

IPR and Innovation Systems: An international comparison

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Introduction: What is an innovation system?

This chapter deals with IPRs in innovation systems. Even if both innovation systems and IPRs as such have been studied extensively, the specific problematic of this chapter has hardly been analysed before. This is even so much surprising as the form and extent of IPR regulations potentially have big impacts on the functioning of an innovation system. According to Granstrand (2005), ‘IPRs, particularly patents, play several important roles in innovation systems – to encourage innovation and investment in innovation, and to encourage dissemination (diffusion) of information about the principles and sources of innovation throughout the economy’ (Granstrand, 2005, p. 280). Thus, the extent, intensity and type of interactions between firms and universities, which represent the constituting relations of an innovation system, will obviously be effected by the way the IPR are constructed. This is especially the case in science driven activities, such as biotech, which is the focus of this book, being the object of the majority of implemented IPR regulations. This chapter will investigate this problematic through a comparative approach looking at how IPR are implemented and their consequences for industry-university collaboration in the US and Europe with special focus on Germany, Switzerland and Denmark. This represents a contribution to the analysis of the importance of national variations in institutional frameworks, which in addition to sectoral differences (which in this chapter are handled by the differentiated knowledge base perspective), has been surprisingly little covered in the literature so far. The chapter starts with a short introduction of the innovation system concept as a national as well as a regional system.

The concept of innovation system (IS) - originally developed by Bengt-Åke Lundvall - is a relatively new one, and was first used by Chris Freeman in his analysis of Japan’s blooming economy (Freeman, 1987). The concept of regional innovation system (RIS) appeared in the early 1990s (Cooke, 2001), approximately at the same time as the idea of the national innovation system was becoming more widespread, thanks to the books by Lundvall (1992) and Nelson (1993). Characteristic for a systems approach to innovation is the acknowledgement that innovations are carried out through a network of various actors underpinned by an institutional framework. This dynamic and complex interaction constitutes what is commonly labelled systems of innovation

(Edquist, 1997), i.e. systems understood as interaction networks (Kaufmann and Tödting, 2001). A set of variations on this approach have been developed over time, either taking territories as their point of departure (national and regional) or specific sectors or technologies (Fagerberg et al., 2004).

The National Innovation Systems approach highlights the importance of interactive learning and the role of nation-based institutions in explaining the difference in innovation performance and hence, economic growth, across various countries. The rationale of having territorially based innovation systems (national and regional) is either the existence of historical technological trajectories based on 'sticky' knowledge and localised learning that can become more innovative and competitive by promoting systemic relationships between the production structure and knowledge infrastructure in the form of national or regional innovation systems (a policy of 'localised change' (Boschma, 2004)), or the presence of knowledge creation organisations whose knowledge could be exploited for economic useful purposes through supporting new emerging economic activity (a policy of 'structural change' (Boschma, 2004)). The 'innovation system' concept can be understood in both a narrow as well as a broad sense. A narrow definition of the innovation system primarily incorporates the R&D functions of universities, public and private research institutes and corporations, reflecting a top-down model of innovation. A broader conception of the innovation systems includes 'all parts and aspects of the economic structure and the institutional set-up affecting learning as well as searching and exploring' (Lundvall, 1992, p. 12), and, thus, has a weaker system character. The formation of innovation systems must be understood in this context of creating a policy framework aiming at a systemic promotion of knowledge creation and learning, in which universities play a strategic role, as well as an efficient transfer to industry in order to secure the innovativeness and competitive advantage of nations, regions and firms (Freeman, 1995; Cooke et al., 2000). According to Mowery and Sampat (2005) 'governments have sought to increase the rate of transfer of academic research advances to industry and to facilitate the application of these research advances by domestic firms since the 1970s as part of broader efforts to improve national economic performance. In this 'knowledge-based economy', according to this view, national system of higher education can be a strategic asset, if links with industry are strengthened and the transfer of technology enhanced and accelerated' (Mowery and Sampat, 2005, 214).

IPR in regional innovation systems

When discussing the role of IPRs in Innovation Systems it is specifically the second rationale for innovation systems which is of relevance, i.e. securing the exploitation of new knowledge creation at universities for economic useful purposes, applying a narrow definition of an innovation system. According to Mowery and Sampat (2005) this can be achieved by two types of policies: ‘(1) policies encouraging the formation of regional economic ‘clusters’ and spin-offs based on university research, and (2) policies attempting to stimulate university patenting and licensing activities’ (Mowery and Sampat, 2005, 225).

Mowery and Sampat (2005) emphasize that especially the first type of policy typically takes place at the regional level, in the context of RIS, seeking ‘to spur local economic development based on university research, e.g. by creating ‘science parks’ located nearby universities campuses, support for ‘business incubators’ and public ‘seed capital’ funds, and the organization of other forms of ‘bridging institutions’ that are believed to link universities to industrial innovation’ (Mowery and Sampat, 2005, 210).

A RIS is constituted by (1) The regional production structure or knowledge exploitation subsystem which consists mainly of firms, often displaying clustering tendencies, and (2) the regional supportive infrastructure or knowledge generation subsystem which consists of public and private research laboratories, universities and colleges, technology transfer agencies, vocational training organisations, etc. Thus, in case the following two subsystems of actors are systematically engaged in interactive learning it can be argued that a regional innovation system is in place (Cooke, 1998). From this follows that clusters and RIS can (and often do) co-exist in the same territory. But whereas the regional innovation system by definition hosts several clusters, a cluster is not part and parcel of a RIS (Asheim and Gertler, 2005).

According to Mowery and Sampat (2005) also ‘the increased interests in ‘Bayh-Dole type’ policies is rooted in the motives similar to those underpinning policy initiatives that seek to create ‘high-technology’ regional clusters’ (Mowery and Sampat (2005), 228). As with the Bayh-Dole Act, the majority of these initiatives to support university-based research for the promotion of innovation and economic performance emphasize the importance of codification of knowledge as a precondition to impose property rights to individual inventions, based on the premise that the impact of university research primarily happens through the production by new knowledge for commercialization (e.g.

patented discoveries). (Mowery and Sampat, 2005). According to Mowery and Sampat (2005), ‘in many respects, the Bayh-Dole act is the ultimate expression of faith in the ‘linear model’ of innovation – if basic research results can be purchased by would-be developers, commercial innovation will be accelerated’ (Mowery and Sampat, 2005, 229).

The central role university research plays in contemporary economies with respect to the creation and diffusion of new knowledge, has resulted in additional analytical frameworks – complementing the innovation system approach – pointing to the importance of strong links between universities, industry and government in knowledge-based economies. Two such concepts, the new interdisciplinary ‘Mode 2’ (Gibbons et al. 1994) and the ‘Triple Helix’ (Etzkowitz and Leydesdorff, 2000), both argue that such interactions have increased (Mowery and Sampat, 2005).

Specificities and contradictions of knowledge generation

With the increasing socialization of knowledge production also the knowledge produced by the enterprises themselves increases. For this reason they depend more on “intellectual common goods” in the form of generally available qualifications, information and knowledge . The contradiction between increasing socialization of production and private appropriation inherent to capitalism appears even more obvious with knowledge production. The production of knowledge and new technologies is a process based on division of labor in complex systems and networks. Often innumerable people take part in this process. The classic contradiction between economic and business rationality, thus between privatization of the benefit and externalization of the expenses, becomes a particular guise. The enterprises aspire to free access to knowledge and information, and at the same time they want to reserve as much private property thereof as possible.

