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Theme E
New Competition Policies and Intellectual Property Rights

PATENTS AND PHARMACEUTICALS IN THE UK: AN INSIGHT INTO THE PATENTING PROCESS

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Abstract

The purpose of this paper is to present some findings of how UK pharmaceutical firms use the patenting process to help in getting excludability in the marketplace, and why those firms file patent applications. A qualitative approach was used to investigate that topic. In particular, we run semi-structured interviews with the personnel who head the decision-making process concerned with patents. A common response on why firms engage in the patenting process was the long development time of a new product, and the costs associated with that. As patents help in keeping imitators apart those who come up with new technical knowledge are more likely to recoup the investments in R&D. Excludability is also sought by patenting, in the major markets, several embodiments of the invention in the form of either a single patent or a series of patents, and by patenting complementary technologies that come out along the R&D process.

Key words: patents, intellectual property, pharmaceutical industry, innovation, UK

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1. INTRODUCTION

Our review of the literature indicates that a plethora of studies have used patents as an indicator of innovative performance. Much of this literature relies upon either policy issues or econometric modelling of patent statistics rather than detailed empirical investigations of companies' perception of patenting activity[1].

Regarding firms' attitudes to the effectiveness of patents as a mechanism of appropriability, and the reasons firms have to take out patents, although there has been some empirical work done in other countries[2], especially for the US by Mansfield (1986), Levin et al (1987) and, more recently, by Cohen et al (2000), for the UK there has been little advance in our knowledge since the path breaking work undertaken by Taylor and Silberston in 1973[3].

It seems, therefore, that it is a convenient time to undertake such investigation because both the UK and the international arena have changed in what concerns patent legislation since Taylor and Silberston's study in the early 1970's. The Patents Act 1977 and the Copyright, Designs and Patents Act 1988 are examples in the UK. The Patent Co-operation Treaty (PCT) and the European Patent Convention are examples in an international context – both came into force in 1978. Moreover, as far as we know when it comes down to the patenting process[4] there has been no attempt to look more meticulously at how firms use that process in order to build up an excludability in the marketplace.

Therefore, it is this vacuum that this piece of research will primarily try to fill by addressing i) the reasons firms have to take out patents and ii) how they use the patenting process. We focus on four decision variables which, though not exhaustive, may outline to a certain degree the dimensions of the patenting process and, therefore, may help us to understand how firms aim to strengthen their competitive position by using patents. In particular, we examine why firms patent, what is patented, when patents are applied for, and where patents are registered.

In order to shed light on the dynamics of the patenting process we run 6 semi-structured interviews with the personnel who head the decision-making processes concerned with patents in UK pharmaceutical firms (one interview for each firm).

[1] See for example Guellec & Van Pottelsberghe (2000), Jaffe (2000), Grupp & Schmoch (1999), Mazzoleni & Nelson (1998), Griliches (1990); Patel & Pavitt (1987); Scherer (1983); Wright (1983).
[2] See Harabi (1995) for the Swiss industry.
[3] See also Pitkethly (2001) and Thumm (2001) for a mail-survey approach on patents.

Although, there might be interindustry differences in what concerns patenting activity we concentrated upon the pharmaceutical industry for as Levin et al (1987), and Taylor and Silberston (1973) have shown, pharmaceuticals is one of the industries where patents play a major role.

The paper firstly addresses a general framework to understand the role played by patents. Secondly, we describe the research method employed. Thirdly, we turn to the empirical findings gathered by the research. Finally, we draw some conclusions.

2. PATENTS: A GENERAL FRAMEWORK

2.1. Basic definitions

As described by Silberston (1971:224) the patent system is 'the system under which monopoly privileges are granted to those who succeed in making technical progress of a special kind in particular fields'. Thereby, a patent is strictly related to inventions, which the World Intellectual Property Organisation (WIPO) defines as 'a solution to a specific problem in the field of technology' (WIPO, 1997:123). This technological character of patents is one of the aspects that make patents different from other intellectual property rights. In specific, a patent is a legal title issued upon application which enables its holder (so called patentee) to enforce, for a limited time and geographical area, exclusive rights over an invention by excluding others from making, using or selling it without his/ her authorisation.

It is worthy noting that a patent is not a requirement to commercialise an invention. A firm can market its invention without taking out a patent since any part of the invention is not protected by the patent of someone else, and the invention fulfils, when necessary, the requirements of other regulatory bodies, such as health authorities. That is, a patent does not necessarily give the patent holder the right to practice the invention claimed. Had any part of the invention been covered by a valid patent of someone else, the patent holder would not be able to practice his/ her invention, unless the owner of the other patent had given permission. Therefore, a patent only provides the right to exclude others, a negative right (Cornish, 1999).

[4] For the purposes of this research we consider the patenting process as a series of events which take place from the moment an invention comes out to the moment a patent is issued.

2.2. The economic rationale

For many firms competitive advantage arises from the development and use of new technologies. Moreover new technology could also arise from learning by experience. Although to some degree these new technologies may be acquired from outside the organisation, a large residual will be the result of the firms' own innovative efforts. In larger companies innovative efforts, in a technological sense, tend to be formally structured as a research and development (R&D) activity, although this is not necessarily so.

As articulated by Jones (1998) technology has been recognised as one of the main elements responsible for promoting economic growth. Therefore, a typical issue of concern for policy makers is how to encourage firms to engage in innovative activities. That aspect has led to a search for useful rewarding systems, such as the patent system[5].

What can, however, undermine the incentives to innovate? One possible, but certainly not unique reason lies in the characteristic of the output of R&D. It is common in the literature[6] 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 (Romer, 1993). The first is that knowledge is nonrivalrous, that is, it can be used by one economic actor without precluding its use by another. A characteristic that most economic goods do not share. On the other hand, knowledge shares a common characteristic with other economic goods: it is, at least partially, excludable. If we wonder that excludability is to some extent imposed by the owner of the good, perhaps we realise that such attribute may vary between goods.

Referring back to the output of R&D, once it is implemented or disclosed by one agent other agents can also have access to it. Therefore, if we think in terms of knowledge generated by R&D, it will not only be an output itself but also an input to other agents. The presence of spillovers may, however, preclude its producer to reap adequate benefits from investments in R&D. The reasoning behind this argument is that, assuming that most firms are profit seeking and the inventor is operating under competition, if knowledge is both nonrivalrous and nonexcludable it can be cheaply copied. Thus, inventors or originators of that knowledge will be unable to appropriate

[5] More discussion on incentive systems for innovation can be found in Gallini & Scotchmer (2001); Geroski (1995); and Waterson (1990).
[6] See for example Pavitt (1992); Griliches (1990).

the true social value of that knowledge, and, therefore, they will be likely to underinvest in the production of knowledge.

The argument above was well elaborated in the seminal work by Kenneth Arrow in 1962, and using his own words:

> *'In the absence of special legal protection, the owner cannot, however, simply sell information on the open market. Any one purchaser can destroy the monopoly, since he can reproduce the information at little or no cost. Thus the only effective monopoly would be the use of the information by the original possessor. This, however, will not only be socially inefficient, but also may not be of much use to the owner of the information either, since he may not be able to exploit it as effectively as others'.* (Arrow, 1962:615)

It is largely as a reaction to the excludability or alternatively the appropriability problem that patent systems have been developed (Geroski, 1995). Such systems operate by providing a legal framework within which, for a fee and for a specific geographical area, inventors own and are able to enforce property rights over the knowledge embodied in their patent grant for a fixed time period.

The common characteristic of all patent systems, however, is that the knowledge to be patented must be disclosed to the world, and it is publicly disclosed before a patent is granted. It avoids the presence of 'submarine patents' – patents which are kept secret for quiet a long time due to deliberate delays and are only granted after the technology has been adopted by someone else and thus incurring in payment of royalties. Such disclosure aims also to speed the diffusion of knowledge and to avoid duplication of R&D. There is thus an implicit cost to owning a patent; i.e. secrecy over the patented knowledge is no longer available. This is the socio-economic contract between the patent owner and society.

