

TIGHTENING APPROPRIABILITY THROUGH THE PATENTING PROCESS: AN EXPLORATORY ANALYSIS OF PHARMACEUTICALS¹

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Recebido em 05/09/2008

Aprovado em 12/01/2010

Disponibilizado em 20/12/2010

Avaliado pelo sistema *double blind review*

Editor: Luís Felipe Nascimento

Revista Eletrônica de Administração

ISSN 1413-2311 (versão on-line)

Editada pela Escola de Administração da Universidade Federal do Rio Grande do Sul.

Periodicidade: Quadrimestral

Sistema requerido: Adobe Acrobat Reader.

1. Introduction

The economics literature has made huge progress over the past twenty years in extending our understanding on the benefits and costs of patent protection (GRANSTRAND, 2003). Nevertheless, the business literature has not followed the same pattern. Our knowledge as to how firms manage both patents and the patenting process to capture the benefits realised from innovative effort is still scant (WINTER, 2000). For the purposes of this research we consider the patenting process as a series of patent-related events which begin at the moment an invention comes out and continue until a patent is issued.

Insofar as competitive advantage derives not only from the creation and use of assets that are difficult to imitate but also from their ownership and protection (BARNEY, 1991), an insight into the patenting process will shed more light on how firms capture value from their innovative effort. Thus, this paper addresses how firms use the patenting process to enhance appropriability conditions. In particular, we examine what is patented, when patents are applied, and where patents are registered. Answers to these questions give considerable understanding as to how firms use the patent system to build up ownership positions in the marketplace and to strengthen their competitive positions.

Although there might be inter-industry differences in what concerns patenting activity we concentrated upon the pharmaceutical industry for as the literature has shown, pharmaceuticals is one of the industries where patents play a major role (LEVIN et al., 1987), and hence pharmaceutical firms are the most likely to master the process with which our study is concerned. So, as part of our exploratory approach we conducted six case studies of pharmaceutical firms established in the UK.

Our findings indicate that firms are particularly keen on the scope of protection. According to our sample firms it is mainly by managing a whole portfolio of patents that they will derive the full benefits of patents and limit competitive behaviour of rivals. Moreover, in order to broaden the scope of protection firms tend to pursue patents in a broader territorial coverage. And critical in determining the scope of the final patent grant and other related follow-up patents is the timing of patent applications.

The paper firstly reports a literature review on the role played by patents to tighten appropriability. Secondly, we explain the process a patent application generally follows up to become a granted patent. Thirdly, we describe the research method employed. Fourthly, we turn to the empirical findings which are presented and discussed. Finally, we conclude.

2. Background

Innovative efforts tend largely to be formally structured within firms as a research and development (R&D) activity (although this is not necessarily so). It is common to consider the output of innovative efforts as knowledge, in a general sense, and it has become topical to discuss two characteristics of knowledge as a good i) it is non-rivalrous, that is, it can be used by one economic actor without precluding its use by another and ii) it is generally only partially excludable (ROMER, 1990). If knowledge is not fully excludable then other agents may be able to access that knowledge and exploit that access to the detriment of the originator of that knowledge (the inventor). In such circumstances, inventors or originators of knowledge will be unable to appropriate the true social value of that knowledge, and, therefore, will be likely to underinvest in its production (ARROW, 1962). It is largely to correct this excludability (or alternatively appropriability) problem that patent systems have been developed (GEROSKI, 1995).

Patent systems have been designed as a reward system to combat underinvestment in socially desirable inventive activities through the concession of a temporary monopoly over the outcomes of R&D, provided that those outcomes have the requirements specified by law. Such systems operate by providing a legal framework within which, for a fee and for a specific geographical area and a specified time, inventors own and are able to enforce property rights over the knowledge embodied in their patent grant. However, patents not only give property rights to inventors but also require that the knowledge to be patented must be disclosed to the world. This has the social benefit of re-basing future research activity but may have a private cost in that any benefits of secrecy over the patented knowledge are no longer available. Yet, the usefulness of the patent system should not be distorted. As Arrow (1962) observed, the extent that patents are successful, they may provide an underutilisation of the information disclosed. A conflict emphasised by Scotchmer (1991), who observed that stronger protection granted to the first generation of producers might lead to higher costs for the second generation of producers. Moreover, despite its relatively high importance in some industries, such as pharmaceuticals, the role played by patents as incentives for innovation seems to be less important than the market structure that precedes the generation of knowledge and that is imposed by using the knowledge (BENKLER, 2001).

Competitive advantage derives from the creation, ownership, protection and use of assets that are difficult to imitate (BARNEY, 1991). Nowadays these assets are often argued to be knowledge-based, and thus an emerging stream in the literature has advocated that the firm is a repository of knowledge, and knowledge, as opposed to tangible resources, is the most strategically relevant resource (GRANT, 1996). As such, differences in knowledge stock, and in its development and deployment, lead to differences in firms' performance (FOSS, 1996 a,b; GRANT, 1996).

