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Regulation as an enabler for emerging industries

Literature review

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Abstract

The common perception of regulation as red tape has progressively given way to a more positive approach according to which standards and regulation can play a constructive and enabling role to support the emergence of new industries. Such an enabling role includes the establishment of common vocabularies and the creation of technological platforms, the strengthening of investors' and consumers' confidence, the acceleration of the commercialisation process and the promotion of competitive advantages.

This paper provides a scoping review of both academic and practice literature on how regulation may impact industry emergence. This literature is still in an exploratory phase with little clarity on how best to use regulation to support industry emergence.

Contents

1. Introduction

As part of the Emerging Industries Programme, which explores the different drivers affecting the emergence of science-based industries, this paper reviews the literature on the link between regulation and emerging industries. Its aims are twofold:

- to map and structure the research field to present in a clear way the numerous issues raised by the topic ;
- to provide a theoretical background to historical and practical case studies dealing with the constructive role regulation can play in some industry sectors.

This paper adopts a scoping approach to the literature as the research area it explores is still at an early stage of development and is addressed by an increasing number of disciplines. It nonetheless provides a structure under which some systematic reviews can be built. It conducts a selective overview of literature combining academic papers in the areas of political science and sociology of science and technology, as well as government documents. The academic papers provide both theoretical and practical insights whereas the government reports are used as examples of practical evidence about the role played by regulation. This distinction has been established on purpose to ensure that the referred literature does not encompass any political claims but only analytical pieces.

The definition of emerging industries the paper adopts is inspired from Porter who describes emerging industries as “newly formed industries, or re-formed industries” whose creation has been triggered by some economic, social or technological changes (1). In this paper, a focus is put on emerging industries that have been created by technological innovation. The definition adopted for regulation reflects the different concepts that have been introduced in the regulatory literature in the last fifteen years (2). A distinction is made between traditional command-and-control regulations and alternative regulatory instruments like self-regulation and co-regulation (3-5). The first type of regulation is mandatory whereas self-regulation and co-regulation are more voluntary. Self-regulation occurs when industry manages and enforces its own requirements to address issues without regulators being involved. Co-regulation implies that regulators set the general framework then “stakeholders fill in the details” (3). The traditional perspective and the alternative perspectives have been respectively labelled “hard” and “soft” regulatory paths in some papers (2). In her analysis about regulatory strategies to address nanotechnologies, Dorbeck-Jung combines these two regulatory paths in a concept of “smart hybridisation” and advocates the development of partly voluntary and partly mandatory regulatory instruments (6). Interestingly, standards, which are codified best practices often initiated by industry but also by regulators and which are developed through standardisation bodies, can present characteristics of both self and co-regulation.

This paper provides an overview of the literature exploring the interplay between regulations and emerging technologies from the perspective of mandatory regulations and standards (as an example of voluntary regulations). It addresses two questions: how regulations and standards can be enablers for the emergence of industries (section 2) and what the implications of this are in terms of regulatory design (section 3).

2. How can regulation and standards be enablers for the emergence of industries?

Previously considered as red tape, hindering the exploitation of new ideas and technologies, regulation has been progressively recognised as a possible enabler and spur to emergence. This shift in perception was first pinpointed by Porter in a landmark paper on environmental regulation. According to the win-win theory he developed, regulation, including stricter regulation, can provide incentives to develop innovative technologies and therefore stimulate the emergence of industries (7).

Since Porter's article, the literature has further highlighted that, far from imperilling new businesses, regulation is a key factor to shape a supportive environment for industry and a consensus has emerged amongst regulators and in academia that "a supportive regulatory environment" is one of the factors which are the more likely to positively impact on the industry capacity to innovate (8-12). A number of recent public reports have also further demonstrated that the pace of the transition from emerging technologies to a new industry highly depends on the degree of appropriateness, clarity and predictability provided by the regulatory framework in place (9, 13, 14). Appropriate regulations and standards are seen as significant drivers to foster the growth of emerging industries by performing several functions, such as facilitating the commercial exploitation, and providing a context for innovation (15) (16).

Conversely, excessive and poorly tailored regulations, as well as inappropriate or obsolete standards, are considered as a deterrent for emerging industries as the compliance costs they imply can imperil the creation of new businesses and hamper firms' capacity to innovate. A specific example from the recent literature is pharmaceutical innovation, with regulation being directly held responsible for acting as a brake by making the development of new drugs unaffordable for companies. For a number of authors, the spiralling costs caused by the regulation of drug development explain why the advances made in molecular genetics and molecular biology have not led to a flow of new therapeutics (17-19). Interestingly enough, when it comes to addressing this issue, the vast majority of authors do not question the fact that healthcare products need to be regulated but recommend streamlining the regulatory requirements.