Patents were created to combat underinvestments in inventive activities through the concession of a temporary monopoly over the outcomes of what was invented, provided that those outcomes have the requirements specified by law. When such property is assigned it means that the owner can exploit it in different ways (e.g. licensing, blocking competitors technological movement, etc.). However, 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. 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). Also, to analyse the patent system one must proceed with caution since this is an 'one size fits all' system. The following paragraphs will give more details about the perceived usefulness of patents and their role.

2.3. The usefulness of patents

Both Winter (2000) and Benkler (2001) stress that there has been a considerable distortion on the role played by patents and intellectual property in general. The former draws attention to an existing intellectual property 'industry' which, as any other one, aims to promote its wares. The latter argues that an overemphasis in intellectual property may lead to predictions which have 'no basis in any competent economic theory' (ibid.: 270).

Arora et al (2000) investigated recently the belief that patent protection encourages R&D investments. They concluded that the critical factor to incentive firms to engage in R&D is the degree to which a firm controls the complementary technologies needed to commercialise an innovation. Kaufer (1989) used the examples of Germany, Holland and Switzerland - countries where industrialisation occurred without a national patent system - to defend the point of view that there is no need for believing that the absence of patents would hamper industrialisation. However, as the author recognises, it does not mean that patents are unimportant. It only shows that a less-developed country may take advantage of patent systems of other countries to promote its own development before having a stronger patent system.

From another perspective, one of the most revealing studies of firms' perceptions about appropriability is that by Levin and associates (1987). They investigated typical conditions of appropriability in 130 lines of business for US firms. The results of their survey suggest that the efficiency of the patent system is restricted. The authors found that process patents are the least effective mechanism of appropriability amongst those examined. Product patents were rated higher than process patents as a method of appropriability. In turn, secrecy was rated higher than process patents but lower than product patents. Their study also detected that lead-time, learning curve, and sales or service efforts are generally more effective than patents.

Those results appear to confirm the UK findings of Taylor & Silberston (1973) that patents do not provide perfect appropriability as many theoretical models of patenting suggest. Levin et al (1987) also detected that many patents can be circumvented, others are not so effective when subject to stringent legal requirement for proof that they are valid or are being infringed, and some innovations are difficult to patent. The effectiveness of patents as a method of appropriability thus seems to be limited, it being difficult also to generalise how effective a patent may be.

Mansfield (1986) also reported, studying 100 US firms from 12 industries, that there are interindustry and interfirms differences on the perception of how useful patents are, and that the incentives patents provide to increase the rate of innovation are very small in most of industries studied. Despite that the author found that the bulk of patentable inventions are patented and firms generally prefer to rely on patents than on trade secret protection. Also, the author pointed out some reasons why firms have become more interested in patenting. Firstly, because there has been an increase in perceived competition. Secondly, because there has been a change in firms' product mixes, with more sophisticated product lines, which are more likely to be patented. Finally, because technological path involving analytical equipment has reached a stage where it has been easier for a rival to detect what innovators launch on the market.

Levin et al (1987) detected that in the pharmaceutical industry patents were rated as being more effective than all other means of appropriability because, according to the authors, the discreteness and easy differentiability of the patentable subject matter of that industry help to develop a comparatively clear standard of assessment of a patent's validity.

In a recent analysis on appropriability mechanisms used to reap the returns from innovation Cohen et al (2000) surveyed 1478 managers in R&D laboratories within US manufacturing industry. They observed, again, that the effectiveness of patents varies across industries, but in the majority of manufacturing industries patents tend to be the least effective mechanism. An interesting result that they come up with is that secrecy appears to be more heavily employed across industries than it was previously, according to the results by Levin et al (1987) and Mansfield (1986). Despite being judged low effective patents are still applied for as often as they were. According to the authors one reason for explaining that is the sufficient value of patents added at the margin when they are used with other mechanisms.

There can be added to the above other reasons why firms pursue a patent, though the results do not reveal a consistent pattern. Duguet & Kabla (2000) and

Geroski (1995) pointed out that to take out a patent is to purchase an option (albeit on an asset the value of which is difficult to estimate but that can be defended in due course if necessary) and that the cost of the option is not particularly expensive. Levin et al (1987) observed that patents are mainly used to prevent duplication and to secure royalty income. Cohen et al (2000) confirmed the results that patents are mainly used to prevent copying, but they detected that the second best reason is to block competitors' attempts to patent a closely related invention, by controlling a technology path which enables them to settle themselves in a specific market.

Granstrand (2000) and Geroski (1995) suggest that as patents may be used as reasonable indicators of inventive performance they can be used and thus applied for as part of incentive structures for research workers, though Duguet & Kabla (2000) find no robust evidence for this in French manufacturing industry. Moreover, (i) firms can use patents as assets to trade in technology negotiations; (ii) they can use patents to enter foreign markets where licensing to a domestic firm is required; (iii) they can use patents to avoid litigation initiated by competitors since the length and cost of lawsuits may be related to the amount of technical information provided by each party involved (Cohen et al, 2000; Duguet & Kabla, 2000; Granstrand, 2000; Geroski, 1995).

Adding to that, it is expected that patents can be used as a source of information and knowledge to others since, according to theory, patents disclose inventions in a manner sufficiently clear to permit a person having ordinary skills in the related technical field to carry out the invention (WIPO, 1997). The empirical evidence, however, does not show that this is always the case. Pitkethly (2001:431), for instance, observed that for Japanese companies 'patent information is as important in retaining and increasing a lead as in catching up and decreasing a competitor's lead'. However, he did not found the same evidence for the UK. In turn, Levin et al (1987) reported that the use of patents' disclosure as a method of learning about competitors' innovation was one of the least effective methods. The firms reported that they relied more on independent R&D and licensing, respectively, to learn about competitive technologies, but in the case of product innovations reverse engineering was the second best alternative. Furthermore, to carry out an innovation it is necessary other technical expertise, such as knowledge about how an equipment operates or how technical information can be used, that is only acquired through long experimentation (Grubb, 1999; WIPO, 1997; Knight, 1996). Therefore, it seems that know-how can be captured more effectively when rivals' R&D personnel reach similar type of expertise in practice.

The above reports aspects of the role played by patents and a list of the incentives to take them out, but at the same time highlights some limitations of the patent system. The empirical studies, however, have only in part provided evidence of how the granting procedure is used to reach the excludability sought[7]. Perhaps a glance at that process could help us to address more consistently the extent that patents provide excludability. To have an idea of how that process looks like, it will be described next.

2.4. An overview of the patenting process

2.4.1. What to patent

A patent application has to fulfil some requirements to achieve the status of a patent. Broadly speaking, the invention itself has to meet three main requirements: i) novelty, ii) inventive step and iii) industrial applicability (needless to say that deadlines and fees might apply). 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 to be possible to be carried out in practice (WIPO, 1997).

Inventions, however, have different forms. Generally speaking, an invention lies in one of the following categories: i) products, ii) processes or methods, and iii) machines. Although a machine can also be a product if a firm makes machines for sale, it is better to keep them in different categories because of their characteristics in terms of enforcement. If a firm invents a product it is likely that it will attempt to profit from it, and therefore, that product will be available in the market soon. If the invention is a machine, however, it does not necessarily mean that it will be launched on the market, especially if selling machines is not a firm's core business. A firm can keep in secrecy the apparatus to make a product since it is unlikely that competitors will have access to it and then copy it. It also means that a machine patent tends to be more difficult to prove infringement than a product patent because the latter can be found easily in the marketplace. Processes or methods would be procedures responsible for making a product. Alike machines, processes may never be accessed by competitors,

[7] The debate is mainly on what is patented and where patents are registered.

and, again, it means that process patents tend to be more difficult to enforce. In general, according to Knight (2002), product patents are the most valuable, followed by process and machines patents.

Those categories of inventions may impact on the decision of whether or not to go for a patent. This was already observed by Levin et al (1987), and more recently, by Cohen et al (2000). Both studies agreed that firms are more likely to apply for a product patent as opposed to a process patent. The major justifications are i) it is more difficult to prove an infringement of process patents, and ii) other agents cannot easily access a process since what is generally launched on the market is a product and there might be different ways to get the same product. The possibility of overlapping technologies may affect a firm's motivation for patenting. A product or a process may also embrace more than one patentable element and that may lead firms to make different decisions on what to patent (Cohen et al, 2000).

