

## **Papers in Innovation Studies**

**Paper no. 2014/29**

# **Institutions and Regulations in Innovation Systems: Effects, Problems and Innovation Policy Design**

Susana Borrás (sb.dbp@cbs.dk)

Department of Business and Politics, Copenhagen Business School,  
Denmark and CIRCLE, Lund University, Sweden

Charles Edquist (charles.edquist@circle.lu.se)

CIRCLE, Lund University, Sweden (Holder of the Ruben Rausing  
Chair in Innovation Research)

This is a pre-print version of a paper that has been submitted for publication to a journal.

This version: December 2014

WP 2014/29

# **Institutions and Regulations in Innovation Systems: Effects, Problems and Innovation Policy Design**

Susana Borrás and Charles Edquist

## **Abstract**

Institutions (including regulations) are constitutive elements of innovation systems, and therefore cornerstones of innovation policy. Focusing on (soft and hard) regulation, the paper identifies the most salient regulatory areas from the perspective of the innovation system. When asking about the effects of regulation on innovation, the paper argues that there are three key issues that need careful empirical analysis; namely, whether regulation is effective and efficient in terms of reducing uncertainty and generating incentives, whether it is able to generate ultimately wider social benefits for the innovativeness of the society at large; and the extent to which regulation is adapting to new (social, economic and technological) contexts and is socially legitimate and accepted. These are potentially the three problems that innovation policy needs to address in this area. This provides guidance for the design and re-design of innovation policy, so that policy makers may analyse empirically the social dynamics actually generated by regulation rather than simply assuming deductively their effects.

**JEL codes:** L38, M38, O25, O31, O32, O33

**Keywords:** Innovation system; innovation policy; knowledge production; R&D; universities; innovation policy instruments; institutions; institutional change

Disclaimer: All the opinions expressed in this paper are the responsibility of the individual author or authors and do not necessarily represent the views of other CIRCLE researchers.

# Institutions and Regulations in Innovation Systems: Effects, Problems and Innovation Policy Design

Susana Borrás and Charles Edquist

## Abstract:

Institutions (including regulations) are constitutive elements of innovation systems, and therefore cornerstones of innovation policy. Focusing on (soft and hard) regulation, the paper identifies the most salient regulatory areas from the perspective of the innovation system. When asking about the effects of regulation on innovation, the paper argues that there are three key issues that need careful empirical analysis; namely, whether regulation is effective and efficient in terms of reducing uncertainty and generating incentives, whether it is able to generate ultimately wider social benefits for the innovativeness of the society at large; and the extent to which regulation is adapting to new (social, economic and technological) contexts and is socially legitimate and accepted. These are potentially the three problems that innovation policy needs to address in this area. This provides guidance for the design and re-design of innovation policy, so that policy makers may analyse empirically the social dynamics actually generated by regulation rather than simply assuming deductively their effects.

JEL Codes: L38, M38, O25, O31, O32, O33

Keywords: Innovation system; innovation policy; knowledge production; R&D; universities; innovation policy instruments; institutions; institutional change

## **Contents**

1. Introduction.....	2
2. Institutions and regulation in the innovation system.....	3
3. Core regulation areas for innovation.....	6
4. The effects of regulation and innovation-related problems.....	8
5. Patent regulations and innovation .....	11
6. Environmental regulations and innovation .....	14
7. Conclusions: General criteria for designing innovation policy .....	16

## 1. Introduction

During the past three decades economists have become increasingly interested in the role that institutions and regulations play in the economy. This growing interest has drawn them closer to other disciplines in the social sciences like sociology, law and political science, which have largely acknowledged the role of institutions and regulations in the organising of social, economic and political life. For this reason, there is an endless literature dealing with these matters, both across disciplines and within disciplines. Yet, in spite of some interdisciplinary efforts, differences across disciplinary approaches are still remarkable. Likewise, intra-disciplinary differences are also significant given the diverse assumptions of social action upon which different theories are based.

This paper examines the role of institutions and regulations from the particular perspective of innovation. In so doing, it takes its point of departure from innovation systems in the understanding that institutions are constitutive elements of the innovation system, while regulations are specific mechanisms of state intervention (more below). More concretely, the general aim of this paper is to discuss the role of institutions and regulations in the context of the design of innovation policy. The reason for such a focus is that the policy perspective in studies about the role of institutions and regulation has tended to be rather limited. The growing literature on regulatory impact on innovation is providing interesting insights, and is perhaps an exception to this rule. But there is more to it.

The paper starts by acknowledging what we define as “the double nature of regulations”, by which regulations, like any other institution, are constitutive elements of the innovation system, and given the “visible hand of the state” in regulation, they are at the same time innovation policy instruments. This double nature is a crucial aspect for understanding the way in which innovation policy is highly engaged in the organising of the innovation system. This means that the design of innovation policy should not only be based on impact assessment exercises of regulatory policy instruments’ effects. It should be based as well on the role of institutions and regulations in reducing uncertainty, managing conflict and cooperation and providing incentives in the innovation system more generally.

Following from that, the paper identifies the most salient regulatory areas from the perspective of the innovation system, arguing that the effect of regulation on innovation is not a value statement but an open empirical question. Therefore three key research questions are formulated:

- firstly, the extent to which regulation has a positive or negative effect on innovation performance in the system;
- secondly, whether it has individual costs/benefits for the few or wider benefits for the innovativeness of the economy and society; and
- thirdly, the extent to which regulation is adapting to new (social, economic and technological) contexts and hence is socially legitimate to induce innovation in a wider social context.

More concretely, this paper examines these three matters in two core regulatory areas in an innovation system, namely, patent regulations and environmental regulations.

Taking a step further, the paper argues that a systemic approach to innovation policy needs focusing on a second level of matters, i.e. the problems associated with regulation. These are three: the intrinsic ambiguity of regulation, its degree of enforcement and compliance, and its social (rather than normative) legitimacy among socio-economic agents. This has two implications that are fleshed out in the last section of the paper. Firstly, it shows that social habits are key to understanding the effects of regulation in the innovation system; and secondly, it provides guidance for the design of innovation policy in a learning context, one that analyses empirically the social dynamics actually generated by regulation rather than a policy context that just deductively assumes their effects.

