Intellectual Property, Technological Regimes and Market Dynamics

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Abstract

This paper advances an argument in support of technology-specific tailoring of incentives to innovate. With a focus on patent incentives, the argument proceeds from the identification of the factors likely to have a bearing on (a) the differential role and effectiveness of patents in different technological regimes; (b) the varying degree of relevance of the various functions of the patent system in different technological regimes, and (c) the nature of the limits the IPRs system encounters in performing its functions in different technological regimes. These differences are then exemplified with reference to software and the life sciences and the means through which flexibility in the provision of incentives might be achieved in the two domains are explored.

Keywords: intellectual property, technological regimes, market dynamics, software, life sciences.

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1. INTRODUCTION

The question of the adequate provision of incentives to innovate has become a prominent topic of current debate in recent years. While, during the '90s, the theoretical discourse has focused mainly on the identification of the optimal characteristics of a uniform IP system, this decade has seen an increase in interest for alternative incentive mechanisms and for a more nuanced characterization of the functioning of the IP system in different technological domains. With respect to the latter issue, however, the gap is still very wide between empirical analyses and theoretical reflection.

The aim of this paper is to make one step in the direction of narrowing this gap by reviewing the relevant theoretical and empirical literature from the perspective of the identification of the links between IP incentives and different technological regimes and market dynamics. To ensure tractability, the focus will be on the patent system. The general thrust of the argument will suggest that the varied role and performance of the patent system in different technological domains warrant some sort of technology-specific tailoring of incentives to innovation. In other words, the "one-size-fits-all" principle that seems part of the conventional wisdom on the patent system and has found, to some extent, an expression in the 1994 TRIPs Agreement, should be put into question. This doesn't mean, however, that technology-specific legislation is necessarily called for, as it is sometimes assumed. Indeed, a variety of policy instruments might be used to ensure the necessary flexibility in the provision of incentives adequate to different technological domains.

These ideas will be exemplified by reference to the life sciences and the software domains. The choice of these technological domains is, of course, all but coincidental. Software and the life sciences are most apposite for our purposes for a variety of reasons. On one side, these domains display attributes sufficiently well characterized to allow a meaningful comparison. On the other side, both domains have recently experienced and are still currently experiencing significant changes in the legal framework within which innovation takes place. In the U.S., a series of court decisions has effectively extended patentability to genetically-modified organisms[1], software[2] and business methods[3] starting from the 1980s. In Europe, patentability of biotechnology inventions has been regulated through Directive 98/44/EC and a proposal for a Directive on the patentability of computer-implemented inventions is currently under discussion. These changes, resulting mainly in easier access to patent protection for inventions falling within the two domains, have gone hand in hand with a remarkable increase in patent applications, which surely magnifies the effects of the legal changes we have briefly mentioned. This makes the two sectors an important

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[1] The landmark court case in this regard is *Diamond v. Chacrabarty* (1980). The U.S. Supreme Court affirmed in that occasion the eligibility for patents of genetically engineered organisms.

[2] Among the most prominent U.S. cases concerning the patentability of software can be mentioned the *Diamond v. Diehr* case (1981), the *In re Alappat* decision (1994) and the *AT&T Corp. v. Excel Communications Inc.* (1999).

[3] The most significant decision in this regard in the United States is the *State Street Bank & Trust v. Signature Financial Services* decision (1998).

stage for exploring the opportunity of technology-specific tailoring of incentives to innovate.

The paper is organized as follows. In section 2, the general rationale for patent protection is presented, with a view at highlighting the most salient aspects of the current policy debate on the patent system and the most pressing tensions presently affecting its functioning. Section 3 sets out to identify the factors likely to have a bearing on the differential role and effectiveness of patents in different technological domains as well as the varying degree of relevance of the various functions of the patent system in different technological regimes. Of course, technological regimes differ also as to the nature of the limits the IPRs system encounters in performing its functions and to the nature of the remedies available to confront these shortcomings. We introduce the comparison between software and the life sciences in section 4, making a case for technology-specific tailoring of incentives to innovate. Section 5 provides an overview of the means through which flexibility in the provision of incentives might be achieved. Section 6 concludes.

2. THE INCREASINGLY COMPLEX RATIONALE FOR PATENT PROTECTION

Patent protection has been historically credited with a variety of functions, the most widely acknowledged of which is surely the **incentive function**, generally associated to the so-called "reward theory" of patents. The argument for the existence of an incentive function of patents rests on the hypothesis that, absent patent protection, innovators would find difficulties in appropriating the returns from their intellectual creations, with obvious negative consequences in terms of innovation incentives. Society is thus ready to grant a limited monopoly for a fixed term on the newly created intellectual assets in return for the inventor's innovative effort, so that a trade-off between monopoly costs and benefits in terms of increased innovation is established. The convenience of incurring such trade-off, however, has long been put into question by those emphasizing the virtues of competition as a stimulus to innovation. This alternative view, expressed among others by Kenneth Arrow (1962) and more recently by Hellwig and Irmen (2000), Boldrin and Levine (2002) and Quah (2002), stresses the existence of incentives to innovate other than state-created monopolies over ideas and suggests that monopoly may be less effective than competition in creating an environment conducive to innovation.

A second relevant function attributed to the patent system is the **transactional function**. Patents aim to solve the well-known Arrovian paradox, allowing for the exchange of intangibles. This is true not only when intangibles are in the form of end products, but especially when they constitute inputs into further innovative activities. Thus, the availability of patent protection has been identified as a necessary precondition for the emergence of markets for technology and specialized technology suppliers (Arora, Fosfuri and Gambardella, 2001) and the existence of patent protection over the inputs to a collaborative research endeavor is commonly held as a factor facilitating inter-firm R&D collaboration. To be sure, the incentive and the transactional functions are strictly intertwined. On one side, by assigning ownership entitlements to successive innovators, patents determine bargaining positions that facilitate welfare-enhancing transactions and enable some sort of division of profits among subsequent contributors to a given stream of research. This, in turn, affects the extent of incentives available to successive innovators. On the other side, in absence of transactional impediments, the assignment of strong and broad patent rights may constrain the duplication of innovative effort while preserving sufficient incentives for further product development and refinement (Kitch, 1977). More generally, recent literature in the IP field emphasized that private parties' ability to rearrange sensibly patent rights through bargaining substantially affects the optimal design of initial entitlements (Gallini and Scotchmer, 2002).

Patents also perform a **disclosure function**, according to the so-called "contract theory" of patents (Denicolò and Franzoni, 2004). Disclosure of technical information that would otherwise be kept secret is seen as the *quid* for the *quo* of legal protection in a bargain between the inventor and society. In other words, patents constitute a legal instrument inducing the free dissemination of innovative knowledge. In this perspective, the requirement common to most patent systems that patent applications provide sufficient information to enable a person skilled in the art to reproduce the invention (EPC art. 83; section 112 U.S.C. 35) can be interpreted both as a way of clearly delimiting the boundaries of the object of legal protection and as an expression of the disclosure objective embedded in the patent system. Under the "disclosure function" label can be categorized also an indirect effect of patents, prevalent in the life sciences. Indeed, the availability of patent protection encourages researchers in corporate laboratories in the pharmaceuticals and biotechnology industries to diffuse their research results at conferences and scientific meetings once patents have been applied for (Cohen et al., 2002).

Finally, patents are valuable for their **signaling function**. Possession of patents may serve the purpose of signaling a firm's innovative capabilities and increase its ability to raise the necessary capital, especially through venture capital financing. In so doing, patents thus help channeling funds in the most appropriate directions and play a role in promoting market entry. The relevance of the signaling function tends, of course, to be inversely correlated to firm size. Indeed, small innovative firms are capital-constrained and often lack means other than venture capital financing in order to pursue their innovative endeavors. This function has proven particularly crucial in the biotechnology realm, where the astonishing innovative results achieved by small start-ups could arguably materialize absent the patenting/venture capital financing link that has strongly characterized the sector in recent years especially in the U.S. (Powell, 1996; Coriat and Orsi, 2002).

While the four above-mentioned functions are naturally and necessarily complementary, their relative relevance and the emphasis put on them from a policy perspective has somewhat changed in the past two decades. A shift in focus away from the incentive rationale for patent protection and toward the transactional and signaling rationales has characterized, to some extent, the public policy debate. The transactional role of patents has featured as an essential component of the conceptual toolkit of proponents of the patentability of publicly-funded research results. In this connection, the argument in support of patentability has rested largely on the assumption that patenting would facilitate public-private and university-industry transactions and would therefore help turning university inventions into useful innovations (see, e.g., Mazzoleni and Nelson, 1998)[4]. On the negative side, the impact on the effectiveness of the patent system of various forms of transactional failure has also received greater attention in recent years – the metaphor of the "tragedy of the anticommons" (Heller and Eisenberg, 1998) being perhaps the most notable expression of this debate. As for the signaling function, its increasing relevance goes hand in hand with the steady increase in investment in venture capital as a percentage of GDP in most developed countries (OECD STI Scoreboard, 2003).

This shift in focus of the public policy discourse is accompanied by an amplification of a number of tensions affecting the current patent system. Some of these tensions can be categorized as exogenous to the system itself. This is the case, for instance, of the pressures exerted on the patent system by the shrinking distinction between basic and applied research in most scientific domains. The distance between fundamental knowledge and practically applicable research results is lessening. On the one hand, corporate laboratories increasingly invest in basic research and abide by rules of dissemination once distinctive of public institutions (peer-reviewed journals, conferences, etc.). On the other hand, research at public institutions more and more frequently leads to the development of intellectual assets that are dual in character and relies, sometimes aggressively, on IP management strategies that were once the prerogative of the corporate world (OECD, 2003a). Consider, for instance, "pure" mathematical algorithms that constitute both the foundation of further research in mathematics and the building blocks of valuable software products. Similarly, biotechnology inventions often constitute both the raw ingredients of research and practically applicable diagnostics and therapeutics. The conventional wisdom advocating research exemptions for public laboratories on the premise of the existence of some sort of division of labor between the public and the private sphere reflecting the distinction between basic and applied research is thus put under strain at the same time that access issues are becoming more prominent for reasons that will be explored later (Merrill et al., 2004).

Another source of exogenous tensions is the increasingly marked interdisciplinarity of innovation. This is apparent especially in the life sciences domain, where the so-called "Functional Genomics Revolution" set off in the '80s (Kafatos, 2002), while introducing mass-scale, rapid and global descriptive analysis methods in biology, has reinforced the need for a strong link with experimental biology. New disciplines sprung out of the "Revolution" such as bioinformatics, proteomics and expression genomics have a strong interdisciplinary nature. The primary consequence of this phenomenon can be described as a more pressing demand that the patent system perform effectively its transactional function. Interdisciplinarity implies a need for coordination of multiple and diverse actors that if, on one side, calls for strong and well-defined IP rights as the precondition for effective exchange of intangible information, on the other side exacerbates bargaining difficulties due to biases in the evaluation of entitlements and differences in cultural backgrounds, especially as regards the interaction of public and private actors (Eisenberg, 1999). In addition to this, interdisciplinarity may impose in some fields,

[4] See below the discussion of the 1980 Bayh-Dole Act.

and most notably in bioinformatics, a need to deal with multiple types of IP (database protection, copyright etc.).

The most intense pressures currently experienced by the patent system are perhaps those endogenous to the system itself. First, the mentioned overlap between basic and applied research has been accompanied by the upstreaming of patentability. Starting from the '80s in the United States and slightly later in other developed countries, most notably European countries and Japan, patentability has been extended to encompass previously excluded technological domains, such as software, business methods and biological inventions. Patents in the latter domains tend to be granted for intellectual assets that might be far removed from a direct commercial application and close to the realm of pure science and abstract ideas. Second, and closely related to the first aspect, is the shading of the distinction between pure information and practically applicable knowledge from the perspective of patenting standards.

