NEW ZEALAND INSTITUTE OF PATENT ATTORNEYS INC (NZIPA)

Response by NZIPA to the Joint Study-Discussion Paper released by The Productivity Commissions of Australia and New Zealand entitled "Strengthening economic relations between Australia and New Zealand"

17 October 2012

Further submission by the New Zealand Institute of Patent Attorneys Inc

We refer to our submission on the Issues Paper released by The Productivity Commissions of Australia and New Zealand entitled "Strengthening economic relations between Australia and New Zealand" dated 31 May 2012.

Following a review of the submissions made on the Issues Paper, the Commissions have released a draft Joint Study - Discussion Paper.

We comment now on that Discussion Paper.

Our comments are directed primarily to the question raised under Q4.1.

Would a single application process affect the rate of patent filing in Australia and New Zealand?

The proposed change involves two aspects that may influence patent filing in New Zealand by foreign applicants: a reduction in cost, and a streamlining of process.

Parallel with states joining European Patent Convention

Conclusions may be drawn from analysis of patent filing data in Europe. When a country joins the European patent convention (EPC) they move from a system with a single route for obtaining a national patent, to a system with two routes:

- a national patent application with the national patent office or
- a European patent application filed with the European Patent Office (EPO).

A European application is a two stage process. The application is filed and processed through the EPO. The application designates certain states in which the applicant intends to eventually proceed with patent protection. Fee structures mean that it is common to designate all states at this stage. Once the EPO grants the European patent application, the applicant "validates" the application in each country they wish to continue with patent protection, and subsequently pays renewal fees as long as they wish to keep the validated patent in force.

Although the EPC has been established for more than 40 years, additional countries continue to join the EPC. A country does not need to be part of the European Union to join the EPC. For these new EPC countries data is available on the following:

- the number of national patent filings before accession
- the number of national patent filings after accession
- the number of EPC filings that designate the country after accession
- the number of EPC filings that eventually validate in the country.

A foreign applicant for a patent in a newly joining country is already filing an EPC application in a very high percentage of cases. After accession, foreign applicants overwhelmingly switch to obtaining patents in the country through the EPC system – for administrative simplicity and moderate cost savings.

A country joining the EPC has a strong parallel with the proposed single application process for patents. In particular, a foreign applicant filing in New Zealand is already filing in Australia in a very high percentage of cases, and the proposed portal offers foreign applicants a streamlining of process and a reduction in cost, similar to that offered by the EPC system.

We have located one study regarding the impact on patent filing in countries that accede to the EPC. In *The impact of joining the regional European Patent Convention System* (see *attached*) Hall and Helmers analyse the impact of accession to the EPC on 14 countries that acceded between 2000 and 2008. The find "*a strong change in the filing behaviour among foreigners seeking patent protection in the accession states, substituting domestic patents with EPO patents, mostly in chemical and pharmaceuticals*".

The EPC states studied in the quantitative analysis were restricted to those that acceded between 2000 and 2007. These were Turkey, Bulgaria, Czech Republic, Estonia, Slovakia, Slovenia, Hungary, Romania, Poland, Iceland, Lithuania, Latvia and Malta. Unfortunately the data is presented in the study in aggregate, so it is not possible for us to specifically extract data for countries that are more like New Zealand.

However, considering this group in aggregate against the pre-existing EPC group that they joined (Belgium, France, Germany, Luxembourg, Netherlands, Switzerland, United Kingdom, Sweden, Italy, Austria, Liechtenstein, Greece, Spain, Denmark, Monaco, Portugal, Ireland, Finland and Cyprus), the situation is not unlike New Zealand joining with Australia.

For example, in *Patent Filing Strategies for Pharmaceutical Products: A simple cost benefit analysis based on filing costs and pharmaceutical sales* (AIPLA 2005; Vol 33 Number 2 at page 153 - see *attached*) the authors provide (Table 3, at page 171) an aggregate Return Value Score (normalised) for the pre-existing EPC states of 574.8, compared with 79.6 for the accession states (excluding Romania and Iceland which do not appear in the study). In the same study (Table 2, at page 162) Australia has a Return Value Score (normalised) of 40.7 compared with 7.3 for New Zealand. This is a particularly relevant measure as the pharmaceutical industry are the most prolific users of the patent system in fringe countries (such as New Zealand).

Impact on number of patents granted in new EPC states

In Figure 3, you can find that in the combined dataset for these countries the number of patent filings by non-residents per quarter was about 4500 immediately prior to accession. After accession, national filings by non-residents dropped by nearly 70% immediately on accession and continued to decline over time. This is offset by an increase in national patents obtained through the EPC. This data is presented at Figure 5. Because the national patent through the EPC is only obtained post grant the dataset only includes granted EP patent applications, but the dates in the dataset are based on the filing date of the patent applications.

The EPO process can take many years (even 10 years or more), so many applications filed are not granted within the timeframe of the dataset. This shows (misleadingly)as a declining number of EPC filings and a declining number of EPC designations of the accession states. There are a corresponding increasing number of patent applications that are still pending at the EPO, and which would appear in the graphed data once they are granted. This is solely an effect of the way the data is processed, and is explained at page 14 of the paper.

In reality the number of EPC filings over this period increased steadily and the number of validations would also be increasing steadily. However, in the graphed data the number of validations in the accession states is stable, which implies that over time a larger share of designated patents is eventually also validated in the accession countries. In the long run (as more of the patents filed in the period after accession are granted) the numbers of patents validated would increase. Reading from the scale on the graph it appears that, even at the time of the study, validations of EPC patents by non-residents, in the accession states, were above 11,000 per quarter.

Therefore, using the data presented in this paper we see that for these combined group of accession states, national patent filings per quarter declined from 4500 to about 1500 immediately after joining the EPC and to about 600 after 2.5 years. These are applications filed, and numbers actually granted may be substantially lower than the applications filed. For example, in New Zealand we understand that a significant number of patent applications that are filed by foreign applicants do not proceed to grant.

Even from those EPC patents that were granted by the time the study was conducted, the aggregate patent validation in the accession countries amounted to more than 11,000 per quarter. The nett result on patent coverage in the accession countries of the study is an increase from less than 4500 to at least 11500 patents per quarter.

In addition, at least 60% of all EPC applications immediately designate the accession country, and impose a spectre of patent coverage while they are pending.

Conclusion: single filing portal may lead to at least 100% more foreign owned patents in New Zealand

The conditions of the studied accession states joining the EPC are similar to New Zealand agreeing a single patent filing system with Australia. So we could expect a similar experience to these accession states – an increase of greater than 100% in the number of patents granted in New Zealand. There may also be a pool of applications that "tick the New Zealand box" and provide a spectre of protection, but which are not eventually pursued.

Greater cost to establish freedom to operate

The cost of establishing the freedom to operate for a new product, process or method is typically proportional to the volume of patents covering the field of technology. No review can be considered definitive, so most FTO reviews are conducted within a budget and with a desired degree of confidence in mind.

A typical review includes combinations of keyword, subject classification and proprietor searching, followed by increasingly deep iterative reviews of the patents and patent applications located. Each document must be individually reviewed, at least at a high level, and more relevant documents may need detailed consideration.

Any increase in patents filed (in a country) will increase the number of documents that must be considered in an FTO review – the technology field is the same, it is just more densely covered by potential patent traps.

A survey of large New Zealand export manufacturers of innovative products with a primary focus on USA would likely reveal that more money is spent researching the ability of an enterprise to operate in a particular filed than is spent obtaining patent protection for the innovations involved. It would also reveal that patent freedom to operate is considered a key business risk. For these businesses, the opportunity afforded by the USA market is sufficient to justify this cost and risk.

For a small market such as New Zealand, any increase in freedom to operate costs or risk must pose a substantial barrier.

The Sapere report

We referred in our initial submissions to the report commissioned by the then Ministry of Economic Development by the Sapere Research Group into Trans-Tasman harmonisation of intellectual property law regimes.

The analysis undertaken by Sapere confirmed that there is a very low economic benefit to be achieved from the joint filing portal proposal.

For further information, please contact

The Secretary
NZIPA
P O Box 5116
Wellington

Email: secretary@nzipa.org.nz

The impact of joining the regional European Patent Convention system*

Bronwyn Hall[1]

Christian Helmers[2]

Revised Version

July 2012

Abstract:

We analyze the impact of accession to the regional patent system established by the European Patent Convention (EPC) on 14 countries that acceded between 2000 and 2008. We look at changes in patenting behavior by domestic and foreign applicants at the national patent offices, the European Patent Office (EPO) as well as the World Intellectual Property Organization (WIPO). Our findings suggest a strong change in patent filing behavior among foreigners seeking patent protection in the accession states, substituting domestic patents with EPO patents, mostly in chemicals and pharmaceuticals. At the same time, there is no discernible reaction among domestic entities in terms of domestic filings. Yet, we find some indicative evidence at the firm-level that manufacturing companies in accession states increased their propensity to file patents with the EPO post-accession.

Key words: European Patent Convention, accession, patents

JEL code: F53, O34

* We gratefully acknowledge financial support from the European Patent Office (EPO) and comments from Nikolaus Thumm. The views expressed here are those of the authors. They are not necessarily those of the European Patent Office.

[1] University of California at Berkeley and University of Maastricht; bhhall@econ.berkeley.edu

[2] Universidad Carlos III Madrid and SERC LSE; christian.helmers@uc3m.es

1. Introduction

The well-documented growth in worldwide patenting, coupled with economic growth in many formerly less-developed countries, raises questions about whether it is cost-effective for firms and countries to rely on national patent systems to protect inventions when these inventions are exploited internationally. Fink et al. (2010) show that much of the recent growth in patent applications is largely accounted for by an increase in the number of offices at which protection is sought for the same invention. In fact, as a response to this growth, the larger patent offices (the USPTO, EPO, and JPO) have begun to explore work-sharing in search and examination. But a situation in which every country operates its own patent system is still the norm, even though this leads to a great deal of duplicated work around the world.

In this context it is natural to ask what happens when a country joins a regional patent system. What effect does this step have on patenting by its residents at the national and regional level? What effect does this have on innovation and firm performance in the country? Finally, does the impact on residents and non-residents of an accession country differ? These are the questions this paper is designed to answer using data on patenting for a set of 14 countries that joined the European Patent Convention (EPC) between 2000 and 2008, to explore the impact of the accession on patenting behavior by firms in those countries. The EPC offers an interesting setting between 2000 and 2008 to study these questions because a number of transition economies that are still characterized by relatively weak economic and technological development joined the EPC regional patent system that is mainly composed of more advanced EU countries. We expect that the results obtained here will provide some insight into the impact of such regional patent systems on developing countries in the rest of the world.

