainable Development', 1(3) *Global Policy* 237 (2010).

5 Open Access: A Means to Enhance Copyright Protection

It is evident from the discussion in the preceding sections that scholars have been communicating thoughts, considerations, claims, research outcomes and examinations of these throughout the ages in a diversity of forms. For instance, lectures, discussions, essays, manuscripts, monographs, articles and books are among the most common ways of sharing intellectual ideas or scholarship. With the coming of the Enlightenment, the first scholarly periodicals, *Philosophical Transactions of the Royal Society of London* and *Journal des Sçavans*, appeared in 1665 from leading learned societies.¹¹³

Since that time, scholarly articles became a principal form for beneficial scholarly communication.¹¹⁴ Learned societies took authority and responsibility for editing and publishing scholarly journals during their early years.¹¹⁵ This trend continues; various contemporary scholarly societies publish some of the leading journals in a variety of science areas. However, after World War II, government investment in Western Europe and the United States in the field of scientific research increased the numbers of scholarly researchers who could communicate with their fellows. Simultaneously, it should be mentioned that the learned societies were slow to adapt to this instant flow of investment and that the representatives of the printing press industry entered the area in growing numbers to provide new titles in a variety of scientific areas.

The growing literature obligated subscribers of scholarly journals, such as academic libraries, government agencies, industrial research centres and individuals, to obtain access to scholarly data.¹¹⁶ However, the expenses associated with such access began to increase with the rise of electronic publication.¹¹⁷ In addition, journal publishers were forced to produce their content in two different forms – the hard copy journal and the electronic or digital version, hosted on a digital network. As the prices of scholarly journals surpassed costs, worries regarding maintenance of affordable access to this sort of literature began to amplify. What is more, the development of the Internet, and specifically the World Wide

Web (WWW), introduced new terms, challenges and circumstances regarding scholarly communication. Therefore, I advocate the attachment of the printing press with digital or online platforms to follow up with the Internet, which in turn offers a contemporary way to publish.

Regardless of the emergence of the Internet, which promised the possibility of extending access to the scholarly literature via cost-effective ways, for-profit publishers instead of non-profit scholarly societies inhabit scholarly publishing to a greater extent and have increasingly consolidated their economic power. By using their collective power over pricing, for-profit publishers have firmly increased journal subscription prices, making it a struggle for academic libraries and other subscribers to benefit from their patrons' desire for access to up-to-date research.

A renowned author in the OA area, Michael Carroll, argues that as a result of frustrations over foregone opportunities to grow Internet diffusion of scholarly research and ever-rising journal prices, academic librarians, autodidacts and some academic leaders unified to initiate OA.¹¹⁸ Accordingly, Carroll argues that the principal goal of OA is quite simple, as within OA scholarly literature and relevant resources, information is freely available on the public Internet for end users and researchers of all kinds.¹¹⁹

OA is a useful innovation, even if there are minor obstacles to online availability of information that end users could enjoy while using scholarly journal articles. However, more significantly, copyright protection issues have emerged and should be considered. In this context, advocates argue that there are two ways scholars can make their articles accessible while simultaneously protecting copyright. They can do so by publishing either via the 'gold road' of OA, in which publications are freely available online to the public, or via the 'green road' of OA in a subscription-access journal, in which the author should self-archive an e-print of his/her work in an online OAR.¹²⁰ Once an article is freely accessible by either method, it is indexed by search engines and is immediately locatable and retrievable by anyone with Internet access.¹²¹ Taking everything into account, the concept of OA is a response to current technological developments in conjunction with creative efforts that should be formulated and attached to modern copyright laws, appropriately.

113. D. Weber, *Barbaros: Spaniards and Their Savages in the Age of Enlightenment* (Yale University Press, 2005).

114. C. Bergstrom, 'Measuring the Value and Prestige of Scholarly Journals', 68(5) *College & Research Libraries News* 314 (2007); C. Tenopir et al., 'Electronic Journals and Changes in Scholarly Article Seeking and Reading Patterns', 61(1) *Aslib Proceedings* 5 (2009).

115. J. Hopkins, 'The Role of Learned Societies in Knowledge Exchange and Dissemination: The Case of the Regional Studies Association, 1965-2005', 40(2) *History of Education* 255 (2011).

116. D. Boyd and K. Crawford, 'Critical Questions for Big Data', 15(5) *Information, Communication & Society* 662 (2012).

117. F. Turner, *From Counterculture to Cyberculture: Stewart Brand, the Whole Earth Network, and the Rise of Digital Utopianism* (University of Chicago Press, 2010); D. Lyon, *The Electronic Eye: The Rise of Surveillance Society – Computers and Social Control in Context* (John Wiley & Sons, 2013).

118. M.W. Carroll, 'Movement for Open Access on Law, The', 10 *Lewis & Clark Law Review* 741 (2006).

119. M.W. Carroll, 'Creative Commons and the Openness of Open Access', 368(9) *New England Journal of Medicine* 789 (2013).

120. S. Harnad, 'The Green Road to Open Access: A Leveraged Transition', in *The Culture of Periodicals from the Perspective of the Electronic Age* (L'Harmattan, 2007).

121. S. Cramond, *Explainer: Open Access vs Traditional Academic Journal Publishers* (2011) The Conversation.

6 Conclusions

The article traced the historical development of the concept of copyright as property right. In addition, it discussed the transition from property of goods to property of ideas, using arguments that relied on old and modern philosophies about property.

To understand the significance of OARs, it is necessary to know the context of the debate. In modern times, a response to rapid technological evolution and relevant issues of intellectual protection is OA, which comprises a collection of possible conditions and solutions (for instance, those offered from Creative Commons licences) under which the creator can protect his or her work and deliver free reproductions of copyright works.¹²² Considering the efforts by trade companies to develop new technologies for publishing should not neglect social benefits. Hence, OA practice can be considered as an instrument for social prosperity.

IP rights are a significant part of the regulatory environment designed to support economic development in the digital age.¹²³ Current illustrations of growth in production are strongly related to investments in advances in IT (posts in Facebook, 'tweets' in Twitter, creating and uploading videos in YouTube and so forth) and correlate with the extent to which such technology-driven goods and services are disseminated throughout the economy.¹²⁴ Thus, granting property rights in the fruits of innovative and creative endeavours has long been the policy instrument of choice to accomplish these objectives.¹²⁵ All in all, highlighting IT as a basic contributor to economic growth demonstrates that OA practice, as one of its significant parts, should be considered a tool that supports dissemination of information resources that are distinguished by exclusive ownership.

122. J. Willinsky, 'The Nine Flavours of Open Access Scholarly Publishing', 49(3) *Journal of Postgraduate Medicine* 263 (2003).

123. K.E. Maskus and J.H. Reichman, *International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime* (Cambridge University Press, 2005).

124. OECD, *The New Economy: Beyond the Hype* (2001).

125. J. Fairclough, *Rethinking Construction Innovation and Research – A Review of the Government's R&D Policies and Practices* (2002) 96; K. Gangopadhyay and D. Mondal, 'Does Stronger Protection of Intellectual Property Stimulate Innovation?', 116(1) *Economics Letters* 80 (2012); K.J. Boudreau, 'Does Opening a Platform Stimulate Innovation? The Effect on Systemic and Modular Innovations', *MIT Sloan Research Paper No. 4611-06* (2007).

Access and Reuse of Machine-Generated Data for Scientific Research

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Abstract

Data driven innovation holds the potential in transforming current business and knowledge discovery models. For this reason, data sharing has become one of the central points of interest for the European Commission towards the creation of a Digital Single Market. The value of automatically generated data, which are collected by Internet-connected objects (IoT), is increasing: from smart houses to wearables, machine-generated data hold significant potential for growth, learning, and problem solving. Facilitating researchers in order to provide access to these types of data implies not only the articulation of existing legal obstacles and of proposed legal solutions but also the understanding of the incentives that motivate the sharing of the data in question. What are the legal tools that researchers can use to gain access and reuse rights in the context of their research?

Keywords: machine-generated data, Internet of Things, scientific research, personal data, GDPR

1 Introduction

When Nicola Tesla was describing the society of the future, he envisioned Earth as ‘a huge brain, which in fact it is, all things being particles of a real and rhythmic whole’. In 1990, John Romkey created what is considered among the first Internet of Things¹ devices; he created a toaster that could turn on and off over the Internet. The challenge was part of a conference, which earned its creator a well-earned place among the exhibitors. At around the same time, Neil Gross described a society that ‘don(s) electronic skin. It will use the Internet as a scaffold to support and transmit its sensations’.²

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1. According to Art. 29 Working Party, it is ‘an infrastructure in which billions of sensors embedded in common, everyday devices [...] are designed to record, process, store and transfer data and [...] interact with other devices or systems using networking capabilities’: Article 29 Working Party, ‘Opinion 8/2014 on the on Recent Developments on the Internet of Things’, *Opinion WP 223*, available at: <http://ec.europa.eu/justice/article-29/documentation> (last visited 15 April 2019). According to the Federal Trade Commission: ‘The Internet of Things (“IoT”) refers to the ability of everyday objects to connect to the Internet and to send and receive data’. Federal Trade Commission, ‘Internet of Things – Privacy & Security in a Connected World’, *FTC Staff Report* (2015), available at: www.ftc.gov/system/files/documents/reports/ (last visited 15 April 2019).
2. N. Gross, ‘The Earth Will Don an Electric Skin’, *Bloomberg*, 30 August 1999, available at: [https://www.bloomberg.com/news/articles/1999-](https://www.bloomberg.com/news/articles/1999-08-29/14-the-earth-will-don-an-electronic-skin)

08-29/14-the-earth-will-don-an-electronic-skin (last visited 15 April 2019).

The world of interconnected things – that is, things that connect to each other and to the environment – is here: from cars to houses and from body sensors to industry applications, data is being produced at an unprecedented daily pace.³

The fast accelerating production of data has led to a natural curiosity over its untapped potential by both private and public actors. For example, and as part of the initiative aiming to create a common data space in the EU, the European Commission published two communications related to the building of a European data economy and addressing the issue of growing accumulation of privately held data. The emergence of the open data movement brought forward the idea that open sharing of special categories of data contributes in achieving transparency, accountability, justice, equality and overall better democratic processes. Consequently, data sharing has stayed at the forefront of several policy proposals and legislative reforms in the latest years. Open government data, open research data, open science and more have all been developed to address social problems through advancements in collecting, accessing, analysing and processing big data. The innovation potential that drives the enhancement of data access and reusability practices illustrates the significant value derived from the expansion of data sharing practices.⁴ The transformative effect from the use of data towards serving the goals of a democratic society can be witnessed in our economy and also in research and knowledge production; in fact, knowledge derived from data-based services has the potential to revolutionise citizens’ quality of life, to establish the ground that would provide evidence-based policy actions and to create new growth business opportunities. Examples of recent reforms that address the free flow of data on a European level include the General Data Protection Regulation⁵ whose goal is to create a normative framework for the free circulation

08-29/14-the-earth-will-don-an-electronic-skin (last visited 15 April 2019).

3. It was in 2005 when Jonathan Zittrain described the impact of cheap sensors in augmenting data production and surveillance states: J Zittrain, *The Future of the Internet-And How to Stop It*, Yale University Press, New Haven (2008) 205.
4. OECD, *Data-Driven Innovation: Big Data for Growth and Well-Being* (2015) 195, available at: www.oecd.org/sti/data-driven-innovation-9789264229358-en.htm (last visited 15 April 2019).
5. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (hereinafter GDPR).

of personal data as well as the Public Sector Information directive⁶ aiming to facilitate participatory democracy, to improve administrative efficiency and to promote economic development through open access to public sector data. Finally, the legal framework is completed by sector-specific legislation among different types of data production, standardised licenses and data policies that regulate and promote special cases of data sharing.

A new data category consisting of data generated by machines and sensors has emerged, qualified under the generic term of ‘machine-generated data’. This nascent category has been progressively attracting the attention of both the market and regulation as data is produced en masse from private entities. Machine-generated data is comprised of data automatically generated by a computer process, application or other mechanism without the active intervention of a human.⁷ The most prominent examples come from the Internet of Things, whose business model is founded on the automated collection of user data towards ameliorating user experience and services provided. In fact, various business sectors (*i.e.*, the motor vehicle sector with the emerging autonomous car technologies) have already seen significant disruption from the amount of data produced, collected and processed. For instance, the functioning of autonomous cars is largely interconnected with data collection and processing in order to not only perform its basic function but also to provide better services.⁸ Similarly, smart homes are comprised of a set of Internet-connected and interconnected devices collecting and processing data in order to produce services that allow for maximum comfort and efficiency. Also, smart thermostats allow energy-saving both through remote controlling of the temperature and through learning the owners’ schedules and behaviour. In the agricultural sector, smart farming devices have revolutionised production and the overall economy by permitting the collection, processing and dissemination of data related to the farming processes. The data collected create the necessary breeding ground for the optimisation of farming practices and of energy and overall financial costs. Overall, there is high value and market potential surrounding this type of data, which ‘is a primary resource, asset, and product of the digital economy’.⁹

The fast-paced technological environment that relies on the generation, collection and processing of machine-generated data has highlighted regulatory gaps in the

6. Directive 2003/98/EC of the European Parliament and of the Council of 17 November 2003 on the reuse of public sector information amended by Directive.
7. The term is not new. Talking about data control systems, Chorafas uses the term machine-generated data to point out that ‘information has the amazing ability to generate more information’. D.N. Chorafas, *Control Systems Functions and Programming Approaches*, Volume B, Applications, Academic Press, New York and London (1966) 114.
8. A connected smart car, for example, is susceptible to produce up to 25 GB of data every driving hour.
9. N. Elkin-Koren and M.S. Gal, ‘The Chilling Effect of Governance-by-Data on Data Markets’, 86(2) *University of Chicago Law Review* 403 (2019).

process of fostering a data-based economy. In fact, machine-generated data hold two unique traits that should be taken into inherent consideration before implementing any regulatory framework: firstly, it consists of data which are not directly produced by humans and as such they do not automatically fall under the same logics and conditions; secondly, this type of data is predominantly held by private companies that create the objects destined to function in the hands of data-producing users. The companies in question contractually restrict access to data for market purposes. Realising the market value and innovation potential, the European legislator picked up the regulatory challenge for the further fostering of a Digital Single Market.¹⁰ In that context, the European Commission pledged to build a ‘data economy’. More specifically, when the ‘Free Flow of Data’ initiative was announced in 2016, it promised to address the obstacles in the free movement of data. The objective was to establish a regulatory framework on the cross-border use of data especially in the context of the Internet of Things. Similarly, the OECD report on data-driven innovation has also highlighted the importance of sharing big data due to their overall beneficial effect in society.¹¹ With data science technologies making rapid advances, ‘access to data and to the information based on it becomes a strategic and valuable asset’.¹²

The European Commission’s guide on the free flow of data¹³ points out that innovation based on privately held machine-generated data is lacking because the actors involved in this sector of the data economy do not possess the tools necessary to explore the full potential of the data in question. The ‘Guidance on Sharing Private Sector Data in the European Economy’ document is one of its kind, which sets the way forward for the regulation of data sharing of private sector data.¹⁴ In fact, data control strategies further raise the entry barrier for new or smaller actors in the current competitive environment related to innovation services. Data sharing is an indispensable tool for innovation in this context, but the proper incentives for sharing actions initiated by private actors are still lacking.¹⁵ The European Commission has recognised that horizontal legislative efforts would be inadequate and premature in the context of machine-

10. The creation of a Digital Single Market was part of the current European Commission’s ‘priority projects’. See European Commission, ‘A Digital Single Market for Europe: Commission sets out 16 initiatives to make it happen’, Press Release of 6 May 2015, available at: http://europa.eu/rapid/press-release_IP-15-4919_en.htm (last visited 15 April 2019).
11. OECD, above at n. 4.
12. D.L. Rubinfield and M.S. Gal, ‘Access Barriers to Big Data’, 59 *Arizona Law Review* 339 (2017), at 363-64.
13. Commission staff working document, Guidance on sharing private sector data in the European data economy, 25 April 2018, SWD(2018) 125 final.
14. B. Gonzalez Otero, Evaluating the EC Private Data Sharing Principles: Setting a Mantra for Artificial Intelligence Nirvana, 10 *JIPITEC* 66 (2019).
15. Incentives for sharing vary from reputation gains to economic benefits and also to further market prospects. See Y. Lev-Aretz, ‘Data Philanthropy’, *The Hastings Law Journal* (forthcoming 2019), available at: <http://dx.doi.org/10.2139/ssrn.3320798> (last visited 15 April 2019).

generated data. The suggestion to create a *sui generis* ownership right for data producers was met with criticism by academics, market players and civil society. It has become clear that a ‘one-size-fits-all’ approach cannot be easily envisaged because it is very hard to identify patterns across different types of machine-generated data and across different sectors.

Scientific research is progressively becoming more data-intensive with complex structures of scientific discovery. The development of models based on the abundance of diverse data sets and on the advancement of computer analytic processes such as machine learning have altered the landscape of scientific method. Advances in data analytics, along with the dominance of big data, have revolutionised research even in disciplines that were not fundamentally founded on traditional data collection and analysis. Both the business sector and the European Commission have pointed out the innovation potential and the social benefits that can be drawn from the scientific outputs of the processing of machine-generated data. For this reason, the Commission examined the possibility of creating regulatory pathways for the ‘enhanced access to commercially-held data for scientific researchers funded from public resources’. In that sense, the question emerging is whether the machine-generated data market can be regulated by exceptional legal rules that allocate specific access rights to expressly designated actors in order to foster innovation and knowledge production for the broader public good.

The issue raised can be further positioned within the question of data regulation, which dominates the legal discourse under multiple facets. It has progressively been approached through different legal perspectives and disciplines, expressed through the issue of establishing property rights on (personal) data and of regulating access through private ordering mechanisms or through direct sector-specific regulation. This article takes the approach of focusing on a specific category of data, that of machine-generated non-personal data, and aims to evaluate how can access to this specific subcategory data be regulated in order to benefit scientific research.

2 Defining Machine-Generated Non-personal Data

Machine-generated data acquired significant market value due to some of its distinguishing features and also due to its societal impact. In fact, the *volume* of data generated by different sensors, Things or ‘machines’, in general, is a distinguishing characteristic, since machine-generated data is placed in the broader, encompassing category of Big Data. In addition, the overall demonstrated *quality* of the data sets created by

the collected data contributes to the production of valuable insights as an (un)expected outcome. The innovations behind these data processing activities have become common ground for all businesses operating towards offering services for citizens. In this context, data sharing becomes a significant vector for generating innovation and economic growth. On a practical level, many private actors holding large and diverse data sets establish data sharing practices and standardised agreements in order to extract the maximum value from the decision-making and analysis processes. A priori, a universal approach that delineates the context of data sharing has not yet been identified, not only due to the nature and diversity of data produced and shared but also due to the uses related to data sharing and the different actors involved in the process. For instance, data sharing activities that involve sharing of sensitive anonymised data are subject to stricter regulatory regimes¹⁶ than that of other types of non-sensitive data, such as meteorological data.

Admitting the nuances and the diversity in existing data in the domain of machine-generated data, the European Commission has been progressively showing a special interest on ‘machine-generated non-personal data’. In fact, while personal data flows are predominantly governed by the GDPR, the Commission recognised the potential in regulating the concave space of non-personal data left by the convex scope of application of personal data regulation. The first issue highlighted even before envisaging the framing of the aforementioned category is defining the non-personal data that would fall under its scope of application. On a fundamental level, the concept of personal data is surrounded by ambiguity. Data categorisation is challenging for many reasons, the major issue being the lack of a clearly delineated definition of ‘personal data’. In this context, and even if the qualification as machine-generated is relatively straightforward, this is not the case with non-personal data because it is highly dependent on the personal data demarcation. Without such a demarcation it is impossible to create a trustworthy reliant framework on which to base data sharing practices.

According to Article 4(1) GDPR, the definition of personal data is as follows: ‘any information relating to an identified or identifiable natural person (“data subject”)’. In a 2007 Opinion,¹⁷ the Article 29 Working Group (A29WP) elaborated on the different components of this definition in order to guide the scope of application and its enforcement by courts. Within the constituting elements of the above definition, lies also the context-dependent approach that characterises data protection regulation. More specifically, the concepts of ‘relating to’ and ‘identified or identifiable’ are increasingly volatile and ultimately encompass a broad range of

16. See, Art. 89 GDPR.

17. Art. 29 Working Party, ‘Opinion 4/2007 on the Concept of Personal Data’, WP 136, available at: <http://ec.europa.eu/justice/article-29/documentation> (last visited 15 April 2019).

data. For this reason, the concept of personal data – as it is currently outlined and enforced – has been criticised for being too broad and inapplicable.¹⁸ The *identifiability* test carries a lot of nuance, as it is further distinguished into directly identifiable and indirectly identifiable data.¹⁹ It is further determined by the A29WP that this test is dynamic, leaving ample room for a more flexible application according to a wide range of factors related to the data in question.²⁰ A fortiori, the concept of non-personal data incorporates the same inherent fluidity found in the concept of personal data. The two types of data that are included in the category of non-personal data are anonymised personal data (which – due to their nature – escape the GDPR scope of application) and non-identified or identifiable data.²¹ It is not within the scope of this article to discuss the evolution of the contextual concept of personal data.²² It suffices to point out at this stage that the creation of a distinct category for data that do not qualify as personal data as a concave definition to the convex one of personal data is inefficient because of the fluidity involved in personal data qualification. According to Graef *et al.*:

On the basis of such a contingent and context-based application of the definition of personal data, it is difficult to see how a legislative proposal targeting non-personal data could be applied in practice. We foresee substantial difficulties maintaining two separate legal frameworks, one regulating personal data and another one regulating non-personal data, when personal data cannot be clearly distinguished from non-personal data.²³

Within this context of increasing ‘technological capacities to combine and interpret data, personal data will show up ever more frequently in the zettabytes of the twenty-first century information flows’.²⁴ Many data protection scholars develop critical approaches of the personal data protection, claiming that the distinction

18. For an overview of the positions in favour and contra the current state of the concept of personal data, see, e.g. F. Zuiderveen Borgesius, ‘Singling Out People Without Knowing Their Names – Behavioural Targeting, Pseudonymous Data, and the New Data Protection’, 32 *Computer Law & Security Review* 256 (2016) 271.
19. See, A29WP 2007 Opinion on the concept of personal data, above at n. 13.
20. See, for instance, the guidelines derived from Rec 26 of the GDPR.
21. According to A29WP’s opinion on the concept of personal data, a further distinction can be made between directly and indirectly identifiable data. This distinction serves to underline the context-specific nature of personal data: directly identifiable data are the ones that achieve to single out directly an individual through a specific piece of information and indirectly identifiable data are the ones that single out but through the combination of different data points provided.
22. Established CJEU case law illustrates the application of the context-specific character of personal data. See, e.g. Breyer (2016) CJEU C-582/14; *Scarlet Extended* (2011) CJEU C-70/10; Lindqvist (2003) CJEU C-101/01.
23. I. Graef *et al.*, ‘Feedback from Tilburg University on the European Commission’s Proposal’, available at: https://ec.europa.eu/info/law/better-regulation/initiatives/com-2017-495/feedback/F8922_en (last visited 15 April 2019).
24. B.J. Koops, ‘The Trouble with European Data Protection Law’, 4(4) *International Data Privacy Law* 250 (2014).

becomes meaningless²⁵ and anonymity is considered no longer possible.²⁶ Besides the critical view of the ‘all-encompassing notion’ of personal data, this broad definition is ‘welcomed in light of the aim of data protection law to ensure effective and complete protection of data subjects’.²⁷ However, at the same time, accepting the duality of personal and non-personal data is at odds with the coming technological reality of constant automated collection and processing of data because in this reality ‘any information has the potential to affect people’.²⁸ According to Koops, it would be more useful for data protection if ‘instead of trying fitfully to establish where the border lies between personal and non-personal data, we would allow for categories of data that have certain effects on people when they are processed, regardless of whether or not they relate to identifiable individuals’.²⁹ Sector-specific regulation for data is an approach that has been proposed by scholars, as a way out of the dissonance created between the innovation potential and the regulatory and market complexities.

Without prejudice to the scope of application of personal data regulation, the scope of the article extends to examining the processing of machine-generated non-personal data for research and scientific purposes. As a matter of fact, according to the GDPR, personal data can be processed for the purposes of scientific research as long as the principle of data minimisation is respected, and based on one of the lawful grounds for processing of Article 6(1). In that sense, the Regulation envisages the implementation of legal and technical protection measures such as pseudonymisation and – when possible – anonymisation of personal data. Pseudonymous data fall under the scope of application of the GDPR, while anonymous data are not subject to the Regulation. According to Article 89, paragraphs (1) and Article 89(2), the processing of personal data for scientific or historical research purposes or statistical purposes can also result in the limitation of data subjects’ rights in order to satisfy the purposes of the research in question. Thus, data protection regulation leaves some room for derogations from the absolute protection of the individual control of personal data if these rights risk to ‘seriously impair or render impossible the achievement of the research’.³⁰ Recognising the importance of its potential benefits, the Regulation expressly clarifies that ‘the processing of personal data for scientific research purposes should be interpreted in a broad manner

25. O. Tene and J. Polonetsky, ‘Big Data for All: Privacy and User Control in the Age of Analytics’, 11(5) *Northwestern Journal of Technology and Intellectual Property* 258 (2013).
26. P. Schwartz and D. Solove, ‘The PII Problem: Privacy and a New Concept of Personally Identifiable Information’, 86 *New York University Law Review* 1814 (2011).
27. N. Purtova, ‘The Law of Everything: Broad Concept of Personal Data and Future of EU Data Protection Law’, 10(1) *Law, Innovation and Technology* 40 (2018).
28. *Ibid.*
29. Koops, above at n. 24.
30. European Union Agency for Fundamental Rights, *Handbook on European Data Protection Law*, Publications office of the European Union, Luxembourg (2018) 340.

including for example technological development and demonstration, fundamental research, applied research and privately funded research'.³¹ In a similar approach to balancing the benefits of research with those of effective data protection and because the specific delimitation ex ante of the purposes of the processing for scientific research can be quite complex, the GDPR creates a derogation from the requirement of purpose limitation when asking for express consent for research and scientific purposes. The creation of a specific favourable regime towards fostering scientific research and innovation takes into account the fact that the analysis still constitutes personal data processing and should thus be subject to appropriate safeguards in order to ensure a responsible and lawful treatment of personal data.³²

Frequently, when significant effort is required for de-identification, machine-generated data produced from Internet of Things devices is susceptible to qualify as 'high-dimensional data'.³³ According to Narayanan and Felten, 'high-dimensional data is now the norm, not the exception...[T]hese days it is rare for useful, interesting datasets to be low-dimensional'.³⁴ In the case of Internet of Things, personal data is produced, collected and kept in privately owned databases with the consent of the users,³⁵ and they can be made available to researchers under the conditions set out by the GDPR. However, there is a significant part of machine-generated data that can be qualified as non-personal because of the nature of the data in question or because of the context in which it is processed. The value that can be derived from the raw data generated towards promoting researchers is recognised as a significant scientific tool.³⁶ Although the GDPR sets a framework with specific conditions applicable to the processing of personal data for research purposes, the conditions under which researchers can access non-personal data remain unclear or subject to access contractual conditions set out by the

big data-holder companies. This regulatory uncertainty and the adoption of a very fragmented approach in accessing these data sets limits research and restricts the scientific output of researchers according to the chosen data sharing practices by private entities.

3 Non-regulatory Data Sharing Practices

In 2014, Intel decided to share data sets from smart farming data produced by its agricultural sensors with the researchers from the University of California.³⁷ More recently, the development of apps during a hacking competition was made possible with the use of data shared by private companies related to smart agriculture, such as Agrisyst, ForFarmers and Hendrix Genetics. Multiple examples of voluntary sharing of data from private companies can be found more and more frequently. Data sharing constitutes an established practice among businesses and private entities in general or between data-holder companies, on the one hand, and institutions or researchers, on the other hand. The sharing of private sector data is not a completely new practice, and it has existed under various denominations such as data philanthropy, data donorships and data partnerships, corporate social responsibility, data collaborativism and 'data for good'. The developed practice includes various aspects of making data available for third actors: it can concern making available privately held data for purposes related to the public sector and the public interest; it can relate to data shared between companies, but it also covers the making available of these data to researchers for purposes of scientific advancement. There is little standardisation in the practice of data sharing principles; freedom of contract prevails and the sharing terms vary depending on the actors involved, the type of the data and the nature of the envisaged uses. As previously mentioned, sector-specific approaches are dominating the market:

Sector-specific regulation appears as the road to take, since the security interests of the state will most likely need different rules than the prevention of infectious diseases, the protection of the environment or the functioning of smart cities or traffic control systems.³⁸

Lacking a specific legal framework, the conditions for granting access and use rights to the machine-generated non-personal data are generally established by the man-

31. Rec 159, GDPR.

32. There have been examples where research results have been published without taking the appropriate precautions against the identification of data subjects: W. Hartzog, 'There Is No Such Thing as "Public" Data', *Slate*, 19 May 2016, available at: <https://slate.com/technology/2016/05/okcupids-data-leak-shows-theres-no-such-thing-as-public-data.html> (last visited 15 April 2019).

33. According to Cavoukian and Castro, high-dimensional data 'consist of numerous data points about each individual, enough that every individual's record is likely to be unique, and not even similar to other records': A. Cavoukian and D. Castro, 'Big Data and Innovation, Setting the Record Straight: De-identification Does Work', 16 June 2014, available at: www2.itif.org/2014-big-data-deidentification.pdf (last visited 15 April 2019).

34. A. Narayanan and E.W. Felten, 'No Silver Bullet: De-identification Still Doesn't Work', 9 July 2014, available at: <http://randomwalker.info/publications/no-silver-bullet-de-identification.pdf> (last visited 15 April 2019).

35. Consent is expressed by accepting privacy policies and the terms and conditions – necessary precondition to use the device in question.

36. See, for instance, P. Rubens, 'Can Big Data Crunching Help Feed the World?', *BBC News*, 11 March 2014, available at: <https://www.bbc.com/news/business-26424338> Last visited 15 April 2019; R. K. Perrons and J.W. Jensen, 'Data as an asset: What the oil and gas sector can learn from other industries about big data', 81 *Energy Policy* 117, (2015).

37. L. Gilpin, "How Intel is using IoT and big data to improve food and water security", 13 June 2014, <https://www.techrepublic.com/article/how-intel-is-using-iot-and-big-data-to-improve-food-and-water-security> (last visited 15 April 2019); see also, Y. Lev Aretz, 'Data Philanthropy', *The Hastings Law Journal* (forthcoming 2019), available at: <http://dx.doi.org/10.2139/ssrn.3320798>.

38. J. Drexler, 'Designing Competitive Markets for Industrial Data – Between Propertisation and Access', 8(4) *JIPITEC* 257 (2017).

manufacturer of the smart object that generated the data through its use by the user. In these cases, the collector of the data is responsible for the data sharing practices enforced through broadly defined contractual agreements.³⁹ Economic benefits and reputation gains in performing data exchanges between private actors as well as overall financial incentives have been the main factor in establishing data sharing practices.⁴⁰ At the same time, advancements in artificial intelligence technology brought forward the need to train the corresponding algorithms, elevating the value of big data sets such as the ones generated by the Internet of Things. In fact, the large data sets produced are ideal candidates for training powerful algorithms. To this day, the industry stresses that the implementation of current business models involving data sharing practices is possible by relying solely on contract law⁴¹ because it allows for the modularity needed in providing dynamic access and usage rights depending on the nature of the data set and the purpose of the use.

The exercise of access and usage control over the data in question through private ordering has demonstrated that contract law serves as a strong instrument imposing restrictions over the subject matter, potentially even stronger than any legally recognised property right. At the same time, the current landscape of data sharing practices illustrates how the absence of legally recognised economic property rights over such data and databases is not prejudicial to the development of a data-driven economy. In fact, the proposal advanced by the Commission to introduce property rights in data has been met with large criticism by scholars⁴² and with scepticism by the industry. The market value of the data generated and its central role in the development of the current economic models is undeniable. However, maintaining access to data for the benefit of the public good in view of its societal value is taken into consideration when designing data sharing principles and when considering regulation.

The type of the data generated and their relevance in the context of a general societal or scientific purpose is inciting private companies to engage in sharing of data in the context of ‘data for good’ movements or data philanthropy in general.⁴³ In its guide for sharing private

sector data, the European Commission uses the term ‘data donorship’ to describe the voluntary sharing of private sector data with the public sector. These terms aim to describe an aspect of what is called ‘corporate social responsibility’; the term is not new and multiple definitions have been advanced in the last years.⁴⁴ According to a renewed strategy of the European Commission,⁴⁵ corporate social responsibility implies the obligation of companies to

have in place a process to integrate social, environmental, ethical, human rights and consumer concerns into their business operations and core strategy in close collaboration with their stakeholders, with the aim of – maximising the creation of shared value for their owners/shareholders and for their other stakeholders and society at large – identifying, preventing and mitigating their possible adverse impacts.

The main elements of the definition of social responsibility are therefore that it is voluntary and that it is found in private entities pursuing public interest objectives that go beyond the pursuit of their private interests and of the compliance with current regulatory and contractual obligations. The potential high relevance of certain types of privately held data towards fulfilling greater societal goals has been recently admitted. According to the Commission, the use of the aforementioned data ‘can, for example, lead to a more targeted response to epidemics, better urban planning, improved road safety and traffic management, as well as better environmental protection, market monitoring or consumer protection’.⁴⁶ Thus, the concept of corporate social responsibility is undergoing a transformation that aims to incorporate those companies that hold useful for the societal good data. Naturally, facilitating data sharing through collaboration between private actors who hold data considered valuable and interested third parties could result in generating value towards the greater public good.⁴⁷

Without a proper normative framework, private voluntary initiatives have emerged so as to foster the sharing of data across companies, sectors, projects and research-

39. V. Mayer-Schönberger and Y. Padova, ‘Regime Change? Enabling Big Data through Europe’s New Data Protection Regulation’, 17 *Columbia Science and Technology Law Review* 315 (2016).

40. T. Klein and S. Verhulst, ‘Access to New Data Sources for Statistics: Business Models and Incentives for the Corporate Sector’, Discussion Paper No. 10 (2017), available at: <http://dx.doi.org/10.2139/ssrn.3141446> (last visited 15 April 2019).

41. Drexler, above at n. 38.

42. *Ibid.*; B. Hugenholtz, ‘Data Property: Unwelcome Guest in the House of IP’, Paper presented at *Trading Data in the Digital Economy: Legal Concepts and Tools*, Münster, Germany (2017).

43. As it is explained by Lev-Aretz, the data-for-good movement promotes ‘data-driven projects that can increase the efficiency of social initiatives, extend their reach, and better tailor them to specific communities. The data-for-good movement has spotlighted the imperative role of the private sector in producing useful data for social action, sparking an active conversation about models and incentives for sharing. As part of this

conversation, the term “data philanthropy” was born’: Lev Aretz, above at n. 15.

44. Up to twenty competing definitions of corporate social responsibility have been found: A.B. Carroll, ‘Corporate Social Responsibility: Evolution of a Definitional Construct’, 38(3) *Business & Society* 268 (1999).

45. European Commission, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. ‘A Renewed EU Strategy 2011-14 for Corporate Social Responsibility’, COM(2011) 681, 25 October 2011.

46. European Commission, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. ‘Towards a Common European Data Space’, COM(2018) 232, 25 April 2018 at 12.

47. See, e.g. Liander, an energy network administrator in the Netherlands has made data related to energy consumption available in order to permit research and innovation on energy conservation and smart energy use. See, F. Welle Donker, B. Van Loenen & A.K. Bregt, ‘Open Data and Beyond’, 5(4) *ISPRS International Journal of Geo-Information* 48 (2016).

ers. The goal of these initiatives is to create an environment encouraging contributions and sharing through the use of contractual tools. The agreements in question are generally described by the term ‘data collaboratives’,⁴⁸ which refers ‘to a new form of collaboration, beyond the public-private partnership model, in which participants from different sectors — including private companies, research institutions, and government agencies — can exchange data to help solve public problems’. They are voluntary initiatives created to facilitate access to various types of data and for different uses or for the benefit of different actors.⁴⁹ The term primarily used by Stefaan Verhulst and David Sangokoya⁵⁰ is not devoid of criticism. As it is described by Yafit Lev-Aretz,

the term data collaborative is both under-inclusive and over-inclusive. The emphasis on collaboration leaves many instances of data sharing outside the scope of data collaboratives. For example, open data initiatives in the private sector, where datasets are released to the public with no continuous interaction between the public and the provider of the data following the release, can hardly be described as collaborative. The data collaboratives universe (...) does not underscore the sharing of privately-held data or privately owned data-driven insights. It fails to highlight the monetary and business value of the data and does not reflect the ecosystem in which private sector data is shared.⁵¹

The author uses the broader term of ‘data philanthropy’, which she defines as being the ‘combination of three elements: (1) unpaid for sharing of or access to (2) privately held data or proprietary data insights for (3) the greater good’.⁵²

A lot of predominant data sharing practices that subsequently result in the creation of data collaboratives aim towards advancing research with the goal of deriving knowledge from the large amount of existing data. While there is not a distinct procedure to facilitate the sharing of machine-generated data, multiple initiatives of data sharing for research have emerged lately,⁵³ not

without inciting controversy over risks related both to data protection violations⁵⁴ and to the lack of informed consent from data subjects as to the further processing of their personal data. Current examples that illustrate the market potential of sharing privately held machine-generated data (both personal and non-personal) for the purposes of advancing academic research also showcase the absence of standardised approaches and the lack of legal clarity in the enforcement of rules in order to make the data economy work.

