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Between Permission and Protection: AI as a Challenge to Established Approaches to Law and Innovation

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BETWEEN PERMISSION AND PROTECTION:

AI AS A CHALLENGE TO ESTABLISHED APPROACHES TO LAW AND INNOVATION

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ABSTRACT

Legal literature does not offer any sound theoretical development on the relationship between law and innovation. In practice, two broad rival approaches – protective or permissive – emerged over time as social regulation was introduced in sectors of activity where innovation looms large. The protective approach requires evidence that an invention has a positive impact on society before it can be diffused (e.g. pharmaceuticals), whereas the permissive approach allows for diffusion without prior examination (e.g. digital sector). Each of these approaches is by now embedded in the "innovation culture" of their respective sectors. In recent years, the limits of these approaches have become more apparent. This contribution surveys the two approaches and the innovation cultures associated with them. Furthermore, co-existence between them became fraught, once the dynamism of the digital economy induced convergence with heretofore distinct sectors under a protective approach. Seeing that none of these approaches is appropriate for AI, the contribution then investigates whether a third approach, based on responsible innovation would be feasible and how the EU seems to follow it in the AI Act.

1. Introduction

The relationship between law and innovation has always been fraught, in no small part because the climate of openness and flexibility needed to handle the inherent

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unpredictability of innovation is in many ways antithetical to the bedrock legal principles of certainty and stability.

In an earlier contribution, one of us explained how the two main bodies of legal literature that relate to that relationship both fail to account for the entirety of innovation (Butenko and Larouche 2015).

On the one hand, the "law and technology" literature (Brownsword and Yeung 2008; Brownsword and Goodwin 2012; Brożek, Kanevskaia, and Pałka 2023) tends to treat invention as exogenous to law, ignoring how law influences which invention obtains. That literature also often identifies "issues" with inventions without a proper risk analysis (harm and probability); it also frequently proposes to intervene without first having ascertained whether current legal and other tools might not suffice. Finally, calls for "regulation" ensue, where despite a relatively broad understanding of regulation (Lessig 2009), the nuanced and sophisticated analysis featured in regulatory studies (Baldwin, Cave and Lodge 2012) is usually missing.[1] Command-and-control regulation is the go-to solution.

On the other hand, the subset of Law and Economics dealing with innovation does recognize that invention is endogenous to law, but it typically focuses primarily on how to incentivize and stimulate invention (Cooter 2011; Bohannan and Hovenkamp 2012). Law and Economics tends to assume that innovation is invariably good for society; it ignores or at least neglects that inventions do not always lead to "good" innovations from a public policy perspective.

Instead of relying on these two flawed bodies of legal literature, one can go back to the literature on innovation in neighbouring disciplines – including economics, business, sociology or philosophy of science – to build a model of innovation that would be suitable

[1] Regulatory studies point to the diversity of regulatory avenues available to public authorities next to command-and-control, among others incentive-based regulation, market-harnessing controls, disclosure regulation, design solutions and private-law remedies relying on rights and liabilities (Baldwin, Cave and Lodge, 2012, 105-136).

for legal and policy analysis. In short, according to that model, innovation comprises three elements:

(i) an invention, that is an addition to the existing stock of knowledge. It is a discrete event, i.e. it occurs at a given time and place and results from the actions of one or more inventors;[2]

(ii) the diffusion of that invention throughout society. Diffusion is a collective event, yet it results from the disaggregated decisions of members of society whether they each want to adopt the invention or not.[3] In principle, it is a descriptive element (the invention is adopted or not);[4]

(iii) a positive impact of that invention on society upon diffusion and adoption, so that the resulting innovation is in line with fundamental rights and public policy. Much like diffusion, impact also has a collective dimension, except that it is typically assessed at the aggregate level by the State or the polity. It is a normative element (whether it is a "good" innovation or not).

Element	**Dimension**	**Decision**	**Decider**
Invention	Discrete		
Diffusion	Collective	Disaggregated / Descriptive	Market / Society
Impact	Collective	Aggregated / Normative	State / Polity

Figure 1 - Triangular model of innovation

[2] Invention is a discrete event. The invention element covers a vast literature and includes many sub-elements, such as sagacity – itself comprising individual motivation and organisational incentives – and the occurrence of accidental events that trigger the thoughts of the sagacious person. The scope of this paper does not allow for further details to be provided.

[3] Adoption can arise from market decisions (buy, license, use, etc.) or other social interactions (consent, vote, etc.), depending on the invention.

[4] Much as for invention, the diffusion element spans much diverse literature, e.g. on entrepreneurship, the sociology of diffusion and network effects.

Although it is natural to put them in chronological order – invention then diffusion then impact – these three elements can occur in any specific order or even simultaneously. Furthermore, they are interrelated; the three element pairs (invention-diffusion, invention-impact and diffusion-impact) are almost as important to the analysis as each element in isolation. From a legal or public policy perspective, these three elements feature in every innovation. Yet they might not always hold the same significance for the analysis, as the rest of this contribution will elaborate upon.

This triangular model is useful to structure the analysis across the many issues where the relationship between law and innovation is at stake, including competition law, intellectual property or public procurement. In this contribution, we focus on one specific subset of issues, namely the interplay between innovation and what is called "social regulation". Social regulation follows from central public policy aims and seeks to prevent harm to the population (Ogus 2004). Those policy aims are often regrouped under the "SHEC" (Safety, Health, Environment and Consumers) moniker, whose four main themes cover most of social regulation.

Crisply put, when it comes to innovation, the main aim and function of social regulation is to single out "bad" innovation and prevent it from causing harm to society. Accessorily, if "good" innovation can also be fostered, then social regulation is even more successful. At first sight, when transposed upon the triangular model, social regulation appears to be primarily mapping over the "impact" element: it is a matter of ensuring that inventions – if and when successfully diffused – are aligned with SHEC regulation and hence conform with this important area of public policy that aims to prevent harm to society or individuals. Yet as will be explained below, a deeper examination in the light of the triangular model shows that the matter is more elaborate. In current law, the interplay between social regulation and innovation hinges on the diffusion-impact element pair, more specifically on the balance between "diffusion" and "impact".

Social regulation truly took off in the post-War era, and more specifically from the 1960s onwards. It includes vast swathes of legislation and regulation in developed countries,

which are often so intricate that researchers focus on specific subsets rather than on the horizontal issues common to all social regulation (notable exceptions include Ogus 2004; Baldwin, Cave and Lodge 2012; Breyer 1984). At the risk of overgeneralization, we chose to take a horizontal perspective. In order to sharpen the analysis somewhat, we present two general approaches to the treatment of innovation in social regulation, with their respective features and limits. Section 2 sets out the *protective approach* that characterizes many bodies of social regulation, with pharmaceutical regulation as the illustrative case. In contrast, Section 3 presents the *permissive approach* that is the default rule, whereby inventions can be freely diffused amongst prospective adopters.[5] Section 4 explores how the interaction between these two approaches has become problematic. Section 5 puts forward a third approach, derived from *responsible innovation* literature, which could be suitable for AI. Section 6 concludes.

2. The protective approach

The protective approach, as its name indicates, puts the emphasis on protecting society against potential or actual harm flowing from what would be "bad" innovations.

In terms of the triangular model of innovation sketched out above, the protective approach places the impact element in at the forefront, and accordingly downplays the diffusion element. Whilst the precise rationale for opting for a protective approach might vary from one area to the other, a common finding is that the potential harm from certain inventions is so significant (because of its probability or its magnitude, or both) that it is irrelevant or unnecessary to investigate whether the invention is or could be successfully diffused and adopted. An exact assessment of the potential harm associated with an invention is not always possible or achievable, and sometimes the assessment will be erroneous. Under a protective approach, the priority is to avoid Type II errors (false negatives), where the risk associated with an invention is incorrectly evaluated, the invention is then diffused and adopted, and harm ensues. In other words, the objective is to ensure that no harmful

[5] Although it is customary to begin with the default state, for the purposes of our analysis it is preferrable to begin with the protective approach.

inventions are allowed into the market. Therefore, the protective approach makes diffusion of inventions conditional upon a prior finding regarding impact.

Many industries or economic sectors are regulated in accordance with a protective approach to innovation. The best and most elaborate illustrations are found in pharmaceuticals and commercial aircraft. Other sectors where innovation is governed along the lines of the protective approach, but perhaps not as thoroughly as pharmaceuticals or aircraft, include medical devices, motor vehicles, or financial services, to name but the main ones.[6] As we delve deeper into the main features of the protective approach, we will be using pharmaceutical regulation as an example.[7]

2.1 Main features of the protective approach

In a nutshell, as mentioned above, the protective approach subjects the diffusion (and eventual adoption) of an invention to a prior examination of its impact.

When this basic principle is implemented in a concrete legal and regulatory framework, the following features are typically present.