## 2. Institutions and regulation in the innovation system

Innovations are the outcome of interactions that take place within firms, between firms and other organizations, between firms and consumers, etc. Interaction here means that innovations are invariably produced and used in relation to others, and that the innovation process is one that is socially-embedded; that is, a process that occurs in a social and economic context. Institutions and regulations are the rules of the game for those interactions and for the social-embeddedness of the innovation process. For that reason, institutions and regulations shape the way in which those interactions and social contextualizations take place. In other words, innovation is a social phenomenon, subject to the rules of the game by which any society organises itself.

During the past few decades, different strands in the field of economics have looked more carefully at how institutions are actually organising the economy, and how they can organise it in more efficient and effective ways. Highly inspired by other fields related to human and social sciences, like sociology or anthropology, new institutional economics has developed interesting insights into economic history and economic organisation (Menard and Shirley 2008).

Social theories inspired in rationalist approaches to institutions tend to take their point of departure from the understanding of social action as being intrinsically a rationalist and utility-maximising behaviour. Actors are motivated by individual and materially-defined interests, which are a specific position defining their preferences in social-interactions. Actors (inter)act following a logic of consequentiality on the basis of their material interests (March and Olsen 1989), and utility optimize their behaviour. Institutions are perceived here as specific rules that actors aim to utilize (and if necessary to bend) in order to achieve their individual goals.

Actors might act differently vis-à-vis institutions. They might somehow tend to be opportunistic, making the most of institutions that are not clearly defined, or searching for some specific interpretations of those rules that might benefit their own interests (Mahoney and Thelen 2010). Hence, from the rationalist perspective of these institutionalist approaches, actors might behave differently, but always following their specific material interests and with a logic that seeks to be consequent with that. From the perspective of the economy, theories inspired by rational approaches tend to look at institutions from the perspective of efficiency. The main issue here is the extent to which institutions constitute efficient rules for market-based interactions. Focus on transaction costs is one such approach (North 1990).

Alternatively, other strands in the social sciences consider that social action is not always based on rational calculations. Rationality is bounded by social ties and the history of previous decisions. Moreover, social actors might have aspirations other than maximising individual material interests (like altruism). The axiom of social action is not only the rational pursuit of one's individual interest, but also the need to be accepted. Hence social behaviour is not really an issue of just "following the rules" in order to achieve a goal, but mainly an issue of endogenising those rules as "the right thing to do" and incorporating them to everyday routines and habits (Hodgson 1997).

From the perspective of an innovation system, these brief theoretical considerations are paramount for two reasons.

Firstly, innovation is the fruit of social action by the innovators. Naturally, innovators engage in innovation activities in the expectation of obtaining some gains. These are normally monetary gains, but can also be of other kinds, like social recognition. The theoretical considerations above remind us that the innovator's motivation and incentives to engage in innovative activities is a crucial aspect of institutions. Likewise, the theories remind us that the relations between an actor (organization) and institutions might be different, but in any case institutions shape the way in which actors' interactions take place, and provide certainty about what to expect from those interactions (more about this below).

Secondly, these theoretical considerations tend to indicate the constitutive nature of institutions. Either perceived exogenously (rational institutionalism) or endogenously (sociological institutionalism), institutions are the 'glue' that organises a society. This links with our current innovation system perspective, where the whole is larger than the sum of the parts. That is, an innovation system is not just a mere juxtaposition of individual innovators or organizations at a specific territorial level. The system is formed by sets of complex interactions and ways of organising innovation activities that are unique to that system. Institutions are those constitutive elements that are crucial to understanding the idiosyncrasies of each innovation system.

However, the richness of this literature in theoretical as well as in conceptual terms still leaves us with difficulties of operating from a coherent analytical perspective. For this reason, some conceptual clarification is needed at this point. We see institutions as "sets of common habits, routines, established practices, rules, or laws that regulate the relations and interactions between individuals and groups" (Edquist and Johnson 1997) p. 46). This definition shows that institutions are rather broad, as they include not only politically-determined laws and formal rules enforced by the state or other authorities, but also socially-defined rules of behaviour that tend to be more open-ended and implicitly defined, like routines and established practices. In a sense, this definition of institution tells us that an institution is any type of rule of the game that organises social interactions among individuals and organizations.

Yet, not all institutions in a social order affect innovation processes directly. For that reason, from the perspective of innovation and innovation systems, some institutions might be more relevant than others. This is particularly the case if we look at some technological or industrial sectors, for example the agro-food sector. Some institutions might be more relevant than others for the innovativeness of this sector in a given country, for instance, the laws pertaining to food safety controls, or the eating habits and traditions in that society (fast or slow food, preference for ecological/non-GMO foods). Acknowledging this, we define

“institutional frameworks” as those sets of specific institutions that are most relevant for a given sector or area.

Looking carefully at the way in which we have formulated these definitions, the verb to “regulate” comes to the fore. This is so because regulation has for many years been associated with institutions and institutional frameworks. Political scientists in particular have studied the changing role of regulation in our contemporary political systems, which has transformed along with the changing nature of the state and of governance dynamics (Jordana and Levi-Faur 2004). Notions like the regulatory state (Majone 1994) or ‘governance’ (Pierre and Peters 2000) have captured these transformations. All this shows that the notion “regulation” might be quite complex, and that “regulating” can mean different things.

For the reasons above, we generally follow a definition of *hard regulation* that refers to the narrow understanding of the concept; namely, “an authoritative set of rules, accompanied by some mechanism, typically a public agency, for monitoring and promoting compliance with these rules” (Baldwin, Scott et al. 1998) p. 3 in (Jordana and Levi-Faur 2004). “Authoritative” here means legally binding, in the understanding that hard regulation refers to obligatory rules that must be followed by citizens, firms and organizations. Some of these obligatory regulations come directly from the state, hopefully as the outcome of democratic legislative processes. Some other obligatory hard regulations might come from regulatory agencies, which are public organizations to which the state has delegated regulatory powers. These regulatory powers are typically in specific sector and technical areas, for example environmental protection, or drug and medicine regulations, where technical expertise is required. Accordingly, hard regulations are a sub-category of institutions.