4 Normative Framework in Extracting Knowledge from Data

The amount of data generated, processed and generally controlled by the industry as well as its prospects as a precious tool for data-driven services has not gone unnoticed from the legislator on a European level. Firstly, the predominant normative tool for data sharing is data protection and privacy regulation. The European Union has created a solid framework for producing digital trust, a precondition for the sustainable development of the data economy. According to the European Data Protection Regulation (GDPR), which entered into force on 25 May 2018 replacing Directive 95/46/EC, ‘natural persons should have control of their own personal data’. In that sense, the GDPR guarantees individual autonomy and attributes rights to data subjects that would prevent non-intended uses of their personal data. The European data protection regulation aims to enforce a balancing act between protection and free flow of personal data in order to protect the individual rights without stifling economic potential of data. In order to lay the foundations for a future competitive advantage and according to the Commission’s plans to create a European harmonised data-based digital economy, the regulation of the free flow of data within the EU implies the regulation of personal data and the restriction flows that lie beyond this type of data. The main solutions

48. S. Verhulst and D. Sangokoya, ‘Data Collaboratives: Exchanging Data to Improve People’s Lives’, *Medium*, 22 April 2015, available at: <https://medium.com/@sverhulst/data-collaboratives-exchanging-data-to-improve-people-s-lives-d0fcfc1bdd9a> (last visited 15 April 2019).

49. For a proposed taxonomy of data collaboratives, see, I. Susha, M. Jansen, S. Verhulst, ‘Data Collaboratives as a New Frontier of Cross-Sector Partnerships in the Age of Open Data: Taxonomy Development’, in *Proceedings of the 50th Hawaii International Conference on System Sciences* (2017) 2691.

50. *Ibid.*

51. Lev-Aretz, above at n. 15.

52. *Ibid.*

53. The latest example can be found in the Social Science One project. It consists of a specifically designated expert commission responsible for handling access to data from Facebook for research and scientific purposes. According to the commission in question, ‘Social Science One implements a new type of partnership between academic researchers and private industry to advance the goals of social science in understanding and solving society’s greatest challenges. The partnership ena-

bles academics to analyse the increasingly rich troves of information amassed by private industry in responsible and socially beneficial ways. It ensures the public maintains privacy while gaining societal value from scholarly research. And it enables firms to enlist the scientific community to help them produce social good, while protecting their competitive positions’. The first thematic area will be focused on projects related to ‘the effects of social media on democracy and elections’, available at: <https://socialscience.one/>.

54. For instance, the data sharing deal between Google’s DeepMind and Royal Free NHS Foundation Trust was determined to be violating of data subjects’ privacy according to the ruling issued by the Information Commissioner’s Office (ICO) in the United Kingdom. According to Elizabeth Denham, Information Commissioner, ‘there’s no doubt the huge potential that creative use of data could have on patient care and clinical improvements, but the price of innovation does not need to be the erosion of fundamental privacy rights’. See, ICO’s letter outlining the results of the investigation: E. Denham, RFA0627721 – provision of patient data to DeepMind, 3 July 2017, available at: <https://ico.org.uk/media/action-weve-taken/undertakings/2014353/undertaking-cover-letter-revised-04072017-to-first-person.pdf> (last visited 15 April 2019).

raised surrounding ownership and access rights on non-personal data did not finally manage to produce a legal framework as intended by the Commission's 'Free Flow of Data' initiative announced in 2016.

Data access regulation takes multiple forms and can be found in different normative approaches. For instance, the latest example comes from regulation regarding data mining processes. Data mining has been one of the core issues at the data flow agenda of legislative efforts both at the European and national levels. As a matter of fact, the public interest in allowing text and data mining for (at least) research purposes – if not for all purposes – is gradually being recognised for its societal and economic benefits. It is considered to be a fundamental tool for researchers of all disciplines.⁵⁵ Data mining refers to an ensemble of computer science techniques used to extract knowledge from large digital data sets, by looking patterns that are usually difficult to notice with human only research. Data mining is a subset of 'knowledge discovery in databases'. While it may not be perfect, the mining analogy serves to explain roughly what content mining entails. Machine learning algorithms go through large amounts of data, eventually finding valuable information and gaining insights by making combinations that were difficult to foresee without the technological process at hand.

According to Fayyad *et al.*, 'KDD⁵⁶ refers to the overall process of discovering useful knowledge from data, and data mining refers to a particular step in this process. Data mining is the application of specific algorithms for extracting patterns from data'.⁵⁷ The necessary technological conditions to execute data mining process are the following: (legal) access to the data in question, the availability of practical tools to complete the searching process and the articulation of the purpose of the process in view of an expectation.

According to existing legislation, data mining required the rightsholders' express permission because it triggers copyright and sui generis rights existing in the databases.⁵⁸ In addition, it could encroach on contract limitations imposed by the private entity that holds the data sets in question. It is often the case that the legal obstacles to getting access to the data are not confined to copyright, but that they are the result of restrictive contractual policies⁵⁹ coupled with the imposition of tech-

nological limitations and lack of interoperability or technical standards in data type formatting. Thus, the barriers that need to be overcome in order to facilitate and streamline data mining operations are not only purely legal but they are also technical and market-related. So while the market value of providing data mining services is not negligible, the existing legal framework (or absence thereof) based on private ordering and licensing formed the normative baseline that limits further opportunities.⁶⁰ Recognising the value of data mining and the fact that prima facie data mining appears to be hindered by copyright and database protection legislation, multiple examples of national laws demonstrate already implemented text and data mining exceptions to the exclusive copyrights and database rights. For example, countries such as the United Kingdom, Germany, Estonia and France have all included the exception in various forms⁶¹ and with different requirements.⁶² Recently, the text and data mining exception to copyright was adopted in the final text of the Directive on copyright and related rights in the Digital Single Market⁶³ voted by the European Council. According to the adopted text, 'there is widespread acknowledgment that text and data mining can in particular benefit the research community and, in so doing, support innovation'.⁶⁴ In fact,

L. Monnoyer-Smith (eds.), *Ouvrir, partager, réutiliser: Regards critiques sur les données numériques*, Éditions de la Maison des sciences de l'homme (2017).

55. The value of the effective use of data in research has been estimated in billions of euros: See, J. Manyika *et al.*, *Big Data: The Next Frontier for Innovation, Competition, and Productivity*, McKinsey Global Institute, San Francisco (2011).

56. Knowledge discovery in databases.

57. U. Fayyad, G. Piatetsky-Shapiro & P. Smyth, 'The KDD Process for Extracting Useful Knowledge from Volumes of Data', 39(11) *Communications of the ACM* 27 (1996).

58. In the United States, data mining is not considered to be copyright infringement because it is qualified as fair use.

59. According to M. Dulong de Rosnay, 'right holders have been asking text and data mining to be submitted to re-licensing for an additional remuneration of texts to libraries, researchers or the public for that purpose'. See, M. Dulong de Rosnay, 'The Legal and Policy Framework for Scientific Data Sharing, Mining and Reuse', in C. Mabi, J.-C. Plantin &

60. According to Professor Benabou, 'it is my belief that mass digitization of works – whatever the purpose is: linking, mining, crawling – implies other answers than the mere individual exclusive right and that establishing a differentiated regime of protection depending on the existence of a "sensitive" contact of the human being with a work at the end of the process would be a solution'. V.-L. Benabou, 'Text and Data Mining Issues', in *Academics Meet Policy Makers: Better Regulation for Copyright* (2017) 59, available at: <https://juliareda.eu/events/better-regulation-for-copyright> (last visited 15 April 2019).

61. According to Section 29A of the UK Copyright Act, making a copy of a work for text and data analysis does not infringe the copyright on the work provided that the act is made for the purpose of non-commercial research. See, A. Guadamuz and D. Cabell, 'Data Mining in UK Higher Education Institutions: Law and Policy', 4 *Queen Mary Intellectual Property Review* 1 (2014), at 3. According to Art. L122-5 (10°) of the French *Code de Propriété Intellectuelle*, the act of exploration of data and text associated with scientific research access to which has been obtained legally, does not encroach intellectual property rights as long as it maintains a non-commercial research goal. Also, according to Art. 60d of the German Intellectual Property Law (*Urheberrechtsgesetz*), text and data mining are permitted for scientific research absent a commercial purpose. Finally, Estonian law allows text and data mining of all types of material protected by exclusive rights, provided that the purpose of the act is not commercial.

62. While the common denominator is the use of text and data mining for non-commercial purposes, there is a divergence in the type of material covered by the exception in question. France demonstrates the most restrictive subject matter of the exception by limiting it to only text and data related to scientific research. Another divergence is also found in the requirement of prior legal access to the subject matter of the mining process. This condition is found in French law but not in the equivalent German or Estonian one. Finally, the exception in most cases covers only the right to reproduction for the purpose of the act of mining and does not include further communication to the public of the material used, or if it does, it limits its scope.

63. Art. 3 of the Directive of the European parliament and of the council on copyright and related rights in the Digital Single Market and amending Directives 96/9/EC and 2001/29/EC.

64. Rec 8.

Articles 3 and 4 of the EU Directive on copyright in the Digital Single Market ('DSM Directive') provide two types of exceptions and limitations to copyright for text and data mining purposes. According to Article 3, 'for reproductions and extractions made by research organisations in order to carry out text and data mining of works or other subject-matter to which they have lawful access for the purposes of scientific research'. This exception also foresees that any contractual provision preventing this operation will be unenforceable. However, the same does not apply to text and data mining activities realised pursuing commercial interests according to Article 4 of the same European text. The creation of favourable conditions towards the pursuing of research activities is evident in the European Directive.⁶⁵ Given this set of legal tools, the Commission's proposal on promoting data sharing for research purposes reflects the processes of adopting the text and data mining exceptions nationally and on an EU level.

Data – including machine-generated data – do not qualify for copyright protection because they do not fulfil the originality condition and they do not constitute human creations embodying the authors' personality. However, databases are susceptible to benefit both from copyright – if the database is deemed an original creation – and from the *sui generis* database right provided that there was a substantial investment made by the database owner in presenting the material of the database. Despite the absence of such rights on data, the CJEU has ruled that database owners are free to impose contractual restrictions to access on data and databases.⁶⁶ Thus, access and data mining can still prove disproportionately difficult for researchers, irrespectively of the enforcement of a text and data mining exception to copyright. Given the contractual framework that governs data use, which also reflect the asymmetries between various actors, the existing exception to copyright for text and data mining purposes is pushed to its limits. In fact, data mining restrictions are not solely dependent on exclusive rights; when state actors and public researchers inquire about getting access to privately held data sets, based on the benefits towards the public interest such as public health and environmental research, the private database holders can rely on their right to conduct a business, to claim respect for their trade secrets and to receive fair compensation. What's more, the adopted phrasing of the data mining exception links the applicability of the exception to the 'lawful access' of the researcher to the data sets in question.⁶⁷

65. See, R. Ducato and A. Strowel, 'Limitations to Text and Data Mining and Consumer Empowerment: Making the Case for a Right to Machine Legibility', *CRIDES Working Paper Series*, 2018, available at: <http://dx.doi.org/10.2139/ssrn.3278901>.

66. CJEU, 15 January 2015, *Ryanair Ltd c/ PR Aviation BV*, aff. C-30/14. According to para. 45 of the decision, 'the Directive does not preclude the author of such a database from laying down contractual limitations on its use by third parties'.

67. From the European jurisdictions that have already implemented a text and data mining exception, the only country not imposing the 'lawfully accessed source' requirement is Germany.

Subordinating the applicability of the exception to getting legal access to a data set could significantly impact research. According to the European Copyright Society, 'the exception can effectively be denied to certain users by a right holder who refuses to grant "lawful access" to works or who grants such access on a conditional basis only'.⁶⁸

The data set holders' strong negotiating power could lead to the inflation of the costs of granting lawful access in order to factor in the previously imposed data mining prices. In that sense, a parallel can be drawn between the mitigation of costs related to making data available for mining purposes in accordance to the Directive and the charges for the reuse of public sector documents. The PSI 2013/37/EU Directive addressed the issue of costs of making information available openly that public administrations faced. According to the Directive (and the recently published reform proposal), administrations have the right to charge for the marginal costs of making documents available and, in certain cases, they can go above the marginal costs limit if the charge is determined 'according to objective, transparent and verifiable criteria'.⁶⁹ The reform proposal adds to the following exception by determining that 'the costs of anonymization of personal data or of commercially sensitive information should also be included in the eligible cost'.⁷⁰ Similarly, and based on the public interest justification of the text and data mining exception, a framework for charges could be implemented in order to ensure preferential conditions for the effective collaboration between the private sector and publicly funded research. The fact that the private actors concerned are the sole-source data managers could contribute to the introduction of a structured and well-defined obligation for them to provide the machine-generated non-personal data under fair and non-discriminatory terms to researchers.⁷¹

5 Attempts at Normative Cross-Sectorial Rules of Data

The creation of access privileges to researchers is a noble goal. However, the solutions that could be implemented face challenging questions concerning the adoption of sector-specific rules or of cross-sectorial

68. European Copyright Society, 'General Opinion on the EU Copyright Reform Package', 24 January 2017, available at: <https://european-copyrightsocietydotorg.files.wordpress.com/2015/12/ecs-opinion-on-eu-copyright-reform-def.pdf> (last visited 15 April 2019).

69. Rec 22, PSI 2013/37/EU.

70. Rec 32, Proposal for a Directive of the European Parliament and of the Council on the reuse of public sector information, *COM(2018) 234*, 25 April 2018.

71. Professor Hugenholtz proposed such a measure as a possible solution to overly protective contractual restrictions to databases that are not subject to copyright or *sui generis* database rights. B. Hugenholtz, 'Abuse of Database Right: Sole Source Information Banks under the EU Database Directive', in F. Lévêque and H. Shelanski (eds.), *Antitrust, Patents and Copyright: EU and US Perspectives*, Edward Elgar, Cheltenham (2005) 203.

ones, as well as the flexibility that these rules would need to incorporate taking into considerations the risks involved. Among the few attempted solutions to direct the opening of privately owned data sets, the most recent and innovative one comes from France. During the legislative process of implementing the ‘Digital Republic’ bill, the French legislator established normative concepts that could be further explored as an alternative solution to dealing with accessing machine-generated data.

5.1 The French Example: Public Interest Data

Mandated sharing of data exists in the form of legislation that was adopted recently in France and introduces the concept of ‘public interest data’. According to the text, the objective is to ‘enhance the circulation of data and knowledge’ in order to give France a competitive edge in the digital economy.

The Digital Republic Bill⁷² created a special category of ‘public interest data’ because it recognised the potential of opening up specific privately held data sets to the public for specific purposes that serve the public interest. This is the case, for example, with commercial data for the establishment of official statistics, or data relating to gas and energy consumption and production held by transmission and distribution systems operators for reuse by another party as well as data relating to changes in real estate ownership for reuse by certain third parties. In this respect, the law states that the licensor must provide the licensing authority with data using an electronic format that is open and freely reusable standard, and that ‘the licensing authority or a third party designated by it may extract and freely exploit all or part of these data and databases, in particular with a view to making them available free of charge for reuse for free or for a fee’.

However, the contours of the definition of the concept remain opaque. Public interest data is not defined in the adopted legislative text, but it rather simply constitutes the title of the second section of chapter one of the Digital Republic Bill. It is therefore essential to refer to the content of the section in question – largely inspired by a report drawn up in 2015 dedicated to describing the concept of public interest data⁷³ – who advocated in favour of a general ‘open data clause’. The Minister of Economy and Finance specified that this new concept incorporates all data ‘of private nature but whose publication may be justified by their role in improving public policies’.⁷⁴ It is a significant legal innovation and it also

aligns with an underlying ideological approach towards favouring access to data. The introduction of such an innovative concept is unfortunately at odds with the lack of clear definitions and guidelines as to the scope of its application. The enforceability of the provisions related to public interest data remain still largely opaque, as is the case with different data-related aspects of the Digital Republic Law.

Constituting one of the few national attempts to create a normative framework for the regulation of a data economy, the legislator takes into consideration the significant role that access to data plays in developing public policies, shaping innovation potential with respect to fairness and transparency. For this reason and recognising the need to diversify access to privately held data, the law aimed to create gateways that achieve an optimal balance between favouring market innovation and maximising societal impact. In an attempt to highlight and promote the social benefits of sharing various types of data for scientific and research purposes, the generalisation of this newly created category of data that have the potential to serve the public interest could be considered as a gateway towards better access to machine-generated data. The creation of this distinct category signals a regulatory approach towards privately held data – one that could be generalised or that could inspire a European-wide solution on the basis of the fostering of a data-based economy.

5.2 Towards a New Concept: Infrastructure Data

The public interest data definition has yet to be tested in practice in France; the ambiguity around the distinguishing elements of the concept and the scope of its application remains. For example, the scope of the public interest qualification as an autonomous concept appears to be regularly approached as a narrow definition. This is due to its nature as constituted by exceptional circumstances, applicable as an exception and not as the norm. For this reason, public interest data cannot be perceived as a general category but as an *ex post* qualification according to the various exceptional contributing factors. The generalisation of such a category could end up both over-burdening the concept of public interest – thus making it lose its significance – and disproportionately affect private entities that hold the data in question. The public interest nature is thus perceived as an exception to the general norm of privately held data, and, as such, it is destined to show its inefficiencies because of the elevated interest in improving access conditions to privately held data. What’s more, recognising public interest as a legal justification to normalise data access can only be applied in a sector-specific way due to the diversity in machine-generated data. Thus, it cannot constitute a cross-sectorial rule.

As a way out of the dissonance between the exceptional nature of the concept of public interest and the need for exceptional access rights to diverse types of machine-generated data, the qualification of data as infrastructure

72. Loi n° 2016-1321 du 7 octobre 2016 pour une République numérique, JORF n°0235 du 8 octobre 2016.

73. Conseil d’Etat/CGE/IGF (2015), Rapport relatif aux données d’intérêt général, Inspection générale des finances – Conseil général de l’économie – membres du Conseil d’Etat, available at: <https://www.economie.gouv.fr/files/files/PDF/DIG-Rapport-final2015-09.pdf> (last visited 15 April 2019).

74. Ministère de l’Economie et des finances, République numérique: ouverture des données d’intérêt général, 22 September 2016, available at: www.economie.gouv.fr/republique-numerique-ouverture-donnees-d-interet-general (last visited 15 April 2019).

could create a less invasive category. The qualities of data as infrastructure have been used to justify, for example, public policies regarding Open Data. Namely, the potential social value that can be derived by accessing and reusing public data, which also possess a non-rival character, has led to the perception of open data as infrastructure provided by the public sector towards maximising social economic value and innovation.

Similarly, the potential for further innovation deriving from privately held machine-generated data has been recognised by the cases where data gathered and stored by big data companies have been used towards generating value or improving society in general.⁷⁵ The most prominent example and use case for the innovation perspectives that can be derived by granting access and use rights to the large databases of machine-generated data comes from the potential that they hold as training data sets for algorithms used in public services.⁷⁶ Within the range of the interrelations born between different data sets according to the environment in which they were gathered, the concept of infrastructure data can be developed for the benefit of the societal good in the form of scientific research. In some cases, providing access to data sets can be mandated when it is recognised that the amount of related data and the accumulated concealed knowledge potential are almost impossible to duplicate by any reasonable means for research purposes. Admittedly, the concept of infrastructure data is more easily associated with market terms in order to identify data that have a significant place in the function of a specific technology or that are imperative for further development of a technology. If in these hypotheses, fair licensing options constitute a viable solution and have been promoted as a vector for competition that results in mutual expected benefits, it has not been proven sufficient for research purposes.

6 Conclusion

This article has attempted to highlight an emerging but dominant category in the new data economy: that of machine-generated data. A growing part of current data-related literature focuses on machine-generated data from a data protection perspective. However, what this article seeks to introduce is a discussion around the implementation of rules that involve balancing of market interests, innovation, data protection and promotion of scientific advancements. In this context, the choice to focus on machine-generated non-personal data is not random. It is founded on the European Commission's proposals for the fostering of a data economy and it attempts to explore how and under what circumstances

researchers can gain access to privately held machine-generated non-personal data.

Following an overview of the difficulties in delimitating the scope of application of a framework destined to apply to non-personal data, the article traces development of normative and practical approaches to the sharing of data between researchers and private entities that hold and control big databases. While we show that the applied practices have started to gain growing popularity among big companies, data sharing is far from becoming a standardised practice destined towards researchers. The need for creating legal certainty is the main impediment towards a better collaboration between research institutions and private actors. In fact, sharing data for research purposes has to ensure legal conformity with a range of property rights, private ordering clauses and the broader public good. After a description of applicable models in data sharing practices – from non-regulatory solutions (data collaboratives, data philanthropy) to regulatory ones (data mining exception to copyright, GDPR provisions for scientific research, etc.) – the article examines the recently adopted French Digital Republic Bill and the introduction of the concept of public interest with relation to data. While not undermining the potential that this concept could have should it become a more generalised category, the article underlines its shortcomings and limitations in promoting better access to machine-generated data for researchers. In fact, the qualification of public interest is a qualification that cannot be normalised without the risk of devaluing the actual concept of public interest and without risking to disproportionately affect private actors' interests. Finally, the article concludes with the concept of infrastructure data, as a similar term that could contribute towards creating data access arrangements proportional to societal needs while also taking into consideration market interests.

The goal of this article was to illustrate a range of different factors that need to be considered before attributing access privileges for research purposes. According to the needs identified, the solutions adopted have to consider whether access has to come free of charge or not and who should bear the costs of the making available. Similarly, the advantages in applying sector-specific solutions need to be assessed against the ones applying cross-sectorial ones. Before creating any type of regulatory framework that could prove to be ineffective, not flexible, and failing to respond to the needs of researchers according to rapid technological advancements, any exceptional categories created have to apply a proper balancing mechanism of interests of the actors involved towards the goal of safeguarding both market innovation and high-quality research.

75. The cases of 'corporate social responsibility' demonstrate that contribution.

76. As a matter of fact, in France, lately there has been discussion on applying the notion of public interest beyond data but also to qualify algorithms.

Changes in the Medical Device's Regulatory Framework and Its Impact on the Medical Device's Industry: From the Medical Device Directives to the Medical Device Regulations

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Abstract

Similar to pharmaceutical products, medical devices play an increasingly important role in healthcare worldwide by contributing substantially to the prevention, diagnosis and treatment of diseases. From the patent law perspective both, pharmaceutical products and a medical apparatus, product or device can be patented if they meet the patentability requirements, which are novelty, inventiveness and entail industrial applicability. However, regulatory issues also impact on the whole cycle of the innovation. At a European level, enhancing competitiveness while ensuring public health and safety is one of the key objectives of the European Commission. This article undertakes literature review of the current and incoming regulatory framework governing medical devices with the aim of highlighting how these major changes would affect the industry at issue. The analysis is made in the framework of an on-going research work aimed to determine whether SPCs are needed for promoting innovation in the medical devices industry. A thorough analysis the aforementioned factors affecting medical device's industry will allow the policymakers to understand the root cause of any optimal patent term and find appropriate solutions.

Keywords: Medical Device Directive, Medical Device Regulation, regulatory, European Union, reform, innovation, SPCs, policy

1 The Need for a Regulatory Framework for Healthcare Products

Medicines and medical devices have been in existence for centuries. According to the literature, there is evidence that scalpels, slings, splints, crutches and other medical devices were used as long ago as 7000 BCE by the Egyptians.

Neither drugs nor medical devices are ordinary consumer products. In most instances, consumers are not in a

position to make decisions about when to use them, which to use, how to use them and how to weigh potential benefits against risks as no medicine or device is completely safe. While the concept of ensuring their quality has evolved gradually over time, the modern health products regulation started only after breakthrough progress in the nineteenth century, especially in chemistry, physiology and pharmacology.

Historically, countries have tended to introduce regulation or tighten existing regulation only when forced to do so by a public outcry over an unexpected and unfortunate event. First and foremost, concerns raised over adulterated foods triggered the creation of the Federal Drug Authority (hereinafter 'FDA') in 1906. Although it was not known by its present name until 1930, FDA's modern regulatory functions began with the approval of the 1906 Pure Food and Drugs Act, a law that prohibited interstate commerce in adulterated and misbranded food and drugs.¹ In 1937, the death of over 100 Americans who had taken a cough mixture containing an anti-freeze-type chemical facilitated the introduction of pre-market testing to their medicinal regulatory requirements. Later, in the 1960s, with the thalidomide incident, a tranquilliser and sleeping pills that caused phocomelia in newly born children as a side effect,² the international community has shared consensus that drug, medical technologies and products used in patient care must be subject to stricter regulation than other consumer goods. In fact, however, regulation for medical devices started relatively late, triggered mainly by a major public concern in the 1960s and 1970s regarding the risk of micro-shock from an electrical current via devices connected to patients.³ During the 1970s and 1980s, demand for stronger regulatory legislation arose

1. W.F. Janssen, 'The Story of the Laws Behind the Labels', 15 *FDA Consumer*, 32-45 (1981), available at: <https://www.fda.gov/downloads/AboutFDA/History/FOrgsHistory/EvolvingPowers/UCM593437.pdf>.
2. Resulting in the shortening or absence of limbs. *Helix Magazine, The Thalidomide Tragedy: Lessons for Drug Safety and Regulation* (28 July 2009), available at: <https://helix.northwestern.edu/article/thalidomide-tragedy-lessons-drug-safety-and-regulation> (last visited 7 April 2019).
3. M. Cheng, 'HNP brief. No. 8: An Overview of Medical Device Policy and Regulation', *World Bank*, February 2007 http://www-wds.worldbank.org/external/default/WDSContentServer/WDSP/IB/2007/03/02/000310607_20070302113845/Rendered/PDF/388190HNPBrief801PUBLIC1.pdf (last visited 7 April 2019).

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from serious effects caused by intrauterine contraceptive devices (the Dalkon shield and the Copper-7 device) and several brands of tampons. Beginning in the 1970s, countries with a strong medical device industry⁴ initiated the process of either developing or strengthening their regulatory systems.⁵

While in most countries around the world the need for regulation arose primarily to enable patients' access to high-quality, safe and effective medical devices, and avoid access to products that are unsafe,⁶ in Europe the regulatory environment became more stringent mainly to enhance the cohesion of the Single Internal European Market.

Indeed, with the signature of the Treaty of Rome in 1957⁷ (hereinafter 'EC' Treaty) a Single Market for the European Union was created, with the aim of, among others, removing barriers to trade within the European Community (EU) Member States. In line with such an objective, Article 30 of the EC Treaty⁸ forbids 'qualitative restrictions on imports and all measures having equivalent effect between Member States', although derogations are allowed, based, inter alia, on grounds of protection of health and life of humans, animals or plants. Therefore, this can only confirm Altenstetter's arguments:⁹ in Europe, regulation of the medical device sector in a harmonised manner would not only ensure patients' access to high-quality, safe and effective medical devices but would also contribute to the smooth functioning of the internal European market, enhancing competitiveness of the Eurozone.

2 The Medical Device Industry at a Glance

Pharmaceuticals and medical devices are similar in certain respects: both are health technologies; both can be used to diagnose, treat, alleviate and cure disease; both

require regulatory oversight and a post-market surveillance system; both have intellectual property issues; both need a supply chain; and both have become an integral part of modern healthcare.

The pharmaceutical industry has been economically relevant in the European Union for quite some time; the world pharmaceutical market was worth €934.8 million in 2017. By contrast, the medical device industry has only recently become more visible, reaching a global market value of €360.8 billion¹⁰ for the same period. Yet, according to the European Commission, the medical device sector has turned increasingly important for the healthcare of the European Union's citizens, with a market estimated at roughly €110 billion¹¹ in 2016.

The United States is the largest market for both pharmaceuticals and medical devices, which are estimated to be 48.1% and 43% of the global market, respectively. The European pharmaceutical and medical devices market is the second largest, representing 22.2 % and 29% of the global market, respectively. According to the Medical Devices Sectoral Overview – Galway City and County Economic and Industrial Baseline Study,¹² the leading European Union medical devices markets are Germany, France, the United Kingdom, Italy and Spain. These top five countries make up 71% of the European medical devices market, while Germany and France together make up nearly half.

The medical devices industry is highly fragmented, consisting of small niche markets with only a few products. According to the European Medical Device Industry Trade Association (hereinafter 'EUCOMED'), of the approximately 27,000 medical technology companies in Europe, 95% are classified as small and medium-sized companies. The highest percentage of these is based in Germany, followed by the United Kingdom. After the United Kingdom, the leaders in terms of the number of companies are Italy, Switzerland, France and Spain. The industry includes companies such as Siemens, Hewlett-Packard, Philips and, GE-Healthcare, which operate mainly in electrical-medical equipment, as well as companies such as Boston Scientific and Medtronic, which dominate the implantable device sector.¹³

Owing to their intensive research,¹⁴ the protection of intellectual property is crucial to preserve the competitiveness of these industries. Indeed, the lack of enforce-

4. Among them Canada, United States, Japan and the European Union. These countries nowadays account for close to eighty percent of the medical devices market share. Medtech Europe, *Facts and Figures 2018*, available at: https://www.medtecheurope.org/wp-content/uploads/2018/06/MedTech-Europe_FactsFigures2018_FINAL_1.pdf (last visited 4 April 2019).
5. The role of medical devices and equipment in contemporary healthcare systems and services. World Health Organization. Technical discussion document for the Fifty-third Regional Committee for the Eastern Mediterranean, Agenda item 7 (b), (EM/RC53/Tech.Disc.2), (2006).
6. For instance, this idea was institutionalised in the Medical Device Amendments of 1976 in the United States, manifested in the 2002 Japanese Pharmaceutical Affairs Law as amended in 2005 and partially incorporated in the EU legislation of 1987 creating the single European market, the legal foundation of the medical device framework initiated in the 1990s. C. Altenstetter, 'Medical Device Regulation in the European Union, Japan and the United States. Commonalities, Differences and Challenges', 25 *Innovation*, 362-88 (2012).
7. Treaty Establishing the European Economic Community (ECC), signed on 25 March 1957 and applied from 1 January 1958, available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM%3Axy0023> (last visited 11 March 2019).
8. EC Treaty, Arts. 30-36, *ibid.*
9. Altenstetter, above n. 6.

10. Worldwide Medical Devices Forecast 2020 Report, available at: <http://info.evaluategroup.com/rs/607-YGS-364/images/mtwp15.pdf> (last visited 9 April 2019).
11. Medtech Europe, *The European Medical Technology Industry in Figures 2018*, available at: https://www.medtecheurope.org/wp-content/uploads/2018/06/MedTech-Europe_FactsFigures2018_FINAL_1.pdf (last visited 8 April 2019).
12. J. Cunningham, B. Dolan, D. Kelly, C. Young. *Medical Device Sectoral Overview, Galway City and County Economic and Industrial Baseline Study* (2015).
13. MDDI Ranking.
14. According to the EU Industrial R&D Investment Scoreboard 2018, the R&D shares of the health sector – comprising pharmaceuticals and medical devices – accounts for 22% of the EU R&D expenditure, available at: https://ec.europa.eu/info/news/2018-industrial-rd-scoreboard-eu-companies-increase-research-investment-amidst-global-technological-race-2018-dec-17_en (last visited 6 March 2019).

ment of Intellectual Property Rights creates disincentives for innovation and prevents companies from recouping their investments in R&D. In 2017, medical technology ranked first in patent applications at the European Patent Office,¹⁵ with 13,134 applications (6.2 % +), most of which were filed by applicants from the United States (37%), Japan (9%) and, among the European countries, Germany (10%), France (5%), United Kingdom (3%), Italy and Spain. In comparison, around 5,534 applications were filed in the same period in the pharmaceutical field, most of them by applicants from the United States, followed by Germany, France and Switzerland.

Any discussion about the regulatory issues around health products in Europe may only start meaningfully if there is clarity about the terms ‘medicinal products’ and ‘medical devices’. Medicinal products refer generally to any substance or combination of substances that may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or animals.¹⁶ A product is classified as a medicinal product on the basis of either its presentation and therapeutic purpose or the type of action exerted by the substance.¹⁷ By contrast, medical devices overall refer to any apparatus, software, material or other similar or related item intended to be used in the diagnosis, prevention, monitoring, treatment or alleviation of a disease or injury and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means.¹⁸

The foregoing shows that the difference between medicinal products and medical devices lies substantially in the interpretation of the main concepts that define them, namely therapeutic effect and mechanism of action.¹⁹ Both medical devices and pharmaceuticals (or, more precisely, medicinal products) share the common property of exerting a therapeutic effect, although they are different in regard to their mechanism of action. Medicinal products achieve their principal intended action in or on human bodies by pharmacological, immunological or metabolic means. In contrast, a medical device does not achieve its principal intended action

in the human body by pharmacological, immunological or metabolic means but may be assisted in its function by such means. Differences such as these justify distinct regulatory regimes.

Developing a new medicinal product or a new use of an existing drug takes a long time; safety and efficacy must be proven before it can be brought to market. This process is enormously expensive because of laboratory, animal and various human trials, as well as high costs of trials needed for regulatory approval.²⁰ The most recent analysis by the Tufts Center for the Study of Drug Development estimated the average cost of developing and gaining marketing approval for a new drug at \$2,6 bn., based on estimated average out-of-pocket costs (\$1,395 bn.) and the expected returns that investors forego while a drug is in development (1,163 bn.).²¹ By contrast, the dimension, complexity and function of medical devices vary significantly. Hurdles to proving safety and efficacy differ according to the risk level associated with the use of the medical device: more complex and more invasive devices generally require substantial clinical trials and assessment before approval for market launch is granted, whereas non-invasive and low-risk devices face minimal regulatory hurdles before they can be marketed.

Interestingly, most of the earlier comparative studies on medical device regulatory framework concluded that Europe has been granting faster access to medical technology (e.g. compared with the United States). In a report²² John Wilkinson, chief executive of EUCOMED, commented: ‘The current European Union regulatory system makes innovative medical technology available to people the fastest in the world while ensuring the highest safety standards.’ In line with it, Migliore²³ argued that many independent studies showed that the path to obtaining regulatory approval works faster in the European Union than in the United States. Further, Hwang *et al.*,²⁴ who analysed the regulatory delays for major innovations (e.g. cardiovascular devices), found that, on average, the delay, defined as median time difference between European Union approval marking and the United States approval, is up to 36.3 months in the case of the United States’ approval. Academic literature suggests that, compared with

15. European Patent Office, *Annual Reports and Statistics* (2017), available at: <https://www.epo.org/about-us/annual-reports-statistics/statistics.html#filings> (last visited 15 January 2019).

16. Art. 1(2) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. *Official Journal of the European Communities* No. L-311/67 of 28 November (2001).

17. The definition of medicinal product was issued originally in Directive 65/65/ECC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products and referred only to the purpose of the product. *Official Journal of the European Communities* no. P-022 of 9 February (1965).

18. European Union Directive 93/42/ECC concerning medical devices of 14 June 1992. *Official Journal of the European Communities* No. L-169 of 12 July (1993).

19. M. Racchi, S. Govoni, A. Lucchelli, L. Capone, E. Giovagnoni, ‘Insights into the Definition of Terms in European Medical Device Regulation’, 13 *Expert Review of Medical Devices*, 907-17, (2016).

20. J.H. Barton, J.E. Ezekie, ‘The Patents-based Pharmaceutical Development Process’, 294 *JAMA*, at 2076 (2005).

21. J.A. DiMasi, H.G. Grabowski, R.W. Hansen, ‘Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs’, 47 *Journal of Health Economics*, 20-33 (2016).

22. J. Wilkinson. *EU Regulatory System Brings Europeans Fastest Access to Medical Technology Without Compromising Safety*. Eucomed press release (28 January 2011); D. Cohen & M. Billingsley, European are left to their own devices, *BMJ* 2011; 342:d2748 doi: 10.1136/bmj.d2748 (Published 14 May 2011)

23. A. Migliore. ‘On the New Regulation of Medical Devices’, 14 *Expert Review of Medical Devices*, at 921-3 (2017).

24. T.J. Hwang, E. Sokolov E. et al, ‘Comparison Rates of Safety Issues and Reporting Trial Outcomes for Medical Devices Approved in the European Union and United States: Cohort Study’, 353 *BMJ*, at i3323 (2016).

the Japanese market, medical devices in the European Union are available around five years ahead.²⁵

3 Existing Regulatory Framework for Medical Devices

Regulation of medical drugs and devices involves the competing goals of assuring safety and efficacy while providing rapid movement of innovative products. There are several components of the European regulatory framework that are common to the countries manufacturing the vast majority of medical devices in use today (e.g. Australia, Canada, Japan, the United States and the European Union). These components comprise, at a minimum,²⁶ regulatory rules; a government-approved regulatory authority (to enforce the rules); one or more conformity assessment bodies (which are accredited by a European Union Member State and which may issue market approval) to assess whether a manufacturer or a device conforms to regulatory requirements; a classification scheme that ranks devices by level of potential risk associated with their use; a quality assurance or management system to ensure compliance of a device with quality standards and norms; a system for evaluating the clinical safety and performance of a device; a system for granting marketing (market entrance) approval for a device that complies with the regulatory rules; and a surveillance system capable of detecting and investigating adverse events associated with the actual use of a device on the market. These elements will now be explained further.