As superior performance is seen as dependent on the ability of firms to be good at innovation, protecting intangible knowledge assets and using them (TEECE, 2001), it is the firms' best interests to avoid imitation of knowledge assets. To this end, firms can use mechanisms that are impediments to the imitative dissipation of rents (RUMELT, 1987). Those mechanisms are known as isolating mechanisms, and analogous to them are appropriability mechanisms (TEECE, 1986), which focus on avoiding replication and capturing value from knowledge assets. Patents are typical isolating/ appropriability

mechanisms to the extent that they enable knowledge creators to deter imitation. Thus, they are expected to be part of firms' strategy, at least for those technology-based firms.

Although imitation barriers, such as patents, can influence the creation of sustainable competitive advantage, recombination of knowledge in creative ways to pursue new market opportunities is also critical (KOGUT; ZANDER, 1992). Firms, therefore, may specialize in the creation and transfer of knowledge (KOGUT; ZANDER, 1996), even if knowledge spillovers are associated with the way research is structured amongst firms in a particular industry (KEEP et al., 1994). Thus, firms evolve in part through the combination of knowledge, and hence they are keen on controlling how knowledge is transferred both within and outside their boundaries (KOGUT; ZANDER, 1996). However, organisational structures and management practices that develop and leverage knowledge within a variety of innovation contexts are difficult to build up (COLLINSON, 2001). Even intra-firm transfer of knowledge has proved to be difficult (what is referred to in the literature as knowledge 'stickiness'). Szulanski (1996) argues that organisations 'do not know what they know' because of knowledge-related barriers (e.g., absorptive capacity, difficulties in the relationship between source and recipient) rather than their lack of willingness to learn.

There are elaborate definitions of what knowledge is, but it is most typically defined in two categories: i) explicit (or codified) knowledge, and ii) tacit (or implicit) knowledge (POLANYI, 1967). The former is knowledge about facts and theories, and can be transmitted via formal systematic language. The latter is experientially based, that is, it is personal, it is specific to a domain, and more difficult to be formatted, communicated and shared with others. As a consequence explicit knowledge can be captured more easily than tacit knowledge. Nevertheless, even if for the purpose of this paper we do not envisage any additional benefit in a more elaborated treatment of knowledge, we should be cautious in using the above dichotomous categories since the extent to that knowledge is explicit/ tacit may vary in degree, and these categories are perhaps the extreme points of a spectrum (SAVIOTTI, 1998). Moreover, the tacit/ explicit approach may lead to a comparison of ease/ difficulty in transmission/ use of knowledge that may be misleading. As observed by Malerba and Orsenigo (2000) such a dichotomy does not address a proper comparison because tacitness and codification are not simple properties of knowledge itself. They are partly influenced by economic incentives and other social/ institutional processes. Kogut and Zander (1992), however, observed that intra-firm transfer of tacit knowledge is more likely to happen

than is inter-firm transfer. Moreover, they detected that tacit knowledge is in fact slower to be transferred. Nevertheless, despite knowledge being difficult to transfer an innovator should be concerned about other firms having access to his/ her knowledge. Other firms' own knowledge may enable them to codify, absorb, and transform new knowledge at various degrees, and perhaps on occasions derive more value from the transferred knowledge than its originator.

Because of the fuzzy boundaries of property rights and of the nature of knowledge, a key challenge for top management is to figure out how to protect and retain the firm's own knowledge. The ease/ difficulty with which knowledge can be transferred poses challenges to managers who need to control the flow of knowledge if the returns of the creation of this knowledge are to be appropriated. There have been attempts to unveil how firms use granted patents to appropriate the returns from knowledge they create (GRAHAM; SOMAYA, 2004; GRANSTRAND, 1999; LEVIN et al., 1987; PITKETHLY, 2001; THUMM, 2001), and some effort has been put on understanding how patent characteristics affect firms' performance (HALL, 2000; REITZIG 2004 a,b; TOIVANEN et al., 2002) but few have devoted attention to the patenting process itself. Grabowsky and Vernon (2000), for example, stressed the importance of the patenting process insofar as firms tend to file patent applications early in the innovation process.

Although the process through which a patent is issued is well documented, little is known as to the impact of the patenting process on firms' ability to recoup the expenses with the creation of new knowledge. We conjecture that an insight into the patenting process should be helpful to unravel how firms may tighten appropriability through that process, and hence how they increase the likelihood of appropriating the returns from innovation. The underlying rationale for our interest in the patenting process is that patents' characteristics are dependent not only on the corresponding inventions but also on the decisions made along that process.

3. The Process of Obtaining a Patent: General Issues

A patent is a legal title issued upon application as long as the application fulfils some requirements (e.g., novelty, inventive step, industrial applicability). The date a patent application is first filed is labelled the priority date, and it is used to evaluate prior knowledge to the application. A patent application may be filed in a national patent office or in supra-REAd – Edição 67, Vol. 16, Nº 3 - setembro/dezembro 2010

national patent offices, such as the World Intellectual Property Organisation (WIPO). Once a patent application is filed it will be either examined or registered. The latter case implies that a patent will automatically be granted and its validity will only be tested in court. Nevertheless, it is common practice amongst most countries to demand an examination of the application before a patent is (or not) granted (CORNISH, 1999).