It is likely, however, that a particular invention may have its function accomplished in a different manner. That is, although competitors might not be liable to do exactly the same invention, they could come up with variations of the invention to perform nearly the same function without infringing anyone else's patents. It could mean that a technical progress is happening, and that is one of the goals of the patent system. However, it takes time for others to invent something that can perform the same function in a different way. And the longer it takes, the more likely it is that the first to reach the market will recoup the expenses on R&D. In this sense, the degree of excludability achieved by the enforcement of a patent might be quite important and it is determined by the scope, or breadth, of a patent.

The scope of a patent is basically described by its claims, which are sentences at the end of each patent that describe the invention. They may pose a threshold to others keen on performing the invention. There exist broad and narrow claims, and they are granted on the basis of what is specified in a patent application, and on the existing prior art. Therefore, they determine the degree of excludability a patent holder can get. If what is claimed only covers few variations of the invention, that is a narrow patent, it is more likely that it will be easier for others to duplicate the function of the invention, without copying it in strict terms. If, however, an array of embodiments of an invention is described by the claims the patent holder will get a broad patent, which on average gives a higher degree of excludability. This is so because the scope of the patent will make more difficult for others to develop a competing invention for a close related purpose (Knight, 2002; Granstrand, 1999; Grubb, 1999; Knight, 1996).

Therefore, what firms patent is quite important to the extent that it impacts on the degree of excludability and thus, on a firm's competitive position since it can keep competitors apart for a while. The excludability that patents give is also dependent on the timing, along the R&D process, that firms apply for a patent, and that is going to be discussed later. Before that it might be useful to have an idea of a typical formal procedure to take out a patent.

2.4.2. How to obtain a patent

A patent is a legal title issued upon application. So, the first step in the process is obviously to apply for it. The date a patent application is first filed is labeled the priority date (we will see later the importance of that date). A patent application may be filed in a national patent office or in supra-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. The procedure that follows is reliant on the UK Patent Office and there might be variations from country to country.

In particular, the UK Patent Office requests a fee to be paid on filing. And within 12 months the applicant[8] 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 is kept secret until the 18th month from the priority date, and then the patent application is published[9]. 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 invention is.

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[8] 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).

[9] This practice has also been adopted by the USPTO since 29th November 2000 (Johnson & Popp, 2001).

After a patent application is published it will start soon another stage of the prosecution. The next phase is the substantive examination which is carried out by a patent examiner, who aims to investigate whether or not the invention claimed meets the requirements of novelty, inventive step and industrial applicability. This stage is also made upon request, within six months of the publication date. 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. In the UK renewal fees are requested from the fifth year from the priority date and must be paid yearly[10] until the end of the term of protection or until the patentee thinks it is worth. The prosecution of a patent application is of course preceded by the moment a firm decides that it will apply for a patent. Therefore, it might be relevant to take a look at that issue.

2.4.3. When to patent

The date when a patent application is first filed with a patent office (priority date) is of crucial importance for the subsequent prosecution of the application. It is the date which is used to give priority to an invention. It means that if more than one institution, or individual, seek protection for the same invention, a patent might be granted for the one who applied first. This regime of first-to-file is spread worldwide. An exception is the US which adopts the first-to-invent regime[11]. The priority date is also the date which a patent, if granted, will have as the beginning of its lifetime (in general, 20 years). Furthermore, that is the date used to check whether or not an invention is actually new. In other words, everything publicly available before the priority date is considered prior art and can be used against the rights claimed. Prior art might also be used as an underlying issue to verify to what extent the inventive step requirement is fulfiled (WIPO, 1997).

Since the regime that governs the vast majority of national patent law is the first-to-file regime it seems that firms may try to file patent applications as early as possible. So, the timing of applying for a patent is not simply the moment there is something patentable; the perceived competition may impact on that moment. As a consequence, the invention described in a patent document is perhaps based upon research undertaken under laboratory or small-scale conditions. According to the World Intellectual Property Organisation, the ‘true’ invention (the one which a firm launches on the marketplace) is not always completely disclosed because sometimes it

[10] Renewal fees vary from £50 in the 5th year to £400 in the 20th year, as of 2002.

is too late to incorporate in the patent application any improvement made during a later stage, such as on a pilot scale.

The idea that patents are taken out earlier is shared by Grabowski and Vernon (2000:99) who affirm that in particular for pharmaceuticals 'patents are typically granted years before a product completes its clinical testing and is approved for marketing by the regulatory authorities'. Granstrand (1999), however, explores a bit more how patents can be obtained over the time. He suggests that patenting can happen along the product life cycle either in a sporadic way or in a continuous (or follow up) way. That leads to a patent portfolio which comprises not only the patent which describes the basic characteristics of the invention, but also any other patent taken out on improvements of the initial invention.

The importance of the discussed decision variable stems from the fact that the excludability that a patent may provide depends also on the proper information available for the application. According to Knight (1996) a hurry to file a patent application may incur losses in either how broad or how strong a patent can be. Since information is needed to support what is claimed, an early filing may weaken the validity of the patent. If the applicant had not performed the experiments that provide enough data to justify what is claimed, the patent application may be narrowed to the extent that it becomes more likely to be circumvented. Moreover, even if the corresponding patent was not narrowed by the patent examiner it becomes more likely to be challenged. Thus, the time of applying for a patent is not only a matter of being first than others but also a matter of how the technical information available will impact on the overall business objective of that patent.

2.4.4. Where to patent

Firms, and individuals, may patent in as many countries as they want since, of course, i) there is a legal framework concerning the subject in those countries, and ii) the requirements to have a patent granted are fulfiled. Patent systems operate at single country levels (e.g. UK, US) and at supra-national levels (e.g. EPO, WIPO), but 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 use that invention

[11] According to Jaffe (2000) the first-to-file regime has been considered by the U.S. Congress and it may

freely[12]. Also, as patent laws are not completely uniform amongst countries, the granting of a patent is contingent on national laws recognising the subject matter patentable.

Patentees may use supra-national systems to obtain patents abroad. They can also go for individual patent offices and follow local procedures, instead. If the choice is for applying to national patent offices individually, they can also 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. Regarding patents it gives the applicant, in essence, 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 forfeit his/ her rights. Despite the advantage of a 12 months period the applicant incur high costs very early because of translations and patent attorneys necessary to prosecute the application in the desired country. That is, perhaps, one of the disadvantages of going for national patent offices individually as opposed to using supra-national patent offices.

The objective of global treaties is to make the acquisition of intellectual property easier and more uniform. The European Patent Office (EPO), for example, is responsible for carrying out a single patentability examination, which can make it simpler and less costly if compared to several individual applications. If the EPO grants a patent the applicant may need to file translations in each designated European member country 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)[13], though it does not cover all the countries in the world.

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

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be implemented in the future by the United States Patent Office (USPTO).

[12] An exception is the African Intellectual Property Organisation (OAPI) which issues patents automatically covering all 14 member states, unless a patent application is also a PCT application. The Eurasian Patent Office (covering 11 member states of the former Soviet Union) also issues single patents covering all signatory countries (Knight, 1996).

[13] Note that 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. Note also that the choice between PCT and EPO is not mutually exclusive.

increased (Grupp & Schmoch, 1999). Alike the Paris Convention, there are few countries which are non-signatory of the PCT. Also, in the same way as the Paris Convention the PCT allows the applicant to file a PCT application within 12 months from the priority date.

At a first moment the applicant only needs to file a single document designating the states that are likely to be sought protection; 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 is worthy to proceed 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 decide for a preliminary international examination report, which will give an opinion of patentability (this is the second phase and is also called 'Chapter II'). If the decision is positive entry into 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 date[14]. 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.

The literature[15] suggests that firms should file a patent application in countries where they have business interest. What is expected is that a business strategy identifies either where products will be sold or where growing and likely-to-be-profitable markets are located. Knight (1996) argues that the effectiveness of patent protection, the legal framework and the willingness of firms to spend money on patents should also be considered as factors to be taken into account in deciding where to patent. Grupp & Schmoch (1999) observed that there are several different strategies that companies have pursued in the telecom industry regarding the countries where they file patent applications. Guellec & Van Pottelsberghe (2000) inferred from their study of small high-tech companies that patenting in a large number of countries may reflect a lack of maturity of the applicant. They argue that, for many technologies, it is enough

[14] It is worth noting that if the route after the PCT is the EPO those deadlines are 21 and 31 months, respectively.

to combine patenting in the largest markets with economies of scale to get worldwide protection.

