

Governing the European Union's Patent Regime: From market failures to governance failures?

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Very draft version. Please, note that the paper has not undergone English language corrections. And please, be kind not to quote it. All comments about how to improve it are warmly welcomed!

Abstract:

The creation of a new patent regime in the EU poses two general questions. The first one is how far the new regime will enhance innovation in the EU in relation to its own market failure policy rationale and market-making objective. The second question is how far the new regime will be effectively steered and socio-politically accepted. After presenting the main characteristics of the new patent regime and its challenges, the paper devotes special attention to the second question. The main purpose is to define the criteria for a future assessment of the potential “governance failures” of the new regime, a concept which is developed in continuation to the theoretical discussions about market failure, state failure, and system failure, and from the theoretical discussions about governance and regulation within the field of European studies.

1. Introduction

Since the early 1990s, the European Union has engaged in a process of rapid harmonization and unification of intellectual property rights regulations among its member states. Up until today, the EU has enacted a number of laws in the fields of copyright, trademarks, industrial designs, and plant varieties, and it is about to pass regulations which will create an EU-wide Community patent and utility model. This regulatory thrust at EU level responds to the political will to low trade barriers among member states, to lower the transaction costs and uncertainties involved in obtaining and exercising such rights, and more generally, to foster innovation and competitiveness within the single market.

The rapid development of the EU regime on IPR has been taking place in a context hallmarked by at least three general trends. Firstly, the 1990s saw a virtual explosion in the number of IPR and patents across industrial sectors and countries, particularly in Japan and the US (and some EU countries), in what has been characterized as the “pro-patent era” (Kortum and Lerner, 1999), and intellectual capitalism (Grandstrand, 1999). Secondly, there has been a very important movement towards a stronger international institutionalization of IPRs, in particular the TRIPS agreement. In contrast with the “old” treaties, this new generation of agreements link IPR matters to international trade issues. Last but not least, in the past few years the public awareness of IPRs has been growing substantially, with issues typically related to patents, like software patents or Aids-drug patents in the Third World. These three trends are important elements for understanding the attention to IPR matters at EU level. But above all, they constitute the wide context for grasping the specific contents granted to such rights and the institutional problems and solutions related to such regulations.

The establishment of this new IPR regime in the EU poses two general questions, namely, how far will it be able to enhance economic development and innovation in the EU, and how will it be effectively steered and socio-politically accepted. The first question refers to the overall economic effects of the new regulatory regime, as to its own market-failure policy rationale and market-making objectives. The second question deals with the overall socio-political effects of the new regime in relation to the EU’s own ambition of creating a new political order at supra-national level. The aim of this paper is to define a research strategy that addresses these two questions concerning the new IPR regime in the EU, particularly the second one. The creation of these legal figures at EU level is not the end of the road. Quite the contrary, it is the beginning of active EU involvement in these matters. Regulation is not just the act of rulemaking; it also involves the actual enforcement and interpretation of these rules in society and the economy, which is a complex and recursive process that unfolds over time. When discussing issues of governance, the paper distinguishes between the instrumental capacity of regulation, and its institutional capacity. The first links nicely with the economists’ broad discussions about the regime’s ability and efficiency in providing incentives to innovation and socially optimal levels of dissemination. In other words, the instrumentality of the different IPR regimes to deliver what they promise, namely improve the overall economy by fostering the innovation process. The second category, namely the institutional capacity of regulation links with the

long discussions among political scientists about the new trends of politics and policy-making. In particular, this notion refers to the questions of participation and popular support. On the basis of these two dimensions of regulatory governance, the paper goes on defining the concept “governance failures”. It does so in continuation to the discussions among economists about “market failure” “government/state failure” and “system failure”, and it derives as well from the theoretical discussions about “governance” that are taking place within the discipline of political science in general, and of European studies in particular.