Overall, patent applications and the examination procedure are conditional on fees that may have to be paid on filing. Within twelve months the applicant² (i.e. patentee) must request, and pay the corresponding fee for the preliminary examination - to check whether the application is able to proceed - and search - to look for any relevant document which may invalidate or restrict what is claimed in a patent application. There is no need to wait 12 months to request preliminary examination and search, it can be done on filing since the priority date is the one taken into account to determine prior art. The applicant may, however, decide for whatever the reason to file a new patent application, but comprising the same inventive concept, claiming priority from the first one - so called internal priority (GRUBB, 1999).

Unless the one who applied for a patent (applicant) withdraws his/ her application, or simply abandon it, the invention will be disclosed soon. An invention can be kept secret until the 18th month from the priority date, and then the patent application is published³. From that point the disclosed invention also becomes prior art against any application filed later. It also implies that everyone is entitled to know what the patent is about. Inventors however do not have to wait up to the 18th month to have their inventions publicly disclosed. They have the option to request an acceleration of the procedure, and hence their invention will be disclosed earlier.

After a patent application is published it will start soon another stage of the proceeding. This stage is also made upon request, within six months of the publication date. This phase is the substantive examination which is carried out by a patent examiner, who aims to investigate whether or not the claimed invention meets the requirements of novelty, inventive step and industrial applicability. The first requirement, novelty, means that only new inventions can be patented. If an invention is publicly disclosed before a patent application is filed it will not be able of protection. This previous disclosure is known as either prior art or state of the art of the technological field. The second requirement by

definition is reached whenever an invention is not obvious to someone with a good knowledge and experience in the corresponding technical field. Finally, the requirement of industrial applicability implies the invention is able to be carried out in practice (WIPO, 1997). The patent examiner may or may not settle an objection against the applicant. In general, both parties reach an agreement and a patent is issued. Notwithstanding, to keep a patent in force the patentee must pay renewal fees periodically (e.g. yearly) until the patentee thinks the patent should be enforced, which is not necessarily the end of the term of protection.

Patent systems operate at single country levels (e.g. UK, US) and at supra-national levels (e.g. EPO, WIPO). There is no such a thing as an international patent covering all countries in the world. Even if a company chooses to use one of those supra-national systems, it has to designate all countries of interest (as long as the chosen countries have signed any treaty agreeing with the rules of the system) and pay the corresponding fees. Otherwise, anyone in the country not designated is entitled to freely use that invention. Patentees can apply to more than one national patent office individually. In this case, they can make use of one of the most important treaties: The Paris Convention. The Paris Convention for the Protection of Industrial Property is a multilateral treaty which dates back to 1883. In essence, it gives the patent applicant 12 months from the first filing (priority date) to apply for a patent to any other signatory country without risks of losing priority due to intervening prior art. Therefore, if any prior art appears within those 12 months it will not be considered against the foreign patent application. In non-signatory countries, however, any delay in applying for a patent may be crucial to the applicant forfeiting his/her rights.

Despite the advantage of this 12 months period when the country is a signatory of the Paris Convention, the option of going to national patent offices individually, as opposed to using supra-national patent offices, implies earlier patenting costs. The non-use of supra-national routes means that expenses with translations and patent attorneys services necessary to prosecute the application in the desired country have to be made earlier. This is so because the objective of supra-national routes is to make the acquisition of intellectual property easier and more uniform, and hence more beneficial (economic) conditions are offered. The European Patent Office (EPO), for example, is responsible for carrying out a single patentability examination (though patent applications are considered by a committee of three examiners), which can make it simpler and less costly compared to several individual

applications. A patent to be granted by the EPO can be obtained by filing a single application in one of the official languages of that organisation (i.e. English, French or German) in a unitary procedure before the EPO and it is valid in as many of the contracting states as the applicant designates. If the EPO grants a patent the applicant then may need to file translations in each designated European member country⁴ and pay national fees (GRUBB, 1999). If the objective, however, is to protect the invention in as many countries as possible, the alternative route is the Patent Co-operation Treaty (PCT)⁵, though it does not cover all the countries in the world; there are a few countries which are non-signatories of the PCT⁶. The Patent Co-operation Treaty (PCT) was first signed in 1970 and came into force in 1978. The PCT was mainly designed to make international applications simpler for the residents of the signatory countries and it seems that its popularity has increased (GRUPP; SCHMOCH, 1999). Also, in the same way as the Paris Convention, the PCT allows the applicant to file a PCT application within 12 months of the priority date.

Initially the applicant only needs to file a single document designating the states where protection is likely to be sought; neither translation nor payment of national fees is necessary, though other fees (e.g. search fees) need to be paid. The application at this first phase (so called 'Chapter I') will be submitted to a first simple examination, and a search in prior art will be made to enable the applicant to judge whether it is worth proceeding with the application. Based upon the search report the applicant may amend the patent application before it is published (18 months from priority date) in order to adjust the scope of the patent according to the prior art.

After the application is published the applicant has to choose to proceed to a preliminary international examination report, which will give an opinion on patentability (this is the second phase and is also called 'Chapter II'). If the decision is positive, the entry into the national phase will be postponed, unless any designated country is not elected under Chapter II. If the applicant's decision is negative he/ she will face all the costs related to the national phase (e.g. patent attorneys, translation) no later than 20 months from the priority date. A positive decision may delay such costs up to 30 months from the priority date⁷. At that time, and based upon the international preliminary examination report, the applicant may decide whether or not to proceed with the application into the national phase, and later follow national procedures.