Knowledge production and its valorization exhibit some characteristics which are crucial for the transformation of the regime of property rights . In mainstream economics these traits are often described as market failure: First, intellectual activity enables considerable cumulative effects which bear much larger consequences than the productivity gains realized in material production. The benefits of science and information increase according to the number of people who use it. Knowledge develops and increases due to broad and free diffusion. These cumulative effects arise because codified information and knowledge can circulate extremely easily. They result from the collective and open character of intellectual activity (‘public good’ aspect and non-excludability of

technological knowledge). Second, the production of scientific knowledge and of numerous new technologies requires very extensive, concentrated investments, similar to investments in fixed capital. Additionally, technological uncertainty investment leads to a general investment risk. The valorization, however, can often be organized with only marginal additional costs. Knowledge-relevant information can be multiplied and used without large costs.

For these reasons, using intellectual property titles (patents, copyrights) and technical safety devices (e.g. copy protection of computer programs) firms seek to limit the uncontrolled diffusion of their products and to artificially create scarcity. Intellectual property titles are designed to render this artificial scarcity legitimate in the area of knowledge and to exclude others from its use or force them to pay royalties. Intellectual property is a power instrument and contributes to a further accumulation of power. But in contrast to the power which arises for owners of scarce material goods, scarceness of intellectual property must be reproduced artificially by legal regulations.

Sectoral differences in IPR

As mentioned in the introduction, IPRs have potentially big impacts on the functioning of innovation systems. However, 'the importance of these roles varies across sectors (industries) and countries, and over time' (Granstrand, 2005, p. 280). Granstrand underlines that especially with respect to patents, the 'differences across industries or sectors are strikingly large' (Granstrand, 2005, p. 282). Regions and nations display a large diversity when it comes to industrial structure, innovative capacity, competitiveness and economic growth. One way of analyzing regional diversity within industrial sectors is to apply a differentiated knowledge base approach (Asheim and Gertler, 2005; Asheim and Coenen, 2005; Asheim et al., 2007). Despite the general trend towards increased diversity and interdependence in the knowledge process, Pavitt (1984) and others have argued that the innovation process of firms is also strongly shaped by their *specific* knowledge base, which tends to vary systematically by industrial sectors. The typology of Pavitt has been further elaborated into a Synthetic-Analytical-Symbolic knowledge base typology, instead of the more narrowly defined traditional categories such as 'scientific', 'engineering' and 'artistic' knowledge base, in order to capture the character of knowledge as output (Asheim and Gertler, 2005; Asheim et al., forthcoming). More critically, this broader conceptual typology is intended to encompass the diversity of professional and occupational groups and competences involved in the production of various types of knowledge. As an ideal-type, synthetic knowledge can be defined as knowledge to design something

that work as a solution to a practical problem. Analytical knowledge can be defined as knowledge to understand and explain features of the universe. Symbolic knowledge is knowledge to create cultural meaning through transmission in an affecting senseous medium. As only the analytical (e.g. dominating pharmaceutical biotech) and synthetic knowledge (more important in agroindustrial and industrial biotech) bases are relevant with respect to biotech industry, the symbolic knowledge base will not be presented in more detail below.

Analytical knowledge base

This refers to industrial settings where scientific knowledge is highly important, and where knowledge creation is often based on cognitive and rational processes, or on formal models. Examples are biotechnology and nanotechnology. Both basic and applied research as well as systematic development of products and processes is relevant activities. Companies typically have their own R&D departments but they also rely on the research results of universities and other research organisations in their innovation process. University-industry links and respective networks, thus, are important and more frequent than in the other types of knowledge base.

Knowledge inputs and outputs are in this type of knowledge base more often codified than in the other types. This does not imply that tacit knowledge is irrelevant, since there are always both kinds of knowledge involved and needed in the process of knowledge creation and innovation (Nonaka et al., 2000, Johnson et al., 2002). The fact that codification is more frequent is due to several reasons: knowledge inputs are often based on reviews of existing studies, knowledge generation is based on the application of scientific principles and methods, knowledge processes are more formally organised (e.g. in R&D departments) and outcomes tend to be documented in reports, electronic files or patent descriptions. These activities require specific qualifications and capabilities of the people involved. In particular analytical skills, abstraction, theory building and testing are more often needed than in the other knowledge types. The work-force, as a consequence, needs more often some research experience or university training. Knowledge creation in the form of scientific discoveries and technological inventions is more important than in the other knowledge types. Partly these inventions, under specific social and economic conditions, are susceptible to patents and licensing activities. Knowledge application is in the form of new products or processes, and there are more radical innovations than in the other knowledge types. Important routes of knowledge application are out-

licensing activities of universities and publicly funded research organizations, and the creation of new firms and spin-off companies.

According to Granstrand (2005), ‘patents are most likely to support the growth of knowledge-intensive industries in fields characterized by low ratios of imitation to innovation costs. Such low ratios are likely in areas with large-scale R&D projects, especially if the R&D results in highly codified knowledge, as in chemicals’ (Granstrand, 2005, p. 283). This will typically be sectors or industries based on an analytical knowledge base, e.g. the biotech industry (and red bio in particular).

Synthetic knowledge base

This refers to industrial settings, where the innovation takes place mainly through the application of existing knowledge or through the new combination of knowledge. Often this occurs in response to the need to solve specific problems coming up in the interaction with clients and suppliers. Industry examples include plant engineering, specialized advanced industrial machinery and production systems, and shipbuilding. Products are often ‘one-off’ or produced in small series. R&D is in general less important than in the first type. If so, it takes the form of applied research, but more often it is in the form of product or process development. University-industry links are relevant, but they are clearly more in the field of applied research and development than in basic research. Knowledge is created less in a deductive process or through abstraction, but more often in an inductive process of testing, experimentation, computer-based simulation or through practical work. Knowledge embodied in the respective technical solution or engineering work is at least partially codified. However, tacit knowledge seems to be more important than in the first type, in particular due to the fact that knowledge often results from experience gained at the workplace, and through learning by doing, using and interacting. Compared to the first knowledge type, there is more concrete know-how, craft and practical skill required in the knowledge production and circulation process. These are often provided by professional and polytechnic schools, or by on-the-job training.

The innovation process is often oriented towards the efficiency and reliability of new solutions, or the practical utility and user-friendliness of products from the perspective of the customers. Overall, this leads to a rather incremental way of innovation, dominated by the modification of existing products and processes. Since these types of innovation are less disruptive to existing routines and organisations, most of them take place in existing firms, whereas spin-offs are relatively less frequent.

However, this distinction refers to ideal-types, and most industries are in practice comprised of all three or two types of knowledge creating activities. For instance, biotech based technology platforms or discovery tools also rely to large extend on continuously improved engineering knowledge. The degree to which certain activities dominate, is however different and contingent on the characteristics of the industry or phases of innovation processes within an industry (Moodysson et al. (forthcoming)).