Taking into consideration the second transformation mentioned above, we need to include a third definition in order to capture the complexity of regulations and institutions in our contemporary economies and societies. This is the case of “*soft regulation*”, which refers to formal and explicit rules that are not legally binding, for instance a code of conduct or a voluntary agreement. Soft regulation is formal because we are talking about rules that are explicitly formulated in written text. These are typically put forward in semi-official documents and/or other forms of formalized official communications, which serve to provide moral support and/or put pressure on actors, while defining collective expectations and what behaviour is (not) acceptable.

Soft regulation differs from hard regulation because the former is not legally binding, and hence does not enjoy the enforcement mechanisms of the state to force compliance. No one goes to jail for not following the wording of a voluntary agreement, but they might in the case of hard regulation because it is compulsory. Likewise, soft regulation constitutes only a part of the notion of institutions, because the latter include all of the former (hard regulation, soft regulation) as well as many other types of social rules of the game, namely the set of implicit, unspoken and undeclared sets of common habits, routines or established practices. The strongly informal nature of these differs from the (semi-)official and explicit formulation of soft regulations. The box below summarizes these definitions.

Box 1: Definitions of institution, soft regulation, and hard regulation.

Institution: “Institutions are sets of common habits, routines, established practices, rules, or laws that regulate the relations and interactions between individuals and groups” (Edquist and Jonhson 1997) p. 46.

Soft regulation: Formal and explicit set of rules that are not legally binding. For example. a code of conduct.

Hard regulation: “an authoritative set of rules, accompanied by some mechanism, typically a public agency, for monitoring and promoting compliance with these rules” (Baldwin, Scott et al. 1998) p. 3 in (Jordana and Levi-Faur 2004).

From the above it follows that institutions are the broadest form of rules of the game organising social interactions, in our case interactions related to innovation activities. Regulations, in their hard and soft forms, are also rules of the game, but they are far more explicit and formalized than many other institutions. Therefore, we can illustrate the relationship between them as Russian dolls encapsulating each other: Institutions are the broadest and most generic definitions of rules of the game, whereas soft and hard regulations are more specific.

### 3. Core regulation areas for innovation

What particular core areas of regulation are most relevant for innovation activities? In principle, many types of regulations or institutions are related to innovation activities because innovation is a complex and very diverse and widespread human activity. However, seen from an innovation policy perspective, some regulations have more relevance than others, because they have a more direct effect on the process of innovation and on the way an innovation system is organised than others. We consider regulatory areas to be ‘core regulatory areas for the innovation system’ when they have a horizontal effect on the entire system. ‘Horizontal’ refers here to regulatory effects that cut across specific industrial or knowledge sectors, and have a wide effect on the innovative activities of many different socio-economic sectors. This might differ from other more generic taxonomies of regulation, which are not particularly focused on innovation processes but on regulatory reform more generally (OECD 1997).

In this paper we consider five core regulatory areas in an innovation system:

- (1) Immaterial assets and knowledge appropriation regulations;
- (2) Fair market competition regulations;
- (3) Financial and corporate governance regulations;
- (4) Consumer protection and product liability regulations; and
- (5) Environmental protection regulations.



(1) Starting with the first, the appropriation of immaterial assets and new knowledge by means of intellectual property rights is an important area of regulation with a very direct impact on innovation activities. As we will see in the next section, there are different ways of appropriating immaterial assets and new knowledge created/developed by the firm. These regulations determine the conditions under which innovators (firms and individuals) are able to appropriate immaterial assets (brands, trademarks, designs) and/or new knowledge/ ideas produced by them (patents, copyrights, etc). The expected outcome of these regulations is the generation of incentives to invest in new knowledge and in the development of immaterial assets to foster innovation.

(2) Fair market competition regulations in the form of anti-trust laws, merger & acquisition control laws, are also core regulatory areas. These regulations aim at creating a level playing field for all economic actors, and securing a context where innovators are able to compete with new ideas and new products under fair conditions in the market. Therefore these regulations reduce uncertainty, as well as manage conflict and cooperation.

(3) Financial and corporate governance regulations are those regulations that define legal requirements for the creation of new firms, bankruptcy laws, corporate governance structures, etc. These regulations are also the core for any innovation system for several reasons. Access to capital at a competitive market-based price, with transparent and law-enforced conditions, is key to any innovator (start-up or established firm). Likewise, corporate governance regulations determining, among other things, the conditions and responsibilities in the crucial steps of a firm's life (i.e. legal requirements to create a new firm, bankruptcy laws, inheritance laws, etc.) are also fundamental, reducing uncertainty and defining the framework for conflict resolution and cooperation.

(4) Consumer protection and product liability regulations (typically hard and soft laws defining mandatory or quasi-mandatory standard technical requirements for products, laws for consumer protection, liability laws, etc.) are also horizontal and key regulatory areas in the innovation system. Innovators are always confronted with the potential risks that their new products might expose consumers to. These regulations are set up in order to determine the standardized specific technical requirements of products, as well as the procedures to make mandatory decisions that limit possible harm to consumers (food safety, drug safety, product certification, etc). They determine as well the levels and forms of firms' liabilities when harm has been done. As such, these regulatory areas aim essentially at reducing uncertainty and limit risk.

(5) Last but not least, a fifth core regulatory area with wide effects on the innovation system is the area of environmental protection regulation (understood widely to include energy, transport, natural resources, packaging sectors, etc). Some innovative products and processes might have negative effects on the natural environment, whereas others might help in solving endemic problems of pollution and inefficiency. In principle, innovation can go both ways in terms of its impact on the environment. For this reason, environmental protection regulations aim at addressing both dimensions of innovation's impact on the environment, including dealing with negative environmental externalities. In some cases these regulations are oriented towards creating incentives in specific eco-friendly directions; whereas in others they are aimed at setting the legal limits of pollution and assigning liabilities to pollutants.