Hodges, for instance, does not question the existing span of regulations for medicinal products but investigates how a shift in the balance of regulatory controls could permit faster approval of new products (20). The issues surrounding the inappropriateness of regulation for drug development are also being debated by public authorities. In a 2005 report, the Royal Society clearly states that one of the functions of the regulation of medicines is "to encourage the development of innovative medicinal products by not raising unnecessary regulatory difficulties" (21). The initiative launched by the Food and Drug Administration (FDA) to address the slowdown in innovative therapies reaching market shows that regulators are exploring ways to transform regulatory barriers into regulatory enablers (22).

The literature also provides some examples where standards do not support innovation but stifle and hamper it by being inappropriate and outdated. This can occur when users are reluctant to switch to another standard and are therefore "locked-in" to an inferior standard even though another would be more appropriate. This "lock-in" effect has been first pinpointed by Farrell and Saloner (23). Furthering his demonstration, Farrell explains how the investment which is required to switch from one standard to another can be a deterrent for companies and can lead to "excess inertia" (24).

However, the balance of evidence that is put forward by the academic literature and government reports about the effects of regulation and standards on emerging industries remains positive. Numerous papers and reports highlight the different ways in which regulation and standards can act as a spur to emergence. They include:

- establishing common vocabularies and agreed definitions of terms;
- increasing the confidence of investors and consumers;
- increasing the speed at which companies can bring their products to market;
- providing a competitive advantage.

The most basic contribution standards make to create the conditions to allow rapid and sustained technology developments is in establishing common vocabularies. Developing agreed terms and definitions may appear trivial but represents a very useful step in "the widespread development and application of new technologies" (25). For instance, in the case of the marketing authorisation of new drugs, the recent guidelines issued by the FDA in the US are explicitly meant to ensure the consistent definitions of key terms and consequently to advance the field of pharmacogenomics by facilitating innovative drug applications and submissions (26). Measurement standards permitting the characterisation of products and processes also allow for quicker initial development of technology. In a report on ways for the UK to develop its technological capability, the advancement of measurement standards is earmarked by the Technology Strategy Board to support the exploitation of future developments in fast moving areas of technology like photonics and electronics (27). In this regard, Allen and Sriram present several examples which point towards a positive impact of standards on innovation by "codifying accumulated technological experience and forming a baseline from which new technologies emerge" (28). Conversely, the lack of agreed standards for testing is likely to hinder the emergence of an industry. As stressed upon by Dennler, in the specific case of the solar cell industry, such a lack of standards mean that efficiencies are reported under various testing conditions and that efficiency values are impossible to compare. The resulting divergent conditions under which organic solar cell performance and properties are assessed is damaging for the whole sector (29).

From a financial perspective, regulations and standards are essential to increase the confidence of investors and insurers whereas regulatory gaps impede the development of innovative technologies by not providing enough certainty to companies planning investments (30). Standards help raise confidence from the financial and insurance sectors for technologies which are new and unproven and attract investment more quickly and

easily. In addition, they spur the establishment of markets for new technologies by allowing companies to describe their products and services in marketable terms. Illustrating their analysis with a case study of lab-on-a-chip technology for medical and pharmaceutical applications, van Merkerk and Robinson point out that standardisation by "allowing the rise of a technological platform on which actors can build" fosters the journey from a merely scientific stage to actual applications and commercialisation (31). Another advantage of standards lies in the facilitative function they can perform for commercial exploitation by offering a basis for dissemination of information and an accepted framework within which patents can be drawn up (32).

The enabling effects of regulations and standards can be observed in the market-place. For instance, they positively impact the speed with which innovative companies can bring their products to market. Focussing on the healthcare sector, Hughes-Wilson and Mackay advocate that the Advanced Therapy Medicinal Products (ATMP) Regulation, which offers manufacturers a streamlined marketing authorisation process, will simplify and accelerate the introduction of innovative therapeutic treatments (33). Consumer protection regimes as well as quality standards strengthen consumers' confidence in new technologies and innovative products and as a consequence, foster the take up and diffusion of new products and processes (34, 35). Standards also reduce transaction costs by facilitating the recognition of technical characteristics and making the satisfaction of consumers easier (36).