‘Varieties of capitalism’ and national differences in IPRs

Granstrand maintains that ‘these intersectoral differences in the importance of IPRs have led several scholars to criticize the ‘one-size-fits-all’ design of patent system’ (Granstrand, 2005, 283). This criticism becomes even more valid when national differences in institutional contexts, constituted by history, path dependence, and institutional embeddedness, are taken into account. According to Mowery and Sampat (2005), the global diffusion of these policy proposals and initiatives - promoted among others by the OECD - display the classic problems of ‘selective ‘borrowing’ from another nation’s policies from implementation in an institutional context that differs significantly from that of the nation being emulated. ... Indeed, emulation of Bayh-Dole could be counterproductive in other industrial economies, precisely because of the importance of other channels for technology transfer and exploitation by industry’ (Mowery and Sampat, 2005, 232-33).

Lam (2000) underlines that learning and innovation cannot be separated from broader societal contexts when analysing the links between knowledge types, organisational forms and societal institutions in order to meet the needs of specific industries in particular with respect to learning and the creation of knowledge in support of innovations. Soskice (1999) argues that different national institutional frameworks support different forms of economic activity, i.e. that coordinated market economies (e.g. the Nordic and (continental) West-European welfare states) have their competitive advantage in ‘diversified quality production’ (Streeck, 1992), based on problem solving, engineering based knowledge developed through interactive learning and accumulated collectively in the workforce (e.g. the machine tool industry based on a synthetic knowledge base), while liberal market economies (e.g. the US and UK) are most competitive in production relying on scientific based, analytical knowledge, i.e. industries characterised by a high rate of change through radical innovations (e.g. IT, defence technology and advanced producer services). Following Soskice, the main determinants of coordinated market economies are the degree of non-market coordination and cooperation which exists inside the business sphere and between private and public actors, the degree

to which labour remains ‘incorporated’ as well as the ability of the financial system to supply long term finance (Soskice, 1999). While coordinated market economies on the macro level support co-operative, long-term and consensus-based relations between private as well as public actors, liberal market economies inhibit the development of these relations but instead offer the opportunity to quickly adjust the formal structure to new requirements using temporary organisations frequently.

These differences - due to the impact of the specific modes of organisation of important societal institutions such as the market, the education system, the labour market, the financial system, and the role of the state - both contribute to the formation of divergent ‘business systems’ (Whitley, 1999), and constitute the institutional context within which different organisational forms with different mechanisms for learning, knowledge creation and knowledge appropriation have evolved (Casper and Whitley, 2004).

Varieties of capitalism differences between the liberal and the coordinated market economies can be observed when it comes to the ownership of IPR for inventions (either the academic institution or the researcher), the level of inter-university competition as well as the relative importance of private research universities. In Germany and Sweden, both typical examples of coordinated market economies ‘researchers have long had ownership rights for the intellectual property resulting from their work, and debate has centered on the feasibility and advisability of shifting these ownership rights from the individual to the institution.’ (Mowery and Sampat, 2005, 232). This was changed in Denmark – another coordinated market economy, though with more liberalist traditions than Sweden and Germany - in 2000, when the Danish Law on University Patenting (LUP) became effective (see later section for a discussion of its effects on university – industry cooperation within the pharmaceutical biotech industry).

With the exceptions of the university systems of the US and Britain, typical representatives of liberal market economies, inter-university ‘competition’ has been limited in most national systems of higher education. Inter-university competition played an important historical role in the evolution of US universities and their collaboration with industry; especially when university patenting began to change after 1970s, as private universities expanded their share of US university patenting in the same period as the share of biomedical patents within overall university patenting grew (Mowery and Sampat, 2005). A good illustration of the key role of a well-funded, high-quality research university for establishing a successful industry–university collaboration is MIT, and, thus, not surprisingly,

research has found that a model design of Triple Helix based on MIT works less efficiently in different contexts with more average universities and regions (e.g. Australia and Sweden) (Cooke, 2005).

While the US model of implementing IPR might function reasonable efficient in the context of liberal market economies, these differences – based within a varieties of capitalism context – could lead to anomalies as well as dysfunctional situations and suboptimal allocation of resources in coordinated market economies. Mowery and Sampat, 2005, mention several potential criticism of, in particular the Bayh-Dole Act (Mowery and Sampat, 2005, 230-32)¹:

- Firstly, that the commercialization incentive resulting from the Bayh-Dole could shift the focus on university research away from ‘basic’ and towards ‘applied’ research.
- Secondly, another potentially negative effect of a higher level of university patenting and licensing is a ‘weakening of academic researchers’ commitments to ‘open science’, leading to publication delays, secrecy, and withholding of data and materials’ (Mowery and Sampat, 2005 2005, 230-31).
- Thirdly, in view of the importance of the ‘nonpatent/licensing’ channels of interaction with universities in many industrial sectors, it is important that these channels are not restricted or impeded by the strong focus on patenting and licensing in many universities. Thus, the ‘emulation of the Bayh-Dole Act is insufficient and perhaps even unnecessary to stimulate higher levels of university-industry interaction and technology transfer’ (Mowery and Sampat, 2005, 231-32).

From closed to open innovation – or from open science to patent-enclosed innovation?

The question of the role of intellectual property rights in innovation processes is controversial. On the one hand, intellectual property rights are justified as an answer to the market failure of technological knowledge which is an outcome of the specific characteristics of knowledge generation such as the inseparability of research expenditures and the burden of huge fixed costs for investors, the general investment risk that goes along with technological uncertainty, the ‘public good’ aspect and the non-excludability of technological knowledge . Thumm states that strengthening the patent system is likely to permit more trade in disembodied knowledge. Therefore, it is likely to facilitate the vertical disintegration of knowledge-based industries and to enable the entry of new firms that possess mainly intangible assets. Similarly Arora and Merges argue that a strong intellectual property regime supports vertical disintegration and the innovation activities of small firms. Chesbrough describes the

¹ The Bayh Dole Act policy can, however, have disadvantageous effects even in the US. However, the US system is a global system and only works ‘reasonable’ because it can attract values from other parts of the globe.

new configuration characterized by an increased vertical disintegration and a bigger share of extramural research activities, in a quite uncritical way as *open innovation*. On the other hand, David or Orsi and Coriat emphasize the questionable effects of the extension of intellectual property rights. This controversy recalls the crucial issue already raised by Dasgupta and David , who argued that knowledge produced by academic institutions should retain the status of a ‘public good’. Coriat, Orsi and Weinstein emphasize a finance-driven model of innovation linked to institutional changes and the move from ‘open science’ to ‘patent intensive’ science . They emphasize that the rules of the game shaped by institutions such as financial markets, labor markets, the intellectual property regime, public research funding, the division of labor between academic and industrial research and the underlying accumulation regime must be considered.

New industry organization and stronger intellectual property rights

The discussion on these issues has to be put into the context of a far-reaching reorganization of the industry organization in the pharmaceutical and biotech industries. Due to the enormous differentiation of drug discovery technologies and in order to minimize their own risk, large pharmaceuticals outsource numerous research activities to biotech firms and academic research centers. They systematically observe technological development on a global scale and acquire promising substances and technologies. Thus, 'big pharma' heavily relies on appropriating externally produced knowledge. This analytical knowledge is generated in a few regional innovation arenas . Publicly financed institutions play a central role in this generation. Out-licensing of drug candidates and technologies has become an important source of income for biotech firms and even universities. Biotech companies often have a mediating role. They transform and develop basic analytical knowledge generated in publicly financed institutes. They then can further develop promising projects together with pharmaceuticals or out-license.