The European Union regulatory system for medical devices is quite young; it is twenty-five years behind the regulation of medical devices in the United States and about twenty-five years behind the European regulation of pharmaceuticals. Factors evidenced before, including differences in the type of industry, the profile for the products, the risk assessments of the products and the approach to generating efficacy and effectiveness data, reflect the difference in regulations for the devices compared with pharmaceuticals: while methods and research protocols for drug safety had been internationally agreed for around twenty-five years, standards, essential requirements, consensus protocols for clinical investigations and common technical specification for medical devices' approval emerged only recently. Yet some components of certain medical devices might be covered by pharmaceutical regulation.

Unlike in the case of the United States, which relies on a strictly centralised process through one agency, the FDA, the European medical devices' regulatory framework is synchronised with the regulations of the twenty-eight national European Union Members who have considerable discretion in how they enforce compliance with European Law.²⁷ Another key difference between these systems is that in the United States, the FDA oversees all regulation of devices. In contrast, the European system confers significant authority on a governmental body and private bodies to oversee device evaluation, market approval and post-market surveillance. For this reason, Chowdhury²⁸ defines the European Medical Device regulatory framework as a 'multilevel regulation', in which all the critical aspects of the regulatory life cycle are dispersed across multiple administrative and territorial levels and among both public and private actors.

The formal regulation of devices in Europe began only in the mid-1990s and followed the 'New Approach' concept, introduced for most consumer goods by the European Commission in 1986. This approach is based on the concept of a minimum set of mandatory essential requirements for safety and performance for a product to be sold in the European Union. The approach does not prescribe detailed technical specifications or solutions but promotes the use of voluntary standards (known as 'harmonised standards') that are developed by recognised standards organisations. Products in compliance with harmonised standards benefit from a presumption of conformity and can therefore be marketed throughout the whole European Union area.

Following the new approach, medical devices within Europe have been regulated by means of three directives, namely Directive 90/385/ECC concerning the Active Implantable Medical Devices (AIMDD), Directive 93/42/ECC concerning Medical Devices (MDD) and Directive 98/79/ECC concerning In Vitro Diagnostic Medical Devices (IVDD).²⁹

The choice of a directive rather than a regulation as a legal instrument for the regulation of medical devices in Europe denotes that, unlike in the pharmaceutical sector, which is subject to regulations, medical devices have a lower level of harmonisation, since the provisions of the directives have to be written into national law of each Member State. Over the past few years, the system has been subject to amendments and has been complemented by standards and several non-binding technical guidance documents, reflecting the consensus of stakeholders regarding the implementation of the directives. In Europe, governmental regulatory authorities (hereinafter 'Competent Authority') and conformity assess-

25. J.P. Boutrand, *EU Medical Device Regulatory Framework: Practical Impact of New Regulations*, NAMSA White Paper, available at: <https://www.namsa.com/wp-content/uploads/2015/10/WP-EU-Medical-Device-Regulatory-Framework.pdf> (last visited 13 April 2019).

26. World Health Organization, *Medical Device Regulations: Global Overview and Guiding Principles* (2003), available at: http://www.who.int/medical_devices/publications/en/MD_Regulations.pdf (last visited 10 April 2019).

27. C. Altenstetter, 'EU and Member State Medical Devices Regulation', 19 *International Journal of Technology Assessment in Health Care*, 228-48 (2003).

28. N. Chowdhury, *European Regulation of Medical Devices and Pharmaceuticals* (2014), at 109.

29. Except where otherwise stated, this article focuses on the Medical Devices Directive No. 93/42/ECC, as it is the most comprehensive of the three.

ment bodies (hereinafter ‘Notified Body [ies]’) are key players within the medical devices regulatory cycle, each having different responsibilities. Each Member State has its own Competent Authority who acts on behalf of the government to ensure that the requirements of the Medical Device Directives are transposed into the national law of that country. Each Competent Authority is also responsible for the designation and supervision of the conformity assessment bodies, as well as for post-market surveillance, including the report of adverse incidents of medical devices. Besides the responsibilities cited in rule-making, the Competent Authority also has responsibilities for the approval and monitoring of clinical trials.³⁰

Typically, these competences are delegated to bodies such as Ministries of Health, for instance in Italy,³¹ or an agency within the Ministry, as in the United Kingdom,³² Germany³³ and France.³⁴ Despite their being competencies limited to the jurisdiction of the country where these authorities have been created, Competent Authorities participate actively in rule-making activities (e.g. guidance documents) at the European level as well.

Conformity assessment bodies, or so-called notified bodies, are certification organisations tasked with the enforcement of rules; most of them are privately owned and run commercial organisations. Notified bodies are designated and supervised by a European Union country’s Competent Authority to assess the conformity of medical devices before being placed on the market. Their primary function is to carry out tasks related to conformity assessment procedures set out in the applicable legislation, which are aimed at demonstrating that the device complies with the requirements of the directive. They are, furthermore, responsible for suspending or withdrawing conformity certificates when they find that a device no longer satisfies the essential requirements set forth in the directives.

The European Commission, through the New Approach Notified and Designated Organisations website (hereinafter ‘NANDO’), maintains an up-to-date list of bodies notified by European Union Member States and makes the necessary information available to all interested parties.

Manufacturers seeking approval to place a medical device in the European Union market are free to choose any notified body operating within the European Union, since there is no territorial linkage between the manufacturing site and the location of the notified body. This means that the manufacturer shares a contractual relationship with the notified body in which the former

chooses the latter to undertake assessment. Critics have argued that a commercial relationship of this kind may compromise public interest.³⁵ It is noteworthy that a substantial share of literature shows that although the assessment procedures are the same de jure, there are some variations de facto regarding how notified bodies implement them,³⁶ as well as in the way notified bodies are designated and monitored by the relevant Competent Authorities. These disharmonies have resulted in widely differing quality in the performance of existing notified bodies.³⁷

Fundamental to the regulation of medical devices in the European Union is the use of a classification scheme to determine the level of control over a device. The classification of the device dictates the appropriate conformity assessment procedure: the higher the classification, the greater the level of assessment required by the notified bodies. This graduation is justified by the fact that medical devices cover wide-ranging products and it is more feasible and economically appropriate to categorise them rather than to subject all to the same rigorous conformity assessment procedure.³⁸ Similar schemes are utilised in the United States and other developed countries; however, while the United States has three classes of devices, the European Union and Japan use a four-class scheme.³⁹ More precisely, medical devices in Europe are divided nominatively into three classes, but class II is divided into IIa and IIb with different requirements for each, so that, in essence, the European Union has four classes.

This classification system considers the extent of human vulnerability to a device, as well as criteria concerning the time of uninterrupted contact of the device with the body and the degree of invasiveness.⁴⁰ Class I medical devices pose low risks associated with their use; manufacturers of these devices may declare to the Competent Authority conformity to the marketing requirements without a need to involve a notified body in this declaration. However, they must maintain a prescribed set of technical documentation available for inspection. This assessment procedure is known as ‘self-declaration’ or ‘self-certification’ and is described in Annex VII, Mod-

30. D.B. Jefferys, ‘The Regulation of Medical Devices and the Role of the Medical Devices Agency’, 52 *British Journal of Clinical Pharmacology*, 229-35 (2001).

31. Ministero della Salute – Direzione generale dei dispositivi medici e del servizio farmaceutico.

32. Medicines and Healthcare Products Regulatory Agency.

33. Bundesinstitut für Arzneimittel und Medizinprodukte.

34. L’Agence Nationale de Sécurité du Médicament et des Produits de Santé.

35. It has been contended that the ‘individual Notified Bodies will be under commercial pressures to not be perceived as more “difficult” than others’ and this may lead to a race towards dilution of oversight. P. Feldschreiber, T. Robinson, PIP and Hips. Do We Need a New Regulatory System for Medical Devices? *Lexology* (25 July 2012), available at: <https://www.lexology.com/library/detail.aspx?g=1e97243d-fb34-4208-8ecd-86456742fcfd> (last visited 18 April 2019).

36. I.C. Santos, G.S. Gazelle, L.A. Rocha, J.M. Tavares, ‘Medical Device Specificities: Opportunities for a Dedicated Product Development Methodology’, 9 *Expert Review of Medical Devices*, 299-311 (2014).

37. European Commission, DG Health and Food Safety, DG (Sante) 2017-6255, *Overview Report Joint Assessment of Notified Bodies designated under the Medical Devices Directives* (2017).

38. E. French-Mowat, B. Joanne, How Are Medical Devices Regulated in the European Union?. 105 *Journal of the Royal Society of Medicine*, S22-8 (2012).

39. Altenstetter, above n. 6.

40. L.R. Horton, ‘Medical Device Regulation in the European Union’, 50 *Food & Drug Law Journal*, at 461 (1995).

ule A, EC Declaration of Conformity of the Medical Device Directive.⁴¹

Approval for more complex devices (classes IIa to III) is directly handled by notified bodies; nevertheless, while the marketing of a class IIa device requires verification only at the production stage, class IIb and III devices are high-risk devices for which the notified body's verification is necessary at both the design and the production stages.

In any case, the conformity assessment procedure for devices falling in classes IIa and IIb requires a Full Quality Assurance System (QA), which must comprise the assessment by a notified body of the technical documentation for at least one sample of the device, including the audit of the quality system through the inspection of manufacturers' premises and, when justified, the premises of suppliers and subcontractor.

Class III medical devices must meet the additional requirement of submitting the design dossier to the notified body for approval under audit of the Full Quality Assurance System (Annex II),⁴² and the device must undergo clinical investigations to prove safety as a condition for approval. When clinical trials are involved, the ethics committee must be consulted. After the opinion of an ethics committee has been declared, and at least sixty days before an investigation begins, manufacturers may begin the studies unless notified to the contrary. An annex to the directive contains general requirements for clinical investigations, including requirements for preclinical safety evaluation and protection of human subjects.

It should be noted that, although clinical data are required for high-risk devices, the evidence requirements are vague, not available to the public and non-binding for manufacturers. Generally, clinical trial is unnecessary for a device that utilises an accepted technology to manage a medical condition for which the technology is an accepted indication of use. For instance, for manufacturers claiming similarity to an existing product, a comparative literature review typically suffices.⁴³

The directives call upon the manufacturers, notified bodies and Competent Authorities to exchange information concerning medical device safety; for this purpose the establishment of a European Databank on Medical Devices (hereinafter 'EUDAMED') has been provided for since 1998. This database stores information on manufacturers, data related to approvals and clinical studies and details on post-market events. Despite the good purpose, the utility of EUDAMED has been criticised because so far it has been accessible only to national and European Union authorities; but not to the public.⁴⁴

When determining whether devices comply with the essential requirements set forth in the directive, notified bodies are expected to rely on national voluntary standards adopted pursuant to the so-called harmonised standards.⁴⁵ The standards are voluntary, and manufacturers, users, certification bodies, public authorities and healthcare professionals participate in their elaboration; many are subsequently adopted or incorporated into international standards by the International Standards Organization (ISO) or included in the so-called guidance documents (hereinafter 'MEDDEV') generated by the European Medical Device Expert Group convened by the European Commission. Notwithstanding their voluntary character, the European Union Medical Devices Directive⁴⁶ offers a powerful incentive for manufacturers to comply with these standards by providing that Member States must presume that devices that conform to standards adopted pursuant to the harmonised standards the references to which have been published in the *Official Journal of the European Communities* comply with essential requirements.⁴⁷

A device that meets all the foregoing provisions of the relevant legislation is granted the conformity mark in one Member State. It consists of the initials 'CE', which stand for 'Conformité Européen'. This mark means, among others, that the device can be freely marketed in all the other European Member States and the European Economic Area (EEA) without further controls and no further evaluations. Thus, if, for instance, a German notified body approves the device, then the manufacturer can market it immediately in France, Italy and any other European Union country. This is significantly different from the position for medicinal products, for which market approval is needed in each Member State unless the centralised approval through the European Medicine Agency (EMA) is available.

In the post-marketing phase, manufacturers are required to report all serious adverse events to the Competent Authorities; all that information is further collated into the EUDAMED database. The post-market surveillance comprises both active monitoring of medical devices during their use and the notification to Competent Authorities of those situations that led or have led to serious injury of a patient, user or other person, death of a patient, user or other person; severe deterioration of the state of health of a patient, user or other person; or significant damage of the device. Reporting was voluntary from 1998 until 2011, when it became mandatory for manufacturers to directly report adverse events.

41. Directive 2001/83/EC, above n. 16.

42. J. Chai, 'Regulation of Medical Devices in the European Union', 21 *Journal of Legal Medicine*, at 537 (2000).

43. C. Sorenson, M. Drummond, 'Improving Medical Device Regulation: The United States and Europe in Perspective', 92 *Milbank Quarterly*, at 114-50 (2014).

44. Altenstetter, above n. 27.

45. R.F. Kingham, 'Regulation of Medical Devices in the European Community', 47 *Food & Drug Law Journal*, at 563 (1992).

46. Art. 5, Directive 2001/83/EC, above n. 16.

47. Horton, above n. 40.

4 Political Landscape and the Need for Revision

While there are agreed European standards for medical devices, the previous decades have witnessed rising concerns that these standards are not uniformly applied.⁴⁸ In the *British Medical Journal*, Freemantle⁴⁹ asserted that the current European Union regulatory framework was inadequate to provide enough safeguards for technologies that affect morbidity, mortality and health-related quality of life. Eikermann et al.⁵⁰ reached similar conclusions, by highlighting safety issues related to the market authorisation pathway and the need for a more transparent, evidence-based process for medical device approval. Furthermore, as evidenced before, the lack of uniformity in the designation and monitoring of notified bodies among the Competent Authorities has been identified by various scholars as one of the prime reasons for the widely differing quality in the performance of notified bodies.⁵¹ Such segmentation has undoubtedly led to different levels of health and safety protection and has created obstacles to the internal market.

At the same time, efforts towards harmonisation have been hampered by uncertainties due to regulatory gaps derived from new medical device technology that has been developed in the past years. As Dr. Redberg explains:

In the past 10–20 years the number and complexity of medical devices has exploded ... in contrast to most devices in the 1970s, the newer products pose substantially greater risks – even life-threatening risks – to patients. For example, many new medical devices are permanently implanted in a patient's body and can be moved or changed, if at all, only with great risk to the patient.⁵²

In this regard, it is interesting to note that while medical devices historically included software applications with algorithmic calculations and automated functionality, which capabilities resided within the physical medical device, modern software-based medical devices increasingly integrate artificial intelligence (hereinafter 'AI'),⁵³

making it possible to reveal patterns in patient records, scanned images or even data stored in mobile phones to improve diagnosis of patients, assist in their treatment and even change something about a medical device without human interaction or by recommending some action to a human recipient who then interacts with the medical device to accept or reject the recommendation. Similarly, wearables and other medical devices produced by general product manufacturers and mobile application (known as 'app') developers have become tremendously popular. These advances, however, challenge the legally defined concepts of a medical device and the associated boundaries of regulation.⁵⁴

Underlining the need to consolidate and simplify the regulatory framework, promote its uniform interpretation across Member States and fill in the regulatory gaps that emerged with regard to a number of new technologies, the Commission initiated in 2008 a fundamental revision of the three Medical Device Directives.⁵⁵

To this end, the Commission conducted two public consultations – one in 2008 and the second one in 2010 – seeking input from industry members, regulatory authorities, professionals and other stakeholders regarding the regulatory system and possible targets for reform. A process for reviewing the medical devices regulatory legislation followed the aforementioned consultations, which was expected to conclude with the draft of the proposals for reform by the beginning of 2012.

In the meantime, two high-profile incidents that occurred between 2010 and 2012 prompted the Commission to push for the replacement of the former, less restrictive European Union Medical Device Directive with a more stringent system.⁵⁶

In 2010, metal-on-metal (hereinafter 'MoM') hip replacements were recalled because of high failures rates; these implants were originally designed as an alternative in younger osteoarthritis patients, for whom long-term total hip replacement device survival is poor. However, MoM prostheses have raised concerns about the release into the body of metals such cobalt and chromium and entry into the bloodstream and soft tissues.⁵⁷ The problem caught the attention of the European Union, where around 100,000 patients have been subjected to MoM hip replacement. Investigations showed that 650 patients were fitted with hip prostheses with modifications that had not been approved in the European Union.⁵⁸

48. D. Cohen, M. Billingsley, 'Europeans Are Left to Their Own Devices', 342 *BMJ*, at d2748 (2011).

49. N. Freemantle, 'Evaluating and Regulating the Device Industry', 342 *BMJ*, at d2839 (2011).

50. M. Eikermann, C. Gludd, M. Perleth, C. Wild, S. Sauerland, I. Gutierrez-Ibarluzea, S.-L. Antoine, J. Demotes-Mainard, E.A.M. Neugebauer, 'Commentary: Europe Needs a Central, Transparent, and Evidence-based Regulation Process for Devices', 346 *BMJ*, at f2771 (2013).

51. Santos et al., above n. 36.

52. R.F. Redberg, *Testimony to Subcommittee on Health, House Committee on Energy and Commerce* (17 February 2011), available at: <https://it.scribd.com/document/325129078/HOUSE-HEARING-112TH-CONGRESS-IMPACT-OF-MEDICAL-DEVICE-REGULATION-ON-JOBS-AND-PATIENTS> (last visited 19 April 2019).

53. S. Kumba, *AI in Medical Devices – Three Emerging Industry Applications, Business Intelligence and Analytics* (2019), available at: <https://emerj.com/ai-sector-overviews/ai-medical-devices-three-emerging-industry-applications/> (last visited 19 April 2019).

54. C.A. Tschider, 'Deus Ex Machina: Regulating Cybersecurity and Artificial Intelligence for Patients of the Future', 5 *Savannah Law Review*, at 177 (2018).

55. European Commission Directorate for Health and Consumers, *Revision of the Medical Device Directives* (26 October 2013), available at: www.ec.europa.eu/health/medical-devices/documents/revision/index_en.htm (last visited 20 January 2019).

56. European Commission Press Release, *Medical Devices: European Commission Calls for Immediate Actions – Tighten Controls, Increase Surveillance, Restore Confidence*, available at: http://europa.eu/rapid/press-release_IP-12-119_en.htm (last visited 20 January 2019).

57. D. Cohen, How Safe Are Metal-on-metal Hip Implants? 344 *BMJ*, at e1410 (2012).

58. D. Cohen, 'Faulty Hip Implant Shows up Failings of EU Regulation', 345 *BMJ*, at e7163 (2012).

Similarly, since 2010, potential health concerns have been raised in regard to silicone breast implants manufactured by the French firm Poly Implant Protheses (hereinafter ‘PIP’). In 2012 an unexpectedly large number of women were diagnosed as suffering from ruptured breast implants, leading to the breast implant controversy. The controversy turned into a scandal as PIP has been manufacturing implants using industrial grade silicone. The French government called the women who had received this implant for recall at no cost, but because of poor record keeping women were unable to find out whether they had received these implants or not.

These separate incidents, besides having highlighted the need for strengthening of the European Union Medical Devices Directives, led to a debate on the need for actions to enhance the traceability and long-term monitoring of devices in terms of safety and performance. In a resolution adopted in June 2012,⁵⁹ the European Parliament called for a more stringent surveillance, placing on the market requirements and safety controls, a stronger vigilance system as well as better patient information about the quality of high-risk, implantable devices and the potential risks.

In September 2012 the European Commission finally adopted a proposal⁶⁰ for Regulation on Medical Devices and In-Vitro Diagnostics and submitted the draft for approval to the European Parliament and the Council, which introduced several changes in 2014 and 2015, respectively.⁶¹ The final text of the two regulations was agreed in 2016 and, after being translated into the official European Union languages, both texts were finally adopted in April 2017. The process concluded with the publication in the Official Journal of the European Union in May 2017^{62,63}; both regulations became legally binding on 25 May 2017.

5 New Regulations for Medical Devices: Main Changes

The new regulations promise to introduce a series of extremely important improvements to modernise the current system and to properly address the gaps of the past.

The proposals take the form of a Regulation; unlike directives, which need transposition by national parliaments, regulations are directly enforceable, and stakeholders are accountable under European Union law. It is believed to be the appropriate legal instrument as it imposes clear and detailed rules that will become applicable in a uniform manner at the same time throughout the European Union. Furthermore, since for historical reasons the Active Implantable Device Directive and the Medical Device Directive were regulated in two separate legal instruments, in the interest of simplification, these two directives have been replaced by a single legislative act applicable to all medical devices other than in vitro diagnostic.⁶⁴

Although the new regulations are already legally binding, they will apply three years⁶⁵ after publication in the case of Medical Device Regulation and five years⁶⁶ after publication in the case of In Vitro Diagnostic Device Regulation. This transition period is meant to allow all major stakeholders, including the European Union Commission, Competent Authorities, notified bodies and manufacturers, to meet their respective obligations from the date of application.

While under the new Regulation the classification scheme into four classes has been retained, rules have tightened and changed for some products, and, as a result, some devices will be reclassified to higher classes.⁶⁷ For the purpose of the product’s classification, the criterion is still the vulnerability of the human body, although the potential risk associated with the technical design and manufacture of the device will also be taken into account.⁶⁸ In addition, some devices lacking medical purpose that were previously exempt from the regulations but that present a high-risk profile are now within the scope of the new legislation.⁶⁹

Interestingly, while the definition of medical devices in the Regulation essentially maintains the legacy of the previous legislation, the ‘intended purpose’ under the new medical device definition has been broadened to

59. European Parliament Resolution on Defective Silicone Gel Breast Implants Made by French Company PIP, <https://publications.europa.eu/en/publication-detail/-/publication/1b63129f-4e29-11e3-ae03-01aa75ed71a1/language-en> (last visited 25 January 2019).

60. Commission Proposal for a Regulation of the European Parliament and the of the Council on Medical Devices and Amending Directive 2001/83/EC, Regulation (EC) No. 178/2001 and Regulation (EC) No. 1223/2009, COM(2012) 542; Commission Proposal for a Regulation of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices, COM(2012) 541.

61. L. Hancher, M.E. Földes, ‘Revision of the Regulatory Framework for Medical Devices in the European Union: The Legal Challenges’, 4 *European Journal of Risk Regulation*, 429-35 (2013).

62. Regulation European Union 2017/745 on Medical Devices of the European Parliament and of the Council of 5 April 2017. *Official Journal of the European Communities* No. L-117/1 (2017).

63. Regulation European Union 2017/746 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU of the European Parliament and of the Council of 5 April 2017. *Official Journal of the European Communities* No. L-117/176 (2017).

64. Recital 5, Regulation European Union 2017/745 on Medical Devices, above n. 62.

65. The Medical Device Regulation will apply as of May 2020.

66. The In Vitro Diagnostic Device Regulation will apply as of May 2022.

67. For instance, active implantable devices and their accessories, devices incorporating nanomaterials, some software devices as well as devices intended specifically for use in direct contact with the heart or central circulatory system will be classified as Class III.

68. Recital 58, Regulation European Union 2017/745 on Medical Devices, above n. 62.

69. For instance, it includes aesthetic devices that may not have a medically intended purpose (coloured or non-corrective contact lenses) as well as devices designed for the purpose of ‘prediction’ of a disease or other health condition. Arts. 1 and 2 Medical Device Regulation, above n. 62.

include ‘prediction’ and ‘prognosis’ of disease and other health conditions. This may bring certain digital health-care technologies⁷⁰ under the scope of this definition.

The substantive requirements and conformity assessment procedures are more complex and burdensome under the Medical Device Regulation. For instance, the revised text demands more rigorous clinical evidence for class III and implantable medical devices. With only certain exceptions, these categories of devices must go through clinical investigations; equivalence principles as compliance with current MEDDEVs guiding documents on clinical requirements⁷¹ will in many cases be insufficient to comply with the new rules. In particular, manufacturers will therefore need to conduct clinical investigations⁷² in case they lack sufficient clinical evidence to support the claims done on both safety and performance of a dedicated device,⁷³ ‘sufficient clinical evidence’ being only clinical data produced either by the manufacturer on its own or by the competitor, although in this latter case a contract must be available to justify access to the clinical data. Essentially, under the new Regulation full access to clinical data used to support the safety and performance claim is mandatory in order to satisfy the clinical investigation’s requirement.

In line with it, the clinical evaluation procedure for certain high-risk profile devices will need to be carried out under the ‘scrutiny’ of a newly formed Committee Medical Devices Coordination Group (hereinafter ‘MDCG’) made up of members appointed by Member States due to their role and experience in the field of medical devices, who will assess the preliminary report of the notified bodies and will eventually review it before granting the ‘CE’ certification mark.⁷⁴ Justified by the need to harmonise evaluation of high-risk devices on clinical aspects to solve problems experienced in the past, this scrutiny mechanism empowers the authorities to have a ‘second look’ at individual assessments and make their views known before a device is placed on the market.

The forthcoming changes will undoubtedly represent a huge challenge for manufacturers; however, they might also act as a trigger for implementing an operationalised approach while ensuring consistent high standards. As Altenstetter expressed,

The twenty-year-old system has relied on manufacturers’ claims of the performance of high-risk medical devices, but with little input from clinical practitioners and academic scientists. Hence it makes a great deal of sense to give more considerations to

clinical data, clinical assessments, and make use of clinicians’ experience with patient outcomes.⁷⁵

Nevertheless, (probably) in response to the stakeholders’ constant requests of rendering the application of the MDR to legacy products more viable, one step back to the older approach has been taken in this regard. Indeed, on 22 March 2019 the MDCG published a document on the interpretation of Article 54(2)b of the Medical Devices Regulation, which states:

The Clinical evaluation consultation procedure shall not be required where the device has been designed by modifying a device already marketed by the same manufacturer for the same intended purpose, provided that the manufacturer has demonstrated to the satisfaction of the notified body that the modifications do not adversely affect the benefit-risk ratio of the device.⁷⁶

In addition, a post-market clinical follow-up evaluation report (PMCF) and summary of safety and clinical performance is required to be updated annually for class III devices and class IIb implantable devices and at least every two years for class IIa and class IIb non-implantable devices to facilitate the gathering of quality, performance and safety data throughout the device’s lifetime. This requirement raised some concerns among stakeholders, who prima facie construed this rule as requiring annual clinical data – in line with the MEDDEV guidance documents applicable in the context of the medical device’s directives, namely, as requiring further clinical investigations. Nevertheless, it is worth noting that under the Regulation the definition of PMCF is broad and relates to all types of clinical information, namely vigilance, complaints, technical information and publicly available information; by contrast, clinical follow-up under the umbrella of the directives is very much focused on clinical studies and clinical data.⁷⁷ To enhance transparency within the system, the summary of safety and clinical performance shall be made available via EUDAMED, to which access will now be extended to notified bodies, the MDCG, economic operators (manufacturers, authorised representatives, importers, sponsors), experts and the public, including medical institutions.⁷⁸ The inclusion of data sourced from clinical investigations will become mandatory for new class III or implantable medical devices; the details of these clinical investigations will be stored in a system

70. For instance, digital health apps.

71. Guidance document MEDDEV 2.7/1 Rev.4 on Clinical Evaluation Reports (CER) for Medical Devices, European Commission, DG Internal market, Industry, Entrepreneurship and SMEs.

72. Clinical investigations refer to a systematic investigation involving one or more human subjects, undertaken to assess the safety or performance of a medical device.

73. Art. 49, Regulation European Union 2017/745 on Medical Devices, above n. 62.

74. Arts. 78 and 80, Regulation European Union 2017/745 on Medical Devices, above n. 62.

75. C. Altenstetter, ‘US Perspectives on the EU Medical Device Approval System, and Lessons Learned from the United States’, 4 *European Journal of Risk Regulation*, at 443 (2013).

76. Interpretation of Art. 54(2)b of 22 March 2019, Medical Device Coordination Group.

77. Indeed, the notion of PMCF was first introduced in the guidance document on post-market clinical follow-up studies MEDDEV 2.12 rev 2.

78. Arts. 26 and 27, Regulation European Union 2017/745 on Medical Devices, above n. 62.

that is interoperable with the clinical trial database for medicinal products.⁷⁹

In the past, lack of data management has been perceived as a major obstacle to reaching final recommendations on the use of medical devices; and having the chance to access clinical investigation data will facilitate post-market analysis and will give more transparency to the system.⁸⁰ Likewise, the aforementioned centralising measures such as the creation of the Medical Device Co-ordination Group, a central database and more stringent clinical trials seem to demonstrate the legislature's intention towards a medical device's authorisation and monitoring system similar to that currently applying to pharmaceuticals in Europe.

The forthcoming Medical Device Regulation places further responsibilities on the notified bodies, which will be empowered to carry out unannounced inspections of manufacturers and their sub-contractors' sites to check whether they are complying with quality management systems, alongside physical or laboratory tests on devices. Supervision of notified bodies will also change considerably, starting with the requirements that Competent Authorities must apply for a new designation⁸¹; notified bodies will also be under heightened scrutiny from Competent Authorities as well as under joint assessment with experts nominated by Member States and the Commission.⁸² The proposal also requires rotation of the notified body's personnel involved in the assessment of medical devices at appropriate intervals to strike a reasonable balance between the knowledge and experience required to carry out thorough assessments. Stakeholders⁸³ claim that while all these new measures will ensure a more rigorous oversight and uniform performance of the assessment procedures, they might also result in a shortfall of resources owing to the reduction in the number of notified bodies that are going to be re-notified. This argument is further supported by the information already available on NANDO, the European Union's notified body database, according to which the number of notified bodies has dropped from about eighty to fifty-nine.⁸⁴ A possible shortfall is especially worrisome in the *in vitro* devices' arena, where about 80% of products – an estimated 35,200 – will require notified body oversight for the first time. Interestingly, even under the umbrella of the implementation of the current legislative framework, administrative capacities varied greatly across Member States, most of whom

were unable to provide enough skilled manpower capacity for enforcing compliance with the directives.⁸⁵

The revised regulatory framework further includes the introduction of a Unique Device Identification System (hereinafter 'UDI'),⁸⁶ consisting of a series of numerals of an alphanumeric identification code, which will need to be displayed on every medical device to allow the unambiguous identification of a specific device on the market.

The complexity of the UDI system is reflected in the multiple regulatory requirements that it encompasses; it also imposes obligations on all actors of the supply chain, from manufacturers to healthcare professionals, with the involvement of notified bodies and Competent Authorities. The intended result is to improve the traceability of devices throughout the supply chain and thereby help the authorities and manufacturers to take prompt and appropriate actions in response to concerns about device safety.

From a labelling approach, the UDI contains a device identifier (known as 'UDI-DI'), which is an identifier of a device model and is also used as the 'access key' to information stored in the UDI database, such as certificates, declaration of conformity, technical documentation and summary of safety and clinical performance. Furthermore, it comprises a production identifier (known as 'UDI-PI') that identifies the unit of device production. The UDI shall, in addition, be used for reporting serious incidents, and, to support this effort, all the information will be channelled and publicly available via EUDAMED. All stakeholders shall be able to obtain information on the clinical safety performance of a targeted medical device and to track who supplied a medical device and to whom. This is likely to enhance the effectiveness of post-market safety-related activities, in line with the objectives pursued by the reform.

The UDI requirements described in the Medical Device Regulation are completely new for the European Union market – since the Medical Device Directive, which is still in force, has no provisions on the traceability of medical devices and follows the global trend in handling the traceability of medical devices.⁸⁷ In this regard, despite the labelling and operational overhaul that would be required to implement the UDI system, mostly seen as 'cost-prohibitive' and 'technically challenging', it has been reasonably argued⁸⁸ that a globally harmonised approach to UDI is critical to realising the benefits of such a system, is a prerequisite for medical device traceability in a globalised economy and lays the groundwork for the worldwide exchange of medical device data.

79. S. Milmo, 'New Regulations for Combination Products', 28 *Pharmaceutical Technology Europe* (2016).

80. Migliore, above n. 23.

81. Art. 29, Regulation European Union 2017/745 on Medical Devices, above n. 62.

82. Art. 35, Regulation European Union 2017/745 on Medical Devices, above n. 62.

83. Medtech Europe, *Implementing the New MD and IVD Regulations: Industry Calls for Solutions to Ensure Continuity of Care to Patients* (2018), available at: https://www.medtecheurope.org/wp-content/uploads/2018/07/MTE_PolicyPaper_MDRIVDRImplementationCallforSolutions_July2018.pdf (last visited 11 April 2019).

84. This number refer to the information available by December 2018.

85. Altenstetter, above n. 27.

86. Art. 24, Regulation European Union 2017/745 on Medical Devices, above n. 62.

87. Similarly, in the United States, device manufacturers will be required to place a UDI on the device's labels.

88. Global Medical Technology Alliance, *Unique Device Identification: Insights and benefits from a single UDI System in the International Arena*, White Paper (2018), available at: <http://www.globalmedicaltechnologyalliance.org/papers/GMTA%20UDI%20White%20Paper.pdf> (last visited 23 April 2019).

In conclusion, one thing is clear: a new regulatory system was necessary to improve the clarity of the regulatory requirements and harmonise the application of regulations across the European Union's Member States. However, this may mean a major overhaul of the European regulatory framework, with the risk that the tougher requirements for the industry lead to a potentially greater timeline to certification, creating disincentives for bringing new medical technologies to the market.⁸⁹

6 Chief Challenges Resulting from the Regulatory Framework: Would an Extension of the Term of Patent Protection Be Needed for Medical Devices to Promote Medical Device Innovation?

The World Health Organisation (WHO) defines innovation as a 'process cycle of three major phases that feed into each other: discovery, development and delivery'.⁹⁰

Medical device innovation refers not only to the invention of new devices but also to adjustments to, or incremental improvements of, existing devices and clinical practices. In brief, innovation of medical devices must demonstrate added value for patient health.

On the one hand, the apparent nexus between the patent system and economic development, which depicts patents as a lever of industrial progress, has undoubtedly played a role in innovation incentive theory, becoming probably the most quoted argument in favour of (medical device) patents.⁹¹ Adopting a patent system is thought to encourage investment of resources in making inventions by giving inventors limited monopoly rights in exchange for public disclosure of their invention. On the other hand, however, regulatory issues impact on the whole cycle of the innovation as well. The latter means that the regulatory framework has to be taken into account in the early stages of the medical device design and development, during preclinical and clinical evaluation, product regulatory evaluation, manufacturing and post-marketing surveillance. For this reason, the relationship between medical devices developers and

the regulatory framework is also critical for innovation and competitiveness in this sector.⁹²

In this regard, scholars have empirically found that in relation to pharmaceutical innovations, owing to the entire regulatory bundle, the effective patent life for pharmaceutical innovations, that is, the period between the patent application date and the date when a pharmaceutical is put on the market, is significantly reduced; frequently, at least half the patent term has expired before a product reaches the market.⁹³

To cope with this issue, some countries have introduced in their statutes an extension of the patent term by providing a supplementary term of protection for pharmaceutical⁹⁴ inventions. The balance between the exclusive right conferred by patents on innovative pharmaceutical products and the regulatory rules for their marketing approval seem to have been achieved in certain European Union Member States, which started to regulate this matter independently. Lastly, at the European level patent-term extension has been introduced by means of a new title, the Supplementary Certificate Protection (hereinafter 'SPCs'),⁹⁵ to provide a harmonised solution and to deter pharmaceutical R&D from shifting to non-European markets, e.g. Japan or the United States.⁹⁶

No wonder why while much has been written about extending the patent-term protection in the pharmaceutical field, little has been discussed in relation to SPCs (or analogous title) for medical devices. If the intended purpose of the introduction of such a patent-term extension was to compensate the patentee that has experienced significant regulatory delays in getting its patented pharmaceutical products into the market, at the time that the SPCs regulation was introduced, no lengthy regulatory delays significantly affected medical devices.⁹⁷

The gradual expansion of the medical device regulatory framework has resulted from the complex interaction of various stakeholders' interests, driven by the interest or perspectives of these stakeholders: the industry seeks legal certainty and transparency, and speed to market their devices, while patients and the general public seek access to innovative medical technology at zero risk and in respect of fully tested efficacious products.

89. J.J. Howard, 'Balancing Innovation and Medical Device Regulation: The Case of Modern Metal-on-metal Hip Replacements', 2016 *Medical Devices*, 267-75 (2016).

90. World Health Organization-Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG). *The Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA)*, (2008/2009).

91. F. Machlup, E. Penrose, 'The Patent Controversy in the 19th Century', X *The Journal of Economic History*, 1-29 (1950).

92. K.D. Lind, 'Implantable Devices: Regulatory Framework and Reform Options', 130 *AARP Public Policy Institute* (2017).

93. A study published by the Intellectual Property Institute on 31 August 2007 showed that by 1990 the European effective patent life for pharmaceutical products was between ten and twelve years. D. Curley, *Extending Rewards for Innovative Drug Development: A Report on Supplementary Protection Certificates for Pharmaceutical Products* (2007).

94. United States in 1984, Japan in 1988, Europe during the 1990s, France and Italy in 1991. T. Rolling, 'How Europe's SPC Regime Works in Practice', 54 *Managing Intellectual Property*, at 260 (2016).

95. Council Regulation (EEC) No. 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, *Official Journal of the European Communities* No. L 182 (1992), later updated and replaced by (EC) Regulation No. 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, *Official Journal of the European Communities* No. L 152 (2009).

96. Recitals 6 and 7 of EC Regulation No. 469/2009, *Ibid*.

97. Migliore, above n. 23.

Nonetheless, the continued overhaul of the regulatory framework of medical devices, culminating with the entry into force of the two new regulations, seems to lengthen the time needed for placing medical devices on the market. At the same time, stakeholders have raised concerns about the more stringent Medical Device Regulation, claiming that it would ultimately result in late access to new technologies and would therefore be linked to human costs. Likewise, some literature contends that regulatory uncertainty leading to longer timelines for the approval process for new medical products may create disincentives for pioneer entry by meaningfully increasing the length of the product development period for novel devices.⁹⁸

Despite the merits of the forthcoming medical device regulatory framework, a notable challenge remains that might hinder medical device innovations in Europe. Evidenced shifts in the regulatory framework for medical technology might result in the erosion of the effective term of patent protection,⁹⁹ leading to undesired market failures and barriers to major medical device innovations.¹⁰⁰ As has been evidenced,¹⁰¹ new innovative medical devices are characterised by a large product heterogeneity and significant uncertainty about the regulatory process itself. This regulatory uncertainty is likely to bring some discouragement into medical device innovation.