Regulatory domain with defined boundary – First of all, a regulatory domain is defined, within which the legal framework implementing the protective approach applies. For

[6] For example, medical devices are often classified in different level and assigned regulatory controls accordingly. For a discussion of medical device regulation, see Galgon 2016.
[7] For a crisp overview of pharmaceutical regulation, see Rägo and Santoso 2008.

instance, the EU Medicinal Code[8] and the US Food and Drugs Act[9] contain a definition of "medicinal product"[10] or "drug"[11], respectively. These are not just definitions of key legislative terms, a standard practice in legislative drafting. These definitions are also meant to delineate the scope of application of pharmaceutical regulation. Only products that qualify as medicinal products or drugs, as the case may be, fall under the regulation. Setting out and delineating a regulatory domain – typically via a legislative definition – is an essential feature of the protective approach, because that approach constitutes an exception to the default rule (permissive approach). A borderline must therefore secure the domain covered by the exception. Of course, as a side-effect of the definitional apparatus put in place to delineate the regulatory domain,[12] significant resources – usually legal

[8] Pharmaceutical regulation is generally carried out by Member States pursuant to Directive 2001/83 of 6 November 2001 on the Community Code relating to medicinal products for human use [2001] OJ L 311/67, as last amended by Directive 2022/42 [2022] OJ L 118/4 (the "EU Medicinal Code"). This paper refers to the consolidated version available at < http://data.europa.eu/eli/dir/2001/83/2022-01-01>. The Code is currently undergoing a legislative review and overhaul, following a Commission proposal, COM(2023)192 (26 April 2023). The proposal does not change the elements of the current EU Medicinal Code discussed in this paper, unless otherwise indicated. A subset of pharmaceutical products is regulated at Union level pursuant to Regulation 726/2004 of 31 March 2004 laying down [EU] procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [2004] OJ L 136/1, as last amended by Regulation 2019/5 [2019] OJ L 4/24 (the "EU Medicinal Regulation"). This paper refers to the consolidated version available at <http://data.europa.eu/eli/reg/2004/726/2022-01-28>. The Regulation is also currently undergoing a legislative review and overhaul, following a Commission proposal, COM(2023)193 (26 April 2023). Here as well, the proposal does not change the elements of the current EU Medicinal Regulation, unless otherwise indicated.

[9] Food and Drugs Act of 30 June 1906, ch. 3915, 34 Stat. 768, as amended. The Act and its numerous subsequent amendments have been codified at Chapter 9 of Title 21 of the US Code, 21 USC §§ 301 and ff.

[10] EU Medicinal Code, *supra* note 8, Art. 1(2). A medicinal product is "(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or (b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis."

[11] Food and Drugs Act, *supra* note 9, 21 USC § 321(g). Drugs are "(A) articles recognized in the [official pharmacopeia]; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C)."

[12] In our example, only the core definitions of medicinal product and drug were mentioned, but of course the delineation of the regulatory domain is usually more elaborate, since many elements of these definitions are themselves legislatively defined, and neighbouring concepts (foods, supplements, homeopathic products, etc.) are also defined.

professionals and consultants – will be engulfed in litigation on and around this definitional apparatus, with a view to situating cases on the desired side of the regulatory border.

No market access without prior authorisation – Secondly, within the regulatory domain, no product (no invention) can be marketed without obtaining prior authorisation from the competent authorities.[13] The prior authorisation requirement is usually enforced through stringent remedies, including the issuance of administrative fines, the revocation or suspension of (other) authorizations, and the closure of facilities. Breaching it may even result in criminal sanctions.[14]

Authorisation available if criteria are met — Thirdly, market access is available for inventions – and the products that would embody them – that meet certain criteria. The prior marketing authorization is a critical regulatory mechanism designed to ensure that inventions are compatible with the applicable public policy requirements as set out in social regulation. The actual requirements depend on the regulated sector: for instance, human health is at the core of pharmaceutical regulation, whereas commercial aircraft regulation bears more on safety and environmental impact. Financial regulation concerns prudential stability and consumer protection. In all cases, however, the requirements are detailed into specific criteria that inventions need to meet. For instance, new pharmaceutical products must meet specific criteria relating to safety (absence of side-effects), efficacy (ability to achieve the effect sought) and quality (ability to manufacture at consistent quality level).[15]

Prior testing – Fourthly, in order to show that the criteria for obtaining a marketing authorization are met, prior testing is required. Typically, prior testing is a long and

[13] For pharmaceutical products: EU Medicinal Code, *supra* note 8, Art. 6 and EU Medicinal Regulation, *supra* note 8, Art. 3; Food and Drugs Act, *supra* note 9, 21 USC § 355.

[14] In the EU, enforcement of the EU Medicinal Code and the EU Medicinal Regulation is left to the Member States, in line with the basic principles of EU law (see EU Medicinal Regulation, *supra* note 8, Art. 84, reflecting the state of EU law). In the United States, for serious Food and Drugs Act violations, including the marketing of unauthorized drugs, the FDA is authorized to impose criminal penalties, see Food and Drugs Act, *supra* note 9, 21 USC § 333.

[15] EU Medicinal Code, *supra* note 8, Rec. 7 and Art. 8 and 26; EU Medicinal Regulation, *supra* note 8, Rec. 13 and Art. 6; Food and Drugs Act, *supra* note 9, 21 USC § 355 (b) and (d).

expensive process, conducted according to guidelines and standards that have been developed specifically for such testing. It is conducted in laboratory or other experimental settings that are separate from society at large and strictly controlled. Testing produces the evidence that the authority expects to review and assess in order to decide on the authorization request. In pharmaceutical regulation, a firm seeking an authorization for a new drug will carry out clinical trials on that drug, aimed at discovering or verifying the effects of that new pharmaceutical invention. This process often involves multiple phases of testing, including laboratory research, animal studies, and human clinical trials, spanning many years and costing billions of dollars or euro. Regulatory authorities rely on the results of these clinical trials and other detailed documentation to form their opinion on the authorization of medicines.[16] As is the case with other sectors where a protective approach is followed, the regulatory authorities enjoy rule-making powers in specifying how prior testing is to be conducted.[17]

Post-marketing surveillance — Finally, even though the protective approach is geared towards avoiding false negatives (Type II errors), it cannot be excluded that an invention – and the product embodying it – does turn out to cause the kind of harm that the regulation was meant to prevent. A market authorization does not guarantee a "good" innovation, if and once the invention has been successfully diffused. After all, the authorization is based on evidence collected in a controlled test setting. Once the invention is diffused in the population at large and in a real-life environment, situations might arise that were not – or more likely not properly or entirely – provided for in prior testing. For that reason, it is crucial to keep abreast of all information arising from the experiences with the product once it is on the market. Regulation in sectors under a protective approach will therefore typically include a post-marketing surveillance (monitoring) obligation on the part of the producer, with a duty to notify the authority of any relevant information obtained as to the

[16] See EU Medicinal Code, *supra* note 8, Art. 8(3); Food and Drugs Act, *supra* note 9, 21 USC § 355(d).
[17] In the EU, see EU Medicinal Code, *supra* note 8, Annex I and Art. 120. Annex I is further developed in scientific guidelines: see EudraLex: Volume 3 - Scientific guidelines for medicinal products for human use, Volume 4 - Good Manufacturing Practice (GMP) guidelines, and Volume 10 - Clinical trials guidelines, available at: https://health.ec.europa.eu/medicinal-products/eudralex_en. In the US, see Food and Drugs Act, *supra* note 9, 21 USC § 355(b) and (d). In addition, the FDA can enter into agreements with individual applicants on the design and size of clinical trials: 21 USC §355(b)(5).

harmfulness of the product. Should a significant incident arise, a range of remedial paths are available to the producer and the authority, starting from public warnings, moving to product recalls and going all the way to withdrawal from the market. To continue with pharmaceutical regulation as an example, in the EU, adverse drug reactions – noxious and unintended responses to medicines – are estimated to cause around 200,000 deaths annually in the EU.[18] To address this, EU law mandates that each marketing authorization holder, national competent authority, and the European Medicines Agency (EMA) operate a pharmacovigilance system.[19] US law contains similar provisions.[20] Pharmaceutical products are then put under continuous monitoring to collect data on their actual use and long-term effects. This post-market surveillance helps update the evidence gathered during pre-market testing.[21] In case of adverse incidents, regulatory agencies can implement a range of remedies as mentioned above, from issuing public warnings to recalling the product or even withdrawing it from the market entirely.[22]

2.2 The protective approach and innovation

A longstanding criticism directed at the protective approach is that it leads to higher costs for inventors and therefore stifles innovation. In 1973 already, in an influential study, Sam Peltzman argued that US pharmaceutical regulation, with its protective approach, can lead to increased deaths and morbidity because of the cost and delay involved in the process (the so-called "drug lag") (Peltzman 1973). Peltzman and subsequent literature mainly

[18] See European Medicines Agency, Legal framework: Pharmacovigilance, available at: https://www.ema.europa.eu/en/human-regulatory-overview/pharmacovigilance-overview/legal-framework-pharmacovigilance. This estimate (197,000 deaths per year) was made 25 years ago, but it is still considered accurate, see Bouvy and Koopmanschap 2015. It was based on extrapolations from US data, such that the corresponding figure in the US should be in the same range.

[19] The pharmacovigilance system is at EU Medicinal Code, *supra* note 8, Art. 101 and ff., and EU Medicinal Regulation, *supra* note 8, Art. 21 and ff. It was largely developed in subsequent amendments to the original EU Medicinal Code and Medicinal Regulation, consolidated in the versions cited *supra* note 8.

[20] Food and Drugs Act, *supra* note 9, 21 USC § 355(k), imposing record-keeping and information-sharing obligations. The FDA can also require postmarket studies and clinical trials: 21 USC § 355(o). For certain drug categories or when the FDA so requires, the producer must draw a risk evaluation and mitigation strategy before marketing can occur: 21 USC § 355(p) and 355-1.

[21] For an assessment of the state of medical devices PMS in different regions, see Badnjević, Pokvić, Deumić, and Bećirović 2022.

[22] EU Medicinal Code, *supra* note 8, Art. 107f-107g, 107i-107k, 116-117; EU Medicinal Regulation, *supra* note 8, Art. 28; Food and Drugs Act, *supra* note 9, 21 USC § 355(e).

contend that the requirement to prove to the regulatory authority (here the FDA) that a new drug is safe and effective typically demands a series of costly and lengthy clinical trials. This significantly raises the costs of developing new drugs and delays their introduction into the market.[23] Accordingly, protective drug regulation may erode the profits of pharmaceutical firms and thereby diminish their incentive to invest in innovative drugs, leading to a loss of welfare for society as well. A similar line of argument could be made in other sectors where regulation follows a protective approach to innovation.