The notion of open innovation and the problematic of knowledge transfer through channels and pipelines need to be clarified. In the sense of Chesbrough open innovation means that “firms commercialize external (as well as internal) ideas by deploying outside (as well as in-house) pathways to the market.” The boundary between a firm and its surrounding actors has become more porous, enabling innovation to move easily between the interested players . However, the notion ‘open innovation’ is misleading. Increased division of innovative activities, network membership and sharing of knowledge do not automatically mean augmented openness. On the contrary, exactly

because the boundaries between a firm and its surrounding environment are more porous, intellectual property rights must be enforced as a consequence. In- and out-licensing are only possible when based on property rights. They have become bargaining chip for the exchange of technology between companies and for venture capital .

An increased, but highly selective openness can be observed in the sense of intensified knowledge transfer from universities to firms and between firms. However, science and knowledge generation have not become more open in the sense of a free dissemination of knowledge and information. On the contrary, the stronger IPR regime encloses knowledge more than before. There is even the danger that knowledge produced by academic institutions loses the status of a ‘public good’ .

Open channels and closed pipelines of knowledge transfer closely interfere with one another . Transactions are ‘pipelines’ when legally binding, confidential, contractual business is being transacted. But they rely on free contacts to ‘open science’. Publicly funded research institutes are major magnets for profit-seeking biotech firms and for large pharmaceuticals exactly because they operate with relatively open science conventions. However, in doing so, ‘big pharma’ tries to absorb a good portion of that knowledge exclusively . This shows that closed and open science, respectively innovation are inseparably related. Closed corporate innovation enclosed by property monopolies profits from open science in universities. How the processes of knowledge generation, acquisition and subsequent valorization interfere and interact depends on financial constraints, regulatory conditions and power relations within an industry, between firms, and even within firms.

Only codified knowledge can really be commercialized, either materialized in products or in the form of licenses. The acquisition of knowledge through open channels is necessary in order to convert this knowledge into commerciable information. In contrast to the idealistic picture of open science and open innovation, in the regime of monopolized intellectual property rights, the economy is increasingly shaped by secretiveness and patent disputes. Thus, technological progress adopts a quite specific face .

Enforcing intellectual property rights and the Anti-Commons Regime?

The effects of the strengthened and extended intellectual property rights are increasingly the subject of critical discussions. Various studies show that an extensive granting of patents can block the free usage and accumulation of knowledge and hence hinder innovation processes .

First, this can happen if patents are granted too broadly and therefore gate off subsequent research in the same area. Second, there is the frequent, so-called Anti-Commons Regime in biotechnology. If companies obtain private rights on DNA sequences, including fragments of a gene, before the corresponding gene, protein or the corresponding active substance has been identified, no one will be able to unify the rights or buy all licenses, respectively. In such a case, various owners of a good's fragments are given the right to exclude all others, with the ultimate effect that the product will not be produced . By creating the possibility of patenting gene fragments, regulatory authorities encouraged the race for private appropriation. However, the production of a recombinant protein drug and new genetic diagnostic test requires the combination of gene sequences. Third, innovation can be blocked if research tools, preliminary products for broad areas of research, or key approaches are patented, and if the patent holder aggressively prosecutes unlicensed users or only appoints one exclusive license . Those who are willing to pay a large sum, generally speaking large companies, may be best capable of tackling those obstacles and creating monopoly-like situations with exclusive rights.

In biotechnology, primarily in the area of genomics, different firms have practiced a systematic accumulation of patents. This has permitted them to enclose whole areas of drug targets, substances or technologies and, accordingly, to impose an 'immaterial toll' to block other interested parties if they are not willing to pay licensing fees. Entire cascades of products, such as the sequence of a protein encoded by a gene, the antibodies of a protein, gene vectors, host cells and genetically manipulated animals used in the preclinical trials, are often based on patents on gene sequences. Patent holders can thus block future, still unknown usages and respectively obtain rents from royalties .

Patents not only became a central valuation criterion for firms but also for academic research institutes. The US universities increased their license-based income from 186 million USD in 1991 to 1,3 billion USD in 2001. Many universities depend to large extent on such income to finance their research expenditures . The tendency to patent extensively and on an increasingly broad scale can hinder innovation processes. Companies which finance academic research require reliable and

confidential results. This again discourages open interaction between researchers. But it is exactly in this way that academic research in the biosciences can distinguish itself from the business-oriented .

Changes of IPR regimes and national innovation systems in the USA and Europe

All industrial sectors have experienced a drastic increase in granting of patent during the last two decades. The United States Patent and Trademark Office (USPTO) granted 76,748 patents in 1985, already 107,124 in 1991 and even 221,437 in 2002. A similar development happened in Europe. There were 42,957 applications for patents in 1985, 60,148 in 1991 and 110,640 in 2002 at the European Patent Office (EPO) . From 1990 to 2000, the number of patents granted in biotechnology rose 15% a year at the USPTO and 10.5% at the EPO, against a 5% a year increase in overall patents. The number of gene patents granted has risen dramatically since the second half of the 1990s. In 2001, over 5,000 DNA patents were granted by the USPTO, more than the total for 1991-95 combined. Similarly, the EPO estimates it has approved several thousand patents for genetic inventions . Applications to the EPO for biotechnology patents rose from 2,453 in 1991 to about 6,200 in 2000, and slightly declined to 5,876 in 2002 . The European Commission described this trend towards increased patenting activity as the ‘pro-patenting era’ . This trend is expected to continue in the future, as different surveys have confirmed.

This inflation of patenting does not necessarily reflect an increase in inventive activity. It also expresses that patents are used for other reasons than the traditional appropriation function. This is generally known as ‘strategic patenting’ . This is not surprising in a context where knowledge and know how in form of patents have become a strategic commodity of firms. Kortum and Lerner explained this pro-patenting era with the change in the management of innovation, involving a shift towards more applied activities. Moreover, firms are more conscious of the importance of intellectual property rights. An increase in the bargaining power of companies and higher product market competition are the most important factors underlying this trend in patenting .

These explanations need to be complemented with a broader societal and economic perspective. The explosive expansion of intellectual property monopolies is less a result of technological breakthroughs than of far-reaching economic and institutional changes. A new regime of intellectual property rights consisting of far-reaching institutional changes emerged. It was accompanied by a changed role for universities and publicly funded research, and cannot be separated from the ascent of

concentrated financial capital, changes in financial markets and the entry of pension funds into venture capital. These complementing and reinforcing *institutional complementarities* strongly influence national and regional innovation systems .

The patent system is an important element of national innovation systems and of innovation policies in national states. However, OECD countries are currently converging with respect to their policy designs in science and technology policies, which reflect similar constraints imposed by liberal policies. The US is the main model of reference for most changes and reforms . This convergence happens also in the field of intellectual property rights. In the context of globalization of markets and the increasing importance of patents as means to secure investments the international patent system increases continuously its importance at the expense of national patenting procedures. The changes in the intellectual property regime in the USA in the past three decades are crucial: first because of the relevance of the US economy to global dynamics and second because of the pioneer role of US policy. In the course of the implementation of the TRIPs (*Trade Related Aspects of Intellectual Property*) agreement, the US were able to enforce their “philosophy” of intellectual property rights almost on a global scale .