3. RESEARCH METHOD

The first step toward answering a research question is to design the procedure that is supposed to provide the answer sought. As Yin (1994:19) observed, 'Every type of empirical research has an implicit, if not explicit, research design'. In order to outline a research design Punch (1999) argues that a pragmatic approach might be useful, that is, to start by focusing on what is aimed to be found out in the research without engaging fully with the philosophical considerations involved. Following Punch's argument, we will describe in the next paragraphs how the research method was designed and how it was operationalised. However, we also agree with the author when he says that despite being pragmatic one should be aware of the philosophical issues. Moreover, a pragmatic choice does not dispense with philosophical issues; they are always present, even if implicitly.

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 on the actual research situation and what will work most effectively in that situation to give the data necessary. 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 pharmaceutical 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). Face-to-face interviews were the data collection tools used because, according to Kvale (1996:105), 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'. As there are different types of interviews, we opted by running semi-structured

[15] Miele (2000); Knight (1996).

interviews since they have a sequence of both themes to be covered and questions to be asked, whereas, at the same time, they enable changes in that sequence in order to follow up the answers given (Kvale, 1996). Also, as the technique chosen needs to fit the character of what one is asking, a semi-structured interview is suggested by Gillham (2000a) when the research questions require an elaborated in-depth response.

After consideration of the advantages and constraints of the circumstances, mainly the time-cost factor, it was decided to collect the information by running between 6 and 8 semi-structured interviews – one interview per company – with the personnel most likely to know the patenting process within UK companies (this is the so called elite interview). We expected that this would enlighten us as to the issues we were interested in investigating as regards the decision-making process. In particular, we were keen on what firms patent, why they seek patent protection, when they apply for patents and where they are more likely to register their patent applications. Although we are aware that there might be interindustry differences with respect to patenting activity 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 semi-structured interviews were run making use of an interview guide which was designed with the support not only from the literature on patents but also from the literature on research methods. Our objective was to construct an interview guide which could help us to pose the questions most efficiently. At that stage the recommendations by Gillham (2000b), by Kvale (1996) and by Foddy (1996) were quite helpful in what concerns the structure of the interview guide and the wording of the questions. In line with the nature of this type of interview, a series of questions was formulated as a loose guide for reference during the meeting. We also made use of prompts and probes to help the interviewees to come up with the information that we were seeking. That is a technique commonly reported in the qualitative research method literature and that is helpful to keep the focus during the interview. That is, it enables interviewers to have some control over the situation and to steer, even if loosely, for the direction of the conversation and to cover the topics aimed. The ultimate objective was to make the interview process to some extent open but not vague, keeping the flexibility desired without missing the information that was being sought.

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 company originally from other country rather than the UK. As Gillham (2000a) observes, there is a lot more to interviewing than asking questions. In that sense, a pilot test was also useful to provide a first insight into the interviewing process and to help in detecting essentially how to make interviews work. Moreover, it provided us with an understanding of the meaning that particular phenomena and events had for the actors involved.

A requirement for the validity of a research design is that the sample must fit in with other components of the study. In order to do that we followed Miles and Huberman (1994) recommendations regarding a qualitative sampling plan. We tried to manage to get our sample falling into the purposeful sampling category since it could help us in capturing any heterogeneity and, therefore, more likely to be representative of the population (Maxwell, 1998). The main criteria to select the companies would be their size and their technology – attributes that might impact on the way firms seek patent protection. Nevertheless, as observed by Gillham (2000a: 5) 'In real world research you have to use the methods that are possible' and since the access to the interviewees was restrict we ended up with a convenience sample (Table 1). Despite that the final sample seems to have the heterogeneity that was being sought.

	# Employees[a]	# Internal PA[b]	# Patents	Sales[a] (M£)	R&D[a] (M£)
Company A	3,000 – 3,500	03	600	360	57
Company B	100 – 150	Nil	09	7.8	3.0
Company C	50 – 100	Nil	75	1.00	8,570
Company D	>100,000	104	15,000	17,200	2,600
Company E	>50,000	45	10,000	11,400	1,900
Company F	1,000 – 1,500	06	NA	498	106

[a] Source: Annual reports.

[b] Patent attorneys.

Table 1 – Sample profile

To end up with the sample above we firstly consulted the Department of Trade and Industry R&D Scoreboard, from where we got a list of UK pharmaceutical firms (a total of 54 firms). Then, we got the companies' addresses either from the Association of British Pharmaceutical Industry (ABPI) or over the internet. The names of the individuals who should hold the information we were looking for were obtained either on the internet or by telephone calls to the companies. After that we approached them by a formal letter explaining the purposes of the research, requesting assistance, and assuring confidentiality in that no source of material would be explicitly named in the

research output. We dealt that stage with formality since the setting up of an interview could indicate how we valued the contribution the interviewees would make (Gillham, 2000a). We received 10 replies of which 6 acceded to our request (5 of them are publicly traded); a number which the researchers deemed to be feasible according to the objectives of the study and according to time constraints. Also, as the characteristics of the firms which replied positively were to a certain degree matching with the heterogeneity we were aiming, it was not necessary neither to send follow-up letters, nor to disregard any company. So, the interviews were arranged, and prior to any meeting a checklist of topics that would be addressed was forwarded to the interviewees.

Due to budgetary restrictions it was not possible to run all the 6 interviews in person and one of the interviews had to be run on the telephone. The day after each interview, a letter was sent to the firm expressing our gratitude for their willingness to help with the research and for being able to set aside a period of time to be interviewed.

On average the interviews lasted 70 minutes each (ranging from 60 to 90 minutes). In order to ease the analysis of the responses the researcher asked each interviewee for authorisation to record the conversation, which was replied positively. Apart from the interview run on the telephone, that was not recorded, the recorded interviews were transcribed later on. As it was previously known that it would not be possible to record the phone interview, we arranged to conduct that only after we had run the others and had transcribed the material. This was so to minimise missing important information since we would have a better idea of the most relevant topics and we could take notes more appropriately. Finally, we carried out a content analysis, in which we identified substantive statements made by the interviewees and put them into categories. Our findings are presented in the next section.

4. THE DYNAMICS OF THE PATENTING PROCESS

This section is dedicated to highlight the findings provided by the semi-structured interviews, which outline to some extent the dynamics of the patenting process in 6 pharmaceutical firms. Firstly, we examine the reasons firms have to take out a patent and the effectiveness of the patent system. Secondly, we report what firms tend to patent and why. Thirdly, we address the timing firms choose to file patent applications. Finally, we point out where the firms interviewed apply for patents, and the reasons for that.

4.1. Reasons for obtaining patents

4.1.1. The excludability incentive

From the interviews there emerged many reasons for getting patents. The answers confirm, to a certain degree, what is found in the literature. The primary reason pointed out by the interviewees is the fundamental one: to stop other people copying their inventions for a limited period. That is, patents give some certainty for the product that is marketed, enabling firms to have some exclusivity in the marketplace.

The underlying argument to justify the seek of patent protection in the pharmaceutical industry is the long development time of a new product and its costs. The interviewees mentioned that the costs of researching and developing in the pharmaceutical industry are extremely high. Pharmaceuticals differ from other industries in which concerns the development time of a product because its core product is also subject to inspection by regulatory bodies. In order to get a drug on the market a company has to go through a number of years of expensive clinical trials, which are also risky. So, it tends to delay the time that a product is launched on the market and to raise the costs associated with that. By obtaining patents firms become able to get the premium price that covers the costs of the research, and the costs of all products that were never made in their pipeline.

Another justification presented was the characteristic of the core products of the pharmaceutical industry – drugs. As they are very specific in terms of the structure of the chemical compound, inventors can detect with more certainty whether any other drug falls within the scope of their patents. Thereby, it is relatively easy to detect infringements in pharmaceutical patents. Adding to that, according to the interviewees, the importance of patents in pharmaceuticals stems from the fact that their inventions once disclosed are simple to perform. Therefore, all the companies stated that the period of exclusivity which patents give is essential to help to recoup the huge amount of money spent on R&D.