The combination of the above two factors has deep consequences for the functioning of the patent system. For one thing, identification of the boundaries of patent rights tends to be harder than for patents covering downstream products not least because potential applications of patented upstream knowledge are generally unknown at the time of patent grant. This, in turn, increases the degree of uncertainty associated to the normal functioning of the patent system and brings about obvious consequences in terms of likelihood of patent litigation. Most importantly, the upstreaming of patentability in cumulative technological domains raises doubts as to the ability of the patent system both to ensure an adequate division of profits among successive innovators (i.e. to avoid excessive imbalances in favor of holders of upstream patents) and to impede that the early attribution of property entitlements entirely foreclose some streams of research. Concerns in this regard arise because many patents are now granted on objects that have no other use than as tools for the pursuit of further research and many of such patents, especially in the life sciences, cover discoveries and naturally occurring substances for which no close substitutes can be found.

The relaxation of patenting standards constitutes a third source of tension endogenous to the patent system. Requirements analogous to the "inventive step" requirement of art.56 EPC or the "non-obviousness" requirement of section 103 U.S.C. 35, but also the standards of utility and novelty embedded in most patent systems, are reportedly applied in a more lenient way than in the past (Barton, 2000; Dreyfuss, 1989; Lunney, 2001) in most developed countries. This is likely to result in a significant increase in the number of "trivial" patents granted over time, although accurate empirical estimates of the extent of such increase are hard to make and much of the concerns in this regard are raised on the basis of anecdotal evidence. The problems with the proliferation of trivial patents do not reside exclusively in the decrease of consumer welfare that is associated to the granting of monopoly rights over inventions that do not constitute genuine scientific or technical advancements. After all, the monopoly deadweight loss associated to patenting of "inventions" whose triviality makes them of scarce utility to the public is not likely to be substantial and judicial decisions may help to wipe out undesirable patents. Nonetheless, the proliferation of trivial patents is worth of attention primarily because of the feed-back effects that may result from the increase in patent applications associated to low patentability thresholds. The more the applications, the higher the pressures put on patent offices, and the lower the quality of the patents granted. The most worrying effect of this vicious circle is thus the increased uncertainty innovators might face as regard the validity and enforceability of both their own and their competitors' patents. Low patentability thresholds may therefore end up bringing about an increase in transaction costs (and in particular negotiation and litigation costs) without a corresponding increase in incentives to innovate.

The relaxation of patentability standards might also exert a negative influence on the effective performance of the patent system disclosure function. This is most easily discernible in relation to the patentability of the subset of biotechnology inventions made up by genetic inventions. Patent laws and regulations of most OECD countries tend to converge in this regard on a common ground according to which protection is granted to genetic material in so far as at least a single function of the gene or part of gene for which protection is claimed has been identified and is disclosed in the patent application. While this sort of utility requirement might not be problematic *per se*, the discrepancy between the inventive step effectively disclosed in the patent and the absolute nature of the protection the patent grants, which encompasses uses not described in the application, raises doubts as to the extent of information such patents are effectively able to convey.

A fourth factor at the origin of the tensions currently experienced by patent systems worldwide is the trend towards the strategic use of IP assets. Relative to the past, patents are increasingly used as strategic weapons to obtain access to externally developed technologies or as defensive tools rather than as means to prevent direct imitation by competitors (Cohen et al., 2000). Patent rights are asserted more aggressively both in the context of firms' innovation strategies and in the context of revenue-raising licensing strategies (Rivette and Kline, 2000). This phenomenon, in conjunction with the rise in the costs of patenting (Allison and Lemley, 2002) and the costs of prosecuting patent litigation (Lanjouw and Schankerman, 2003) is likely to exert non-trivial effects on the effectiveness of the patent system as an instrument for the promotion of innovation. This is at least for a twofold reason. On one side, the increased relevance of the role of IP management strategies for firms of all sizes is likely to redirect firms' internal resources away from research and toward the administrative expenses necessary to enforce patent rights and negotiate licenses. This has proved to be a sensible strategy for firms such as IBM, Texas Instruments and Lucent Technologies, who have all experienced a marked change in attitude toward the management of their IP in the past two decades (Rivette and Kline, 2000). On the other side, some evidence exists that research patterns, especially those pursued predominantly by Small and Medium Enterprises (SMEs), have been distorted by patenting patterns: investment in patent-intensive areas tends to be avoided in favor of less patent-crowded areas (Lerner, 1995). Of course the costs of litigation fall most heavily on small firms (Lanjouw and Lerner, 1997), which has consequences for innovation that are hard to fully assess.

Finally, starting from the '80s, the enactment of policies promoting recourse to patenting for the results of publicly-sponsored research has opened up a new set of opportunities as well as problems for the patent system. The landmark event in this respect can be considered the issuance in the United Stated in 1980s of the Bayh-Dole Act, which strongly encouraged the patenting of federally funded research results by universities, small firms and public research organizations more generally. The promulgation of this piece of legislation in the United States has not only spurred an internal debate that remains still unsettled (Henderson, Jaffe and Trajtenberg, 1998; Jensen and Thursby, 2001; Colyvas et al., 2002; Rai and Eisenberg, 2003; Siegel, Waldman and Link, 2003), but has also encouraged many governments around the world to follow suit in various guises and with similarly uncertain outcomes.

While the primary objectives of the bill – to encourage more effective technology transfer from public to private labs and to ensure that publicly-funded inventions are turned into useful commercial innovations – have surely their own merits, the evidence on the effectiveness of this policy move is so far mixed. For one thing, although most universities, both in the United States and in other developed countries, have proved ready to incur the administrative costs necessary to set up technology transfer offices and get into the IP management business, for most of them IP management costs are not outweighed by benefits in terms of licensing revenue, although closer links with industry through licensing often result in an increase of sponsored research whose extent is difficult to factor in the benefit-cost analysis of the consequences of the Act. [5]

Thorny issues arise also in other regards. The culture of "open science" distinctive of public research (Dasgupta and David, 1994) and Mertonian science more generally (Merton, 1973) is sometimes described as jeopardized by the new IP rules, with obvious consequences for the free dissemination of research results. Some modification of the scientific culture has perhaps taken place, especially in the life sciences, where research materials are withheld from public access more frequently than in the past and contractual agreements between university and industry often impose publication delays and/or the deletion of some information from publishable papers (Thursby and Thursby, 2002), but the effects of the Bayh-Dole Act are hard to disentangle from effects of a different origin. Free dissemination is also claimed to be endangered by the exclusivity clauses contained in some licensing arrangements, and especially those concerning research tools subject to broad patent protection. Although some well-known cases such as that of the OncoMouse patent testify that in some instances these concerns are well-grounded[6], the true extent of exclusive

[5] According to the 82 respondents to the Association of University Technology Managers' 1991 and 2001 surveys, inventions disclosed increased by 84%, new patent applications by 238%, license agreements by 161%, and royalties by more than 520%. The distribution of both patenting activity and licensing revenues is, however, very skewed, with the top 10 university patent holders accounting for 66% of licensing revenues in 2000 (AUTM, 2003).

[6] The so-called "oncomouse" patent, covering genetically modified mice useful, among other things, for testing of anticancer drugs, was granted to Harvard University in 1988. Effective use of this patent has been severely restricted by the exclusive licensing agreement granted by Harvard University to DuPont, who has aggressively asserted her rights toward academic licensees, imposing restrictions on the use of the patent in industry-sponsored research and suing for infringement when licensing conditions were not respected.

licensing by public research organizations is hard to determine and some evidence exists that most licensing is non-exclusive (Henry et al., 2002).

Another concern that has been raised in regard to the patentability of publicly funded research results is that a shift may occur in the research agendas of most public institutions away from basic research and towards applied, and more directly rewarding, research endeavors. The limited evidence available to date does not give substance to this concern (Mowery et al., 2001: Colyvas et al., 2002), although this possibility should probably not be dismissed too quickly. Lastly, the more intense IP-orientation of public research institutions, by making less clear the distinction between pure and commercial research, has made it more difficult to sensibly define the extent of "research exemptions" to the enforcement of patent rights. This, in turn, has added an additional layer of complexity to the already broad range of currently debated "access issues" (Merrill et al., 2004).

3. PATENTS, TECHNOLOGICAL REGIMES AND THE CURIOUS GAP BETWEEN THEORY AND EVIDENCE

The discussion of the previous paragraph has highlighted a number of exogenous and endogenous tensions that are currently affecting most patent systems worldwide. Although it was not made explicit in the discussion, these tensions impinge to a different extent on different technological domains. This is a rather natural consequence of the more general observation that the patent system has a differential impact and effectiveness in different technological environments. The latter statement can be substantiated on the basis of a plethora of empirical studies conducted both in Europe and in the U.S. (Sherer et al., 1959; Taylor and Silberston, 1973; Mansfield, 1986; Levin et al., 1987; Arundel et al., 1995; Harabi, 1995; Cohen et al., 2000; Arora et al., 2002). In spite of the abundance of empirical evidence, however, the theoretical discourse on the patent system has tended to proceed on the (implicit) assumption of the appropriateness of an all-encompassing approach. Questions concerning the factors likely to have a bearing on the differential role and effectiveness of patents in different technological domains as well as the varying degree of relevance of the various functions of the patent system in different technological regimes have not been particularly appealing to theorists. It is therefore questions of this sort that this section aims to tackle, starting from a broad-brush paint of the empirical evidence available to date.

The mentioned empirical studies typically focus on the incentive function of patents and aim to assess the effectiveness of patents as inducements to innovate in different industries, often relative to other means of appropriation. The main findings of these studies include the observation that: (a) patents rank relatively low as appropriability mechanisms – in fact they are reported to be the least effective mechanism in most industries, although they are relatively more effective in industries such as medical equipment and pharmaceuticals, special purpose machinery, computers and autoparts (Levin et al., 1987; Cohen et al. 2000); (b) the absence of patent protection would have little or no impact on innovation in most industries, except pharmaceuticals (Mansfield, 1986); (c) firms in all industries rely on multiple appropriability mechanisms (exploitation of lead time, rapid movement down the learning curve, secrecy, possession of complementary sale and service capabilities), often to protect the same invention (Levin et al., 1987; Cohen et al., 2000); (d) both the reasons for patent protection and the intensity of reliance on other appropriability mechanisms differ across industries.

A more direct measure of the payoffs from patent protection in different industries has been recently offered by Arora et al.'s 2002 study, based on data from the 1994 Carnegie Mellon Survey. This study measures the "patent premium", namely "the proportional increment to the value of innovations realized by patenting them" finding that, while in no industry besides medical instruments patents provide on average a positive expected premium net of patent costs, the premium for innovations that are in fact patented is substantial in many industries (a 50% increase relative to no patenting in most industries and up to 60% in health-related industries). Note, however, that both the conditional and the unconditional premiums differ greatly across industries.

Some empirical evidence showing that the specific features of the transactional role played by patents differ across sectors also exists. In particular, Cohen et al. 2000 survey underlines a distinction in this regard between "discrete" and "complex" product industries. The traditional role of patents as means to garner licensing revenues is more relevant in the first category of industries than in the second (37,5% of respondents report licensing as a motive for patenting in discrete product industries relative to a 28,8% in complex product industries). Also, within the first category of industries, the use of patents for licensing purposes is more common where patents are effective as appropriability mechanisms, notably in pharmaceuticals, while in discrete products contexts where patents are less effective in this regards they tend to be used as building blocks of "fences" of patented substitutes with the purpose of impeding the development of competing products. In complex product industries, by contrast, patents transactional function gains a strategic twist. In fact, the largest firms in these sectors are more likely than in other sectors to use them as bargaining chips in cross-licensing negotiations (54,8% of respondents in complex product industries use patents for this purpose, as compared to only 10,3% in discrete product industries), both as means to obtain access to external technologies and as means to prevent infringement suits.[7]

Finally, it is worth mentioning that the relevance of patent disclosures also varies across industries.[8] European data analyzed by Arundel and Steinmuller (1998), for instance, show that the importance attributed to patent databases as a source of information is (perhaps unsurprisingly) correlated to the sectoral propensity to patent.