4. Research Method

Each research strategy has its own advantages and disadvantages, and different sorts of questions require different methods (PUNCH, 1999). Maxwell (1998) asserts that the selection of the research method depends not only on the research questions but also on the actual research situation and what will work most effectively in that situation to give the information needed. Yin (1994) suggests that the choice of a research strategy should be according to i) the type of research question; ii) the control that an investigator has over actual behavioural events; and iii) the focus on contemporary as opposed to historical phenomena. As our objective is to understand how firms deal with the patenting process, in particular how some decision variables take place along that process, we chose a qualitative approach to our research. Our choice for a qualitative approach was reliant on the major strength of that approach which is its ability to get at the processes by which events and actions take place, processes that experimental and survey research are often poor at identifying (MAXWELL, 1998). Thus, we run case studies of pharmaceutical firms established in the UK.

We focused on the pharmaceutical industry primarily because the literature reports that this industry is the one where patents play a major role. As such it would be more likely to yield the information we were looking for. The UK was the geographic area chosen to develop this study as it has a tradition of research on patent-related issues and exhibits an intensive use of patents. According to statistics from the World Intellectual Property Organization (WIPO, 2007) the UK Patent Office was amongst the ten largest receivers of patent applications in the world in 2005 (excluding supra national offices), accounting for nearly 28,000 applications. Also the UK is still one of the major sources of technology in the world.

Face-to-face interviews were the data collection tools used because, according to Kvale (1996, p.105), they are “particularly suited for studying people’s understandings of the meanings in their lived world, describing their experiences and self-understanding, and clarifying and elaborating their own perspective on their lived world”. In order to check the suitability of the interview guide and the way the questions were organised a pilot interview was undertaken with the head of intellectual property of a pharmaceutical company. Interviews were run with the person in charge of patents in each company. Prior to any meeting a checklist of topics that would be addressed was forwarded to the interviewees.

A requirement for the validity of a research design is that the sample must fit in with other components of the study (MILES; HUBERMAN, 1994). Our sample derives from a report produced yearly by the UK Department of Trade and Industry, also known as R&D Scoreboard, which lists R&D spenders in the UK and abroad. As for the UK there were fifty-four pharmaceuticals firms listed. The main criteria to select the companies would be their size and their innovative effort – attributes that are known as determinants of inter-firm differences in patenting behaviour (SCHERER, 1983). We ended up collecting information from six pharmaceutical companies and pivotal for us not to pursue an amplification of our sample size was the similar pattern of information obtained from the sample, which did not justify further effort to gather redundant evidence. In particular because the information gathered was based upon a sample that presented the variability of attributes (i.e. size and innovative effort) that we were pursuing (Table 1). On average the interviews lasted ninety minutes each and they were tape recorded to facilitate content analysis, which was addressed by grouping interviewees' comments on general (i.e. what, where, when to patent) and specific (e.g. scope, timing, follow-up applications, returns foreseen, technology content) topics of interest. Our findings are presented in the next section.

Table 1: Sample Firms' Attributes

Firm	Number of Employees	Number of Internal Patent Agents	Number of Patents	Sales (£ million)	R&D (£ million)
A	3,000 – 3,500	3	600	360	57
B	100 – 150	Nil	9	7.8	3
C	50 – 100	Nil	75	1	8.6
D	100,000+	104	15,000	17,200	2,600
E	50,000+	45	10,000	11,400	1,900
F	1,000 – 1,500	6	NA	498	106

Source: Elaborated by the author based on firms' disclosed information.

5. Results and Discussion

From the outset interviewees stated that the basic premise of the pharmaceutical industry is that in order to get reasonable returns from the investments in R&D a temporary monopoly provided by patents is necessary. This is in line with prior literature that both advocates the importance of patents for pharmaceuticals (e.g. GRABOWSKY; VERNON, 2000), and stresses firms' concern with the extent knowledge is transferred (e.g. KOGUT; ZANDER, 1996; RUMELT, 1987). Despite firms' concern with appropriability, interviewees reported that secrecy (either by trade secrets or 'pure' secrecy) is rather important when it is

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difficult to police the invention, such as processes and equipments. In addition, they revealed that there might be situations where know-how is outdated at a high rate, and hence it might not be worth seeking patent protection because there would be resources allocated to something that would have its value deteriorated too soon.

The interviews revealed that firms' practice is largely to patent new products. A pharmaceutical product, however, can take various forms. For instance, it can be a chemical entity, which in general is the active ingredient responsible for fighting against a disease (some of these compounds are not active themselves but are metabolised in the body to form an active drug, they are known as prodrugs); it can be a composition (a combination of two or more active ingredients, or combination of a pharmaceutical carrier with a compound not used as a drug before), or a drug delivery system (which is a composition that its constituents enable to be administered in a particular way).