Norms and standards not only make the market for a new technology more transparent, they are also an important prerequisite for competitive advantage. There is therefore a major interest for countries to participate in their setting and to gain regulatory leadership (6). For instance, as part of a regulatory strategy, it is reported that the standardisation process for nanotechnologies was exploited by the UK to ensure that a global market, with a common understanding of terms and standards, would develop in an area of interest to national businesses. By taking a strong leadership of the standards work programme, at European and international levels, the UK gained credibility and competitive advantages in the field, further enabling the development of nanotechnologies in the country (37). Another example of the UK's first mover advantage in setting standards is documented by the BSI. Exploring renewable sources of energy, the UK has developed guidance documents about wave and tidal energy on the basis of which international standards are going to be drafted. According to the BSI experts, this is going to foster the growth of these nascent technologies into fully viable industries and give the UK industry an advantage over other countries (32).

Further evidence of the positive impact of regulation on emerging technologies has been provided by the case study literature. For instance, Firth observes that the television license regulation established an appropriate environment for the advancement of digital technology for voice communication in the telecommunications industry (11). A similar acknowledgment can be made in the energy retail market with regulation creating a flux of activities and transactions which have promoted innovations (38). For Vollerbergh, regardless of the type of interventions, environmental regulations have a determinant impact on innovation, especially on the direction of technological change (39). A thorough analysis conducted by Kemp points toward a similar observation

when he advances that whereas regulation is generally viewed as stimulating merely the diffusion of environmental technology, there is more evidence of regulation stimulating radical innovation (40). Significant evidence from international research shows that environmental regulation can be beneficial by creating pressure that drives innovation and alerts business about resource inefficiencies and new opportunities (41). In the case of pesticide regulation, Tait demonstrates that it is the regulation which pushed the market towards innovative products and triggered the development of new and cleaner technologies (42). Semiconductor and nanotechnology industries are highlighted as good examples of how standardisation can reduce the production cost in emerging technologies (43). In the area of biomedicine, a direct link between the type of regulation and biomedical innovation is demonstrated by Lovell-Badge who concludes that United-Kingdom is over performing thanks to the liberal regulatory regime the country has adopted to regulate stem cell research (44).

3. What are the implications in terms of regulatory design?

Regulating emerging industries raises specific design issues for regulators which have recently begun to be addressed by the literature. An example from practice is a listing of the key factors influencing the impact regulation has on innovation by BERR in a report issued in December 2008. Interestingly enough, all these factors relate to the design, implementation and enforcement of regulation and comprise: "the degree to which particular behaviours and outcomes are prescribed; the extent to which businesses can comply using existing technologies and practices; the amount of advance notice businesses are given of forthcoming changes in regulation and the amount of time they have to comply with new rules and requirements; how much uncertainty there is surrounding the regulatory framework in the future and the legal interpretation of any new regulations which are introduced; the compliance cost; the way in which changes in regulation interact with other government market-based and regulatory policies" (14). Such a list is useful as it gives a general perspective but it does not provide any prioritization.

Gunningham and Sinclair have explored what a successful regulatory design is and concluded that it depends on two factors: the adoption of key principles to guide the actions of regulators, like moderate interventionism and the empowerment of third parties, as well as the combination of traditional control-and-command regulations with less coercive and more voluntary based regulations. This combined approach was conceptualised by the two authors under the name of "smart regulation" and was initially developed in the specific context of environmental regulation (45). But the practicality of smart regulation has been questioned by a number of authors. For instance, Baldwin sees an inherent tension between better regulation and smart regulation and demonstrates that the way regulations are evaluated by government does not leave much room to alternative and less coercive or less restrictive forms of regulations (46). This point of view is shared by Radaelli who further argues that the use of impact assessment to evaluate "mixed regulatory regimes" proves to be problematic (47).

A number of academic papers have provided useful insights into some of the design issues current approaches to regulation comprise. For instance, the introduction of a precautionary principle in regulations dealing with emerging technologies has been highly debated. While some authors advance that the strict application of such a principle would turn it into a "paralyzing principle" and put an end to technological advances and innovative industries (48-50), others consider invoking the precautionary principle as an useful enabler to work under uncertainty (51, 52). Some authors have also questioned the relevance of the precautionary principle by challenging the assumption that "scientific certainty is a normal characteristic of scientific knowledge" (53) or by observing that applications of this principle are no more than a "glorified version of cost-benefit analysis"(54).