At the state of play and by contrast to pharmaceutical innovations, the SPCs legislation does not expressly foresee a medical device to be an eligible product for obtaining an SPC,¹⁰² and judicial decisions among the European Union jurisdictions have been rather reluctant to grant it.¹⁰³ Sound policy considerations are urgently needed to optimise the existing European Medical Device innovation system. Worth mentioning here is that there is no primary source of law preventing secondary law from amending the term of protection for medical devices.¹⁰⁴ Nonetheless, for the time being, the

Commission has only timidly introduced this topic on its table for discussions.^{105,106}

98. R. Guerra-Bretaña, A.L. Flórez-Rendón, 'Impact of Regulations on Innovation in the Field of Medical Devices', 34 *Research on Biomedical Engineering*, 356-67 (2018).
99. S. Sterckx, Does European Patent Law Unfairly Discriminate Against Medical Devices as Compared with Pharmaceuticals? 25 *Expert Opinion on Therapeutic Patents*, 845-8 (2015).
100. E. Klar, 'Medical Device Regulation als aktuelle Herausforderung für die rechtssichere Einführung neuer Technologien', 2018 *Chirurg*, 755-9 (2018).
101. A.D. Stern, 'Innovation under Regulatory Uncertainty: Evidence from Medical Technology', 145 *Journal of Public Economics*, at 181-200 (2017).
102. A. Hutchinson, N. Fischer, P. Schröler, Is There a Future for Medical Device SPCs? 16 *Bio-Science Law Review* (2017).
103. Lastly, Court of Justice of the European Union, C-527/2017, *Boston Scientific*, ECLI:EU:C:2018:867, <http://curia.europa.eu/juris/liste.jsf?language=en&num=C-527/17> (last visited 1 December 2018).
104. Max Planck Institute For Innovation and Competition, Study on the Legal Aspects of SPC – Final Report MPILC (2018), available at: <https://ec.europa.eu/docsroom/documents/29524> (last visited 23 April 2019).
105. 'The scope and sectors covered by the SPC Regulation were decided over 20 years ago. However, in these two decades many of the underlying aspects of the SPC Regulation have changed, among others,

changes in innovation patterns, big data, bio-medicines, personalised medicines, increasing importance of medical devices as well as changes in marketing authorisation procedures European Commission', European Commission Call for tender: Study on the economic impact of Supplementary Protection Certificates, pharmaceutical incentives and rewards in Europe (2017).

106. Commission Staff Working Document, Summary of the replies to the public consultation on Supplementary Protection Certificates and patent research exemption for sectors whose products are subject to regulated market authorisations, SWD(2018) 242 final, available at: <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SWD:2018:0242:FIN:EN:PDF> (last visited 1 December 2018).

On the Eve of Web-Harvesting and Web-Archiving for Libraries in Greece

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Abstract

This conference paper submitted on the occasion of the 8th International Conference on Information Law and Ethics (University of Antwerp, December 13-14, 2018) that focused on modern intellectual property governance and openness in Europe elaborates upon the Text and Data Mining (TDM) issue in the field of scientific research, which is still-by the time of composition of this paper-in the process of discussion and forthcoming voting before the European Parliament in the form of provision(s) included in a new Directive on Copyright in the Digital Single Market. TDM is included in the proposal for a Directive of the European parliament and of the Council on copyright in the Digital Single Market-Proposal COM(2016)593 final 2016/0280(COD) that was submitted to the European Parliament.

Keywords: web harvesting, data analysis, text & data mining, TDM: Proposal EU Copyright Directive

The paradox of intellectual property lies in a “system that promotes, or at least, aspires to promote knowledge [...] by restricting it.”
P. Bernt Hugenholtz

1 What TDM Is

This conference paper submitted on the occasion of the Eighth International Conference on Information Law and Ethics (University of Antwerp, 13 and 14 December 2018) focused on modern intellectual property governance and openness in Europe elaborates upon the text and data mining (TDM) issue in the field of scientific research, which is still – by the time of composition of this article – in the process of discussion and forthcoming voting before the European Parliament in the form of provision(s) included in a new Directive on Copyright in the Digital Single Market. TDM is

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included in the proposal for a Directive of the European parliament and of the Council on copyright in the Digital Single Market – Proposal COM(2016)593 final 2016/0280(COD) that was submitted to the European Parliament.

On 11 September 2018, the aforesaid proposal was furnished to the European Parliament for voting in its plenary sitting. However, controversies concerning Article 11 that caters for protection of press publications regarding digital uses and Article 13 that pertains to use of protected content by information society service providers storing and giving access to large amounts of works and other subject matter uploaded by their users resulted in the proposal being referred back to the Commission pursuant to Rule 59(4) of the Rules of Procedure of the European Parliament; Parliament’s first reading was therefore not closed and negotiations with the Council begun.

This article considers the text of the Proposal COM(2016)593 final 2016/0280(COD) as it has been until the composition of this writing, that is, until January 2019. This COM(2016)593 final 2016/0280(COD) proposal is consistent with the existing EU copyright legal framework. This proposal is based upon and complements the rules laid down in Directive 96/9/EC – the Database Directive¹ –, Directive 2001/29/EC – the Information Society (InfoSoc) Directive² –, Directive 2006/115/EC,³ Directive 2009/24/EC,⁴ Directive 2012/28/EU⁵ and Directive 2014/26/EU.⁶ Those Directives, as well as the Proposal COM(2016)593 final 2016/0280(COD) contribute to the functioning of the internal market, aim at the smooth development of the Digital Single Market within the EU, ensure a high level of protection for right holders and facilitate the clearance of rights.

1. Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases.
2. Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonization of certain aspects of copyright and related rights in the information society.
3. Directive 2006/115/EC of the European Parliament and of the Council of 12 December 2006 on rental right and lending right and on certain rights related to copyright in the field of intellectual property.
4. Directive 2009/24/EC of the European Parliament and of the Council of 23 April 2009 on the legal protection of computer programs.
5. Directive 2012/28/EU of the European Parliament and of the Council of 25 October 2012 on certain permitted uses of orphan works.
6. Directive 2014/26/EU of the European Parliament and of the Council of 26 February 2014 on collective management of copyright and related rights and multi-territorial licensing of rights in musical works for online use in the internal market.

TDM is understood as the automated computational analysis of information in digital form, such as text, sounds, images or data, that is enabled through the use of new computational technologies.⁷ In a broad sense, TDM is called any activity where computer technology is used to index, analyze, evaluate and interpret mass quantities of content and data.⁸

The statutory exception of TDM pertains to activities that are confined to acts of ‘automated processing of large amounts of structured digital textual content, for purposes of information retrieval, extraction, interpretation, and analysis’,⁹ which are undertaken for scientific research purposes. In her benchmark 2011 report, Eefke Smit refers to TDM as ‘automated tools, techniques or technology to process large volumes of digital content that is often not well structured – to identify and select relevant information; to extract information from the content, to identify relationships within/between/ across documents and incidents or events for meta-analysis’.¹⁰ Aside from the term ‘text and data mining’, which is usually referred with the TDM initials, the notions of text mining, text data mining, content mining and computational text analysis are often used interchangeably with the ‘text and data analysis’ or the ‘text and data mining’ with the aim to describe a TDM inquiry¹¹ or an analytical TDM approach.¹²

TDM works in the following manner:¹³

1. It identifies input materials to be analyzed, such as works, or data individually collected or organized in a pre-existing database;
2. It copies substantial quantities of materials – which encompasses
 - a. pre-processing materials by turning them into a machine-readable format compatible with the

technology to be deployed for the TDM so that structured data can be extracted and

- b. possibly, but not necessarily, uploading the pre-processed materials on a platform, depending on the TDM technique to be deployed;
3. It extracts the data; and
4. It recombines data to identify patterns into the final output.

Once access to content is available or granted, TDM generally implies the reproduction of the text or the data, either temporarily, for example, by caching the content or permanently, for example, by creating a database of key elements for facilitating searches (index). There are also TDM technologies that allow for analyzing content without making any copies of the analyzed content, for example, by website crawling or screen-scraping. TDM tools involving minimal copying of few words or crawling through data and processing each item separately could be operated without running into potential liability for copyright infringement. This follows from the fact that copyright law does not protect data but only original expressions within copyright-protected subject matter. In this respect, the proposal for a new Directive on copyright in the Digital Single Market clarifies that ‘text and data mining may also be carried out in relation to mere facts or data which are not protected by copyright and in such instances no authorization would be required’.¹⁴ Obviously, although the proposal, as it has by the time of this writing, fails to specifically mention that, also works and other subject matter not protected by copyright or the sui generis right can be freely mined.¹⁵

Content that is text and data mined may come in different formats, such as machine-readable formats (*e.g.*, XML) or PDFs, which may be more or less easily mined. The data retrieved often needs to be normalized, annotated and aggregated into a corpus to allow for an efficient use of mining software. The normalization and annotation can be done either by the publishers, including as part of a commercial offer (*e.g.*, data in an XML format, provided in a structured way) or by the researchers themselves, which is more the case for researchers in the public interest research organizations, who tend to prefer using their own tools (relying also more on PDFs than commercial users). The normalization and annotation phase of TDM activity involves the preprocessing to standardize materials into machine-readable formats; activity in this phase might trigger infringement of the right of reproduction of works found online.¹⁶ Likewise, the uploading of the pre-processed material on a platform – which might occur or not depending on whether the TDM technique adopted makes use of a TDM software crawling data to be analyzed directly from the source – might also violate the right of reproduction. The process of analyzing the texts or data is to be distinguished from its result. The output

7. See, Proposal COM(2016)593 final 2016/0280(COD), Recital 8; see also, European Commission, COM(2016)593 final 2016/0280(COD) (2016), according to which *Text and Data Mining (TDM)* is a term commonly used to describe the automated processing (‘machine reading’) of large volumes of text and data to uncover new knowledge or insights.

8. M. Caspers, L. Guibault, K. McNeice, S. Piperidis, K. Pouli, M. Eskevich & M. Gavriilidou, *Reducing Barriers and Increasing Uptake of Text and Data Mining for Research Environments Using a Collaborative Knowledge and Open Information Approach*, Baseline report of policies and barriers of TDM in Europe (extended version of D3.3) (2016) 9, available at: https://cordis.europa.eu/project/rcn/197301_en.html (last visited 20 November 2018).

9. B.F. Reilly, *When Machines Do Research, Part 2: Text-Mining and Libraries* (2012) 75-76.

10. E. Smit and M. Van der Graaf, *Journal Article Mining, a research study into practices, policies, plans....and promises*, Commissioned by the Publishing Research Consortium, Amsterdam (2011), available at: <http://publishingresearchconsortium.com/index.php/128-prc-projects/research-reports/journal-article-mining-research-report/160-journal-article-mining> (last visited 20 November 2018).

11. See, C. Bergman, L. Hunter & A. Rzhetsky, *Announcing the PLOS Text Mining Collection* (2013), available at: <https://blogs.plos.org/everyone/2013/04/17/announcing-the-plos-text-mining-collection/> (last visited 20 November 2018).

12. Reilly, above at n. 9, pp.75-76.

13. C. Geiger, G. Frosio & O. Bulayenko, *The Exception for Text and Data Mining (TDM) in the Proposed Directive on Copyright in the Digital Single Market-Legal Aspects* (2018) 5-6, available at: [www.europarl.europa.eu/RegData/etudes/IDAN/2018/604941/IPOL_IDA\(2018\)604941_EN.pdf](http://www.europarl.europa.eu/RegData/etudes/IDAN/2018/604941/IPOL_IDA(2018)604941_EN.pdf) (last visited 20 November 2018).

14. Recital 8 of COM(2016) 593 final.

15. Geiger *et al.*, above at n. 13, p. 6.

16. *Ibid.*

of TDM might consist, for example, of a summary of the analyzed text and data, visualizations such as graphics or charts and also of new knowledge, patterns and combinations of data that may lead to new discoveries and research results.¹⁷ However, the analysis and extraction of the TDM process, that is, the phase where data is finally extracted – can also infringe upon the right of reproduction depending on the mining software deployed and the character of the extraction.¹⁸

Regarding TDM activity on databases, TDM might involve the reproduction, translation, adaptation, arrangement and any other alteration of a database protected by copyright, which means the original selection and arrangement of the database's content.¹⁹ TDM activity might, also, infringe sui generis database right, in particular the extraction – and to a minor extent the re-utilization – of substantial parts of a database or the repeated extraction of insubstantial parts of a database. In this context, even if extraction does occur without reproduction of the original materials, extraction itself would infringe upon the exclusive sui generis right provided to the database owner.²⁰ According to the CJ,²¹ the infringement occurs by unauthorized actions for the purpose of reconstituting, through the cumulative effect of acts of extraction, the whole or a substantial part of the contents of a database protected by the sui generis right and/or of making available to the public, through the cumulative effect of acts of re-utilization, the whole or a substantial part of the contents of such a database, which thus seriously prejudice the investment made by the maker of the database. Article 7(5) of the Database Directive refers to unauthorized acts of extraction or re-utilization the cumulative effect of which is to reconstitute and/or make available to the public, without the authorization of the maker of the database, the whole or a substantial part of the contents of that database and thereby seriously prejudice the investment by the maker.

17. European Commission, Commission Staff Working Document, 'Impact Assessment on the Modernization of EU Copyright Rules', SWD(2016) 301 final PART 1/3 (2016) 158, available through: <https://ec.europa.eu/digital-single-market/en/news/impact-assessment-modernisation-eu-copyright-rules> (last visited 20 November 2018).

18. Geiger et al., above at n. 13, p. 6.

19. *Ibid.*, p. 7.

20. *Ibid.* See, CJ, *The British Horseracing Board Ltd and Others v. William Hill Organization Ltd*, C-203/02 (9 November 2004), available at: [http://curia.europa.eu/juris/liste.jsf?oqp=&for=&mat=or&lgrc=el&jge=&td=%3BALL&jur=C%2CT%2CF&num=C-203%252F02&page=1&dates=&pcs=Oor&lg=&pro=&nat=or&cit=none%252CC%252CCJ%252CR%252C2008E%252C%252C%252C%252C%252C%252C%252C%252C%252Ctrue%252Cfalse%252Cfalse&language=en&avg=&cid=5068790](http://curia.europa.eu/juris/liste.jsf?oqp=&for=&mat=or&lgrc=el&jge=&td=%3BALL&jur=C%2CT%2CF&num=C-203%252F02&page=1&dates=&pcs=Oor&lg=&pro=&nat=or&cit=none%252CC%252CCJ%252CR%252C2008E%252C%252C%252C%252C%252C%252C%252C%252C%252C%252Ctrue%252Cfalse%252Cfalse&language=en&avg=&cid=5068790) (last visited 20 November 2018).

21. *Ibid.*

2 Article 3 on TDM of the Proposed Directive on Copyright in the Digital Single Market

The provision of Article 3 of the proposed Directive on copyright in the Digital Single Market has as follows:

Article 3 Text and data mining

1. Member States shall provide for an exception to the rights provided for in Article 2 of Directive 2001/29/EC, Articles 5(a) and 7(1) of Directive 96/9/EC and Article 11(1) of this Directive for reproductions and extractions made by research organizations in order to carry out text and data mining of works or other subject matter to which they have lawful access for the purposes of scientific research.
2. Any contractual provision contrary to the exception provided for in paragraph 1 shall be unenforceable.
3. Rightholders shall be allowed to apply measures to ensure the security and integrity of the networks and databases where the works or other subject-matter are hosted. Such measures shall not go beyond what is necessary to achieve that objective.
4. Member States shall encourage rightholders and research organizations to define commonly-agreed best practices concerning the application of the measures referred to in paragraph 3.

Regarding this provision, the following are striking: The TDM exception's beneficiaries are limited to research organizations. The meaning of 'research organizations' is defined in Article 2(1) of the proposed Directive; according to it:

'research organization' means a university, a research institute or any other organization, the primary goal of which is to conduct scientific research or to conduct scientific research and provide educational services, too:

- a. on a non-for-profit basis or by reinvesting all the profits in its scientific research; or
- b. pursuant to a public interest mission recognized by a Member State;

in such a way that the access to the results generated by the scientific research cannot be enjoyed on a preferential basis by an undertaking exercising a decisive influence upon such organization.

The term 'scientific research' in Article 3 of the proposed Directive on copyright in the Digital Single Market is understood as in the definition of 'research' put forward by the OECD; according to it, research is understood as 'creative work undertaken on a systematic basis in order to increase the stock of knowledge,

including knowledge of man, culture and society, and the use of this stock of knowledge to devise new applications'.²² Scientific research lies in the ambit of that definition. In any case of questionable research activity, the burden would lie on the shoulders of the user to prove that the TDM activity undertaken was carried out for scientific research purposes.

The statutory exception of Article 3 in the text of *COM(2016)593 final 2016/0280(COD)* does not discriminate between types of subject matter covered, between the sources of works or kinds of databases, or between categories of beneficiaries. From the wording of Recital 10 of the aforesaid proposal for a Directive on copyright in the Digital Single Market, it becomes evident that the EU legislator aims at a wide variety of entities throughout Europe – the primary goal of which is to conduct scientific research or to do so together with the provision of educational services. These research organizations or research and educational services providers are the beneficial organizations across the EU, which the EU legislator targets regarding the TDM new mandatory exception. Article 3 of said proposal does not discriminate between types and subject matter covered by the beneficiary organizations since the wording of Article 3 applies to different legal forms and structures of research organizations across Member States, which have in common that they act either on a not-for-profit basis or in the context of a public-interest mission recognized by the State. Such a public-interest mission may, for example, be reflected through public funding or through provisions in national laws or public contracts. For profit organizations, commercial entities are not excluded from the application of Article 3 of the proposal insofar as they operate and/or deploy TDM in the context of a public-interest mission recognized by the State. The fact that for-profit organizations are not excluded from the provision of Article 3 regarding TDM activity gives this provision – the trait of being inclusive.²³ For research organizations in which the commercial undertakings have a decisive influence allowing them to exercise control because of structural situations such as their quality of shareholders or members, which may result in preferential access to the results of the research, Recital 10 of the proposed Directive clearly sets them out of the pool of beneficiary

organizations aimed by the EU legislator regarding TDM mandatory exception.²⁴

This approach in the statutory exception of Article 3 of the proposed Directive on copyright in the Digital Single Market, which does not discriminate between types of subject matter covered, between the sources of works or kinds of databases or between categories of beneficiaries coincides with the research exception recognized in Article 5(3)(a) of the Information Society Directive and in Article 6(2) of the Database Directive; said provisions for which there's further analysis below in this text do not discriminate between categories of works, sources or users. The introduction of the statutory exception of Article 3 regarding TDM aims at altering Directive 2001/29/EC and Directive 96/6/EC regarding right-holder's power on copyrighted works and databases, which could hamper the deployment of text and data mining activity. This goal of adaptation of the aforesaid Directives is clear through the text of Recital 5 of *COM(2016)593 final 2016/0280(COD)*.²⁵

The proposal for a new Directive on copyright in the Digital Single Market indicates that confining the TDM exception to non-commercial research activities only was not the choice of EU legislator. Such a restriction for the application of the TDM exception could slow down the pace of innovation, for it is not only non-commercial research that generates socially and economically valuable outcomes. Moreover, making the distinction between what is commercial and what is non-commercial may be very difficult in practice, especially in the case of public/private partnerships (PPP), the commercial character of which is often very difficult to ascertain.²⁶ Thus, in said cases wherein there exists a commercial aspect of the undertaken research, the key-point to consider is the existence of a public-interest mission recognized by the State within which TDM may be deployed leveraging on the exemption of Article 3 of the proposed new Directive on copyright in the Digital Single Market. Thus, in addition to the requirement of the non-commercial nature of the scientific research activity, there is also the requirement of a public-interest mission of the organization which undertakes the research activity. The former notion is narrower than the latter, in the sense that public-interest mission could include commercial research activities.

The requirement of non-commercial research activities follows the lines already set by the Database Directive

22. I. Hargreaves, L. Guibault, C. Handke, B. Martens, R. Lynch & S. Filippov, *Standardisation in the Area of Innovation and Technological Development, Notably in the Field of Text and Data Mining – Report from the Expert Group* (2014), European Union, *Study on the Legal Framework of Text and Data Mining (TDM)*, De Wolf & Partners (2014) 55; F. Manual, *Proposed Standard Practice for Surveys on Research and Experimental Development*, OECD (2002), available at: <https://www.oecd-ilibrary.org/docserver/9789264199040-en.pdf?expires=1542611355&id=id&accname=guest&checksum=39B756986E0ECF728154E3785B2AA363> (last visited 20 November 2018).

23. See, Geiger *et al.*, above n. 13, p. 19, according to who the TDM exception's scope is very inclusive as it applies both to commercial and non-commercial uses and – very importantly – cannot be overridden by contract.

24. According to Recital 10 of the proposed Directive on copyright in the Digital Single Market: 'organisations upon which commercial undertakings have a decisive influence allowing them to exercise control because of structural situations such as their quality of shareholders or members, which may result in preferential access to the results of the research, should not be considered research organisations for the purposes of this Directive'.

25. According to Recital 5 of the proposed Directive on copyright in the Digital Single Market: 'For uses not covered by the exceptions or the limitation provided for in this Directive, the exceptions and limitations existing in Union law should continue to apply. Directives 96/9/EC and 2001/29/EC should be adapted'.

26. Hargreaves *et al.*, above at n. 22, p. 56.

and the Information Society Directive. Recital 42 of the latter Directive specifies that

when applying the exception or limitation for non-commercial educational and scientific research purposes, including distance learning, the non-commercial nature of the activity in question should be determined by that activity as such. The organizational structure and the means of funding of the establishment concerned are not the decisive factors in this respect.

Outside the context of non-commercial research, though, the creation of corpora can be difficult to reconcile with the strict rules of copyright and database rights. In all circumstances, or commercial scientific research or even with non-commercial research, and provided that there's no element of public-interest mission of the organization doing the research, license agreements and website terms of use can impose TDM deployment under certain restrictions.

The provision of Article 3(3) of the proposed Directive on copyright in the Digital Single Market sets a limitation allowing rightholders to introduce measures to protect the 'security and integrity' of their networks and databases where works are hosted. However, such measures shall not go beyond what is necessary to achieve that objective of the provision of Article 3. Recital 12 of the proposed Directive is very clear per subject matter of said limitation: In view of a potentially high number of access requests to and downloads of their works or other subject matter, rightholders should be allowed to apply measures where there is risk that the security and integrity of the system or databases where the works or other subject matter are hosted would be jeopardised. Those measures should not exceed what is necessary to pursue the objective of ensuring the security and integrity of the system and should not undermine the effective application of the exception. Besides, according to Article 3(2) of the proposed Directive, any contractual provision contrary to the exception provided for in Article 3(1) shall be unenforceable; thus, the provision of Article 3(2) sets protection from possible contractual override of the TDM mandatory exception.

In accordance with the international obligations of the European Union under Article 10 of the WIPO Copyright Treaty, the new exception described in Article 3 of the proposed Directive for copyright in the Digital Single Market needs to comply with the requirements of the so-called 'three-step-test', for example, that the exception is applicable only in certain special cases that do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the author.²⁷ For this reason, Recital 6 of the proposed Directive clearly states that the exceptions and the limitation set out in the proposed Directive seek to achieve a fair balance between the rights and interests of authors and other rightholders, on the one hand, and of

users, on the other hand. They can be applied only in certain special cases which do not conflict with the normal exploitation of the works or other subject matter and do not unreasonably prejudice the legitimate interests of the rightholders. Also, Article 6 of the proposed Directive rules that Article 5(5) and the first, third and fifth subparagraphs of Article 6(4) of the InfoSoc Directive 2001/29/EC shall apply to the exceptions and the limitation provided for under the proposed Directive. Article 5(5) of the InfoSoc Directive rules, the so-called 'three-step-test', while Article 6(4) first subparagraph refers to Technological Protection Means (TPM) and specifically to the obligation of Member States to prevent the derogation from the provision of TDM activity as an exception to copyright in the sense that they are obliged to take appropriate measures to ensure that rightholders make available to the beneficiary of the TDM exception the means of benefiting from that exception, to the extent necessary to benefit from that exception and where that beneficiary has legal access to the protected work or subject matter concerned. Also, Article 6(4) third and fifth subparagraphs refer to the protection afforded to TPMs.

TDM technologies allow researchers to process large amounts of information to gain new knowledge and discover new trends. While TDM technologies are prevalent across the digital economy, there is widespread acknowledgment that TDM can, in particular, benefit the research community, and in so doing encourage innovation. Jonathan Clark²⁸ notes four main reasons to engage in TDM:

- a. To enrich content: Mining can improve indexing, be deployed to create relevant links, and improve the reading experience.
- b. To engage in systematic review of literature: Mining can help researchers systematically review larger bodies of content, faster than they could do it themselves and to keep up with their field, without missing relevant information.
- c. To discover new knowledge: Mining can be used to create databases that can themselves be mined.
- d. To engage in computational linguistics research: Mining itself is the subject of research, for example to improve the extraction of meaning from texts.

3 TDM in a New Copyright Directive in the Digital Single Market

Exceptions and limitations to copyright and neighboring rights have not yet being harmonized at the EU level, and this fragmentation in the implementation of exceptions and limitations from the Member States causes

27. *Ibid.*, p. 54.

28. J. Clark, *Text Mining and Scholarly Publishing, a report for the Publishing Research Consortium*, Loosdrecht, The Netherlands & London (2013) 7.

legal uncertainty that affects TDM Europe-wide.²⁹ The non-mandatory nature of most of InfoSoc Directive's list of exceptions and limitations to copyright is a cause of failure in the process of harmonization of copyright rules applicable in all Member States of the EU.³⁰ The non-harmonized EU legal framework for exceptions and limitations, especially those pertaining to scientific research and teaching, which have not implemented nationally by EU Member States in the same way due to their non-mandatory nature, cause significant difficulties in leveraging on the existing legal framework for Copyright for covering the TDM activity. Though these exceptions per research or teaching, a.k.a. education, aim at achieving public policy objectives, there is no sameness in understanding and fulfilling said objectives among Member States. In addition, as new types of uses have recently emerged, it remains uncertain whether these exceptions are still adapted to achieve a fair balance between the rights and interests of authors and other rightholders, on the one hand, and of users, on the other hand. Besides, these exceptions remain national and legal certainty around cross-border uses is not guaranteed. As a consequence, cross-border collaborations of researchers are hindered by the lack of sameness in understanding and applying the research exception or limitation to copyright; this affects TDM activities directly since researchers are unaware – or face high transaction costs for clearance – of whether TDM would be lawful across all EU jurisdictions involved in the research collaboration.³¹ The situation of legal uncertainty is further affected by combinations of contractual and technical measures, which are frequently used to create insurmountable hurdles for researchers engaging in TDM projects. Actually, contractual and technological barriers are also frequently used to prevent TDM activities on materials not protected by copyright or on public domain subject matter,³² and the CJ has ruled that said use of contractual and technological means on non-protected by copyright or the sui generis right databases is not illegal.³³

In order to overcome the problems caused due to the lack of harmonization of Copyright law, and especially in the field of exceptions and limitations of copyright,

which impedes the Digital Single Market goal, the European Commission has identified three areas of intervention; these three areas of intervention are the following:

- a. digital and cross-border uses in the field of education,
- b. text and data mining in the field of scientific research, and
- c. preservation of cultural heritage.

The objective of the European Commission is to guarantee the legality of certain types of uses in these fields, including across borders. As a result of a modernized framework of exceptions and limitations, researchers will benefit from a clearer legal space to use innovative text and data mining research tools, teachers and students will be able to take full advantage of digital technologies at all levels of education and cultural heritage institutions (*i.e.*, publicly accessible libraries or museums, archives or film or audio heritage institutions) will be supported in their efforts to preserve the cultural heritage, to the ultimate advantage of EU citizens.

Regarding TDM, four options were considered for its proposed regulation:

- a. Option 1 consisted in self-regulation initiatives from the industry. This option pertained to contractual agreements, including clauses allowing for TDM. This option was deemed to be inappropriate for harmonization.
- b. Option 2 consisted in the introduction of mandatory exception for TDM covering uses pursuing a non-commercial scientific research purpose.
- c. Option 3 allowed uses for commercial scientific research purpose but limited the benefit of the exception to some beneficiaries.
- d. Option 4 went further as it did not restrict beneficiaries.

Of these options, the introduction of mandatory exception for TDM covering uses pursuing non-commercial scientific research purposes, but also allowing uses for commercial scientific research purposes limited to some beneficiaries seems to have prevailed – at least, so far – being deemed to be the most proportionate one.³⁴ This option was deemed to be the best in terms of maximization of legal certainty and minimization of copyright clearance costs for research organizations in the EU, including research projects which are carried out with a possible commercial outcome.³⁵

29. Geiger *et al.*, above at n. 13, p. 12.

30. Geiger *et al.*, above at n. 13, pp. 14-15 and references in footnotes 65, 68, 70. A unified and mandatory approach is especially crucial in the digital environment as the Internet involves uses that, most of the time, affect several copyright legislations, leading to a major insecurity regarding what is allowed.

31. Geiger *et al.*, above at n. 13, pp. 12-13.

32. Geiger *et al.*, above at n. 13, p. 13.

33. In case, *Case C-30/14 (2015), Ryanair Ltd v. PR Aviation BV*, the CJ ruled that Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases must be interpreted as meaning that it is not applicable to a database which is not protected either by copyright or by the sui generis right under that directive, so that Arts. 6(1), 8 and 15 of that directive do not preclude the author of such a database from laying down contractual limitations on its use by third parties, without prejudice to the applicable national law. See, CJ's ruling on *Case C-30/14*, available at: <http://curia.europa.eu/juris/document/document.jsf?docid=161388&doclang=EN> (last visited 20 November 2018).

34. See, European Commission, Commission Staff Working Document, 'Executive Summary of the Impact Assessment on the Modernization of EU Copyright Rules', *SWD(2016) 302 final* (2016), according to which 'For TDM, the preferred option is a mandatory exception applicable to research organizations acting in the public interest such as universities or research institutes. The exception would allow them to carry out TDM on content they have lawful access to, for the purposes of scientific research'. The Executive Summary of the Impact Assessment is available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52016SC0302&from=EN> (last visited 20 November 2018).

35. See, European Commission, above at n. 34, according to which 'The new TDM exception would increase legal certainty and reduce rights clearance costs for research organizations, including when research pro-

Option 1, and specifically the view that TDM could be self-regulated in the market through contractual agreements, was supported in France.³⁶ In July 2014, the High Council on Artistic and Literary Property (*Conseil Supérieur de la Propriété Littéraire et Artistique* [CSPLA]), the advisory body in charge of advising the Ministry of Culture on copyright issues, submitted its report on TDM.³⁷ The approach, analysis and the recommendations of the French report were almost the opposite of those of the Hargreaves Review in the United Kingdom.³⁸ While the British report asked how to adapt copyright to the needs of the economy, the French report was more concerned with affording as much protection as possible to copyright against TDM, which it compares to a parasite.³⁹ The CSPLA report on the legal aspects of TDM concluded that none of the exceptions in French copyright law offered enough guarantees to allow TDM; especially not the teaching exception, the French implementation of Article 5(3)(a) of the InfoSoc Directive, given its very limited scope in French law.⁴⁰ According to the CSPLA report, it is not possible to modify national law without a change in the EU framework. Implicitly, the CSPLA report rejected the British analysis on the ability to create a new exception within the existing framework. Crucially, for the French report the creation of such a new exception was not even necessary as contractual solutions should be promoted. It proposed to ‘favor self-regulation over statutory changes’ and set ‘a two-year period after which a sectorial overview will be conducted and the need for legislative change assessed’.⁴¹ The CSPLA report also recommended that the French government should share this wait-and-see approach and oppose any initiative to reform copyright at European or international level.⁴² Once more, this was in stark contrast with the Hargreaves review, which had urged the UK government to press the EU to change its copyright law.

Evidence gathered through the review process that preceded to the proposal for a new Directive on Copyright in the Digital Single Market has highlighted that the

jects are carried with a possible commercial outcome, e.g. in the context of PPPs’.

36. N. Jondet, ‘L’ Exception Pour Le Data Mining Dans Le Projet De Directive Sur Le Droit D’ Auteur: Pourquoi L’ Union Européenne Doit Aller Plus Loin Que Les Législations Des États Membres (The Text and Data Mining Exception in the Proposal for a Directive on Copyright: Why the European Union Needs to Go Further Than the Laws of Member States)’, 67 *Propriétés Intellectuelles* (2018) 25-35, available at: <https://ssrn.com/abstract=3239374> (last visited 20 November 2018).
37. J. Martin and L.D. Carvalho, *Mission sur l’ exploration de données* (« Text and Data mining ») (2014), available at: <https://docplayer.fr/1430465-Mission-sur-l-exploration-de-donnees.html> (last visited 20 November 2018).
38. I. Hargreaves, *Digital Opportunity – A Review of Intellectual Property and Growth* (2011), available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/32563/ipreview-finalreport.pdf (last visited 20 November 2018).
39. Jondet, above at n. 36; Martin and Carvalho, above at n. 37, p. 2.
40. Jondet, above at n. 36; Martin and Carvalho, above at n. 37, p. 30.
41. Jondet, above at n. 36; Martin and Carvalho, above at n. 37, p. 4, recommendations 5, 6 and 7, respectively.
42. Jondet, above at n. 36; Martin and Carvalho, above at n. 37, p. 5, recommendations 11 and 12, respectively.

research exception has not been implemented in all Member States and that in any event it has generally been implemented without explicitly taking into account of TDM (which can be explained by the relatively novelty of these techniques). So far, a specific TDM exception in the context of the research exception has been adopted by the United Kingdom, which is going to exclude itself from being a Member State of the EU, very soon.⁴³ Estonia has also introduced a TDM exception to its Copyright Law. France and Germany have amended their Copyright laws passing a TDM provision, too. Greece has yet to amend its Copyright law regarding TDM. However, recently a law regulating subject matter on the National Library of Greece introduced TDM – actually, the Web Archiving – as one of the many responsibilities and statutory goals of the National Library of Greece (NLG).

As a consequence of the fact that very few Member States, such as the United Kingdom,⁴⁴ France,⁴⁵ Estonia⁴⁶ and Germany,⁴⁷ have amended their laws allowing for TDM, considerable legal uncertainty exists as to the EU framework applicable to TDM in scientific research and different conditions apply depending on the Member States and rightholders’ licensing practices.⁴⁸

43. European Commission, Commission Staff Working Document, ‘Impact Assessment on the Modernization of EU Copyright Rules’, *SWD(2016) 301 final PART 2/3* (2016) 51, available through: <https://ec.europa.eu/digital-single-market/en/news/impact-assessment-modernisation-eu-copyright-rules> (last visited 20 November 2018).
44. The UK legislator amended its Copyright law by S.I. 1992/3233, regulation 7, S.I. 1997/3032, regulation 8 and S.I. 2003/2498, regulation 9. Section 29A that was added to the Copyright and Rights in Performances (Research, Education, Libraries and Archives) Regulations 2014 came into force on 1 June 2014. The amended Copyright law in the United Kingdom provides for TDM to the lawful user for the sole purpose of computational analysis for non-commercial research, but does not cover the reproduction of databases. See, www.legislation.gov.uk/uksi/2014/1372/regulation/3/made (last visited 20 November 2018).
45. In France, the legislator of Law No. 2016-1231 for a Digital Republic (Loi pour une République numérique) introduced TDM exceptions both applying to works (Art. L.122-5, 10 of the CPI) and databases (Art. L.342-3, 5 of the CPI). French exceptions cover acts of reproduction from ‘lawful sources’ (materials lawfully made available with the consent of the rightholders) for TDM as well as storage and communication of files created in the course of TDM research activities. The introduction of TDM in the French Intellectual Property Code was implemented in Art. 38 of the Law No. 2016-1231 for a Digital Republic which added paragraph 10 to Art. L.122-5 and paragraph 5 to Art. L.342-3 of the French Intellectual Property Code (Code de la Propriété Intellectuelle, CPI).
46. The Estonian legislator amended the country’s Copyright Act of 1992 and as of 1 January 2017 introduced TDM in paragraph 3 of Art. 19 titled ‘Free Use of Works for Scientific, Educational, Informational and Judicial Purposes’.
47. In 1 September 2017 Germany amended its Copyright law and the amendment has come into force as of 1 March 2018 introducing TDM in Section 60d titled ‘Text and Data Mining’. The TDM exception in German law covers the acts of reproduction necessary for undertaking TDM and the acts of making available of the corpus of materials produced by TDM activity (e.g., source materials that were normalized, structured and categorized) to a specifically limited circle of persons for their joint scientific research, as well as to individual third persons for the purpose of monitoring the quality of scientific research.
48. European Commission, above at n. 43, p. 52.