The short review of empirical evidence provided in the first part of this paragraph was meant to give an intuition of the fact that the role performed by patents

[7] Note, however, that the distinctions traced are not completely clear-cut and there is some degree of heterogeneity within sectors. The use of patents for negotiations, for instance, is relevant also to a handful of discrete products industries such as pharmaceuticals, steel and metal products.

[8] Of course the effectiveness of patents disclosure function varies greatly across national patent systems. For instance, for a comparison between the U.S. and the Japanese patent systems see Cohen et al., (2002).

varies greatly across sectors. In the remainder of this paragraph, we will attempt to identify factors that are likely to impinge both generally on the role of patents in different technological regimes and, specifically, on the relative importance and effectiveness of the different functions patents play in different technological domains. We take as a starting point of our analysis the notion of technological regime, first introduced by Nelson and Winter (1982) as a way to characterize the knowledge environment in which firms operate and later refined by Malerba and Orsenigo (1996, 1997). The attributes relevant to the definition of technological regimes – opportunity, cumulativeness, appropriability and the knowledge base (Malerba and Orsenigo, 1996, 1997) – are, however, spelled out in detail and complemented by additional attributes we deem salient to the analysis. It is for this reason that we will use interchangeably the terms "technological regime", "technological domain" and "technological environment".

First, consider the set of factors that goes under the label of **appropriability conditions**, namely conditions affecting the ease of protection of the results of innovation from appropriation by competitors. Of course, differences in appropriability conditions across sectors impinge mainly on the differential relevance of patents incentive function in different sectors. To this category of factors can be ascribed, first of all, the **costs of imitation in absence of patent protection**. It is firmly established in the conventional wisdom of intellectual property theory that the lower the costs of imitation of a given technology, the more relevant is the incentive role played by IPRs. Such conventional wisdom seems well-grounded on the empirical observation that, in industries characterized by high R&D costs and ease of imitation such as chemicals, pharmaceuticals and machinery, patents do tend to be valued highly as an appropriation mechanism (see the above-mentioned empirical studies).

Further, the **degree of substitutability of patented technologies** (or, in other words, the ease of inventing around patented technologies) affects the effectiveness of the incentive function performed by patents. The degree of substitutability typically varies across different technological domains and tends to be lower in those domains such as the life sciences where patents often cover naturally occurring substances and discoveries rather than inventions *strictu sensu*[9]. In principle, a low degree of substitutability of patented technologies should reinforce the effectiveness of the incentive function. It is surely so for sectors where difficult-to-invent-around patents mostly cover end products as it is the case, again, in pharmaceuticals. However, the effectiveness of patents incentive function is more difficult to assess in those sectors where scarcely substitutable patented technologies mostly constitute inputs into further research. In these contexts, such as software and biotechnology, innovators generally find themselves both in the position of licensors and licensees and the net effects of patents on incentives is harder to evaluate. Under such circumstances, a low

[9] Note, however, that the fact that patents in some domains cover naturally occurring substances does not imply *per se* that such patents cannot be invented around. To take the example of biotechnology, it should be considered that there are in general multiple ways of treating the same disease and that the same result may therefore be achieved in different ways.

degree of substitutability of patented technologies might imply imbalances in the division of profits between subsequent innovators, with detrimental effects on incentives and might also play a role in putting under strain the effective performance of patents transactional function, as the "anticommons" story (Heller and Eisenberg, 1998) suggests.

Finally, the **effectiveness of alternative appropriation strategies** can be also included in this set of factors. Clearly, the more effective are appropriation strategies other than patents, the more limited is the incentive function the latter perform in different technological domains. The effectiveness of non-patent mechanisms of appropriation is partly dependent on the nature of the production process. Technological domains characterized by high investment costs and a relatively high importance attributed to possession of complementary capabilities tend to rely on mechanisms such as lead time, rapid movements down the learning curve and secrecy more intensively than on patents.

A second set of factors relates to the **nature of the R&D process**. The **structure of R&D costs** constitutes a particularly relevant factor to differentiate among technological domains. The more capital-intensive the R&D process is in a given technological domain, the more relevant patents' incentive function tends to be in such domain. Note, however, that there might be instances in which IPRs are not sufficient to recover costs but it would still be desirable from a social welfare point of view to induce innovation, so that we observe a failure of patents incentive function[10]. The incentive patents provide tends to play a less central role in labour-intensive contexts such as software development. When the major input into R&D is given by human creativity, it might well be the case that a mixture of non-patent related incentives (both monetary and non-monetary) suffices to induce innovation. In software, this happens not only in innovative environments openly averse to patents such as Free/Open Source software communities, but also where innovators profit more from the provision of complementary services and assistance than from the direct sale of innovations.

Another factor relevant to the distinction among different domains is given by the costs associated to the testing of innovative results. In some technological domains, such costs can be shifted upon willing users and therefore need not be recouped directly by the innovator. We refer here, again, to the software domain, where the open source development model has demonstrated the viability of an innovation process in which such shift does occur. In other technological domains, by contrast, testing costs depend on the need to abide by biosafety and biosecurity regulations (reference is made here to the life science domain) and testing costs cannot be shifted on to consumers because of obvious concerns for public health.

The **degree of uncertainty of the innovation process** is also a relevant element of distinction among technological domains. Uncertainty surely strengthens the

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[10] Maurer and Scotchmer (2004) suggest that this might be the case for "big science" projects such as those aimed at the obtainment of energy through nuclear fusion. In the latter case, the social value of the innovation clearly exceeds its commercial value appropriable under IPRs protection.

relevance of the incentive function – the pharmaceutical industry being the prototypical example of a highly uncertain innovative domain where incentives would be significantly undermined absent patent protection.[11] Uncertainty also raises the relevance of the disclosure and signaling functions. Patent disclosures become especially relevant in technological domains characterized by pronounced uncertainty and a high degree of technological diversity (Rosenberg, 1976; Nelson and Winter, 1982), namely in presence of a high number of possible technological trajectories along which the process of technological learning takes place. This is because of the role patents play in signaling promising directions of research and therefore in lowering, to some extent, firms' R&D uncertainty. It is, indeed, not coincidental that the relevance of patent databases as information sources is highest in fields characterized by significant uncertainty such as the life sciences (Arundel and Steinmuller, 1998).

As for the function performed by patents in signaling firms' competencies and capabilities so as to attract financing, it is worth noting that its importance tends to be significant especially in those contexts where uncertainty contributes to confer a crucial role to forms of relational financing such as venture capital that, relative to other forms of financing, display an advantage in performing a screening and monitoring function with respect to competing innovative projects (Aoki, 2001; Gompers and Lerner, 2001). Note that the link between uncertainty of innovation, venture capital financing and patents' role in sustaining innovative activities is worth of particular attention. In addition to signaling firms' innovative potential, patents sustain the relationship between investors and innovators in that they ensure effective disclosure of the innovators' technologies reducing the likelihood of misappropriation by the investor more effectively than simple non-disclosure agreements. Most importantly, patents do influence investors' confidence in contexts of risky and uncertain innovation where profitability is initially really low, sales and revenues are slow to rise and firms that don't pay any dividend can pay investors only through capital gains. In so doing, patents ensure an adequate flow of funds toward innovative activities that would find difficulties in exploiting other sources of financing. Luckily, this seems to result in a positive effect on innovation, as shown by recent empirical estimates of the venture capital-innovation link (Kortum and Lerner, 2000)[12].

The **pace at which innovations occur** in a given technological domain also affects the role patents play in such domain. In particular, patents disclosure function

[11] According to estimates provided by PhRMA, the trade association of U.S. pharmaceutical firms, uncertainty is so high that only one in five efforts lead to the successful delivery of a product. Moreover, only 30 per cent of those drugs that successfully reach the market produces revenues that exceed costs (PhRMA, 2003). Independent estimates report that it takes on average 10-15 years and about $800 million of expenditures to bring a drug from the conception stage to FDA approval (DiMasi et al., 2003).

[12] Kortum and Lerner (2000) show not only that venture capital activity has had, in the United States, a significant impact on the rate of patenting, but also that it has had a strong positive impact on innovation. Their estimates suggest that "venture capital, even though it averaged less than 3% of corporate R&D from 1983 to 1992, is responsible for a much greater share – about 8% - of U.S. industrial innovation in this decade" (Kortum and Lerner, 2000, p.675).

might be to some extent undermined in contexts of rapid technological innovation, where patent-revealed information that is made available much later than the time of invention might turn out to be scarcely valuable once it reaches its potential users. This is typically the case of the software sector, where patent databases are deemed rather useless as a source of information and rarely consulted (Aharonian, 1998). Moreover, in technological domains characterized by a rapid pace of innovation some problems might arise as regards the effectiveness of patents incentive function. Indeed, the lengthy patent grant procedure may not satisfy the need for protection when it is felt the most and the statutory length of patent protection of 20 years may not balance correctly the incentives of successive patent holders because initial patent holders may tend to get a grasp on innovations far removed from their initial contribution.

To conclude the list of factors inherent to the nature of the R&D process, consider the **organization of R&D**. In this regard, it should be noted that the role performed by patents in enabling transactions is particularly important in those technological domains where R&D is conducted predominantly in a collaborative fashion. The existence of IPRs covering knowledge inputs contributed by firms or institutions collaborating to a common research endeavor is often indispensable in the initial phases of technological cooperation because it reduces the risk of involuntary leakage of proprietary knowledge (see, among others, Powell, 1996). Moreover, the rules of attribution of IPRs over the research results of the common project crucially affect the parties' innovation incentives (DeLaat, 1997).

A third set of factors likely to influence the role and relevance attributed to patents in different technological domains is given by the **nature of technology**. This category of factors includes the complex/discrete nature of the technology developed, the degree of technological cumulativeness, the degree of technological modularity and the relevance of issues of technological standardization. The first factor – the **degree of technological complexity** - has deep consequences for the use that is made of patents in different technological environments, as was mentioned when reviewing Cohen et al.'s 2000 empirical study. In complex technological areas patents tend to be used less to prevent imitation and more as tools to enable transactions. This is partly because complex products are more difficult to replicate and partly because in the case of complex technologies the relationship patents to innovation is generally a many-to-one relationship that makes it harder to appropriate through IPRs the value of innovations, while making it easier to exercise hold-up threats on competitors (Bessen, 2004), especially through the strategic accumulation of patent portfolios.[13] More conventional uses of patents characterize, by contrast, discrete products industries.

The **degree of technological cumulativeness** refers to the extent to which present technological knowledge lays the foundation for future advancements. Cumulativeness may be observed at different levels, namely at the technological, firm, sectoral and local levels (Malerba and Orsenigo, 2000). The property of

[13] Acs and Audretsch (1988) show that the number of patents per innovation can vary substantially, ranging by industrial sector from an average of 49 to 0,6 patents per innovation.

cumulativeness at the firm level might be considered a primary determinant of the specific trajectories firms follow over time according to their developed competencies, organizational capabilities and learning dynamics. Thus, considered at this level, a high degree of cumulativeness tends to improve appropriability conditions and therefore might imply a more limited role attributed to patents. Moreover, cumulativeness at the firm level might also reduce the effectiveness of patents transactional function, as it might imply a need for direct, face-to-face interactions to overcome problems of technological "stickiness" (von Hippel, 1994) and to effectively transfer technologies in domains different from those in which they were created.