Table 1: Five core regulatory areas in the innovation system

<b>Regulatory Areas</b>	<b>Expected effects in the innovation system</b>
<b>Immaterial assets and knowledge appropriation regulations</b> (Intellectual property rights)	Provides incentives to invest in new knowledge and in the development of immaterial assets, fostering innovation.
<b>Fair market competition regulations</b> (Anti-trust law, merger & acquisition control law, etc.)	Creates a level playing field for market interactions, reduces uncertainty and manages conflict/cooperation in cross-firm innovation interactions.
<b>Financial and corporate governance regulations</b> (Requirements for the creation of new firms, bankruptcy laws, corporate governance regulations, etc.)	Provides incentives to invest by defining rules and fair price of capital as well as reducing uncertainty about conditions and responsibilities in key steps of firm's life (creation of new firms, bankruptcy, inheritance, etc.)
<b>Consumer protection and product liability regulations</b> (Hard and soft law defining technical requirements for products, standards, consumer protection principles, and rights)	Reducing the uncertainty of existing and particularly of new/innovative products, and eventually also limiting innovative products' risks of harming consumers.
<b>Environmental protection regulations</b>	These regulations deal with the negative environmental externalities of products in different ways, sometimes by creating incentives in specific innovative eco-friendly directions, and at other times by defining the limits and responsibilities of pollutants and forcing them to find innovative alternatives.

#### 4. The effects of regulation and innovation-related problems

Our current societies and economies are largely regulated, and those regulations have been behind part of the innovation performance outcomes since the industrial revolution. In particular, the advancement of the contemporary state after World War II has been largely based on an increasingly sophisticated regulatory activity on the part of the state, which has shaped the evolution of developed and developing economies and societies, here including innovation performance. This historical co-evolution does not automatically mean that regulation is good or bad, socially fair-unfair, flexible or rigid through time. It means only that there has been a clear co-evolutionary process between the state-promoted regulatory institutions and

technology (Nelson 1994). The effect of regulation on innovation is an empirical question, not a value statement.

From a theoretical perspective, institutional economics has identified three generic (expected) effects of regulation (as particular forms of institutions) in the economy: reducing uncertainty, managing conflict and cooperation, and providing incentives (Edquist and Johnson 1997). Table 1 above summarizes the expected effects of these particular core regulations on the innovation system, according to these three overall issues.

More recently, however, these theoretical issues have been given an empirical dimension, for instance by being used to address such things as the actual effect of regulation in the economy, here including the effects on innovation (see (Blind 2012) for an excellent review). It is worth noting that these empirical studies go beyond the three theoretically-deduced items above, and include a myriad of other issues and questions, sometimes rather specific to the regulation in question.

From these, we can identify three empirical research questions on the effect of regulation on innovation.

- (1) The first one closely follows the items mentioned above, i.e., what is the effectiveness of the regulation in terms of the costs of compliance and the incentives it generates? This is what Knut Blind has examined in a seminal paper, when he measures the effects of “compliance costs on the availability of resources for innovation on the one hand, and the incentives set for performing innovation activities on the other hand” (Blind 2012): 392. His comparative study of 6 regulatory frameworks in 21 OECD countries over a 6-year span shows mixed results: whereas product and service regulations, and environmental regulations seem to have an overall negative influence on innovation performance at country level (the benefits of innovation incentives do not overcome the costs of compliance), non-restrictive price regulations, intellectual property right regulations and the regulatory framework encouraging the competitiveness of enterprises seem to have positive effects on innovation performance.

This general approach to the impact of regulation on innovation, which is also based on a cost-benefit focus on costs of compliance, is very useful and relevant, as it serves to provide an overall and comparative view. However, this macro-level perspective loses detail, as it is not able to sufficiently acknowledge the complexity of each regulatory framework (IPR for example encompasses quite broad and diverse types of regulations), or the diversity of the regulatory effects on innovation across firm sizes (SMEs or large firms), across industrial sectors (patent regulations have different effects on innovation in the biotech sector than in the ICT sector), or across economic regions in the same country.

- (2) The above remarks lead to a second crucial question about the effect of regulation on innovation: the balance between private benefits and social benefits. This is an issue that lies at the core of state action when regulating. Some regulations, like intellectual property rights, grant individual proprietary rights to firms or innovators as a mechanism to create incentives to innovate. Other regulations impose obligations and restrictions as a way of shaping specific behaviour (like competition regulation prohibiting cartels, or environmental regulations obliging firms to introduce specific technologies in their products).

The extent to which these individual rights and/or obligations-restrictions generate private costs/benefits and/or social costs/benefits is an important question. We assume that the state regulates in the expectation that individual costs and benefits in a society will be distributed in a way that will ultimately generate a positive effect over the entire society and economy. Even if some socio-economic agents bear more costs than others, the overall bottom line for the economy and society needs to be positive and stimulate innovation. This is, however, an empirical question, as some regulations and their application might generate unbalanced social outcomes.

One example is the US medical device regulations, which has encouraged incremental rather than radical innovations on the grounds that the former are safer for patients than the latter. The recent case of the hip prosthesis, where “safer” incremental innovations proved to be very problematic for patient safety, makes the point that the assumptions upon which regulations and their approval procedures are based do not prove to be always right, and that a dynamic view on the actual impact of regulation (not just the assumptions) is needed for achieving general social benefits as well as individual (patient) benefits (Barberá-Tomás and Molas-Gallart 2014).

- (3) The third crucial empirical question on the effect of regulation of innovation has to do with the adaptability and legitimacy of regulation. Here the debates have recently revolved around the issue of whether hard or soft forms of regulation are best in innovation-related areas that change rapidly. For example, it has been argued that hard regulation of new and advanced materials might not be the best way of regulating them. This is so because hard regulation tends to treat them as if they were chemicals, but these materials do not behave like chemicals and there is considerable uncertainty about their properties. The argument is that the relatively rigid nature of hard regulation does not allow a sufficiently rapid adaptation to the new needs posed by technological advancements. Therefore, the argument continues, soft law in the form of self-regulation by the industry and experts is more rapid and flexible. These arguments however, tend to disregard the crucial issue of the (social and political) legitimacy problems that soft forms of self-regulation typically entail, particularly when consumer protection or environmental protection is at stake. Therefore, for others, self-regulation as a soft form of regulation is only a first and preliminary step towards an eventual hard regulation that might secure both adaptability and legitimacy.