Although intuitively appealing, this argument does not fully capture the role of regulation. Referring back to the triangular model, the additional costs and delays imposed by a protective approach relate not to the invention, but to the impact element. The basic motivation of researchers to seek to invent, and the incentives of firms or other organisations to finance those endeavours, will always be there. In the case of pharmaceuticals, there are always unmet needs and room for medical progress, and the patent system offers a path to profitable diffusion and eventually adoption (DiMasi and Grabowski 2012).[24] And indeed pharmaceutical research has delivered innovative products, most recently during the Covid-19 pandemic.[25]

The aim of the prior authorization requirement, with the attendant testing, is to establish that the invention has a positive impact, i.e. it is aligned with public policy aims as translated in the relevant regulation. The protective approach shifts the assessment of

[23] Peltzman also noted that, assuming that the new drug is patented, the time it takes to get the approval encroaches upon the period of effective patent life where the inventor can reap rents arising from patent protection. That issue, however, has been addressed in most jurisdictions by extending the duration of the patent for a period commensurate with the time required to obtain marketing approval: see Regulation 469/2009 of 6 May 2009 concerning the supplementary protection certificate for medicial products [2009] OJ L 152/1, as amended, for the EU, or the Hatch-Waxman Act of 1984 for the US, codified at 35 USC § 156.

[24] It is apparent from the historical survey made by DiMasi and Grabowski that, next to the regulatory impact identified by Peltzman, many other factors have affected the innovative performance of the sector over the last decades.

[25] It is still an open question whether the successful development of Covid-19 vaccines within a short time frame qualifies as an instance where the protective approach showed that it could perform under pressure (through abbreviated procedures and quicker testing) or where that approach had to be set aside given the crisis. For an interesting initial analysis of the broader innovation policy context, drawing a parallel with the WWII R&D effort, see Gross and Sampat 2022.

impact – and the costs related thereto – upfront. That positive impact, however, is expected of any innovation, from a public policy perspective: society needs innovations to be good. "Bad" innovations will somehow be sorted out, the only question being how: through prior authorization as in the protective approach, or through events taking place while or after the invention is diffused.[26] Irrespective of how it takes place, this sorting out is not free; it involves a cost, which can be conceptualized as an information cost, i.e. the cost of finding out whether the invention leads to a "good" or "bad" innovation, whether it is aligned with public policy or not (Katz 2007).[27] The real questions are therefore how that cost is minimized and borne, and how to handle errors in the sorting out process.

With the protective approach, it can be expected that firms will concentrate their research efforts on potential inventions that are likely to survive the testing and authorization process. Some inventions will probably be so promising that successful diffusion and a positive impact are predictable with some confidence; firms will pursue these inventions irrespective of regulatory policy, and the issue is whether the protective approach induces undue delay and costs.[28] For other potential inventions, there is no discernable path to diffusion and the likely impact on society strongly appears negative; in such cases, the

[26] These include post-marketing intervention by public authorities against the invention, the aftermath of liability claims brought by harmed parties, or simply a failure of the invention to be successfully diffused and adopted, or a combination of these.

[27] On that account, one can argue that rather than decreasing the expected returns to innovation, prior authorization under the protective approach can address market failures resulting from information imperfections (of the 'market for lemons' type) by offering a trusted quality certification from the outset, and thereby may actually encourage innovation, see Katz 2007.

[28] Fortunately, regulations have been adapted to expedite the process of prior testing and market authorization. For example, in the pharmaceutical sector, the U.S. regulatory agency has developed tools like Priority Review, Fast Track, Priority Review and Breakthrough Therapy to enhance the efficiency of drug therapy review and approval. (See Food and Drug Administration Safety and Innovation Act, July 9, 2012, Pub. L. No. 112-144, Section 802, 803, 901 and 902)Similarly, the EU regulatory agency has implemented tools such as Accelerated Assessment (EU Medicinal Regulation, *supra* note 8, Art. 14(9)), Conditional Marketing Authorization (EU Medicinal Regulation, *supra* note 8, Art. 14-a, further elaborated in Commission Regulation (EC) No 507/2006 of 29 March 2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council, OJ L 92/6), Compassionate Use (EU Medicinal Regulation, *supra* note 8, Art. 83), and the Priority Medicines (PRIME) scheme (PRIME: priority medicines | European Medicines Agency (europa.eu)) to streamline the approval process for promising therapies.

protective approach might be beneficial in that the attention of firms is rapidly shifted to other projects.

Between these two ends of the spectrum, a large "grey zone" includes prospective inventions where the chances of successful diffusion and a positive impact are less clearly ascertainable, one way or the other. The influence of the protective approach on innovation is mostly felt in that grey zone. Some inventions will not be pursued whereas they would in fact have led to desirable innovations, because a given firm and its researchers consider rightly (or erroneously), that the protective approach imposes costs and delays that would constrain profitability too much. To some extent, this is a predictable consequence of the policy orientation underpinning the protective approach, which is to accept Type I errors (preventing desirable inventions) for the sake of avoiding Type II errors (allowing the diffusion of inventions that ultimately have a negative impact), which society must accept.

Yet the protective approach also distorts innovation paths in other, more subtle ways. By definition, prior authorization occurs before any attempt at diffusion. The authorization process is conducted without any data regarding acceptance and adoption by prospective customers and more broadly by society, and without any actual data regarding impact. Impact is estimated on the basis of assumptions; these assumptions necessarily involve a measure of generalization and abstraction. For instance, in pharmaceuticals, testing is carried out on a sample of the general population. There are never-abating discussions on the representativeness of trial samples, as regards not only medical condition but also population data (FDA 2020; National Academies of Sciences and Medicine 2022). The paucity of diversity in clinical trials often creates a racial and ethnic data gap, leading to medical evidence and innovations that may not adequately reflect the efficacy and safety of therapies for minority populations. This is a significant source of bias in high-tech medical innovation. Often, the blame for these deficiencies is placed on algorithms; however, the underlying issue is frequently the biased training data. Algorithms trained on non-representative data are likely to produce biased outputs, perpetuating inequalities in healthcare outcomes (Cahan, Hernandez-Boussard, Thadaney-Israni, and Rubin 2019).

However, greater representativeness is a means and not an end in itself. Even if representativeness were optimal, the aim of the exercise remains merely to establish that the new drug meets regulatory requirements for the entire population (or as much of it as possible), with the fewest use restrictions or indications. This generalizing effect, inherent in the nature of testing and approval processes, can stifle innovation by limiting opportunities for developing more nuanced or targeted products. In particular, the lack of agility in these processes means that products with mitigated effects – those that might be highly beneficial for specific subgroups – may be overlooked or discarded because they do not meet the broad, generalized criteria. This approach potentially sacrifices valuable innovations that could cater to niche markets or specific patient needs.

In addition, the protective approach will tend to channel inventive efforts towards sustaining, as opposed to disruptive, innovation. It will be recalled that disruptive innovation occurs when an innovation shifts the value network – i.e. the socio-economic parameters within which firms operate[29] – or replaces the dominant supply architecture (Gans 2016).[30] In order for disruption to occur, the legal framework must possess sufficient flexibility and room to accommodate the disruptive innovation. In other words, disruptive innovation undermines assumptions and certainties not just in the business sphere, but also in regulation. Yet some of the key features of the protective approach – the bounded regulatory domain, the prior authorization and the accompanying testing process – are conducive to baking the value network or the supply architecture into law, even if carefully conceived and drafted.[31] For instance, pharmaceutical regulation is premised on mass-produced drugs being administered to patients with a limited amount of intervention (essentially posology). More personalized medical treatments, where the composition of the drug would depend on the patient, do not readily lend themselves to traditional

[29] For example, when streaming disrupted DVDs and Blu-ray discs as the main vector for viewing selected content at will. Streaming added new dimensions to the value network – ubiquity, portability, on-the-spot transactions, massive increase in available content – whilst eventually matching discs on existing dimensions – image quality, control features around viewing – so much so that discs became marginal.

[30] For example, when the iPhone ushered in the contemporary smartphone architecture and displaced the Blackberry model.

[31] It is very difficult to avoid incorporating elements of the value network or the dominant architecture into the law, particularly if the law relies on some conception of the value (production) chain.

pharmaceutical regulation (Tabarrok 2017). Similarly, in civil aviation regulation, the advent of unmanned aerial vehicles (UAVs), i.e. drones, caused major difficulties to a regulatory framework that was designed for either commercial manned aircraft or hobby-level projects (Portuese 2024). Hence in sectors where a protective approach to regulation and innovation is in place, sustaining innovation tends to prevail. Within sustaining innovation, the balance between breakthrough/radical or incremental innovation[32] will vary depending on the characteristics of each sector: the pharmaceutical sector features much breakthrough innovation, often in the form of successive generations of treatments for a given disease, whereas the commercial aircraft industry exhibits a mix of breakthrough and incremental innovations.

Ultimately, with the passage of time, the protective approach becomes internalized in the operations of firms and embedded into an ambient "innovation culture". The actual contours and intricacies of the legal and regulatory framework become less salient as firms learn to comply with the law and avoid running into difficulties.[33] Product development teams learn to assess the risk of harm (and the prospects for prior authorization to be granted) thoroughly and early in a product life cycle, so that – even if this may not be explicitly acknowledged – R&D decisions are shaped by the protective approach.

2.3 Limits of the protective approach

Over the decades since the protective approach to innovation was introduced in social regulation, its functioning has been steadily improved in the light of experience. At the same time, its limitations have also become clear.

For one, public authorities suffer from a considerable information deficit when they must rule on a prior authorization request, before an invention has been marketed and hence

[32] The distinction between breakthrough and incremental innovation relates to the size of the technological jump, and should not be confused with the distinction between disruptive and sustaining innovation, which refers to socio-economical aspects (value network, supply architecture). Sustaining innovations can be either breakthrough or incremental, whereas that distinction is of less relevance to disruptive innovations.