When cumulativeness is considered at the technological or sectoral level, however, the effects of this property on the role patents perform and on the efficiency properties of the patent system more generally are less clear-cut. While it might still be the case that a high degree of technological cumulativeness improves appropriability conditions and thus decreases reliance on patents as incentive tools, patents' transactional role might be enhanced in those highly cumulative contexts where next generation technologies are not necessarily developed by the initial innovators due to the peculiar configuration of the other technological and market factors. In other words, when technological cumulativeness does not confer significant advantages to firms exploiting cumulativeness at the firm level because, for instance, development of a given technology requires knowledge and competencies in areas unrelated to the firm's cumulative pattern of development, transfer of technologies and, possibly, of know-how tends to rely more intensively on patents as enablers of transactions than would otherwise be the case. While patents transactional function might be enhanced in contexts of high technological cumulativeness, however, the latter puts under strain patents incentive function. Indeed, when innovations build upon each other in a highly cumulative fashion, appropriate patent design becomes crucial to ensure a division of profit among subsequent innovators that provides adequate overall incentives to innovate (see the survey by Scotchmer, 1999).

The third factor – the **degree of technological modularity** – has a less clear-cut effect on the role played by patents. The attribute of modularity refers to the decomposable nature of a given technology (Simon, 1962): a complex system can be defined as modular if it is decomposable in a number of components or subsystems that are relatively independent but still concur to support the functioning of the whole. Modules can be highly complex and interdependent within, but are connected through interfaces that tend to be standardized so as to minimize communication costs (Baldwin and Clark, 2000). Technological modularity might have two contrasting effects on the role patents play in a given technological domain. On one side, both the transactional and the signalling functions of patents might become more relevant than in presence of a non-modular technology. Indeed, patents may be one essential precondition for the development of innovative processes characterized by the ex-post combination of modules of technology developed independently by autonomous innovators. This is the case, for instance, of the Silicon Valley model nicely described by Aoki (2001). On the other side, technological modularity may also constitute one essential ingredient of a process of distributed innovation such as the Free/Open Source software phenomenon in which patents play no role and are, actually, vividly opposed. Modularity has, in the latter context, the effect of sustaining a system of non-monetary, non-patent-induced incentives[14] that represents, in turn, the basis of a model of innovation that has demonstrated so far a high degree of vitality. It is important to note that, in both cases, the degree of technological modularity should be considered an endogenous attribute. The process of modularization involves costs as well as benefits (see, e.g., Brusoni and Prencipe, 2001) and the degree of technological modularity should thus be considered the outcome of an intentional choice over the trade-off between the static and dynamic costs of setting up a modular architecture and the benefits in terms of flexibility of product/component change, economies of scale and increased product variety.

Consider, finally, **technological standardization**. In technological regimes where standardization plays an important role, the role of patents as transactional tools is generally enhanced. Indeed, patent pools and cross-licensing tend to be more easily attained when significant standardization issues are involved, as it is in the telecommunication and computer industries, although this might involve antitrust concerns (Shapiro, 2001). When standards are in existence or are in the process of being implemented, it might be easier to identify a restricted set of essential patents to be included in a pool and transactional problems are more easily overcome.

The diverse role and relevance of patents in different technological regimes is also affected by a fourth set of factors, associated to the **nature of the knowledge base** essential to innovation. One important factor of this sort is given by the relevance of fundamental knowledge to a given sector and the **distance between fundamental knowledge and its application**. Given the observed trend towards the upstreaming of patentability in current patent systems of developed countries, the role of patents both as incentive mechanisms and as transactional tools is currently becoming more central to innovative strategies in sectors where the distance between fundamental knowledge and its concrete translation into innovative results is substantial. Indeed, the greater such distance, the greater will tend to be the investment required to implement new technologies and thus the greater the relevance played in a given sector by patents' incentive and transactional functions. At the same time, however, it should be noted that, on one side, it is exactly in presence of knowledge well upstream of commercial application that patents incentive function might fail and might need to be complemented by non-patent incentives such as direct public sponsorship and, on the other side, that the transactional role of patents tends to display its most pernicious defects in such technological domains. This is partly because valuation biases and

[14] Adoption of a modular technology sustains a system of non-monetary, non-patent-induced incentives in that it: (a) facilitates the identification of individual contributions, and thus contributes to sustain a system of non-monetary incentives based on reputation and peer-recognition that has an analogous in the academic environment; (b) allows a form of division of labor that is consistent with intrinsic motivations because it does not involve repetitive tasks but rather the performance of a multiplicity of tasks on the same module; and (c) reduces the extent of incentives necessary to induce individual contributions (Benkler, 2002).

other sorts of transactional hurdles tend to be most thorny when patents cover upstream knowledge (Heller and Eisenberg, 1998). In addition to this, patent transactions in technological regimes of this sort often take the form of exclusive licensing, which is generally claimed by firms as indispensable to induce a sufficient amount of innovative investment. One of the problems with exclusive licensing of upstream knowledge is that, while scientific advances increase the level of technological opportunities for all firms in a given technological domain, exclusive licensing restricts the number of firms to which such opportunities are effectively available.[15] This might be of concern when there is strong uncertainty as to the direction of research that would most effectively ensure that novel scientific inventions are translated into useful innovations and many innovative efforts are thus preferable to a single one. In other words, the characteristics of IPRs exchange when patented knowledge is well upstream of commercial application may negatively feedback on incentives, reducing the effectiveness of patents incentive function.

As for the other attributes of knowledge that might be of relevance, it is worth mentioning those singled out by Winter (1987), namely observability, tacitness, complexity and the systemic nature of knowledge. **Observability** refers to the amount of knowledge that is disclosed by using the knowledge itself and has obvious consequences for the incentive function performed by patents. Similarly, the degree of **systemicness** and/or **tacitness** of the knowledge involved by innovation in a given technological regime also affects the ease with which innovations can be imitated. Knowledge that is remarkably systemic in nature might both increase and decrease patents incentive function. On one side, a high degree of systemicness tends to decrease the relevance of the role patents play because it imposes a need for possession of complementary assets in order to successfully enter the industry (Teece, 1986). On the other side, it might increase patents' relevance because strategic patenting of such complementary assets might become a relevant part of firms' innovation strategies in this kind of innovative environments. As for knowledge tacitness, it might diminish the relevance of both the incentive and the transactional role of patents; the first because it enhances the effectiveness of appropriation mechanisms such as lead time and secrecy, the second because it decreases the effectiveness of market-based forms of knowledge transfer relative to more direct means such as direct interactions and inter-firm circulation of researchers. It should be noted, however, that patents might in some instances constitute an important precondition for the exchange of tacit knowledge (Arora, 1995), especially if one considers that tacitness should be considered not so much as an inherent property of knowledge, but rather as a property of knowledge at least partially endogenous and dependent on the prevailing economic incentives (Cowan et al., 2000).

To conclude, consider the set of factors related to the **nature of the market**. One obvious factor to consider is the **size of the market** for the innovation. In some technological domains it is more common than in others that patents incentive function fails because the size of the market underlying some innovations is small and

[15] This issue has been recently the subject of a rather heated debate in connection with the evaluation of the effects of the Bayh-Dole act in the United States.

does not provide a sufficient incentive to invest yet the social value of such innovations would justify research expenditures. This is, for instance, the case of the life sciences sector, and of orphan drugs and vaccines for diseases affecting mostly populations in less developed countries more precisely. Another obvious factor that should be taken into account is **market structure**. However, statements about the relationship between the role of patents and the structure of the market are at least as difficult to make as statements on the long-standing question of the relationship between innovation and market structure. Perhaps it is only possible to highlight the observed regularity that patents transactional role tends to be most effective in concentrated industries such as the semiconductor industry, where the limited number of players has favoured the development of effective cross-licensing strategies (Hall and Ziedonis, 2001). Finally, the **nature of competition** in the market (the relative importance of price versus being cutting-edge) is also likely to have an impact on the importance attributed to patents as inducements to innovate in different technological domains.

Table 1: Main factors affecting the role and effectiveness of patents in different technological regimes

Appropriability conditions	• Costs of imitation in absence of patent protection • Degree of substitutability of patented technologies • Effectiveness of alternative appropriation strategies • Nature of the production process
Nature of the R&D process	• Structure of R&D costs • Capital-/labour-intensity of the R&D process • Degree of uncertainty of the innovation process • Pace of innovation • R&D organization
Nature of technology	• Degree of technological complexity • Degree of cumulativeness • Degree of technological modularity • Relevance of issues of technological standardization
Nature of the knowledge base	• Distance between fundamental knowledge and its application • Observability • Tacitness • Systemicness
Nature of the market	• Size of the market • Market structure • Nature of competition (e.g. price vs. being cutting-edge).

4. "ONE SIZE DOES NOT FIT ALL": THE RATIONALE FOR TECHNOLOGY-SPECIFIC TAILORING OF INCENTIVES TO INNOVATE.

Technological regimes do not differ only in relation to the role and relevance of the different functions of IPRs. Most importantly, they differ as to the nature of the limits the IPRs system encounters in performing such functions and to the nature of the remedies available to confront these shortcomings. In this section, to make the discourse more concrete we will exemplify these differences by reference to the life sciences and the software domains. We understand the life sciences domain to include technologies related to agricultural, biological, medical and health-related research, according to the National Science Foundation (NSF) science and engineering field classification. The discussion will, of course, only scratch the surface of the issues involved, but will help us make the point that some tailoring of incentives to innovation to different technological regimes is, indeed, indispensable. Section five will then provide an overview of the ways in which this might be achieved.

There are some important similarities between software and the life sciences. These concern, in particular, the nature of technology and the nature of the knowledge involved in innovation in the two technological domains. Indeed, innovation in both sectors depends heavily on upstream knowledge – algorithms and fundamental results in physics, mathematics and electrical engineering in the case of software, naturally occurring substances and genetic information in the case of the life sciences. Moreover, technology is characterized in both cases by a high degree of complexity and cumulativeness: inventions build sequentially on each other and are linked by relationships of complementarity. Finally, to some extent in both technological regimes technology can be modularized and large, complex projects can be broken up in multiple relatively independent subprojects. The scope for modularization tends, however, to be greater in the software domain, as shown by the success of large F/OSS projects such as the Linux operating system, than in the life science domain, where large-scale innovative efforts are often excessively difficult to modularize.

The differences between the two sectors we consider are, perhaps, even more apparent than similarities. First of all, the ease with which innovations can be imitated in absence of patent protection constitutes an important element of differentiation between the two sectors. Software is, as a practical matter, extremely prone to imitation by exact duplication of the object code because of the negligible costs of this sort of operation. However, the availability of both legal (copyright and trade secrets) and non-legal (lead time, learning lags, possession of complementary assets) alternative forms of protection of innovation significantly improves appropriability conditions (Liebeskind, 2000). In the life sciences, and in particular in the biomedical domain, lead time, secrecy and learning lags do not constitute effective appropriability mechanisms, in part because firms must comply with a lengthy regulatory process that implies significant disclosure, and the range of legal instruments available is more limited than in software.[16] Within the life sciences,

[16] Note, however, that outright imitation is more difficult in the life sciences than in the software domain because simple access to a given molecule does not necessarily imply the

however, it is perhaps possible to trace a further distinction in this regard between ease of imitation of small molecule new chemical entities (NCEs, developed by pharmaceutical firms) and of biopharmaceuticals (predominantly developed by biotechnology firms). According to some (see, e.g., Grabowski, 2002), the former are to be considered more prone to imitation than the latter, due mainly to the greater difficulties involved in efficient-scale manufacturing of biopharmaceuticals relative to NCEs and to greater regulatory hurdles.

Second, the degree of substitutability of patented technologies also differs between the two sectors, in that patented inputs more akin to the realm of discoveries than to that of inventions tend to be particularly difficult to invent around and their functions are predetermined by nature, rather than by human ingenuity.