These three items (the effectiveness-efficiency of regulation to promote innovation; its social and private benefits in the society and economy; and its adaptability and social acceptance in complex and uncertain technological contexts) constitute potential problems in an innovation system, which innovation policy makers might like to address. As mentioned above, from an empirical perspective, *they are the three key research questions when examining the effects of regulation in an innovation system*. This paper examines them in more detail in two core regulatory areas for the innovation system: patent regulations (specific legal rights among other intellectual property rights), and environmental protection regulations. Both sets of regulations are quite different. The first one focuses on granting individual rights in the form of appropriation of new and industrially-applicable knowledge, and hence generates individual incentives to invest in the production of new knowledge and its utilization. Environmental regulations, on the other hand, deal with the negative environmental externalities of innovative and existing products in different ways, sometimes by creating incentives in specific eco-friendly directions, and at other times by defining the limits and responsibilities of pollutants.

## 5. Patent regulations and innovation

Intellectual Property Rights are institutions (legal forms) that allow economic actors (individuals, firms or any organization) to appropriate and protect knowledge or other immaterial assets. Patents are one such legal form that states grant an individual or organisation. They are particularly important for innovators because they allow them to obtain a time-limited monopoly over the use of specific new knowledge. Despite the old discussions of whether patents are natural rights or not, there is a widely accepted assumption that patents are important for innovation in the economy (Guellec and ven Pottelsberghe de la Potterie 2007) More on this issue below.

To obtain a patent an individual or organization has to file an application to a national patent office – or to the European Patent Office, in the EU. The “claims” is the specific section of the application where the applicant describes the knowledge for which s/he requests a patent. Patent offices are specialized regulatory agencies in charge of examining those applications and making the decision to grant (or not) a patent. Those agencies employ scientific and technical experts (patent examiners) who examine the technical nature of the applications. It can take several years between an application and the actual filing (granting) of a patent.

It is worth noting that not all knowledge can be patented. Knowledge that is patentable must generally comply with three criteria: novelty (the knowledge should not have been patented before/ publicly available), “inventive step” or non-obviousness (the knowledge should not be common sense in the particular field it relates to), and the knowledge must have an industrial applicability. Naturally these conditions are different for each patent regulation, but most national patent regulations follow these three criteria, which are anchored in economic theory (Encaoua, Guellec et al. 2006).

During the past two decades there has been a series of public debates about the limits of patentability, or the limits of the subject matter eligible to be patented. This refers specifically to the debates about whether biotech discoveries/inventions and whether software can be patentable. The source of the debates have to do with the three criteria mentioned above, as some authors argue that the clear-cut lines between discovery (not patentable) and invention (patentable) is in reality blurred, and many discoveries are actually being patented (Nelson 2004). Likewise, other debates revolve around the ethical limits of patenting, particularly in the biotech sector. And yet more debates are about the negative effects of patenting vis-à-vis other more open types of intellectual property rights, for example software, which is already protected by copyrights. The limit of patentability is a topic that remains open to discussion along with the rapid changes of patent systems worldwide during the past few years (Borrás and Kahin 2009).

Due to national jurisdictions, patents are nationally-based rights<sup>1</sup>. However, the rapid globalization of economic and innovative activities since the 1990s has put considerable pressure on national patent

---

<sup>1</sup> The formal agreement in December 2012 by 25 of the 28 EU member states to create the Unitary Patent will grant the same patent rights across these countries. All other patent rights in the world are based on national-only jurisdiction.

systems, which has led to a rapid internationalisation of intellectual property rights' regimes. This has taken place in different dimensions, both formal and informal. One of the most significant formalized ones is the TRIPS Agreement in the 1990s, signed under the auspices of the WTO, which linked the issues of intellectual property rights to trade policy arrangements (Borrás and Ougaard 2001).

Likewise, there has been a rapid de-facto collaboration across the largest patent offices worldwide, particularly the USPTO, the European Patent Office, and the JPO (Japan Patent Office). The role of the World Intellectual Property Organization (WIPO), a UN organization focusing on intellectual property rights in the developing world, has also gained considerable saliency the past years. Yet the tension between national rights and the efforts to create a coherent international framework for the exercise of these in the international context is still there, particularly among developed and developing countries, due to their different economic interests in intellectual property.

The economic rationale behind the regulation of patents is that patents stimulate innovation by granting time-limited monopoly power to patent-owners, which lets them exploit new knowledge. This gives patent-owners an advantage in the market, as no one else is allowed to use that knowledge without the explicit permission from the patent-owner (usually with licence payments). The background to this economic rationale is the non-rival and non-excludable nature of knowledge (which can be easily copied), naturally resulting in new knowledge being rapidly copied by competitors. The nature of knowledge is a powerful disincentive for private investments in knowledge creation, because no economic actor would like to invest in creating new knowledge only for it to be rapidly copied by competitors. Patents allow patent-owners to exploit in exclusivity the new knowledge, and thereby stimulate further private investments in knowledge creation. Besides, patents disclose knowledge because the claims are publicly available. This is also positive for the economy because it allows transparency of the knowledge-frontier.

Even if the theory above is well articulated and serves as a solid rationale for patent regulations, the extent to which patent regulations *actually* stimulate innovation performance in an economy is an empirical question. Several scholars have approached the topic, with mixed results. In the same vein of positive findings by Blind 2012 above, other authors have found a positive relation between IPR and economic growth (Eicher and García-Peñalosa 2008). However, many caveats apply. Firstly, it is strongly related to the quality of the legal and judicial institutions enforcing IPRs (Eicher and García-Peñalosa 2008). Secondly, and very important, IPR and, in particular, patents have very different impacts on different economies and different industrial sectors (Guellec and van Pottelsberghe de la Potterie 2007). For this reason, there is no strong evidence showing that stronger protection of IPR would invariably increase innovation performance in an economy (Encaoua, Guellec et al. 2006).

Economic evidence has shown that the specific features of patent regulation affect the appropriation and exploitation of knowledge in the economy (for a review see (Encaoua, Guellec et al. 2006) (Rigby and Ramlogan 2012). Yet, hard regulations are embedded in a larger set of institutions which include informal interactions. Particularly relevant in this regard is the finding of Lerner in his study of changes in patent applications in 60 nations as a result of changes in national IPR regulations over 150 years (Lerner 2009). His findings are negative, meaning that the strengthened patent regulation has not generated the expected results in the number of patent applications. Partly complementing these findings, Furukawa shows that there is an inverted U-relationship between strong IPR and innovation (Furukawa 2010). There might be many reasons for these findings, among them the time-lag issues between regulatory change, patent

applications, and innovation outcomes; as well as differences between developed and developing countries; or differences across firm size. Particularly important are the sectoral differences across industrial sectors, as some pro-patenting sectors like pharma or biotech are more dependent on patents to secure their business model than the software engineering sector, for example.