[33] With the risk of a "chilling effect", where firms would refrain from certain activities the legality of which is defensible but ambiguous, for fear of breaking the law. This amounts to an additional set of Type I errors, this time self-induced by firm behaviour instead of public intervention.

before any real-life data on diffusion and impact could arise and be observed by the authorities. The relevant information, to the extent it exists when the process starts, is almost entirely in the hands of the inventor. In addition to the information asymmetry, there is also an element of asynchrony. Even if the public authorities in charge of administering a regulatory scheme based on a protective approach are competent and diligent, they carry out their tasks at a point when firms have already spent time and resources on their invention. Authorities must then catch up with the inventor as regards knowledge of the invention as such. Afterwards, authorities also need to learn about risks relating to the applicable public policy objectives, and again they are running behind. Much of the most relevant information on risks is with the inventor, or it will be generated by the inventor during prior testing. Such information asymmetry and asynchrony can lead to government failures, which have been identified and analysed in the public choice literature (overview in Baldwin, Cave and Lodge 2012, 68-82). Regulatory capture is perhaps the best-known form of government failure, next to shirking or self-preservation of the agent against the interests of the principal (Stigler 1971; Dal Bó 2006). Beyond these cases, even on the assumption that no government failure would occur, the protective approach has become very resource-intensive. In most sectors under a protective approach, gathering and producing the data required to inform and educate the public authorities evolved into a multi-year process running in the hundreds of million dollars or euro, as the case may be.

Secondly, however much time and resources are dedicated to the prior authorisation process, that process remains focused on the impact of a given invention. Diffusion and adoption are neglected, if not altogether ignored. The intensity of the scrutiny on impact can create an illusion, if not an expectation, that the invention will successfully diffuse and be adopted by prospective users. After all, if the invention is shown to be aligned with public policy, one could be forgiven for assuming that customers will welcome it. Yet receiving a marketing authorization does not imply that there is a market. Sometimes market realities are not as anticipated, or they changed during the authorization process. In the commercial aircraft sector, the Airbus A380 did not enjoy the expected commercial success, since the hub-and-spoke airline formula that it relied on had fallen out of favour by the time the aircraft entered in service, more than 15 years after development started. In

the pharmaceutical sector, a case in point is the Alzheimer drug Aduhelm (aducanumab), which received an FDA marketing authorization under controversial circumstances in 2021.[34] Although it was granted accelerated approval, Aduhelm did not represent such a marked improvement over existing drugs, especially in view of its price as a new patented drug. Health insurers were hesitant to cover it, and physicians did not prescribe it widely. As a result, Aduhelm was not successful, and it was terminated by its producer in 2024.[35] Unlike the FDA, counterparts such as the EMA (EU) and PMDA (Japan) rejected the marketing application.[36]

3. The permissive approach

As mentioned in the introduction, the permissive approach to innovation is the default approach in most countries worldwide, and has been so since at least the Industrial Revolution. In essence, it entails that inventors may freely attempt to diffuse their inventions amongst prospective takers. If diffusion is successful and the invention is adopted, an innovation has occurred, for the benefit of society, until and unless it appears that the invention runs counter to public policy. The permissive approach flows directly from fundamental principles of private law – notably freedom of contract – and of public law – freedom of trade, freedom of thought, scientific freedom and market economy, to name but the main ones – that form the bedrock of liberal democratic orders,[37] hence its default status.

As regards the triangular model of innovation set out in the introduction, and in direct contrast with the protective approach, the permissive approach emphasizes diffusion over

[34] See the Aduhelm page on the FDA site at https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=761178. The controversy is described in Alexander et al., 2021.

[35] Biogen to Realign Resources for Alzheimer's Disease Franchise, January 31, 2024, https://investors.biogen.com/news-releases/news-release-details/biogen-realign-resources-alzheimers-disease-franchise.

[36] In the EU, the European Medicines Agency (EMA) issued a negative recommendation on the application for a marketing authorization in December 2021, and the application was subsequently withdrawn: https://www.ema.europa.eu/en/medicines/human/EPAR/aduhelm#overview.

[37] It is also possible to follow these principles, at least in part, outside of a liberal democratic order.

impact. It reflects a more relaxed attitude towards the risk of harm arising from inventions, in the absence of an existential or even significant threat, such as would typically underpin a shift to the protective approach. In practice, the permissive approach amounts to a presumption that innovation is good for society, which can be derived from the fundamental principles of law set out above and from the relaxed attitude towards risk. The permissive approach also chimes with the literature on innovation, which increasingly emphasizes the close link between the invention and diffusion elements: many authors posit a feedback loop between invention and diffusion (Rogers et al. 2005; Abrahamson and Rosenkopf 1997), and some would even consider that the two elements are nowadays fused (von Hippel 2016). With the permissive approach, diffusion and adoption data will generally be available, together with information about the invention, in order to guide the assessment of impact.

As underlined in the previous section, errors are bound to be made in ascertaining the potential harm arising from innovation. Contrary to the protective approach, however, the permissive approach prioritizes the avoidance of Type I errors (false positives), where an erroneous decision would mean that beneficial innovations are kept from society. In other words, the welfare gains from innovations are deemed to be worth the cost of allowing harmful inventions to be diffused (and dealing with them at a later stage).

Being the default rule, the permissive approach applies in a host of economic sectors. But it has been best theorized, and as will be seen below, furthest developed, in what is now called the "digital economy".[38] The digital economy is also where the limits of the permissive approach have been most explored and tested. Accordingly, it will be used as the prime illustration for the permissive approach.

3.1 Main features of the permissive approach

[38] Formerly called variously the IT (information technology) sector or the ICT (information and communications technology) sector, among others. It is beyond the scope of this contribution to discuss these terminological nuances.

Even though it is the default choice, we chose to present the permissive approach after the protective approach (the exception to the default), because as will be seen, the main features of the permissive approach are often underplayed and underanalysed, so that they are best explained when seen in contrast with the protective approach.

No bounded regulatory domain – Since the permissive approach is the default choice, it applies to any sector or activity, unless the legislature chose to place that sector or activity under a protective approach. Whereas the protective approach then requires that its domain be delineated with a boundary, no such boundary is needed for the permissive approach to operate. This may seem like stating the obvious, yet this feature has consequences. Firstly, it means that no resources are wasted in litigation on and around a boundary. Secondly and perhaps more fundamentally, the boundary does not weigh in on the inventive process: not only are inventors free to disregard scientific, technological or commercial conventions, but they need not worry about fitting in or out of a legal definition that influences the regulatory fate of their invention.

Market access without prior authorization – Under a permissive approach, any invention can be brought to market in order to try to diffuse it amongst prospective takers. Some authors extol this as "permissionless innovation" (Thierer 2016), but this is an overstatement. For one, even with market access, success is not guaranteed. The hurdles are elsewhere, though. Success depends more squarely on the ability to convince individuals to adopt an invention than on the ability to convince an authority that the results of prior testing warrant a marketing authorization. In this sense, the permissive approach does put the emphasis on diffusion over impact.

Market access subject to general laws – Not only is there no guarantee of success, but there are legal constraints as well. Even though no prior authorization scheme is in place, a host of laws still apply, starting with constitutional law and fundamental rights, as well as laws governing socio-economic activity (private law, competition law, intellectual property), including those parts of social regulation that apply outside of any specific protective approach (general laws on safety, health, the environment and consumer protection).

Bringing an invention to market must be carried out in compliance with these laws, even if no prior authorization is required.

Much like the absence of a domain boundary, this uncontroversial proposition (existing law must be complied with) has wide-ranging import, as illustrated by the Lessig-Easterbrook controversy over cyberspace law in the 1990s. In line with the permissive approach that presided over the birth of the Internet, Frank E. Easterbrook argued against the creation of a specific legal regime for "cyberspace", famously assimilating to trying to build a "law of the horse" (Easterbrook 1996). He contended that established general legal principles, as reflected in existing law, are sufficient to govern activities on the Internet, just as they do in other areas or spaces. On the other hand, Lawrence Lessig advocated for a more tailored regulatory approach to accommodate the unique characteristics and challenges of the fledgling Internet, that general laws might not adequately address (Lessig 1999). Lessig argued that the rapid and transformative nature of digital innovations requires specific legal frameworks to manage issues such as privacy, intellectual property, and digital rights, which in his view were not fully covered by existing legal norms. While Lessig seemed to have the upper hand at the time, history vindicated Easterbrook: only a limited amount of Internet-specific legislation was ever enacted – to be sure, no protective approach to Internet-related innovation was envisaged, even by the Lessig camp – and today for the law, the Internet is mostly just a feature in the backdrop of every legal domain.

The permissive approach therefore goes hand-in-hand with the proposition that existing laws are generally adequate to deal with inventions and their diffusion; if any specific legal development is needed, it can either take place incrementally, in a "bottom-up" fashion through the reshaping of existing law (via case-law or soft-law instruments), or wait until actual evidence has emerged through the diffusion of an invention.

If on substance existing law is deemed sufficient to deal with the impact that follows from the diffusion of an invention (i.e. to sort out "bad innovations"), then it follows that no specific procedure is needed either. Whereas the protective approach requires a separate procedural and institutional apparatus to carry out prior testing and decide on marketing authorizations, the permissive approach can rely on the procedural and institutional

vehicles available under existing law. In other words, innovation becomes just like any other socio-economic phenomenon. Under the permissive approach, dealing with the environmental consequences of, say, an invention that boosts the efficiency of solar panels but at the price of increasing their waste toxicity, is conceptually similar to assessing the environmental impact of building more power plants, and as such that invention could be dealt with under the same substantive legal principles and with the same procedures and institutions. When the permissive approach downplays impact, this does not mean that impact is ignored altogether: rather, innovation processes are deemed not to warrant specific legal attention in comparison with other socio-economic phenomena that also have an impact on society. In that sense, one could say that the permissive approach embodies a more holistic take on innovation, where both the invention and diffusion elements are included and put in the broader context of other socio-economic phenomena.