4 The EU Legislator's Approach on TDM

For the EU legislator, TDM is just a means to achieve the goal of Digital Single Market. The goal for an EU Digital Single Marketing is a goal for the free movement of goods, persons, services and capital where individuals and businesses can seamlessly access and exercise online activities under conditions of fair competition, and a high level of consumer and personal data protection, irrespective of their nationality or place of residence. The Digital Single Market strategy⁴⁹ considers three pillars in its foundation:

1. Better access for consumers and businesses to online goods and services across Europe. This requires the rapid removal of key differences between the online and offline worlds to break down barriers to cross-border online activity.
2. Creating the right conditions for digital networks and services to flourish. This requires high-speed, secure and trustworthy infrastructures and content services, supported by the right regulatory conditions for innovation, investment, fair competition and a level playing field.
3. Maximizing the growth potential of the European Digital Economy. This requires investment in ICT infrastructures and technologies such as Cloud computing and Big Data, and research and innovation to boost industrial competitiveness as well as better public services, inclusiveness and skills.

Regarding the achievement of the first pillar, that is, better access for consumers and businesses to online goods and services across Europe, there's a requirement for a more harmonized copyright regime which provides incentives to create and invest while allowing transmission and consumption of content across borders, building on Europe's rich cultural diversity. To this end, the Commission has been working on proposed solutions that include:

- a. portability of legally acquired content,
- b. cross-border access to legally purchased online services while respecting the value of rights in the audiovisual sector,
- c. greater legal certainty for the cross-border use of content for specific purposes (*e.g.*, research, education, text and data mining) through harmonized exceptions,
- d. clarification of the rules on the activities of intermediaries in relation to copyright-protected content and
- e. modernization of enforcement of intellectual property rights, focusing on commercial-scale infringements

49. See, *COM(2015) 192 final*, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions, A Digital Single Market Strategy for Europe, available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2015%3A192%3AFIN> (last visited 20 November 2018).

(the 'follow the money' approach) as well as its cross-border applicability.

The TDM issue pertains to the harmonization of exceptions and limitations in copyright law of Member States, the creation of legal certainty for cross-border use of content for the purpose of scientific research.

The EU legislator has considered – at least for the time being – recommendations made by various scholars upon the TDM and how it should be regulated in the proposed Directive on copyright in the Digital Single Market. The suggestion that it is best to have a mandatory exception for TDM which would be inspired from and contain partly the same conditions as the scientific research exception, but which would have its own characteristics has prevailed, so far.

The mandatory character of the provision of Article 3 on text and data mining in the text of the proposed Directive on copyright in the Digital Single Market can normally be decomposed into three elements, that is:⁵⁰

- a. be implemented across all Member States in order to ensure effective harmonization of the law;
- b. do not be subject to contractual overrides; and
- c. do not be subject to lock-up behind technological protection measures.

Even when the owner (or holder) of the data cannot exercise copyright or database rights, contractual restrictions or technical protection measures may render TDM more burdensome or even impossible.⁵¹ For this reason, the wording in the proposed Article 3 rules that:

- a. Member States 'shall provide' for an exception ...
The wording is not 'may provide' but 'shall provide' which indicates the mandatory character of the proposed provision.
- b. Art.3(2) of the provision rules that any contractual provision contrary to the exception provided for in paragraph 1 shall be unenforceable, thus the owner (or holder) of the data cannot exercise copyright or database rights through contractual restrictions that could hamper the TDM activity.
- c. Art.3(3) of the provision rules that rightholders shall be allowed to apply measures to ensure the security and integrity of the networks and databases where the works or other subject-matter are hosted. Such measures shall not go beyond what is necessary to achieve that objective. These measures include technological protection measures such as DRM. Thus, technical protection measures may not render TDM burdensome or even impossible.

There were many suggestions on how to encourage TDM for research purposes without fear of infringing IP rights. The goal for such an encouragement through legislative action could be achieved in a number of ways:⁵² through an adjustment of licensing practices; through a revised, normative interpretation of the

50. Hargreaves, above at n. 22, p. 57.

51. Hargreaves, above at n. 22, p. 59.

52. Hargreaves, above at n. 22, p. 52.

reproduction right in copyright; through the introduction of a new mandatory exception in copyright and database laws, or through the adoption of an ‘open norm’ designed to guide the courts to take a more flexible view of what users are permitted to do.

In consideration of *COM(2016)593 final 2016/0280(COD)*, there’s no doubt that the EU legislator is inclined towards the choice of introducing a mandatory exception for TDM covering uses pursuing non-commercial scientific research purposes, but also allowing uses for commercial scientific research purposes limited to some beneficiaries, and also of ensuring that TDM regulation cannot be over-ridden through the enforcement of restrictive contractual clauses or technological protection measures. The point of contention between the introduction of a new mandatory exception and the facilitation of TDM in consideration of the existing exception for scientific research has found its solution in the introduction of a new mandatory exception. The license option, a.k.a. the encouragement of TDM through licensing was deemed to be inefficient and not adequate for creating legal certainty among Member States regarding TDM for scientific research.⁵³ The extent to which TDM in Europe is facilitated by any existing exceptions to either EU copyright or database law appeared unclear. The application of a copyright and database exception relating to teaching or scientific research is optional and has not been implemented at all in some Member States. This has contributed to uncertainty in the European scientific research community.⁵⁴ Moreover, it was considered that unless a TDM mandatory exception applicable horizontally for all Member States were passed, the possibility of enacting different TDM legislations in Member States is possible, and as a consequence, the fragmentation of the Single Market is more than likely to increase over time as a result of Member States adopting TDM exceptions at national level which could be based on dif-

ferent conditions, which is likely to happen in the absence of intervention at EU level.⁵⁵

The introduction of a new mandatory exception in copyright and the database law may take one of two forms:

- a. an exception specifically permitting TDM for the purpose of scientific research or
- b. an open norm.

The first form provides more immediate clarity and the second form offers more flexibility in a fast-changing technological environment.⁵⁶ With an exception on copyright and database right specifically permitting TDM for the purpose of scientific research the assessment of whether an act of TDM is lawful is made ex ante by the legislator, while with an open norm the assessment of the lawfulness of an act of TDM would be made ex post by the judge.⁵⁷ Article 3 of the Proposal of the European Parliament and of the Council on copyright in the Digital Single Market, a.k.a. *COM(2016)593 final 2016/0280(COD)*, describes clearly the form of an exception specifically permitting TDM for the purpose of scientific research. The EU legislator has opted not to frame TDM through an open-norm description in the proposed Directive for copyright in the Digital Single Market because of considerations for possible legal uncertainty; it was deemed best to address the issue of TDM by providing for a mandatory exception to the right of reproduction and also to the right to prevent extraction from a database. The new mandatory exception should be understood as being without prejudice to the existing mandatory exception on temporary acts of reproduction laid down in Article 5(1) of Directive 2001/29/EC, which should continue to apply to text and data mining techniques which do not involve the making of copies going beyond the scope of that exception.⁵⁸

The open norm as a form to regulate TDM is presented as an option by Ian Hargreaves et al. (2014) expert group report on TDM.⁵⁹ The idea for an open norm in European Copyright law is not new. The introduction of an open norm – or general exception – similar to U.S. fair use has long been considered in the EU legal scholarship and policy debate.⁶⁰ Supporters of the open-

53. Researchers have generally considered that licenses-based solutions would not be able to fully solve the problems of legal uncertainty they face as regards the use of TDM techniques. This was also confirmed in these stakeholders’ replies to a 2013-2014 public consultation (institutional users such as libraries and universities generally considered licenses an inadequate source of transaction costs for TDM and indicated that a legislative change is needed to introduce a mandatory exception for text and data mining in EU copyright law). See, European Commission, above at n. 43, pp. 51-52.

54. Researchers are generally convinced of the potential of TDM but they put forward legal uncertainty, caused by the current copyright rules, as one of the reasons for the slow development of TDM in the EU (in addition to aspects unrelated to copyright, such as lack of awareness and skills and infrastructural challenges). A considerable level of legal uncertainty exists among researchers regarding TDM and copyright law. Research organizations and researchers do not always know whether TDM is copyright-relevant at all, whether it may be covered by an exception or whether a specific rightholders’ authorization is required. See, more at European Commission, Commission Staff Working Document, ‘Impact Assessment on the Modernization of EU Copyright Rules’, *SWD(2016) 301 final PART 1/3* (2016) 104-5, available at: <https://ec.europa.eu/digital-single-market/en/news/impact-assessment-modernisation-eu-copyright-rules> (last visited 20 November 2018).

55. European Commission, above at n. 54, p.106.

56. Hargreaves, above at n. 22, p. 54.

57. *Ibid.*

58. Recital 10, the proposed Directive for copyright in the Digital Single Market, clarifies that this exception still applies but its application would be limited to TDM techniques which involve only the making of temporary reproductions transient or incidental to an integral and essential part of a technological process which enables a lawful use with no independent economic significance. According to Recital 10, ‘The new exception should be without prejudice to the existing mandatory exception on temporary acts of reproduction laid down in Article 5(1) of Directive 2001/29, which should continue to apply to text and data mining techniques which do not involve the making of copies going beyond the scope of that exception. Research organisations should also benefit from the exception when they engage into public-private partnerships’.

59. Hargreaves, above at n. 22, pp. 6, 54, 57.

60. See, M. Senftleben, ‘The Perfect Match – Civil Law Judges and Open-Ended Fair Use Provisions’, 33 *American University International Law*

norm option in TDM claim that the open norm could introduce flexibility so as to allow TDM activities to take place, along with other types of activities that would pass the test. The introduction of an open norm in Copyright and Database law, though, would have required an interpretation of the ‘three-step test’ in copyright law in a balanced way⁶¹ along the lines of the ‘Declaration on a Balanced Interpretation of the “Three-Step Test” in Copyright Law’.⁶² Instead of a restrictive reading of the test that would require exceptions and limitations to be interpreted narrowly, the aforesaid Declaration suggests ‘an appropriately balanced interpretation of the three-step test under which existing exceptions and limitations within domestic law are not unduly restricted and the introduction of appropriately balanced exceptions and limitations is not precluded.’⁶³ The non-restrictive reading of the ‘Three-Step Test’ in European Copyright law could be seen as an attempt to instil in the European Copyright law the flexibility and adaptiveness to new circumstances in the market imposed by technological evolution that characterizes the provisions of Common Law – especially the flexibility and adaptiveness of American Law on applied Copyright through the ‘fair use’ doctrine. The decision of the EU to propose a new Copyright Directive with the aim to boost the Digital Single Market comes at a time when considerations upon the appropriateness of the existing legal framework for Copyright acknowledge that there’s hardly a solid legal

foundation for TDM in the ‘acquis communautaire’. Provisions such as Article 5(1) or Article 5(3)(a) of the InfoSoc Directive or Article 6(1), Article 6(2)(b) and Article 9(b) of the Database Directive do not suffice for covering TDM.

5 Article 4(4)(b) of Greek Law 4452/2017 for TDM of NLG

A recent development in Greece’s legal framework on the National Library of Greece (NLG) stipulates for activities that are within the TDM operation. Specifically, law 4452/2017 which is titled ‘Regulation on State Language Certificate subject matter, on the National Library of Greece and on other provisions’ includes in its text the provision of Article 4(4)(b), according to which the National Library of Greece operates as the official National Depository and Archive of digital publications, data and metadata produced in the country or related to Greek culture. This operation includes the monitoring and archiving of the Internet (web archiving) or other technology environment. To this end, the National Library of Greece shall undertake, allocate and coordinate the actions concerned at national level.

This provision of Article 4(4)(b) of law 4452/2017 is the first provision in the Greek legal system that caters for TDM activities. Said provision is too general, probably vague, and not proper in its wording. However, the analysis in this text does not aim at elaborating upon the bad phrasing or vagueness in the provision of Article 4(4)(b) of law 4452/2017.

Article 4(4)(b) of law 4452/2017 sets the TDM activity under the responsibility of the National Library of Greece which is named as the organization to undertake, allocate and coordinate action of text and data analysis at national level. The ‘monitoring’ of the web is meant to be the web harvesting activity; the archiving of the Internet is meant to be the archiving of works harvested from the Internet. Thus, the National Library of Greece is ruled to be the proper organization for TDM activity in Greece. Other organizations may deploy TDM activities under the coordination of the National Library of Greece, which is the national depository and archive of works on the Internet, including data and metadata, produced in Greece or are related to the Greek culture.

Article 4(4)(b) of law 4452/2017 precedes any EU regulation upon TDM. The proposal for a Directive on copyright in the Digital Single Market has yet to pass the European Parliament’s vote. Article 3 of said proposal has yet to become part of the ‘*acquis communautaire*’.

6 Conclusion

Regarding the proposal of the European parliament and of the Council on copyright in the Digital Single Market

Review 231 (2017) 286, available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3002275 (last visited 20 November 2018); B.P. Hugenholtz, ‘Flexible Copyright: Can EU Author’s Rights Accommodate Fair Use?’, in Irini Stamatoudi (ed.), *New Developments in EU and International Copyright Law*, Kluwer Law International, Leiden, The Netherlands (2016) 417-33; B.P. Hugenholtz and M. Senftleben, *Fair Use in Europe: in Search of Flexibilities*, Amsterdam Law School Research Paper No. 2012-39 – Institute for Information Law Research Paper No. 2012-39 (2012), available at: <https://ssrn.com/abstract=2013239> (last visited 20 November 2018); M. Senftleben, ‘Comparative Approaches to Fair Use: An Important Impulse for Reforms in EU Copyright Law’, in Graeme Dinwoodie (ed.), *Methods and Perspectives in Intellectual Property*, Edward Elgar, Cheltenham (2014); A. Dnes, ‘Should the UK Move to a Fair-Use Copyright Exception’, 44(4) *International Review of Intellectual Property and Competition Law* 418 (2013) 444; R. Van der Noll, S. Gompel, L. Guibault, J. Weda, J. Poort, I. Akker & K. Breemen, *Flexible Copyright: The Law and Economics of Introducing an Open Norm in the Netherlands*, SEO Economic Research Report N. 2012-60 (2012), available at: https://www.ivir.nl/publicaties/download/Flexible_Copyright.pdf (last visited 20 November 2018); C. Geiger, ‘Flexibilising Copyright – Remedies to the Privatisation of Information by Copyright Law’, 39(2) *International Review of Intellectual Property and Competition Law* 178 (2008) 197, available at: https://www.researchgate.net/publication/43233985_Flexibilising_Copyright_-_Remedies_to_the_Privatisation_of_Information_by_Copyright_Law (last visited 20 November 2018).

61. Hargreaves, above n. 22, p. 6; Geiger, above n. 13, p. 16.

62. See, *Declaration – A Balanced Interpretation of the “Three-Step Test” in Copyright Law*, available at: <https://www.jipitec.eu/issues/jipitec-1-2-2010/2621/Declaration-Balanced-Interpretation-Of-The-Three-Step-Test.pdf> (last visited 20 November 2018).

63. See, C. Geiger, D.J. Gervais & M. Senftleben, *The Three-Step-Test Revisited: How to Use the Test’s Flexibility in National Copyright Law* (2013), available at: <https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?referer=https://www.google.gr/&httpsredir=1&article=1041&context=research> (last visited 20 November 2018).

– Proposal COM(2016)593 final 2016/0280(COD) as its text has till January 2019 – for a new Copyright Directive, the major positive impact of it lies in its focus on harmonization of Member States’ Copyright laws, through a mandatory solution for TDM. Directive 2001/29/EC has failed to address adequately the intersection between Copyright, technological measures and contracts. Rather, it has provisioned in such a way that Copyright exceptions may easily prove to be ineffective because of the contractual override enabled by the interplay of electronic contracts setting out conditions of legal access to the copyrighted work and access- and copy-control technologies such as DRM systems. Also, the InfoSoc Directive has failed to put in place regulatory mandatory ceilings which could have an adverse effect for the possibility to derogate from existing limitations on a contractual basis.⁶⁴ Substantive ceilings should have been provisioned in the InfoSoc Directive stipulating that exceptions such as non-transformative private use of works or use of them for the purpose of scientific research are mandatory in the sense that they can neither be contracted away nor being denied through the use of DRM technology which expands technological exclusivity beyond Copyright laws or has the capacity to bypass statutory limitations to Copyright.⁶⁵ Said regulatory mandatory ceilings could positively oblige rightholders to ensure that beneficiaries can exercise the exceptions and limitations in Copyright law in spite of contractual agreements or DRM technology that leave room to the contrary.⁶⁶

The proposal for a new Copyright Directive which understands – at last – that harmonization in Member States’ Copyright laws may come through the mandatory nature of exceptions or limitations to Copyright is a welcome arrangement that promotes harmonization and, therefore, the Digital Single Market. As such, a harmonized framework for TDM research will be driving innovation in the expectation for a Digital Single Market in the EU, promoting EU-wide, integrated, larger research projects. Said harmonization as well as EU’s competitiveness will also be supported by an expansive scope of the limitation, covering both commercial and non-commercial uses of the TDM output, and the unenforceability of contrary contractual provisions or a deviation from DRM technology that could nullify TDM attempts.

Further than that, there’s serious consideration whether the TDM exception’s beneficiaries should not be limited to ‘research organizations’. We believe that they should not. Leveraging on text and data analysis will gradually become a key-point for development for all legal entities; consideration for individual researchers or physical persons should be described in the TDM mandatory exception, too. Actually, the existing UK exception for text and data analysis does not discriminate between legal and physical persons, but rather allows TDM activity to any person with lawful access to a work.

Also, consideration for cultural heritage institutions should be taken, too. Limiting beneficiaries only to ‘research organizations’ would undermine a widespread assumption that the ‘right to read should be the right to mine’.⁶⁷ In addition, limiting the TDM mandatory exception only to non-commercial research does not seem reasonable. Both, commercial and non-commercial research could fit in the TDM mandatory exception from the reproduction right of the copyright holder.

The notion of ‘lawful access’ to a work could hamper TDM in the sense of de facto subject TDM research to private ordering. According to the European Copyright Society, ‘the exception can effectively be denied to certain users by a right holder who refuses to grant “lawful access” to works or who grants such access on a conditional basis only’.⁶⁸ In addition, subjecting TDM to

64. There are examples in international treaties’ law of such mandatory exceptions which can override contractual limitations, such as Arts. 5(2), and (3) and Art. 6 in connection with Art. 9(1) of EC Directive 91/250/EEC on the legal protection of computer programs. Also, Art. 5(1) of the InfoSoc Directive 2001/29/EC, as well as Art. 6(1), and Art. 8, and Art. 15 of the EC Directive 96/9/EC on the legal protection of databases. In addition, EU Commission’s, ‘Green Paper on Copyright in the Knowledge Society’, (COM(2008) 466 final, available at: <https://eur-lex.europa.eu/legal-content/GA/TXT/?uri=CELEX:52009AE0613> (last visited 28 December 2018) raises the issue of making certain categories of exceptions from the InfoSoc Directive mandatory for all EU Member States.

65. According to EU Commission’s, above n. 64, at present, the Community list of copyright exceptions comprises one mandatory exception and twenty optional exceptions; Member States being therefore free to decide whether or not they wish to implement the optional exceptions. The EESC believes that this represents a key obstacle to the genuine harmonisation of those exceptions which may be justified in a knowledge economy, via technological methods which are constantly changing in the digital age. However, since this list is exhaustive, it prevents the introduction of other exceptions by various Member States. Furthermore, through the application of the ‘three-step test’ drawn up by the WTO and the WIPO, such limitations are subject to three conditions: they may apply only to certain special cases (e.g., visually impaired users), they may not be in conflict with the normal exploitation of the work and they may not unreasonably prejudice the legitimate interests of the right holder.

66. Prescribing a minimum framework of mandatory public policy exceptions which must be available in all national laws of WIPO members, i.e., prescribing a regulatory-ceiling framework for exceptions and limitations of Copyright is a task that has already been undertaken by the WIPO Standing Committee on Copyright and Related Rights through a proposal made by Brazil, Chile, Nicaragua and Uruguay. See, World Intellectual Property Organization, *Proposal by Brazil et al. Relating to Limitations and Exceptions* (SCCR/16/2), 17 July 2008, available at: www.wipo.int/meetings/en/doc_details.jsp?doc_id=107712 (last visited

28 December 2018). See, also, The A2K (Access to Knowledge), *Treaty on Access to Knowledge*, draft text (2005), available at: www.cptech.org/a2k/a2k_treaty_may9.pdf (last visited 28 December 2018) which contains a catalogue of mandatory limitations and exceptions to Copyright including provisions regarding distance education, provisions for persons with disabilities, the first sale doctrine for library use, provisions for ISPs, for DRMs, for orphan works, for the term protection for Copyright, provisions expanding the knowledge commons, provisions promoting the Open Standards, etc. Though the Treaty on Access to Knowledge has been drafted with the aim to become part of WIPO agenda, it has yet to become part of it officially.

67. See, P. Murray-Rust, ‘Open Knowledge Foundation’, *The Right to Read Is the Right to Mine* (2012), available at: <https://blog.okfn.org/2012/06/01/the-right-to-read-is-the-right-to-mine> (last visited 28 December 2018).

68. European Copyright Society, *General Opinion on the EU Copyright Reform Package* (2017) 4, available at: https://www.ivir.nl/publicaties/download/ECS_opinion_on_EU_copyright_reform.pdf (last visited



Ευρωπαϊκή Ένωση
Ευρωπαϊκό Κοινωνικό Ταμείο

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Εκπαίδευση και Διά Βίου Μάθηση
Ειδική Υπηρεσία Διαχείρισης
Με τη συγχρηματοδότηση της Ελλάδας και της Ευρωπαϊκής Ένωσης



ανάπτυξη - εργασία - αλληλεγγύη

lawful access will make TDM research projects harder to run by raising related costs.⁶⁹

The notion of ‘normal use’ of a database might receive multiple interpretations according to the Member States in which it is applied. Therefore, harmonization of TDM exception could be accompanied with a delineation of the notion of ‘normal use’ of a database Europe-wide.⁷⁰

Regarding the provision of Article 4(4)(b) of law 4452/2017 in Greece, this is far from being the introduction of the mandatory TDM exception in the Greek legal framework. As is described above hereto, it is merely a provision assigning NLG with the responsibility of undertaking TDM activity in Greece as well as of coordinating TDM activities enacted by other organizations. Said provision in the Greek law sets the notion of ‘web archiving’ for the first time in the Greek legal system. Despite the fact that the Greek legislator’s aim was to describe the notion of TDM which includes the activity of ‘web archiving’ through this provision – it was hardly achieved through a clear and articulate provision in law – the important thing is that it describes in the statutory goals of NLG the activity of researching the Web on the purpose of archiving works or data which refer to the Greek culture. By no means this should drive to the conclusion that NLG is or will become the only entity with the capability for TDM activity in Greece. However, by Article 4(4)(b) of law 4452/2017 NLG is assigned with – and will probably manage to keep – prime role in the TDM activity deployed on the purpose of scientific research upon Greek culture. It remains to be seen.

The fact that the Greek legislator passed a law catering for the NLG’s statutory responsibility for TDM on the purpose of scientific research for Greek culture subject matter, but has yet to pass a law on the exception of TDM to copyright is not uncommon. There are other Member States which have assigned the responsibility for TDM to their National Library, but in which TDM has yet to become an exception to copyright. Ireland is one such Member State. The National Library of Ireland (NLI) has a long-standing tradition of collecting, preserving and making accessible the published and printed output of Ireland. The NLI has been archiving the Irish web on a selective basis since 2011, and it has

over 17 TB of data in the selective web archive,⁷¹ openly available for research through the NLI website. In 2007 and 2017, the NLI undertook domain crawling projects and there is now over 43 TB of data archived from these crawls. The National Library of Ireland is a legal deposit library, entitling it to a copy of everything published in Ireland. However, unlike many countries in Europe, legal deposit legislation in Ireland does not currently extend to online material so the NLI cannot make these crawls available to the public. Despite these barriers, the NLI remains committed to preserving the online story of Ireland in whatever way it can.⁷²

An amendment to the Greek Copyright Law 2121/1993 is expected, regarding a provision for TDM, at least, and as a consequence of the pass of the proposed Directive on copyright in the Digital Single Market – when it will be set for voting before the European Parliament, again. In addition to the text of the forthcoming Directive provisioning the TDM mandatory exception, there are expectations from the Greek legislator regarding the amendment of the Greek Copyright Law per TDM exception. The Greek legislator should firmly resist over-regulation of TDM activity which does not prejudice the central objective of copyright, namely the provision of incentives to authors. Thus, aside from defining the notions of ‘lawful access’ or ‘normal use’ we would welcome a provision setting the TDM exception in the Greek law which allows TDM to persons, both legal entities and physical persons without discriminating against individual researchers for scientific research purpose; introduce the TDM activity as an exception to the right of reproduction as well as to the right of communication to the public of the author’s work including the author’s right to database and the database right-holder’s sui generis right; specifically mention that works and other subject matter not protected by copyright or neighboring rights can be freely mined; and enable freely the storing and communication to the public of research files created for TDM, a.k.a. the TDM output.

28 December 2018); see also, Max Planck Institute for innovation and Competition, *Position Statement on the Proposed Modernisation of European Copyright Rules*, available at: www.ip.mpg.de/en/research/intellectual-property-and-competitionlaw/position-statement-modernization-of-european-copyright-rules.html (last visited 28 December 2018); Geiger, above at n. 13, p. 22.

69. Geiger, above at n. 13, p. 22.

70. Geiger, above at n. 13, p.25.

71. See, NLI’s selective web archive collections, available at: <https://www.nli.ie/en/udlist/web-archive-collections.aspx> (last visited 28 December 2018).

72. See, NLI’s blog post on IIPC’s site, available at: <https://netpreserveblog.wordpress.com> (last visited 28 December 2018).

Text and Data Mining in the EU 'Acquis Communautaire' Tinkering with TDM & Digital Legal Deposit

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Abstract

Text and Data Mining (hereinafter, TDM) issue for the purpose of scientific research or for any other purpose which is included in the provisions of the new EU Directive on Copyright in the Digital Single Market (hereinafter, DSM). TDM is a term that includes Web harvesting and Web Archiving activities. Web harvesting and archiving pertains to the processes of collecting from the web and archiving of works that reside on the Web. In the following analysis we will elaborate briefly upon provisions in EU Copyright law which were discussed during the proposal for a new Directive on Copyright in the DSM as well as provisions which are included in the text of art.3 and art.4 of the new Directive 2019/790/EU per TDM. In addition, the following analysis presents legislation in very few EU Member States which pertains to TDM and preceded the rulings of Directive 2019/790/EU. Digital legal deposit remarkable examples from EU Member States are also presented in this paper. The example of Australia is also presented below hereto because it is one of the oldest and most successful worldwide. The National Library of Australia's digital legal deposit is state-of-the-art.

Keywords: Web harvesting, data analysis, text & data mining, TDM, computational text

1 Introduction

In the analysis of the first part¹ of this article on Text and Data Mining (hereinafter, TDM) in Directive 2019/790/EU, it was supported that TDM is treated by Directive 2019/790/EU on Copyright in the Digital Single Market (hereinafter, DSM) as a means for research and innovation that allows uses of copyrighted works as well as of non-copyrighted material that are not clearly covered by the existing *Acquis Communautaire* on exceptions and limitations to copyright, and especially on the exception or limitation to copyright for the purpose of scientific research.

The new Directive on Copyright in the DSM rules in its Article 3 the purpose-specific TDM as a mandatory exception to the rights provided for in Article 5(a) and Article 7(1) of Directive 96/9/EC, Article 2 of Directive 2001/29/EC and Article 15(1) of Directive 2019/790/EU, while in its Article 4 rules TDM as a mandatory exception to the rights provided for in Article 5(a) and Article 7(1) of Directive 96/9/EC, Article 2 of Directive 2001/29/EC, Article 4(1)(a) and (b) of Directive 2009/24/EC and Article 15(1) of Directive 2019/790/EU. In both Articles 3 and 4 of Directive on Copyright in the DSM there is no reference to Article 3 of Directive 2001/29/EC. Thus, TDM is not provisioned as an exception to the right of communication to the public of works and the right of making them available to the public. For this reason, any discussion on TDM as an exception to the right of communication to the public and the right of making available to the public is of limited value in consideration of the provisions of the new Directive on Copyright in the DSM. This, however, does not lead to the conclusion that TDM and the right of communication to the public through the use of hyperlinking on the Web is a subject of limited value. But this subject was analysed in the authors' contribution² to the 24th Panhellenic Confer-

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1. M. Bottis, M. Papadopoulos, C. Zampakolas, P. Ganatsiou, 'Text and Data Mining in Directive 2019/790/EU – Enhancing Web-harvesting and Web-archiving in Libraries and Archives', 9 *Open Journal of Philosophy*, (2019).

2. See M. Papadopoulos, C. Zampakolas, P. Ganatsiou, M. Kanellopoulou-Bottis, *Web Harvesting Is Ante Portas of Greek Public and Academic Libraries* (2018), Conference paper submitted to the 24th Panhellenic Conference of Academic Libraries, PALC24, Larissa, available at: <http://>

ence on Academic Libraries, and this analysis would suffice for the time being.

Therefore, in the following analysis we elaborate briefly on provisions in EU Copyright law that were discussed during the proposal for a new Directive on Copyright in the DSM as well as provisions that are included in the text of Articles 3 and 4 of the new Directive 2019/790/EU per TDM. The following analysis refers to Article 5(3)(a) of InfoSoc Directive and Article 6(2) (b) and 9(b) of Database Directive and explains why these articles in EU Copyright law could not cover TDM as its legal foundation in the existing – before Directive 2019/790/EU – ‘*Acquis Communautaire*’. It also refers to Article 5(a) and Article 7(1) of Database Directive as well as Article 2 of the InfoSoc Directive, which are included in the text of Articles 3 and 4 of Directive on Copyright in the DSM and to the ruling of which TDM is provisioned as an exception.

In addition, the following analysis presents legislation in very few EU Member States that pertains to TDM and preceded the rulings of Directive 2019/790/EU. These EU Member States are the United Kingdom, Germany, Estonia and France. There is, also, legislation in Greece that preceded Directive 2019/790/EU and that assigns the National Library of Greece with the responsibility to monitor and archive the Internet (harvesting and archiving of works that reside on the Internet) or other technology environment. To this end, the National Library of Greece has been assigned the tasks to undertake, allocate and coordinate actions for Web harvesting and Web archiving at the national level even before the pass of Directive on Copyright in the DSM.

Remarkable examples of digital legal deposit from EU Member States are also presented in this article. The most notable examples are the ones from the United Kingdom and Ireland, Germany, the Netherlands and France. The example of Australia is also presented later because it is one of the oldest and most successful worldwide. The National Library of Australia’s digital legal deposit is state of the art.

The execution of TDM for Web harvesting and archiving of works found on the Internet is based on algorithmic applications and information technology. It is thus an automated computational process, the precision of which depends on the evolution of algorithms and the software used for their implementation. Later in this article we make a reference to the most commonly used algorithms used in libraries for crawling and harvesting of works found online as well as for analysing their content with the aim of discovering new scientific knowledge from their analysis.

Finally, in the text of this article we will address General Data Protection Regulation (GDPR) issues that pertain to TDM and the data subjects whose works have been harvested and/or archived by a library deploying TDM.

2 The Provision of Article 5(3)(a) of InfoSoc Directive Could Not Cover TDM

The text of Recital 5 of Directive 2019/790/EU refers to research, innovation, education and preservation of cultural heritage. The EU legislature in Recital 5 of this new Directive on Copyright in the DSM makes a nuanced reference to Article 5(3)(a) of Directive 2001/29/EC (the InfoSoc Directive), which provides for non-mandatory exceptions or limitations to the reproduction right of Article 2 of the InfoSoc Directive as well as to the right of communication to the public of works and the right of making available to the public other copyrighted subject matter of Article 3 of the InfoSoc Directive.

According to Article 5(3)(a) of the InfoSoc Directive, Member States may provide for exceptions or limitations to the rights provided for in Articles 2 and 3 in the case of, among others, use for the sole purpose of illustration for teaching or scientific research, as long as the source, including the author’s name, is indicated, unless this turns out to be impossible and to the extent justified by the non-commercial purpose to be achieved. Not all EU Members have adopted the provision of Article 5(3) (a) of the InfoSoc Directive, and among those EU Members that have implemented this provision in their national law, there are significant differences in the texts and accorded protection of national laws.

The provision of Article 5(3)(a) of the InfoSoc Directive was rightfully deemed not to be a sufficient legal foundation for TDM. Specifically:

Under Article 5(3)(a) of the InfoSoc Directive, Member States may provide for exceptions and limitations in the case of use for scientific research. Article 5(3)(a) of the InfoSoc Directive allows Member States to provide for exceptions in the case of ‘*use for the sole purpose of illustration for teaching or scientific research, as long as the source, including the author’s name, is indicated, unless this turns out to be impossible, and to the extent justified by the non-commercial purpose to be achieved*’. This exception is optional in ‘*Acquis Communautaire*’, which means that the question of its implementation was left to Member States. As a result, Member States have different rules and regulations in this regard currently, and some countries, like Greece, the Netherlands and Spain, recognise no research exception at all.

While research is the exploration of a certain subject matter with a view to finding data or any other kind of information or to gain knowledge, ‘*scientific*’ research must be carried out in a methodological and systematic way. The beneficiaries of the exception or limitation for scientific research provisioned in Article 5(3)(a) of the InfoSoc Directive are primarily professors, researchers and students at universities and similar institutions, but may also be others, such as practising lawyers or medical doctors when they carry out scientific research in order to write an article or inquire about the state of the art;

even private persons may be beneficiaries if they carry out research according to scientific methods.³

The most important use as regards scientific research is the reproduction of materials (see Article 9(2) of the Berne Convention) and, possibly, the making available of material online.⁴ Broadcasting or other traditional forms of communication to the public hardly seem relevant in practice for uses of scientific research. The Berne Convention and other international laws do not allow for a limitation of the right of communication to the public, including broadcasting, for the purpose of scientific research; Article 10(2) of the Berne Convention addresses only teaching, and the three-step test of Article 9(2) refers only to the reproduction right. Therefore, Article 5(3)(a) of the InfoSoc Directive must be interpreted in light of the international copyright law, and the term ‘use’ is thus to be understood as not including any communication in traditional form. Consequently, the provision of Article 5(3)(a) of the InfoSoc Directive does not allow for exceptions and limitations of the right of communication to the public (Directive 2001/29/EC)⁵ in traditional form.

In addition, the provision of Article 5(3)(a) of the InfoSoc Directive provides for the exception for ‘scientific research’ provided that it is the sole purpose of the use for which the exclusive rights may be restricted. Accordingly, when the reproduction or other use also fulfils an additional purpose, the exception or limitation does not apply.⁶ Thus, all TDM projects that do not qualify as scientific research and/or have a commercial purpose, both direct or indirect economic or commercial advance, are excluded from the outset from the application of the exception of Article 5(3)(a) of the InfoSoc Directive.

Also, the exception of Article 5(3)(a) of the InfoSoc Directive applies only as long as the source, including the author’s name, is indicated. This condition corresponds to Article 10(3) of the Berne Convention, which specifies that the name of the author need be indicated only if it appears on the work used. The InfoSoc Directive is thus more demanding. At the same time, where the author has chosen to stay anonymous, there is no obligation to include his name – but rather a prohibition on doing so. Beyond the author’s name, the source includes the title of the work and the publishing house or the website from which the work or other subject matter was taken. The user is obliged to indicate the source provided that it does not turn out to be impossible. There are cases of legal impossibility, in particular

where the author has chosen to stay anonymous and the mentioning of his name, if known to the user, would even violate his moral right. The InfoSoc Directive does not indicate what efforts must be made to find the author’s name or other indication of source before such indication may be considered impossible.

The use under Article 5(3)(a) of the InfoSoc Directive may be permitted only to the extent justified by the non-commercial purpose to be achieved. First, the use must aim to achieve a non-commercial purpose. This condition reflects the condition of Article 10(2) of the Berne Convention that the use is compatible with fair practice, and to some extent it integrates the conditions of the three-step test. Recital 42 of the InfoSoc Directive clarifies that ‘non-commercial’ refers to the activity of teaching and research rather than to the organisational structure or the means of funding of the institution. Accordingly, a professor at a non-profit academic institution who writes a legal opinion for a company on payment of a fee carries out the related research for a commercial purpose and is thus not privileged by the exception of Article 5(3)(a). ‘Commercial’ should be read as including direct or indirect economic and commercial advantages. Also, such research must be strictly non-commercial (likely excluding mixed industry academic research, unless a sufficient separation of sub-projects is obtained), and must also indicate the source (including the author’s name) of each work used ‘unless this turns out to be impossible’. It is unclear whether such impossibility indeed exists for TDM research, where thousands, if not millions, of documents are involved.

From the wording of Article 5(3)(a) of the InfoSoc Directive, it is not sufficient that the use is to serve a non-commercial purpose; rather, it must also be justified by this purpose and is privileged only to the extent that it is thereby justified. This element again stems from Article 10(2) of the Berne Convention and has to be interpreted accordingly.⁷

3 The Provisions of Article 6(2)(b) and Article 9(b) of Database Directive Could Not Cover TDM

Aside from Article 5(3)(a) of the InfoSoc Directive, the provisions of Article 6(2)(b) and Article 9(b) of the Database Directive were rightfully deemed not to be a sufficient legal foundation for TDM. The EU legislature in Recital 5 of Directive 2019/790/EU on Copyright in the DSM makes a reference to the Database Directive, *i.e.* Directive 96/9/EC, and to the Computer Programs Directive, *i.e.* Directive 2009/24/EC. Specifically, and regarding the Database Directive:

3. M. Walter, S.V. Lewinski, *European Copyright Law – A Commentary* (2010), at 1043.

4. *Ibid.*

5. Art. 3(1) of the InfoSoc Directive titled ‘Right of communication to the public of works and right of making available to the public other subject-matter’: Member States shall provide authors with the exclusive right to authorise or prohibit any communication to the public of their works, by wire or wireless means, including the making available to the public of their works in such a way that members of the public may access them from a place and at a time individually chosen by them.