The traditional approach to IPRs regulation has been based on the “market failure” rationale, which justifies the creation of these legal figures (particularly patents) on the basis that the market alone is unable to generate the necessary incentives for innovators. By granting a temporary monopoly to the innovator, the legal system can generate these incentives which are missing in the market. Beyond this concept, political economists in the 1980s started discussing the existence of “state failures” (or also “government failures”), when state intervention proved to be occasionally problematic by generating unexpected costs bound to hierarchically decided allocation decisions, and to bureaucratic inefficiencies (time delays, legal uncertainty, low quality or high costs of public service/decisions). Lately, scholars working on the field of innovation economics have been pointing out the fact that IPRs might also display “systemic failures”, since the protective scope of such rights, which defines the formal/legal regime for knowledge appropriation (codified knowledge), has a wide resonance in the overall socio-economic and innovation system. Examples of systemic failures are the problems related to the growing commodification of open science, the lack of functional substitution of the private sector, which cannot carry out all the functions of the public research sector (i.e. basic training of scientists), or the potentially negative effects of proprietary rights in the overall functioning of the public sector (particularly the public health care and the public education sectors). Beyond these “market failures”, “state failures” and “system failures”, which mainly refer to the economic effects of the IPR regime, the notion “governance failures” refers to the problems associated with the overall socio-political dimension of the IPR regime in relation to the nature of political processes and institutions. Here the issues of control and accountability have a paramount importance in the political steering of this regime and its ultimate popular and social legitimacy.

This paper focuses on the patent regime emerging in the European Union, which is being rapidly constructed these days. For a number of reasons, governing this regime is very challenging. Firstly, because the co-existence of the three patent systems (the national patent, the European patent and the newly created Community patent systems) under one single patent regime in the EU is a rather complex institutional matter. Secondly, because the patent laws cannot define in an unequivocal ex-ante manner the limits of patentability, namely because by nature, patents deal with “the technological frontier”, and are constantly challenging the way in which the patentability criteria should be interpreted. Thirdly, because the patent-granting system is highly decentralized, since decisions are made by individual patent examiners, who enjoy a rather high level of autonomy. And finally, the governance of the patent regime is challenging because it has a rather strong bottom-up dimension, since the entire regime depends of socio-economic actors’ interest in applying for patent protection.

The paper proceeds as follows. The next section gives a short account of the transformations of the EU IPR regulations and the general lines that define the newly emerging EU patent regime. The third section succinctly presents some theoretical considerations about regulation and governance in the EU context, briefly relating it to the new patent regime. After that, the fourth section examines the contents of the market failure rationale of patent regulation. The section that follows introduces the analysis of the governance of the patent regime by defining the concepts of state failure, system failure and governance failure, according to the instrumental and institutional capacity of the new regime. The last section provides a roadmap for an empirical analysis of the questions identified at the beginning of this paper.

2. IPRs regulation and the patent regime in the EU

In contrast with standardization issues, the single market project launched in 1985 envisaged very little about intellectual property rights. Despite early admonition from the Commission in the early 1960s, IPRs did not manage to receive political attention from national representatives, and when they did, political tensions prevented further progress. The most notorious example of this is the Luxemburg Convention of 1975 about the Community patent and the subsequent agreement in 1989, none of them ever enforced. The successive political fiascos might partly explain that the single market project devoted much more attention to the creation of common European standards (and the building up of an effective standardization process) than to IPRs, as means of dealing with technical barriers to intra-EU trade. Paradoxically enough, the political stalemate of EU-wide regulations on IPRs during these decades contrasted sharply with the growing jurisprudence of the European Court of Justice ruling about the exercise of nationally granted IPRs and their effects upon fair competition and free trade in the EU. In virtue of the extended EU powers in competition policy and of the Treaty provisions about the common market, the Court has a central role in the generation of such a trans-national market. The creation of a market by tearing down such barriers has been defined as the process of negative integration, complemented by the positive integration efforts of EU-wide regulation (Scharpf, 1999).

Therefore, in the late 1980s there was an asymmetric situation in the EU, with a significant advance in negative integration but virtually no common EU regulation on these matters. This asymmetry became an issue of concern among experts (Anderman, 1998; Govarere, 1996) and among policy-makers (Commission, 1997). Arguably, the parallel political debates about the need to enhance EU competitiveness in world markets fostered this appreciation. The novelty in the early 1990s was the understanding that tearing down the intra-EU barriers to trade could not alone improve European competitiveness in world markets. Policy-makers' eyes (particularly national policy-makers ones) turned to wider issues of technology and innovation, among them, the IPR regime (or the lack of it) at EU level. In other words, the competitiveness agenda of the early 1990s re-opened the IPR issue at EU level.