Below, first the major changes of the IPR regime in the US are presented. Then the measures towards homogenization intellectual property rights in Europe and creation of a European IPR regime is described. Finally is showed how Germany, Switzerland and Denmark adapted their intellectual property rights regime to this changing framework.

Bayh Dole Act and changing legal practice in the USA

Technologies developed over the course of the 1970s permit the modification of genetic substance. In 1980, the US Supreme Court for the first time granted a patent for a genetically engineered micro-organism to General Electric (*Diamond vs. Chakrabarty*). This decision marked a decisive turning point in U.S patent policy. Henceforth, they could enforce a monopoly claim on life-forms and gene sequences. Such patents unleash a considerably larger monopoly effect than one which monopolizes only a production process .

A comprehensive change in the property rights regime then occurred: First, the judges decided that discoveries and not only inventions could be patented. Second, the directives of the USPTO in 1995 and the US courts also authorized patents which could be a basis for different further developments,

even if their use could not be proven at the time of the patent application. The renunciation of industrial “utility” as a criterion by the courts enabled the granting of patents on inventions whose uses were in the very early stages of research . Thus scientific insights became objects of systematic privatization. Since research results also can be patented now at an early stage of the innovation process, it has become possible to block research activities which rely on these insights. Generally, the scope and reach of patents has been greatly extended.

These institutional changes were conducted in light of a change in the universities’ role. In the 1970s and 1980s, universities were increasingly assigned the task of contributing to the re-establishment of the US economy’s international competitive position and technologic leadership in certain areas. A cornerstone of this development was the *Patent and Trademark Amendments Act*, known as the Bayh-Dole Act, in 1980. It gave universities and public research institutes the chance to own property rights on results from research financed by federal money. The passage of the Bayh-Dole Act, which could thus be viewed as ‘one part of a broader shift in US policy toward stronger intellectual property rights’ (Mowery and Sampat, 2005, 228), was strongly promoted by US research universities active in patenting. Previously, universities once understood their mission to be the practice of open sciences and the elaboration of publicly accessible knowledge. Thus since 1980, universities have been able to patent their findings and subsequently commercialize them, be it by new start-up firms or through licensing of patents to other firms .

Homogenization of regulatory framework in Europe

Although later, Europe is experiencing the same development towards stronger intellectual property rights. Two changes in the institutional landscape are to be mentioned: First, in the context of the creation of a single European market, the harmonization of intellectual property rights systems became more important. Second, the implementation of the TRIPS reinforced intellectual property right protection. Different national systems of intellectual property rights are in this political and economic context considered as non-tariff trade barriers.

Intellectual property laws are usually nationally based, whereas competition is transnational. The national, European (European Patent Convention, EPC) and international (Patent Convention Treaty, PCT) patent rights exist in parallel within Europe. The use of the European patent system has risen

tremendously during the last decade and has largely eclipsed the number of national patent applications in Europe .

The existing European patent system is based on the 1973 Munich Convention on the European Patent, according to which the European Patent Organization was established. The European Patent permits a patent application in an official language (English, French, German) of the European Patent Office (EPO) to receive in unified procedure patent protection in all designated member states of the European Patent Convention of 1973. The European Patent Convention promoted administrative ease but did not introduce a single patent in the sense of enforcement with a material Europe wide patent law .

A European Community patent, covering with one right the entire territory of the European Union, has not yet been implemented. The proposal for a community patent, made in 1975 (Convention for the European Patent for the common market) and again in 1989 (Agreement relating to Community patents), has still not been adopted. The member states were reluctant to a European Community patent because of the high translation costs into all the official EU languages and because member states still consider the granting of patents as a matter for national sovereignty . Currently, the Community Patent is still object of controversial debates. However, the [European Commission](#) launched a new initiative to move towards the implementation of a Community Patent on [January 16, 2006](#) . This renewed effort is in line with the life sciences and biotechnology strategy demanding explicitly a European Community patent adopted in January 2002 which is an element of the competitive agenda of the EU decided at its Lissabon summit in 2000.

There is still a possibility of different interpretations by national laws and national courts in the European patent system. But during the 1980s, European industry amplified its pressure to unify the European regulation for biotechnological inventions and to obtain patents on life forms. The Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, adopted after 10-year lasting debate was a further step toward harmonization . The EU countries should have integrated it in their national law until July 2000. But the directive still continues to be debated in some countries. The directive does not create any specific patent law for biotechnological inventions. It is rather making adaptations and amendments which the

national legislators must implement. National patent laws remain the essential basis for the legal appropriation of biotechnological inventions .

Heavily discussed was the patentability of DNA sequences. The directive excludes the human body and the discovery of one of its parts (e.g. a gene) or parts of it from patentability. However, a part of the human body (e.g. a human hormone, a human gene or nucleotide sequences) that is derived from genetic research and isolated from the human body by means of technical procedure is patentable, even if the isolated part is completely identical to the natural part in the human body. In this respect, there is a convergence of patent policy in Europe and in the US. Both patent offices provided a large number of patents for gene sequences .

A major difference between the patent system in the European countries and the U.S. concerns the point of time of the patent application. The first to invent system in the US requires for novelty that an invention must not have been in public use or on sale or patented or described in a printed publication until 1 year before the US filing. The European system is a first to file patent system. The researcher applying first a patent has priority before those having made the same invention but going later to the patent office. In the US the researcher can profit from a so-called grace period of twelve months during which she/he can publish her/his results without making impossible a later patent application. The grace period is criticized in particular by industry representatives because it creates a period of uncertainty mainly in complex and competitive fields such as biotechnology. However, universities, research institutes and firms collaborating with public institutes favor such a grace period also in Europe .

Bayh-Dole inspired legislation steps up the role of universities in taking out patents on the inventions of their employee scientists. Preparations for this legislation have not included systematic studies of the ways and the extent to which university scientists, prior to the legislation, were involved in commercial patenting, nor was it examined how this involvement could be affected by such legislation.

In the wake of this wave of legislation across Europe several recent studies demonstrate that university invented patents are far more prevalent than university owned patents, e.g. Italy , Finland , Germany . The same pattern is identified for single large universities e.g. University Louis Pasteur . A recent study offers a useful overview of these findings and presents results from a large analysis of

9000 EPO patents across 6 European countries, identifying one inventor in each. The sample also includes a small segment of 294 inventor contributions from university scientists, which gave rise to only 85 university assignments.

University-invented, company-owned patenting turns up as a far more prevalent mode of academic contribution to technological invention than is the mode in which universities are assigned patent rights. For the overall contribution of academia to the technological performance of European companies it emerges as an important issue if that contribution is negatively affected by Bayh-Dole inspired legislation, and if, in that case, adequate new mechanisms appear as substitutes. These issues are addressed below based on an empirical study on effects of the Danish version of Bayh-Dole.

Strong federalist support policy and regulatory adaptation to the international context in Germany

During a long period Bayer and Hoechst were among the leading chemical and pharmaceutical companies in the world. This traditionally strong position got lost in the 1990s. There is not any more one German pharmaceutical company among the top ten. Only focused pharmaceutical firms such as Schering (acquired recently by Bayer) and large firms still owned by families such as Boehringer Ingelheim and Merck KGaA were able to defend their strong position. Also in the early 1990s, more than ten years later than in the US, emerged the biotech industry in Germany. The rise of the biotech industry in Germany has been characterized by the economic and political ambition to catch up compared to the US and Britain.