6. Walter and Lewinski, above n. 3, at 1044.

7. *Ibid.*, at 1045.

Regarding Article 6(2)(b) of the Database Directive, it posits that Member States shall have the option of providing for limitations on the rights set out in Article 5 of the Database Directive in a number of strictly reported cases, among which is

‘... (b) where there is use for the sole purpose of illustration for teaching or scientific research, as long as the source is indicated and to the extent justified by the non-commercial purpose to be achieved.’

The rights provided to the author of a database in Article 5 of the Database Directive are the following:

- a. The temporary or permanent reproduction by any means and in any form, in whole or in part;
- b. The translation, adaptation, arrangement and any other alteration;
- c. Any form of distribution to the public of the database or copies thereof. The first sale in the Community of a copy of the database by the rights holder or with his consent shall exhaust the right to control resale of that copy within the Community;
- d. Any communication, display or performance to the public;
- e. Any reproduction, distribution, communication, display or performance to the public of the results of the acts referred to in (b).

In consideration of the provision of Article 6(2)(b) of Directive 96/9/EEC, Member States may also exempt uses of a database for the sole purpose of scientific research from the protection of Article 5 of the Database Directive. Recital 36 of the Database Directive clarifies that whereas the term *‘scientific research’* within the meaning of this Directive covers both the natural sciences and the human sciences, the scientific research must be justified by a non-commercial purpose, which means that it must not aim at the achievement of any economic advantage.⁸ The requirement for non-commercial purpose allows exemption from the protection conferred on the database author through Article 5 of the Database Directive even to uses of a database made by for-profit organisations or professionals provided that those specific uses are made for non-commercial purpose. Thus, the exemption is applicable provided that the pursued purpose of use of the database is non-commercial irrespective of the nature of the organisation or individual that made use of the database.⁹ When the use of the database is intended for commercial purpose, this use does not qualify for the exception of Article 6(2)(b) of the Database Directive regardless of the nature of the organisation or individual that carried out the use of the database. Thus, non-profit organisations such as academic (public) libraries that carried out TDM in the sense of use of a third party’s database aiming at commercial advantage, could not leverage on the provision of Article 6(2)(b) of Directive 96/9/EEC.¹⁰

Article 6(2)(b) of the Database Directive, apart from the indication of the source of a database, sets only one condition for the use of a database, namely that the research is justified by the non-commercial purpose to be achieved. The expression *‘to the extent justified by the non-commercial purpose’* implies the need for balancing the rights of the authors, on the one hand, and the interests of the general public, on the other. This balancing of the seemingly conflicting rights, namely the rights of the author of the database with the rights of the public, is required for the application of Article 6(2)(b) of the Database Directive in the sense that it is not sufficient that the use described in the said provision is possible or useful for non-commercial purposes; rather it must be *‘justified’* by such purposes, hence a proper balance between the conflicting rights must be achieved.¹¹ In that sense, TDM activities carried out by a library for scientific purposes could not find legal foundation under Article 6(2)(b) of the Database Directive unless the library can prove that it achieved a balance between the rights of the authors, on the one hand, and the interests of the general public, on the other.

Regarding the *‘use for the sole purpose of illustration for teaching’*, the term *‘teaching’* is understood to be the same as in Article 10(2) of the Berne Convention and refers to education delivered by the teacher in public and/or non-commercial private schools, including secondary and vocational schools as well as universities.¹² Teaching activity that aims at economic advantage – it is not necessary to achieve the intended economic advantage – could not leverage on the exemption of Article 6(2)(b) of the Database Directive. The exemption is permitted in favour of the teacher; the wording of the exemption refers to *‘teaching’* rather than *‘learning’* and thus cannot be interpreted so widely as to include in the meaning of the exemption every use of a database that is favourable to the learner/student. For this reason, use of a protected database in the framework of a test or of an examination is not covered by the provision of Article 6(2)(b) of the Database Directive because the examination occurs not in the framework of teaching but rather only after the teaching has been concluded. Examination usually occurs in the framework of evaluation of a student after the conclusion of teaching; it does not occur for the purpose of conveying new knowledge.¹³

All limitations under Article 6(2)(b) of the Database Directive must comply with the three-step test according to Article 6(3) of this Directive, which posits that in accordance with the Berne Convention for the protection of Literary and Artistic Works, Article 6 of the Database Directive may not be interpreted in such a way as to allow its application to be used in a manner that unreasonably prejudices the rights holder’s legitimate interests or conflicts with normal exploitation of the database. Article 6(3) of the Database Directive provides the three-step test as a safety net for the limitations pro-

8. *Ibid.*, at 734.
9. *Ibid.*, 734-5.
10. *Ibid.*, at 734.

11. *Ibid.*, at 735.
12. *Ibid.*, 733-4.
13. *Ibid.*, at 734.

visioned in Article 6(1) & 6(2). Thus, the three-step test functions as the outer limit of the provisioned limitations, *i.e.* it is the yardstick used for delineating how far the limitations set through Article 6(1) & 6(2) of the Database Directive can go.¹⁴

Regarding the provision of Article 9(b) of the Database Directive that pertains to the extraction only – there is no wording for allowance of the reutilisation – where implemented, the substantial¹⁵ extraction¹⁶ of the content of a database is allowed for the purposes of illustration for teaching or scientific research; no act of reutilisation can be performed on the basis of Article 9(b) of the Database Directive. There is no exempted coverage for the use of a database or of its online transmission regarding the *sui generis* right.¹⁷ In this respect, the limitation to the *sui generis* right of the database maker is narrower than the limitation of Article 6(2)(b) on the copyright of the author of the database. This restriction, in effect, removes any practical value of the scientific research exception on the database right.¹⁸

4 TDM as Mandatory Exception from Article 5(a) of Database Directive

Article 5 of the Database Directive, *i.e.* Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases, OJ L 77 of 27 March 1996, 20, contains an exhaustive list of the exclusive rights vested in the author of a database subject to Article 2(b) that leaves without prejudice of the Rental and Lending Rights Directive the rights of rental and lending of a database under the provisions of Directive 2006/115/EC.

Article 5(a) of the Database Directive refers to the right of reproduction of the database. According to it:

In respect of the expression of the database which is protectable by copyright, the author of a database shall have the exclusive right to carry out or to authorise:

- a. temporary or permanent reproduction by any means and in any form, in whole or in part;

14. *Ibid.*, at 730.

15. The notion of insubstantiality of a part of a database must be evaluated through quantitative and qualitative criteria.

16. In C-203/02, (2004), *The British Horseracing Board Ltd and Others v. William Hill Organization Ltd.*, available at: <http://curia.europa.eu/juris/liste.jsf?num=C-203/02> (last visited 1 July 2019) the CJ has clarified that the assessment upon the extraction or the reutilisation of the contents of a database must consider the investment in the creation of the database and the prejudice that the extraction or reutilisation cause to that investment. If there is a prejudice to the assessed investment there is infringement of the *sui generis* database right.

17. Walter and Lewinski, above n. 3, at 773.

18. European Union, *Study on the Legal Framework of Text and Data Mining (TDM)* (2014), at 51, available at: <https://publications.europa.eu/en/publication-detail/-/publication/074ddf78-01e9-4a1d-9895-65290705e2a5/language-en> (last visited 1 July 2019).

The right of reproduction of a database has a wide formulation in the sense that it covers any direct or indirect way of reproduction, complete or partial reproduction, and any permanent or temporary act of reproduction of a database in compliance with Article 9(1) of the Berne Convention. A transient form of reproduction is also included in the notion of the reproduction of a database of Article 5(a) of the Database Directive. The broad wording of ‘*temporary*’ and the fact that the obligatory exception of Article 6(1) of the same Directive takes into account the interests of the ‘*lawful user*’ of the database attest to the conclusion that the reproduction right of the database of Article 5(a) considers all forms and ways of reproduction, including the ‘*transient*’ reproduction.¹⁹ Therefore, in the case of TDM upon a database, even transient reproduction, in whole or in part, of the database is subject to the protectable copyright of the author of the database, who has the exclusive right to allow or forbid it.

Articles 3 and 4 of the new Directive on Copyright in the DSM mandatorily exclude the TDM executed upon a database in compliance with the requirements that the said provisions describe from the exclusivity power of the author of the database and the requirement of his or her prior written consent.

The mandatory exception of Articles 3 and 4 of the new Directive on Copyright in the DSM pertains to acts of TDM that may impact on the expression of the database that is protected by copyright, *i.e.* the selection or arrangement of the contents of the database. For any possible impact of TDM on unprotectable parts of the database’s structure, upon which there is no exclusive right of the author of a database, there is no provision in the Database Directive that could hamper the TDM.²⁰

5 TDM as Mandatory Exception from Article 7(1) of Database Directive

Article 7(1) of the Database Directive rules that:

1. 1. Member States shall provide for a right for the maker of a database which shows that there has been qualitatively and/or quantitatively a substantial investment in either the obtaining, verification or presentation of the contents to prevent extraction and/or re-utilisation of the whole or of a substantial part, evaluated qualitatively and/or quantitatively, of the contents of that database.

TDM is set in Articles 3 and 4 of the new Directive on Copyright in the DSM as an exception to the rights provisioned in Article 7(1) of the Database Directive. This means that the maker of a database cannot claim

19. Walter and Lewinski, above n. 3, 9.5.7, 715-6; I. Stamatoudi, P. Torremans, *EU Copyright Law – A Commentary* (2014), 9.21, 313-4.

20. Walter and Lewinski, above n. 3, 9.5.4., at 715.

his/her/its sui generis right with the aim of forbidding TDM activity. Also, it means that it is not necessary for the holder of the sui generis right to license the right extraction and/or reutilisation of the whole or of a substantial part of the database for the implementation of TDM. TDM may be implemented with or without the licence of the maker of a database for acts of extraction and/or reutilisation of the whole or of a substantial part of the database.

The holder of the sui generis right may be a natural person or a legal entity or a group of natural persons and/or legal entities such as partnerships or group of companies since the sui generis right is not an author's right under the Continental European legal system.²¹ The maker of the database and the holder of the sui generis right is the person who/which took the initiative to make the protected database that is set under TDM activity and who/which bears the risk of investing for the aforesaid database (Directive 96/9/EC).²² A defining issue for naming the holder of the sui generis right is to spot the person/entity who/which made the substantial investment for the creation of a database.²³

TDM is set as a mandatory exception of Article 7(1) of the Database Directive regarding actions of extraction and/or reutilisation of the whole or of a substantial part, evaluated qualitatively and/or quantitatively, of the contents of a database. These actions may pertain to the whole database or a separate module of a database that by itself fulfils the conditions for protection of a database.

Extraction means removal and copying of contents of a database. Extraction includes translation of the database's content. The meaning of 'extraction' is wide, covering at least the same acts covered by the term 'reproduction' under copyright and related rights.²⁴ Therefore, in a typical TDM activity in which the contents of a database are copied, turned into a machine-readable format compatible with the TDM technology and uploaded onto a platform, there is no doubt about the fact of extraction of the contents of a database through the TDM activity. Besides, TDM entails extraction of contents of a database since in almost all cases of TDM activity there is permanent transfer of the contents that are stored in a permanent manner in a medium other than the database for more than a limited period of time after extraction.²⁵

'Reutilisation' means all forms of making, directly or indirectly, a database available to the public.²⁶ It covers both acts of exploitation and acts performed by users

without the aim of obtaining proceeds from marketing the contents of a database.²⁷

6 TDM as Mandatory Exception from Article 2 of InfoSoc Directive

TDM is set in Articles 3 and 4 of the new Directive on Copyright in the DSM as an exception to the right provisioned in Article 2 of the InfoSoc Directive. Specifically:

Article 2 of the InfoSoc Directive refers to the reproduction right, which is at the core of copyright and related rights and is of eminent importance within the concept of copyright protection.²⁸ Through the provisions of Articles 3 and 4 of the new Directive on Copyright in the DSM, TDM is set as a mandatory exception to the reproduction right in its broad meaning and extension including all categories of works. It includes, also, direct and indirect and permanent and temporary reproductions with the exception of the application of Article 5(1) of the InfoSoc Directive regarding temporary acts of reproduction that are transient and incidental and an integral and essential part of a technological process the sole purpose of which is to enable transmission in a network between third parties by an intermediary or a lawful use of a work or other subject matter, and that have no independent economic significance. It includes reproduction by any means and in any form, as well as reproduction of the whole work or parts of a work provided that the part concerned complies with the originality requirement.

The broad meaning of the reproduction right of Article 2 of the InfoSoc Directive is described in Recital 21 of the InfoSoc Directive, according to which a broad definition of the acts of reproduction is needed to ensure legal certainty within the internal market in the EU and has been confirmed by the CJ in the *Infopaq* case.²⁹ The meaning of reproduction is to be determined technically rather than functionally.³⁰

Therefore, reference to Article 2 of the InfoSoc Directive in the provisions of Articles 3 and 4 of Directive 2019/790/EU was necessary in consideration of the typical TDM operation, which includes reproduction of works by copying them in whole or in part with the aim of preprocessing them and turning them into machine-readable format compatible with the technology to be deployed for the TDM operation, as well as by uploading – depending on the TDM technology – the preprocessed materials on a platform for further extraction of

21. *Ibid.*, 9.7.16., at 750.

22. See Recital 41 of the Database Directive according to which the maker of a database is the person who takes the initiative and the risk of investing; ... this excludes subcontractors in particular from the definition of maker.

23. Stamatoudi and Torremans, above n. 19, 9.42, at 325.

24. Walter and Lewinski, above n. 3, 9.7.25., at 754.

25. See CJ Case C-545/07, *Apis-Hristovich EOOD v. Lakorda AD*, [2009] ECR I-1627, mn.55, available at: <http://curia.europa.eu/juris/liste.jsf?num=C-545/07> (last visited 1 July 2019).

26. See CJ Case C-203/02, mn. 67.

27. Walter and Lewinski, above n. 3, 9.7.35., at 758.

28. *Ibid.*, 11.2.1., at 963.

29. See CJ Case C-5/08 (2009), *Case C-5/08 Infopaq International A/S v. Danske Dagblades Forening*, 2009 I-06569, available at: <http://curia.europa.eu/juris/liste.jsf?num=C-5/08> (last visited 1 July 2019).

30. Walter and Lewinski, above n. 3, 11.2.17., at 968.

data from works and recombination of the data for the identification of patterns into the final output.

7 TDM in the Text of National Laws of a Few EU Members

7.1 UK

The UK legislature amended its Copyright law by S.I. 1992/3233, regulation 7, S.I. 1997/3032, regulation 8 and S.I. 2003/2498, regulation 9. Section 29A, which was added to the Copyright and Rights in Performances (Research, Education, Libraries and Archives) Regulations 2014, came into force on 1 June 2014. The amended Copyright law in the UK, which provides for TDM to the lawful user for the sole purpose of computational analysis for non-commercial research, but does not cover the reproduction of databases, provides as follows (emphasis added):³¹

29A Copies for text and data analysis for non-commercial research

1. The making of a copy of a work by a person who has lawful access to the work does not infringe copyright in the work provided that –
 - a. the copy is made in order that a person who has lawful access to the work may carry out a computational analysis of anything recorded in the work for the sole purpose of research for a non-commercial purpose, and
 - b. the copy is accompanied by a sufficient acknowledgement (unless this would be impossible for reasons of practicality or otherwise).
2. Where a copy of a work has been made under this section, copyright in the work is infringed if –
 - a. the copy is transferred to any other person, except where the transfer is authorised by the copyright owner, or
 - b. the copy is used for any purpose other than that mentioned in subsection (1)(a), except where the use is authorised by the copyright owner.
3. If a copy made under this section is subsequently dealt with –
 - a. it is to be treated as an infringing copy for the purposes of that dealing, and
 - b. if that dealing infringes copyright, it is to be treated as an infringing copy for all subsequent purposes.
4. In subsection (3) “dealt with” means sold or let for hire, or offered or exposed for sale or hire.
5. To the extent that a term of a contract purports to prevent or restrict the making of a copy which, by virtue of this section, would not infringe copyright, that term is unenforceable.

Research and private study

31. See <http://www.legislation.gov.uk/uksi/2014/1372/regulation/3/made> (last visited 1 July 2019).

1C. –

1. Fair dealing with a performance or a recording of a performance for the purposes of research for a non-commercial purpose does not infringe the rights conferred by this Chapter.
2. Fair dealing with a performance or recording of a performance for the purposes of private study does not infringe the rights conferred by this Chapter.
3. Copying of a recording by a person other than the researcher or student is not fair dealing if –
 - a. in the case of a librarian, or a person acting on behalf of a librarian, that person does anything which is not permitted under paragraph 6F (copying by librarians: single copies of published recordings), or
 - b. in any other case, the person doing the copying knows or has reason to believe that it will result in copies of substantially the same material being provided to more than one person at substantially the same time and for substantially the same purpose.
4. To the extent that a term of a contract purports to prevent or restrict the doing of any act which, by virtue of this paragraph, would not infringe any right conferred by this Chapter, that term is unenforceable.
5. Expressions used in this paragraph have the same meaning as in section 29.

Copies for text and data analysis for non-commercial research

1D. –

1. The making of a copy of a recording of a performance by a person who has lawful access to the recording does not infringe any rights conferred by this Chapter provided that the copy is made in order that a person who has lawful access to the recording may carry out a computational analysis of anything recorded in the recording for the sole purpose of research for a non-commercial purpose.
2. Where a copy of a recording has been made under this paragraph, the rights conferred by this Chapter are infringed if –
 - a. the copy is transferred to any other person, except where the transfer is authorised by the rights owner, or
 - b. the copy is used for any purpose other than that mentioned in sub-paragraph (1), except where the use is authorised by the rights owner.
3. If a copy of a recording made under this paragraph is subsequently dealt with –
 - a. it is to be treated as an illicit recording for the purposes of that dealing, and
 - b. if that dealing infringes any right conferred by this Chapter, it is to be treated as an illicit recording for all subsequent purposes.
4. To the extent that a term of a contract purports to prevent or restrict the making of a copy which, by virtue of this paragraph, would not infringe any right

conferred by this Chapter, that term is unenforceable.

- Expressions used in this paragraph have the same meaning as in section 29A.

7.2 FR

In France, the legislature of Law No. 2016-1231 for a Digital Republic (*Loi pour une République numérique*), introduced TDM exceptions both applying to works (art. L.122-5, 10 of the CPI) and databases (art. L.342-3, 5 of the CPI).³² French exceptions cover acts of reproduction from ‘lawful sources’ (materials lawfully made available with the consent of the rights holders) for TDM as well as storage and communication of files created in the course of TDM research activities.³³

The French ruling for TDM, Article 38 of the Law No. 2016-1231 for a Digital Republic, has as follows:³⁴

After the second paragraph of 9° of article L.122-5, a 10° is inserted as follows:

10° Electronic copies or reproductions realised from a legal original, for the purpose of text and data mining included or associated in a scientific publication for the needs of the public research, excluding commercial exploitation. A decree lays down the conditions in which text and data mining are employed, as well as the modalities of preservation and communication of the files produced at the end of the research activities for which they have been produced; these files constitute research data;

After the 4° of the article L.342-3 is inserted a 5°, thus written:

32. Art. 38 of the Law No. 2016-1231 for a Digital Republic added paragraph 10 to art. L.122-5 and paragraph 5 to art. L.342-3 of the French Intellectual Property Code (Code de la Propriété Intellectuelle, CPI).

33. C. Geiger, G. Frosio, O. Bulayenko, *The Exception for Text and Data Mining (TDM) in the Proposed Directive on Copyright in the Digital Single Market-Legal Aspects* (2018), 17-8, available at: [http://www.europarl.europa.eu/RegData/etudes/IDAN/2018/604941/IPOL_IDA\(2018\)604941_EN.pdf](http://www.europarl.europa.eu/RegData/etudes/IDAN/2018/604941/IPOL_IDA(2018)604941_EN.pdf) (last visited 1 July 2019).

34. Unofficial translation. The original text in the French law provides as follows:

Art. 38

Le code de la propriété intellectuelle est ainsi modifié:

1° Après le second alinéa du 9° de l'article L. 122-5, il est inséré un 10° ainsi rédigé:

« 10° Les copies ou reproductions numériques réalisées à partir d'une source licite, en vue de l'exploration de textes et de données incluses ou associées aux écrits scientifiques pour les besoins de la recherche publique, à l'exclusion de toute finalité commerciale. Un décret fixe les conditions dans lesquelles l'exploration des textes et des données est mise en œuvre, ainsi que les modalités de conservation et de communication des fichiers produits au terme des activités de recherche pour lesquelles elles ont été produites ; ces fichiers constituent des données de la recherche ; »

2° Après le 4° de l'article L. 342-3, il est inséré un 5° ainsi rédigé:

« 5° Les copies ou reproductions numériques de la base réalisées par une personne qui y a licitement accès, en vue de fouilles de textes et de données incluses ou associées aux écrits scientifiques dans un cadre de recherche, à l'exclusion de toute finalité commerciale. La conservation et la communication des copies techniques issues des traitements, au terme des activités de recherche pour lesquelles elles ont été produites, sont assurées par des organismes désignés par décret. Les autres copies ou reproductions sont détruites. »

5° Electronic copies or reproductions of a database realised by someone who has a legal access to it, for the purpose of text and data mining included or associated to scientific publications for the needs of a research activity, excluding commercial exploitation.

The preservation and the communication of the technical copies made during the process, at the end of the research activities for which they have been produced, are provided by institutions appointed by decree. Other copies or reproductions are destroyed.

The French legislature opted to leave the ruling of the matter of the conditions under which TDM can be undertaken as well as the modalities for storing and communicating research files that were created for TDM purposes to an actualisation decree. TDM is restricted solely to text and data included in or associated with scientific writings. TDM is ruled only for non-commercial purposes; it cannot pursue commercial objectives and should be limited to the needs of (public) research.³⁵

7.3 EE

The Estonian legislature amended the country's Copyright Act of 1992 and, as of 1 January 2017, introduced TDM in paragraph 3 of Article 19 titled ‘Free use of works for scientific, educational, informational and judicial purposes’. The Estonian Copyright Act (emphasis added) makes the following provision:

The following is permitted without the authorisation of the author and without payment of remuneration if mention is made of the name of the author of the work, if it appears thereon, the name of the work and the source publication ... 3) processing of an object of rights for the purposes of text and data mining and provided that such use does not have a commercial objective;

The Estonian Copyright Act (1992) already has a research exception (Section 19) applicable within the framework of language research. However, for the sake of legal clarity, it was considered relevant to add a specific exception for TDM. The UK approach is used as a benchmark. The exception provided in Estonian law is applicable for work and objects with related rights (such as performances).

7.4 DE

Also, in 1 September 2017 Germany amended its Copyright law, and the amendment has come into force as of 1 March 2018, introducing TDM in Section 60d titled ‘Text and data mining’. According to this provision in German Copyright Act of 9 September 1965, as last amended by Article 1 of the Act of 1 September 2017 (emphasis added):

1. In order to enable the automatic analysis of large numbers of works (source material) for scientific research, it shall be permissible 1. to reproduce the source material, including automatically and systematically, in order to create, particularly by means of normalisation, structuring and categorisation, a cor-

35. Geiger, Frosio, & Bulayenko, above n. 33, at 18.

pus which can be analysed and 2. to make the corpus available to the public for a specifically limited circle of persons for their joint scientific research, as well as to individual third persons for the purpose of monitoring the quality of scientific research. In such cases, the user may only pursue non-commercial purposes.

2. If database works are used pursuant to subsection (1), this shall constitute normal use in accordance with section 55a, first sentence. If insubstantial parts of databases are used pursuant to subsection (1), this shall be deemed consistent with the normal utilisation of the database and with the legitimate interests of the producer of the database within the meaning of section 87b (1), second sentence, and section 87e.
3. Once the research work has been completed, the corpus and the reproductions of the source material shall be deleted; they may no longer be made available to the public. It shall, however, be permissible to transmit the corpus and the reproductions of the source material to the institutions referred to in sections 60e³⁶ and 60f³⁷ for the purpose of long-term storage.

The TDM exception in German law covers the acts of reproduction necessary for undertaking TDM and the acts of making available the corpus of materials produced by TDM activity (*e.g.* source materials that were normalised, structured and categorised) to a specifically limited circle of persons for their joint scientific research, as well as to individual third persons for the purpose of monitoring the quality of scientific research. Once the TDM project is completed, the ‘*corpus*’ can be sent to institutions designated by law for long-term storage. Any other copy made should be deleted.

8 Article 4(4)(b) of Greek Law 4452/2017 for TDM of NLG

A recent development in Greece’s legal framework on the National Library of Greece (NLG) stipulates activities that are within the TDM operation. Specifically, law 4452/2017, which is titled ‘*Regulation on State Language Certificate subject matter, on the National Library of Greece and on other provisions*’, includes in its text the provision of Article 4(4)(b), according to which the NLG operates as the official National Depository and Archive of digital publications, data and metadata produced in the country or related to Greek culture. This operation includes the monitoring and archiving of the Internet (Web archiving) or other technology environment. To this end, the NLG shall undertake, allocate and coordinate the actions concerned at the national level.

36. Section 60e refers to libraries, namely *Publicly accessible libraries which neither directly nor indirectly serve commercial purposes (libraries)*.

37. Section 60f refers to archives, museums and educational establishments.

This provision of Article 4(4)(b) of law 4452/2017 is the first in the Greek legal system that caters for TDM activities. The provision is too general, probably vague, and not proper in its wording. However, the analysis in this text does not aim at elaborating on the bad phrasing or vagueness in the provision of Article 4(4)(b) of law 4452/2017.

Article 4(4)(b) of law 4452/2017 sets the TDM activity in Greece under the responsibility of the NLG, which is named as the organisation to undertake, allocate and coordinate action of text and data analysis at the national level. The ‘*monitoring*’ of the Web is meant to be the Web harvesting activity; the archiving of the Internet is meant to be the archiving of works harvested from the Internet. Thus, the NLG is ruled to be the proper organisation for running and overseeing TDM activity in Greece. Other organisations may deploy TDM activities under the coordination of the NLG, which is the national depository and archive of works on the Internet, including data and metadata produced in Greece or related to the Greek culture.

Article 4(4)(b) of law 4452/2017 preceded any EU regulation on TDM. The proposal for a Directive on Copyright in the DSM was not part of the ‘*acquis communautaire*’ when the Hellenic Parliament passed law 4452/2017.

9 Tinkering with TDM in NLG

As noted previously, the NLG is described in Article 4(4)(b) of law 4452/2017 as the official national depository and archive of digital publications, data and metadata produced in the country or that is related to Greek culture. NLG’s operation includes – among other legally founded statutory goals – the monitoring and archiving of the Internet (Web archiving) or other technology environment. To this end, NLG shall undertake, allocate and coordinate the actions concerned at the national level. There is no other provision for TDM in the Greek legal framework to date. Actually, the provision of Article 4(4)(b) of law 4452/2017 is not a provision that sets an exception or limitation to copyright for TDM and for scientific or other purposes, but rather one that describes NLG’s prime role in TDM activity, limited to the sense of Web archiving, in Greece.

Regarding TDM, the paradox in the ruling of law 4452/2017 is obvious: the Greek legislature rules upon the key TDM player in the Greek market despite the fact that it has yet to rule upon the TDM game! That said, and with all due respect for the Greek legislature, this is by no means the sole paradox one can find in the national legal system.

Once the provision of Article 4(4)(b) of law 4452/2017 became effective, NLG made its first attempts with TDM. The first attempts of NLG with TDM were supported technically by the Research Team of Data &

Web Mining (DB-net)³⁸ of Athens University of Economics and Business. Leveraging on the technical expertise of DB-net, NLG has tinkered with TDM repeatedly, so far.

On February 2017 NLG deployed TDM for the first time, targeting Greek websites at the national level. This first attempt was a broad crawling of the Web for websites under the *.gr* domain or websites under the *.edu* or *.com* domains that were composed in Greek. By that time – and even currently – NLG was aware of the fact that the Greek legal system does not leave any room for consideration of making the output of TDM available to the public. The first NLG's attempt with TDM – and actually all subsequent ones – were made for scientific purposes, more precisely for the purpose of extracting new knowledge from statistical information coming out of the TDM process upon the works submitted to it, as well as for purposes related to NLG's statutory goals such as the purpose of saving and preserving Greek Web archives as part of Greece's national cultural heritage.

Before NLG's first TDM activity, the DB-net research team had tested its TDM know-how by deploying TDM activity targeting the websites of Athens University of Economics and Business (AUEB).³⁹ Experimental TDM activity targeting Greek websites deployed by the DB-net research team had also preceded NLG's tinkering with TDM.⁴⁰ The DB-net research team of AUEB had cross-tested TDM technology upon Greek websites starting from February 2010 and repeatedly at least four times until May 2010.

As of February 2017, NLG has deployed two broad TDM activities on the Greek Web.⁴¹ The first Web harvesting was deployed with an interest in mining and archiving only text data from websites on top level *.gr* national domain in Greek or other languages or from other websites that used Greek and were for this reason considered Greek sites. Websites composed in Greek under the *.edu* and *.com* domains were harvested too.

Websites allowing authorised access to their content were not targeted during NLG's Web harvesting. NLG's TDM activity excluded, also, websites using the Robots Exclusion Protocol⁴² (included *.txt* files) or those considered as media resources.

In order to delimit the Greek sites, as a target group of the first mining, extensive research through Web search engines and through thematic portals related to Greek websites was conducted. The volume of the first broad crawling of the Greek Web was an archiving amounting to 18 TB of information.

The stages of the first implementations of TDM in Greece by NLG are presented in Table 1.

During the second deployment of TDM activity for archiving the Greek Web, the first mining of selective content took place in consideration of the following themes:

- Local government,
- News and
- Education (schools, universities, etc. Mainly *edu.gr*, *sch.gr* and *mysch.gr*.)

The National Archiving System of Greek Web ('ΕΣΑΕΠ National System)⁴³ has a user interface in the Greek and English languages and search tools to archive from the Greek Web archiving process and TDM procedure.

In this ΕΣΑΕΠ National System the act of website-searching refers to selective-thematic harvesting, and the user searches by keyword, URL name and thematic category name.

The aforesaid system also offers the option of using a time frame selection tool in combination with keyword and domain-search tools.

The system has not become available to any third party, whether researcher or not, except the NLG. Until today the sole user has been the NLG librarian since, as already mentioned, there is still no proper legal framework to facilitate the making available to the public of the harvested and archived content from the Web to the research community owing to legal restrictions for intellectual property protection according to Greek legislation.

NLG has set specific goals to improve the 'ΕΣΑΕΠ' National System and evolve TDM and Web archiving in the near future. Specifically, it aims to improve the categorisation of websites in order to make it possible to implement selective Web harvesting into new categories in the foreseeable future. In addition, NLG intends to improve accessibility tools, as well as to focus on part-

38. See DB-net, a.k.a. the *Research Team of Data & Web Mining*, Athens University of Economics and Business, available at: <http://www.db-net.aueb.gr> (last visited 1 July 2019).

39. A detailed announcement of the first Web archiving attempt in Greece by AUEB was presented during the 19th Pan-Hellenic Conference of Academic Libraries in 2010 in Athens. See V. Plachouras, C. Kapetis, M. Vazirgiannis, *Archiving the Web Sites of Athens University of Economics and Business* (2010), Athens, available at: http://www.db-net.aueb.gr/files/ArchivingAUEB_CameraReady_V6.pdf (last visited 1 July 2019).

40. See C. Lampos, M. Eirinaki, D. Jevtuchova, M. Vazirgiannis, *Archiving the Greek Web* (n/a), available at: <http://www.db-net.aueb.gr/files/LEJV04-IWAW.pdf> (last visited 1 July 2019); S. Paulakis, C. Lampos, M. Eirinaki, M. Vazirgiannis, *SEWeP: A Web Mining System Supporting Semantic Personalization* (n/a), available at: <http://www.db-net.aueb.gr/files/PLEV04-PKDD.pdf> (last visited 1 July 2019).

41. The information about TDM deployed by NLG by the authors of this article straight from the NLG. NLG scientists made a public announcement upon NLG's first two efforts to archive the Greek Web during the proceedings of the 24th Pan-Hellenic Conference of Academic Libraries that took place on November 1-2, 2018, in Larissa, Greece; D. Chios, M. Vazirgiannis, P. Meladianos, G. Angelakis, *Archiving the Greek Web* (2018).

42. For the meaning of Robots Exclusion Protocol see <http://www.robotstxt.org/orig.html> (last visited 1 July 2019).

43. Greek logo of the System ("ΕΣΑΕΠ") connotes the ancient Greek language, specifically the phrase (εσαεί < ἐξάει), which means 'forever'.

Table 1 Working Stages of Web Archiving in Greece by NLG

Stage I	Economic and technical study on the needs and content of the Greek Web harvest. Study of international experience	1st Web harvest: broad crawl – national level: text data only
Stage II	Definition of 'Greek' sites to be mined	
Stage III	Data Analysis of 1st Web harvest to create a National Web Archiving System	
Stage IV	Installing and checking the operation of tools for all phases of national Web archiving: extraction, archiving/classification and, finally, user search and access: Heritrix for harvesting, Solr for indexing and Open Wayback for website reconstitution. Use of Netarchive Suite.	2nd Web harvest: broad – national level: text only thematic (text and images)
Stage V	Developing a National Archiving System of Greek Web ('ΕΣΑΕΙ'): the Greek user interface/librarian	

Figure 1 The National Archiving System of Greek Web user interface



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Figure 2 Search tools of The National Archiving System of Greek Web



Figure 3 Search tools of The National Archiving System of Greek Web



nership development regarding TDM in Greece. NLG is already a member of the International Internet Preservation Consortium (IIPC),⁴⁴ which lists as members the EU Member States' National Libraries and other international entities for the purpose of preservation of the World (Cultural) Heritage that 'lives' on the Web. The task of crawling the Web and retrieving from its content works relating to the Greek culture and Greeks

has been vested with NLG through the provision of Article 4(4)(b) of law 4452/2017. This is a difficult task that, aside from the proper legal framework – which does not exist, currently – requires collaboration at the national and international levels such as partnership between NLG and the Internet Archive.

Regarding the possibilities for researchers to delve into the collection of works that form the output of NLG's TDM activity, the sky is the limit. NLG has expressed strong interest in researching the TDM output on scientific purposes related to the Greek language itself, and as a means of inferring from such output ideas with a

44. See about IIPC at: <https://netpreserveblog.wordpress.com/2018/05/22/iipc-content-development-group-whats-on-in-2018> (last visited 1 July 2019).

global resonance over time. The development of any kind of language tools (huge dictionaries, word roots, embedded words etc.) that preserve and highlight the Greek language as a communication medium and as a transmitter of spirit and culture is one of NLG objectives. These language tools will also help in the association and identification of websites based on the semantic relevance of Greek words. In addition, Greek language tools could help in user-communities' identification. Researchers who can benefit from research on collections that originate from Web harvesting and TDM functions could include linguists, historians, journalists, sociologists and other scientists.

One of the issues intended to be subject to thematic Web harvesting by NLG pertains to websites and data related to Greek emigrant Hellenism. This intention demonstrates cultural values, particularly major national particularities and needs as well as the essential concept of 'nation' and the Greek national heritage.

10 TDM and Digital Legal Deposit

TDM and legal deposit as technological and administrative processes, respectively, are not in sync, currently. The legal deposit is an administrative process in which the publishers or authors submit one or more copies of each of their publications for specific deposit with the aim of preserving the written cultural heritage or the cultural heritage that has been imprinted on some medium. Where the deposit of copies of works is provided by law, a legal deposit is made and may be described in law either as compulsory or as voluntary. Compulsory legal deposit is provisioned as mandatory in law, while in the case of voluntary legal deposit the law rules that legal deposit is left to voluntary agreements between the institution to which the deposit is made and publishers or authors who ought to proceed to legal deposit of their works. In most cases of legal deposit, the national library of the country where the law applies is defined as the institution to which the works must or ought to be deposited. Alternative deposit areas and other libraries, such as parliamentary, academic, public, community libraries as well as public archives, may, however, be envisaged in legal deposit provisions.

The statutory legal deposit in Greece was provisioned for the first time through law ΣΜΗ/1867, which was amended by law ΓΧΑΖ#/1910.⁴⁵ Both laws ruled the compulsory legal deposit in which each work had to be deposited in the NLG in two copies as well as in the Library of the Parliament of Greece in one copy. These laws were amended by law 2557/1997. In 2003, law 2557/1997 was amended by law 3149/2003, which

45. See law ΓΧΑΖ#/1910 amending the provisions of law ΣΜΗ# regarding the National Library of Greece and applying to the Library of the Parliament of Greece, including provisions for public and private libraries, Themis 1910.

ruled on subject matter for the NLG. Regarding the legal deposit of works in the NLG, the provisions of Article 12(7), (9), (10) & (12) of law 3149/2003 are important.

The World Intellectual Property Organization provides information on the legislation for administrative systems for legal deposit in effect, worldwide.⁴⁶ There are both compulsory and voluntary legal deposit systems; there are both hard copy (traditional) and electronic legal deposit systems.