Finally, and more tentatively, emphasizing diffusion under the permissive approach might also signal that diffusion matters for the assessment of impact. In the introduction, diffusion was presented as a collective element made up of individual decisions of a descriptive nature: do prospective takers adopt the invention or not? Yet in deciding whether to adopt an invention, individuals could conceivably also internalize the public policy objectives that matter for the impact assessment: for instance, individuals could stay away from inventions that appear to be dangerous for their health or for the environment, or they could be reluctant to purchase a novel device or subscribe to a new service that seems to expose their personal data. Of course, the aggregate wisdom of individuals in their adoption decisions does not provide foolproof evidence regarding impact, but it should probably not be entirely dismissed either (Rogers 2003). The permissive approach could then also rest in part on diffusion as an – imperfect – indicator of impact, one which is not available under the protective approach.

Post-marketing surveillance – At first sight, both the permissive and protective approaches converge when it comes to post-marketing surveillance. Even once an invention is diffused and adopted, it must be closely monitored, and data on its actual use must be collected. Should an innovation turn out to be harmful, a spectrum of remedies are available (warnings, recalls, withdrawal). Under the protective approach, prior testing plays a

dominant role in the assessment of impact, so that post-market surveillance is often subdued (Lemmens and Gibson 2014). In contrast, post-market surveillance plays an essential role under the permissive approach, which largely relies on flexible, bottom-up solutions for post-market oversight to mitigate potential risks (Thierer 2017).

At this juncture, the regulation of innovation in the digital sector diverges from the permissive approach as it applies by default elsewhere. Post-market surveillance comprises not only traditional regulatory mechanisms, but also – and sometimes more importantly – civil liability law. Liability law plays a role both as a compensation mechanism to address the harm caused by innovations, and as a constraint (deterrence) on inventors: the threat of civil liability drives inventors to take appropriate care to contain the risk of harm, even if they otherwise may freely bring their invention to the market. That threat can be very effective: when collective means of redress are used, missteps can easily lead to damage awards in the billion range, which will affect the financial results and the reputation of any firm. In addition, in many jurisdictions, liability for defective products has been strengthened by removing the requirement of fault on the part of the manufacturer, thereby moving to a strict liability regime.[39] In the digital sector, however, to the extent that what is offered is not a physical product, but rather a dematerialized service,[40] product liability regimes do not apply. Rather, firms benefit from a more relaxed liability regime, exemplified by the wide-ranging immunity from liability granted to online intermediaries at the turn of the century, which broadly shields them from liability for defamation or intellectual property violations, among others.[41] It should be noted that this immunity is under question in the US (Citron 2023), and that it has been curtailed in the EU.[42] By way

[39] For the EU, see Directive 85/374 on liability for defective products [1985] OJ L 210/29, as amended. For the USA, most jurisdictions still follow the strict liability model of §402A of the *Restatement (2nd) of Torts* (1966), rather than the more mixed model of the *Restatement (3rd) of Torts: Product Liability* (1998), see Reimann 2021.

[40] Software is typically marketed in the form of a license to use a programme. Services, applications and content offered over the Internet are usually either dematerialized products (files to stream, read or visualize, etc.) or access- or license-based transactions (as opposed to sales).

[41] This was done though the *Communications Decency Act*, being part of the *Communications Act, 1996*, Pub L. 104-104 (1996), now codified at 47 USC § 230. In the EU, similar provisions were enacted at Art. 12 to 15 of Directive 2000/31 of 8 June 2000 on e-commerce [2000] OJ L 178/1.

[42] The provisions of the E-commerce Directive, *ibid.*, have been moved to Art. 4-6 and 8 of the Digital Services Act (Regulation 2022/2065 of 19 October 2022 on a Single Market for Digital Services [2022] OJ

of exception from the general design of the permissive approach, the constraint arising from civil liability law is therefore much reduced in the digital sector.

3.2 The permissive approach and innovation

In comparison with the protective approach, the permissive approach exerts less influence on the flow of innovation. Unlike the protective approach, which can channel innovation along certain paths, the permissive approach lets innovative forces deploy themselves, without significant directional or structuring effect coming from law and regulation (through definitions and procedures). This creates a fertile ground for all sorts of innovation paths to be pursued organically (bottom-up), including more complex ones that would not easily emerge if law and regulation had a structuring effect. As a result, the overall "innovative landscape" (i.e. the environment within which innovation takes place, and which in turn is shaped by innovation) is more diverse and dynamic.

For instance, ecosystems can arise, where incremental innovation is centred around standards that appeared largely spontaneously. These standards themselves can emerge *de facto*, for instance when an operating system (Windows, iOS, Android) becomes a platform around which developers organize their innovative efforts. They can also be developed *de jure*, through a Standards Development Organisation (SDO) following established basic governance principles (Baron et al. 2019), as is the case with successive generations of mobile communications standards. Theoretical models and empirical evidence show that standardization, functioning as a technology transfer channel, and standards, serving as enablers and facilitators, contribute to innovation (Blind 2016; Foucart and Li 2021).

Because of this minimal structuring effect, the permissive approach is also more amicable to disruptive innovation. Disruptive innovation then plays out as a mostly socio-economical game of reshuffling value networks or established architectures, with no additional need to overcome legal obstacles arising from regulatory definitions or prior authorization procedures. And indeed, disruptive innovation flourished in the digital sector,

L 277/1). While their wording has not changed much, the Digital Services Act imposes significant new duties on intermediaries, which severely curtail the ambit of the immunity

ranging from the emergence of smartphones that redefined the way for communication, work and entertainment, to cloud computing that revolutionized data storage and access, and the development of artificial intelligence that is reshaping industries with automation and predictive analytics (Schwab 2017).

Much like the protective approach, over time, the permissive approach spills over into the ambient "innovation culture" of firms. Nowhere is this better encapsulated than in the mantra "Move fast and break things" championed by Meta and other large digital platforms (Taplin 2017). This phrase catches the essence of the permissive approach and turns it into an operational maxim for an entire business organisation. It prioritizes rapid innovation and diffusion as eminently desirable, at the expense of caution and compliance with established norms and conventions, which are seemingly there to be broken. There is no hint of any reflection on impact, which is either deemed positive or left aside as an afterthought: if any difficulties arise as a result of moving fast and breaking things, they can presumably be fixed in due time.

3.3 Limits of the permissive approach

While the digital sector is the poster child for the permissive approach, its performance in the last decade shows that this approach also suffers from some limitations.

First of all, in the absence of any significant structuring or directional effect coming from law and regulation, innovation can spiral in any direction, depending among others on scientific and technological progress or on entrepreneurial drive. This implies that successive innovations can subtly lead to a point where the relaxed attitude towards risk that characterizes the permissive approach is no longer tenable ("risk creep"). In the digital sector, that point was probably reached in the 2010s with the rapid growth of social networks. Beforehand, from the onset of personal computing in the 1980s through the networking of computers in the 1990s to the creation of new means of communication, information and exchange in the 2000s, the permissive approach seemed to fit the sector perfectly, presiding over successive waves of innovation that broadly aligned with public

policy objectives and brought welfare gains to society. Social networks also evolved under that permissive approach. Yet they magnified existing threats to privacy and personal data, for one, and were also linked with severe psychological effects on minors and vulnerable users, with social fragmentation and isolation and with the spread of disinformation that undermined civic and political life. Once it started to become apparent that social networks created significant risks beyond what academics and policymakers were used to witness with innovation in the digital sector, they started to revise their views (US House of Representatives 2020b), but in the meantime the permissive approach was so entrenched in the digital sector – it is part of the culture – that it cannot easily be jettisoned.

Secondly, as an often unstated condition for it to work, the permissive approach requires a competitive market environment. Without competition, diffusion does not work reliably for the purposes of the permissive approach. Prospective takers of an invention must have a meaningful choice if the sum of their individual decisions is to provide a reliable indication of whether the invention is acceptable or not. If the only choice offered to prospective takers is to adopt the invention as offered or forego its benefits altogether, the decision is skewed. Ideally, prospective customers should have a choice between alternative inventions competing for their favour. At the very least, they should have the ability to signal dissatisfaction with some aspects of an invention, so that a feedback loop would ensue and the invention would be modified (or versioned). This is a competition law issue, at the core of cases such as *Meta v. Bundeskartellamt*.[43] But it also affects the effectiveness of the permissive approach: in the absence of robust competition, the diffusion and adoption of innovations can become skewed, leading to market dominance by a few firms, stifling further innovation, and resulting in suboptimal outcomes for consumers.

[43] Judgment of the Court: Grand Chamber 4 July 2023, *Meta Platforms Inc and Others v Bundeskartellamt*, Case C-252/21, ECLI:EU:C:2023:537.

The following table provides an overview of the two approaches and their main features.

	Protective approach	**Permissive approach**
Starting assumption	Risk is presumed to be significant	Risk is presumed to be acceptable
Sorting out "good" and "bad" innovation	Invention must be shown to meet criteria before it is deemed "good"	Innovation is presumed to be "good" until proven otherwise
Status	Exception to the default rule; requires a regulatory domain to be defined	Default rule
Market access and diffusion	Upon prior authorization only Authorization available if defined criteria are met Prior testing required	Free
Risk assessment	Based on invention and abstract use cases	Based on invention and actual use data from diffusion/adoption
Post-marketing surveillance	Regulatory surveillance, with warnings, recalls and withdrawals Civil liability	Regulatory surveillance, with warnings, recalls and withdrawals Civil liability (exception for digital sector)
Impact on innovation	Channels invention towards sustaining innovation	Limited effect on invention
Limits	Information deficit of authorities Successful diffusion not guaranteed	"Risk creep" over time Requires a competitive environment

4. Dynamic interplay between the protective and permissive approaches

As was mentioned in the introduction, the protective and permissive approaches are idealized versions of the two prevalent models. Across the economies of most developed countries, social regulation will deal with innovation according to the broad lines of one of these two approaches. The overall result is a patchwork, where within a given country, some economic sectors are under a protective approach and others, left to a permissive

approach.[44] Because of the differences between the two approaches, as explained in the preceding headings, they cannot be combined or mixed, however: a given invention should be handled under either one, but not both.