Another aspect of excludability is the use of patents to try to undermine other companies technological path. The patentee may not for any reason be interested in marketing an invention protected by a patent but may be interested in keeping that patent in force. Despite the costs of maintaining a patent, the objective in doing so is that it may delay competitors movement in terms of access to the market. This bank of patents, which may include patents not used to protect a product that is being or is about to be commercialised, was observed mainly among the larger firms studied.

Smaller firms stated that they cannot give themselves that luxury because of their more limited funds to cover the costs of maintaining patents. Larger firms said they review their patent portfolio periodically to make an assessment of which patents should be kept in force, and which patents should elapse. Perhaps that is an assessment that all companies do but that seems to be harder for larger companies; not only because of their likely higher number of patents but also because of the existing blocking patents in their portfolio.

As suggested by the literature, it was detected that firms do not deal with patents in strict terms. As inventive activities and the protection associated with that may involve a huge financial commitment, it was observed that firms tend to spin out the benefits of patent protection to maximise as much as they can the use of patents. That leads to complementary incentives for seeking patent protection.

4.1.2. Complementary incentives

Alternative forms of using patents were also detected. Perhaps they are not the main reasons for a firm take out patents but they seem to extend the possibilities of using those legal rights granted by the government. They may contribute to encourage firms in using the patent system and they may compensate to a certain degree as to any deficiency the system may have. One of those complementary incentives detected was that patents can be used to secure royalty income. The possibility of out-licensing a technology is an issue that the companies interviewed definitely take into consideration. Although it was not detected among the firms studied any pattern of when to out-license[16], it was clear that to out-license a technology they need to have that technology protected by patents.

It seems that out-licensing is even more important for smaller companies because their existence might depend to a certain degree on their ability to convince other companies to in-license their technology. As it is necessary a huge investment to launch a new product on the market, smaller companies might not be able to cope alone with all the expenses. They tend to approach larger pharmaceutical companies in order to out-license their invention, which might not be completely successful at that time (e.g. still needing to go through clinical trials) but that might be a promising one. They said that if their inventions are not well protected by patents it is more unlikely that larger pharmaceutical companies will in-license them. If a patent is still pending it may be more difficult to persuade larger companies but it is still possible to reach an

[16] As technology transfer is not the objective of this study that issue was not dealt with more details.

agreement. However, if they have an invention that is neither patented nor has a patent application being prosecuted, they tend not to approach other companies. This is so not only because other companies are less likely to in-license their invention but also because they need to settle nondisclosure agreements, which were mentioned to be risky.

In case of larger companies, they stressed that their size enables them to operate worldwide and that might not be necessary to out-license a technology to other companies. If for any particular reason they are not able to have access to a certain market they can go for out-licensing since that procedure might enable them to maximise the use of a technology and, therefore, to increase the returns from R&D. Nevertheless, the requirement of a patent protected technology is still paramount. In this sense, suppliers may use patents as a marketing tool to build up a relationship with a potential receiver.

A close related activity to out-licensing was also mentioned by the company studied, that is, cross-licensing. One of the smallest companies also said that it may consider to put its intellectual property into joint-ventures. The possibility of settling cross-license agreements is also considered and patent, again, was said to be commonly used as an asset during the negotiation. Apart from one company, the remaining 5 companies mentioned that they had participated in cross-licensing. Perhaps that practice tends to happen amongst competitors because the parties involved can be dependent on each other. One of the interviewees said that a cross-license is usually an exercise where there are competing intellectual properties. Another one said that when they engage in cross-licensing there is an implication that they may not have total freedom to operate. However, the companies interviewed understand that sometimes it might be more likely to get faster to the target if they join forces rather than compete.

According to the interviewees the role played by patents in those agreements is not only as a single transactional element but also as an element that deserves in depth analysis. In this sense, if a company is willing to move forward and its movement infringes third party's patents two possible alternatives need to be analysed before going through cross-license agreements, or in-licensing. Firstly, an assessment of the third party's patent needs to be made in order to determine its strengths and its weaknesses. If it is realised that it is very weak, it can be attacked and challenged in court. Secondly, they said that it is important to analyse how much effort will be required to do something completely different to avoid third party's patents. If none of

these alternatives is feasible the option for either in-licensing or cross-licensing needs to be taken to remove that obstacle of not being able to move forward.

The interviewees were also asked whether patents used in out-licensing differ from those used in cross-licensing. According to them the difference is in terms of the prospects patents may bring to business, and not in terms of the strength of protection that a particular patent can provide. There does not seem to be a distinction of whether or not a patent is strong associated with the action taken. As mentioned above the receivers tend to require a strong patent protection for the technology that they are going to pay royalties.

Apart from one company, which is driven by a foundation, all other companies studied are publicly traded in the stock market. Two of them, the smallest ones, pointed out they also use not only patents but also intellectual property in general to try to give confidence to investors. To corroborate its argument one of them gave the researcher a report of its admission to the official list of the London Stock Exchange. In a report where nearly one third of its content is concerned with patents it seems in fact that the company tries to use patents to persuade investors.

It was also noticed amongst the companies studied that they tend to use patents to boost the morale of researchers. Due to the limitations of this research it was not possible to observe whether or not patents in fact play that role but the companies in the sample agreed that it helps as an incentive mechanism. None of the companies, however, reported that patents have a direct relationship with researchers' salaries. Patents seem to be one item amongst others to measure the performance of human resources. According to the interviewees there might be areas where it is easier to patent than others. Therefore, it may be unfair to deal with number of patents in strict terms since people who are placed in areas difficult to come up with something patentable will not benefit. Also, there are areas where the output of inventive activities will not be anything patentable at all. They also think that there is a broad range of things people can be measured on. The R&D personnel in particular can publish their inventions in academic journals; but in that case companies monitor the timing of the publication to avoid losing priority over the patent application.

It has been reported so far some reasons that may motivate firms to seek patent protection. It seems that the fundamental objective of the patent system of enabling firms to cope with the excludability problem is to some extent complemented.

4.1.3. The threshold of protection

The extent that patents are effective was also tackled during the interviews. According to the interviewees they cannot think of a situation where there is no patent protection and firms keep on investing massively in R&D. Nevertheless, they agreed that although patents are quite important in the pharmaceutical industry, its effectiveness depends a lot on the legal framework and on the subject matter that is patented.

The interviewees responded that it is pointless to pursue a patent protection if that patent cannot be stood in court. That situation can basically happen when i) a patent has weaknesses due to the lack of information to substantiate its scope, making it liable to be challenged by competitors, or ii) there is a weak legal framework in a particular country which restricts the extent that a patent can be enforced. Although the respondents agreed that the litigation process itself is uncertain, they complained that the usefulness of patents are somewhat limited in an environment where little can be done when a patent is infringed. Thereby, the jurisdiction where firms operate affects the effectiveness of patents. One of the interviewees said that although he believes that a patent stops other people from copying his company products, a patent is nothing more than a ticket to court. As such its effectiveness is reliant on the extent that it can be valid, and it is in fact valid only if a court determines so. Sometimes the court may not decide favourable to the plaintiff[17]. However, the respondents agreed that the feedback along the patent prosecution and the final decision of patent examiners are reasonable indicators of the validity of a patent – the more valid a patent is, the stronger it is.

Firms also stressed that sometimes a patent takes too much time to be issued. That may raise the uncertainty of the returns from a particular product. However, as observed previously, even if a patent is granted there is a certain degree of uncertainty associated with that.

Regarding the subject matter, it was reported that due to its specificity the core product (drugs) of the pharmaceutical industry is relatively easy to protect from copying. A firm can stop others from marketing exactly the same thing that it is selling because it is easy to detect once the copied product is launched on the market. Nevertheless, if a copied invention does not reach the market it may never be possible to the inventor to stop others from producing it. In general, inventors may be able to

[17] The one who blames someone else in court for infringing his/ her rights.

block competitors in terms of a specific product they are selling rather than a broader area of technology. There might be different ways of doing the same thing, or things closely related – 'relatives' as one of the interviewees said. In this sense, if other companies have the necessary capabilities to circumvent a patent, or a patent portfolio, they will also be able to get a share of the market. Thereby, it seems that in most cases patents can make things more difficult but cannot stop competition, which in fact is the objective of the patent system.