The European Patent Office (EPO) offers a regional patent system through the EPC. This system provides a single procedure to obtain patent protection in any country signatory to the EPC and so-called extension states (Article 64(1) EPC). While a patent application is fully examined and granted by the EPO, it has to be validated and maintained in force in each designated signatory state. The validated patent is subject to the same national regulations as patents granted directly by the national patent office.[3] This means that the EPC route offers an alternative to filing for patent protection directly with national patent offices that are part of the EPC, that is both systems co-exist and applicants can choose between filing for an EPO or national patent.[4] Since its coming into force in 1977, the number of signatory states has grown from seven to 38 (as of October 2011) covering a wide range of countries including large former Eastern bloc economies such as Poland and Hungary, wealthy Scandinavian countries such as Norway, as well as transition economies that are not part of the European Union such as Turkey.[5] The

[3] While the EPO deals with complaints and opposition, validity and infringement are dealt with exclusively by national courts in the same way as for patents filed directly with the national patent office.

[4] Applicants can also choose to apply for a patent through the so-called Patent Cooperation Treaty (PCT) route, which offers a way for an applicant to obtain patent protection in several countries worldwide through a single application in the same way as if the applicant had filed separate applications in all countries. While the application is filed with WIPO, the decision of whether the patent will be granted remains with the national patent authorities.

[5] Countries have joined the EPC either through accession to the EPC system or an extension agreement (that eventually resulted in accession). While being a member of the European Union (EU) is not a condition for joining the EPC, being an EU member requires eventually joining the EPC. This means that the set of countries that joined the EPC since 1977 comprises mostly countries that have joined the EU,

differences in economic development across these countries on the one hand and the uniformity of the patent system adopted by joining the EPC make the study of the accession of this set of countries particularly interesting also with a view to understanding the impact of a strengthening of the patent system on innovation and technology transfer for economies at different stages of economic development.

Joining the EPC imposes a uniform patent system on all member and extension states which potentially has two main effects on the country joining. First, it becomes cheaper for residents to simultaneously obtain patent protection both domestically and the countries signatory to the EPC. Second, it also becomes cheaper for foreigners to obtain patent protection in the country as they can validate an EPO patent in the country instead of filing a separate patent application with the national office of the country. This implies that on the one hand, it becomes cheaper for domestic firms to obtain simultaneously patent protection at home and abroad, and on the other, it becomes cheaper for foreign firms to obtain patent protection in the country provided they obtain patent protection in another country signatory to the EPC. Thus the effect of joining the EPC is to harmonize and simplify administrative procedures of obtaining patent protection in the regional system. Joining the EPC, therefore, effectively represents a strengthening of patent protection within the EPC because obtaining international patent protection is facilitated by the regional EPC system. In addition, a substantial share of the work burden associated with the filing and examination of patents is shifted from national offices to the EPO, which may have implications on patent prosecution, such as the speed of examination and hence backlogs (this is an aspect of accession that we do not investigate here).[6]

This suggests that one might observe the following effects in terms of patenting behavior: (a) domestic entities file fewer patent applications with the national office and more with the EPO which are eventually validated domestically, (b) more domestic entities obtain patent protection domestically because of the possibility to validate an EPO patent domestically, (c) fewer foreign entities apply for patent protection with the national office and validate instead an EPO patent, (d) more foreign entities obtain patent protection in the country by validating the EPO patent in the country. This means there could be changes in patenting behavior at the intensive as well as extensive margin, i.e., more filings by entities that have been patenting previously with the national office and more entities obtaining patent protection also domestically (through the EPO). The latter effect could arise as firms, prior to accession, may have obtained patent protection only in major European markets, such as Germany, but not domestically as the costs of obtaining protection through a separate domestic patent outweighed the potential benefits. This is more likely to be the case for smaller economies that joined the EPC, such as Slovenia or Slovakia. Following accession, firms obtain an EPO patent which they can validate both in their major European markets of interest as well as domestically.

---

but nevertheless also contains countries that are not (yet) members of the EU, such as Iceland, Norway, or Turkey. For a complete list of member states see http://www.epo.org/about-us/organisation/member-states.html

[6] It may also have implications for national patent office budgets, due to the change in both fee levels and their allocation between national offices and the EPO.

Our objective is to analyze the presence and impact of these effects on 14 countries that joined the European Patent Convention (EPC) between 2000 and 2008.[7] The list of countries is shown in Appendix Table A1. Note that 2005 GDP per capita averaged US$33,800 in those countries that joined before 2000, whereas it averaged US$18,700 in those countries that joined between 2000 and 2008. Our analysis, therefore, provides empirical evidence on the impact of the harmonization of patent systems on countries that join an existing regional patent system as well as the impact of a strengthening of the system (in transition economies) on patenting and (potentially) on innovation.

From a policy point of view, our analysis may also provide lessons for the potential impact of the unitary European patent. Under the current proposal for a unitary patent,[8] validation of the EPO patent in a national office is no longer required for the patent to enter into force. This may lead to a sudden and persistent increase in the number of valid EPO patents in countries that so far recorded few validations of EPO patents. Given the expected costs savings in obtaining patent protection across several European countries if the unitary patent were to be implemented, the effect may materialize in a similar way to what occurred after accession to the EPC.

The remainder of this paper is organized as follows. Section 2 reviews the existing literature on the impact of patent strength and harmonization of patent systems on countries' innovative activity and patenting. Section 3 describes the data used in our analysis. Section 4 discusses the changes in patent filing behavior brought about by accession to the EPC. Section 5 contains our descriptive analysis of patent filings. Section 6 presents the results from a firm-level analysis and Section 7 concludes.

2. Literature

To date there is no systematic evaluation of the economic impact of joining the regional EPC patent system by either becoming a signatory state to the EPC or an extension agreement. Similarly, there is no research on the impact of joining the Patent Cooperation Treaty (PCT), which represents another important international treaty that harmonizes procedures to obtain patent protection.[9] However, there exist a number of empirical studies that analyze the impact of the availability and strength of patent protection on innovation which we review in this section.

In this literature, there are two types of analyses. The first type seeks to understand the determinants of patent strength whereas the second type analyzes the impact of patent strength on innovation. With regard to our study on the EPC, the former type of analysis is related to the question of why countries choose to join the EPC whereas the second type relates to the impact

[7] The countries are: Bulgaria, Czech Republic, Estonia, Croatia, Hungary, Lithuania, Latvia, Iceland, Norway, Poland, Romania, Slovenia, Slovakia, Turkey.

[8] http://register.consilium.europa.eu/pdf/en/11/st11/st11328.en11.pdf

[9] The PCT, which was signed in 1970, provides a uniform filing procedure for patents in all 174 signatory states (as of February 2012). While the PCT system unifies at an international level the filing of patents and the provision or search reports, the examination of patents is still done by the designated national offices. In this sense, the EPC system provides a much more harmonized patent system than the PCT.

that a change/strengthening of the patent system has on domestic innovation and economic performance.

Ginarte and Park (1997) investigate the determinants of the strength of patent protection in 48 countries over the period 1965-1990. They measure patent strength by constructing an index based on national patent laws capturing the following dimensions of statutory patent protection: (a) extent of coverage of patent protection, b) membership in international patent agreements, c) provisions for loss of protection, d) enforcement mechanisms, and e) duration of protection. The results indicate that countries characterized by higher R&D levels, market freedom, and openness tend to have stronger patent protection. Moreover, the results suggest that there is a critical size of a country's R&D activity that drives countries to adopt stronger patent protection. The authors speculate that the required investment to set up and maintain a strong patent system is only worthwhile beyond a certain threshold level of R&D. An even more comprehensive cross-country study in terms of number of countries and time period covered is offered by Lerner (2002). He looks at changes in the presence and strength of patent protection in 60 countries over a period of 150 years (1850-1999). Lerner finds a country's GDP to be positively correlated with having a patent system in place. He also finds civil law as well as democratic countries to be more likely to have a (stronger) patent system in place.

The second type of research originates in the debate on the "optimal" patent strength depending on a country's level of economic and technological development (e.g. Nordhaus, 1969; Helpman, 1993; Diwan and Rodrik, 1991). From an empirical point of view, most studies rely on aggregate country-level data to explore correlations between some measure of the strength of intellectual property rights protection and innovation. For example, Kanwar and Evenson (2003) find a strong positive correlation between the strength of patent protection, as captured by the Ginarte and Park (1997) index discussed above, and innovation measured as R&D intensity for a sample of 29 countries over the period 1981-1990. Similar evidence supporting a positive relationship between intellectual property protection and innovation is provided by Chen and Puttitanum (2005) for a sample of 64 developing countries (1975-2000) measuring innovation as patenting.

There is also some firm-level evidence. McCalman (2001) focuses on the impact of the harmonization of intellectual property systems induced by TRIPS ands projects that there will be substantial income transfers resulting from harmonization, mostly from developing to developed countries. However, the analysis disregards the role played by multinationals and international trade in patented inventions. It is specifically this aspect that Branstetter et al. (2006) examine to find that a strengthening of intellectual property protection in 16 countries during the period 1982-1999 had a positive impact on technology transfer within US multinationals. Technology transfer is measured by the amount of royalty payments made by the US-based company to its affiliates abroad for the use or sale of intangible assets. They also find affiliates' R&D expenditure to have increased as well as their number of patent applications, where this effect is strongest for affiliate firms that have highly patent-active parent companies in the US. Park and Lippoldt (2008) look at the impact of the strength of intellectual property rights protection on technology transfer from developed to developing countries. For a sample of 46 countries covering the period 1990-2005, Park and Lippoldt (2008) find stronger patent protection to be positively correlated with technology transfer, in particular of technology intensive goods, services, and FDI.

A key problem in this empirical analysis is the endogeneity inherent in a country's strength of patent protection. The studies discussed above suggest the strength of a country's patent protection to impact on innovation and technology transfer. However, in light of the research on the determinants of patent strength, it is conceivable that countries with superior innovative performance are more likely to choose strong patent protection. Sakakibara and Branstetter (2001) address this problem by exploiting a credibly exogenous change in the patent law in Japan in 1988, which extended the scope of patents mainly by allowing applicants to include several independent claims in a single patent specification. Their firm-level analysis shows no discernible impact of stronger patent rights on firms' R&D investment or patenting. Similarly, Scherer and Weisburst (1995) exploit a change in patent law in Italy in 1982 that allowed patentability of pharmaceutical compounds. The authors treat the law change as exogenous because it was mandated by the Italian Supreme Court rather than the direct outcome of lobbying by pharmaceutical companies. Their analysis, which is based only on aggregate industry-level data, suggests no statistically significant impact on R&D spending although an increase on patenting by domestic companies in the US following the law change. The authors interpret this as indicative of a change in patenting propensity, i.e., firms patented more for a given amount of R&D investment.[10]

The only study looking directly at the impact of joining a patent treaty is Bilir et al. (2011), who study the impact of the U.S. acceding to the Paris Convention in 1887 on patent filings by foreign nationals in the U.S. Using a sample of patents filed with the U.S. Patent and Trademark Office (USPTO) between 1865 and 1914, the authors find a strong positive impact following the accession of the U.S. to the Paris Convention on patent filings by inventors from countries that were already members of the Paris Convention prior to the U.S. relative to inventors from countries that joined later. The positive effect is more pronounced for countries with high pre-treaty levels of GDP per capita and education (measured as primary schooling), suggesting that countries with higher levels of economic development respond stronger to the international strengthening and harmonization of patent rights.