Since then the EU has engaged in an almost frenetically rapid regulation of trademarks, copyrights, industrial designs, plant varieties, utility models and patents.

The table below provides an overview of the most important EU regulations on the IPR field to date¹.

Table 1: Most relevant EU regulations on intellectual property rights, by February 2003.

<i>Generic type of IPR</i>	<i>Area</i>	<i>Regulation</i>	<i>Remarks</i>
Copyrights	Harmonization in the information society	Directive 2001/29/EC; OJ L 167 22.06.2001 p.10	
	Computer programs	Council Directive 91/250/EEC; OJ L 122 17.05.1991 p.42	
	Rental and lending rights	Council Directive 92/100/EEC; OJ L 346 27.11.1992 p.61	
	Satellite broadcasting and cable retransmissions	Council Directive 93/83/EEC; OJ L 248 06.10.1993 p.15	
	Databases	Directive 96/9/EC; OJ L 077 27.03.1996 p.20	
Trademarks	Approximation of laws	Council Directive 89/104/EEC; OJ L 040 11.02.1989 p.1	
	Community Trade Mark	Council Regulation (EC) No 40/94 of 20 December 1993; OJ L 011 14.01.1994 p.1	
Designs	Harmonization	Directive 98/71/EC; OJ L 289 28.10.1998 p.28	
	Community design	Council regulation EC/6/2002, OJ L 3, 5.1.2002, p.1	
Utility models	Harmonization	Commission proposal COM (1999) 309 final	No regulated yet
Plant variety rights	Community plant variety rights	Council Regulation (EC) No 2100/94 of 27 July 1994; OJ L 227 01.09.1994 p.1	
Patents	Community patent	Commission proposal: Com (2000) 412 final	Not regulated yet
	Patentability of biological inventions	Directive 98/44/EEC; OJ L 213, 30.07.98.p.13	Highly controversial
	Patentability of computer-implemented inventions	Commission proposal: Com (2002) 92 final.	Not regulated yet

Own elaboration from EU legal database, EUR-lex (Borrás, 2003a).

By providing the name and date of the most relevant IPR laws in the EU, the table above shows that most rule-making efforts in this field have been undertaken since the beginning of the 1990s. The EU is now well on its way to completing the range of conventional legal figures in IPR that traditionally exist at national level. This is an

¹ The list provided in the table is by no means exhaustive. It is the personal choice of the author concerning the most relevant pieces of EU regulation in the field of IPR.

important transfer of competences from the national to the EU level in positive integration terms. Two dimensions of this astounding process are worth examining briefly, namely, the logic and politics behind the Europeanization of IPRs, and the overall contents of these new rules.

Starting with the first, the Europeanization of IPRs follows a triple logic, which is the dismantling of national technical barriers to intra-EU trade by creating EU-wide legal figures, the creation of a truly single market in the EU for the exercise and tradeability of these rights, and the improvement of innovation by lowering the costs and uncertainties involved in the acquisition and litigation of these rights. This is to say that EU rule-making in this field is as much related to the lowering of barriers, costs and legal uncertainties, as it is to the positive generation of a single economic space for their exercise and commercialisation. In formal terms, the creation of EU-wide IPRs does not nullify the existing national IPRs, since they will coexist side by side. Nevertheless, it is still unclear how both levels will work together, and how far the EU-wide figures could eventually supersede nationally-granted ones.

Before moving ahead, it is important to note at this point that IPRs have historically been bound to the state's constitutional capacity of granting and protecting proprietary assets in a capitalist economy. In other words, a primary function the state-economy relation associated to the onset of the liberal capitalist economic systems of the 19th Century. By transferring these powers to the EU level, the IPR regime has not only constitutional effects upon an emerging European system of innovation (Borrás, 2003b), but also upon the overall nature and features of the new politico-economic order at supra-national level.