From a static perspective, a peaceful co-existence of the two approaches in their respective sectors should be feasible. The permissive approach applies everywhere by default, save in the sectors where the State chose to implement a protective approach by way of exception to the default rule. In these sectors, a regulatory domain was defined, and a set of definitions marks the boundary of that domain.[45] That boundary shields the exception from the default rule, and it prevents overlaps and conflicts.

Once a more dynamic view is taken, that peaceful co-existence is shattered. As indicated above, when socio-economic conventions (value networks) or organizational assumptions (dominant architecture) are enshrined in law or regulation, as is frequently the case with the protective approach, regulated firms will tend to work within those constraints and will emphasize sustaining innovation. In contrast, the permissive approach knows of no regulatory domain, because it is the default, and it does not weigh in on innovative paths through boundary definitions and prior authorization procedures. In the absence of such legal and regulatory obstacles, it is particularly conducive to disruptive innovation, as pointed out earlier. Frictions are almost foreordained as soon as innovation paths lead firms used to operate under a permissive approach near the boundaries of sectors evolving under a protective approach. For these firms, whose innovation culture rests on questioning and disregarding conventions and assumptions, the legal and regulatory constraints imposed by the permissive approach are just another hindrance to be challenged. Firms from the digital sector, in particular, epitomize this attitude.

[44] One could also take an orthogonal perspective and observe, for a given economic sector, which approach was chosen in each country. This is not the focus of this paper. We surmise that there is less variation in the treatment of a given sector across countries than can be observed in the treament of various sectors within the same country.

[45] Of course, interpretation issues can always arise around the boundary definitions, but legal systems offer avenues to solve them and eventually provide an answer to the question of which side of the boundary an invention falls on.

The process by which innovation in the digital sector brings it in contact with another sector is usually branded "convergence". Very often, regulation in that other sector follows a protective approach towards innovation. Since the 1980s, successive waves of convergence evidenced a similar pattern.

In a first step, disruptive innovation originates in the digital sector and presents an alternative to offerings in the other sector. That disruptive innovation therefore breaches the regulatory boundary of the other sector, and the two sectors are in contact: firms from the respective sectors suddenly find themselves competing with one another.

Mayhem ensues in a second phase. Firms from the digital sector are typically more aggressive and dynamic, and they wreak havoc. Firms from the other sector are caught flat-footed, and since their innovation culture is different, they find it difficult to keep up with the changes. Around the two sectors, public authorities, lawyers, consultants and academics organize seminars about "convergence" and ponder about the legal, policy and economic implications.

More often than not, in a third phase, the other sector is transformed. As the protective approach is abandoned or confined to a smaller domain, firms in the other sector learn to espouse the innovation culture of the digital sector (or engage into mergers with firms in the digital sector).

By way of examples,[46] a first wave of convergence occurred when the digital sector breached the regulatory domain of telecommunications, with the rise of networking in the 1980s and 1990s (culminating with the Internet). There the protective approach was almost completely abandoned.[47] Afterwards, convergence with media took place in the 2000s. Broadcast media regulation, which followed a protective approach, was shrunk and confined to traditional broadcasting only, leaving new media services under a permissive

[46] The limited scope of this contribution does not allow for a full discussion (with references) of any of these examples.

[47] One could argue that the protective approach in telecommunications was already being softened at the time.

approach to innovation. These two waves of convergence were so extensive that we now consider the digital sector to encompass telecommunications and media. Subsequently, the rise of the "sharing economy" changed the landscape for taxis and accommodation, forcing firms in these two sectors to evolve rapidly to keep up with the changes wrought by firms from the digital sector. When the digital sector started to interact with the energy sector, with smart meters and home automation, the energy sector ended up being confined to smart metering, leaving the rest of the innovation space to the digital sector. The financial sector might have bucked the trend, in that its firms and its regulatory structure have survived the onslaught of the digital sector, but even there financial operators had to change their strategy and operations in order to safeguard their position in a changed technological environment.

Whilst society undeniably benefits when firms face new competitive pressures and entire economic sectors become more dynamic, abandoning or downsizing the protective approach also raises some concerns. When the innovation culture linked with the permissive approach takes over, formerly cautious firms can decide to be more aggressive in bringing inventions to the market, on the assumption that any problems that could ensue can be fixed later. In a rush to diffuse inventions, firms begin to focus more on the benefits to the average user and to society in general, and less on the nagging cases where the invention could be used maliciously or incompetently.

The two Boeing 737 Max crashes in 2018 and 2019 provide a vivid and tragic case in point. A failure of the Maneuvering Characteristics Augmentation System (MCAS) was quickly suspected to be at the root of both crashes, accompanied by a host of other shortcomings in strategic and operational management, aircraft design and communications with airlines (US House of Representatives 2020a). One of the most troubling facets of the subsequent investigation was how it revealed the risks that arise when the digital sector converges with commercial aircraft manufacturing, which has always been regulated following a protective approach to innovation. The MCAS is a piece of software that is linked to a sensor near the nose of the aircraft; it automatically activates the aircraft controls to bring the nose down, in order to correct a weakness of the legacy 737 design that causes the

newest generation of aircraft engines to tilt the plane upwards. As one seasoned observer put it,

> Hardware defects... are notoriously hard to fix. And by hard, I mean expensive. Software defects, on the other hand, are easy and cheap to fix. All you need to do is post an update and push out a patch... I believe the relative ease—not to mention the lack of tangible cost—of software updates has created a cultural laziness within the software engineering community. Moreover, because more and more of the hardware that we create is monitored and controlled by software, that cultural laziness is now creeping into hardware engineering—like building airliners. Less thought is now given to getting a design correct and simple up front because it's so easy to fix what you didn't get right later (Travis 2019, 9; See also Herkert, Borenstein, and Miller 2020).

As the innovation culture of the digital sector takes hold in sectors regulated under a protective approach, therefore, it displaces the cautious, safety-oriented culture in a way that, as the case of the Boeing 737 Max shows, created risks that escaped the attention of a regulatory authority perhaps too fixated on traditional hardware issues of aircraft safety.[48]

5. AI governance and the responsible innovation approach

Artificial intelligence (AI) is rapidly becoming an integral part of our daily lives, offering myriad benefits for society. With the diffusion to the general public of ChatGPT 3.0 at the end of 2022, generative AI gained a hold on the collective consciousness (as a proxy for the new generation of AI based on machine learning) and gave greater salience to ongoing debates about how to govern AI.

Amongst the key issues in those debates is the "alignment problem", i.e. "how to ensure that these [AI] models capture our norms and values, understand what we mean or intend, and, above all, do what we want" (Christian 2020, 13). The alignment problem ties into the impact element of the triangular model of innovation used in this contribution. As the current discussions show, alignment plays out at two levels: more immediately in that current AI systems touch upon fraught issues linked with public policy (including

[48] As the US House of Representatives 2020a, points out at 34-54, the regulatory oversight of the FAA was itself deficient in relying too much on a delegation of its own authority to Boeing engineers.

discrimination and fundamental freedoms, health and safety, up to environment protection), and more remotely with the prospect of general artificial intelligence (Christian 2020). The level of concern is such that leading academic researchers and industry CEOs called for a pause on giant AI experiments in 2023.[49]

At the same time as generative AI came of age, the debate on AI governance shifted from a prolonged phase of conceptual examination – framed mainly as an investigation into AI and ethics (OECD 2019) – to concrete legislative proposals (Larouche 2024), many of which were enacted in the last year, starting with a Presidential Executive Order in the USA[50] and culminating with the enactment and entry into force of the AI Act in the EU.[51] In the course of this shift, two prevalent myths from the conceptual examination phase were dispelled. One is the perception that "artificial intelligence" as such is a standalone object of law or regulation ("shiny object syndrome") (Larouche 2024, 59). AI is not an isolated and insular technological phenomenon, rather it is associated with other technologies and integrated into various products or services offered by a diverse array of actors, including firms, individuals, and public authorities (Smuha 2021). In other words, AI is technologically and socio-economically embedded. The second myth is the "blank page" fallacy, namely that AI evolves in a legal vacuum and a new regulatory corpus specifically dedicated to AI must be built from scratch.[52] Rather, a substantial body of general law, such as contract, liability, and property law, as well as special laws like intellectual property law, competition law and data protection law, can already be applicable to AI, albeit with some adaptations (Hoffmann-Riem 2020).

[49] See Future of Life Institute, Pause giant AI experiments: An open letter, https://futureoflife.org/open-letter/pause-giant-ai-experiments/, accessed on July 12th, 2024. However, as of July 2024, a pause has not materialized. Instead, AI companies have continued to invest heavily in infrastructure to train increasingly larger AI systems. See Anthony Aguirre, The Pause Letter: One year later, Future of Life Institute, March 22, 2024, available at: https://futureoflife.org/ai/the-pause-letter-one-year-later/.

[50] Executive Order 14110 of 30 October 2023 on Safe, Secure and Trustworthy Development and Use of Artificial Intelligence, 88 Fed. Reg. 75191.

[51] Regulation 2024/1689 of 13 June 2024 laying down harmonised rules on artificial intelligence (Artificial Intelligence Act, AI Act) http://data.europa.eu/eli/reg/2024/1689/oj.