3. The impact of accession to the EPC

The key feature of the EPC is the harmonization and standardization of the granting procedure of patents in all member and extension states. Patent applications are filed with a single office, the EPO, which examines and grants the patent. Nevertheless, patentees are required to validate the granted patent in each national office of each country in which the patent should be enforceable. This means that despite the harmonized and centralized granting procedure, patents remain national rights. Validation in a national office requires prior designation during the grant process. Once granted, it requires the payment of validation fees as well as translation costs, although exceptions apply for contracting states to the London Agreement.[11] The national character of patents implies that they have to be kept in force in each individual country by paying renewal fees. Hence, turning an EPO patent into nationally enforceable rights requires

[10] See also Moser (2005) and Lerner (2002).

[11] Since May 2008, Germany, France, Liechtenstein, Luxembourg, Monaco, Switzerland and the UK do not require an EPO patent to be translated into their national language (it nevertheless has to be in one of the three official EPO languages).

(a) all the costs associated with the grant of an EPO patent (application fee, European search fee, examination fee, grant fee, and EPO renewal fees beginning the 3rd from the date of filing) as well as (b) the specific costs incurred for obtaining national patent rights (designation fee, translation fees, and validation fees). These account for the main difference between obtaining a patent right in a given member/extension state of the EPC through the EPO or directly with the national office. Renewal fees with the national office are applicable irrespective of how the national patent right was obtained. An additional difference arises from potential cost differences between employing the services of a European patent attorney and a national/local patent attorney.

To obtain an EPO patent, fees payable to the EPO beginning the third year counting from the application date until grant of a European patent that designates two EPC countries amount to about EUR 4,360.[12] To file with the EPO, domestic applicants in our set of accession states also need to translate their patent specification into one of the three official languages of the EPO, which is likely to be costly.

Before 1 April 2009, which is the relevant period for our analysis, designation fees per designated country amounted to EUR 90 and are capped at EUR 630, i.e., there is no additional cost to designating more than seven countries. Validation fees at national offices vary across offices. While for example Norway and Slovenia do not charge validation fees, they amount to nearly EUR 170 in Turkey. Table A-1 in the Appendix summarizes the different applicable validation fees. Apart from designation and validation fees, to validate an EPO patent nationally, applicants may also incur additional expenses due to translation requirements.[13]

In contrast, obtaining a patent directly with a national office is considerably cheaper than the EPO route. Similar to validation fees, the costs differ considerably across national patent offices. For example, fees amount to approximately EUR 220 in Lithuania and to over EUR 900 in Norway.

While national renewal fees are incurred irrespective of the route taken, Harhoff et al. (2009) suggest that their level still impacts on a patentee's choice of whether to validate a given EPO patent in a designated state. This means that the level of renewal fees may still impact on the choice of countries in which a patent is obtained, whether it is through the national office or the EPO route. Nevertheless, for a specific country the renewal fees are irrelevant for the choice between filing with the national office and the EPO.

In our firm-level analysis in Section 6, we are interested in estimating the impact of accession specifically on the patenting behavior of domestic companies. The discussion above suggests that any effect of accession to the EPC should come mainly from a shift in costs associated with obtaining a patent in a given country. To illustrate this slightly more formally, let the incremental value of a patent in each European country be denoted V_i and the cost of patenting

[12] As of April 2010 (EPO Supplement 1 to Official Journal 3, 2010), the total cost can be computed as follows: application fees EUR 105 (filed online); European search fee EUR 1,105; examination fee EUR 1,480; grant fee EUR 830; renewal fees for 3rd and 4th year from the date of filing: EUR 420 and EUR 525.

[13] In the countries signatory to the London Agreement, foreign applicants only need a translation of the claims of their EPO patent into the local language in order to validate the patent in the country. Among our set of countries, translation of the complete patent specification is still required by Bulgaria, the Czech Republic, Estonia, Norway, Poland, Romania, Slovakia, and Turkey.

be denoted C_i with countries denoted $i = 0,1,...,J$. The value and cost of domestic patenting are V_0 and C_0. A firm will take out a patent in every country where $V_i - C_i > 0$, with one complication due to the fact that the EPO is cheaper after a certain point. Assume that $V_0 - C_0$ is larger than all the others. That is, if a domestic firm patents at all, it patents in its home country (which is supported by our data as shown in Section 5.1 below). We disregard maintenance fees in our analysis because they are the same regardless of the route through which patent protection is obtained. We also disregard any differences in legal fees across the two patenting strategies.[14]

Before accession to the EPC, firms make the following computation when they decide whether to patent domestically:

$$V_0 - C_0 > 0 \tag{1}$$

In contrast, their decision to obtain an EPO patent or instead to patent directly with the individual national patent offices is determined by the following condition (assuming that $\sum_i^J (V_i - C_i) > 0$):

$$\sum_{i=1}^{J} V_i - C_{EPO} > \sum_{i=1}^{J} (V_i - C_i) \tag{2}$$

Which is to say that firms choose the EPO route if the net value of taking out a patent with the EPO exceeds the sum of the net values of obtaining patent rights with the individual offices. After accession, expression (2) changes into

$$\begin{aligned} V_0 + \sum_{i=1}^{J} V_i - C_{EPO} &> V_0 - C_0 + \sum_{i=1}^{J} (V_i - C_i) \\ \text{or} \quad C_0 + \sum_{i}^{J} C_i - C_{EPO} &> 0 \end{aligned} \tag{3}$$

If the value of a patent and fees stay the same after accession, then the effect of accession works exclusively through C_0, that is, for sufficiently large costs at the domestic patent office, firms choose an EPO patent over several national patents including a patent with their domestic patent office.

Then the main question is for which number J, expressions (2) and (4) hold. If we assume that the threshold is $J \geq 3$, this means that for $J=1$ *or* 2, domestic firms only wanted to patent in one or two countries in addition to their own before accession. After accession, domestic patenting enters the set J, which means that patentees that were formerly patenting in only $J=2$ countries, find themselves at the threshold level $J \geq 3$ after accession. This in turn means that expression (3) holds and these firms will choose an EPO patent instead of patenting separately at each national patent office. Hence, our simple analysis implies that for $J=1$ and domestic patenting before accession, EPO accession will not affect domestic firms' patenting strategies for most inventions.

[14] Alternatively, we could include the legal fees in the cost variable, which would mean that we can no longer use the patent office fee schedules to calibrate it. It is likely that legal fees for applying at the EPO exceed those for domestic offices. However, if an applicant wants to pursue applications at several national offices, legal and translation fees could be substantial.

That is, if firms only wanted to patent in one or two countries in addition to their own before accession, accession does not change this.

4. Data

We analyze the impact of accession to the EPC for the 14 contracting states shown in Table 1 where EU members are shaded in grey (see also Appendix Tables A-1 and A-2):[15]

[Table 1 about here]

As shown in Table 1, all accession states that also became part of the European Union (EU) joined the EPC before officially becoming a member of the EU (except for Latvia). The set of countries covered by our analysis is heterogeneous. It includes a large number of former Eastern bloc countries, the Scandinavian countries Iceland and Norway, as well as the large transition economy Turkey. As noted earlier, these countries generally have lowere GDP per capita than the EPC founding states, with the exception of Norway and Iceland.

The patent data for the analysis presented in Sections 5 and 6 come from EPO's Patstat database (version April 2011). We extracted patents filed with national patent offices, at the EPO and via the PCT route at WIPO. Our analysis focuses for the most part on patents filed by residents of the countries listed above with the national office as well as the EPO (and WIPO). Part of our analysis also draws on patents filed at the EPO and the national patent offices by residents of other countries (referred to as "non-residents" in the analysis).

We rely on legal status information to identify the countries designated by an EPO patent application and use information on patent renewals to determine whether a patent was validated in a given country.[16] Using designations has the advantage, however, that we have a longer time series available to study the post-accession filing pattern because designation fees have to be paid within six months after publication of the search report (Article 79(2) and Rule 39(1) EPC), whereas validation occurs only *after* a patent has been granted. Given the average time lag between application and grant of about 43 months at the EPO (EPO Annual report 2009), this leaves us with a considerably shorter time series of post-accession EPO filings. In order to determine whether an EPO has entered into force in a given accession state, i.e., has

[15] Due to a lack of sufficient data, the following contracting states are excluded from the analysis: Albania, Former Yugoslav Republic of Macedonia, Serbia, Montenegro and San Marino.

[16] Legal status information is necessary because validation cannot be determined from equivalents, that is, from checking whether an EPO patent has national equivalents. Validated patents are only registered in national patent registers, which does not trigger a national patent publication that would be visible in Patstat. National equivalents are only visible when the national patent office requires a translation in accordance with Article 65(1) of the EPC. However, contracting states to the London Agreement do not necessarily require such translations. Among the countries included in our analysis, Croatia, Hungary, Iceland, Latvia, Lithuania, and Slovenia have ratified the London Agreement. Croatia, Hungary, and Iceland require only the translation of a patent's claims into their official language provided the European patent has been granted in English. Latvia, Lithuania, and Slovenia require a translation of the claims regardless of the language in which a patent was granted. Hence, relying on national equivalents, i.e., published translations of the complete patent specification, is likely to grossly and non-randomly underestimate validation.

been validated, we use information on whether a patent has lapsed in a designated country.[17] Since validation only occurs after the granting of a patent, this severely limits the sample to EPO patents that have already been granted. To minimize sample selection, we only use granted patents that have been applied for before 1 January 2008. For these patents, a lapse date is available if a patent is no longer in force or has never entered into force. The latter is due to the need to pay validation fees for the patent to enter into force in an EPC state. In all accession countries included in our sample, validation has to occur within three months upon grant by submitting a translation into the country's official language (see discussion in Section 3). Hence, we determine whether a patent has entered into force in a country for which it has been designated by verifying whether the patent has lapsed within six months upon grant to allow for some delay in the non-payment to be recorded.[18] Employing this approach, we find that on average in 44 per cent of designated countries a given patent was eventually also validated.[19]

The firm-level data used in the analysis presented in Section 6 come from Bureau van Dijk's Amadeus database.[20] We use annual versions of the data covering the period 1999-2007.[21] The dataset contains firm-level data in form of basic company information including profit and loss information. The Amadeus data was matched to the patent data by applicant name due to the absence of a unique identifier that would allow merging the datasets. We matched the data manually for all countries to minimize the occurrence of "false positives", i.e. firms are erroneously matched to patents, and "false negatives", firms are erroneously not matched to their patents (see Helmers et al. (2011) for more detailed discussion of the problems associated with name based matching).

5. Analysis of patent filings

This part of the analysis looks at broad trends in patent filings over time. The objective is to uncover and document any changes in patent filings following accession to the EPC across all accession countries listed above. In our analysis, we look at filings by residents and non-residents and disaggregate filings by application authority, IPC/technology class, and applicant type. Note that we drop Norway and Croatia from the sample for the descriptive analysis because of the lack of post-accession data for these two countries (both countries acceded only in 2008). They are nevertheless part of the regression analysis in Section 6 for reasons explained below.

---

[17] We thank Dietmar Harhoff for providing the data on designation/validation. We also cross-checked the data with information extracted from Patstat's extended legal event data contained in table tls221.