The second dimension about IPRs at EU level has to do with the way in which those rights have been regulated. In other words, the actual legal contents of those rights are as important as their constitutional dimension. At least two sets of interrelated questions emerge in this regard. One deals with the relationship and difference between the contents of EU rules and the contents of national rules. An important and generic question in this regard is whether EU rights contain innovative elements in legal terms vis-à-vis some common legal principles at national level, and if so, what effects might these novelties have. Another set of questions about the contents of these EU rights is the breadth and strength of the new IP rules. The definition of IPRs is always a matter of striking a balance between the private interest of those owning the right and the public interest of securing innovation incentives while avoiding the abuse of monopolistic power from the property right owner (particularly relevant for patents). In striking such a balance, the breath of the rights (the limits of patentability and the scope of the knowledge/asset enshrined in the property) and the strength of the protection granted (how protective is the law about the limits of exercising this right), are central issues. Recent empirical studies point to different potential problems in this direction either because of the apparently wide scope of each IPRs in the EU (Vinje, 1995) and because some legal innovations seem to grant unnecessarily strong protection (David, 2000). We will turn back to these matters later on this paper in relation to the new patent regime.

The current discussions about the way in which such legal contents have to be defined, and about what role the IPRs have in the social, economic and political realms more generally, will not end once these laws have been passed. Quite the

contrary, the above mentioned dimensions will become more relevant, with questions concerning how these rights are going to be implemented and used, and what effects will they have upon the innovation process and upon the overall political economy of the EU. In other words, questions about the regulation and governance of IPRs in the EU.

These questions are particularly important to the patent regime that is currently emerging in the EU. ((Unfinished paragraph: Description of the patent regime in the EU: national, international and EU regulations, the formal role of EPO, the Commission, and future Community Patent Court)).

3. Regulation and governance in the EU

A host of scholars have defined the EU as a regulatory state, because the EU has primarily used regulatory instruments in the unfolding of EU policy goals, particularly in its market-making objective (Majone, 1996; Egan, 1998, Héritier-patchwork article). The construction of a supra-national political and economic space, and especially a truly trans-national market, imply a double process of de-regulation at national level and re-regulation at EU level. That is, the partial dismantling or adaptation of previous national rules to the hierarchically superior and newer supra-national rules that define a new context for economic activities beyond national borders (Armstrong and Bulmer, 1998).

Nevertheless, talking about the centrality of regulation at EU level should not be interpreted as a mere rule-making process nor as a simple hierarchical mechanism for socio-economic steering. Starting with the first, regulation is much more than rule-making since it also includes the actual enforcement and interpretation of these laws and rules in society and in the economy, in a way that they are collectively endorsed and perceived to be useful, adequate and fair. This extended notion of regulation understands that regulation involves a degree of self-organisation in society and the economy, where the formal and informal dimensions of rules are largely entangled with each other. Therefore, when talking about regulation, this paper also refers to this other sphere beyond rule-making (Egan, 2001), which includes jurisprudence, delegated agencies' role, administrative implementation of laws, and the behaviour of social and economic actors in relation to all of these. In other words, regulation refers in this paper to both the formal and informal aspect of law, which refers as much to the contents of the law, as to the administrative praxis and the behaviour of socio-economic actors directly associated to it.

This wider notion of regulation allows us to move away from a simplistic understanding of the relationship between the “governor” (as rule-maker) and the “governed” (as the public that obeys such rules or not) in a hierarchical manner. A broader understanding of regulation should accept that such relationship is much richer and complex, where elements of hierarchy are combined with other forms of socio-economic and political coordination that involve a strong “bottom-up” dimension of the socio-economic actors' actual engagement and expectations from the regime. In this wider notion, regulation includes important aspects such as, control, accountability and legitimacy, understanding that the structural interdependence

between the governor and the governed means that their relationship is a recursive and complex process. From this latter understanding of regulation it is possible to have a wider view about the role that formal and informal rules have in an economic system. Those formal and informal dimensions are precisely the constitutive institutions of any politico-economic order, being essentially a social order.