Although product patents are the dominant type firms reported that they also consider process patents and new use patents. The former refer to inventions which describe new ways of manufacturing a product. The latter relate to substances or compositions which did not have prior pharmaceutical use, or had it had a pharmaceutical use before, it was for different purposes. However, firms' interest lies mainly in product patents because according to interviewees these patents tend to be the most difficult to rivals overcome. For example, there might be alternative routes to manufacture a product but those are easier to bypass than the product itself. If competitors develop new processes to manufacture a patented product they will only be able (in the absence of a licence) to market the process itself and not the product. To develop and to market a new competing product competitors will require more resources (financial and time) than simply copying an invention. A product patent will therefore delay competition and help in appropriating the returns from innovation. This is consistent with the literature (e.g. GRANSTRAND, 1999; LEVIN et al., 1987). Moreover, interviewees also pointed out that the difficulty and resultant high costs associated with the development of new drugs have been increasing the importance of patents relating to drug delivery systems. These inventions may provide more effective ways for an existing drug to be released into the body, an attribute that may strengthen firms competitive positioning.

Although when an invention is a pharmacologically active ingredient patents work best as isolating mechanisms because they protect the product however it is made or

formulated, interviewees also revealed that they seek protection not only for the marketed product itself, but also for as many embodiments of the invention as possible. They stated that if what is patented is only the product which is commercialised (which perhaps is the optimal or the most feasible form of the invention), a minor change in the conceptual invention will possibly give competitors the opportunity to access the market with a competing product. Although a slight modification may not result in a patentable invention (it may be deemed obvious by patent examiners, for example), it may enable competitors to operate freely without infringing a patent holder's rights. This means that a patent was circumvented (or invented around), and hence innovators' ability to capture value from innovation was mitigated.

Respondents also stressed that should a firm come up with a breakthrough invention that will possibly serve as a platform technology for others, the benefits of patents may be particularly high. As a result firms might attempt to pursue intellectual property rights not only upon the technology directly related to their own products but also upon other technology fields around. These findings are in line with what Granstrand (2000) observed for Japanese firms. According to our sample firms, this phenomenon (also known as 'blanketing' or 'flooding') is most likely when there is an emerging technology which is not close to the prior art. According to interviewees the blocking of a technology field and the 'flooding'/'blanketing' phenomena have happened, for example, amongst biotech firms. So, the life cycle of technology seems to influence firms patenting behaviour. According to Cardinal et al. (2001) it is expected that the technology life cycle impacts on the codifiability of knowledge because firms in developed and developing fields tend to have different processes through which knowledge is generated and transferred throughout the value chain (R&D, production, marketing sales). Saviotti (1998) also observed that the more mature a technology field is the easier it is for firms codify knowledge in that field, which our sample firms seem to corroborate.

In addition, interviewees revealed that they also aim to patent anything that may stop themselves moving forward freely. That includes products or processes (and machines) that are not part of their business, or that come up as a result of non-routine activities, but that may be valuable to other firms. An invention may not lie in its innovator's core business but may be useful to the innovator commercialise the final innovation. Thus, in addition to patenting the technology that leads to the marketed product firms (i.e. innovators) may also attempt to

pursue property rights over complementary knowledge that can improve a product's performance or its differentiability. According to Arora et al. (2000) the control of these complementary technologies is a major incentive for firms to invest in R&D. Although smaller firms of our sample seemed to be more selective because of financial constraints they did mention to consider that behaviour *vis-à-vis* the benefits foreseen.

According to the interviews, it seems that the degree of excludability achieved by using patents depends on the extent that several parts of the invention are also patented. Although in pharmaceuticals the nucleus of the invention is the therapeutic agent, if there are various ways to formulate the product, more effective forms of releasing the active ingredient in the organism, or even other uses for the product and these variations are also in a company's patent portfolio, that company has more freedom to operate and more power to block others trying to launch a competing product. For this reason non-product patents (e.g. process and new use patents) may appear, if they do so, later in the drug discovery process (or perhaps even after a product is launched on the market). So, by securing property rights on the various aspects of an invention the innovator is more likely to reach a higher degree of excludability, raising higher barriers to competitors. This should facilitate the capture of higher returns to R&D.

Our findings thus reveal that although the theory correctly states that patents can operate as isolating mechanisms (WERNERFELT, 1984), it overlooks the conditions under which patents can be more effective, or which patent attributes are more likely to enhance the level of excludability and how the patenting process might be related to these attributes. Our results add to the current knowledge by showing that firms are able, to a certain degree, to manipulate the breadth of a patent (an attribute that seems to impact on the extent patents can be effective). Although patent examiners may restrict the scope of a patent and an originally broad patent application may become a narrow one, interviewees said that they rarely have the scope of their patents severely restricted to the extent that they immediately drop a patent. This finding is particularly useful for the literature on appropriability mechanisms because it shows that innovators' decisions to patent (or not) also encompass an analysis about how isolating (or strong) a patent can be. If proper attention is not drawn to the necessary resources that will extend the breadth of a patent application, imitators may be able to easily bypass innovators' granted patents.