[18] This means that we only keep patents in our sample that have been granted before October 2010.

[19] While this implies a considerably larger number of designated countries than validations, we also find that applicants do not automatically designate all EPC member states despite the fee cap at six designated countries.

[20] http://www.bvdinfo.com/Products/Company-Information/International/AMADEUS.aspx

[21] Using annual versions of Amadeus is necessary in order to avoid sample attrition as Bureau van Dijk drops inactive firms after four years, which means we would potentially miss firms that were active in 2000, but went out of business in 2002, if we were to use only a 2007 version of Amadeus.

5.1. Patent filings

Figure 1 shows the total number of patent applications (including filings with the national office, EPO and PCT filings) by quarter by residents of the accession countries. We corrected the total number of filings for equivalents, i.e., we count inventions only once, as our objective is to look at the total number of patented inventions rather than the total number of patents.[22] We have reliable patent data on applications up to the first quarter of 2009, which means that we have at least 15 quarters of post-accession patent data for all the other countries.[23] This ensures that changes in the number of patent filings are not driven by entry and exit of countries into the sample. In order to visualize any potential changes following accession, we rescale the time period for all countries (the accession date is t=0).

Figure 1 shows that total patent filings by residents oscillate considerably by quarter during the five years preceding accession. We observe a dip in patent filings shortly after accession. However, patent filings appear to recover about 2.5 years following accession. The tentative conclusion that emerges from Figure 1 is that there was no visible trend change in overall patent filings across the 12 countries included in the sample for Figure 1; if anything, there was a drop in patent filings that coincides with accession. This will be investigated more formally in Section 5.4 In addition we observe a drop in the variation of patent filings after accession, although there is no apparent explanation for this change in the filing pattern.

---

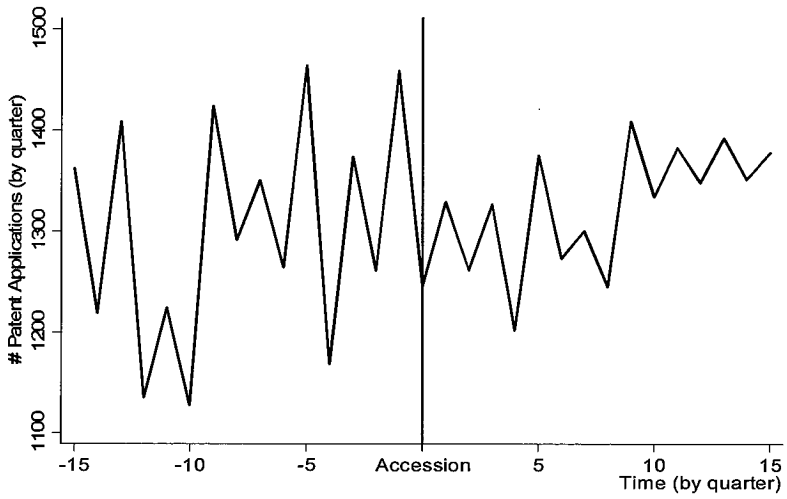
[22] Without the correction, we might over-count filings before accession as firms may file a patent with both the EPO and the domestic patent office on the same invention. Since this possibility is much less likely post-accession, we would double count certain inventions before accession. To correct for this, we construct equivalent groups based on priority documents. Our algorithm assigns patents into the same equivalent group if patents share exactly the same priority documents. We also assign patents to the same equivalent set that display the following patterns:

1)	Application_id	Priorityid_1	Priorityid_2
A	B		
B	A		
C	A	B	

2)	Application_id	Priorityid_1	Priorityid_2	Priorityid_3
A	B	C		
D	A	B	C	

[23] For Latvia there are only 14 quarters of data available.

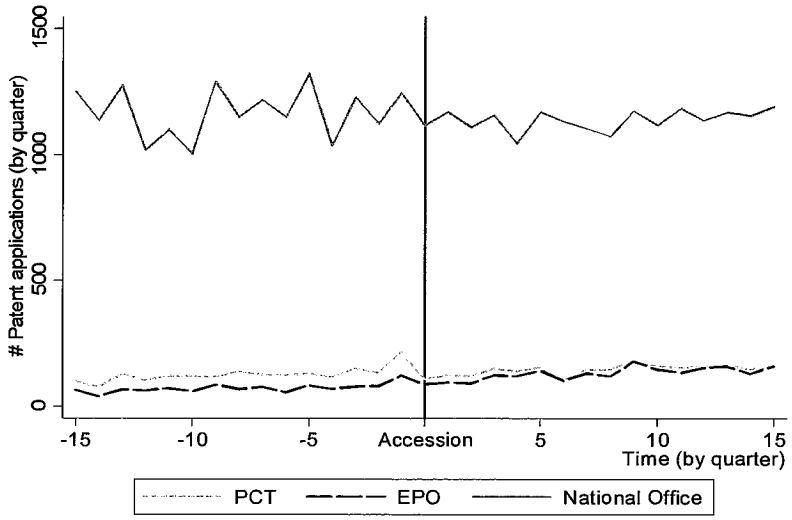
Figure 1: Total patent filings by residents (by quarter)



Note: time represents the application date of a patent; patent applications have been corrected for equivalents; excludes Norway and Croatia due to limited post-accession data.

Figure 2 investigates whether the drop in patent filings is due to a specific type of patent application. We show filings by residents split between the national office, the EPO, and WIPO (PCT patents applied for through either the EPO or the national office). For Figure 2, we do not correct filings for equivalents as we are interested in the actual number of filings with the different offices. Interestingly, Figure 2 shows that national filings dominate the filings by residents. Both EPO and PCT filings account only for a very small share of total filings by residents. Moreover, Figure 2 shows a slight downward trend in national filings. In contrast, EPO and PCT filings show a moderate upward trend, albeit at a low level. In any case, there does not appear to be any trend break following accession confirming the overall picture drawn by Figure 1. Figure 2, therefore, suggests that the post-accession dip in total filings observed in Figure 1 is caused by a drop in national filings that was not fully compensated by EPO and PCT filings. The figure also indicates that the reduction in volatility of patent filings observed post-accession can be attributed to domestic filings.

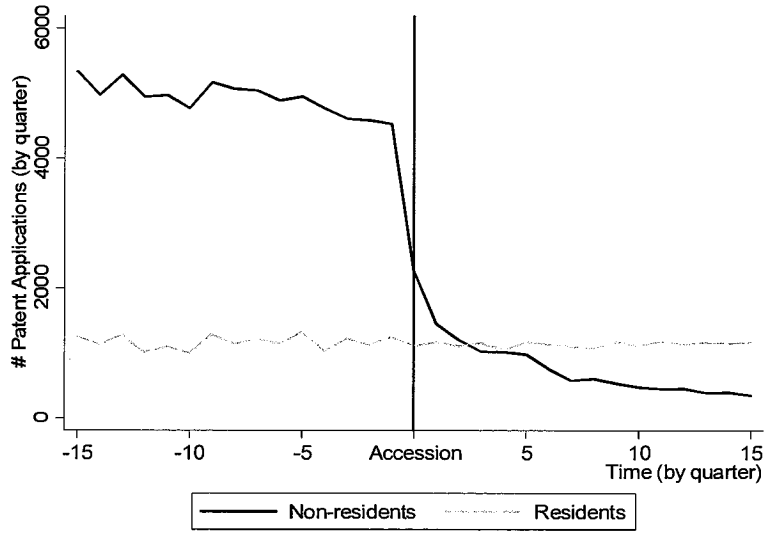
Figure 2: Patent filings by residents by application authority (by quarter)



Note: time represents the application date of a patent; excludes Norway and Croatia due to limited post-accession data.

In Figure 3, we compare filings by residents and non-residents with the national offices (these figures are not corrected for equivalents). The figure shows an (expected) dramatic effect of accession to the EPC on filings by non-resident applicants at the national offices. Non-residents' filings drop between the pre-accession and post-accession quarters by nearly 70% from about 4,500 to 1,450 applications. Resident filings, in contrast, seem to be unaffected as already discussed above. Hence, Figure 3 indicates that total non-resident filings decline sharply on the date of accession and fall further over time whereas resident filings remain largely unchanged.

Figure 3: Patent filings at national office by non-residents and residents (by quarter)



Note: time represents the application date of a patent; excludes Norway and Croatia due to limited post-accession data.

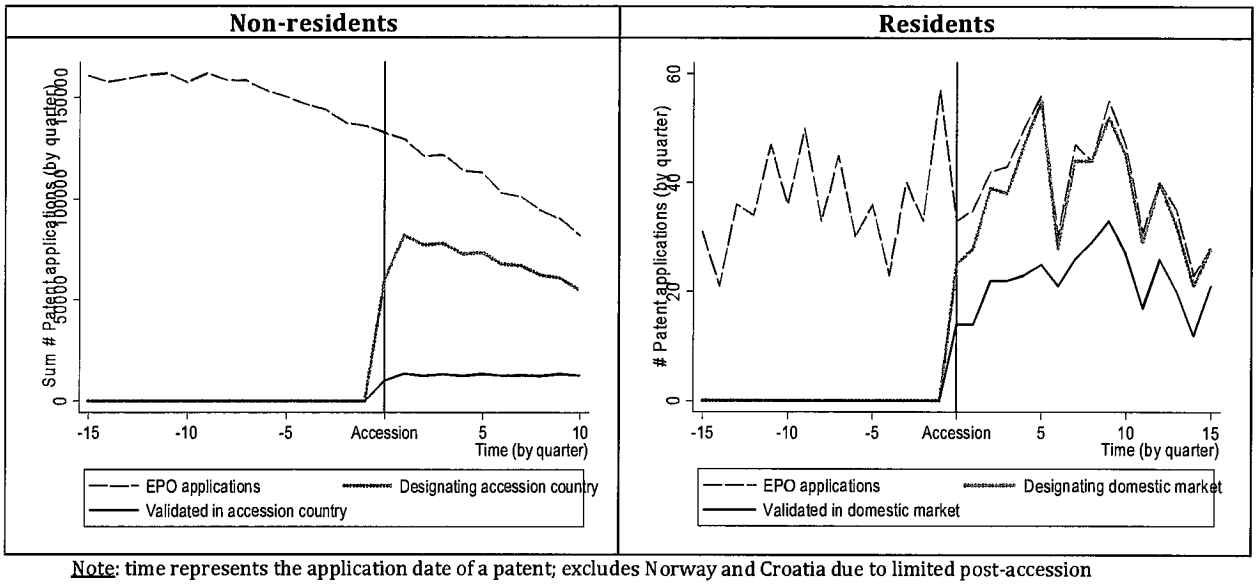
Figure 4 looks at the filings behavior of residents and non-residents with the EPO. As explained in Section 4, we can only establish whether a patent has been validated in a given EPC member state once the patent has been granted. This means we need to restrict the sample of patent filings with the EPO to patents that have been granted. This also implies that we limit the post-accession period to ten quarters to account for the shorter time series available post accession. Looking at the application date of granted patents, we see interesting changes in the filing behavior of non-residents and residents.