Third, differences exist also with regard to the nature of the R&D process. Reliable and comparable data are, indeed, difficult to gather on R&D in the two sectors, due to definitional and aggregation problems. Data provided for the U.S. by the National Science Foundation for FY2001, for instance, show that absolute R&D expenditure levels reach $13 billion in the software publishing industry and $9 billion in computer systems design and related activities, while R&D expenditure levels amount to around $15 billion in the pharmaceutical and biotechnology sectors[17]. Actual R&D expenditures in the two sectors might, however, substantially diverge from the reported data, given that the latter only include companies with an estimated total R&D of above $5 million (NSF Science and Engineering Indicators, 2004). Moreover, intersectoral R&D comparisons should more meaningfully be based on the ratio of R&D costs to sales rather than on absolute R&D levels. Their limitations notwithstanding, these data might provide an indication of the fact that conventional distinctions between software and the life sciences based on R&D intensity tend to fade away as R&D expenditures in software increase.[18] Three important differences between the two sectors might be traced with regard to R&D: (a) the costs of innovation in software are made up predominantly by labor costs, measured in month-programmer units, while innovative activity in the life sciences requires significantly

ability to replicate it at negligible costs, in absence of information concerning the protocol and the conditions of chemical synthesis.

[17] These data include biotechnology R&D expenditures categorized under the label of "scientific R&D services", which fall within the non-manufacturing sector and biotechnology and pharmaceutical R&D expenditures, falling within the manufacturing sector.

[18] The National Science Foundation Science and Engineering Indicators underscore the stunning increase in software R&D investment reporting that "[i]n 1987, when an upper-bound estimate of software and other computer-related services R&D first became available, companies classified in the industry group "computer programming, data processing, other computer-related, engineering, architectural, and surveying services" performed $2.4 billion of company-funded R&D, or 3.8 percent of all company-funded industrial R&D. In 2001 the company-funded R&D of a comparable group of industries (excluding engineering and architectural services) was greater by a factor of 10 and accounted for 13.2 percent of all company-funded industrial R&D."

more intense capital investments;[19] (b) the "D" aspect of the R&D process takes place relatively rapidly in software while absorbing considerable time, capital and efforts in the life sciences;[20] (c) the degree of uncertainty associated to innovative activity is also much more pronounced in the life sciences than in software: biomedical innovation constitutes, in particular, the prototypical example of the high-cost, high-risk innovative activity[21].

Fourth, the organization of R&D activities displays remarkably different characteristics in the two domains. Innovation in the life sciences tends to occur on the basis of a three-layered market dynamics that roughly reflects a distinction between basic research, still predominantly conducted in public laboratories although increasingly less so, explorative applied research, conducted by biotech firms, and delivery activity (including clinical development and commercialization), accomplished primarily by large pharmaceutical companies (see, e.g., Orsenigo et al., 2001). The sector is replete with both ex-ante and ex-post collaborative agreements and inter-firm and public-private interactions abound. The extent of such interactions is comparatively more limited in the software field, although inter-firm relationships are currently on the rise (Blind et al., 2001) and basic research plays as fundamental a role as in the life sciences (CSTB, 2003). What is worth mentioning here is, however, that we do not observe in software the same kind of division of labour between research, development and commercialization that is observable in the life sciences. More generally, the organization of R&D activities in software reflects a long-standing custom of firms' self-reliance according to which needed components are generally developed from scratch in-house rather than acquired on the market.[22]

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[19] A distinction should be made, however, between mass-market software and specialized software. Innovation in the first segment is becoming more and more capital-intensive due in particular to the costs involved in gathering information on the characteristics of consumers' demand so as to better tailor innovation to consumers' needs.

[20] To be precise, the bulk of software development costs is made up by debugging costs, which should be included in the development cost category. Nonetheless, development is much more rapid in software than in the life sciences, where development of a given innovative product takes an average of 10 to 15 years to complete in the case of the creation of new vegetable varieties and an average of 10 years (4 to identify a new molecule and 6 to 8 years to develop it) to release a new medical product (Joly and Ducos, 1993).

[21] Conventional estimates of success rates of innovative efforts in the pharmaceutical industry indicate that, typically, less than 1 percent of the new compounds object of pre-clinical investigation reach the human testing stage and that only around 20 percent of compounds going through the clinical trials ultimately gains FDA approval (DiMasi, 1995). In addition to the uncertainty related to the medical effectiveness of new drugs, there are also uncertainties related to market success. The distribution of returns to R&D for new drug introductions is, indeed, highly skewed, with few blockbuster drugs accounting for most of the returns (Grabowski et al., 2002).

[22] See, for instance, Samuelson et al., (1994). The practice of software reinvention is generally seen as extremely wasteful. Indeed, in the mid-nineties acknowledgement of the waste from foregone opportunities of software reuse led to the endorsement of specific software reuse programs by the U.S. Government (Lemley and O'Brien, 1997).

The nature of the venture capital-patents link also differs in the two technological domains. While venture capital constitutes an important source of innovation financing in both domains (PWC MoneyTree™ Survey, 2004), at least one key difference should be acknowledged. Patents are much less effective in helping to attract venture capital investors in the early stages of innovation (seed capital and start-up financing) in software than in biotechnology. Empirical studies of the venture capital/patents link in the software sector both in the U.S. (Mann, 2004) and in Germany (Blind et al., 2001) show that patents do not perform as effectively as in the biomedical sector their signaling function. The results for the U.S. indicate that "patents are not often useful in helping the early-stage software company demonstrate the sustainable differentiation from its competition that is the focus of the venture investor" (Mann, 2004), though they may play a role in later stages. As for Germany, Blind and colleagues clearly state that "the theory that patents facilitate market access, above all for young companies, could not be confirmed" (Blind et al., 2001). These results may perhaps be explained on the basis of a threefold observation. First, in software one can find no trace of the uncertainty-venture capital-patents link that is acknowledged to be crucial to biotechnology innovation financing (BIO, 1994), among other things because of the lower degree of technological uncertainty characterizing the software sector and the short length of product life cycles. Second, differently from biotechnology, a single patent does not offer in software any real protection against competitors, in that end-products may comprise large numbers of (patentable) functionalities. This implies, in turn, that software patents do not sustain investors' expectations as effectively as biotechnology patents. Third, and related to the previous observations, there is the fact that sustaining the enormous costs of patent enforcement hardly constitutes a sensible strategy for capital-constrained software SMEs, especially if one takes into account the short product life cycles that characterize the sector.

Sixth, another important difference between the two technological fields concerns the relevance of issues of standardization, interoperability and network effects – pervasive in the software domain and almost irrelevant to the life sciences. On these issues we will, however, come back later.

Finally, the extent to which economic actors rely on patents still varies considerably across the two domains, although the IT field has registered in the past decade a stunning increase in patent propensity rates. According to one study (Hicks at al., 2001), IT patents per R&D dollars have increased in the U.S. from an average of 0,28 to 0,48 between the periods 1989-1992 and 1993-1996. These figures should be compared to an increase from 0,23 to 0,24 in health-related technologies. Similar results are reported by the study of intellectual property protection in the U.S. software sector conducted by Graham and Mowery (2002), which also underlines that large packaged software firms are substituting patents for copyright. The increase in patent propensity rates characterizes, however, disproportionately more large firms than small firms, as shown by one statistical exploration of 1700 publicly quoted U.S. and Canadian software companies representing half of the world industry (Chabchoub and Niosi, 2004) and by the mentioned study based on a survey of the German software sector (Blind et al., 2001). In the life sciences, by contrast, both large and small companies value highly patent protection as an appropriability mechanism, as previously noted.

Table 2: Main similarities and differences between software and the life sciences.

=	Reliance on upstream knowledge	=
=	Degree of technological complexity	=
=	Degree of technological cumulativeness	=
=	Possibility of technological modularization	=
=	Absolute levels of R&D spending (in the US)	=
High for both large and small firms	Patent propensity rates	High for large firms, low for small firms
High (lower than in software)	Ease of imitation absent patent protection	High
Low	Effectiveness of alternative forms of protection	High (alternative forms of legal protection available)
Low	Degree of substitutability of patented assets	Generally high
High	Degree of uncertainty of the R&D process	Low
High	Ratio of capital costs to labor costs	Low
High	Relevance of the venture capital-patent link in financing innovation	Low (especially in the start-up fase)
High	Informative role of patent databases	Low

Not only the two technological domains we consider differ as regards the characteristics of innovative activity but they also differ, as mentioned, as regard the most critical aspects of the functioning of the IPRs system. Consideration of these aspects has led some scholars to question the very desirability of patent protection for both software-related and biotechnology inventions. The latter issue is, however, outside the scope of this paper. In what follows, we will take for granted the current state of IP regimes in developed countries and thus the availability, by and large, of patent protection for both biotechnology and software-related inventions and we will identify the most pressing concerns that are currently raised in connection to the operation of the IPRs system in the two technological domains. The discussion constitutes a prelude to the exploration of the way in which such concerns might be addressed, pursued in the next section.

Before addressing technology-specific issues, however, it is worth directing our attention to one issue common to both technological regimes – that of patent scope.[23] There is widespread concern that patents with an excessively broad scope are being issued both in software and the life sciences. In the life sciences, claims to biotechnology inventions have been analogized to claims to chemical compounds for the purposes of patentability. What this means is that biotechnology patents and, in particular, the controversial subset of genetic patents, can be claimed both as processes and as products (material compounds) and their scope is therefore essentially determined by nature, given that product *per se* claims confer absolute protection for all the uses of a product.

Genetic inventions deserve special attention in this regard. In most developed countries patents covering nucleotide (DNA or RNA) sequences that may encode genes or fragments of genes are granted provided the sequences are isolated from their natural source and at least one potential application of the genetic information has been identified. The scope of protection, however, is not limited to the utility disclosed in the application and extends to uses not indicated in the original patent, though new uses might be patented ("dependent" patents). The broad scope accorded to genomics patents causes a number of concerns (Bar-Shalom and Cook-Degan, 2002). As mentioned in section 2, gene patents may not perform effectively their disclosure function, due to the discrepancy between the extent of protection and the actual content of patent applications. Moreover, concerns are often voiced in relation to the discrepancy between the rewards implicit in patents with broad coverage and the costs of innovation in genomics. Indeed, recent technological innovations in genomic sequencing (e.g. robots and automatic sequencers) have reduced at least by a factor of five the costs of genomics research relative to its infancy and most innovative efforts amount to routine activities, which leads to question the need for substantial rewards in order to induce innovation. Finally, the discrepancy between the inventive step effectively disclosed in patent applications and the extent of protection also causes fears of possible imbalances of incentives between early innovators and subsequent developers. Given that isolating and characterizing a gene can hardly be considered a "pioneering invention" and that the costs of the underlying research are low, there are reasons to question, in light of IP scholarship, the appropriateness of broad patents and even of patents more generally in this context (Scotchmer, 1991, 1999; Henry et al., 2003).

As for the software domain, Cohen and Lemley (2001) have argued at great lengths that software patents are likely to be very broad if no special measure is taken to narrow their scope. These two authors, together with others (Samuelson, 1995; Warren-Boulton, Baseman and Woroch, 1995), have also advanced reasons why it might be wise to construct patents for software-related inventions narrowly. One of the main arguments they propose in support of this view is that a policy that attributes

[23] The economists' notion of patent scope or patent "breadth" usually refers to the extent to which substitute inventions must differ from the patented invention in order not to be infringing. For a more nuanced characterization of the notion of patent breadth and a distinction between "leading breadth and "lagging breadth" see O'Donoghue et al. (1998).

strong protection to pioneer inventors is not appropriate to an industry characterized by networked, interdependent products. In such a context, according strong protection to pioneer inventions may encourage the realization of larger rather than smaller changes to existing programs, which may induce a pattern of innovation "by leaps and bounds" that reduces social welfare because of reduced interoperability and reduced testing of programs (Cohen and Lemley, 2001).

A more general argument in support of narrow patent protection for software has to do with the likelihood of bargaining failures in the software domain. The literature on cumulative innovation has shown that appropriate patent design is critically dependent on the ability of private parties to contract around their property entitlements in order to rearrange assigned rights in privately and socially beneficial ways (Gallini and Scotchmer, 2001). Whether broad patents are efficient thus depends on whether efficient licensing will take place, allowing follow-on improvers to build on previous innovations. Bearing this in mind, an argument for narrow patents in the software field can be constructed on the basis of the fact that the heterogeneous and dispersed nature of industry players, the frequency of new entries and the fine-grained nature of inventions constitute impediments to contracting that are likely to make broad claims suboptimal.