This paper examines one single element of the IPR regime in the EU, namely, the patent regime in the EU. This is interesting for at least three reasons. Firstly, due to the complexity involved in the simultaneous coexistence of the European, national and Community patent regimes. Secondly, due to the economic centrality of patents for the innovation process (new inventions typically associated with heavy investments in scientific research), which render the patent regime a key element of the innovation policy. And thirdly, due to the especially decentralized nature of the patent-granting procedures: the interpretation of the legal criteria of patentability corresponds to patent examiners, the technical experts who make the decisions on the basis of search work.

4. Market failure and market creation in the EU

Due to the nature of knowledge as a “non-rival good” (infinitely expandable without being diminished in quality or quantity) and as a “non-excludable good” (impossible to exclude others from using it), the market is unable to generate, by itself, the optimal conditions for an innovator to reap the benefits of his/her own knowledge production. This inability of the market has been termed “market failure”. State intervention creating IPRs (particularly patents) is then justified because it allows the innovator to enjoy the benefits of his/her own investments, without which there would be no clear incentives to invest in such innovative activities. By granting a temporary monopoly to the innovator, the state can generate these missing incentives. Therefore, the primary function of state intervention is to introduce corrective instruments for improving market conditions through the generation of adequate incentives.

The “market failure” rationale, with its explicit goal of generating incentives, is the cornerstone of the current regulation of IPRs worldwide. This is not just the case for the historical establishment and gradual development of IPRs at national level, but also for the current creation of them at EU level. The EU documents dealing with this matter point to the costs of non-EU patents, both in terms of the actual high price of filing patents, and in terms of the high degree of legal uncertainty of operating within 15 different legal and judicial systems.

National IPRs have large co-existed and interacted in Europe. It has been argued that IPRs in Europe are today in reality largely harmonized, due to this co-existence and of some international arrangements (Commission, 2000). Even if the extent of this de facto harmonization is an interesting object of research, the point to raise here is that the creation of single EU-wide IPRs has the added value of simplifying procedures and reducing costs. In other words, by creating a single right that covers the entire EU at once, the regulation at supra-national level provides an advantage over regulations at national level, no matter how harmonized they are. In the case of patents, the additional advantage of obtaining a single patent for the 15 countries within the EU improves, structurally, the situation with the European patent, which is an aggregation of national rights channelled by one single administrative agent (the EPO).

It is also worthwhile pointing to the fact that the “market failure-incentive” and market making rationales of the EU IPR regime (particularly of the Community patent) are based on the understanding that the benefits of EU intervention are the positive effects upon the behaviour of each single economic actor operating in the EU (that is the innovator). The incentives expected by the “market failure/market making” rationale of EU action are essentially incentives to the individual innovator, the aggregation of which generates invariably positive effects to the overall European economy, not least the creation of a truly EU market in these items.

This focus of the EU on the generation of incentives at individual level, and the invariable positive effects of their aggregation over economic dynamics, has been perhaps strengthened by the long tradition of measuring the innovative capacity of an economy by the number of patents it produces. The equation might be rather simple: the more patents an economy produces, the more it indicates its capacity to produce knowledge and the better individual incentives to appropriate and exploit this knowledge economically.

While still endorsing the “market failure” rationale as a valid principle for state action for the generation of market incentives, institutional and evolutionary economists are currently questioning important aspects of the neo-classical approach. They are doing so in at least two interrelated manners. First of all, these authors are questioning that the aggregation of individual benefits would invariably mean a positive social benefit. Empirical evidence shows that granting of individual rights does not always have positive effects for the economy, and therefore there has to be a careful analysis of how to strike the balance between individual rights and social costs/benefits to the economy. That is, the need to find an explicit political agreement about how to balance the private interests against the collective interest. Secondly, these authors are questioning the appropriation logic implicit in the neo-classical theory. They stress the fact that obtaining formal IPRs is by no means the only way by which firms and innovators appropriate and exploit knowledge in the economy (Cohendet and Meyer-Krahmer, 2001; Arundel, 2001a), that there is a large diversity among industrial sectors in terms of IPR-usage (Arundel, 2001b), and that some types of patent-coverage might prevent the effective exploitation of knowledge (Foray, 2001).