The left panel of Figure 4 shows EPO filings by non-residents. The actual numbers in this graph are somewhat difficult to interpret as we count the same EPO filings multiple times, once for each accession country. This allows us to count the number of designations and validations and set this figure in relation to the number of EPO filings. The first thing to note in this graph is the drop in filings over time. This drop is simply the result of the "grant restriction" that we have to impose on the data, i.e., only granted patent are included in the sample. Hence, we should not interpret this as an actual drop in filings over time and rather focus on the relative pattern of total filings, number of designations and validations. As would be expected, a substantial share of EPO filings designates accession states post-accession. However, the considerably lower number of validations suggests that the accession countries are rather at the economic periphery among EPC member states. It is still noteworthy that the number of validations stays flat over time, whereas the number of filings and designations falls. This implies that over time a larger share of designated patents is eventually also validated in the accession countries.

We already know from Figure 2 that EPO filings by residents have not changed substantially post-accession. This is confirmed in the right panel of Figure 4 (note the difference in scales of

the two figures), although we do observe an immediate change in the filing behavior in terms of designations and validations. Nearly all domestic applicants designate their home market in their EPO filing, although we see a moderately lagged response (i.e., not all applications immediately designate their home market). Validations, in contrast, are considerably below the number of designations, which implies that not all EPO patents by domestic entities obtain patent protection in their home market. Yet, a substantial share does. Hence, the conclusion is that the overall number of EPO filings does not respond, but domestic entities do rely on the EPO patent to obtain domestic patent protection. Given the overall low level of EPO filings, this would explain at least in part the moderate drop in domestic applications observed in Figure 2, i.e., firms that filed EPO patents before now substitute domestic patents through EPO patents as predicted by our stylized model in Section 3.

Figure 4: EPO patent filings by non-residents and residents (by quarter)



Note: time represents the application date of a patent; excludes Norway and Croatia due to limited post-accession data.

5.2. Patent filings by technology class

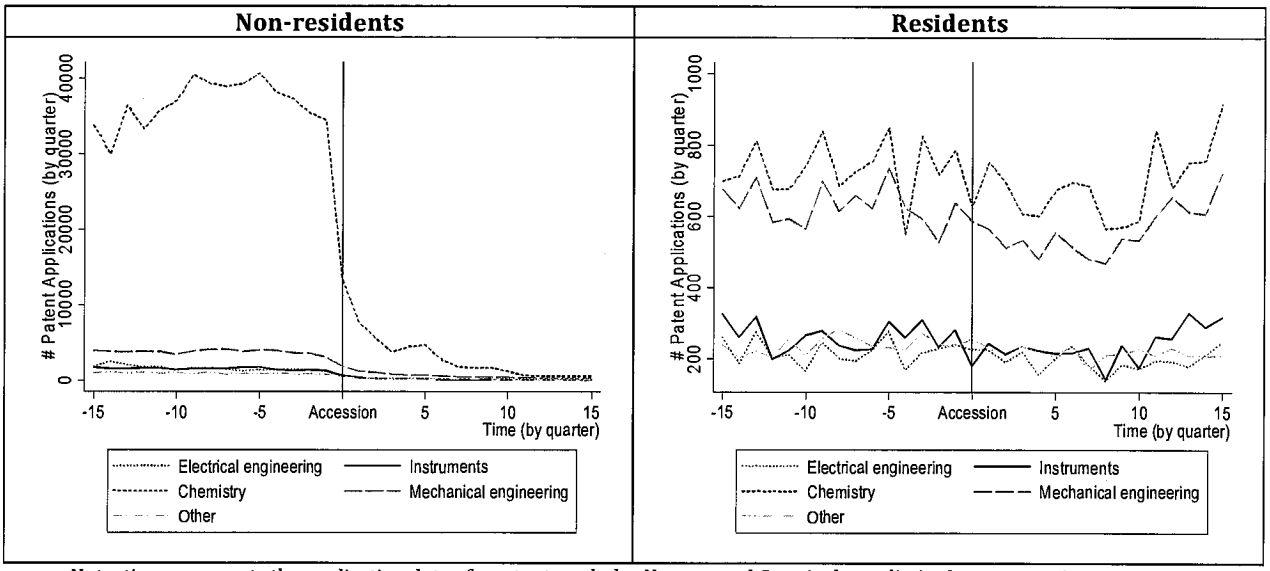
As a next step, we disaggregate total filings by residents and non-residents into broad technology classes. We map patents' IPC codes into technologies by relying on a concordance table.[24] The concordance table provides us with five technology classes: (a) Electrical engineering, (b) Instruments, (c) Chemistry, (d) Mechanical engineering, (e) Other fields (including (i) furniture, games, (ii) other consumer goods, and (iii) civil engineering). For more detailed information on the technologies subsumed under these classes, see the note underneath Table 5. While the technology classes are still relatively broad, likely masking some underlying heterogeneity, the disaggregation provides an idea of potential trends in filings

[24] The concordance table that maps IPC class symbols to technology categories was developed by the Fraunhofer ISI and the Observatoire des Sciences et des Technologies in cooperation with the French patent office (see Schmoch, 2008).

across technology areas and are more informative than a breakdown of for example IPC sections.

Figure 5 shows separate figures for filings with the national offices by non-residents and residents across technology areas (Table A-2 in the Appendix provides total filings by residents including the national offices, the EPO and PCT). The plot showing filings by non-residents mirrors Figure 3 and it becomes evident that the dramatic change in filing behavior by non-residents is entirely driven by pharmaceutical and chemical patents. These patents accounted for the overwhelming share of foreign filings with national offices and hence reacted accordingly to accession to the EPC. Filings in other technological areas where much lower before accession and hence adjustments occurred at a much lower level. Looking at filings by residents, in contrast, does not reveal such a clear-cut picture. While domestic entities also file most patents in chemicals and pharmaceuticals, patents in mechanical engineering come a close second. These two technology areas are also those that react strongest post-accession and are thus responsible for the post-accession dip in domestic filings observed in Figure 2.

Figure 5: National patent filings by residents by technology class (by quarter)

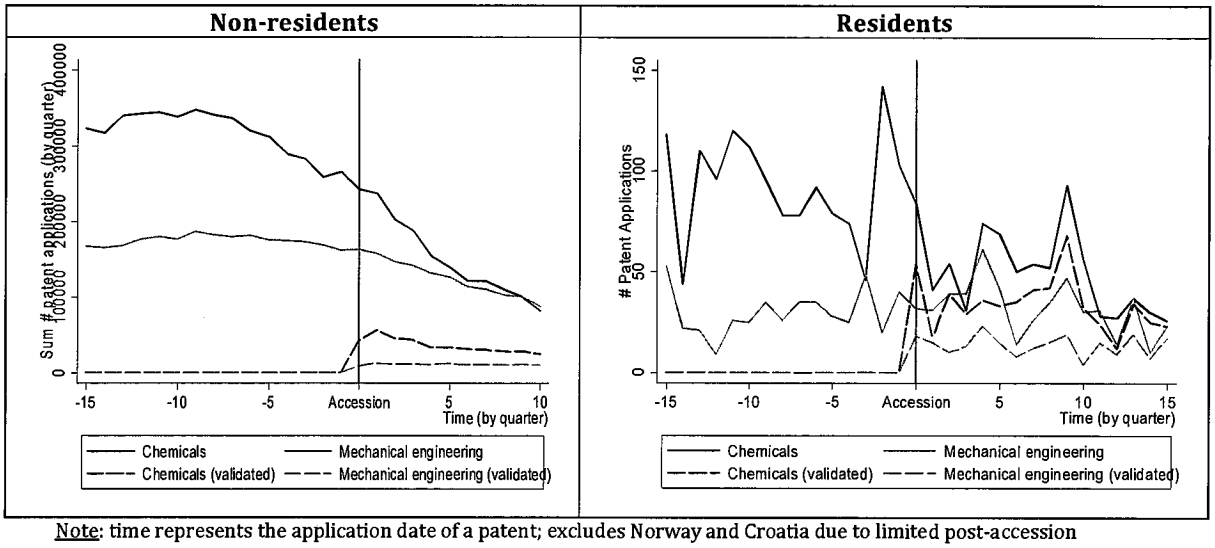


Note: time represents the application date of a patent; excludes Norway and Croatia due to limited post-accession data. Technology classes: (a) Electrical engineering (including Electrical machinery & apparatus & energy, Audio-visual technology, Telecommunications, Digital communication, Basic communication processes, Computer technology, IT methods for management, Semiconductors), (b) Instruments (including Optics, Measurement, Analysis of biological materials, Control, Medical technology), (c) Chemistry (including Organic fine chemistry, Biotechnology, Pharmaceuticals, Macromolecular chemistry, polymers, Food chemistry, Basic materials chemistry, Materials & metallurgy, Surface technology, coating, Micro-structural and nano-technology, Chemical engineering, Environmental technology), (d) Mechanical engineering (including Handling, Machine tools, Engines & pumps & turbines, Textile and paper machines, Other special machines, Thermal processes and apparatus, Mechanical elements, Transport), (e) Other fields (including furniture, games, other consumer goods, and civil engineering).

Figure 6 shows the equivalent of Figure 5 for EPO filings by residents and non-residents. Since we show both total filings as well as validations, to keep the figures readable, we only show the data for the two most important technology classes in terms of number of filings and validations: chemicals and mechanical engineering. The left panel shows filings by non-

residents. Similar to Figure 4, we see a pronounced drop of EPO filings over time. Again, the drop is entirely driven by the need to restrict the data to granted patents. Hence, we focus on a comparison of the number of applications and validations. We see that for both technology classes, validations remain relatively flat over time post accession, which suggests an increase in the share of validations over time. There is a slight drop in validations in chemicals shortly after accession, but it is difficult to interpret as it might be partly driven by data truncation. The right-hand-side panel shows EPO filings and validations by residents. Interestingly, we observe a drop in filings in chemicals and pharmaceuticals. Validations in pharmaceuticals track filings relatively closely over time, with a high share of patent applications being also validated in an assignee's home market. Patent filings in the field of mechanical engineering do not display any clearly discernible drop immediately upon accession, although there is a fall in filings over time (there may also be an issue of data truncation).

Figure 6: EPO patent filings by residents by technology class (by quarter)



Note: time represents the application date of a patent; excludes Norway and Croatia due to limited post-accession data. Technology classes: (a) Electrical engineering (including Electrical machinery & apparatus & energy, Audio-visual technology, Telecommunications, Digital communication, Basic communication processes, Computer technology, IT methods for management, Semiconductors), (b) Instruments (including Optics, Measurement, Analysis of biological materials, Control, Medical technology), (c) Chemistry (including Organic fine chemistry, Biotechnology, Pharmaceuticals, Macromolecular chemistry, polymers, Food chemistry, Basic materials chemistry, Materials & metallurgy, Surface technology, coating, Micro-structural and nano-technology, Chemical engineering, Environmental technology), (d) Mechanical engineering (including Handling, Machine tools, Engines & pumps & turbines, Textile and paper machines, Other special machines, Thermal processes and apparatus, Mechanical elements, Transport), (e) Other fields (including furniture, games, other consumer goods, and civil engineering).