The problem of patent scope in these two technological domains is made more acute by the ever more critical issue of decreasing patent quality (Kahin, 2003). Although accurate assessments of the quality of patents granted are difficult to make because of the difficulty of definition of the relevant metric, there is a widespread perception that quality has been decreasing in recent years (Lemley, 2001). This is partly due to administrative problems: patent offices of developed countries seem to be experiencing difficulties in keeping up with the surge in patent applications. Workload pressures have increased everywhere and the increased complexity of patent claims, often requiring interdisciplinary knowledge to be examined, has generated an unsatisfied need for ever more qualified personnel (Allison and Lemley, 2002). This, in turn, allegedly translates into decreased patent quality. The same effect is often attributed to a reported more lenient application of non-obviousness standards both by patent offices and by courts (Barton, 2000; Hall, 2003b). The proliferation of trivial patents, confirmed to some extent by anecdotal evidence, compounds the problems created by the attribution of broad patent claims in the software and biotechnology domains because of the uncertainty it adds to the functioning of the patent system in these fields.

Turning now to technology-specific issues, in the rest of this section we will consider in turn the most salient concerns currently raised in relation to the operation of the patent system in the life sciences and in software.

Life Sciences

A great part of the issues relevant to the life sciences domain relates to instances of failure of patents transactional function and can be categorized under the broad heading of access issues. Along with these issues, an important instance of failure of patents incentive function also deserves attention: the case of orphan drugs and, more generally, of research on drugs for which the size of the underlying market does not constitute a sufficient inducement to invest.

Failures of patents transactional function may occur for two reasons. Efficient transations may not take place, on one side, because of difficulties in the aggregation of a high number of fragmented patent rights and, on the other side, because of undesirable contractual behavior of patent holders. The first case is that identified by Heller and Eisenberg's metaphor of the "tragedy of the anticommons" and refers to situations in which *"multiple owners each have a right to exclude others from a scarce resource and no one has an effective privilege of use"* (Heller and Eisenberg, 1998; see also Parisi et al., 2004). In other words, an excessive fragmentation of patent rights, such as that resulting from the patentability of genes, genetic material and in particular of expressed sequence tags (ESTs), prevents coherent aggregations of rights that are essential to the pursuit of further research and innovation. Property rights fragmentation multiplies transaction costs and results in the building up of a "tollbooth" on future innovation due to "royalty stacking" – an extreme manifestation of the complements problem first identified by Cournot (Shapiro, 2001). This situation might be particularly pernicious because of the involvement in biomedical innovation of a large number of heterogeneous actors, both public and private, which exacerbates transactional difficulties associated to asymmetric information and valuation problems (Eisenberg, 2001) and brings to the forefront the issue of access to patented assets by budget-constrained public institutions.

The few empirical accounts of the "anticommons" phenomenon available to date tend to confirm the existence of growing concerns by both private and public actors over their ability to successfully pursue the negotiations necessary to access patented inputs essential to their research (National Institute of Health, 1999; OECD, 2002; Walsh et al., 2003). At the same time, however, they also highlight the (often successful) efforts of researchers to overcome transactional difficulties by finding "workable solutions". These solutions include working around the claims, challenging patent validity and intentionally or unintentionally infringing patents that can potentially block future research. It would thus seem that there are few instances in which bargaining breakdowns have effectively occurred and the hypothesis that the increasingly complex IP landscape is slowing down biomedical innovation was not confirmed by the mentioned studies. Nevertheless, the increase in costs due to royalty stacking should not be underestimated. One notable case is that of the Malaria Vaccine Initiative, pursued by the not-for-profit international institution *Program for Appropriate Technology in Health* (PATH). The project was intended to sustain the development of vaccines for some forms of malaria affecting predominantly developing countries but, before it could really set off, its initiators have had to confront a jungle of 22 partially overlapping patents related to the antigene MSP-1, spending considerable time and money in the enterprise (Nuffield Council on Bioethics, 2002).[24]

[24] A similar instance of overlap of patent rights is that concerning the pursuit of research on the GoldenRice, namely a technology aimed at enriching vitamin A content of rice. According to

As mentioned, a second source of failures in the effective performance of patents transactional function relates to patent holders unilateral contractual practices. There are at least three forms of contractual behavior that merit attention. The first case is that of refusals to license or, more generally, of circumstances in which patented assets are exclusively exploited by patent-holders. This is, of course, a perfectly legitimate way in which a patent holder may decide to exploit the exclusive rights patents grant. However, the fact that patents in life sciences innovation often cover inventions well upstream of commercial application makes this behavior potentially undesirable from society's standpoint because multiple efforts exerted by agents with heterogeneous abilities and research objectives will in general be more effective than a single effort exerted by a given patent holder at searching the space of potential applications of the patented upstream knowledge.

The second case is that of exclusive licensing. Again, it is not the legitimacy of such practice that is in question, but rather its impact on the progress of research in the life sciences. The more upstream is the knowledge that is licensed exclusively, the greater the concerns exclusive licensing raises, because of the magnitude of potential applications exclusive licensing curtails. Moreover, an additional concern arises here because of the possibility that exclusively licensed patents are offered at a prohibitive price. This is a concern especially relevant to the provision of genetic testing services (Schissel et al., 1999).

The third case regards patent or contractual provisions such as reach-through claims and grantback clauses. Reach-through claims are increasingly inserted in patents covering research tools, i.e. markers, assays, receptors, transgenic animals and other patented elements whose main form of utilization is as inputs into further research and development. Reach-through claims extend patent protection to products that are "identified by" the patented tool or method, so that patent holders hold rights to royalties on the sale of innovations that involved the use of the patented research tool to come into existence.[25] Grant-back clauses, on the other hand, are clauses granting licensors of patented technologies the option to acquire exclusive or non-exclusive licenses over or even outright ownership of patented technologies eventually realized with the help of their research tool. This sort of contractual practices allows early innovators to leverage their patent rights into future innovations for which their contribution may or may not be relevant, given serendipity of research. Fears about reach-through claims and grantback clauses arise, however, mostly because of the transaction cost burden multiple negotiations over routine methods, material and data impose (Eisenberg, 2001). Licensees may find themselves in the difficult situation of having to grant multiple exclusive licenses on their future discoveries in order to obtain access to essential research tools as they go along with their research and this might discourage the pursuit of promising research endeavors.

The instances of failure of patents transactional function that we have just recalled

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one study, more that 70 patents, held by about a dozen patent holders, impinge on this technology (ISAA, 2000).

[25] For an overview of the issues related to the licensing of research tools, see the 1998 report of the NIH Working Group on Research Tools.

affect both pursuit of research and commercialization of innovations. The adverse consequences for commercialization might be attributed mostly to problems of property rights fragmentation. These problems are not peculiar to patent protection and may arise also in fields where the dominant form of legal protection is different from patents, as it is the case for the *sui generis* protection of databases.[26]

The impact on research might be threefold. Indeed, research patterns might be distorted in patent-crowded areas by fears of infringement and "anticommons"-like problems. Lerner (1995) empirically confirms this hypothesis in biotechnology as do Walsh et al. (2002), Merz at al. (2002) and Cho et al. (2003) in their survey-based studies. Secondly, some research avenues might be effectively blocked by one of the problems discussed above. Third, the recalled transactional failures might imply wasteful duplication of innovative efforts, as it might be suggested by the birth of a significant number of new companies specializing on the legal circumvention of patents on genes or genetic molecules. These companies (Sangamo BioSciences, Athersys and Transkaryotic Therapies, to make a few examples) are developing technologies that allow to change the expression of the patented gene inside the body or cell, with a process called "gene switching" or "endogenous activation" (Stix, 2002). Note, however, that these circumvention efforts might also generate useful innovations in addition to duplications of existing technologies.

All of these problems merit particular attention in the realm of genetic testing services, where patent holders' contractual practices have already frequently raised concerns about costs and limitations of access to tests of the genetic predisposition to diseases. This is not only detrimental because it cuts on the number of providers of clinical testing services but also because it limits the scope for improvement of the tests (Merz, 2000) and the possibility to compare a given service with its alternatives (Caulfield et al., 2000). Some notable cases in this regard involve the American company Myriad Genetics, holding rights to the diagnostic tests for the two genes BRCA1 and BRCA2, relevant to the diagnosis of breast cancer. The company has so far applied very high per-test fees (over 2500 USD) and imposed very stringent licensing conditions, such as for instance the requirement that all testing be performed in their own laboratories, and has aggressively prosecuted non-compliant licensees. As a consequences, strong public opposition has set off in many OECD countries, including France (Cassier and Gaudillière, 2001), the United Kingdom (Nuffield Council on Bioethics, 2002) and Canada. Another relevant case concerns a patent on a method of diagnosis for a rare genetic disorder called the Canavan Disease, held by the Miami Childrens' Hospital. In this case, parents' associations succeeded in reversing patent holders' policy of exclusive licensing and in substantially reducing licensing fees.

[26] Maurer and Scotchmer (1999) highlight the possibility that the commercialization of new databases requiring data gathered from multiple existing databases might be stymied by the need to contract with a very high number of right-holders. They conclude (p.1130): « *Finally, scientists could decide that acquiring all of the rights needed to build a particular database isn't worth the effort. Some biotechnology databases would have to negociate more than 100 separate contracts* ».

Software

Turning now to software-specific issues we would like to highlight a few issues that are either technology-specific or that tend to be more prevalent in software than in other technological domains. One such issues concerns the relationship between patent protection and other forms of IP. As mentioned in section 2, software is peculiar in that copyright, patents and trademarks are all relevant to the protection of the same products and technologies. Recent empirical evidence on litigation has shown, for instance, that these means of protection are complements, rather than substitutes in the software field (Graham and Somaya, 2004), although it should be noted that small firms are much more likely to rely exclusively on copyright protection (Oz, 1998; Tang et al., 2001). Software creations share some characteristics of literary works, and are thus amenable to copyright protection, and some characteristics of useful machines, as such prone to patent protection (Samuelson et al., 1994). Copyright protects the expression of a given program and is thus useful to prevent outright imitation of one's innovative effort, while patents protect the function the program performs and therefore provides protection against non-literal imitation and the development of substitutes performing the same function. Trademarks, in turn, play a role in setting in motion the sort of "bandwagon effects" widespread in networked industries, by allowing the easy identification of logos and symbols associated to given would-be standards.

The complementarity between different forms of IP protection might raise some concerns as regard the possibility of an excess of protection. The patent-copyright interface is, in particular, worth of attention. In principle, patents ensure protection also against outright copy and therefore provide a form of protection equivalent to copyright. The overlap between the two forms of protection might generate uncertainty as to the effective scope of protection each grants (Samuelson et al., 1994). Moreover, certain limitations to the scope of copyright protection that have developed over time to make copyright protection more suitable to the software field, as for instance the provision allowing for reverse engineering of copyrighted interfaces (see e.g. art. Directive 91/250/EC) have so far found no analogue in patent law, although scholars have suggested the opportunity to introduce a right to reverse engineering in patent law (Cohen and Lemley, 2001; Samuelson and Scotchmer, 2002; Burk and Lemley, 2003). In addition to this, it is worth noting that the relationship between secrecy and patent protection might be characterized by interesting twists not present in other technological domains. Indeed, it might be the case that the availability of patent protection in its current form will have the effect of increasing, rather than reducing secrecy, as the disclosure rationale for patent protection would suggest. This is because there is at present no explicit requirement to disclose a patented invention source code. By making available their source code, patent-holders would thus facilitate competitors' search for proof of infringement, while not gaining any appreciable benefit (Smets-Solanes, 2001).