What these economists are pointing to at this stage is that the economic impact of IPRs needs to be carefully studied. This is so because the IPR regime might produce undesired and unexpected socio-economic consequences with important effects upon the innovation process. These authors argue for a wider economic perspective, integrating the analysis of the IPR regime within the overall economy. As such, they reject the neo-classical notion of a neat division between the market as exogenously given, a natural situation, and the regulator, and adopt the understanding that markets are socially constructed by a wide variety of social and economic institutions that have formal and informal nature. In this way, these authors follow the broad understanding of governance and regulation mentioned earlier.

5. Examining the governance of the EU patent regime

As was mentioned earlier, the aim of this paper is to develop a research strategy that addresses the two main questions about the recent establishment of the EU patent regime, namely, how far the new regime will be able to enhance economic development and innovation in the EU, and how it will be effectively steered and socio-politically accepted. The first question refers to the overall economic effects of the new regulatory regime. It asks whether the regime will make it up to the rationale of generating incentives in a way that positive economic effects largely exceed the negative effects, both at the levels of the individual actor and of collective interest. The second question deals with the socio-political consequences of the new regime in relation to the EU's overall ambition of creating a supra-national political order that is effective and democratic.

Needless to say, both questions are strongly related to each other. The regime's own ability to generate positive economic results is related to the regime's ability to coordinate effectively and transparently the semi-autonomous organizations involved in the administration of these rights, in a way that is socially legitimate. In spite of this interrelation, it is however necessary to separate both questions in analytical terms mainly because answering each of them comprises different venues for empirical analysis. But before moving ahead, a conceptual distinction at this stage helps to separate these two lines of enquiry, also showing their eventual complementarity.

In a recent seminal work Adrienne Héritier distinguishes between the instrumental and the institutional capacities of the new governance instruments in the EU (Héritier, 2002). Although still in a conventional "old" governance instrument as law-making and law-enforcing (in contrast to the "open method of coordination" or soft law now extensively used in the EU), this analytical distinction seems particularly useful when studying the governance of the patent regime in the EU.

The instrumental capacity of the IPR regime deals with the regime's own ability to generate outcomes that respond to the actual needs of providing individual incentives (overcoming market failure) while securing positive social benefits for that particular economy. Instrumentality here refers not just to the ability of the IPR regime to correspond to its own defined goals of individual incentives and market-making, but also to its role within the overall economy. When examining the instrumental capacity of the IPR regime it is obvious that the success of the regime can be measured by its own ability to avoid under-protection and over-protection. If the regime is under-protective it means that it is unable to reverse the appropriation problems associated with the non-rivalry and non-excludable nature of knowledge, and therefore the initial "market failure" that the regulation aimed at palliating continues to exist. On the other hand, if the regime is over-protective it means that state intervention, by means of granting private property and attaching some specific rights to it, has generated other problems itself, for example disturbing severely competitive dynamics and knowledge dissemination, which are necessary conditions for a well performing innovation process. This is what the theoretical literature of political economy has generally termed "state failure" or "government failure", namely, when the state intervention is in itself generating new and unexpected problems because it is deciding inefficiently in economic terms. Thus, the unsuccessful instrumental capacity of an IPR regime is to a large extent either a "market failure" or a "state/government failure". The examination

of such failures corresponds to empirical economic analysis, assessing the impact of these regulations in the innovation process. Furthermore, it can be asserted that both these failures (market and state) are related to what the literature about systems of innovation has generally termed “systemic failures”, “learning failures” or “institutional failures”, which refer to the unsuccessful accomplishment of policy objectives to foster innovation in the economic system, or to the system own techno-economic lock-inns (Malerba, 1996; Smith, 1996). Further examples of systemic failures are the problems related to the growing commodification of open science (Mazzoleni and Nelson, 1998), the lack of functional substitution of the private sector, which cannot carry out all the functions of the public research sector (i.e. basic training of scientists) (Foray, 2003), or the potentially negative effects of proprietary rights in the overall functioning of the public sector (particularly the public health care and the public education sectors). On the basis of all this, it can be asserted that the instrumental capacity of the IPR regime in the EU deals essentially with its ability to establish a balance between protection and dissemination in a way that the individual and collective costs involved are kept to a minimum, so that the overall economy benefits from the existence and the specific regulatory style of the IPR regime.