The question regarding the effectiveness of (strong) patent regulations in terms of stimulating innovation must also be linked to questions related to the costs of obtaining and enforcing patents (efficiency questions). Patent applicants must pay for the application of the patent, and once obtained, they must also pay an annual renewal fee to the patent office (the state). For this reason, patent owners might decide to drop the renewal of a patent some years after they obtained it if it turns out that the patent has not lived up to their initial expectations. In fact, it is quite expensive for the patent owners to keep a portfolio of patents. In the European Union the debate on costs has been particularly intense, as the costs of language translation and patent litigation in different EU-country legal systems have traditionally been very high. Reducing those costs has been one of the reasons for the recent efforts to create a EU-single “unitary patent” (Borrás and Kahin 2009). Furthermore, there is also a cost of defending patents in any legal patent system. This is particularly problematic for small and medium sized enterprises (SMEs), particularly in litigation against large companies. This has led to some policy-related discussions about creating accessible and cost-effective forms of “insurance” for SMEs that could help them to defend their patents in these costly litigations.

The second empirical question concerning patent regulations and the innovation system has to do with the balance between the individual benefits of patent ownership and the overall social benefits that this might generate. There are several interlinked issues related to this question, but perhaps the most exciting one has to do with the hypothesis of the “anti-commons” problem. This is a problem where knowledge, which largely advances in a cumulative way based on previous knowledge, becomes gradually (time-limited) private property, reducing the free flow of scientific knowledge and ultimately of scientific advance and innovation.

The debate about the anti-commons problem is related to several general matters. One is the surge in the number of patents during the last two decades, which might pose difficulties, particularly for SMEs (Guellec and van Pottelsberghe de la Potterie 2007). The second matter has to do with the strength of patent regulations, which might reduce the “knowledge pool” available to everyone in an economy (Stiglitz 2014). Third, the anti-commons problem has been related to the growth of academic patenting, particularly in Anglo-Saxon universities, a phenomenon that started in the early 1980s with the Bayh-Dole act in the US allowing universities to own the knowledge produced by their employees (Grimaldi, Kenney et al. 2011).

This represented a major shift in the way US research universities had traditionally transferred their knowledge and technology (Feldmann and Breznitz 2009). In the early 2000s most European countries abolished the traditional “Teacher’s exception” by which university professors were entitled to own the result of their knowledge. Abolishing that meant that it was no longer the professor who personally owned this knowledge, but his/her employer, the university. Little is known yet if the trends towards university patent ownership (Geuna and Rossi 2011) represent a reduction of the free accessibility of knowledge (Sampat 2006), but some evidence tends to indicate that the overall effect of the anti-commons might be more modest than hitherto assumed (Murray and Stern 2007).

Patent regulations have been changing in quite a substantial way in the past decades. This is due not only to the international trends mentioned above, with formal treaties and informal collaborations between patent agencies, but also to new views and expectations of the role of patents in the economy and society. Patents are no longer the turf of technical experts or legal attorneys in ivory towers, but the subject of heated social and political debates about what is just, fair and ethical, as well as economically best. Time and again, there has been a tendency to see that a patent system is diametrically opposed to its social legitimacy, as if policy-makers are confronted by an unsolvable dilemma. This is far from being the case in the day-to-day implementation of regulatory decisions, and in the political considerations of major changes in the regulatory framework, because the effectiveness of a patent regulatory framework largely depends on the way in which its stakeholders perceive it to be legitimate, valid and worthwhile (Borrás 2006).

Two of the most salient examples of the adaptability of patent regulatory frameworks are the US changes introduced by the “America Invents Act” and the EU creation of the Unitary Patent, both in the 2010s. It is naturally too early to see how these major substantive, administrative and procedural changes will affect both innovation systems. In any case, they were the outcome of extensive political debates not only among the traditional stakeholders of this regulatory area (large-small firms, patent attorneys, inventors, etc), but new stakeholders from civil society organisations interested in the ultimate societal impact of this key regulatory area. The effectiveness of the changes will not only have to do with the way in which the new rules and procedures work, but also how far they are able to engage particular forms of socio-economic behaviour that materialize in the expected outcomes of the new framework. In other words, how socially legitimate they are.

## 6. Environmental regulations and innovation

Environmental regulations are normally designed in order to reduce the negative externalities for the environment, and hence aim at protecting the natural environment. Innovation might be an outcome of this because environmental regulation, among other things, encourages (by different means) firms and individuals to develop and use innovative eco-friendly solutions. This might in turn generate innovation dynamics in the economy. However, the extent to which environmental regulations foster innovation is a difficult question to answer for several reasons:

- Firstly, because the causal relationship between regulation and innovation might not be direct, but most likely indirect. Many complex factors, not least wider socio-economic and technical factors (based on important technical and sectoral differences) may intervene in different ways.
- Secondly, because there might be a considerable time lag between changes or creation of a new regulation, and its possible effects on innovation as it takes time to develop and diffuse innovations.
- Thirdly, because environmental regulations rarely operate in isolation. Many environmental regulations operate in complex interactions with other regulations (at different levels: regional, national, international, supranational; or regulations of complementary/close sectors), and with other policy instruments of non-regulatory nature (i.e. economic instruments or voluntary



instruments). This interaction with other regulations and other types of policy instruments makes the link between regulation and innovation more complex, and therefore it is more accurate to talk about the effect of regulatory frameworks (rather than the effect of individual regulations) on innovation.

There is currently an extensive literature that deals with different aspects of the innovation effects of environmental regulations. This literature has focused on various dimensions of the three questions mentioned in the previous section (on patents): (1) the extent to which environmental regulations actually positively stimulate innovation performance in an economy; (2) the question regarding the balance between the individual benefits/burdens of environmental regulation and their overall benefits for the society and the economy, and (3) last but not least, the adaptability of environmental regulations and their wider social acceptance as instruments of innovation.