The academic controversy is not reflected in public reports, as regulators seem to have adopted a workable compromise when designing regulations for unproven technologies. As highlighted by Levidow, the precautionary principle has allowed regulators to acknowledge the limits of science to support regulations (55). From the regulators' perspective, the precautionary principle acts essentially as "an impetus to take a decision notwithstanding scientific uncertainty about the nature and extent of the risk" (56). Applying it does not therefore prevent regulators from taking decisions but highlights the necessity to assess risks in the decision-making process (57). To this regard, the purpose of regulation is to fix the "limits of tolerability and acceptability" for technological changes and the hazards they may pose (58).

The delay between the emergence of a novel technology and regulatory responses appears to be a key issue when it comes to designing new regulations for an emerging field. Currently, a pattern can be observed in the approach adopted by regulators who first establish a regulatory inventory to check potential gaps and second design new regulations to fill them. However, this reactive approach toward regulation may not be assisting the industry to emerge in an optimum manner (59). This innovation-first/regulation-after perspective is challenged by Faulkner who considers regulation and regulatory process as more active forces (60). The timing of regulation in the case of innovation is explored in the specific context of biotechnology by Brown et al. The authors demonstrate how regulatory definitions and regulatory boundaries have evolved, depending on circumstances in terms of timeline and location, and how they have influenced established institutional arrangements (61).

How can regulators adopt a more proactive stance in order to address regulatory issues in advance and sustain the growth of emerging fields? Examples of structures responsible for "horizon scanning" into the decision making process and providing regulators with information they need to anticipate the regulatory hurdles emerging industries may have to face in the future have been documented in a few papers. For instance, Hunter reports on the technology platforms the EU has launched through its framework programmes to support industrial innovation and competitiveness. Amongst other issues, these platforms allow the discussion of potential regulatory issues and inform both developers and regulators about developments to come (62). A similar experiment, carried out by the US Food and Drug Administration (FDA), is reported by Wagner, Dulaart et. al. In this case, working groups have been established within the FDA to identify the scientific and regulatory challenges in the area of nanotechnology. A specific task force has also been set up to determine whether new regulations or authorities are needed for oversight of nanotechnology (30).

Some focus has also been put on the timing of regulation. Without establishing a very precise timeline, Marchant advocates a chain of regulations to regulate emerging technologies, from data collection and dissemination to the passing of legislation (63). However, this incremental approach appears too much as a one-size-fits-all solution to be considered as a valid regulatory strategy for all emerging industries. The approach espoused by the UK Government, in response to the Better Regulation Task Force Report on scientific research issued in January 2003, seems far more practical as it takes into account the specifics of

each technology. In this document, an emphasis is placed on the need for regulators to determine and to implement regulations not according to the development stage of an innovation but by the risk, the environmental impact or the ethical concerns the underlying scientific research potentially poses (64). In the case of standards, timing of adoption is very important as a too early adoption may "shut out promising and superior technologies" whereas a belated adoption may result in a too costly transition to the new standard and therefore prevent its diffusion (65). Some studies tend to conclude that when it comes to fostering a rapid translation of research into commercial products and services, standardisation at an early stage is determinant (35).

Another major issue lies in the flexibility regulatory frameworks have to permit in order to keep pace with technological evolutions. This is a prerequisite in the design of regulations dealing with emerging technologies which, by definition, are fast-moving areas. As pointed out by EU regulators, in a working draft on the regulation for advanced therapy medicinal products, they had to find a way to embed in some of the regulatory provisions sufficient flexibility to adapt to the evolution of science and technology (66). They opted therefore for a two-staged regulatory strategy, with an overarching framework limited to fundamental issues and technical provisions to be filled through guidelines. However, such option has resulted in a complex regulatory design and in a patchy draft with numerous gaps (67).

4. Conclusion

The literature dealing with the relationship between regulation and the emergence of industries is quite recent and comprises an interesting combination of academic papers and public reports. Some topics have gathered a lot of interest like the definition and management of the precautionary principle and the positive impact of standards on innovation. The case study literature has begun to collect informative and valuable evidence to characterise the impact of regulation on a number of emerging sectors. At a theoretical level, some concept papers offer an interesting analysis of new models of regulations, especially from an EU perspective.

However, academics and regulators are still in an exploratory phase when it comes to determining a regulatory strategy to assist the emergence of industries in an optimum manner. And whether emergence is best supported by mandatory or voluntary regulations, or a combination of both, has only been addressed by the literature in a fragmented way.

By developing case studies to investigate the approaches and practice of regulation as they apply to different science-based industries, the Emerging Industries Programme is expected to complement and inform the existing literature by providing practical evidence. Building-up on these findings, it is meant to develop an analytical framework and a tool to support decision-making processes in order to improve awareness and engagement with standards and regulation.

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