5.3. Patent filings by applicant type

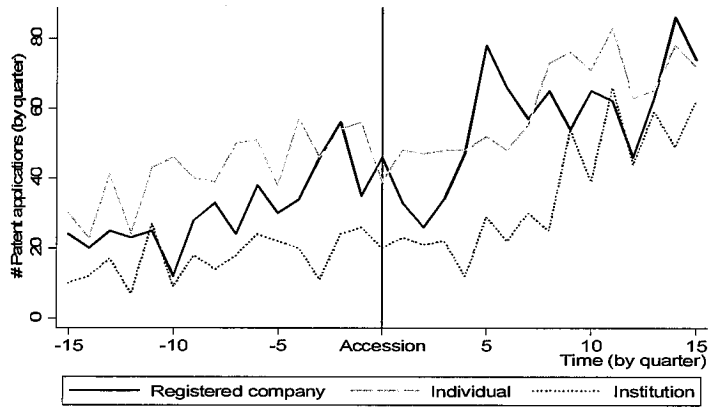
Finally, we split total filings by residents into three different applicant types: individuals, registered companies, and institutions.[25] Individuals commonly account for a significant share of patent applicants. This phenomenon is particularly pronounced in most Eastern European countries. The group of individual applicants comprises individual inventors or

[25] We create the "applicant type" variable manually due to the lack of such information in Patstat.

employees/owners of companies that file for a patent in their own name instead of the company's name.[26] Larger firms, however, tend to have internal mechanisms in place that require the filing of the patent in the company's name. This means that the number of patent applications by individuals may reveal information on filings by smaller companies or more informal businesses. Since it is not uncommon for companies to file for the patent in the company's name as well as the names of employees, we count each patent only once per type. If a given patent application is filed by a company and several individuals, we count the application once as filed by a registered company and once as a patent filed by a natural person.

Figure 7 shows that initially total filings by individuals exceed filings by registered companies. However, filings by companies display an upward trend throughout the period analyzed. As a result, towards the end of the period, filings by registered companies outnumber individuals' filings. However, this seems to be due to a general increase of companies' filings over time rather than a break in the data series following accession to the EPC. A similar positive trend (and absence of trend break following accession) is also displayed by filings by institutions (including research institutes, universities, and government). The upward trend in filings by registered companies may reflect a change in the underlying economic structure, shifting innovation away from individual inventors towards registered business or simply an increased willingness for business owners and employees to also register the name of the company as assignee. Given the increase in the number of filings by all three assignee types, but an overall stagnant number of filings (see Figure 1), Figure 7 suggests that the number of assignee per patent increases over time. This is reflected in co-assignments between individuals as well as between individuals and companies as well as institutions. Yet, the figure does not suggest that this changing filing behavior has anything to do with accession to the EPC.

Figure 7: Total patent filings by residents by applicant type (by quarter)



Note: time represents the application data of a patent; excludes Norway and Croatia due to limited post-accession data. Applicant types identified manually.

[26] The large number of individual inventors may be at least partly explained by fee reductions applicable in some of the countries covered by our analysis. Other reasons may be countries' bankruptcy and tax regulations.

5.4 Regression analysis

In order to test more formally whether patent applicants' behavior changes in response to accession to the EPC, we examine four different patent application series displayed in Figures 2 and 3 above using simple ordinary least squares models. The four series are the following:

1. Application via the PCT route by residents of the country (WPO)
2. Application at the EPO by residents of the country (EPO)
3. Application at the National Office by residents of the country (NAT)
4. Application at the National Office by non-residents of the country (Non-res)

For each of these series p_{it}, we estimate the following models:

$$\log(p_{it}+1) = \alpha_i + \delta_t + f(d_i,t) + \varepsilon_{it} \qquad i=1,...,N \quad t=1,...,T \tag{4}$$

N is the number of countries (12) and T is the number of quarters (77, from 1990q1 to 2009q1). We include a complete set of country and time dummies as shown in Equation (1). $f(d_i,t)$ is a function of the accession date of country i (d_i) and the time period. We use three definitions for the function f:

$$f(d_i,t) = I(t \geq d_i)$$
$$f(d_i,t) = I(t \geq d_i)\cdot(t-d_i)$$
$$f(d_i,t) = Int((t-d_i)/4)$$

The first is a simple post-accession dummy, the second is a time trend following accession, and the third is converted to a set of year dummies pre- and post-accession. The results for all three tell essentially the same story: EPC accession has little impact overall on the residents of a country, but patenting by non-residents at that country's national office falls precipitously.

Table 2 shows the results of estimation for the four series using the post-accession dummy and the time trend. All the standard errors are clustered on country as well as allowing for full serial correlation within country, so although the Durbin-Watson rejects the absence of serial correlation, both the estimates and their standard errors are consistent. The bottom panel of the table shows the estimates with a few observations removed that are either 15 years before accession or 9 years after; these cells contain only one or a few observations and are unreliable.

The two panels both show similar results, with little post-accession impact for the residents of the country at the EPO, WIPO, or the national offices. However, the trend in non-resident applications at the national offices is very large, with a decline of roughly 15 per cent per quarter, which translates into a fall of 200 per cent after two years. Apparently non-residents no longer find it worthwhile to apply at the national office when they are able to add that country to the list of countries validated after EPO grants a patent. But this result deserves further exploration using the validation data from the EPO in the following section.

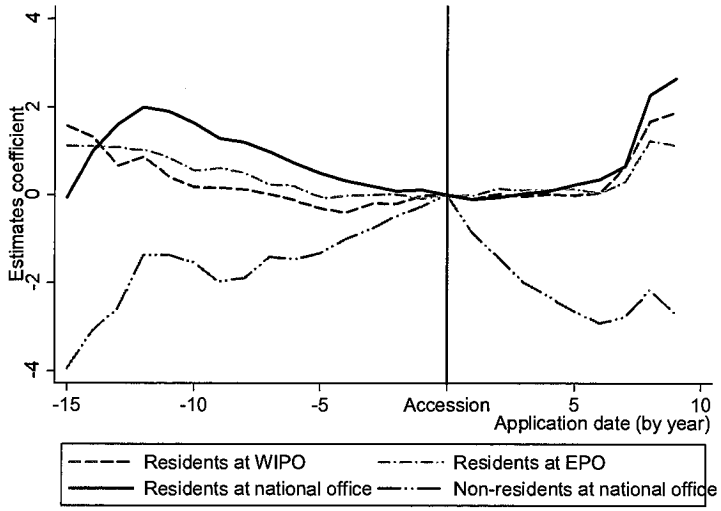
We show the results of estimation using the third functional form, a set of yearly pre- and post-accession dummies, in Figure 7. In this figure, the coefficients are normalized to zero in the accession year. The figure shows clearly that the impact of joining the EPC on residents of the country is extremely small (if not zero), whereas the non-resident application rate declines

sharply, after rising up until the accession date, no doubt reflecting the increased integration of the accession countries with Western Europe.

Following our discussion in Section 3 of the paper, the main conclusion one might draw from these results is that the vast majority of inventors in the accession countries only consider it worthwhile to apply for patents in their home country and one or two additional jurisdictions. If this were the case, then we predict that accession would have little effect on resident inventors, which is what we see in the data.

[Table 2 about here]

Figure 7: Patenting at various offices, controlling for country, year, and years pre- and post-accession (by year)



6. The impact of accession on patenting at the firm-level

In this section of the paper, we use a firm-level panel of 13 EPC accession states over the period 1999-2007 to specifically analyze the patent filing behavior of companies registered in these countries.[27] Turkey had to be excluded because BvD's Amadeus database does not include firm-level information for Turkey. Moreover, we limit the analysis to the manufacturing sector where patents are more widespread than in other sectors, such as retail (Hall et al., 2012).[28] This reduces unobserved heterogeneity across firms and allows us to focus on sectors in which firms normally patent.

The objective of this section is to isolate the impact of accession to the EPC on firms' patent filing behavior from confounding factors such as broader economic reforms, EU accession, and

[27] This includes foreign-owned companies that are registered in an accession country.

[28] Business method and software patents *per se* do not constitute patentable subject matter at the EPO or any of the EPC member states.

unobserved heterogeneity more broadly. To achieve this, we rely on the staggered timing of accession, i.e., we exploit the fact that countries joined the EPC at different points in time (see Appendix Table A-2). Hence, an estimate of the impact of joining the regional system is obtained from comparing patent filings at the firm-level before and after accession in a given country relative to the change observed during the same period of time in another country that has not yet joined the EPC.[29] An important assumption underlying this approach is the exogeneity of the decision to join the EPC and the timing of accession with respect to firms' patenting activities. The descriptive evidence on domestic firms' filing behavior provided in Section 4 reassuringly showed little evidence for accession to have occurred during a general upward or downward trend in patent filing by residents of the accession countries.

As explained in Section 3, conditional on patenting, the domestic firms' choice set consists of filing a patent with (a) the domestic patent office, (b) national patent offices in other EPC member states, and (c) the EPO which is eventually validated in certain EPC member states. The choice set does not change as a consequence of accession to the EPC, the only difference is that firms should not be observed to choose options (a) and (c) simultaneously post accession, i.e., if a domestic firm obtains an EPO patent, it should validate it domestically instead of obtaining a separate patent directly with the domestic patent office. Obviously, this does not rule out the possibility to observe firms to apply for both domestic and EPO patents albeit for different inventions. Hence, we are interested in domestic firms' decisions to file for domestic or EPO patents and therefore focus in our empirical analysis the firms' choice set to these two alternatives. In order to test this prediction empirically, we do two things: first we estimate standard patent production functions in which we estimate the impact of accession on total filings, filings with the domestic office and filings with the EPO; second, we estimate a bivariate probit model that focuses on firms' choice of whether to patent with the domestic office and/or the EPO and allows for the choices to be interdependent.

First we estimate a standard patent production function where the coefficient of interest is obtained from the following (quasi-)differences-in-differences specification of a Poisson regression:

$$p_{ict} \sim f(\alpha_i + \delta_t + \gamma accession_{ct} + X_{ict}\beta) \tag{5}$$

where $i = 1, \dots, N$, time $t = 1, \dots, T$, and country $c = 1, \dots, C$. In Equation (5), p_{ict} denotes the number of patents that firm i in country c in year t applies for a domestic patent and/or an EPO patent. $Accession_{ct} = 1$ after a country acceded to the EPC and zero otherwise. The impact of accession is therefore captured by the coefficient γ. α_i is a firm-level fixed effect, δ_t a time-trend that absorbs common time-specific shocks, and X_{ict} denotes a vector of time-varying firm-level characteristics. We only have a limited number of such time-varying firm-level variables namely total assets and a firm's total number of employees.[30] We include log employment as a proxy for size and the log of total assets per employee as a proxy for capital intensity.[31] We also include a dummy for the cases where Amadeus identified the firm in question as a subsidiary of a larger firm. Standard errors are clustered at the firm level.

[29] This identification strategy is similar to Acharya et al. (2010) and Png (2011).

[30] Total assets are deflated using a country-level GDP deflator provided by the UN Common database.

[31] A major limitation of Amadeus is the lack of R&D data.