Adding to the effectiveness of patents, one has to bear in mind that there are costs associated with patent protection. Perhaps a company operating in just one country will not be impacted that much. However, that changes drastically for firms operating worldwide. Moreover, the number of products firms market is far from representing the number of patents in force. Although one of the products may pay all patent costs, a firm's return could be much higher if a patent portfolio was comprised only of patents directly related to the commercialised products. On the other hand, according to the interviews, if they do not have a consistent patent portfolio they will give more freedom to operate to their competitors and will not be able to recoup more effectively the returns from R&D. Although not all firms studied have a patent portfolio like that, especially the smallest firms, they generally have the international market as a target, which will request them to afford the respective costs.

The limited effectiveness of patents due to competitors capabilities of inventing around (or circumvent) and how firms attempt to overcome that will be, hopefully, better understood by addressing the main characteristics of what firms patent.

4.2. What firms aim to patent

4.2.1. The target category

When asked about the category of invention that their companies are interested in obtaining patents the interviewees said that the target is the product. A 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 (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 it to be administered in a particular way), and so on. Therefore, even if a product patent is the objective, its contents may vary from one company to

another. This is so because of the technology field firms operate, their different technical capabilities, and their business interest, which may lead to different subject matters claimed in patent applications.

Despite the interest of the sample in product patents (mainly comprising a substance or a composition) they also consider process patents and new use patents. The former refers to inventions which describe new ways of manufacturing a product regardless if the product is new. The latter is a patent related to a substance or a composition which did not have pharmaceutical use previously, or if it had a pharmaceutical use before it was for different purposes.

The interest lies in product patents because they tend to be more difficult to invent around, according to the interviews. For example, there might be alternative routes to come up with the same product and those routes are easier to get round than the product itself. If competitors develop new processes to manufacture the same patented product they will only be able to market the process itself and not the product, unless they pay royalties to the holder of the product patent. To develop and to market a new competing product competitors will need more resources (financial and time) than simply copying an invention. It, therefore, tends to delay competition and helps to appropriate the returns from innovation.

It seems that when a product refers to a pharmacologically active ingredient the excludability achieved is higher because that protects the product in any form, however it is made, or however it is formulated. The firms stated that whenever you have a particular formulation, or a particular process, then somebody else is more likely to do something differently. The difficulty and the high costs associated with the development of new drugs have been increasing the importance of drug delivery systems patents since those inventions may provide more effective ways for an existing drug to be released in the body.

According to the interviews, it seems that the basic premise of the pharmaceutical industry is that in order to get a reasonable return from the investment in R&D a monopoly provided by patents is necessary. The firms said that they are keen on patenting a broad range of almost anything surrounding a particular product, even if the invention is not within their core business (e.g. machines). However, the smallest firms tend to be more selective because of financial constraints. Also, firms tend to keep things secret (either by trade secrets or pure secrecy) when it is difficult to police the invention, such as processes and equipments. One of the interviewees also

described that there might be situations where know-how is outdated at a high rate. In those cases, it might not be worth to seek patent protection because there would be allocate resources to something that will not be of any value soon.

Based on what was reported by the sample studied, it appears that to enhance excludability firms attempt to patent not only the corresponding technology that leads to the commercialised product but also complementary technologies that may improve a product's performance or its differentiability.

4.2.2. The scope

Another issue addressed was the extent that the scope of a patent helps firms to recoup their investments in R&D. This is, perhaps, the other dimension of what is patented. It was seen in the literature review that firms are able, to a certain degree, to manipulate the breadth of a patent. That was confirmed by the firms studied. 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), any slight change in the conceptual invention will possibly give competitors the opportunity to access the market with a competing product. It might be the case that a slight modification will not result in a patentable invention (it may be deemed obvious, for example), but at least it will enable competitors to operate freely without infringing someone else's rights. In general, it was detected that firms seek protection not only for the marketed product itself, but also for as many embodiments of the invention as possible. By securing property rights on the various shadings of the invention firms are more likely to reach a higher degree of excludability. That may keep competitors away not only from the inventor's products but also from very closely related things that may enable competitors to launch a competing product in the marketplace.

Notwithstanding, one of the respondents said that one can do whatever he/ she wants with patents. When asked to explain what he meant by that he said that although the degree of excludability is more likely to be higher when broad patents are taken out, it does not necessarily mean that narrow patents are of less value. On average, he said, they may be of less value, and that is why firms seek a broad protection, but if, for example, a narrow patent embraces the lowest cost process it gives the patent holder a better position than his/ her competitors even that patent being narrow.

Two of the interviewees (one from a large company and the other from a small one) also said that they may opt for a narrow patent which covers an improvement of

other firms patents in order to induce a cross-licensing. Adding to that, they said that if competition is severe it might be better to have a narrow patent, which demands less time to gather the information to justify what is claimed, than to not have any patent at all because others filed patent applications before. In the UK, and many other countries, a patent application goes through a process of examination. That may restrict the scope of the patent and an originally broad patent application may become a narrow patent. In that case firms said that they need to make the judgement of whether or not the maintenance of the patent is worth. Although it may be usual to have objections made during the substantive examination of a patent application, interviewees said that they rarely have the scope of their patents severely restricted to the extent that they immediately drop a patent.

Although the broad patent seems to be the favourite amongst the firms studied they involve another risk, according to the interviewees. By their own nature, broad patents attempt to extend the coverage of the protection to each corner of the invention, and that obviously requires more resources. However, if proper attention is not drawn to the necessary resources that will extend the breadth of the patent, competitors may be able to easily bypass the patent, or, even worst, they may apply for a patent first. It implies that more resources were allocated to get a higher excludability but it was lost. Furthermore, a broad patent implies more risks than a narrow patent of having any part of it invalid. Firms said that instead of taking out a broad patent embracing as many embodiments of the invention as possible they may go for a number of narrow patents covering the same embodiments. They said that they tend to do that when they think that there is a high risk of having any part of the broad patent deemed invalid by the patent examiner. It seems that there is always a balance to be struck between the degree of excludability sought and the risks associated with that.

According to the interviewees, if someone comes up with an invention which is something breakthrough that will possibly serve as a platform technology for others, the benefits of patents are higher. If a company is able to be ahead of its competitors it may try to patent not just their products but the whole field around them. So patents can fence-in a whole area from other companies. In doing so the inventor will push the barrier further; and the hurdle will be higher for competitors to surpass. Perhaps, that is the case when there is an emerging technology which is not close to the prior art. As in that case the R&D direction and the economic importance of the scope of a patent are still uncertain, what is commonly observed is the ‘flooding’ (or ‘blanketing’) of a technology field with patents. One of the interviewees said that blocking a technology

field, and the 'flooding' phenomena, is more likely to happen amongst biotech firms. However, all firms, including those more biotech oriented, said that it is very unlikely that taking out patents will block competition at all.

It was also a common view among the respondents that they seek excludability not only based in a single patent but also based on a whole portfolio of patents, which comprises both narrow and broad patents that combined enable them to fence-in the market for its products. According to the responses, the firms studied aim to patent anything that they judge that may stop them moving forward freely. For example, although a firm's the technological path may affect the subject matter that it patents, and its possible variations, if there is any other technology or, in particular, a product, which is perceived to create a dependency on other firms they may try to take out patents on it. 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. The control of those complementary technologies was less emphasised by the two smallest firms, perhaps because of their more limited resources.

4.3. The timing of filing patent applications

As a starting point for our account we are going to describe, with the support of the Figure 1, how a typical route of drug discovery looks like. Although the picture is not clear neither about the cumulative expenses made along the R&D process nor about the duration of each stage, it helps to point out the main phases of that route and to highlight when patent applications start to be filed.

Briefly, research and development activities may last several years before a product is first launched on the market (perhaps an average of 12 years), and pharmaceutical companies' objective is to discover compounds with therapeutic effects. The empirical phase starts with the identification of targets – the point where therapeutic agents should intervene in order to fight against a disease. Then, they run high throughput screening search, at which 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 aiming at changing the structure of those compounds to optimise their activity (lead optimisation). Then, if that is successful they will get a candidate drug which will go to the longest and most expensive stage, the development one. This is so because pharmaceuticals are also regulated by health authorities which issue licences,

according to the results achieved in the clinical trials, for pharmaceutical products to be marketed.