WIPO information on the legal deposit systems worldwide indicates that:

- The majority of countries with a legal deposit system in effect have ruled upon it through statutes for copyright.⁴⁷
- The majority of countries with a legal deposit system in effect have opted for compulsory legal deposit.⁴⁸
- Voluntary legal deposit is an exception to the rule, and few countries have adopted it.⁴⁹
- In almost all cases of legal deposit systems the aim is 1) proof of publication of the deposited work, 2) the production of statistical information regarding the published works, as well as bibliographical information regarding the cultural heritage of works published in the country, 3) meeting the needs for scientific research through the pool of deposited works and 4) cultural preservation and development of libraries and archiving organisations.
- There are countries in which the legal deposit system is not related to or is part of the copyright legal framework of the country.⁵⁰

46. WIPO, *Summary of the Responses to the Questionnaire for Survey on Copyright Registration and Deposit Systems*, Annex B.1, available at: http://www.wipo.int/export/sites/www/copyright/en/registration/pdf/b1_legislation_countries.pdf (last visited 1 July 2019).

47. These countries are the following: Albania, Algeria, Armenia, Argentina, Austria, Bahrain, Republic of Belarus, Belize, Bhutan, Brazil, Burundi, Chile, China, Colombia, Costa Rica, Croatia, Czech Republic, Denmark, Ecuador, Finland, Ghana, Greece, Guatemala, Guinea, Hungary, Ireland, Jamaica, Japan, Italy, Kenya, Kingdom of Saudi Arabia, Republic of Korea, Latvia, Liechtenstein, Lithuania, Luxemburg, Madagascar, Mali, México, Republic of Moldova, Mongolia, Monaco, Montenegro, Namibia, Nepal, New Zealand, Norway, Oman, Pakistan, Peru, Romania, Russia, Serbia, Singapore, South Africa, Spain, Sri Lanka, Sweden, Thailand, Tunisia, Ukraine, United Kingdom and United States of America.

48. The following countries have compulsory legal deposit: Albania, Algeria, Argentina, Austria, Bahrain, Belize, Brazil, Bhutan, Chile, China, Colombia, Costa Rica, Croatia, Czech Republic, Denmark, Finland, Greece, Guatemala, Hungary, Kenya, Republic of Korea, Ireland, Italy, Jamaica, Japan, Latvia, Liechtenstein, Lithuania, Luxemburg, Madagascar, Mexico, Republic of Moldova, Monaco, Montenegro, Namibia, New Zealand, Norway, Pakistan, Peru, Romania, Russian Federation, Saudi Arabia, Serbia, Singapore, South Africa, Spain, Sri Lanka, Sweden, Thailand, Trinidad & Tobago, Ukraine, United Kingdom and United States of America.

49. The following countries have voluntary legal deposit systems: Armenia, Burundi, Guinea, Mali, Mongolia and Oman.

50. The countries in which the national legal deposit system is not part of the copyright law legal framework are the following: Belize, Republic of Belarus, Bhutan, Brazil, Burundi, Colombia, China, Costa Rica, Croatia, Czech Republic, Hungary, Ireland, Jamaica, Japan, Kenya, Republic of Korea, Liechtenstein, Lithuania, Mali, México, Republic of Moldova, Mongolia, Namibia, Nepal, New Zealand, Peru, Serbia, Spain, Thailand, Trinidad & Tobago and the United States of America.

- The legal deposit systems cater for works of culture in print or in electronic – digital – format. There are countries in which the legal deposit legislation describes indicatively what is subject to legal deposit. This description may include 1) print materials and materials in electronic format (government publications, collections of laws, collection of international agreements, banknotes, securities, booklets, flyers, posters, postcards, official and trade forms, maps, atlases, scores, text, notes, maps, special prints, journals, newspapers, magazines, bulletins, geographical and other charts, etc.); 2) materials for the blind or partially sighted; 3) special materials for physically impaired persons, including Braille materials; 4) official documents; 5) software or computer programs; 6) musical works in notation and recorded; 7) audio-visual works/performances, broadcast materials, phonogram; 8) electronic editions; 9) non-published documents; 10) patent documents; 11) databases; 12) standards; 13) coins; 14) combined documents.
- There are countries that do not exclude any work from the legal deposit system.⁵¹
- In most countries in which the law caters for both the legal deposit of hard copies and the digital legal deposit copies in electronic format/means, the law does not differentiate substantially regarding the obligation and the consequences of not abiding by it for the legal deposit. Very few countries have passed laws regarding the digital legal deposit in the sense of harvesting of works from the Web.
- Systems for the legal deposit differ significantly in regard to the number of copies of a work that is required by law to be deposited. Differentiation applies also to the time frame within which a work must be compulsorily deposited.⁵²
- Responsible entities for the operation of the legal deposit are the national libraries; there are countries in which the responsibility for the legal deposit is assigned to legal entities other than the national libraries.⁵³
- Accessibility to works collected through the legal deposit system is free of charge.⁵⁴
- In many countries the legal deposit system is linked to the assignment of the International Standard Books Number (ISBN) or the International Standard Serial Number (ISSN) or other such.⁵⁵
- In consideration of legislation per legal deposit systems listed by WIPO, and especially regarding legal deposit systems of EU Member countries, the following conclusions can be drawn:
 - The main purpose of the legal deposit system in each EU Member country is to facilitate the long preservation of works and to ensure that there is unhindered access to the deposited works as part of the cultural heritage of each country.
 - The legal deposit systems in each EU Member State allow for the achievement of secondary goals such as updating national bibliographic information in consideration of cultural production of works deposited accordingly.
 - In all EU Member countries, legal deposit is understood as a process for adding one or more copies of each deposited work in a national archive maintained, in most cases, by the National Library of the country and/or by academic libraries or archiving institutions provisioned in law.
 - The legal deposit system may describe the process for depositing a hard copy of a work as well as for depositing a digital copy of a work online or offline.
 - The legal deposit system concerns the deposition of a work embedded either in a hard copy or in a digital means featuring the work. In the second case there is the ‘digital legal deposit’, which includes the process for deposition of a work online as well as the process for deposition of a digital copy of a work offline.
 - The default legal deposit system may favour either the compulsory or the voluntary option. In most cases of EU Member countries, the option of compulsory legal deposit prevails as the default.
 - Most EU Member countries have set legislation for the legal deposit of a number of non-digital copies of a work (hard copies). Though there are indications of interest in also setting up a process for the deposit of digital copies of a work, most EU Member countries have yet to finalise their digital legal deposit systems to the point where such a process can smoothly cater for both the legal deposit of a work imprinted in a digital means (CD-Rom, DVD etc.) and the online legal deposit of a work harvested from the Web.
 - Among the EU Member countries very few have developed fully functional legal deposit systems that can cater for e-books, e-journals and e-magazines, *i.e.* works published and marketed online. Furthermore, very few countries have designed and implemented
 - Namibia, Nepal, New Zealand, Norway, Pakistan, Peru, Russia, Serbia, Singapore, South Africa, Spain, Sweden, Thailand, Ukraine, United Kingdom and the United States of America.
- 55. See WIPO, Annex B.4, available at: https://www.wipo.int/export/sites/www/copyright/en/registration/pdf/b4_deposit_and_isbn_numbers.pdf (last visited 1 July 2019) regarding the linking of the legal deposit with ISBN or ISSN or other such numbering.

Web harvesting systems in sync with legal deposit systems.

The ‘digital legal deposit’ of a work imprinted in digital means – it is also called ‘electronic legal deposit’ – pertains to the deposition of a work online through a process that may be linked with Web harvesting and Web archiving, too; it may also pertain to the electronic deposit of a work furnished in digital storage means. During the 1996 International Conference of Directors of National Libraries⁵⁶ a common statement of the participants was issued regarding the electronic legal deposit. In 1998, the Council of Europe and the ELBIDA – European Bureau of Library, Information, and Documentation Associations⁵⁷ – issued guidelines on regulation of a policy and the legal framework for libraries in Europe regarding – among other issues – the electronic legal deposit. In 2012, ELBIDA published a document describing the organisation’s basic principles on the acquisition of and access to e-books in consideration of the balanced interests of all the involved parties, specifically the rights holders and the users of works.⁵⁸ ELBIDA’s text on the basic principles for the acquisition of and access to e-books considered the 1981 UNESCO guidelines on the legal deposit, a text that was amended in 2000.⁵⁹

Among the EU Member countries’ systems for digital legal deposit,⁶⁰ the most noticeable cases are those of Germany, The Netherlands, the United Kingdom and France.

56. *Conference of Directors of National Libraries*, available at: <http://www.cdnl.info/> (last visited 1 July 2019).
57. ELBIDA, available at: <http://www.eblida.org/> (last visited 1 July 2019).
58. ELBIDA, *Basic Principles for the Acquisition of and Access to E-books* (2012), available at: http://www.eblida.org/Special%20Events/Key-principles-acquisition-eBooks-November2012/GR-EBLIDA_Key_Principles_on_the_acquisition_of_and_access_to_E-books_by_libraries.pdf (last visited 1 July 2019).
59. UNESCO, *Guidelines for Legal Deposit Legislation*, available at: <http://unesdoc.unesco.org/images/0012/001214/121413eo.pdf> (last visited 1 July 2019).
60. For the legal deposit legislation of EU Member see for Austria, legislation available at: https://www.ris.bka.gv.at/Dokumente/BgblAuth/BGBLA_2009_I_8/BGBLA_2009_I_8.pdfsig (last visited 1 July 2019); for Croatia, legislation available at: https://narodne-novine.nn.hr/clanci/sluzbeni/1997_10_105_1616.html (last visited 1 July 2019); for Denmark, legislation available at: <http://www.kb.dk/en/kb/service/pligtatlevering-ISSN/lov.html> (last visited 1 July 2019); for Estonia, legislation available at: <https://www.riigiteataja.ee/akt/13315265?leaKehtiv> (last visited 1 July 2019); for Finland, legislation available at: <http://www.finlex.fi/fi/laki/alkup/2007/20071433> (last visited 1 July 2019); for Slovenia, legislation available at: <https://www.uradni-list.si/glasilo-uradni-list-rs/vsebina?urlid=200669&stevilka=2977> (last visited 1 July 2019); for Spain, legislation available at: http://www.bne.es/opencms/es/Colecciones/Adquisiciones/DepositoLegal/docs/LEY_DL.pdf & URL: <https://www.boe.es/buscar/act.php?id=BOE-A-2015-8338> & URL: <https://www.boe.es/boe/dias/2015/07/25/pdfs/BOE-A-2015-8338.pdf> (last visited 1 July 2019); for Germany, legislation available at: <http://www.gesetze-im-internet.de/pflav/index.html> (last visited 1 July 2019); for the United Kingdom, legislation available at: <http://www.legislation.gov.uk/ukpga/2003/28/contents> (last visited 1 July 2019); for Ireland, legislation available at: <http://www.irishstatutebook.ie/eli/2000/act/28/enacted/en/html> (last visited 1 July 2019).

10.1 DE

In Germany, the law of 22 June 2006 per National Library of Germany – Deutsche Nationalbibliothek (DNBG)⁶¹ (*i.e.* the German National Library Act)⁶² – rules the compulsory legal deposit of works in paragraph 14 (mandatory deposit requirement) for works imprinted in any digital means (e-books, e-journals, music – files, website content).⁶³ The obligation for legal deposit pertains to works distributed in any material form, *i.e.* paper, electronic data storage media and other media, as well as to works distributed in immaterial forms, *i.e.* works distributed in public networks.⁶⁴

The German National Library Act requires the German National Library to collect, archive and catalogue all ‘media works’ (*Medienwerke*) published in Germany, all media works published abroad in the German language, all translations of German works published abroad, media works about Germany published abroad in other languages (Germanica), and printed works written or published between 1933 and 1945 by German-speaking emigrants. ‘Media works’ are defined as ‘all representations in text, image, and sound that are distributed in material form or made accessible to the public in immaterial form’. This includes non-commercial publications. ‘Printed publications’ (media works in material form) are defined as ‘all representations on paper, electronic data storage media, and other media’. ‘Online publications’ (media works in immaterial form) are defined as ‘all representations in public networks’. The collection mandate of the Library is further defined in the Legal Deposit Regulation (*Pflichtablieferungsverordnung*) and the Collection Guidelines (*Sammelrichtlinien*).⁶⁵ Publications that are of no public interest may be exempted from the legal deposit programme.⁶⁶ The legal deposit requirements support the mission of the German National Library to collect, archive and catalogue all such media works.

Although not explicitly stated in the Act, the German National Library’s collection mandate also covers the collection of websites.⁶⁷ Unlike other national libraries in Europe, the German National Library did not begin

61. See unofficial translation in English of German law per National Library of Germany–Deutsche Nationalbibliothek (DNBG), available at: http://www.dnb.de/SharedDocs/Downloads/EN/DNB/wir/dnbg.pdf?__blob=publicationFile (last visited 1 July 2019).
62. See *Gesetz über die Deutsche Nationalbibliothek* [DNBG] [Act on the German National Library] (2006), BGBl. I, at 1338, as amended, available at: <http://www.gesetze-im-internet.de/dnbg/DNBG.pdf> (last visited 1 July 2019).
63. See J. Gesley, *Digital Legal Deposit: Germany* (2018), Library of Congress, available at: <https://www.loc.gov/law/help/digital-legal-deposit/germany.php> (last visited 1 July 2019) for extensive description of the Digital Legal Deposit in the German National Library.
64. See paragraph 3 of the German law regarding the National Library of Germany—Deutsche Nationalbibliothek (DNBG).
65. See *Verordnung über die Pflichtablieferung von Medienwerken an die Deutsche Nationalbibliothek [Pflichtablieferungsverordnung] [PflAV]* [Legal Deposit Regulation], 17 October 2008, BGBl. I, at 2013, as amended, available at: <http://www.gesetze-im-internet.de/pflav/PflAV.pdf> (last visited 1 July 2019).
66. See Legal Deposit Regulation, § 1, para. 1, sentence 2.
67. Collection Guidelines, para. 2.2.0.3.2; *Deutscher Bundestag: Drucksachen und Protokolle [BT-Drs.]* 16/322, 12-3.

collecting online publications by Web harvesting, but initially focused only on digital versions of existing physical publications. It started with monographs (e-books) and university publications (such as online doctoral dissertations) and eventually expanded to include other online publications such as e-papers and e-serials.

In 2010, the German National Library started making preparations for Web harvesting with the first Web crawl taking place in 2012. It collects only selected websites whose preservation is in the public interest in selective harvesting runs. Online publications in the public interest may include news websites, but also forums and blogs. However, as such websites are subject to constant change, the harvesting is repeated on a regular basis. The harvesting itself is automated, whereas the address of the website, collection depth and frequency are determined on a case-by-case basis and entered manually. The German National Library uses a 'Web crawler' that searches and stores predefined addresses for that purpose.⁶⁸

Web crawling is assumed to fall under the Library's collection mandate. However, until an amendment of copyright law entered into force on 1 March 2018, the periodic harvesting of all German Internet domains, meaning all '.de' domains, was prohibited. The German Copyright Act originally only allowed the German National Library to save online publications on a first and one-time basis. Repeated retrieval of an online publication was an extension of existing archival contents and therefore a violation of German copyright law.⁶⁹ In 2017, the legislature therefore proposed an amendment to the Copyright Act and the German National Library Act to grant the German National Library the right to automatically and repeatedly harvest works that fall under its collection mandate.⁷⁰ The Library is now entitled to archive websites even without requesting permission from the respective rights holders.⁷¹

10.2 NL

The National Library of the Netherlands (Koninklijke Bibliotheek) has delved into the matter of legal deposit of works in digital means as of 1994. By 1999, Koninklijke Bibliotheek set up its Deposit for Netherlands Electronic Publications (DNEP) and initiated a process for the legal deposit of works in digital media after a five-year experimentation with the subject matter. The

68. Collection Guidelines, para. 2.2.0.3.2.

69. *Copyright Act of 9 September 1965* (Federal Law Gazette I, at 1273), as last amended by Art. 1 of the Act of 1 September 2017 (Federal Law Gazette I, at 3346), available at: https://www.gesetze-im-internet.de/englisch_urhg/englisch_urhg.html (last visited 1 July 2019).

70. *Gesetz zur Angleichung des Urheberrechts an die aktuellen Erfordernisse der Wissensgesellschaft [Urheberrechts-Wissensgesellschaftsgesetz] [UrhWissG]* [Act to Align Copyright Law with Current Requirements of the Knowledge Society] [Copyright-Knowledge Society Act], 1 September 2017, BGBl. I, at 3346, available at: http://www.bgbl.de/xaver/bgbl/start.xav?startbk=Bundesanzeiger_BGBl&jumpTo=bgbl117s3346.pdf (last visited 1 July 2019).

71. German National Library Act, §16a, para. 1 ('automatically and systematically'); Copyright Act, § 60e, para. 1.

DNEP system of Koninklijke Bibliotheek changed in 2005. In 2014 the same system was upgraded to the e-Depot system.⁷²

Currently, there are three ways in which publishers can deposit digital publications in Koninklijke Bibliotheek's e-Depot system: First, e-books are being stored in the Koninklijke Bibliotheek's e-Depot via an e-book platform. Koninklijke Bibliotheek's partner for this purpose is the company Central Bookhouse, which is the largest distribution centre of books and e-books in the Netherlands. Central Bookhouse includes the ISBN and separately delivers all metadata of e-books with ISBNs. Publishers are asked for permission before Koninklijke Bibliotheek stores these e-books. Second, Koninklijke Bibliotheek offers a Web-based application form. Publishers can upload their digital e-books and digital magazines together with the metadata. This platform is intended for smaller publishers who are not connected with Central Bookhouse and for foundations, associations and individual authors.⁷³ Third, larger (international) publishers Koninklijke Bibliotheek are offered the possibility of File Transfer Protocol (FTP)-transfer, which allows Koninklijke Bibliotheek to automatically receive scientific journal articles from the publishers' databases together with the necessary metadata.

Scientific electronic publications from Dutch universities and other scientific research institutions do not need to be deposited as they are automatically retrieved (harvested) by Koninklijke Bibliotheek from the repository of the institution concerned on the basis of the aforementioned mutual agreements.⁷⁴

In 2007, Koninklijke Bibliotheek started archiving selected Dutch websites. As of January 2018, the Library had harvested 13,200 websites totalling 32 terabytes (TB) of data, preserved them and made them accessible to readers on Koninklijke Bibliotheek's premises.⁷⁵ The Library mostly selects websites with cultural and academic content, but also includes ones that are innovative, popular or relevant to Dutch society, such as sports pages.⁷⁶

10.3 UK and IE

In the UK the Legal Deposit Libraries Act of 2003 requires publishers to send one gratis copy of each publication to the Legal Deposit Office of the British

72. Koninklijke Bibliotheek, *History: The KB and Digital Preservation*, available at: <https://www.kb.nl/en/organisation/research-expertise/long-term-usability-of-digital-resources/history-the-kb-and-digital-preservation> (last visited 1 July 2019). See J. Gesley, *Digital Legal Deposit: The Netherlands* (2018), Library of Congress, available at: <https://www.loc.gov/law/help/digital-legal-deposit/netherlands.php> (last visited 1 July 2019) for extensive description of the Digital Legal Deposit in the National Library of the Netherlands.

73. See KB, *Depositing Individual Digital Publications*, available at: <https://www.kb.nl/en/organisation/for-publishers/depositing-publications/depositing-individual-digital-publications> (last visited 1 July 2019).

74. *Ibid.*, note 31.

75. KB, *Web Archiving*, available at: <https://www.kb.nl/en/organisation/research-expertise/long-term-usability-of-digital-resources/web-archiving> (last visited 1 July 2019).

76. KB, *Selection*, available at: <https://www.kb.nl/en/organisation/research-expertise/long-term-usability-of-digital-resources/web-archiving/selection> (last visited 1 July 2019).

Library within one month of its publication. There are six libraries in the UK & Ireland that are assigned by law⁷⁷ with the legal deposit right: the National Library of Scotland, National Library of Wales, Bodleian Library in Oxford, Cambridge University Library and Trinity College Library in Dublin.⁷⁸

The Legal Deposit Libraries Act of 2003 provides in its Chapter 28, Section 6 et seq. for the legal deposit of non-printed works. There are significant restrictions for use and access to deposited works in non-print format that are provisioned in Section 7 of Chapter 28 of the Legal Deposit Libraries Act of 2003. Section 8 of Chapter 28 of the said UK law describes the cases in which the reproduction of works available online is allowed to the Library, including for the purpose of legal deposit. Also, Section 8 of Chapter 28 of the Legal Deposit Libraries Act of 2003 describes the cases in which the reproduction of databases is allowed without any violation of database rights for the purpose of legal deposit.

On 6 April 2013, ten years after the Legal Deposit Libraries Act was enacted, the Legal Deposit (Non-Print Works) Regulations 2013 entered into force.⁷⁹

These Regulations extended the obligation to deposit materials to non-print materials to enable the legal deposit libraries to build and preserve a *'national collection of e-journals, e-books, digitally published news, magazines and other types of content'*.⁸⁰

The 2013 regulations enable the legal deposit libraries to claim and receive non-print publications, notably those in an electronic format, from publishers. The British Library is entitled to one gratis copy of every offline work that is published in the UK. The other deposit libraries are able to request a copy. The format of the copy of offline material *'must be of a quality most suitable for preservation as agreed by the publisher and the library or, in the absence of agreement, of the quality decided by the publisher'*.

In cases where publishers issue two versions of a single publication, an electronic version and a print version, the default form of deposit continues to be print, although the publisher and library may mutually agree

that the work may be deposited in electronic format rather than print format.⁸¹ The 2013 regulations enable the publisher and deposit library to agree to another method of delivering online content, such as through a secure upload, and this agreement will satisfy the requirement contained in Section 1 of the Legal Deposit Libraries Act 2003 to deliver content while continuing to be subject to the restrictions and exemptions that the regulations apply to non-print materials. The material must be provided in the form that is *'most suitable for preservation purposes'*,⁸² as determined by agreement between the deposit library and the publisher or, in the absence of such an agreement, as determined by the publisher. If such an agreement is made, the materials must be delivered within one month after a request is made in writing by the deposit library.⁸³ For cases of offline materials and online materials obtained under agreement, the publisher must include a copy of any computer program and/or information necessary to access the work provided and a copy of a manual or other material that accompanies the work and is available to the public.⁸⁴

In cases where there is no agreement for the deposit of online material, the 2013 regulations permit deposit libraries to obtain a copy of online materials that fall within the criteria of the regulations through an automated process, known as *'Web harvesting'*. This process, which is coordinated between the deposit libraries to ensure sufficient coverage and prevent overburdening publishers' websites, occurs where a computer fitted with software requests content from a website, which responds automatically with a copy of the content and its associated metadata.⁸⁵

The regulations provide that the material be provided automatically once the content has been requested by the software. This applies to content freely available as well as content subject to public-access restrictions, such as behind a login page.⁸⁶ In cases of material behind a login page, the deposit library must provide notice to the publisher at least one month before Web harvesting begins to enable the publisher to provide login details to the deposit library. This login information must be used for subsequent requests to the same site for content contained behind a password-protected wall. In cases of material behind a login page, the visit by the Web harvesting software to the login page is *'deemed to be a request for the online works behind that page'*.⁸⁷

77. Copyright Act of 1911; see, also, Legal Deposit Libraries Act of 2003, Explanatory Notes, §4, according to which *Under section 15 of the Copyright Act 1911, a copy of each book or serial or other printed publication which is published in the UK is required to be deposited, free of charge, in the British Library. In addition, five other libraries (the National Libraries of Scotland and Wales, and the University libraries of Oxford, Cambridge and Trinity College Dublin) are each entitled to receive, on request, one free copy of any book or other printed publication published in the UK. These libraries, together with the British Library, are collectively known as the legal deposit libraries (or deposit libraries).*

78. See C. Feikert-Ahalt, *Digital Legal Deposit: United Kingdom* (2018), Library of Congress, available at: <https://www.loc.gov/law/help/digital-legal-deposit/uk.php> (last visited 1 July 2019) for extensive description of the Digital Legal Deposit in the British Library and the Legal Deposit Libraries of the UK & Ireland.

79. *Legal Deposit Libraries (Non-Print Works) Regulations 2013*, SI 2013/777, §2, available at: <https://www.legislation.gov.uk/si/2013/777/contents/made> (last visited 1 July 2019).

80. British Library, *Depositing Electronic Publications*, available at: <https://www.bl.uk/aboutus/legaldeposit/websites/elecpubs/> (last visited 1 July 2019).

81. *Legal Deposit Libraries (Non-Print Works) Regulations 2013*, §16(1).

82. *Legal Deposit Libraries (Non-Print Works) Regulations 2013*, §5.2.

83. *Legal Deposit Libraries (Non-Print Works) Regulations 2013*, §3.6.

84. *Legal Deposit Libraries (Non-Print Works) Regulations 2013*, §7.1.

85. *Legal Deposit Libraries (Non-Print Works) Regulations 2013*, §13; *Legal Deposit Libraries (Non-Print Works) Regulations 2013*, Explanatory Memorandum, SI 2013/777, §§7.2 & 8.1.

86. *Legal Deposit Libraries (Non-Print Works) Regulations 2013*, §16(3).

87. *Legal Deposit Libraries (Non-Print Works) Regulations 2013*, §3.4.

10.4. FR

In France, Articles 131-1 to 133-1 of French Heritage Law⁸⁸ as amended by Loi 2006-961,⁸⁹ which made Directive 2001/29/EC part of the French legal framework on Copyright, and Decree of 19 December 2011, provision for the legal deposit, including the digital legal deposit.

The default medium for deposit to the National Library of France is still the work's physical copy. However, the National Library of France⁹⁰ may require the deposit of an electronic file as a substitute for the physical copy of the document.⁹¹ The manner in which an electronic file may be deposited in lieu of a physical copy of the document is subject to the depositor's agreement. The National Library of France's online instructions on the deposit of books specify that books published in both electronic and paper formats must be deposited in both media, as 'one type of deposit is not a substitute for the other'.⁹²

Sound recordings and videos may be deposited in digital format. However, they must always be submitted in a medium that allows the public to see them, and with any password or other information necessary to access them.⁹³ Similarly, software and databases must be submitted in a medium that allows their use, and with any password or other information necessary for use or access.⁹⁴ Cinematographic works that are meant to be shown in movie theatres must be deposited with the National Centre of Cinema.⁹⁵ Other movies on a photochemical medium (*i.e.*, film), particularly movies made for the purposes of information, training or promotion, are also to be deposited with the National Centre of Cinema if at least six copies have been produced for

viewing by an audience. For most movies subject to deposit with the National Centre of Cinema, two copies must be provided, one in a photochemical medium and the other in digital format.⁹⁶ The digital copy must be provided on an unencrypted hard disk or USB key.

Internet legal deposit applies to 'all types of publications disseminated on the Internet: institutional or personal websites, free or paid-access periodicals, blogs, commercial websites, video platforms or digital books'. In principle, everything that is published on the Internet in France is subject to legal deposit. In practice, this means that the legal deposit obligation applies to websites registered under a '.fr' top-level domain and to any website edited by persons or organisations domiciled in France.⁹⁷ The legal deposit of websites does not require any action on the part of their editors. Instead, the National Library of France principally relies on automatic archiving via a Heritrix-based open-source 'crawler-bot' software. This automatic archiving proceeds through a sampling method based on 'criteria aimed at ensuring the best possible representation' of content.

The National Library of France conducts two types of website collecting. The first consists of bulk automatic harvesting to collect snapshots of websites belonging to the French domain. The second type consists of focused crawls based on a selection of sites and centred on a particular event or theme. If content is found to be inaccessible at the moment of capture – whether for technical reasons (such as password-protected contents) or commercial reasons (such as paid-access or subscription-based content) – the National Library of France may contact the website editor to find technical solutions on a case-by-case basis.

The Heritage Code requires that Internet content be collected 'at least once a year'.⁹⁸ This means that the National Library of France may conduct several collection sessions throughout the year.

11 The Case of Digital Legal Deposit in AU

The legal deposit system applicable to the National Library of Australia is contained in the Copyright Act 1968. The Copyright Act was amended in 2015 to extend the legal deposit system to digital material. Of particular interest are the Copyright Act's Sections 195CA, 195CB, 195CC, 195CD, 195CE, 195CF.

96. *Code du patrimoine* [Cultural Heritage Code], Dépôt légal au Centre national du cinéma et de l'image animée, Art. R132-28-1.

97. *DÉPÔT LÉGAL DES SITES WEB : MODE D'EMPLOI*, available at: <https://www.bnf.fr/fr/centre-d-aide/depot-legal-des-sites-web-mode-emploi> (last visited 1 July 2019).

98. *Code du patrimoine* [Cultural Heritage Code], Dépôt légal des services de communication au public par voie électronique, Art. R132-23-1.

88. *Code du patrimoine*, available at: <https://www.bnf.fr/fr/legislation-relative-au-depot-legal> (last visited 1 July 2019).

89. *Loi 2006-961 du 1er août 2006 relative au droit d'auteur et aux droits voisins dans la société de l'information*, available at: <https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000266350&dateTexte=&categorieLien=id> (last visited 1 July 2019).

90. See N. Boring, *Digital Legal Deposit: France* (2018), Library of Congress, available at: <https://www.loc.gov/law/help/digital-legal-deposit/france.php> (last visited 1 July 2019) for extensive description of the Digital Legal Deposit in the National Library of France.

91. *Code du patrimoine* [Cultural Heritage Code] art. L132-8, available at: <https://www.legifrance.gouv.fr/affichCode.do?cidTexte=LEGITEXT000006074236> (last visited 1 July 2019).

92. *Dépôt légal des livres* [Legal Deposit of Books], National Library of France, available at: http://www.bnf.fr/fr/professionnels/depot_legal/a.d_livres_mod.html (last visited 1 July 2019).

93. *Code du patrimoine* [Cultural Heritage Code], Dépôt des phonogrammes, vidéogrammes et documents multimédias, available at: <https://www.legifrance.gouv.fr/affichCode.do?cidTexte=LEGITEXT000006074236&idSectionTA=LEGISCTA000024240089> (last visited 1 July 2019).

94. *Code du patrimoine* [Cultural Heritage Code], Dépôt des logiciels et des bases de données, available at: <https://www.legifrance.gouv.fr/affichCode.do?cidTexte=LEGITEXT000006074236&idSectionTA=LEGISCTA000024240075> (last visited 1 July 2019).

95. *Code du patrimoine* [Cultural Heritage Code], Dépôt légal au Centre national du cinéma et de l'image animée, available at: https://www.legifrance.gouv.fr/affichCode.do?sessionid=F9ED292457BF0D7B622541428D97190E.tplgr24s_1?idSectionTA=LEGISCTA000024240111&cidTexte=LEGITEXT000006074236&dateTexte=20190622 (last visited 1 July 2019).

The decision-tree graphic⁹⁹ on the National Library of Australia's website regarding the legal deposit obligation of both hard copy and online works is very clear and succinct in regard to the legal deposit obligation. The key points of the Australian digital legal deposit system are the following:¹⁰⁰

- The amended Copyright Act of Australia authorises the Director-General of the National Library of Australia to request, in writing, a publisher to deliver material that he or she has made available online, where the Director-General ‘*considers that a copy of the material should be included in the national collection of library material*’. Online publications for which a request has been made must be deposited with the NLA within one month of the publisher receiving the request. Publishers who do not receive a request may still deposit their works voluntarily.
- The legislation enables the National Library of Australia to request the deposit of a publication through the use of a Web harvesting robot. The guidance material¹⁰¹ explains that
 - a. If the material is freely available on a website, the publisher must not do anything that would prevent the National Library from automatically collecting (with a robot harvester) the material from that website.
 - b. If the material is available on a website but is not freely accessible, the publisher must deliver the material through the e-deposit service or other means as agreed with the Library, within one month of being requested.
 - c. If the material is not available on a website but is online material, the publisher must deliver the material through the e-deposit service or other means as agreed with the Library, within one month of being requested.
- The e-deposit service on the National Library of Australia's website enables the deposit of online materials, such as e-books, electronic journals, magazines and newsletters, sheet music and maps.¹⁰²

Regarding access to the deposited works, there is a differentiation between commercial publications and non-commercial publications. The commercial status of electronic publications is identified by publishers when depositing the publication. A publisher can allow basic access as permitted by the Copyright Act, meaning that users of the National Library of Australia's services will be able to only view, and not download or copy, a com-

mercial publication in the library's reading rooms in Canberra.¹⁰³ Non-commercial publications with basic access as permitted under the Copyright Act will be available as read-only in Trove, the national discovery service. Users will not be allowed to download these publications.¹⁰⁴ If a publisher allows a publication to be made freely available, then ‘*anyone will be able to download and save deposited electronic publications to their computer or mobile device via a link in the National Library's online catalogue and Trove*’.¹⁰⁵ Publishers can also apply an embargo period of twelve months for books, music scores and maps or a period of six months for journals, magazines and newsletters. During this period only basic access as permitted under the Copyright Act will apply, and after the embargo period ends the publication will be made freely available.¹⁰⁶ When depositing an electronic publication, publishers can also specify that the publication has a Creative Commons licence and select the one that applies.

All works submitted to the National Library of Australia through the legal deposit system must be free from Digital Rights Management (DRM), *i.e.* must be free from any technical means that restrict access to the publication and free from any Technological Protection Measures (TPMs) such as encryption of files, proprietary locks or watermarks.¹⁰⁷

13 Conclusion

TDM is provisioned in Articles 3 and 4 of Directive 2019/790/EU on Copyright in the DSM as a mandatory exception to the right of reproduction (Art. 5(a) of Database Directive; Art. 2 of InfoSoc Directive; Art. 4(1)(a) & (b) of Computer Programs Directive) and to the sui generis right (Art. 7(1) of Database Directive), which includes extraction and reutilisation of the contents of a database as well as to the new right of press publishers regarding the protection of their publications concerning online uses (Art. 15(1) of Copyright in the DSM Directive). TDM is not provisioned as an exception to the right of communication to the public of works (Art. 3(1) of InfoSoc Directive) and the right of making available to the public (Art. 3(2) of InfoSoc Directive). The EU ‘*Acquis Communautaire*’ before the passage of the new Directive on Copyright in the Digital Single Market could not cover TDM and could not eliminate legal uncertainty regarding it and research activity undertaken in consideration of it. Therefore, the passage of Directive 2019/790/EU was necessary to cover TDM throughout EU within the scope of the DSM.

99. See National Library of Australia, *How to Deposit?* available at: <https://www.nla.gov.au/legal-deposit/how-to-deposit> (last visited 1 July 2019).

100. See K. Bunchanan, *Digital Legal Deposit: Australia* (2018), Library of Congress, available at: <https://www.loc.gov/law/help/digital-legal-deposit/australia.php> (last visited 1 July 2019) for an extensive analysis of the Legal Deposit System of Australia.

101. National Library of Australia, *Deposit of Electronic Publications with the National Library of Australia, Guide to Requirements for Publishers* (2016), available at: <https://www.nla.gov.au/sites/default/files/deposit-of-electronic-publications.pdf> (last visited 1 July 2019).

102. See National Library of Australia, above n. 99.

103. See National Library of Australia, *Access*, available at: <https://www.nla.gov.au/legal-deposit/access-to-electronic-publications> (last visited 1 July 2019).

104. *Ibid.*

105. *Ibid.*

106. *Ibid.*

107. *Ibid.*



Ευρωπαϊκή Ένωση
Ευρωπαϊκό Κοινωνικό Ταμείο

Επιχειρησιακό Πρόγραμμα
Ανάπτυξη Ανθρώπινου Δυναμικού,
Εκπαίδευση και Διά Βίου Μάθηση

Ειδική Υπηρεσία Διαχείρισης

Με τη συγχρηματοδότηση της Ελλάδας και της Ευρωπαϊκής Ένωσης



Before the passage of the new Directive on Copyright in the DSM a few EU Member States enacted national law catering for TDM. These EU Member States are the United Kingdom, France, Estonia and Germany. Before the passage of Directive 2019/790/EU, Greece passed a law – *i.e.* law 4452/2017 – assigning TDM to the NLG, which operates as the official national depository and archive of digital publications, data and meta-data produced in the country or related to the Greek culture. This operation includes the monitoring and archiving of the Internet (Web archiving) or other technology environment. To this end, the NLG shall undertake, allocate and coordinate the actions concerned at the national level, which, of course, include TDM. Since the passage of law 4452/2017, the NLG has engaged in TDM focusing on works online and on websites under the .gr domain or websites under the .edu or .com domains that were composed in Greek. Research on works online through TDM is possible at the NLG and through its ‘ΕΣΑΕΠ’ National System, which evolves gradually as Greece’s TDM tool for Web harvesting and Web archiving. ‘ΕΣΑΕΠ’ National System is one of the many new online tools and services developed by the NLG in its new era and premises at Stavros Niarchos Foundation Cultural Centre.

TDM entails the use of new embedding algorithmic applications and algorithms that are essentially the backbone of computational methods applied to solve problems/improve performance based on experience. The application of algorithms for text and document classification is typical in libraries and archives wherein documents available online are harvested and archived. The more algorithmic applications and algorithms developed, the more TDM in the NLG as well as in other EU Member States and beyond can become a research tool of prominent importance for text, data or other works – ‘*text*’ in its widest meaning.

The legal deposit is an administrative process in which the publishers or authors submit one or more copies of each of their publications to specific deposit for the purpose of preservation of the written cultural heritage or of the cultural heritage that has been imprinted on some medium. The National Library of each EU Member State is assigned the legal deposit operation and is responsible for imposing on publishers and authors their legal deposit obligation. In the era of TDM the legal deposit evolves into digital legal deposit, which pertains to works imprinted in digital means – it is also called ‘electronic legal deposit’. Digital Legal Deposit pertains to the deposition of works online through a process that may be linked with Web harvesting and Web archiving too. There are EU Member States, such as Germany,

Netherlands, United Kingdom, Ireland and France, that have developed notable digital legal deposit systems.

The case of Australia and its National Library, in which TDM and digital legal deposit systems have been developed is remarkable. Australia’s Web harvesting and Web archiving have been among the oldest and most effective and operational worldwide.