The evidence above suggests that broader patents are preferred to narrow patents. Notwithstanding, firms should not pursue broader patents indiscriminately. Narrow patents are not necessarily to be ignored even if on average they are of lesser value. By their own nature broad patents extend the coverage of the protection of the invention, and this requires more resources. Thus, narrow patents might be applied for more quickly than broad patents and hence provide earlier (but less extensive) protection. According to interviewees this might be particularly useful if competition is severe. Our sample firms also informed that in comparison to narrow patents broad patents are more likely to have any part of it invalid. In general, patents that present a scope too broad also present higher degree of abstraction that with the information therein is hard to properly substantiate what is claimed. Even if patent examiners do not make severe objections during the substantive examination of a patent application, a competitor may challenge a patent in court and legally restrict its scope. In addition, our findings revealed that a narrow patent can be particularly valuable when it embraces the lowest cost process. As observed by interviewees even if competitors circumvent the patent on the lowest cost process they will not be able to obtain a cost advantage. Our limited evidence thus suggests that there is always a balance to be struck between the degree of excludability sought and the risks associated with that. For example, although broad patents are harder for rivals to circumvent they demand more resources and time that may lead a firm not to win a patent race.

One can observe from the above that there is a relationship between the timing a patent application is filed and the breadth of protection. As a matter of illustration, we start this discussion briefly explaining a typical route to drug discovery (Figure 1). In pharmaceuticals, research and development activities may last several years before a product is first launched on the market (perhaps an average of 12 years). The initial phase starts with the identification of targets – the points at which therapeutic agents should intervene in order to fight a disease. Using a high throughput screening search thousands of compounds are tested, and hopefully some compounds (lead compounds) will be able to act on those targets. After the identification of those active compounds, a series of experiments takes place aimed at changing the structure of those compounds in order to optimise their activity (lead optimisation). If that is successful, a candidate drug will go to the longest and, according to the interviewees, most expensive stage: development. We are interested in where in this process patenting is likely to occur. A typical response from the interviewees was that firms tend to start to apply for patents as soon as they have a promising compound (*italics* in Figure REAd – Edição 67, Vol. 16, N° 3 - setembro/dezembro 2010

1 below). This means that patent applications start to be filed just after the screening phase, (i.e. during lead identification and lead optimisation), which according to the interviewees have already demanded between 10 and 20 percent of the total resources necessary to bring a product to the market. This corroborates the view that patents are applied for at an early stage of the research and development process (GRABOWSKY; VERNON, 2000).

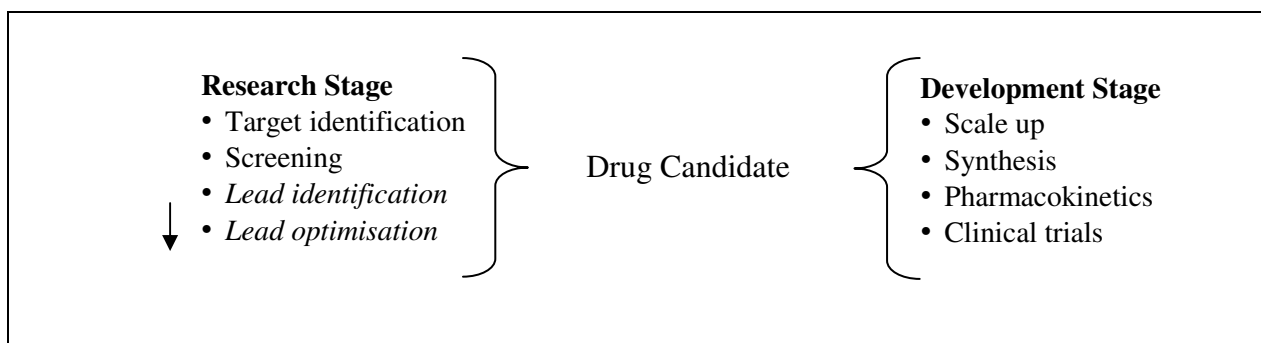


Figure 1: Simplified Model of a Route of Drug Discovery

Although early filing may be peculiar to pharmaceuticals, it is not unreasonable to extrapolate to other industries insofar as patent systems are characterized by ‘the winner takes all’. But filing a patent application early means that firms may not have a clear picture of whether or not the product launched onto the market will be exactly the same as that first identified. On many occasions firms do not know whether the product will be launched because it will not have yet passed through clinical trials. Furthermore, respondents emphasised that R&D is an ongoing process and there are always new results coming out, which will also be analysed as to their patentability. Thus, even after a patent application is first filed, there might appear new results that are also likely to be patented. Depending on when new results appear they may or may not be incorporated in the first patent application.

Respondents revealed that in order to avoid lagging behind in patent races one alternative is to go for a number of different patent applications covering the same or similar embodiments of an invention that may (or may not) be dropped later in the process. Innovators reported that more than one patent application embracing different scopes can be filed at the same time. According to the respondents this is more likely to happen when the pressure to patent earlier is very high and the information available on the invention is still very limited. So, one can file both narrow and broad patent applications at the same time. Narrow filings rely upon the results obtained up to the time of filing whereas broad filings rely upon inventors’ expertise as to the extent that an invention can be broadened in the near

future and thus have a more speculative character. If future results come out and are able to support the broader application then one can drop the narrow application and progress the broader one. Likewise, if the results are not enough to support the broader application this can be dropped and the narrower application progressed.

Alternatively, firms pointed out that they make use of internal priority whenever possible. That is, they file a first patent application, but within twelve months from the priority date they may file a new application claiming priority over the first one. That occurs if the new outcomes of R&D are deemed to be important enough to be specified in a patent application since those outcomes will enable the applicant to better substantiate what is claimed. As a result, a stronger patent⁸ is more likely to be achieved. It was a common view among the respondents that they seek excludability based upon not only a single patent but also a whole portfolio of patents, which comprises both narrow and broad patents that combined enable them to fence-in the market for their innovations.