On the federal level, three political measures substantially influenced the evolution of biotechnology in Germany: first, the establishment of the gencenters in Berlin, Heidelberg, Cologne and Munich between 1984 and 1989, second the adoption of gene technology law in 1990 and its amendment in 1993, and third, the BioRegio contest organized by the BMBF (Federal Ministry for Education and Research) in 1995. This BioRegio contest of 1995 played a crucial role. Actors in regions were invited to submit proposals and to describe how commercialization of biotechnology in their region could be promoted. The winners, the three most organized regional organizations, *Initiativkreis Biotechnologie München*, *BioRegio Rheinland* and *BioRegio Rhein-Neckar-Dreieck*, each received 25 million Euro over five years to invest in biotech. *BioRegio Jena* in East Germany was awarded a further grant of 15 million Euro. This contest activated a start-up dynamics in these winner regions and also in other regions. The BioRegio contest was an expression of a deliberate policy to promote

the commercialization process of the technological potential in order to improve national competitiveness. Due to the federalist structure of Germany this policy was implemented on a regional level, institutionally using the rivalry between regions in Germany .

The BioRegio contest was followed by a series of further promotion programs of the BMBF. BioProfile supported the specialization of established bioregions. BioChance launched in 1999 funded certain highly-risky R&D projects conducted by small and medium-sized biotech companies. It supported until 2005 young firms translating their biotechnology knowledge into new products with totally 50 Mio. Euro. In 2003 succeed BioChancePlus offering 100 million Euro to small and medium biotech which apply for funding with project submissions. With the BioFuture contest the BMBF finances young scientists in biotechnology and related fields with totally 75 million Euro until 2010 .

In the context of a so-called innovation offensive the BMBF started a High-tech Masterplan in 2003 which aimed a better access to venture capital, the creation of a competitive tax environment and new collaboration models between public research and small enterprise. This plan was less specifically directed to biotechnology than to technology-based companies in general. Additionally, on the level of the Bundesländer, especially in Bavaria, the biotechnology industry was promoted by different cluster initiatives implemented by Bundesländer .

In parallel the German government began to adapt its regulatory framework, especially in the field of intellectual property rights, to the general trend in Europe and initiated already before in the US In June 2003 the German government decided to transpose the European Community directive 98/44 into national law and in March 2004 the German parliament started consultations of the directive. The biotech sector strongly supported a fast implementation of the European biopatent directive .

In Germany university patents were traditionally regulated by the “Inventions made by employees Act” (ArbNErfG). In order to promote freedom of research it included a so-called “professor privilege”, according to which the university inventor and not the university was the owner of the patent. This regulation was criticized by some practitioners and industry representatives. They argued that the research institutions had no incentives to support patent applications . In 2002 the ArbNErfG was amended transferring responsibility for patent application from the inventor working at a university to the institution. The aim of this amendment consisted at encouraging patenting activities in universities. Accordingly, since February 2002 an inventor, if he wants to publish his results, has to

present the invention to the employing research institution which has to proof the convenience of applying for a patent. The institution can decide whether it wants to file a patent application or leave the invention to the inventor for application. Inventors receive 30% of the compensation profits . The abolishment of the “professor privilege” encouraged the universities to create their own structures for commercialization of inventions and patents. However, an inventor can abstain from a publication and therefore impede or prevent a patent application. This possibility creates uncertainty for firms being interested in collaborating with universities. This shows that, depending on the specific societal context a regulatory adaptation can provoke results which were not aimed originally.

However, the German biotech industry remained relatively weak compared to Britain and Switzerland, despite of the strong government support and the considerable public financing of the biotech sector. This raises the question to which extent such a promotion policy, applied in specific historical, economic and societal contexts and trajectories, can be an adequate means to improve so-called national competitiveness.

Federalist liberal science policy and adaptation of favorable regulatory conditions in Switzerland

Switzerland has traditionally applied a very liberal policy style in determining technology policy. Although Swiss governments, both at the federal and cantonal level have always fostered the promotion of academic research; undertaking technological research was, for ideological reasons, mainly left to business sector. Federal administration has traditionally been weak .

Swiss government strategy consists in developing excellent research in some selected priority areas. Applied technological research is mainly concentrated in a few multinational enterprises. Particularly, in the field of the pharmaceutical and biomedical industries large transnational companies are responsible for the main part of research expenditures. The Swiss federal government has not conceived a more active technology policy. It focuses on providing a good infrastructure and favorable legal conditions. The innovation system worked almost without extra-university governmental-financed research institutes that could have been used for technology policy purposes. Switzerland has a long tradition of niche specialization and development of high-value added products. This strategy has been highly successful including remarkable results in basic research .

The universities (Basel, Zürich, Lausanne and Geneva) as well as the Federal Institutes of Technology (ETH Zürich and EPF Lausanne) have been crucial for the creation of new ventures and technology transfer. Novartis and Roche, two major pharmaceutical companies, both located in Basel, played another central role in the formation process of the Swiss biotechnology industry. Therefore, the large majority of biotech firms in Switzerland are concentrated in the same regions.

In line with the policy mentioned above which consisted in strengthening selected technological fields the Swiss National Science Foundation (SNF) launched the Swiss Priority Program Biotechnology (SPP Biotechnology) in 1992 with public funds. A total of six research modules in biotechnology and complementary activities in continuing education, information, communication, technology assessment, and technology transfer were designated to receive state support over a period of 10 years, ending December 2001. The SPP Biotechnology had the objective to promote strategic, applied biotechnology research in Switzerland. This program contributed to the creation of eighteen new companies. The program budget contained CHF 100 million allocated by the Swiss Federation. Additionally, some CHF 40 million have been attracted from industry, as well as more than CHF 60 million of venture capital throughout the duration of the program. One outcome of the SPP was the creation of the technology transfer office Biotectra in 1996. Unitectra, the technology transfer organization of the universities of Berne and Zurich and the SNF's SPP Biotechnology was founded in 1999 and is the successor institution of Biotectra. The other universities installed their respective technology transfer organizations. In 2001, the SNF launched the first fourteen National Centers of Competence in Research (NCCR) which represented a new instrument of research and technology policy after completion of the SPP. In the field of life sciences, four NCCR have been started. They have focused on research in genetics, neurosciences, structural biology and molecular oncology.

The CTI (Commission for Technology and Innovation) assumes an important role in the biotech promotion policy. The CTI has been a traditional key instrument of the Swiss federal government's technology policy. In 2000, it became the "federal agency for applied research and development". The CTI promotes applied research and development projects through public-private partnerships and supports start-ups. The CTI Start-up initiative initiated in 1995 boosts the entrepreneurship at the junction between universities and industry. It supports the commercialization process of products and especially companies in their start-up phase. It selects new firms for venture capital financing and grants them the "CTI Start-up label" which qualifies them to access to CTI support and venture capital. This label also helps to convince potential investors investing in a project. Through its Life

Sciences section, the CTI backs applied R&D projects based on a public-private partnership model (50/50 funding as a basic rule) and facilitates a transfer from SNF to CTI funding. For example, it supports follow-up projects stemming from the National Centers of Competence in Research (NCCR)

In contrast to Germany in Switzerland does not know a so-called “professor-privilege”. According to Swiss Law of Obligation (Obligationenrecht / OR), inventions made by employees in the course of their employment belong to the employer. Consequently, the universities and research organizations are applicant and owner of the patents claiming such inventions.