Regarding the two first questions; since the mid-1990s there has been a lively debate among economists about the extent to which (harder) environmental regulations hinder or enable economic competitiveness and the innovativeness of an economy (Porter and Van der Linde 1995) (Jaffe, Peterson et al. 1995) (Jaffe and Palmer 1997). These studies have provided theoretical as well as empirical evidence that assumptions regarding the costs of environmental regulations for the competitiveness and innovativeness of firms and of the economy at large are not acceptable. More recently, this has been analyzed in a more encompassing manner, looking at different firm level economic performance indicators showing a more varied picture as win-win situations between regulation and economic performance vary across different sectors (Stefan and Paul 2008).

More recently, analytical efforts have expanded into broader directions. One such direction looks at the effects of regulations and other regulatory policy instruments on “policy-desired innovation paths”; that is, the innovation path that policy-makers had in mind when designing the regulatory measure (Mazzanti and Zoboli 2006), which might have specific effects on concrete sectors (Walz, Schleich et al. 2011). These studies point towards the effects of different policy instruments (and their mixes) in attaining public goals, underlining the importance of looking at the effects of environmental regulations together with other policy instruments (Borrás and Edquist 2013).

Some other studies look exclusively at the effect of regulatory frameworks on innovation, but instead of looking only at environmental regulations, they take all possible forms of regulation that might have an effect. This gives rise to a series of methodological challenges mentioned above. Therefore much recent effort has been put into developing assessment methodologies, particularly in an ex-ante manner to “screen” the impact of regulation on innovation performance in specific sectors like water management or raw materials (Peter, van der Veen et al. 2013).

Environmental regulation aims at inducing changes that have a positive impact on the environment. Therefore, when asking about the impact of this regulation on innovation, it is important to acknowledge that it is not only a matter of an economic-competitiveness type of innovation, but also social change. That is, changes in the way society organises itself and is able to modify behaviour and actions to promote solutions to complex societal problems by means of using existing resources (not always economic resources).

The credibility of environmental regulation and the trust that its enforcement generates in the society are paramount here. Normally this cannot be achieved solely by a command-and-control involvement of the state through sanctioning and punishment, but a more cooperative mode, based on inter-organisational interactions and networks, that lead to complementary or alternative forms of collaboration of a non-coercive nature. This is the reason why studies devoted to voluntary new modes of governance in the field of environmental protection (like voluntary agreements, codes of conduct, self-defined standards, etc) have been particularly interested in their effectiveness (Bäckstrand, Khan et al. 2010).

The introduction of technological innovations and their wider diffusion in the society and economy are largely related to the societal acceptance of these by citizens and consumers at large. This has more to do with the rates of innovation diffusion than the levels of innovation performance of an economy. However, from the perspective of the wider goals of innovation policy (not only economic growth, but also social wellbeing), the former is an important aspect to consider.

## **7. Conclusions: General criteria for designing innovation policy**

Following the extensive economic literature on institutions, this paper sees regulation as a particular form of institution that sets the rules for innovators by means of the enforcement of legally binding laws, or by means of voluntary non-coercive agreements and standards. Whether hard or soft, regulations must fulfill the generic role of institutions, which is to reduce uncertainty, manage conflict and cooperation, and provide incentives. Institutions are the “rules of the game” that partly define an innovation system. But regulations are also innovation policy instruments, through which a state or government sets up goals and defines courses of public action fostering innovation. For this reason, regulations have a double nature: they are constitutive elements of the innovation system as rules of the game, and at the same time some of them are specific innovation policy instruments. The questions related to the extent to which regulation enhances innovation or not have been debated at length in the literature, with mixed results.

The previous section identified three possible problems associated with the relation between regulations and innovation. This constitutes a good starting point to identify some general guidelines and criteria from the perspective of innovation policy. Innovation policy aims at promoting and fostering the levels of innovative activity in the economy and society, or changing the trajectory of innovation processes. This requires the ‘rules of the game’ to define the interactions between socio-economic actors in the socioeconomic process that innovation is. For this reason, when designing innovation policy it is important to take into account these three possibly general systemic problems.

Following from this, the first guiding criterion for innovation policy in terms of regulation is to be effective and efficient when promoting some specific rights, and to impose obligations and restrictions so that incentives are generated and innovation is promoted. This might sound quite obvious, but it requires that policy-makers do not assume ex-ante that their expectations will be automatically fulfilled when a new law is passed or an existing one is revised. The effects on innovation might be somewhat unpredictable if socioeconomic agents do not behave in the way expected of them. There might be some intentions of

policy-makers and regulators that “get lost in translation” from the plenary rooms of national parliaments to the everyday life of innovators.

The second guiding criterion when designing innovation policy is the need for regulations to achieve overall positive social benefits. Likewise, it requires that policy-makers make sure that there is a balance between the costs and benefits of regulation, particularly from the perspective of the general interest and the wider social benefit of regulation for the entire economy and society. Determining this requires a careful assessment of regulatory impact in an ex-ante (before the law is passed or reformed) and ex-post manner (some time after the law has been enforced, to determine its overall social outcomes).

Last but not least, regulations need to be adaptive and to change over time, as the circumstances and new advances in knowledge might indicate. This is particularly important in innovation-related areas like the ones mentioned above, as technical knowledge advances very rapidly. Hopefully, regulatory reform will be done in a democratic context.