[52] The "blank page" fallacy is related to the "Law of the Horse" debate, *supra* Section 3.1 Main Features of the Permissive Approach.

5.1 **AI and the protective and permissive approaches**

A threshold issue in legislating on AI governance is whether to adopt a protective or permissive approach to innovation. A quick answer is that both approaches have inherent limitations, and neither provides an optimal solution for the AI regulation and innovation.

Given that AI is mostly developed by firms and other actors in the broad digital sector, the permissive approach seems intuitively apposite. However, we saw earlier that the limits of the permissive approach in the digital sector were already reached a decade ago with social networks, where "risk creep" reached the point where an invention with massive impact on society – as it turned out – was allowed to be diffused, and successfully so, without adequate risk assessment. By all accounts, AI pushes further beyond the limits of the permissive approach, with even greater risks than social networks. Furthermore, like preceding innovations in the digital sector, AI has the potential to spill over into sectors governed under a protective approach to innovation, by way of disruptive innovation, where regulatory foundations (bounded regulatory domain, prior authorization procedure) are often shaken to their core. For instance, brain-computer interface devices utilize powerful AI-driven data processing capabilities to interpret complex electroencephalography (EEG) signals, enabling researchers to decode patterns of brain activity associated with different cognitive tasks and to predict imagined movements. However, the integration of AI into such high-stake endeavours raises concerns about interpretability, transparency, the ethics of algorithms, and potential biases that AI systems might introduce (Ienca and Ignatiadis 2020). Even if there is often some upside to putting a regulatory framework under pressure, on balance it does not appear desirable that AI would continue – and amplify – the trend whereby the digital sector and its innovation culture takes over in sectors where a protective approach to innovation is in place.

On the other hand, the protective approach is bound to be largely ineffective for AI regulation. Maybe a protective approach would somehow stifle AI innovation, although as seen previously it is more correct to say that the innovative drive is channelled rather than hampered. In any event, such an effect, if any, would be part and parcel of the choice for a

protective approach, a feature rather than a bug. A more compelling shortcoming comes from the massive informational deficit already present with respect to AI: public authorities currently lack the necessary information and expertise to evaluate AI technologies comprehensively before they enter the market. Prior testing, whereby the inventor generates and collects evidence to remedy the information deficit and demonstrate to public authorities that the invention has a positive impact, would likely be even more cumbersome than for pharmaceutical products or commercial aircraft, for instance. Moreover, the very dynamic nature of AI prevents a regulatory framework based on the protective approach from keeping abreast of rapid progress. Prior authorization procedures can already barely cope with the pace of invention in relatively "slower" sectors like pharmaceuticals.

In conclusion, neither the protective nor the permissive approach to innovation is adequate to secure AI alignment. from AI governance sufficient for effective AI regulation.

5.2 **A third approach based on responsible innovation**

The protective and permissive approaches to the interplay between innovation and social regulation may appear to be the only allowable options, when examined against the triangular model of innovation. As mentioned above, they represent alternative weightings between the impact and diffusion elements: the protective approach emphasizes impact over diffusion, while the permissive approach prioritizes diffusion over impact. There is some conceptual room for a third approach, however.

Both the protective and permissive approaches share a common feature: they are centred on the mission of public authorities to ensure that inventions have a positive impact on society. They both describe how public authorities deal with inventions: the protective approach puts the invention through a prior authorization procedure before it is allowed to be diffused, while the permissive approach allows diffusion and relies on a host of other mechanisms (post-marketing surveillance, civil liability and also the normative implications of successful diffusion) to control for positive impact. In both cases, the invention takes place before either approach begins to operate.

Hence in both cases, the invention element of the triangle is left outside of the approach. Both the protective and permissive approaches eventually connect with invention, but via informal paths outside the reach of public authorities, i.e. what we described earlier as the "innovation culture". Such innovation culture develops as the regulatory framework becomes well established and filters down into the internal operations of firms. That informal path cannot be assumed to happen or to persist, though. It is interesting to note that the potentially harmful effect of convergence, as described above, occurs precisely because of the discrepancy that arises when the innovation culture deriving from the permissive approach takes hold in a sector where the protective approach prevails.

Both the protective and permissive approaches neglect the invention element in the triangular model, and rely on informal channels to bind it with diffusion and impact in the course of implementing the respective approach. Conceptually, a third approach could seek a firmer and more formal inclusion of invention into a more holistic treatment of innovation in social regulation. It would replace the "innovation culture" with a more explicit part of the approach.

Such third approach could be inspired by the literature on responsible innovation, which advocates the enhancement of *anticipatory, reflective, deliberative* and *responsive* elements[53] in innovation governance (Owen et al. 2013, 29). These dimensions collectively align with Von Schomberg's definition of responsible (research and) innovation:

> "Responsible Research and Innovation is a transparent, interactive process by which societal actors and innovators become mutually responsive to each other with a view on the (ethical) acceptability, sustainability and societal desirability of the innovation process and its marketable products (in order to allow a proper embedding of scientific and technological advances in our society)." (Von Schomberg 2011, 9)

[53] While the specific dimensions of responsive innovation may differ in expression among various bodies of literature, these dimensions are built around core concepts, such as technology assessment, "upstream" engagement and anticipatory governance, which collectively form the foundation for responsive innovation.

The core of responsible innovation is the introduction of early societal dialogue, a dynamic mechanism designed not only to avoid potential risks with emerging technologies but also to provide constructive guidance for their successful introduction. Such societal dialogue entails embedding impact analysis – including consideration of ethical acceptance, societal needs and values, and public policy objectives – into the process of innovation as of the stage of invention. The involvement of a broad range of societal actors – not just public authorities – also allows for considerations relating to diffusion to be brought into the exchanges. Firms are required to internalize the results of this social dialogue, ensuring that ethical, legal, regulatory, and policy considerations are integrated with product development from the outset. By incorporating diverse perspectives early in the invention phase, responsible innovation allows for the reframing of issues and the identification of potential areas of contention (Owen et al. 2013). The analysis of impact would thus occur largely "upstream," meaning early in the process, rather than later through monitoring and correction "downstream" of invention (be it ahead of or next to diffusion). Additionally, early dialogue introduces some "learning-by-doing" in the innovation process, which better fits the iterative and bottom-up nature of much invention today.

Building on responsible innovation, not only could firms be expected to factor public policy objectives early in the research and development process, but public authorities also could be involved at that early stage to gain information on the potential impact of eventual inventions or perhaps even nudge firms away from "bad" innovation. In this way, the shortcomings of the two current approaches would be addressed: firms and authorities would be in a better position to predict and avoid a situation where harm could not be "fixed later" under a permissive approach, while the information deficit characteristic of the protective model would be reduced.

The responsible innovation approach proposed here envisions that firms and regulatory authorities will engage in regulatory dialogue (with the involvement of other stakeholders as well). In this context, stakeholders are seen as co-responsible for the innovation process, creating a collaborative environment that fosters co-management, if not co-regulation, with the aim of achieving shared objectives. In practice, measures such as private-sector-led

standardization (Baron, Contreras and Larouche 2022), certification systems, codes of conduct, etc. are concrete manifestations of responsible innovation, providing a structured framework for the assessment and management of innovation by all stakeholders.

For a responsible innovation approach to function, however, two pre-conditions must be met. On the side of firms, willingness to hold and participate in societal dialogue is essential. Given that the interests of firms frequently diverge from those of other stakeholders (and of public authorities), tensions are unavoidable and trade-offs must be made. Firms may not feel incentivized to engage in a frank dialogue with regulatory authorities and other stakeholders. Consider, for example, the implementation of the Digital Markets Act (DMA)[54] in the EU, which provides a model of compliance that is not entirely based on deterrence but also encourages gatekeepers to cooperate with the Commission, and third parties to comply with the Act (de Streel et al. 2024, 6). Unsurprisingly, the Commission is facing increasing backlash from designated gatekeepers, which are mostly US firms that are not used to be active agents in their own regulation (Hancock 2023). Many rounds of exchange may be required in the course of specifying the content of regulatory obligations, given that the digital ecosystem is complex, evolving and not always fully understood (de Streel et al. 2024, 8), and it is always possible that firms disengage from the process, leaving regulatory authorities in a bind.

As a counterpart to engagement by firms, the responsible innovation approach pre-supposes that public authorities put themselves in a position where they can meaningfully participate in the dialogue. In clear terms, public authorities cannot take a more passive attitude and wait either for firms to provide them with evidence and educate them or for risks to surface in the course of diffusion. Consequential investment in capacity-building and expertise are required. In institutional terms, the commitment required from public authorities lends itself well to the structure pioneered in network industries and the financial sector. There the legislative framework sets out broad policy aims in general

[54] Regulation 2022/1925 of 14 September 2022 on contestable and fair markets in the digital sector (Digital Markets Act) [2022] OJ L 265/1.

provisions, and an independent authority is created and endowed with sufficient resources to implement, monitor, and enforce these policy aims.

5.3 **The AI Act: a step in the right direction**

The responsible innovation approach is increasingly present in digital sector legislation. For instance, the principles of "privacy by design" and "privacy by default" were incorporated into data protection and privacy laws across numerous jurisdictions, notably within the benchmark-setting EU General Data Protection Regulation (GDPR). [55] Contemporary discussions around AI governance feature a growing clamour from firms and other stakeholders for the introduction of responsible innovation principles in AI design, even if not explicitly labeled as such (Shneiderman 2022). The EU, once again, stands at the forefront of this legislative movement, with the new AI Act.

A comprehensive examination of the AI Act is beyond the scope of this contribution. We survey features of the AI Act that point to a responsible innovation approach.

Definitions in the AI Act – The definitional architecture of the AI Act shows how it tries to avoid the pitfalls of the protective approach.