Respondents also said that depending on the new results they may decide to apply for other patents within the priority year instead of claiming priority over the first application. That is a judgment based on whether or not the new results will be able to originate a new patent application that does not infringe the first one; and also whether or not it is likely that someone else will file an earlier patent application. When the new output is going to provide only small differences from the first filing and/ or when the perceived competition is very high, it is more likely that firms will use internal priority. Nevertheless, not all results from further experimentation appear within twelve months of a filing and, therefore, priority over the first patent application cannot necessarily be claimed. The alternative is to file a new patent application. As the new filing embraces other variations of the invention one could expect that it would be deemed to be obvious (no inventive step) by the patent examiner and, therefore, a patent would not be issued on that. It was pointed out to us that if those new results come out before the priority filing is published (at most within 18 months from priority date) the risks of that filing being opposed as to its inventive step are low (not taking into account what someone else is doing). That happens because the former application has not yet been published and therefore the latter does not have to be inventive over something that was not in the public domain. Using one of the respondents' words:

‘(...) if you file a lot of applications on similar things then you should do it before publication [of the first filing]. (...) once it [the first filing] is published if you then file them [follow up applications], they have to be new and inventive’.

These findings suggest that the argument by Kogut and Zander (1993) that recombination of knowledge is critical to pursue new market opportunities can also be extended to the patenting process since recombination of knowledge may generate different outputs that demand approaches to patenting accordingly. Given that patents have a fixed life, the timing of patent applications may considerably affect the time that a product will be protected on the market. If a larger part of the fixed patent term is devoted to further research and development, then the period in which protected revenues can be earned will be shorter. This would encourage later rather than earlier application, which in a first to file regime could be critical. In order to partially overcome this issue and extend the period of protection, the interviewees said that at least in pharmaceuticals they may apply for a Supplemental Protection Certificate⁹ (SPC). Although particular to the European Economic Area, this evidence suggests that the territorial dimension might be another important aspect when considering what and when to patent.

Appropriation of revenues derived from innovative effort is dependent on firms' ability to explore their knowledge in other geographical markets for which patents can also be pursued. There was a common response among the sample firms studied as to where patents should be secured. All six companies agreed that the US, Europe (Western) and Japan are the major territories where they should seek patent protection. The chief reason pointed out by the informants was that these countries are the largest markets for pharmaceuticals. The interest in these markets does not mean that the firms studied do not apply for patents in other territories. According to the interviewees, depending on the perceived impact of the invention on their businesses, they can go beyond these major markets. In general, what they reported was that they have a pre-determined list of countries where patent applications are likely to be filed.

Our findings indicate that applications were reported to be motivated mainly by the economic prospects of the invention, which corroborates what Bertin and Wyatt (1988) found for multinationals. This suggests that patents taken out in countries where firms operate, or

foresee participating (e.g. producing, exporting, licensing) in the near future, are likely the most valuable patents. If firms do not envisage doing business in the near future in a particular country, interviewees reported that they still may apply for a patent in that country. If the size of the market justifies patenting expenses and there are potential competitors present in that market firms revealed that patenting means that the market is an option kept available.

When firms decide that a patent application will be filed it also has to decide whether or not the invention will be filed locally first before it is filed in other countries. We were told that the patent applications of a UK company, for example, will not always be filed first in the UK. Some of the firms have R&D units abroad and they need to follow local rules, that demand inventions created in their territories to be filed first there before anywhere else. Regarding the decision to patent abroad the favourite route according to the respondents is through the Patent Co-operation Treaty (PCT); though attention was also drawn to the European Patent Office (EPO) and to the Paris Convention. When firms choose to go straight to other countries' patent offices, as opposed to the PCT, firms reported that they need to pay attention to whether or not the country is a signatory of the Paris Convention. If so, they tend to use perhaps the most practical aspect of the Paris Convention which is the possibility of claiming priority for applications made in another territory within 12 months from priority date¹⁰. If the country is not a 'convention country', firms seem to manage the patenting process to make sure that the invention will not be publicly disclosed after the first filing and are more likely to rush to file in that country in order to avoid forfeiting property rights (in particular because someone else may have filed between the date they first filed and the date they filed in a country that is not a signatory of the Paris Convention).

If the interest is just in the European market firms are more likely to use the European Patent Office (EPO) route. However, if the markets targeted do not justify the costs of this route (economies of scale may not apply), they may go straight to the respective patent offices. The PCT route is considered when there are markets of interest which are not covered by the EPO, and most of the time the PCT is the usual route that firms follow. As costs increase the greater the number of countries a firm applies to, the PCT may be of great advantage since it might be cheaper than filing in each of the target countries (as with the EPO route it all depends on the number of countries designated). Thus, the main advantages of the PCT were considered to be: firms can delay the bulk of the costs which arise when the application goes to the national phase; firms can have a better idea of the invention before

they incur these costs; and firms have both a search and a preliminary examination report that gives a fair idea of the patentability of the invention before the costs of the national phase, which may reduce uncertainty relating to the level of protection.