The government combined the liberal attitude with a careful adaptation of legal conditions. Although Switzerland is not member of the European Union government has very consciously harmonized its regulatory framework in strategically important fields with the framework of the EU. In line with this orientation, in 1999 the parliament engaged the Federal Council to adapt the patent law to the European biotech directive, passed by the European Parliament and Council in 1998. This law revision aims to conform the patent law with the EU directive on the legal protection of biotechnological inventions. Mainly, the pharmaceutical and biotech industries have lobbied for the law revision. This revision partially takes into account also the interests of academic research in biotechnology. The draft revision of patent law adopted by the Swiss Federal Council in November 2005 defines three major issues :

Patentability of genes: According to the EU directive 98/44, isolated genes as such are patentable. In Switzerland, however, naturally occurring genes would be excluded from patenting under the new law. This is a restriction of patentability that goes beyond the practice applied by the EPO. However, it would continue to be possible to patent “derived sequences” such as the cDNA produced by PCR (Polymerase Chain Reaction), under the condition that at least one function of these sequences is known. This means that the properties and applications of sequences that are derived from gene sequences must already be described in the patent application. Adding them later is no longer possible. This is intended to prevent speculative patent applications.

Patentability of human beings and their body parts: In agreement to European Directive 98/44, the human body as such and human physical components in their natural environment shall also be

excluded from patenting. The subject of a patent is a technical teaching as to how human beings can utilize nature in a new way for commercial purposes. This technical beneficial effect makes the discovery an invention under patent law. However, isolated and perhaps technologically modified components of the human body outside their natural environment (such as isolated and possibly genetically modified blood cells) are patentable. Explicitly excluded in the new patent law and also corresponding to Directive 98/44/EC are cloning of human organisms, chimeras with human germ cells, modification of human germ line cells or unmodified human embryonic stem cells.

Role of patents in Swiss biotechnology

There is not much empirical data available on the impact of intellectual property rights in biotechnology. In the context of the revision process of the patent law the Swiss government requested the Swiss Federal Institute of Intellectual Property to analyze the impact of patents on biotechnological innovations and the economic implications of patents .

The number of patent applications rises with firm size. Therefore most patent applications belong to large companies. However some very active, small, companies are strongly dependent on patenting and its commercialization. Small companies consider patents to be highly important in order to use them for the acquisition of venture capital. They are also more innovative in terms of patent applications per employee in research and development. Similarly, research institutes consider their patents to be important to get financing research and development. For most companies having participated on this survey, patents are very important for collaborations with other companies and for timing their scientific publications. Particularly, large companies pay attention to patents when they examine possibilities for collaborations or mergers . Not surprisingly and in line with the economic structure of the country the patent applications of Swiss firms are internationalized. This is expressed in a high number of triadic patents (patents applications filed with European Patent Office, US Patent and Trademark Office and the Japanese Patent Office). Switzerland takes the eighth place in triadic patent families, and measured in patent families per million inhabitants Switzerland, is the leading country, together with Sweden . Swiss biotech firms normally apply also for European and US patents .

Effects of Bayh-Dole inspired legislation on the biotech innovation system in Denmark

This section takes a closer look at some of the implications, which Bayh-Dole inspired legislation (discussed in previous sections) has had for the coherence of innovation systems (discussed in the first

section of this chapter) in Denmark, focusing on the effects on industry-university (I-U) collaboration in biotech research .

In the 1950s both Denmark and Sweden enacted legislation giving explicit exception to academic scientists from the general principle whereby employers hold the right to inventions produced by their employees. Referred to as the “teacher’s exception” (similar to what in Germany was referred to above as the “professor’s privilege”, this principle has been maintained in Sweden until now, but was changed in Denmark as per Jan. 1st 2000 in the Law on University Patenting (LUP)². The act transfers to universities ownership inventions made as part of the work of employees. That also pertains to inventions resulting from collaborative work with third parties (e.g. firms), but in these cases the university may renounce the right to the inventions made by the project.

Sweden so far has maintained its teachers exception, but is currently considering reforms in this area. Hence comparing post-LUP patterns in I-U collaboration in Denmark with that of Sweden offers possibilities of a quasi-controlled experiment. Such a comparison benefits from the broad similarities between and two countries, and from the fact that regulations of university IPR uniformly affect all its academic research, unmodified by country-internal variations between e.g. private vs. public universities, or by variations at lower levels of government(länder or states).

This comparison is particularly informative if referring to a field in which I-U collaboration plays a significant role. That is the case in biotechnology where a number of studies have documented the strong reliance of firms of knowledge transfer from academic science . Biotech also is a field in which the two countries are strikingly similar, particularly when we focus on the segment of Dedicated Biotechnology Firms (DBFs) specialised in drug discovery. This segment emerged in the two countries at the same time through the 1990s, and has grown to the same number of firms, with quite similar patenting profiles. Denmark has 51 DBFs, of which 48 have filed patents. In Sweden 41 of the total of 44 DBFs have filed patents.

The data by which the study compares Denmark and Sweden is extracted from all the 1087 patents filed by these firms. Inventors listed (by name and area only) on each patent front page were identified and their organisational affiliation was established³ as per the date of patent application.

² The “Act on inventions at public research institutions” of June 2nd 1999 may be accessed at http://www.videnskabsministeriet.dk/cgi-bin/doc-show.cgi?doc_id=14206&leftmenu=LOVSTOF. An English translation is available at http://www.videnskabsministeriet.dk/cgi-bin/doc-show.cgi?doc_id=20047&doc_type=22&leftmenu=1 .

³ The methodology for inventor tracking is described in Valentin and Jensen (2006)

These 3640 inventor identifications permit calculation of the share of university scientists for each patent, and of aggregated shares for each country, for specific periods.

Effects of LUP on the share of university scientists in these patents are examined, defining the “event date” with a lag of one year (i.e. Jan 2001), since the law respects collaborative arrangements established prior to its enactment.

Tests are made for LUP-related shifts 1) in the share of *domestic* scientists (i.e. Danish university scientists contributing to patented inventions assigned to Danish DBF, and 2) in the share of *non-domestic* university scientists. For both shares differences between pre- and post LUP levels, comparing Denmark and Sweden, are tested by Difference-in-Difference (DD) regressions.

Furthermore, to enhance interpretation of DD findings, tests are made for LUP-related shifts in *trends*, of shares of university scientists, aggregated separately for the two countries by quarters.

These tests bring out the following:

- Since the mid 1990s the number of DBF patents in Sweden and Denmark as a whole has increased steeply, as has the number of academic scientists contributing to inventions not only in absolute number. An increase also is observed in academic inventors as a share of all inventors.
- Throughout the 1994-2004 period, the academic involvement in Swedish patents is notably above what is seen in Danish patents. However, the Danish pattern, until the introduction of LUP quite systematically *converges* towards the higher Swedish level.
- Compared to the Swedish control group, the DD regression identifies a drop of 12.6% in the share of domestic academic inventors behind the Danish patents, specifically attributable to the event. In the trend analyses this appears as a *reversal* of the previous convergence towards the higher Swedish level into a sharp *downward* trend.
- Non-domestic inventors on the whole are involved with notably lower shares as compared to domestic inventors, and also in this respect the Danish level is below Sweden. However DD regressions identify a significant increase in Danish non-domestic shares of 13.7%, as compared to the Swedish control group, specifically for the post-LUP period. The trend analysis in this case offers only tenuous results, but they suggest a steep increase in the Danish

post-event involvement of non-domestic inventors. Consistent yearly increases are observed over the four post-event years, bringing the level from 4.9% to 11% of all Danish inventor contributions.