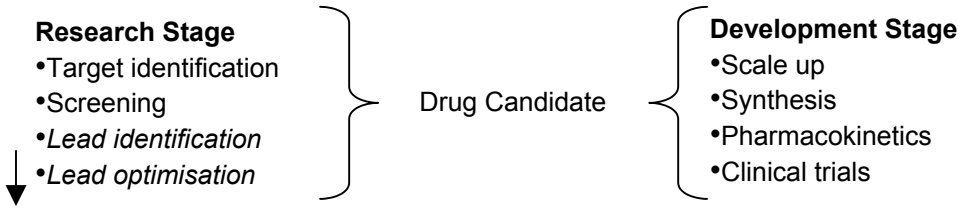

Figure 1 – Simplified model of a route of drug discovery

A typical response was that firms tend to start to apply for patents as soon as they have any promising compound (*italics* in the model above). As observed in the Figure 1, it means that patent applications start to be filed just after the screening phase, that is, after the lead identification and during the lead optimisation. At that point, according to the interviews, they have only made use of 10 – 20% of the resources necessary to bring a product to the market. That corroborates the idea that patents are applied for at the very beginning of the research and development. However, it is worthy noting that in other industries the development time of a new product is much shorter than that and that event might not happen at that point.

Filing a patent application early means that firms cannot have a clear picture of whether or not the final product, the one launched onto the market, will be exactly the same as the one first identified. Also, according to the interviews, they do not know even whether the product will be launched since it has not passed through clinical trials. That may impact on the way firms apply for patents because they need to assure that the characteristics of the final product that reaches the market will be within the scope of the patent they applied for.

One may raise the question of why firms do not wait until a more concrete form of the invention is reached. As we observed in the literature review, the filing of a patent application does not imply that a patent will be granted. It will happen only if the application fulfils the requirements necessary for a patent to be issued. If a patent application is not claiming something new (not publicly disclosed before the priority date) it will not become a patent. Also, and perhaps much more difficult to predict, if someone else filed a patent application before and it has not been published yet, any further patent application will not be able to claim any part of that prior application. This is so because there must exist just one patent issued on each invention and, apart from the US, all other countries use the first priority date to determine who is going to get the

property rights. Competition, therefore, seems to impact on the moment firms apply for patents. That was confirmed by the interviewees, who said that competition is severe within the pharmaceutical industry and it is paramount to apply for patents before someone else does. Quoting one of the interviewees to explain why firms tend to rush to file patent applications as opposed to wait longer:

> *'We work in competitive markets. It is very important to get a patent and then establish our flag on the ground, because if we don't we are in trouble'.*

Filing a patent application, however, does not imply that the expected excludability will be obtained. This is so not only because someone else may have filed earlier an application on a similar invention, but also because patent applications are examined by patent examiners along the prosecution and they may oppose to the scope of the invention claimed. Although firms stress that they generally have to apply for a patent as soon as possible to avoid forfeiting property rights, they wish they could do it later when they had more certainty on whether or not it is worth to get a patent over that particular invention. That certainty gets higher and higher to the extent that a candidate drug goes through clinical trials, though it does not say anything about its success in the market. But, when the candidate drug reaches the clinical trials stage the invention becomes publicly available and it would not be liable to patent protection anymore.

Although there exists situations that firms may decide to keep things secret, if an invention is concerned with a therapeutic agent, most of the times a patent application is filed, according to the respondents. Firms tend to judge whether or not the information they have got is enough to apply for a patent, and whether or not the benefits of patent protection justify the costs that they will incur. As it was pointed out above, the first patent application is typically filed when firms have no certainty about the success of the invention. Sometimes, they do not even have all the results necessary to substantiate their claims, but the pressure to file is very high, and then firms reported that they may take some actions when filing patent applications.

The own nature of the patenting process is risky, but what we came across in doing this investigation is that there seems to have alternatives which may help at least to partially reduce the uncertainty embedded in that process. One possible alternative is to file follow up patent applications. According to the interviewees it is very unlikely that just one patent will be issued due to the outcomes of R&D that will lead to a new product. As described in the section about what firms patent, there might exist

variations of the invention that need to be protected as well in order to get higher excludability. Also, all respondents emphasised that R&D is an ongoing process and there is always new results coming out, which will be analysed as to their patentability. Thereby, even after a patent application is first filed there might appear new results that are also liable to patent protection. In doing so firms will end up with a patent portfolio, which is more likely to give exclusive rights around their products than a single patent. Nevertheless, it all depends on what results come out from R&D and on what other firms are doing.

Depending on the moment those results appear they may be incorporated in the first patent application. Firms pointed out that they make use of internal priority whenever possible. That is, they file a first patent application, but within 12 months from the priority date they file new applications claiming priority over the first one. That occurs if the new outcomes of R&D are deemed to be important to be specified in a patent application since those outcomes will enable the applicant to better substantiate what is claimed. Thereby, a stronger patent[18] will be more likely to be achieved.

They 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 one. That is a judgement on whether or not those 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 patent applications before them. When the new output is going to provide only small differences between the first filing and the following filings and/ or when the perceived competition is very high, it is more likely that firms keep things together, that is, use internal priority.

The continuous character of R&D implies that the boundaries of the invention are likely to be expanded after a first patent application is filed, and if a patent is also taken out on that, a higher excludability might be achieved because possible variations (embodiments) of the invention would be protected as well. However, not all results from further experimentation come out within that 12 months period and, therefore, priority over the first patent application cannot 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 by the patent examiner and, therefore, a patent would not be issued on that. However, it was pointed out that if those new results come out before a patent application is published (at most within 18 months from priority date) the risks of that filing being opposed as to the inventive step

are low (not taking into account what someone else is doing). That happens because the former application has not been published yet and, therefore, the latter does not have to be inventive over something that was not in the public domain. However, when the first filing is published (generally after 18 months from priority date) any results that come out and lead to new patent applications have to meet all the requirements of novelty, nonobviousness and industrial applicability; the advantage regarding the inventive step is gone. Using the respondents words:

> *'So, if you have a lot of smaller variations then you should do those before the first one publishes'.*
>
> *'(…) 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] *publishes if you then file them* [follow up applications]*, they have to be new and inventive'.*

Firms also said that, although it is not a usual route, they can file more than one patent application at the same time comprising variations of the same invention; some of them with a narrow scope and others with a broader one. 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 are relied upon the results obtained up to that point whereas broad filings are relied upon inventors expertise as to the extent that an invention can be broadened in the near future; they 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 keep the broader one. Likewise, if the results are not enough to support the broad application it can be dropped and the narrow one is kept.

According to the interviews, it seems that to build a high excludability in the marketplace also depends on the extent that several parts of the invention are protected by patents. Although the nucleus of the invention is the therapeutic agent, if there are ways to formulate the product, more effective forms of releasing the active ingredient in the organism, or even other utilisation for the product and they are also in a company's patent portfolio that company has more freedom to operate and more power to block others in coming up with a competing products. In this sense, although most of the time we were referring to product patents that regard the therapeutic agent, other sort of patents may also be applied for. In general, they appear later in the route

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

of drug discovery and even after a product is launched on the market, which in this case may can lead to new generations of the product.

In what concerns patents, one has also to bear in mind that a higher excludability is achieved not only by fencing in products with a patent portfolio but also by getting a longer term of protection. That is another reason why the timing of applying for a patent is so important. When a patent is first filed (priority date) patentees have from that moment to the end of the term of the corresponding patent to exercise rights over their inventions. If a company made huge investments to bring a product to the market but it has passed, for example, 10 years from the priority date, the company will only be able to effectively exercise exclusive rights for the remaining 10 years (keeping constant a patent term of 20 years). In other words, a company will have much less time to reap the financial returns from the product than patents are expected to give because the factual patent term is shorter than the theoretical one. As after the end of term of protection anyone else is free to perform the same invention and commercialise it, it is very likely that it will lead to a sharp fall in a company's sales. To partially overcome that problem the interviewees said that whenever possible they apply for a Supplemental Protection Certificate[19] (SPC). However, that certificate is of limited scope since it only covers the marketed product which regulatory approval had been obtained.