Another factor affecting where patents are pursued is the extent that firms can enforce their property rights. Again, US, Western Europe and Japan were cited as examples of places where legal frameworks are consistent and have the appropriate expertise in case of litigation. Moreover, according to the interviewees, patent office personnel in these territories are more skilful in dealing with patent issues and with operational procedures. So, in deciding where to register their patents, the institutional dimension of patent systems is also accounted for. In addition, although patenting everywhere is associated to a broader proprietary position, not all patents are of high commercial importance, and hence the costs of the patenting process may not justify the benefits of the protection achieved which means that a balance needs to be struck between costs and benefits. Our evidence is thus that the choice of where to secure property rights is to a large extent dependent on the perceived importance of the invention for the business, the size of the market, the legal framework, and the costs associated with that. According to Guellec and Van Pottelsberghe (2000) patenting in a large number of countries may reflect a lack of maturity of the applicant. The authors advocate that for many technologies it is enough to combine patenting in the largest markets with economies of scale to get worldwide protection. Our sample firms did not fully reconcile with their argument since it was revealed that the innovative skills of competitors are taken into consideration as well.

6. Concluding Remarks

In this paper we have explored how UK pharmaceutical firms use the patenting process to enhance appropriability. The results arise from a series of interviews with appropriate personnel in six various sized pharmaceutical firms. Our exploratory approach revealed that it is mainly by managing a whole portfolio of patents that firms will generate the full benefits of patents and limit the operations of both actual and potential competitors. Thus, theoretical justification for patenting should not fully rely upon the idea that holding a single patent will generate adequate excludability because it does not fit the facts (although a patent with a broad scope may be rather effective). The portfolio approach is beneficial to the inventor because it enables him/her to secure property rights on several variants of an

invention (making inventing around more difficult) as well as on complementary technologies that may improve a product's performance or its differentiability.

Our findings suggest that patent applications across borders are mainly determined by economic issues. Although the protection achieved is largely determined by the legal framework, the timing of application seems to be quite important in determining the scope of the final patent grant and other related application (if any). The ongoing character of the R&D process as well as uncertainty due to competition require patent applicants to make decisions on filing patents based upon actual results and future contingencies. Our evidence thus suggests that the timing of application influences the ability patents have to protect rents derived from innovations.

Some final reflection seems to be in order. Firstly, the portfolio approach observed by studying a few pharmaceutical firms indicates their concern with substitute and complementary innovations. It is not unsurprising that the market perceives high patent numbers as representing the difficulty of appropriating the benefits of R&D (TOIVANEN et al., 2002). On the other hand, high patent numbers may reflect the strength of firms' technological base upon which they compete. Thus, a deeper analysis has to be carried out if one is willing to understand what the figures mean. Secondly, the effective patent life in pharmaceuticals is often claimed to be rather short. The degree to which patent legislation should accommodate this is unclear. If policy makers are keen on taking this issue further, patent breadth, as expected (MATUTES et al., 1996), has revealed itself to be an important element of the patent system design that can be used to decrease deadweight loss. Finally, the empirical analysis of patent races should be very cautious about using crude patent counts. Although dynamic economies of scale (i.e. 'success breeds success') may take place, patents may be taken out at various points in time for various reasons. For example, the first patent (priority patent) is applied for early in the innovation process so that improvements can be made before the final innovation is commercialized and new patent applications filed; or the 'surrounding' strategy pursued by firms may underscore the possibility of innovations being complements, and thus one may conclude that earlier innovations were motivated by later ones.

In total, however, the evidence provided by the six firms is perhaps a rather thin foundation upon which to make general statements, thus a more comprehensive, and

representative, sample is needed. In addition, there is a growing trend in pharmaceuticals of patenting research tools (WALSH et al., 2003) which has serious implications for subsequent innovation and that our study has ignored. This is certainly a promising avenue of research.

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¹ I am thankful to the CNPq for the support of my stay in the UK. I am also indebted to Paul Stoneman, Qing Wang, Simon Collinson, participants at DRUID Summer Conference, and two reviewers of this journal for valuable comments on this paper. Remaining errors are my own.

² The individual or organisation that applies for a patent. Under the US law the applicants must be inventors. If they work in an organisation they need to legally assign all or limited rights under a patent to that organisation (assignee).

³ This practice has also been adopted by the USPTO since 29th November 2000.

⁴ As of 2004 there are 29 contracting States of the European Patent Office: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Hellenic Republic, Hungary, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Monaco, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, and the United Kingdom.

⁵ If one is solely interested in countries that are members of the European Patent Convention, the European Patent Office is an alternative to the PCT route. The choice between PCT and EPO is not mutually exclusive.

⁶ As of September 2004 there are 124 signatory countries of the PCT.

⁷ If the route after the PCT is the EPO, those deadlines are 21 and 31 months, respectively.

⁸ A patent that can be stood in court if it is challenged by someone else.

⁹ This is a certificate issued by members of the European Economic Area (i.e. EU plus Iceland, Liechtenstein, and Norway), which extends for up to five years the term of protection over an invention which has to undergo an administrative authorisation procedure required by law before it is put on the market.

¹⁰ The date upon which either a patent application is filed (in first-to-file regimes) or an invention is conceived (in first-to-invent regimes).