Next, consider the issue of interoperability. Innovation in software is not only sequential and cumulative (Bessen and Maskin, 2001), but is also characterized by complex horizontal interdependences: the social value of a software innovation is often realized only in combination with other programs performing different functions. In particular, when two programs are complementary, their joint social value is greater than the value of the two programs taken separately and it becomes thus important to ensure that the two programs have compatible interfaces or, in other words, to ensure interoperability. When patent protection extends to program interfaces, however, the question of interoperability might become thorny. On one side, patent protection of interfaces might facilitate the division of rents through licensing between incumbents and entrants, while absent patent protection incumbents may be more reluctant to disclose their interfaces. On the other side, however, patentability of interfaces may determine either situations of complete blockage resulting in the presence on the market of incompatible programs, or situations in which patent holders are able to leverage their power over independently created innovations and can thus appropriate a share of the rents disproportionate with respect to the social value of the interface (Caillaud, 2003).

The issue of network externalities also deserves a few comments. Software technology is characterized by the presence of network externalities: the value of a given product to users increases with the number of other users of the same program, due mainly to benefits in terms of the ability to communicate and exchange files.[27] In markets with network externalities, competition tends to take a peculiar aspect. There is a tendency towards concentration and the dominance of a single product and new entrants may successfully enter the market only in so far as they are able to "tip" the market establishing themselves as dominant products (see, e.g., Katz and Shapiro, 1985). This poses a problem in regard to patent protection. Indeed, one may wonder whether legal protection is needed at all in these circumstances in which lead time and market penetration constitute particularly effective appropriation mechanisms. A positive answer may be suggested by the fact that patent protection, by impeding direct competition from alternative technologies performing functions analogous to the already established program, avoids socially undesirable oscillations among alternative technological platforms. Having said this, however, it should be noted that patent protection also tends to reduce product variety in networked industries and may impede the establishment of superior but infringing technologies.

Finally, the software domain seems more prone than other technological domains to patent portfolio races and the emergence of patent thickets (FTC, 2003). This depends, in part, on the complex set of interdependencies linking software programs that necessarily determines partial overlaps among legal rights. Indeed, a new software program is likely to infringe multiple existing patent rights when it comes into existence. In such context, building a portfolio of patents on related technologies may both protect firms from potential hold-ups and provide a means of limiting entry by competitors. While, however, the accumulation of patent portfolios may be one way around the problems posed by patent thickets, it may also contribute to enhance such problems by contributing to the building up of the thicket of overlapping patent rights.

There are additional reasons why patent thickets and anticommons problems

[27] However, see Dam (1995) for a critical view on the presence of network externalities in software.

might be especially thorny in software. First, it might be particularly difficult to determine the exact boundaries of software patents, among other things, because of the lack of detailed disclosure requirements. Second, the proliferation of trivial patents is a phenomenon affecting software to a greater extent than other technological domains both because of a lack of accessible collections of prior art and because of the inherent indeterminacy of the non-obviousness (inventive step) standard. Third, software patent databases are rarely used as a source of information and firms in the software industry are even advised to refrain from consulting them to avoid charges of willful infringement. This, of course, raises the likelihood of inadvertent infringement.

The empirical evidence gathered so far suggests that the phenomenon of patent thickets appear as a tangible one in the software domain. One recent study of the ICT sector confirms the increased relevance relative to the past of these patenting strategies (Scheelan et al., 2004). This study (the OECD/BIAC survey) finds, among other things, that more than three-quarters of the ICT firms surveyed now patent technologies they would not have patented one decade ago, even if patentability was then unrestricted. Another study, by James Bessen and Robert Hunt (2003), suggests not only that software patents are particularly "cheap" to obtain and that they are generally acquired for the purposes of building patent thickets, but also that greater use of software patents is associated to lower R&D intensity.[28] A majority of panelists in the FTC hearings on competition and intellectual property also provided evidence to support the existence of patent thickets, stressing that strategies of defensive patenting associated to the building up of patent thickets tend to divert resources away from innovative activities (FTC, 2003).

One voice out the chorus is that of Ronald Mann, who has forcefully rejected the "myth" of a software patent thicket on the basis of interviews conducted among 50 industry executives (including software developers, venture capitalists, lenders etc.) in the United States (Mann, 2004). While the latter study aims to demonstrate the usefulness of patents to software SMEs, however, it ends up showing that the lack of patents constitutes a danger ever more prominent for SMEs in a world in which large firms can avail themselves of large patent portfolios.

5. How can technology-specific tailoring of incentives to innovate be implemented?

The preceding section was meant to illustrate the point that some tailoring of incentives to innovate to different technological regimes is indispensable by presenting the specificities of innovation and patent protection in software and the life sciences. In this section, we consider how innovation incentives may be adjusted to take into account the commonalities and the differences highlighted in the previous

[28] It should be noted that Bessen and Hunt's (2003) study uses a comprehensive database of patents on inventions using software, that corresponds to a very broad definition of "software patents". For this and other reasons the paper has been subjected to many criticisms. See, in particular, Hahn and Wallstein (2003).

section. The question of the opportunity to tailor IP incentives to different technological domains has long been debated and emerges periodically whenever new technologies need to be accommodated within existing IP systems, as it has been the case for semiconductors, software and the life sciences. The argument against technology-specific tailoring of incentives rests on three main building blocks: information costs, administrative costs and agency costs. Indeed, the adjustment of innovation incentives to different technological domains is generally discarded as too informationally demanding. The administrative costs entailed by a system in which technological specificities are taken into account are described as excessive. Agency costs in the form of rent-seeking activities are judged as insurmountable obstacles.

While we agree that this sort of costs exerts, indeed, real effects on the scope for technology-specific tailoring of incentives, we submit that strong aversion to technology-specific adjustment of incentives may only result from a fundamental confusion concerning the means through which the latter should be implemented. Indeed, it is the implicit assumption often made that adjustment of incentives necessitates the enactment of technology-specific statutes that suggests the conclusion that it would impose excessive costs and would not ensure the flexibility needed to keep up with the progress of technology. Acknowledgment of the fact that technology-specific tailoring of incentives to innovate may be achieved through means other than the crafting of specific statutes significantly undermines the case against incentive tailoring. The same conclusion is suggested by the fact that informational constraints might be made less binding by the identification of some regularities in the requirements for protection of different technologies. There are no valid reasons to believe that IP incentives should not be adjusted on the basis of the available information so as to ensure that the social benefits stemming from a given set of incentives adopted in the different technological domains outweigh the social costs the provision of these incentives imposes.

As mentioned, technology-specific tailoring of incentives to innovate may be achieved through various means. One obvious way is to exploit the flexibility inherent in the legislative crafting and judicial interpretation of IP law. Some flexibility is achieved by according different forms of IP protection to different subject matters. Patent protection, copyright, trademark legislation, trade secrecy, database protection and *sui generis* forms of protection such as the COV (certificat d'obtention vegetale of the UPOV) all reflect some degree of technology-specific differentiation present in IP law. Moreover, within each of the above forms of IP protection, many policy levers are available to ensure additional flexibility in the treatment of different technologies (see below).[29] In the case of patents, in particular, technology-specific adjustment of protection mostly revolves around a differentiated treatment of patentability requirements and the determination of the appropriate scope of patent protection.

Other means include, of course, provision of incentives in ways not involving private appropriation of innovations, as it is the case for various forms of public sponsorship of both basic research and product innovation. These constitute

[29] Burk and Lemley (2003) analyse, for instance, the policy levers available to U.S. patent law and make a case for the introduction of additional policy levers not currently used.

instruments of technology-specific tailoring of incentives in so far as they allow to fill up technology-specific needs not effectively addressed by IP-based incentives, as it is the case, for instance, for the promotion of scarcely appropriable basic research in science-based regimes.

Antitrust intervention constitutes another means through which some tailoring of incentives might be implemented, even though this may not result immediately apparent. Ideally, intellectual property laws should be designed in a way that takes into account the market structure in which innovators operate, so as to ensure a correspondence between extent of protection and costs of innovation. In practice, adjusting the statutory terms of IP protection to market structure is unfeasible, as length is fixed and courts and patent offices are not required by law to make economics-based judgements when determining the breadth of patent rights. Indeed, to our knowledge there is at present only one piece of IP legislation that explicitly takes into account the costs if innovation in determining the opportunity to grant IP protection. We refer here to the Database Directive passed in Europe in 1996, explicitly linking protection to the investments made in database construction.[30] Given that incentives cannot be made to reflect market structure through IP legislation, it is important to ensure that this sort of link is effectively established through antitrust intervention. The latter has the merit of taking place ex-post, when market-specific needs become apparent, and of being based on detailed factual examination of the specific circumstances of the case. Antitrust application of the rule of reason thus constitutes an essential means through which rewards can be tailored to innovative effort and a market structure conducive to innovation might be preserved. Of the many forms of antitrust intervention, in the present context it is particularly worth recalling those that impinge most on the "access issues" above recalled. Antitrust intervention is likely to be an especially important instrument in technological regimes where these issues more frequently occur, in particular through its role in calibrating its attitude towards cross-licensing and patent pools and through the imposition of compulsory licenses in application of the essential facility doctrine.

In what follows we will consider, first, possible forms of intervention suitable to address needs common to both software and the life sciences but distinguishing these from other technological domains and then instruments directed at addressing the specificities differentiating each of the two domains. As was mentioned in section 4, software and the life sciences share some technological traits, and in particular the complex and cumulative nature of the knowledge base essential to innovation and the relevance of upstream knowledge to productive and innovative activities. These factors, as clarified in section 3, affect the role and performance of patents in the two technological domains. The first – the high degree of technological complexity and cumulativeness characterizing both software and the life sciences – impacts on the effectiveness of patents transactional function and constitutes a precondition for the emergence of the "anticommons" and "patent thicket" phenomena described above. Some antidotes to the emergence of these phenomena have already spontaneously appeared in both technological domains in the form of private initiatives aimed at

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[30] Council Directive 96/9/EC, 1996 O.J. (L 77) 20.

reconstructing the public domain (Merges, 2004; Reichman and Uhlir, 2003). Free/Open Source software represents one such initiative, based on the decentralized efforts of a great number of software developers (Lerner and Tirole, 2002; Benkler, 2002; Rossi, *forthcoming*). Unilateral initiatives by large firms have also been undertaken in order to address concerns for the adverse consequences of the excessive "fencing" and fragmentation of scientific knowledge, especially in the pharmaceutical domain.[31] The extent to which these private initiatives may effectively substitute for a policy expressly requiring disclosure of public research results is, however, difficult to assess on the basis of the present knowledge. Other forms of intervention are thus called for. One possibility is that of enacting transaction-promoting policies either in the form of a lenient antitrust attitude or through more proactive policies aimed at inducing cross-licensing and the formation of patent pools, as it has sometimes been the case in history.[32] Another possibility is to reconsider the role played by research exemptions, of course with a view at avoiding that innovation incentives be undermined.

The first solution seems to us relatively more applicable to the software domain than to the life sciences domain, essentially in consequence of the differential role standardization issues play in the two technological environments. This makes it harder to identify the limited set of patents that might be worth including in each pool. Moreover, the upstream nature of the knowledge assets at issue exacerbates valuation and thus transactional difficulties. Finally, incentives for players to contribute their intellectual assets to a common pool might not be particularly strong in an environment in which patents are often the principal source of strategic advantage. Indeed, we are not aware of the existence of any patent pool in bioscience so far. A case for the promotion of patent pools can, however, be resurrected in circumstances in which the above-mentioned problems are not binding (Marks et al., 2001) and especially in domains at the intersection between computing and the life sciences (e.g. in bioinformatics).

The second solution – an enhanced role attributed to research exemptions – might, on the contrary, be more apposite for addressing anticommons-related issues in the life sciences domain than in the software domain. In the life sciences, two factors concur to make "anticommons" problems most thorny: uncertainty surrounding the value of the object of IP transactions and the heterogeneity of transacting actors that include public along with private agents. Research exemptions might play a role in mitigating the effects of both of these factors. Indeed, they may improve access conditions for public institutions and, if cleverly crafted, they may allow bargaining to take place when most uncertainties on the value of a given patented innovation to its potential users are resolved.