Follow up patent applications have a higher risk of being objected by the patent examiner as to either the novelty or the nonobviousness requirement, and of not being granted because others filed patent applications in between. However, if resulting in a patent, they might be useful, according to the respondents, to 'extend' the term of protection of the first patent, especially if they were the output of applications made up to 18 months from priority date. As we observed before, those patent applications do not have to be inventive over an application that has not been published yet. As those subsequent applications are supposed to be an 'improved version' of the first filing, it will partially incorporate the subject matter of the first filing plus something new that will enable the patentee to get property rights. Therefore, when a product is launched it is likely that it will have incorporated those improvements as well. Thereby, when a patent based on the first filing expires the follow up patents will be still in force. If someone else comes up with a product based on the first filing it may infringe the follow up patents. Furthermore, even if the new product does not infringe the follow up

[19] 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

patents, the competing product will not be as good as the one launched formerly and will not impact on a firm's sales as if there was no follow up patents in force. The company, therefore, achieved a bit 'longer' patent life (up to 18 months) which results in more financial returns that depending on the product can be very substantial.

Other important moments that firms need to draw attention along the patenting process are those regarding international filings. However, they are better understood when described in a properly context. The remaining paragraphs of this section account for where firms apply for patents, and hopefully they will complement the issue of the timeline for patent applications.

4.4. Where to take out patents

One of the interesting issues that we came across when it comes down to where firms seek patent protection is the location of the firms' internal patent attorneys. Apart from the two smallest companies which do not have that expertise in house, firms appeared to have internal patent attorneys spread not only according to the location of R&D[20] but also according to historical reasons. Half of the sample had been taken by mergers in recent years and the location of their patent attorneys has been somewhat impacted by that. Adding to that, the firms said that when they need to go abroad they have a network of patent attorneys which gives support along the prosecution stage. In case of infringement, they tend to contract the services of litigation specialists since it is not worth to sustain an expertise to deal with an activity that is just sporadic.

All of the companies studied appeared to have an outlook of the international market, regardless of their size. No single company interviewed mentioned that it just applies for patents to the UK Patent Office, though it can be the case when firms are willing a quicker granting for any special reason, such as infringement. Even smaller companies, which are more likely to have limitations to cope with costs related to the patenting process, do regard patents at the international level. Although their operational basis are restricted to the UK, the aim to out-license their technology to large pharmaceutical companies implies that the resulting products will be ultimately marketed worldwide and, therefore, patent protection is necessary in the main international markets.

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which has to undergo an administrative authorisation procedure required by law before it is put on the market.

[20] Four of the companies reported to have R&D units abroad.

There was a common response among the firms studied as to where patents should be got. All six companies agreed that the US, Europe (Western) and Japan are the main territories where they should seek patent protection. The rationale behind that is that those markets are the largest markets for pharmaceuticals. Therefore, taking out patents in those territories will enable the firms to stop anyone else from marketing their products without their authorisation. An activity that, if performed by someone else, would hamper firms to appropriate the potential returns on the invention; especially because those territories are the largest markets.

The interest in those markets does not mean that the firms studied do not go for patents in other territories. According to the interviewees, depending on the perceived impact of the invention on their businesses they can go beyond those major markets. Based on the responses it seems that the more important an invention is, the more widely it is protected. An example was given by one of the companies which said that they have been working on drugs for the treatment of the HIV virus, and as such they tried to cover all countries in the world.

Apart from the size of the market, another reason for the choice of the country where patent protection is sought is the extent that firms can enforce their property rights. Again, US, Western Europe and Japan are cited as examples of places where the legal frameworks are consistent and have the appropriate expertise to judge in case of litigation. Moreover, their patent offices are more skilful to deal with patent issues and with the operational procedure. Smaller pharmaceutical firms responded in quite the same way. Thereby, when firms choose the international route they take into account, the size of the market, the quality of protection, the perceived importance of the invention for their business, and, of course, the costs associated with that. In general, what they reported is that they have a pre-determined list of countries likely to be filed in but that, according mainly to the market size, can be reduced.

Another interesting aspect pointed out was whether or not potential competitors are present in the market. That aspect impacts on the choice of where to take out patents because a firm could come up with follow up patent applications and drop the former application since the follow up applications were an improved form of the invention. That procedure could save lots of money for the firms. However, if an application is dropped, as opposed to be progressed, a patent will never be issued and it may give competitors some freedom to operate.

As we observed in the previous sub-section, the time that firms first apply for patents (so called priority filing) is somewhat dependent on the information available about both the invention and competitors. Then, when firms decide that a patent application will be filed another aspect has to be analysed, and this is whether or not the invention must be first filed locally before it is filed in other countries. This is the particular case of the UK. However, it does not mean that all the companies' patent applications will be first filed in the UK since some of the firms have R&D units abroad and they need to follow local rules.

According to the respondents the favourite route to file abroad is through the Patent Co-operation Treaty; though attention is also drawn to the European Patent Office (EPO) and to the Paris Convention. In specific, when the route chosen is to go straight to other countries patent offices as opposed to the PCT, firms reported that they need to pay attention whether or not the country is 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 outside one's home country within 12 months form priority date. Similarly to the internal priority in the UK, any improvement can be incorporated in a patent application within that period or the applicant may decide not to go abroad anymore. If the country is not a Convention country, the firms aim 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.

If the firms are interested just in the European market they tend to use the European Patent Office (EPO) route. However, if the markets aimed do not justify the costs of the former 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 times that is the usual route that firms follow. As there are also costs associated with the number of countries a firm applies for, the PCT may be a great advantage since it might be cheaper than filing in each of the target countries (as the EPO route it all depends on the number of countries designated). Adding to that, and matching what theory says, the main advantages of the PCT were pointed out as: i) firms can delay the bulk of the costs that comes out when the application goes to the national phase, ii) they can have a better idea of the invention before incur in those costs, and iii) they have both a search and a preliminary examination report that gives a fair idea about the patentability of the invention before the costs of the national phase. The delay of the costs as well as

having more information about the invention was always mentioned. As expected, a list of designated countries is filed on application but can be dropped later on. It means that a firm has up to 30 months from priority date, and therefore has a better idea of the potential commercial value of the invention, to elect the countries which are thought of being important.

The timeline of patent filings is also attached to where firms will apply for a patent since the excludability sought may be drastically impacted. Where firms register their patents is also an important issue to take into account when deciding the degree of excludability that will be sought. Patent in everywhere may seem the best way to get the highest excludability. However, as not all patents are of high commercial importance the costs of the patenting process may not justify the benefits of the protection achieved.

5. CONCLUDING REMARKS

Based upon the information gathered it seems that some dimensions of the patenting process examined here, namely the decisions along that timeline on what is patented and where to patent, are quite useful to portrait how firms use that process to build excludability in the marketplace.

Our results suggests that a higher excludability is achieved when firms are able to incorporate a higher number of embodiments of an invention in a patent, conditional to be well supported by the information disclosed. Also, the extent that firms take out patents on complementary technologies they are less likely to depend on anyone else, and the release of a competing product in the market seems to be more difficult for competitors because they will have to circumvent a whole portfolio of patents. However, the effectiveness of patents appears to be limited to the extent that other firms are able to use their technical competencies to engineer around and to come up with a competing invention.

We also observed that careful attention has to be drawn to the timing that a firm applies for patents, especially if the competition is severe. As an ongoing process R&D may supply further results that are likely to increase the strength of a patent or to generate new patents, which will enable a firm to get a higher excludability in the marketplace. Moreover, our analysis suggests that, as private goods, patents can be used to bargain in the marketplace and, therefore, to increase the returns to innovation.

In particular, if a company is able to take out patents in the major markets for its products, for which the Patent Co-operation Treaty (PCT) route may be quite useful.

As expected, firms pursue patent protection not just to stop others from copying their inventions. Patents can be involved in a range of activities that directly, or indirectly, will impact on a firm's performance.

As our results are the views of six firms we understand that it might be difficult to generalise. Therefore, our next research will be a large-scale postal survey, which will identify the occurrence of those events in the UK manufacturing industry. Adding to that, we are going to examine the Community Innovation Survey (CIS) data regarding patents. In doing so we hope to have a broader view of how UK firms use patents.

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