Taken together these findings strongly indicate a Danish pattern, significantly distinct from the Swedish counterpart, of a post-LUP decrease in the involvement of domestic academic scientists. At the same time, non-domestic university scientists to a notable extent substitute for their domestic counterpart in Danish inventor teams.

To see this decline in university involvement in context the study examines if Danish academics in the life sciences in stead *redirect* their inventiveness into *university-owned* patents, as indeed was one of LUP's key objectives.

The number of domestic academic inventor contributions to university-owned patents, in relevant IPC categories, filed subsequent to LUP is identified. This number may be subtracted from the number of inventor contributions equivalent to the 12% post-LUP decline detected in the DD-regression. On this basis the study estimates the extent to which university owns patents provides a substitutive outlet. The two variations of this estimate presented in the study indicate substitutions at rates of 19% and 26%.

University-owned patents, in other words, are very far from providing a substituting outlet for the inventive potential of university scientists previously mobilised for company-owned drug discovery patents. By far the largest part of this academic inventive potential simply seems to have been rendered inactive as an effect of LUP.

To examine the causes behind observed LUP effects the study is underpinned by interviews with academics and DBFs selected from the patent data on which the study is based, identifying explanations consistent with quantitative results from other studies . The interviews bring out that collaborations typically are concerned with *exploratory* research, by some firms referred to as “pre-project research”. DBFs enter such collaborations well aware that it is highly uncertain if and how results will be commercially relevant, and that they become so only based on an unknown body of subsequent in-house R&D. Firms tend to find this set-up inconsistent with the LUP- principle that universities *ex ante* own the rights to resultant inventions, and reduce involvement of *Danish* academic scientists accordingly. For their part, academic scientists typically collaborate in exploratory research to deploy some specialised research experience, which the collaboration may further enhance

by offering better research funding, access to an interdisciplinary environment or to the specialised research facilities of the industrial partner. The academic scientist collaborates on such explorative research, in other words, based on skills and motivations, which would not allow her to pursue equivalent patenting on her own.

This explanation clarifies not only why LUP has brought about a decline in collaboration within exploratory research. It also explains why LUP would *not* necessarily have similar effects in university research operating in “down-stream” fields closer to technology. Down-stream fields are less demanding in terms of complex, post-discovery development, so here academics are better positioned to invent on their own, without relying on clues and information from industrial partners. Furthermore, in cases when such downstream issues are addressed in collaborative projects, they also lend themselves more easily to *ex ante* allocation of IPR.

Implications for the Danish innovation system in biotechnology

Several studies document that research collaborations in biotechnology are established with a strong preference for partners from the same country, even the same region . The advantage of proximate research relationships is not derived from superior qualities of partners, who just happen to be local. Rather it comes from the fact that proximate relations tend to be embedded in networks in which actors have repeated interactions and learn about each other over time via multiple channels . In this way networks become architectures capable of retaining and transmitting vastly richer information about each actor, as compared to arms-length relationships to partners who are distant (in the sense of not being part of the network) . That is why networks offer superior search, allowing actors with complex agendas to access the types of complementarity which gives rise to effective research partnering . However, depending on which activities are carried out and their respective knowledge bases, such networks can also have a global reach as is the case with epistemic communities (Moodysson et al. forthcoming).

For the issues in the present paper the implication of this argument is that an important part of the value emerging from industry-academia collaborations lies in *the quality of the network* through which either side may undertake effective search so as to identify “the right complementarity at the right time”. Danish DBFs have no advantage above that of DBFs from other countries when it comes to search into the global “market” for academic collaboration. But they do have an advantage in search into the Danish academic setting, since there are strong indications that they are particularly

well connected into Danish universities. The authors behind the LUP analysis summarized above in another study identify all founders and board members affiliated with all Danish and Swedish DBFs through their first year of existence . This study shows that the vast majority of founders and board members are recruited from Danish organizations.

Founder teams involving Danish university scientists established more than half of Danish DBFs. Similarly academics were present on more than half of the boards that took firms through their first year of business. These compositions of founder teams and boards make them highly effective in subsequent search into the academic potential for research collaboration.

These figures bring out the particular connectivity, which Danish DBFs have into Danish academia. In turn this connectivity is a key asset for scientists from both the academic and from the industrial side when they look for the complementarity of skills and agendas which are so important for making university- industry research collaboration effective and useful for both commercial and scientific objectives. The paper demonstrates, consistent with this argument, that this composition of founders and boards matters for the ability of Danish DBFs to establish the diversity of inventor collaborations which in turn affects their commercial performance . These observations substantiate that research networks are an important part of the Danish innovation system in biotechnology, and that it matters significantly for the inventiveness and competitiveness of firms. It is therefore cause for concern that LUP, as an unforeseen consequence, induce Danish biotech firms to disengage themselves from the national research network, substituting in stead with search in the global market for academic research partners. It signifies that LUP, as an unintended side effect, seems to have induced an erosion of parts of the national innovation system of considerable value for Danish science-based competitiveness.

6. Conclusions

IPR as a regulatory institution in innovation systems can play a decisive role with potentially big impacts on the governance of the systems. In the chapter we have shown that there across industrial sectors has been a big increase in patent granting during the last two decades both in the US and in Europe. In Europe Switzerland is the leading country measured in patent families per million inhabitants followed by Sweden. This reflects the strength of the pharmaceutical biotech industry in these two countries in contrast to Germany whose biotech industry has remained weak compared to Britain and Switzerland.

However, this big increase in the use of IPRs is more a result of economic and institutional changes than of technological breakthroughs. A new regime of IPRs emerged accompanied by a changed role of universities and publicly funded research, and, thus, had major impacts on the functioning of regional and national innovation systems. The US has been the model of reference for most of these changes and reforms led by the introduction of the Bayh-Dole Act in 1980. Also in Europe Bayh-Dole legislation has been influential, e.g. in stepping up the role of universities taking out patents on the inventions carried out by their employed scientists. However, company-owned, university-initiated patenting represents a more important academic contribution to technological invention than university owned patent rights. Moreover, the Danish example showed that the introduction of a Bayh-Dole inspired law has had negative impacts on university-industry collaboration in contrast to the situation in Sweden, which still practice the principle of ‘teachers exception’.

As shown in the chapter the consequences of introducing IPR differ according to sectors, knowledge bases, phases in the innovation process, and political-institutional frameworks. A patent based IPR makes a ‘better fit’ in certain sectors and knowledge bases than in others, and works better in specific political environments than in others depending on the types of institutional complementarities present. There may, for example, be a real problem with the current IPR system favouring radical innovations when biotechnology develops from early-phase, hi-tech to more generally diffused multi-tech. All this provides strong arguments against a global generic patent system.

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