In contrast with this instrumentality, H eritier defines the institutional capacity of the governance mode as its ability to generate both participation and political support (H eritier, 2002: 189). When referring the institutional capacity of the IPR regime, we can go further stating that its institutional capacity will depend on its ability to generate at least three political goods, namely, regulatory control, political accountability and social legitimacy. Regulatory control refers to the ability of establishing well functioning mechanisms for steering politically the complexity involved in the legal implementation of such rights, particularly given the co-ordination of the organizations involved in the granting, enforcement and exercise of these rights (delegation of power to independent agencies, the role of national IPR agencies, and the central role played by the judiciary). Political accountability is related to the later, but is more focused to the issues of allocating political responsibility and generating political transparency in the (continuous) regulatory transformations of the regime. Finally, but perhaps most important, the institutional capacity concerns the overall social legitimacy of the rules, and of the IPR regime as a whole. Legitimacy, which might be understood as the wide public acceptance, is at the end of the day a central element for the viability and sustainability of the political endeavour of the IPR regime. It could argued that, of these three dimensions, legitimacy is the most important one, for the simple reason that without it the regime will convey serious socio-political tensions shackling its own existence. On the other hand, regulatory control and political accountability are subordinate to legitimacy, since it is difficult to see how without them the regime can still receive social and popular support. Taken together (lack of coordination and control, lack of transparency and accountability, and faltering legitimacy) these three would represent the “governance failure” of the patent regime.

Jessop argues that the inherent logic of governance is its “reflexive rationality”, and that the most complex forms of governance are those involving the self-organization of inter-organizational relations and the co-evolution of different institutional systems (Jessop in Stoker). This distinction suits well our field of analysis, namely the institutional set up of the patent regime in the EU, where important elements of inter-

organizational coordination (between the European Patent Office, the European Commission, the national patent offices, and the forthcoming Community patent Court), are strongly linked to the triple systemic nature of the regime, given the co-existence of national patents, European patents and the new Community patents as three differentiated legal figures, under one single EU patent regime. Our previous focus on control and accountability when assessing governance failure or success, clearly refers to the mechanisms and procedures of this inter-organizational self-coordination. But it does so in a full understanding of the convoluted context of this triple patent system, asking the limits and possibilities of successful coordination based on regulatory control and political accountability, which have legitimacy effects upon the entire regime.

6. Elements for assessing the governance failures of the newly established patent regime in the EU

The complexity of the new patent regime in the EU, which is based on the simultaneous co-existence of the national patent system, the European patent system, and the Community patent system, is an issue that lends itself to asking how the regime will address the issues of coordination and transparency, that is, of regulatory control and of political accountability.

Starting with regulatory control, the analysis will be undertaken in two steps. The first step will be a contrasting examination of the overall control mechanisms in place before the creation of the Community patent system, and after it. This contrast will allow us to identify the open points that the inter-organizational coordination of this regime based on a triple system will have to address in order to provide a control mechanism that is at once consistent with previous practices and coherent with political expectations at national and EU levels of politics. Given the decentralized nature of the patent regime, the second step of the analysis will focus on a particular issue concerning the administrative and organizational response to the inherent tension between the contents of the formal law and its interpretation through the patent-granting praxis, namely, the debates about enforcing a “quality-control” procedures of EPO patent-granting praxis, especially in the context of this organization’s central role in the new regime.

The political accountability of the new patent regime in the EU will be examined in relation to two issues. One will be a general consideration about the transparency of the patent regime as such, both in terms of accessibility of information regarding decisions and in terms of communication strategies of the organizations involved in the administration of the regime. The second issue will be an analysis of the organizations’ own understanding of the limits and nature of their political responsibility in the overall process.

The question of the regime’s legitimacy will then be examined on the basis of the previous two analyses and on the rows created by the patentability of biotechnological inventions and of software patents, as two extreme cases of legitimacy crises related to the new patent regime.

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