First of all, the nature of the AI Act, as a specific regulation on AI, makes a definition of AI indispensable. As is known (Almada and Radu 2024), the EU, the US and other jurisdictions cooperated on a common definition of AI under OECD auspices (OECD 2019). In line with this consensus,[56] the AI Act defines the core concept of "AI system" as "a machine-based system that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment, and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content,

[55] See Art. 25 of the General Data Protection Regulation (GDPR) (Regulation 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 [2016] OJ L 119/1).
[56] See AI Act, *supra* note 51, Rec. 12.

recommendations, or decisions that can influence physical or virtual environments".[57] This definition aims to be flexible and sustainable through technological evolution. It is set out in broad functional terms, in line with the principle of technological neutrality (van der Haar, 2008). It is apparent that the EU and its international counterparts sought to avoid a narrower and sharper definition (which would have generated wasteful boundary litigation), or a definition that would encompass technical or economic (value chain) elements (which would quickly have become outdated). At the same time, the generality and flexibility of the definition of "AI system" indicates that the EU did not envisage that the AI Act would follow the protective approach, in which case a more robust and clear-cut definition would have been required in order to delineate an exception to the default rule.

If anything, some of the subordinate definitions found in the AI Act come closer to the kind of definition one would expect under a protective approach. They concern the most elaborate areas of heavier regulation under the AI Act, namely "high-risk AI systems" and "general-purpose AI models with systemic risk".[58] Even if the AI Act is generally presented as a risk-based framework, the definition of "high-risk AI systems" at Articles 6 and 7 is framed in terms of use-cases, as they result either from the Directives and Regulations listed in Annex I or from the areas of application listed in Annex III. Here the AI Act rests on prior legislative determinations of risk, embodied in descriptive use-cases.[59] Similarly, the definition of "general-purpose AI models (with systemic risk)" through the combination of Articles 3(63) and 51 is based on technical features and performance.

Next to an area of outright prohibition for certain prohibited practices,[60] all other AI systems besides these two categories are governed with a permissive approach to innovation.

[57] AI Act, *supra* note 51, Art. 3(1).
[58] Given the scope of this contribution, we leave aside the set of prohibited practices at AI Act, *supra* note 51, Art. 5.
[59] Certain AI systems can be exempted from obligations incumbent on high-risk systems on a showing that they are not high-risk: AI Act, *supra* note 51, Art. 6(3) to (8). Other use-cases can be added if the Commission is satisfied that they are also high-risk: AI Act, *supra* note 51, Art. 7.
[60] AI Act, *supra* note 51, Art. 5.

Responsible innovation approach – Firms – Even if the definitions of "high-risk AI systems" and "general-purpose AI models (with systemic risk)" may seem like the kind of definitions one would expect around the regulatory domain of the protective approach, these two categories are placed under what appears like a responsible innovation approach.

The Act allocates much of its substantive provisions to AI systems that present a high risk to public interests and fundamental rights, categorized as high-risk AI systems. High-risk AI systems seeking access to the European market need no prior marketing authorization. However, prior to marketing, they must comply with specific mandatory requirements and undergo a conformity assessment. The AI Act requires providers to submit their systems for evaluation by conformity assessment body.[61] If the assessment successful, a declaration of conformity is issued, allowing the high-risk AI system to be marketed.[62]

The Act regulates high-risk AI systems by adopting a set of measures from the responsible innovation toolbox, incorporating anticipatory, reflective, deliberative and responsive elements in the AI innovation process (von Schomberg 2011; Owen et al. 2013). The AI Act draws largely on EU product safety regulations, but it goes further on substance and in greater detail regarding the involvement of firms in their own regulation. The Act pushes AI developers to take responsibility for achieving public policy objectives and to internalize these objectives within their development processes. Specifically, this involves implementing a range of measures, including risk management systems, impact assessments, conformity assessments, and the use of standards.

For instance, the Act requires AI providers to establish a risk-management system to ensure compliance with mandatory requirements, which involves a continuous, iterative process throughout the entire lifecycle of a high-risk AI system.[63] The conformity assessment, as mentioned earlier, is a process of demonstrating that high-risk AI systems meet the requirements set out in the regulation before entering the market, thereby fostering a high

[61] AI Act, *supra* note 51, Art. 43.
[62] AI Act, *supra* note 51, Art. 16(f).
[63] AI Act, *supra* note 51, Art. 9.

level of trustworthiness.[64] As the name suggests, the fundamental rights impact assessment requires deployers of high-risk AI systems to evaluate the potential adverse impacts on fundamental rights, ensuring that their implementation practices comply with these rights.[65] Additionally, the Act allows for the development of harmonized standards by European Standardisation Organisations (ESOs) to specify the technical implementation of the requirements for high-risk AI Systems.[66] Compliance with harmonized standards is a means to demonstrate conformity with the requirements of the regulation. In the process of producing the standards, a balanced representation of interests involving all relevant stakeholders, in particular SMEs, consumer organisations and environmental and social stakeholders should be encouraged.[67]

Even if the provisions on general-purpose AI models are less elaborate than on high-risk AI systems, there as well the AI Act follows a responsible innovation approach. Providers of general-purpose AI models are expected to prepare and provide technical documentation on their models to supervisory authorities and to their customers.[68] For general-purpose AI models with systemic risk, further obligations include evaluation and adversarial testing, risk assessment and mitigation, tracking, documenting and reporting on serious incidents and cybersecurity protection.[69] Providers and other stakeholders are invited to participate in the elaboration of Codes of Practice to specify these obligations.[70]

Responsible innovation approach – Public authorities – In addition to the above provisions obliging and inciting firms to actively incorporate public policy objectives in the development of high-risk AI systems or general-purpose AI models (with systemic risk), the AI Act relies on a dual institutional model, as outlined above, on the side of the public authorities. On the one hand, it establishes a comprehensive horizontal legal framework that outlines broad policy objectives and applies to the common use and supply of AI

[64] AI Act, *supra* note 51, Rec. 123 and Art. 43.
[65] AI Act, *supra* note 51, Rec. 96 and Art. 27.
[66] AI Act, *supra* note 51, Art. 40.
[67] AI Act, *supra* note 51, Rec. 121 and Art. 40.
[68] AI Act, *supra* note 51, Art. 53.
[69] AI Act, *supra* note 51, Art. 55.
[70] AI Act, *supra* note 51, Art. 56.

systems. At the same time, it designates independent authorities, including national competent authorities,[71] and the AI Office and the European Artificial Intelligence Board at EU level,[72] to facilitate the implementation, monitoring, and enforcement of this regulation. The AI Act also contains provisions that enshrine a commitment on the part of public authorities to invest in the requisite capacity and expertise to participate effectively in dialogue with private actors. Authorities set up by Member States must be endowed with adequate resources [73] and at the EU level, an AI Office is created as a centre of expertise and capabilities.[74]

The AI Act therefore paves the way for a third approach, along the lines of responsible innovation, to be implemented and developed as regards the regulation of innovation in AI.

6. Conclusion

This contribution sought to take a horizontal view to the interplay between social regulation and innovation. Even though specific instances of social regulation may always differ slightly, two broad approaches emerge. In broad terms, they differ in how they balance two of the three elements of the triangular model of innovation from a public perspective, namely the *diffusion* of an invention with a view to its adoption in society and the positive *impact* of such invention in the light of fundamental rights and public policy.

Under the protective approach, an invention may not be diffused unless and until the inventor has evidenced that the invention has a positive impact. The protective approach typically rests on a requirement that a marketing authorization be obtained beforehand, on the basis of evidence from prior testing. Used in sectors where risk is deemed significant

[71] AI Act, *supra* note 51, Art. 70.
[72] AI Act, *supra* note 51, Art. 64-67.
[73] See AI Act, *supra* note 51, Art. 28 for notifying authorities and Art. 70 for market surveillance authorities.
[74] AI Act, *supra* note 51, Art. 64. The AI Act also provides for an advisory forum (Art. 67) and a scientific panel of independent experts (Art. 68).

(pharmaceuticals, commercial aircraft), it is designed to avoid Type II errors (false negatives).

Under the permissive approach, an invention may freely be diffused, subject to general laws, including post-marketing monitoring and surveillance whereby cases of negative impact can be identified. The permissive approach is the default, exemplified in particular by the digital sector. It seeks to avoid Type I errors (false positives).

Even though the protective approach does not stamp out innovation, it does channel it, typically towards sustaining innovation. The permissive approach does not exert much influence on innovation paths and is thus amenable to disruptive innovation, for instance. Each approach has filtered down in the "innovation culture" of firms, for instance with the more cautious attitude of pharmaceutical labs or the "move fast and break things" mantra of the digital sector.

Both approaches have shown their limits over time. Among other limits, the protective approach magnifies the information deficit of public authorities and can be very resource-intensive. The permissive approach, on the other hand, allows for "risk creep" through successive innovations, where its more relaxed stance towards innovation is no longer warranted (as with social networks in the digital sector).

The two approaches cannot readily co-exist, since innovation in sectors under a permissive approach will tend to subvert the boundaries of the regulatory domain of the protective approach and subvert its application.

Against that backdrop, the governance of AI cannot follow either approach. Rather, it can become a pioneering area for a third approach, based on responsible innovation. This approach seeks to incorporate considerations of impact (and diffusion) straight into the invention element of innovation, in order to avoid the shortcomings of the protective or permissive approaches. Firms are obliged or at least incentivized to show that they took impact into account at the invention stage of their processes, through various compliance

obligations and through participation in dialogues with other stakeholders and public authorities. Public authorities commit to invest in capacity and expertise to participate fully in the dialogue with firms and stakeholders.

Not only is AI governance paving the way for a broader reassessment of our relationship with the digital sector, it is also opening the path for new approaches to innovation in social regulation.

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