In addition, we estimate a bivariate probit model for the firm-level decision to apply for at least one patent at the EPO and/or the national office. This model allows the two decisions to be correlated conditional on the same regressor variables as in equation (5) – time, accession, and employees, assets, and the subsidiary dummy.

Table 3 shows some descriptive evidence for the data used to estimate Equation (5) and the bivariate probit model. It shows that total number of manufacturing firms in the sample is 65,139. Slightly over a third of the sample is accounted for by Romanian firms.[32] Because of this fact, we conduct a separate analysis excluding these companies to test for robustness of our results. The number of patenting firms is low in all countries, ranging from 0.22 per cent in Estonia to 6.9 per cent in Latvia.[33] The comparison of pre- and post-accession counts of patenting firms indicates an overall increase in patenting firms following accession. However, caution is in order in interpreting this descriptive evidence given the shorter post-accession time series as well as a lower available number of firms during the early sample period. Table A-3 in the Appendix shows a similar breakdown by 2-digit SIC industry.

[Table 3 about here]

Table 4 contains the results from estimating Equation (5), with and without fixed firm effects. Table 4 uses the entire sample, while Table A-4 in the Appendix excludes Romania, due to its overweighting in Amadeus. The data poses a serious challenge to the fixed effect estimators due to the extremely low share of non-zero observations in the dependent variable, which causes a large share of firms to be dropped from these estimations (compare 221,496 observations to 7,852 when firm fixed effects are included). In addition, it is well-known that the coefficients in these regression will be substantially downward biased in firm data with any kind of measurement error. We therefore rely on the cross sectional estimates, presented with standard errors grouped on the firm.[34]

Overall, the regressions seem reasonable when compared to other patent production functions: size enters with a coefficient of roughly unity in the cross section, and capital intensity is strongly associated with patenting in the cross section. Subsidiaries have much lower patent counts, ceteris paribus, which suggests that patents are generally being applied for by the parent firm.

Columns [1] and [2] show results for the total patent count (summing over filings with the domestic office, the EPO, and WIPO). The post-accession dummy enters with a negative sign, but the coefficient is statistically not significant. This implies that firms registered in the accession countries do not change their overall patenting behavior in response to accession, as we found in the aggregate regressions. Columns [3] and [4] restrict the patent count to filings with the national offices, whereas Columns [5] and [6] show results when focusing on EPO filings. If we compare the estimates in Columns [3] and [5], we see that the negative albeit statistically insignificant coefficient associated with the accession dummy in Column [1] was driven by domestic filings. For EPO filings, in contrast, the coefficient is positive and statistically

[32] This is due to Amadeus not relying on a homogenous rule to select samples across countries.

[33] Note that in Bulgaria, inventor certificates are still very common and their widespread use accounts in part for the low share of patenting companies there.

[34] These estimates will be consistent in the case of random firm effects, and clustering the standard errors by firm means that they will also be consistent estimates in that case.

significant suggesting a positive response in terms of EPO filings upon accession to the EPC, on the order of a one hundred per cent increase.

When Romanian firms are excluded from the regression, the estimates remain very similar in magnitude and have the same sign. To sum up, the evidence gathered from the patent production functions indicates a drop in domestic filings paired with an increase in EPO filings following accession. We will investigate this further using the bivariate probit model.

[Table 4 about here]

Table 5 shows the results from estimating a bivariate probit model, in which we focus on firms' decision to file for EPO and/or domestic patents and where we allow these choices to be correlated. The results shown in Columns [1] and [2] for the estimates associated with the accession dummy confirm the results from the patent production function regressions: we see a positive and statistically significant effect on the decision to file a patent with the EPO whereas there is no statistically significant effect for the decision to file with the domestic office. The parameter homogeneity test shown in Column [3] further indicates that the accession dummy has a effect on EPO patents that is statistically distinguishable from the effect on the decision to file with the national office. Note that the results also strongly suggest that the choices are interdependent. That is, a firm that is likely to patent in one jurisdiction, ceteris paribus, is also more likely to patent in the other, suggesting the presence of an unobserved patent propensity that varies across firms. Table A-5 in the Appendix shows that the results hold when we exclude Romanian firms from the sample.

[Table 5 about here]

7. Conclusion

What is the impact of accession to the regional patent system created by the European Patent Convention? Despite the substantial enlargement of the group of states signatory to the EPC, so far there is no evidence on the impact of accession on the acceding states. This paper represents a first step towards filling this gap.

Our analysis of aggregate patent filings suggests that following accession: (a) non-residents drastically reduce their filings with the national office immediately upon accession, (b) this drop is largely due to chemical and pharmaceutical patents, (c) residents' filing behavior appears to be largely unaffected in the aggregate and also across technology classes, (d) the number of EPO patents designating an accession state jump up immediately following accession, although the number of EPO patents that are indeed eventually validated after grant is substantially lower; (f) a firm-level analysis for the manufacturing sector in 13 accession countries suggests no statistically significant impact of accession on filings with the domestic patent offices by companies registered in accession states, but a positive and statistically significant effect on EPO filings. We are currently exploring whether the firm-level effects are due to foreign-owned or domestic firms, given the earlier results for residents and non-residents which suggested no impact on domestic firms.

References

Acharya Viral V., Ramin P. Baghai, and Krishnamurthy V. Subramanian (2010): "Wrongful Discharge Laws and Innovation," mimeo.

Bilir K., P. Moser, and I. Talis (2011): "Do Treates Encourage Knowledge Transfer? Evidence from the Paris Convention," Available at SSRN: http://ssrn.com/abstract=1893052

Branstetter L., R. Fisman, and F. Foley (2006): "Do Stronger Intellectual property Rights Increase International Technology Transfer? Empirical Evidence From U.S. Firm-Level Panel Data," Quarterly Journal of Economics, Vol. 121, pp. 321-349.

Chen Y. and T. Puttitanum (2005): "Intellectual Property Rights and Innovation in Developing Countries," Journal of Development Economics, Vol. 78, pp. 474-493.

Diwan I. and D. Rodrik (1991): "Patents, appropriate technology, and North-South trade," Journal of International Economics, Vol. 30, pp. 27-48.

Fink C., M. Khan, and H. Zhou. (2010): "The surge in worldwide patent applications," presentations to the Third Annual Patent Analysis Workshop, IPTS, Seville, Spain, June 2011.

Ginarte J. C. and W. G. Park (1997): "Determinants of patent rights: A cross-national study," Research Policy, Vol. 26, pp. 283-301.

Hall B., C. Helmers, V. Sena (2012): "The importance (or not) of patents to UK firms," mimeo.

Harhoff, D., K. Hoisl, B. Reichl, and B. van Pottelsberghe (2009): "Patent Validation at the Country Level – the Role of Fees and Translation Costs," Research Policy, 38, pp. 1423-1437.

Helmers, C., M. Rogers and P. Schautschick (2011): "Intellectual Property at the Firm-Level in the UK: The Oxford Firm-Level Intellectual Property Database," University of Oxford, Department of Economics Discussion Paper No. 546.

Helpman, E. (1993): "Innovation, Imitation, and Intellectual Property Rights," Econometrica, Vol. 61, pp. 1247-1280.

Heston, Alan, Robert Summers and Bettina Aten (2012): *Penn World Table Version 7.1*, Center for International Comparisons of Production, Income and Prices at the University of Pennsylvania, downloaded on 30 July 2012.

Kanwar S. and R. Evenson (2003): "Does Intellectual Property Protection Spur Technological Change?," Oxford Economic Papers, Vol. 55, pp. 235-264.

Lerner J. (2002): "150 Years of Patent Protection," American Economic Review, Vol. 92, pp. 221-225.

McCalman P. (2001): "Reaping what you sow: an empirical analysis of international patent harmonization," Journal of International Economics, Vol. 55, pp. 161-186.

Moser, P. (2005): "How Do Patent Laws Influence Innovation? Evidence from Nineteenth-Century World's Fairs," American Economic Review, Vol. 95(4), pp. 1214-1236.

Nordhaus W. D. (1969): "Invention, growth, and welfare: A theoretical treatment of technological change," MIT Press, Cambridge MA.

Park, W. G. and D. Lippoldt (2008): "Technology Transfer and the Economic Implications of the Strengthening of Intellectual Property Rights in Developing Countries," OECD Trade Policy Working Papers, No. 62, OECD.

Png I.P.L. (2011): "Law and Innovation: Evidence from the Uniform Trade Secrets Act," mimeo.

Sakakibara M. and L. Branstetter (2001): "Do Stronger Patents Induce More Innovation? Evidence from the 1988 Japanese Patent Law Reforms," RAND Journal of Economics, Vol. 32, 771-1000.

Scherer F. M. and S. Weisburst (1995): "Economics Effects of Strengthening Pharmaceutical Patent Protection in Italy," International Review of Industrial Property and Copyright Law, Vol. 26, pp. 1009–1024.

Schmoch U. (2008): `Concept of a Technology Classification for Country Comparisons,' WIPO, available at http://www.wipo.int/edocs/mdocs/classifications/en/ipc_ce_41/ipc_ce_41_5-annex1.pdf (accessed February 2012)

Appendix:

A1: Supplementary Figures

Figure A-1: Total filings by technology class (by quarter)

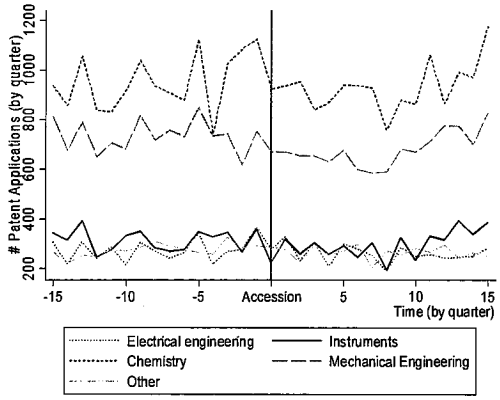


Figure A-2: Filings at national office by technology class

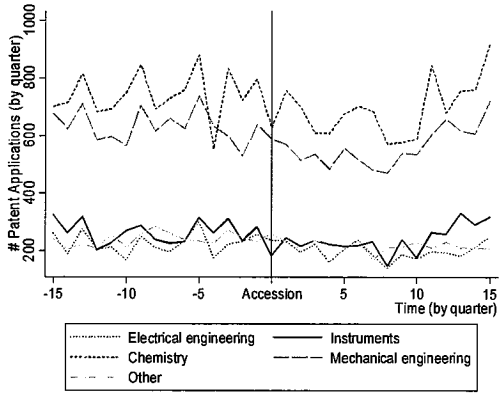


Figure A-3: Filings at EPO by technology class (by quarter)