"Research exemptions" are crafted in significantly different ways in different countries. While the real extent of the exemption is, of course, a matter of

[31] One notable example is the creation of the Merck Gene Index, a publicly available database containing research results obtained by Merck Pharmaceuticals on EST sequences and associated clones for the uniquely expressed human genes.
[32] For historical examples in this connection, see Merges and Nelson (1990).

interpretation, it appears that Europe tends to be more lenient in this regard, perhaps also because the boundaries between public and private research are still less fuzzy than in the U.S.[33] The scope for invigorating the experimental use defense in patent law is, however, large on both sides of the Atlantic. Several proposals have been advanced in this direction, starting with Eisenberg's (1989) important contribution and showing that the problem of the appropriate design of research exemptions is all but trivial and that a relevant risk exists that inappropriate design might undermine incentives.[34] In spite of their drawbacks, solutions requiring an enhanced role for the experimental use defence have the advantage of addressing directly the problems connected to the interface between public and private research in the life sciences domain.

A third (partial) solution not previously mentioned and applicable in both the software and the life sciences domains concerns the application of patentability standards by both patent offices and courts. In particular, the non-obviousness (inventive step) standard has been recently applied too leniently to ensure that "anticommons" and "patent thicket" problems are not exacerbated by floods of patents of dubious innovative content. By ensuring a high non-obviousness threshold, at least this aspect of the anticommons problem could be mitigated. This positive effect would add to a more general one emphasized by recent economic scholarship with regard to technologies characterized by a rapid pace of innovation. According to Hunt (1999), a high non-obviousness threshold may be especially apposite in these circumstances because of the characteristics of the trade-off between decreased likelihood of obtaining a patent and increased patent value the choice of a high non-obviousness standard engenders.[35]

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[33] In the United States, research exemptions have been traditionally interpreted very narrowly, allowing for non-infringing uses of the invention only insofar as the researcher's purpose is that of "philosophical enquiry". A recent Federal Circuit Court of Appeals' decision, *Madey v. Duke University*, has further eroded the extent of the exemption, by specifying that it does not apply to activities conducted in the contest of the normal "business" of a research institution, either for-profit or not-for-profit. In Europe, acts "done privately and for purposes which are not commercial" and acts "done for experimental purposes relating to the subject matter of the invention" are shielded from liability.

[34] See, among others, Gitter (2001), Mueller (2001), O'Rourke (2000), Strandburg (2004). An especially interesting proposal has been advanced by Rochelle Cooper Dreyfuss (2003) and slightly modified by Richard Nelson (2004). This proposal envisages the institution of a waiver that researchers at public institutions might invocate when they are denied access to patented assets on reasonable terms. The waiver would imply the possibility of using the patented technologies without permission but would deny researchers the option of patenting their research results and would impose them an obligation to promptly publish the latter.

[35] There is a substantial degree of consensus on the general opportunity to implement a high non-obviousness standard. Merges (1992) argues that a high patentability requirement may favour the development of larger and riskier innovations in circumstances in which markets would promote the relaization of innovations with more certain rewards. A similar argument is developed by O'Donoghue, Scotchmer and Thisse (1998), who suggest that a high non-obviousness standard may create incentives for firms to seek larger innovations and thus increase R&D. Moreover, Scotchmer and Green (1990) have argued that a high non-

The second trait shared by the two technological regimes – the critical relevance of upstream knowledge to innovative activity – generates, by and large, two sorts of needs for tailoring of incentives. The first relates to the deepening of the transactional problems that often go under the label of access issues. The second relates to the inadequacy of patent incentives to induce a socially desirable amount of investment in basic research. The instruments that have been generally relied upon to address the second concern – public funding of research through the establishment of public research institutions, funding of university research, grants and procurement – has traditionally also played a role in addressing the first concern through the application of the rule of disclosure characteristic of "open science" (Dasgupta and David, 1994). Reliance on public sponsorship in circumstances in which IP does not constitute an effective appropriability mechanism might have various advantages with respect to IP in that it allows not only to extend the range of potential beneficiaries of the knowledge created (Mowery et al., 2001; David, 2003) but also to coordinate the research effort by aggregating relevant information in a more efficient way than that allowed by the decentralized system of IP incentives (Maurer and Scotchmer, 2004). While the function patents perform in signalling the most promising avenues for research implies that information is made available after substantial investments have been incurred, often after "winner-takes-all" races have occurred, the immediate public disclosure associated to public sponsorship might be a more effective way of exploiting knowledge externalities. This holds, of course, provided the rule of disclosure is not abandoned, as it seems to be increasingly the case (see section 2).

As for the elements of divergence between the two domains, we will now go back at the issues highlighted in section 4 to consider what instruments might be appropriate to address these technology-specific concerns and thus tailor incentives to the needs of the two different technologies we consider. With regard to the life sciences, two main issues need being tackled. The first concerns the transactional failures associated to unilateral contractual practices of right-holders (refusals to license, exclusive licensing and restrictive contractual clauses) and the second the failure of patents incentive function in circumstances in which the size of the market for an innovation is too small to support adequate IP-based incentives yet there are no doubts as to its social value. To be sure, the first issue is not entirely peculiar to the life sciences. In the life sciences domain, however, it is exacerbated by the low degree of substitutability of many patented assets involved in the cumulative patterns of innovation characterizing the sector and particularly of genetic inventions. This factor, while deepening transactional difficulties, might justify solutions based on recourse to compulsory licensing in application of the essential facilities doctrine. In fact, three conditions contribute to the legal definition of essential facility: a) the presence of an essential input (an input that is both indispensable to production or innovation and difficult to reproduce); b) control of the input by a firm in a dominant

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obviousness standards may provide firms incentives to race and the race accelerates progress. On the other hand, Denicolò has reversed the latter argument emphasizing the "winner-takes-all" race that may result from a high standard determining an excess investment in major innovations.

position; c) lack of plausible technical reasons to refuse access to the input. In presence of these three circumstances compulsory licensing may be thus relied upon as a way to help fine-tuning the division of profits among subsequent innovators and provide a means of ex-post intervention when the incentive imbalances common in cumulative innovation settings occur. Indeed, in addition to being explicitly recognized by the TRIPs Treaty, compulsory licensing has been proven not to have statistically significant effects on firms' propension to innovate (Sherer, 1998).

The second issue, having to do with an instance of failure of patents incentive function, finds its prototypical example in the case of pharmaceutical innovation directed at the treatment of neglected diseases or diseases affecting predominantly developing countries. Patents are not as effective appropriability mechanisms in this situation as they are in pharmaceuticals more generally for various reasons. These include: a) a "time consistency problem" related to the fact that governments have incentives ex post to use their power to lower the price of drugs to levels not sufficient to cover research costs, which undermines ex ante research incentives; b) a "free rider problem" associated to the fact that pharmaceutical research represents a global public good and small countries may not take into account the consequences of a failure to contribute; c) a "size of the market" problem connected not only to developing countries' budget constraints but also to the fact that most pharmaceuticals for developing countries diseases (and vaccines in particular) are likely to be under-consumed (see Kremer, 2002).

Incentives might thus more accurately be tailored to the needs of this market by relying on mechanisms other than patents. Public sponsorship should, however, take a different form than that it takes in the promotion of basic research. This difference is due to the fact that in the present situation the need to be addressed is known in advance, which makes it easier to implement incentives that require verification of performance standards, while in the case of basic research research objectives are typically not known in advance (Maurer and Scotchmer, 2004). The debate on the best way in which incentives might be provided in such circumstances is, however, far from settled, given both theoretical considerations on the disadvantages of each incentive form and consideration of the obstacles to their practical implementation.

With regard to software, three main concerns were underscored in section 4 as specific to this technological regime. The first is the possibility that existing IP instruments confer to software innovations an excessive degree of protection, both as a result of the overlap of the different forms of protection and as a result of the discrepancy between the statutory length of patent protection of 20 years and the speed of technological progress and short life cycles characterizing software innovation. One way in which incentives might be adjusted, suggested from time to time in the course of debates on software patentability, is through a reduction of statutory patent length. However, while this solution constitutes indeed the staple diet of economic scholarship on IPRs[36], its practical implementation may find a limit in

[36] The economics literature has extensively considered how patent incentives might be adjusted in socially desirable ways (though generally without explicit reference to specific

the fact that, unless an agreement were reached in the competent international fora, unilateral initiatives by States in this direction would probably undermine the trend toward international patent standardization set in motion by the TRIPs agreement. An even more radical solution may consist in denying patent protection altogether to software-related inventions, as suggested by open source lobbyists as well as by some well-known economists (David et al., 2003). In between, there is the possibility of crafting the details of patent protection for software inventions in a way that takes explicitly into account the specific features of software innovation while not undermining the general uniformity of patent law. This brings us to the remaining two issues highlighted in section 4.

The question of interoperability constitutes a second technology-specific issue that might be addresses in various ways. Indeed, determining the appropriate scope of protection of program interfaces is not an easy task, if anything because of the difficulty of determining the boundaries between a given program and its interfaces. The task of avoiding that patent protection of program interfaces allow right-holders to extract rents disproportionate with respect to the real innovative contribution of the patented software products might be addressed in various ways. One option might be that of recurring to compulsory licensing in application of the essential facility doctrine. The major drawback of this option resides, however, in the high transaction costs involved in the determination of the appropriate "reasonable terms" at which interfaces should be licensed. A second option consists in allowing for reverse engineering of interfaces, though this involves wasteful expenditures in software decompilation that might sometimes inhibit the obtainment of interoperability. Third, there is the possibility of imposing the publication in patent applications of the description of program interfaces, which appears not to imply the costs involved by the alternative solutions described.

Finally, there is the question of the limited disclosure function patents perform in the software domain. Addressing this issue is important for a variety of reasons that range from ensuring that software patent databases are useful to software innovators to mitigating the adverse consequences of patent portfolio races. Ways should thus be found to ensure a stringent application of the disclosure requirement in the examination of software patent applications. An extreme and rather indigestible though perhaps desirable form of intervention might be to require compulsory disclosure of the patented invention source code. Alternatively, a right to reverse engineering software may be extended beyond interfaces to the entire patented program, as it has been recently suggested by many L&E scholars (see Cohen and Lemley, 2001; Samuelson and Scotchmer, 2003 and Burk and Lemley, 2003). Note that, of course, providing an effective solution to the problem of patent disclosures would also help address the above-mentioned concerns in regard to interoperability.

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technologies), focusing on the trade-off between length and breadth of protection (for a review of the relevant literature see Gallini and Scotchmer, 2002).

6. CONCLUSIONS

In this paper, we make a case for technology-specific tailoring of incentives, starting from the recognition of the effects exerted by the attributes of different technological regimes on the efficiency properties of the intellectual property system. The analysis, centered in particular on the patent system, aims at identifying relevant factors likely to have a bearing on the effectiveness of its various functions and at connecting these factors to the instances of patent system failure most likely to occur in the different technological regimes. The effort in this direction is motivated by the belief that, although information costs might influence the desirability of technology-specific tailoring of incentives, informational constraints might be made less binding by the identification of some regularities in the requirements for protection of different technologies.

We argue that strong aversion to technology-specific adjustment of incentives may only result from a fundamental confusion concerning the means through which the latter should be implemented. Indeed, it is the implicit assumption often made that adjustment of incentives necessitates the enactment of technology-specific statutes that suggests the conclusion that it would impose excessive costs and would not ensure the flexibility needed to keep up with the progress of technology. Acknowledgment of the fact that technology-specific tailoring of incentives to innovate may be achieved through means other than the crafting of specific statutes significantly undermines the case against incentive tailoring. In the paper, we substantiate this statement with reference to the software and the life science domains, providing an overview of the means through which innovation incentives may be made to reflect the specificities of these two technological domains.

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