## References

- Baldwin, R., C. Scott and C. Hood (1998). Introduction. A Reader on Regulation. R. Baldwin, C. Scott and C. Hood. Oxford, Oxford University Press: 1-55.
- Barberá-Tomás, D. and J. Molas-Gallart (2014). Governance and technological change: the effects of regulation in medical devices. The Governance of Socio-Technical Systems: Explaining Change. S. Borrás and J. Edler. Cheltenham, Edward Elgar.
- Blind, K. (2012). The Impact of Regulation on Innovation. NESTA Compendium of Evidence on the Effectiveness of Innovation Policy Intervention. Manchester, Manchester University.
- Blind, K. (2012). "The influence of regulations on innovation: A quantitative assessment for OECD countries." Research Policy **41**(2): 391-400.
- Borrás, S. (2006). "The governance of the European patent system: effective and legitimate?" Economy and Society **35**(4): 594-610.
- Borrás, S. and C. Edquist (2013). "The Choice of Innovation Policy Instruments." Technological Forecasting and Social Change **80**(8): 1513-1522.
- Borrás, S. and B. Kahin (2009). "Patent Reform in Europe and the US." Science and Public Policy **36**(8).
- Borrás, S. and M. Ougaard (2001). "Patentløsninger - Intellectuel ejendomsret, EU og WTO." GRUS **22**(64): 25-42.
- Bäckstrand, K., J. Khan, A. Kronsell and E. Lövbrand, Eds. (2010). Environmental politics and deliberative democracy: examining the promise of New Modes of Governance. Cheltenham, Edward Elgar.
- Edquist, C. and B. Jonhson (1997). Institutions and organisations in systems of innovation. Systems of innovation. Technologies, institutions and organisations. C. Edquist. London, Pinter: 41-63.
- Eicher, T. and C. García-Peñalosa (2008). "Endogenous strength of intellectual property rights: Implications for economic development and growth." European Economic Review **52**(2): 237-258.
- Encaoua, D., D. Guellec and C. Martínez (2006). "Patent systems for encouraging innovation: Lessons from economic analysis." Research policy **35**(9): 1423-1440.
- Feldmann, M. P. and S. M. Breznitz (2009). The American Experience in University Technology Transfer. Learning to Compete in European Universities. M. McKelvey and M. Holmén. Cheltenham, Edward Elgar.
- Furukawa, Y. (2010). "Intellectual property protection and innovation: an inverted-U relationship " Economics Letters **109**(2): 99-101.
- Geuna, A. and F. Rossi (2011). "Changes to university IPR regulations in Europe and the impact on academic patenting." Research Policy **40**(8): 1068-1076.
- Grimaldi, R., M. Kenney, D. S. Siegel and M. Wright (2011). "30 years after Bayh–Dole: Reassessing academic entrepreneurship." Research Policy **40**(8): 1045-1057.
- Guellec, D. and B. van Pottelsberghe de la Potterie (2007). The Economics of the European Patent System: IP Policy for Innovation and Competition. Oxford, Oxford University Press.
- Guellec, D. and B. ven Pottelsberghe de la Potterie (2007). The economics of the European patent system: IP policy for innovation and. Oxford, OUP.

- Hodgson, G. M. (1997). "The ubiquity of habits and rules." Cambridge Journal of Economics **21**(6): 663-684.
- Jaffe, A. B. and J. Palmer (1997). "Environmental regulation and innovation: A panel data study." Review of Economics & Statistics **79**(4): 610-619.
- Jaffe, A. B., S. R. Peterson, P. R. Portney and R. N. Stavins (1995). "Environmental Regulation and the Competitiveness of U.S. Manufacturing: What Does the Evidence Tell Us?" Journal of Economic Literature **33**(1): 132-163.
- Jordana, J. and D. Levi-Faur, Eds. (2004). The politics of regulation : institutions and regulatory reforms for the age of governance Cheltenham, Edward Elgar.
- Jordana, J. and D. Levi-Faur (2004). The Politics of Regulation in the Age of Governance. The Politics of Regulation: Institutions and Regulatory Reforms for the Age of Governance. J. Jordana and D. Levi-Faur. London, Routledge: 1-28.
- Lerner, J. (2009). "The empirical impact of intellectual property rights on innovation: Puzzles and clues." American Economic Review **99**(2): 343-348.
- Mahoney, J. and K. Thelen, Eds. (2010). Explaining Institutional Change: Ambiguity, Agency and Power. Cambridge, Cambridge University Press.
- Majone, G. (1994). "The Rise of the Regulatory State in Europe." West European Politics **17**: 77-101.
- March, J. G. and J. Olsen, P. (1989). Rediscovering institutions : the organizational basis of politics. New York, Free Press.
- Mazzanti, M. and R. Zoboli (2006). "Economic instruments and induced innovation: The European policies on end-of-life vehicles." Ecological Economics **58**(2): 318-337.
- Menard, C. and M. M. Shirley, Eds. (2008). Handbook of new institutional economics. Berlin, Springer.
- Murray, F. and S. Stern (2007). "Do formal intellectual property rights hinder the free flow of scientific knowledge?: An empirical test of the anti-commons hypothesis." Journal of Economic Behavior & Organization **63**(4): 648-687.
- Nelson, R. R. (1994). "The Co-evolution of Technology, Industrial Structure, and Supporting Institutions." Industrial and corporate change **3**(1): 47-63.
- Nelson, R. R. (2004). "The market economy, and the scientific commons." Research Policy **33**(3): 455-471.
- North, D. C. (1990). Institutions, Institutional Change and Economic Performance. Cambridge, Cambridge University Press.
- OECD (1997). The OECD Report on Regulatory Reform: Volume I: Sectoral Studies. Paris, OECD.
- Peter, V., G. van der Veen, A. Doranova and M. Miedzinski (2013). Screening of Regulatory Framework. European Commission. Brussels: 232.
- Pierre, J. and B. G. Peters (2000). Governance, politics and the state. Basingstoke, Macmillan.
- Porter, M. and C. Van der Linde (1995). "Toward a new conception of the environment-competitiveness relationship." The journal of Economic Perspectives **9**(4): 97-118.
- Rigby, J. and R. Ramlogan (2012). The Impact and Effectiveness of Support Measures for Exploiting Intellectual Property. Compendium of Evidence on the Effectiveness of Innovation Policy Intervention. M. U. Press. Manchester, Manchester University Press.
- Sampat, B. N. (2006). Universities and Intellectual Property. Shaping a new patent policy for government funded academic research. Shaping Science and Technology Policy. The next generation of

research. D. H. Guston and D. Sarewitz. Madison, Wisconsin, The University of Wisconsin Press: 55-76.

Stefan, A. and L. Paul (2008). "Does It Pay to Be Green? A Systematic Overview." The Academy of Management Perspectives **22**(4): 45-62.

Stiglitz, J. E. (2014). Intellectual Property Rights, The Pool of Knowledge and Innovation. N. B. o. E. Research. Cambridge, Ma., NBER. **Working paper 20014**  
<http://www.nber.org/papers/w20014>.

Walz, R., J. Schleich and M. Ragwitz (2011). Regulation, Innovation and Wind Power Technologies – An empirical analysis for OECD countries. DIME Final Conference, 6-8 April 2011. Maastricht.