The Potential of Public Policy on Open Access Repositories

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Abstract

To address the potential of public policy on the governance of OARs it is necessary to define what is meant by public policy and the importance of public policy in designing an efficient governance framework. Critical components are the subject matter of public policy and its objectives. Hence, it is useful to consider declarations, policies and statements in relation to open access practice and examine the efficiency of these arrangements towards the improvement of stakeholders' engagement in governance of OARs. Secondly, policies relating to dissemination of scientific information via OARs should be examined. In this regard, it is relevant to consider the public policy basis for Intellectual Property (IP) laws that concerning the utility of OARs. Therefore, economic theories relevant with the role of IP laws should be examined. Such examination depicts to what extent these laws facilitate the utility of OARs. In order to specify justifications for the desirability of OARs the objectives of social theories should be also considered. Thus, there is consternation that without legal protection against copying the incentive to create intellectual property will be undermined. As scholarly communication infrastructure evolves, it is necessary to recognize the efforts of the relationship between Intellectual Property Rights (IPRs) and communication technologies in the context of public policy and after engagement with it. After employing such multilevel approach, the paper argues about a socio-economic framework to enhance the governance of OARs through public policy.

Keywords: public policy, dissemination, governance, open access, repositories

1 Literature Review

In modern times, the growth of information technologies (IT) is ongoing, and digitisation of creative content is part of institutional norms. Hence, access to scientific information is of paramount importance. The literature shows that there are different options to disseminate scientific information (*i.e.* gold open access and green open access). The creation of Open Access Repositories (OARs) facilitates the dissemination of information. The OARs tool is one of the core elements of green open access. Scholars argue that an OAR is an online

database that makes the full text of items it contains freely and immediately available.¹ According to the OpenAIRE project, an OAR is a database or a virtual archive established to collect, disseminate and preserve scientific output; OARs make scientific articles and datasets freely available.² It is also argued that an OAR is a digital archive created and maintained to provide universal and free access to information in an electronic format as a means of facilitating research and scholarship.³ OARs can be linked either to an institution or to a research field or subject.⁴

To set up an institutional OAR, an enhancement of the associated governance infrastructure and actors involved is also required.⁵ Thus, the governance framework to be adopted is a subject of intense debate.⁶ Furthermore, the example of open government illustrates the importance of citizens' right to access documentation of the government. In turn, such access allows for public oversight. In this regard, public policy could contribute to the green open access (*i.e.* OARs) governance infrastructure. To address the public policy potential on governance using OARs, it is necessary to consider a variety of specific issues. First, it is necessary to define what is meant by public policy, its interaction with social laws and the importance of public policy in designing an efficient governance framework. Critical components that should be addressed are the subject matter of public policy and its objectives.⁷ In this

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1. Stephen Pinfield, 'A Mandate to Self Archive? The Role of Open Access Institutional Repositories' (2005) 18(1) *Serials: The Journal for the Serials Community* 30 ('A Mandate to Self Archive?'); Peter Suber, *Open Access* (The MIT Press, 2012).
2. Paolo Manghi *et al.*, 'An Infrastructure for Managing EC Funded Research Output - The OpenAIRE Project' (2010) 6(1) *The Grey Journal (TGJ): An International Journal on Grey Literature* <<https://pub.uni-bielefeld.de/record/1972842>>.
3. Joan M. Reitz, *Dictionary for Library and Information Science* (Libraries Unlimited, 2004).
4. Clifford A Lynch, 'Institutional Repositories: Essential Infrastructure For Scholarship In The Digital Age' (2003) 3(2) *Portal: Libraries and the Academy* 327 ('Institutional Repositories').
5. Gerard Van Westrienen and Clifford A. Lynch, 'Academic Institutional Repositories: Deployment Status in 13 Nations as of Mid 2005' (2005) 11(09) *D-Lib Magazine* <http://www.dlib.org/dlib/september05/westrienen/09westrienen.html?utm_source=dbpia&utm_medium=article_detail&utm_campaign=referece> ('Academic Institutional Repositories').
6. Carlos Juiz, Carlos Guerrero and Isaac Lera, 'Implementing Good Governance Principles for the Public Sector in Information Technology Governance Frameworks' (2014) 03(01) *Open Journal of Accounting* 9.
7. Christoph Knill and Jale Tosun, *Public Policy: A New Introduction* (Palgrave Macmillan, 2012) ('*Public Policy*'); Charles F. Manski, 'Response to the Review of "Public Policy in an Uncertain World"' (2013)

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regard, it is useful to consider the existing declarations, policies and statements in relation to open access practice and examine the efficiency of these arrangements for the improvement of stakeholders' engagement in the governance of OARs. Open access removes price barriers (e.g. subscriptions, licensing fees, and pay-per-view fees) and permission barriers (e.g. copyright and licensing restrictions) and is aligned with the copyright holder's concession; its evaluation is of paramount importance concerning stakeholders' engagement in the governance of OARs.

Second, policies relating to the dissemination of scientific information via OARs should be examined. In this regard, it is relevant to consider the public policy basis for Intellectual Property (IP) laws concerning the utility of OARs. Therefore, economic theories relevant to the role of IP laws should be examined. This is necessary in order to ascertain the extent to which these laws facilitate the utility of OARs. In order to specify justifications for the desirability of OARs, the objectives of social theories should also be considered. It is an undeniable fact that IP is usually able to be copied by persons that have not borne any of the cost of this creativity type. Thus, there is concern that without legal protection against copying, the incentive to create IP will be undermined.

Third, as scholarly communication infrastructure evolves, it is necessary to recognise the efforts of the relationship between Intellectual Property Rights (IPRs) and communication technologies in the context of public policy and after engagement with it. Such discussion shows the relationship between IPRs and communication technologies to the influence on the public policy. After employing such a multilevel approach, the article argues about the potential of public policy on the governance of OARs.

1.1 Participatory Democracy and Public Policy: Conceptual Foundations

This section argues in favour of fairer regulations that could stem from public policy. In this context, it is necessary for citizens to be informed in order to be able to participate in the formulation of appropriate public policy.⁸ Thus, participatory democracy could be considered a significant innovation in democracy.⁹ Moreover, public policy – in both aspects of its processes and substantive content – requires that people have a voice in its formation.¹⁰ In the context of the argument of the article, an obvious aspect of public policy is that access to information is critical to enabling citizens to exercise their voice, to effectively monitor government and hold government accountable and to enter into an informed dialogue about decisions that affect their lives. More-

over, citizens can improve their living standards and better their lives when they have access to knowledge.¹¹ In the following discussion, a brief explanation of the different types of understanding of public policy sets the context for the argument that participatory democracy is a suitable device for citizens to engage in the processes of forming policies. There are several definitions of public policy, and they highlight relevant theoretical debates. The concept of social justice in the broader sense is about the links between citizens, institutions and governments. Strong public policy should solve problems efficiently, serve justice, support governmental institutions and governmental policies and encourage active citizenship.¹² Thus, the ideal objective of public policy is of direct relevance to social infrastructure and consequently active citizenship.¹³ Public policy and governance are thus interrelated, as both require fairness, and that means adhering to principles of social justice.

Scholars argue that the challenge for governments is to find ways to engage others in the policymaking process and to make citizens' participation fundamental.¹⁴ It is imperative to realise that the term of public value stems from government actions and is an effort to benchmark the total benefits. Nevertheless, it also reflects the public's perception of fairness and distributional equity, implications of service provision for trust and legitimacy and the benefits arising from co-production of services.¹⁵ The issue of citizens' participation is part of a large debate among scholars. Such participation provides an opportunity to influence public decisions and has long been a component of the democratic decision-making process.¹⁶ Public administration is progressively concerned with placing the citizen at the core of policymakers' decisions.¹⁷ Not only is citizens' participation

123(570) *The Economic Journal* F412; Xun Wu et al, *The Public Policy Primer: Managing the Policy Process* (Routledge, 2010) ('*The Public Policy Primer*').

8. Brian Baird, 'To Improve Public Policy' (2013) 340(6131) *Science* 432.

9. Hercules Bantas, *Jurgen Habermas and Deliberative Democracy* (Smashwords, 2010).

10. Frank Fischer and Herbert Gottweis, *The Argumentative Turn Revisited: Public Policy as Communicative Practice* (Duke University Press, 2012) ('*The Argumentative Turn Revisited*').

11. Richard Calland and Kristina A Bentley, *The Impact and Effectiveness of Transparency and Accountability Initiatives: Freedom of Information* (SSRN Scholarly Paper No ID 2305479, Social Science Research Network, 1 July 2013) <http://papers.ssrn.com/abstract=2305479> ('*The Impact and Effectiveness of Transparency and Accountability Initiatives*').

12. Michael Hill and Frederic Varone, *The Public Policy Process* (Routledge, 2014).

13. Avi Brisman, 'The Violence of Silence: Some Reflections on Access to Information, Public Participation in Decision-Making, and Access to Justice in Matters Concerning the Environment' (2013) 59(3) *Crime, Law and Social Change* 291 ('*The Violence of Silence*').

14. Ann Capling, Patrick Low and World Trade Organization, *Governments, Non-State Actors and Trade Policy-Making: Negotiating Preferentially Or Multilaterally?* (Cambridge University Press, 2010) ('*Governments, Non-State Actors and Trade Policy-Making*'); Christopher D. Piros and Jerald E Pinto, *Economics for Investment Decision Makers: Micro, Macro, and International Economics* (John Wiley & Sons, 2013) ('*Economics for Investment Decision Makers*').

15. Jan Donovan, 'Engaging Stakeholders and Citizens in Developing Public Policy' (2003) 3.

16. Denis Bouyssou et al., *Decision Making Process: Concepts and Methods* (John Wiley & Sons, 2013) ('*Decision Making Process*').

17. There are differing views about how public policy is formed. For further discussion about this, see Dunn (2003). For example, there are advocates who claim that public policy can be made by leaders of religious and cultural institutions for the benefit of the congregation and participants. Also see Hesmondalgh (2005) and Kahan and Braman (2005). Hesmondalgh argues that policymakers should be guided by core principles such as transparency, accessibility and openness concerning

crucial to the scope of public policy and long-term efforts, but it can also be an additional instrument for efficient governance.¹⁸

There is extensive literature on participatory democracy, and not every scholar has the same understanding of the concept. For instance, Brown argues that participatory democracy is direct democracy in the sense that all citizens are actively involved in all important decisions.¹⁹ The concept commonly refers to movements, such as the civil rights movement or the women's suffrage movement, which gather a group of people who make decisions democratically about the direction of the group.²⁰ Generally, it is a concept that points to political consideration regarding improving collective decision-making.²¹ It emphasises the right of everyone to participate and considers it important that everybody subjected to a collective decision has the opportunity to participate in consequential deliberation about that decision.²² Pateman argues that participatory democracy is often treated as a normative argument concerned with aspirations. This statement helps me to argue that participatory democracy establishes an ideal and that so do OARs, but both are desirable aspirations. The goal of this thesis is to build or construct an argument that justifies OARs as the foundation for creating a participatory democracy of well-informed citizens. Citizens can influence public policy by being involved in the processes of policy formation. This leads us to the next relevant issue: how to create social consensus within participatory democracy. For this reason, the next part of the argument will develop rationales for engaging people in creating fairer regulations; by implication, and more specifically, this would help in the creation of regulations regarding OARs.

1.2 The Importance of Public Policy as a Basis for Governance

The first issue that is relevant to the focal research question is the importance of public policy as a basis for governance. In order to address this issue, it is necessary to consider the role of public policy in guiding legislative formulation and its value in issues relevant to the governance of OARs. The literature shows that governance has been aptly considered as an instrument for

bureaucratic and decision processes. Moreover, he states, politicians and public servants are accountable to the public, and this principle illustrates the importance of public policy towards desired solutions for social concerns. It follows that policymakers should support freely accessed information sources through proper public policy. Therefore, public policy and its formulation ought to stem from the public will or the public interest.

18. M Fagence, *Citizen Participation in Planning* (Elsevier, 2014).
19. Wendy Brown, 'Power after Foucault' in *The Oxford Handbook of Political Theory* (Oxford University Press, 2006) 65.
20. Ian Brown and Christopher T Marsden, *Regulating Code: Good Governance and Better Regulation in the Information Age* (The MIT Press, 2013) ('*Regulating Code*').
21. Samantha Besson and José Luis Martí, *Deliberative Democracy and Its Discontents* (Ashgate Publishing, Ltd., 2006).
22. Cristina Lafont, 'Deliberation, Participation, and Democratic Legitimacy: Should Deliberative Mini-Publics Shape Public Policy?' (2015) 23(1) *Journal of Political Philosophy* 40 ('Deliberation, Participation, and Democratic Legitimacy').

problem-solving.²³ As far as the public sector is concerned, this takes place within a context that is governed by policy, legislation, organisational design, organisational culture and in which the external environment is shaped by economic, social, political and cultural considerations. Correspondingly, relevant legislation that stems from this governance framework and protects IPRs is of paramount significance and should therefore be examined.

According to Lehman and Phelps, public policy is a principle that no person or government official can legally perform an act that tends to injure the public.²⁴ Furthermore, public policy manifests the common sense and common conscience of the citizens that extends throughout the state and is applied to matters of public health, safety and welfare. Another crucial perspective of public policy is Kilpatrick's work that views public policy as a system of law, regulatory measures, courses of action and funding priorities concerning a given topic promulgated by a government entity of its representatives. Thus, it is realised that public policy gathers imperative content, which is inevitably linked with the law. He argues, moreover, that individuals and groups often attempt to shape public policy through education advocacy or by mobilising interest groups. Therefore, it is logical to assume that the process always follows inherent actions that stem from competing interest groups to influence policy designators in their favour. All in all, he concludes that a major aspect of public policy is law.

Geurts characterises public policy as a complex, dynamic, constantly evolving, interactive and adaptive system. Its 'making' process is stakeholder-driven. Actors are engaged in a goal-driven decision-making process and have a great deal of autonomy in the way they organise their work. The process has two dimensions: a political dimension and a production dimension.²⁵ Thus, it is clear that the subject matter of public policy is of paramount importance from the economic, political and legal perspectives. Hence, public policy can be seen as an attempt by government to address a public issue by instituting laws, regulations, decisions or actions that are pertinent to the problem at hand and that harmonise with concerns that stem from the rapid growth of technology infrastructure.²⁶

Further, Habermas has developed the concept of 'public sphere'²⁷ in order to delineate the proper operation of

23. Christopher Ansell and Jacob Torfing, *Handbook on Theories of Governance* (Edward Elgar Publishing, 2017).
24. Jeffrey Lehman and Shirelle Phelps, *West's Encyclopedia of American Law* (Thomson/Gale, 2005).
25. Thei Geurts, 'Public Policy Making: The 21st Century Perspective', *Be Informed - The Business Process Platform* (18 July 2011) <http://beinformedblog.blogspot.com.au/2011/07/public-policy-making-21st-century.html> ('Be Informed - The Business Process Platform').
26. For further information regarding public policy, see Smith and Larimer (2013), Theodoulou and Cahn (2012) and Birkland (2010).
27. Jürgen Habermas is a German sociologist and philosopher in the tradition of critical theory and pragmatism. He was one of the second generation of philosophers and social theorists in the Frankfurt School whose members included Horkheimer, Adorno, Walter Benjamin, Erich Fromm and Herbert Marcuse. Moreover, global polls consistently find that Hab-

the public sphere.²⁸ On the basis of Habermas' work, the simplicity of the public sphere forms a reality in which different considerations, specifically to address societal needs, are clearly and freely traded, unrestrained by exterior compulsions. Hence, Habermas' 'public sphere' offers an appropriate framework for an effective public policy basis in relation to OARs governance. However, in order to examine public policy as basis and benchmark, it is imperative to adopt Habermas' preceding notion of 'public sphere' and its content. Further, it can be utilised to address the question of how public policy supports as an additional instrument for open access infrastructure and freedom of information. According to Habermas, it is an area in social life where individuals can come together to freely discuss and identify daily problems of society, and within this discourse, political action is influenced. Moreover, Habermas' use of the term 'public sphere' signifies a realm of social life in which something approaching public opinion can be formed. Furthermore, it is admitted that access is guaranteed to all citizens. As a result, citizens act as a public body when they confer in an unrestricted fashion concerning general interest matters. Therefore, in a large public body, this kind of communication requires specific instruments for transmitting information and influencing those who receive it. In addition, the public sphere is an incoherent space where individuals and groups of interest assemble to argue about issues of common interest and, where feasible, reach a mutual judgement. Accordingly, the public sphere can be seen as a theatre in contemporary societies where political participation is enacted through the medium of discussion and as a realm of social life where public opinion can be formed. Moreover, Habermas argues that the public sphere was coextensive with public authority. For that reason, it can be stated that the characteristics of public policy, from Aristotelian perspective and as inherent idioms, is public authority.²⁹ Furthermore, this type of authority can have a parallel meaning to public policy; hence, it is recognised that its norms and forms are of paramount importance in relation to public interest and information access within the public domain.

The significant discourse in relation to the ideal belief in Habermas' 'public sphere' is that the government's laws, policies and regulations should be steered by the 'public sphere', and the only legitimate governments are those that comprehend the importance of the 'public sphere'. Thus, public policy stems from this discussion, and individual needs are a basic part of its subject mat-

ter. Taking everything into account, an efficient governance framework for OARs ought to have an inevitable link with public opinion, public interest and mutual judgement.

Considerable debate prevails over whether there is one coherent set of principles that can govern the study and understanding of the public policy process.³⁰ As in every field of endeavour, the definition of key terms and ideas is often very important, but it can also lead to considerable contention. The proper author of public policy is a subject of continuing debate. It has been suggested that public policies can be made by leaders of religious and cultural institutions for the benefit of the congregation and participants. Literature reflects that there are many possible ways to define public policy.³¹ Scholars argue that public policy is whatever governments decide to do or not to do.³² According to Peters, public policy defines the sum of government activities, whether acting directly or through agents, as it has an influence on the life of citizens.³³ Other scholars state that public policy consists of political decisions for the implementation of programmes to achieve societal objectives.³⁴

Reaching a consensus on one definition regarding the public policy seems to be problematic since all of the variants of the definition suggest that public policymaking is public – it affects a greater variety of people and interests than do private decisions.³⁵ Therefore, government and the policies made by government are sometimes very controversial and frustrating, yet very important. But because the public is the source of political authority – that is, the authority to act on the public's behalf – it is clear that government is at the centre of efforts to make public policy.

As a result, this issue should be examined in relation to open access, its influences and its significant link to technological developments. A contrary view is that public policy and its formulation ought to stem from the public will or the public interest. Piro and Pinto, for example, note that the challenge for governments is to find a way to engage others in the policymaking process.³⁶ However, it should not be forgotten that citizens' participation is fundamental. It is acknowledged that the infrastructure of public administration is progressively

ermas is widely acknowledged as one of the world's leading intellectuals. To sum up, his significant (and continuing) contributions in the late twentieth and early twenty-first centuries to philosophy, political theory, communication theory, critical social theory, legal theory, critical education studies, among other disciplines, are renowned.

28. Jürgen Habermas, *The Theory of Communicative Action: Reason and the Rationalization of Society, Volume 1: Reason and the Rationalization of Society Vol 1* (Polity, 1 edition, 2015) ('*The Theory of Communicative Action*').

29. Aristotle, *The Nicomachean Ethics*, ed Lesley Brown, tr David Ross (Oxford University Press, Revised edition, 2009).

30. E. Sørensen and J. Torfing, *Theories of Democratic Network Governance* (Springer, 2016).

31. Lafont (n. 22).

32. Thomas R. Dye, *Understanding Public Policy* (Prentice Hall, 1995).

33. B Guy Peters, 'Governance as Political Theory' in *Civil Society and Governance in China* (Palgrave Macmillan, New York, 2012) 17 https://link.springer.com/chapter/10.1057/9781137092496_2.

34. Charles L. Cochran and Eloise F. Malone, *Public Policy: Perspectives and Choices* (Lynne Rienner Publishers, 2014) ('*Public Policy*').

35. Beatrice Crona and John Parker, 'Learning in Support of Governance: Theories, Methods, and a Framework to Assess How Bridging Organizations Contribute to Adaptive Resource Governance' (2012) 17(1) *Ecology and Society* <https://www.ecologyandsociety.org/vol17/iss1/art32/> ('*Learning in Support of Governance*').

36. It is imperative to realise that the term of public value stems from government actions and is an effort that concerns benchmarking the total benefits flowed. Nevertheless, it also reflects the public's perception of fairness and distributional equity, implications of service provision for trust and legitimacy and the benefits arising from co-production of services. For further information see Donovan (2003).

concerned with placing the citizen at the core of policy-makers' decisions. Not only is citizens' participation crucial in relation to the long-term outcomes of their governance, but it is also an agent for relevant decisions.³⁷ Additionally, the issue of citizens' participation is part of a large debate among scholars and thus provides individuals with an opportunity to influence public decisions and has long been a component of the democratic decision-making process.³⁸ Simultaneously, the environment for policy and designation has grown in complexity. The ownership of concepts is usually blurred, particularly when more than one department, ministry or levels of government are concerned.³⁹

2 Open Access Practice

Open access can be defined as the practice of providing online access to scientific content that is free of charge to the reader. In the context of research and development, open access typically focuses on access to scientific information, which refers to two critical categories: a) peer-reviewed scientific research articles (published in academic journals) and b) scientific research data (data underlying publications and/or raw data).

In relation to open access, it is crucial to realise what it actually entails. The practice of open access was initially defined during a meeting in Budapest among a diverse group of open access advocates who were brought together by the Open Society Institute in early December 2001.⁴⁰ In accordance with this definition, open access makes articles freely available on the Internet, permitting any user to read, download, copy, distribute, print, search or link to the full texts of these articles; open access also allows readers to trawl articles for indexing, pass them on as data for software or use them for any other lawful purpose, without financial, legal or technical barriers other than those inseparable from gaining access to the Internet itself. The only constraint on reproduction and distribution, and the only role for copyright in this domain, should be to give authors control over the integrity of their work and the right to be properly acknowledged and cited.

2.1 Open Access Repositories

According to Pinfield et al., an OAR is the physical space reserved for permanent or intermediate storage of archival material without any access restrictions.⁴¹ Yet there are advocates who argue that it is where digital

content and assets are stored and can be searched and retrieved for later use.⁴²

It is a given fact that the conditions of the modern information environment have evolved through the years, touching on every social aspect of everyday life.⁴³ It is also worth mentioning that among every generation of end users, there is a gap in skills with regard to information and communication technologies, obtained through education or lifelong learning. Based on these skills, one is able to fully satisfy information needs within access to any type of information service. Thus, it led to a social division between information-rich (*i.e.* those with access to information) and information-poor individuals (*i.e.* those deprived of such access), resulting in informational, and consequently social, inequalities.

By introducing the concept of the Internet and its infrastructure during the 1990s, important change was inflicted on utility and information access opportunities. Moreover, several journals and editions adopted different types of formats. In particular, the traditional print format converted to electronic ones, and journals started publishing their content a few months earlier than the printed edition digitally. As a result, the content of journals became available to registered users by limiting postal delay and annihilating distance by providing home access to information. Thus, it is clear that there is fertile ground for introducing important changes to the information model through an upcoming revolution that could be brought through open access to information via institutional repositories.

3 Public Policies Relating to OAR

To determine the proper public policy basis for OAR, it is necessary to examine relevant economic, social and IT policies in the area. It is further necessary to evaluate the merits of these theories, identify inconsistencies between such theories and consider tensions in the applications of such theories.

3.1 Social Policies in Support of Free Exchange and Access to Information

According to Diamond's lecture at Hilla University for Humanistic Studies, democracy is a system of government with four key elements: (i) a political system for choosing and replacing the government through free and fair elections, (ii) the active participation of the people, as citizens, in politics and civic life, (iii) the protection of the human rights of all citizens and iv) a rule of

37. Douglas R Holmes, *Integral Europe: Fast-Capitalism, Multiculturalism, Neofascism* (Princeton University Press, 2010) (*'Integral Europe'*).

38. Steven Grabow, Mark Hilliker and Joseph Moskal, *Comprehensive Planning and Citizen Participation* (Extension Service, 2006).

39. Henry E Smith, 'Property Is Not Just a Bundle of Rights' (2011) 8(3) 279.

40. Stefan Baack, 'Datafication and Empowerment: How the Open Data Movement Re-Articulates Notions of Democracy, Participation, and Journalism' (2015) 2(2) *Big Data & Society* <<https://doi.org/10.1177/2053951715594634>> (*'Datafication and Empowerment'*).

41. Stephen Pinfield et al, 'Open-Access Repositories Worldwide, 2005–2012: Past Growth, Current Characteristics, and Future Possibilities'

(2014) 65(12) *Journal of the Association for Information Science and Technology* 2404 (*'Open-Access Repositories Worldwide, 2005–2012'*).

42. Peter Suber, 'Timeline of the Open Access Movement', <http://legacy.earlham.edu/~peters/fos/timeline.htm>.

43. Maria Bottis, 'The Protection of Private Life and the European Legislation with Regard to Personal Data: Thoughts on the Protection of Private Life in the USA' in *Honorary Volume, Stathopoulos* (Sakkoulas, 2009) 809.

law, in which laws and procedures apply equally to all citizens.⁴⁴ Moreover, it is understood that governments ought to provide services for citizens' equality and protection of human rights.

Nevertheless, it should be mentioned that there is an imminent link between governments and people that manifests in elections. Furthermore, the preceding democratic procedure aims to elect a new government that ought to serve the virtue of democracy by balancing different types of interests.⁴⁵ Therefore, the relationship between government and citizens should be addressed as it illustrates the importance of a proper public policy basis from the social perspective.

According to Fischer (2003), there are five main strategies that should be implemented by governments for fostering incentives for innovation and constructing a 'social cell' in regard to information preservation and distribution. In addition, within these five strategies there are social theories based on the rapid growth of technology for a proper public policy basis in order to balance the interests of copyright owners and end users. Specifically, the five strategies include (i) the social theory of technological innovation, (ii) innovative initiatives theory, (iii) the theory of productive relationship, (iv) the theory of pros or the positive theory and (v) the theory of grants.

Within the social theory of technological innovation, governments can engage in technological innovation themselves. With respect to many sorts of public goods, governments have for centuries responded to the risk of suboptimal private-sector production by supplying the relevant objects or services themselves. Hence, the same theory can be employed in the governmental public policy context of information protection and dissemination. In particular, governmental initiatives should be increased and spread to society.

According to the second theory of innovative initiatives, governments can contribute to innovative initiatives by private actors and thus illustrate that private sector can further support the public good of information conservation and dissemination by implementing the necessary public policy basis for effective governance of OARs.

Third, the theory of productive relationship is based on the idea that there should be a productive relationship between government and citizens. Therefore, prizes and rewards ought to be offered to individuals and organisations who contribute to society by providing beneficial innovations.

Fourth, the theory of pros or the positive theory, in the context of IP law, posits that governments can assist creators (or innovators) by disguising public information that is essential to implement their innovations.

44. Larry Diamond, 'What Is Democracy?' (2004) <https://web.stanford.edu/~ldiamond/iraq/WhalsDemocracy012004.htm>.

45. Roberto Caso and Federica Giovanella, *Balancing Copyright Law in the Digital Age - Comparative Perspectives: Preface* (SSRN Scholarly Paper No ID 2529954, Social Science Research Network, 24 November 2014) <https://papers.ssrn.com/abstract=2529954> ('Balancing Copyright Law in the Digital Age - Comparative Perspectives').

Thus, incentives are offered to other persons who wish to take advantage of those breakthroughs.

Finally, the theory of grants argues that governments may grant innovators exclusive rights to engage in certain kinds of activities with respect to their innovations. Yet it is illustrated that social justice is of paramount importance for the modern knowledge economy.

3.2 Economic Theories for Intellectual Property Laws

The literature shows that the examination of IP has competing interests involved (*i.e.* those of copyright owners and end users) and could lead someone to investigate their economic impact on the balance among competing IPRs within the legislative framework.⁴⁶ Therefore, economic justifications of IP should be considered as additional means to support the appropriate public policy applied to benefit the governance of OARs.⁴⁷ According to this logic, the economic parameter that stems from IP is of paramount importance. Moreover, economists explore ways of efficiently allocating scarce resources to unlimited wants and realise that private property rights are a plausible way of dealing efficiently with scarcity.⁴⁸ Thus, this issue should be addressed in order to delineate the focal research question of this article.

However, there are advocates who argue that inventions are utilitarian works and that, therefore, the principal economic theory applied is about utilitarianism.⁴⁹ Kapczynski (2012) argues that the field of IP should only use the utilitarian-efficiency approach. Moreover, utilitarian theorists generally endorse the creation of IPRs as an appropriate instrument to foster innovation.⁵⁰ It is argued that the public, authors and inventors have 'signed' a social contract in which the public grants authors and inventors exclusive rights to their works for a limited duration, which provide enough incentive for them to create and develop.⁵¹ Yet once the exclusivity period expires, the rights are transferred to the public and become part of the public domain. Hence, it is acknowledged that freedom of expression, creation, dissemination of information and its protection ought to coexist in order to support effective outcomes such as innovation. Nevertheless, this justification illustrates the importance of a creator's rights in relation to social evo-

46. Daniele Archibugi and Andrea Filippetti, 'The Globalisation of Intellectual Property Rights: Four Learned Lessons and Four Theses' (2010) 1(2) *Global Policy* 137 ('The Globalisation of Intellectual Property Rights').

47. Catherine Colston and Kirsty Middleton, *Modern Intellectual Property Law* (Psychology Press, 2005).

48. Meir Perez Pugatch, *The International Political Economy of Intellectual Property Rights* (Edward Elgar Publishing, 2004).

49. Frank Arntzenius, 'Utilitarianism, Decision Theory and Eternity' (2014) 28(1) *Philosophical Perspectives* 31.

50. Peter S. Menell, *Intellectual Property and the Property Rights Movement* (Social Science Research Network, 12 July 2007) <http://papers.ssrn.com/abstract=1000061>.

51. Richard A. Posner, 'Intellectual Property: The Law and Economics Approach' (2005) 19(2) *The Journal of Economic Perspectives* 57 ('Intellectual Property'); Steven Shavell, *Foundations of Economic Analysis of Law* (Harvard University Press, 2009).

lution and the appropriate way that it can be shared while under protection.

In addition, it is undeniable that the majority of authors who pursued economic analyses of IP have relied on the 'Kaldor-Hicks' criterion. The criterion helps lawmakers select a system of regulations that maximises the aggregate welfare, which is measured by the end users' ability and willingness to pay for goods and services in relation to information.⁵² Nevertheless, they disagree sharply about the implications of that criterion in this discipline. Thus, three different economic justifications dominate the literature.

The incentive theory, which is the most common, claims that an optimal doctrine is the one that maximises the difference between (a) the current discounted value to end users of the intellectual products whose creation is induced by holding out to creators and inventors the carrot of monopoly power and (b) the ensemble detriments generated by such a system of incentives.⁵³ In other words, this theory urges a governmental lawmaker to establish or grow IP protection. Doing so would help end users by stimulating creativity more than it would hurt them by constricting their access to intellectual products or raising their taxes.

Another one important economic justification is relevant to the patent systems.⁵⁴ Further, its objective is to eliminate or reduce the tendency of IPRs to advance duplicative or uncoordinated inventive activity.⁵⁵ Economic waste of this sort can occur at the three stages in the inventive process.

Finally, it is indispensable to realise that copyright and patent systems play crucial roles in letting potential producers of intellectual products know what end users want. Hence, they channel productive outcomes in directions most likely to enhance the welfare of end users. Based on this rationale, sales and licences will ensure that goods get into the hands of people who need them and who have the ability to pay for them. Only under specific circumstances where transaction costs would prevent such voluntary exchanges should the holders of IPRs be denied total scrutinisation in relation to the use of their works. Therefore, the necessity of a public policy basis is imperative when concerning the governance of OARs.

3.3 The Relationship between Communication Technologies and Public Policy

A further dimension to be considered is the interplay between communication technologies and relevant

advancements with public policy and its objectives. It is recognised that the discourse about the relationship between communication technologies and public policy ranges across an extensive assortment of concerns. For example, the concern of this article is about the social role of communication scholarship in relation to the analysis and implementation of public policy. As Peterson (2008) claims, the communication is one site where policy is publicly worked over and is the subject of public policy, most notably in laws and regulations on forms of speech, mass media and telecommunication. Therefore, it is admitted that this issue should be examined from a sociological perspective, based on theories relevant to social policy.

It is recognised that communication technologies have created an enormous change in the way that information is generated, regenerated and distributed. Therefore, relevant decisions to adopt appropriate governance frameworks and copyright laws for arising communication technologies and usages of works are complicated.⁵⁶ Thus, it is understood that this issue should be examined as the focal research question of this article is how the public policy basis should be formed to facilitate OARs. Hence, another issue that should be addressed and offer information relevant to this question is the inevitable relationship between communication technologies and public policy.

The significance of communication technologies in conjunction with public policy was depicted within the twenty first meeting of the International Colloquium on Communication in 2008, which focused on communication and public policy.⁵⁷ Moreover, it is undeniable that information is of paramount importance in relation to communication technologies. As Drahos) states, the term of information is the most significant primary good. Yet he insists that this stems from its role in the economy, the development of knowledge and culture and its impact on power in a society.⁵⁸ This is beneficial in order to understand the crucial role of information regarding the needs relevant to communication.

Other scholars also claim that the importance of information as primary good can be valued beneficially by concentrating on the outcomes of its imperfect deficient dispersion.⁵⁹ Prejudgements of various kinds are paradigms of deficient dispersion. However, it is not acceptable to embrace these negative aspects as far as the concept of communication technologies and its contexts are examined in relation to public policy modern regimes. To sum up, it is understood that public policy is another

52. D.N. Dwivedi, *Microeconomics: Theory And Applications* (Pearson Education India, 2002) ('*Microeconomics*'); Aristides N Hatzis and Nicholas Mercuro, *Law and Economics: Philosophical Issues and Fundamental Questions* (Routledge, 2015) ('*Law and Economics*').

53. Nikos Koutras, *Building Equitable Access to Knowledge Through Open Access Repositories* (Information Science Reference, 2019).

54. Robert P Merges, *Justifying Intellectual Property* (Harvard University Press, 2011).

55. Peter S Menell, Mark A Lemley and Robert P Merges, *Intellectual Property in the New Technological Age 2017: Vol. II Copyrights, Trademarks and State IP Protections* (Clause 8 Publishing, 2017) ('*Intellectual Property in the New Technological Age 2017*').

56. Sophia Christou and Alana Maurushat, 'Waltzing Matilda' or 'Advance Australia Fair'? *User-Generated Content and Fair Dealing in Australian Copyright Law* (SSRN Scholarly Paper No ID 1457570, Social Science Research Network, 17 August 2009) <<http://papers.ssrn.com/abstract=1457570>> ('*"Waltzing Matilda" or "Advance Australia Fair"?*').

57. Eric Peterson, 'An Introduction to Communication and Public Policy' (2009) 1.

58. P. Drahos, *Regulatory Theory: Foundations and Applications* (ANU Press, 2017) ('*Regulatory Theory*').

59. Rochelle Cooper Dreyfuss and Justine Pila, *The Oxford Handbook of Intellectual Property Law* (Oxford University Press, 2018).

concept that can outperform the rapid development of communication technologies. Therefore, it should be adopted to these evolved norms and frameworks rather than being effective and more responsive to the needs of citizens at the national and international levels.

4 Discussion

The previous discussion illustrates that there is a need to propose a socio-economic framework. The proposed framework aims to reconcile and integrate the appropriate social and economic policy discussed earlier. This helps us consider tensions and current options for weighing and reconciling such tensions. In this respect, combining one social theory with one economic theory has the potential to build a scientific approach or strategy to counterbalance competing interests.

Owing to the social theory of technological innovation, governments can engage in technological innovation themselves. In other words, governments ought to take additional initiatives to boost and support individuals' creativity and innovation. As the literature reflects, governments should consider the role of the private sector in the context of public goods production.⁶⁰ Therefore, governments should play a more central role in terms of initiatives that increase innovation. This social theory sets up a societal finality on behalf of governments' role and its contribution to society. Hence, this theory should be complementary to the applied public policy in the context of initiatives to support intellectual protection and further information dissemination.

Given this, the incentive theory demonstrates the economic theory that should be the second complementary element of the proposed socio-economic framework. Accordingly, it is maintained that governmental lawmakers should pursue increased IP protection while stimulating individuals' creativity, which in turn helps further innovation. It is also argued that inventions do not generally implicate the personal interests of the creator.⁶¹

The proposed framework could be called the 'Techinncentive' framework. This framework would set up the appropriate basis for providing incentives for technological innovation. Additionally, it has the potential to be applied in the context of public policy on behalf of government: (a) to further support IP protection, (b) to increase individuals' involvement (for example actors from private sector) in the production of innovations with societal benefits, (c) to facilitate access opportunities to scientific information produced by educational institutes (*i.e.* universities, colleges, senior schools, research centres) and (d) to boost dissemination of

information via green open access. All in all, the objectives of 'Techinncentive' has the potential to benefit also the academic society towards the production of knowledge and distribution of scientific research results.

60. Lionel Orchard and Hugh Stretton, *Public Goods, Public Enterprise, Public Choice: Theoretical Foundations of the Contemporary Attack on Government* (Springer, 2016) ('*Public Goods, Public Enterprise, Public Choice*').

61. Akash Kamal Mishra, *Intellectual Property Rights In Cyberspace* (Cyberlekh Publications, 2019).