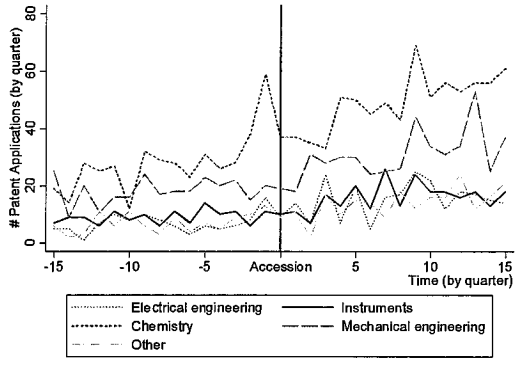
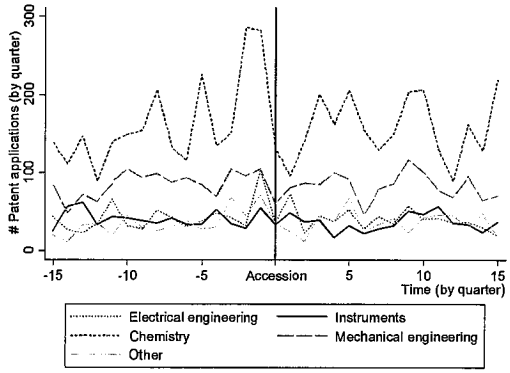


Figure A-4: PCT filings by technology class (by quarter)



A2: Supplementary Tables

Table A-1: Fee overview

Country	*Validation*	*Renewal Fees at national office (Year)*									
	Fees	*1*	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*
Bulgaria	26			26	26	77	102	128	153	204	255
Czech Republic	16	33	33	33	33	66	66	66	66	98	131
Estonia	32	26	26	64	77	96	115	134	153	179	205
Croatia				40	46	53	63	78	94	116	152
Hungary	87*	87	87	87	87	87	87	87	87	87	87
Iceland		96	96	96	108	120	132	144	162	180	198
Latvia	36			86	129	143	150	172	215	258	322
Lithuania	46**	46	46	46	46	46	46	46	46	46	46
Norway		73	73	73	146	182	218	243	279	315	352
Poland	22	117	117	117	61	73	86	98	110	135	159
Romania	60			150	160	180	200	220	240	260	280
Slovakia	7			66	83	100	116	133	149	166	199
Slovenia				30	34	42	50	60	70	80	110
Turkey	169		73	78	86	143	153	191	199	213	247

Notes:

All values in Euros

* plus ~EUR 13 for sixth and each subsequent page

** plus ~EUR 11 for the 11th and each subsequent claim

Source: National Law Relating to the EPC (15th edition)

Table A-2: Accession to the European Patent Convention

Code	*Country*	*Accession date*	*PPP-adj GDP per capita in 2005#*
BE	Belgium	7-Oct-77	33,893
FR	France	7-Oct-77	31,230
DE	Germany	7-Oct-77	31,657
LU	Luxembourg	7-Oct-77	73,243
NL	Netherlands	7-Oct-77	36,402
CH	Switzerland	7-Oct-77	36,994
GB	United Kingdom	7-Oct-77	33,983
SE	Sweden	1-May-78	33,959
IT	Italy	1-Dec-78	29,562
AT	Austria	1-May-79	36,151
LI	Liechtenstein	1-Apr-80	NA
GR	Greece	1-Oct-86	25,308
ES	Spain	1-Oct-86	28,325
DK	Denmark	1-Jan-90	34,677
MC	Monaco	1-Dec-91	NA
PT	Portugal	1-Jan-92	19,949
IE	Ireland	1-Aug-92	40,247
FI	Finland	1-Mar-96	32,293
CY	Cyprus	1-Apr-98	18,240
TR	Turkey	1-Nov-00	9,532
BG	Bulgaria	1-Jul-02	8,904
CZ	Czech Republic	1-Jul-02	20,347
EE	Estonia	1-Jul-02	15,962
SK	Slovakia	1-Jul-02	15,376
SI	Slovenia	1-Dec-02	22,909
HU	Hungary	1-Jan-03	16,476
RO	Romania	1-Mar-03	8,137
PL	Poland	1-Mar-04	13,250
IS	Iceland	1-Nov-04	40,448
LT	Lithuania	1-Dec-04	13,068
LV	Latvia	1-Jul-05	12,031
MT	Malta	1-Mar-07	20,314
HR	Croatia	1-Jan-08	14,028
NO	Norway	1-Jan-08	49,293
MK	FYROM	1-Jan-09	6,573
SM	San Marino	1-Jul-09	NA
AL	Albania	1-May-10	4,939
RS	Serbia	1-Oct-10	7,177

Source: Heston et al. (2012) Penn World Tables.

Table A-3: Regression sample by industry

Industry	*Number of observations*	*Share*	*Number of firms*	*Number of patenting firms*		
				Total	*Pre-accession**	*Post-accession**
Food and kindred products	37,206	16.80%	11,690	58	18	28
Tobacco manufactures	28	0.01%	10	2	1	0
Textile mill products	4,670	2.11%	2,286	18	8	4
Apparel and other textile products	9,531	4.30%	3,356	16	5	8
Lumber and wood products	13,365	6.03%	4,218	27	9	5
Furniture and fixtures	9,304	4.20%	2,732	23	6	6
Paper and allied products	4,446	2.01%	1,241	33	7	20
Printing and publishing	20,715	9.35%	5,731	41	10	8
Chemicals and allied products	11,884	5.37%	3,913	161	70	97
Petroleum and coal products	771	0.35%	307	19	10	12
Rubber and miscellaneous plastics products	13,304	6.01%	4,178	92	24	55
Leather and leather products	237	0.11%	158	3	2	1
Stone, clay, glass, and concrete products	9,792	4.42%	2,773	70	26	32
Primary metal industries	4,576	2.07%	1,255	31	5	18
Fabricated metal products	32,010	14.45%	8,343	177	54	93
Industrial machinery and equipment	20,013	9.04%	5,039	225	54	98
Electrical and electronic equipment	14,239	6.43%	3,849	147	56	91
Transportation equipment	8,347	3.77%	1,946	86	23	38
Instruments and related products	4,719	2.13%	1,348	80	12	35
Miscellaneous manufacturing industries	2,339	1.06%	765	24	3	10
Total	221,496	100.0%	65,138	1,333	403	659

* Excludes Croatia and Norway.

Table A-4: Firm level estimates of the post-accession impact, excluding Romania

Dependent variable	*Number of patent applications in the year*					
	Total		*National Office*		*EPO*	
	[1]	[2]	[3]	[4]	[5]	[6]
Post-accession	-0.145	-0.163	-0.350	-0.337	1.423***	1.137***
	(0.189)	(0.190)	(0.195)	(0.205)	(0.456)	(0.417)
Log (total assets	0.625***	-0.362	0.548***	-0.281	0.746***	-0.644
per employee)	(0.045)	(0.240)	(0.049)	(0.195)	(0.063)	(0.438)
Log (employment)	0.948***	0.092	0.899***	-0.009	1.071***	0.02
	(0.038)	(0.280)	(0.039)	(0.337)	(0.050)	(0.254)
D (subsidiary)	-14.4***		-21.8***		-17.7***	
	(0.4)		(0.3)		(0.4)	
Firm FE	*No*	*Yes*	*No*	*Yes*	*No*	*Yes*
11 Country Dummies	*Yes*	*No*	*Yes*	*No*	*Yes*	*No*
7 Year Dummies	*Yes*	*Yes*	*Yes*	*Yes*	*Yes*	*Yes*
Log likelihood	-30,680.3	-9,784.6	-20,092.0	-6,571.5	-8,479.2	-2,575.6
Observations	143,564	7,219	143,564	6,513	143,564	2,346

Standard errors clustered on firm and adjusted for heteroscedasticity.

The method of estimation is maximum likelihood on a Poisson model.

Table A-5: Firm level estimates of the post-accession decision to patent, excluding Romania

Dependent variable	*Decision to patent*		*Homogeneity testing#*	
	EPO	*National Office*	*Individual*	*Joint*
	[1]	[2]	[3]	[4]
Post-accession	0.302***	0.022	(0.000)	
	(0.069)	(0.035)		
Log (total assets per employee)	0.277***	0.181***	(0.000)	
	(0.017)	(0.011)		
Log (employment)	0.294***	0.293***	(0.950)	(0.000)
	(0.016)	(0.011)		
D (subsidiary)	-3.34***	-4.49***	(0.000)	
	(0.11)	(0.09)		
7 Year Dummies	*Yes*	*Yes*		
11 Country Dummies	*Yes*	*Yes*		
Log likelihood	-11,138.4			
ρ (s. e.)	0.674 (0.017)			
Wald test of ρ=0 (p-value)	676.2 (0.000)			
Observations	143,564			

Standard errors clustered on firm and adjusted for heteroscedasticity.

The method of estimation is maximum likelihood on a bivariate probit model.

ρ indicates the interrelatedness of the two probit models estimated jointly.

#We test the null of parameter homogeneity one by one in the column labelled "Individual." The "Joint" column shows a test for equality of all but the post-accession coefficient

Table 1: Accession states and dates

Country	*EPC Extension Date*	*EPC Accession Date*	*EU Accession Year*
Bulgaria		1/7/2002	2007
Czech Republic		1/7/2002	2004
Estonia		1/7/2002	2004
Croatia	1/4/2004	1/1/2008	
Hungary		1/1/2003	2004
Lithuania	5/7/1994	1/12/2004	2004
Latvia	1/5/1995	1/7/2005	2004
Iceland		1/11/2004	
Norway		1/1/2008	
Poland		1/3/2004	2004
Romania	15/10/1996	1/3/2003	2007
Slovenia	1/3/1994	1/12/2002	2004
Slovakia		1/7/2002	2004
Turkey		1/11/2000	

Note: grey shaded areas indicate country is European Union (EU) member

Table 2: Estimates of the post-accession impact

Dependent variable = log(patent applications +1)

	Post-accession dummy				*Quarters post-accession*			
	WPO	*EPO*	*NAT*	*Non-res*	*WPO*	*EPO*	*NAT*	*Non-res*
				1990-2009 (quarter 1)				
Post-accession coefficient	0.044	0.183	-0.045	**-1.164**	0.045	0.039	***0.072***	**-0.141**
	(0.195)	(0.197)	(0.111)	**(0.321)**	(0.031)	(0.040)	***(0.041)***	**(0.046)**
Standard error	**0.581**	0.551	0.773	1.028	0.572	0.544	0.755	0.998
R-squared	0.787	0.778	0.795	0.734	0.793	0.783	0.804	0.750
Durbin-Watson	**0.971**	**1.277**	**0.324**	**0.182**	**1.004**	**1.304**	**0.340**	**0.187**
				Excluding 8 observations due to small cells*				
Post-accession coefficient	0.083	0.215	0.032	**-1.138**	0.033	0.032	***0.059***	**-0.153**
	(0.219)	(0.213)	(0.112)	**(0.323)**	(0.027)	(0.038)	***(0.034)***	**(0.042)**
Standard error	0.569	**0.545**	0.750	1.028	0.564	0.542	0.739	0.992
R-squared	0.790	0.777	0.850	0.734	0.794	0.779	0.811	0.752
Durbin-Watson	**1.023**	**1.316**	**0.348**	**0.181**	**1.038**	**1.325**	**0.359**	**0.189**

Country & time dummies included

Standard errors clustered on country (for OLS only) and adjusted for serial correlation.

77 quarters*12 countries = 924 observations

* 2 observations in 1990 (Latvia and Iceland) and 6 observations for Turkey (2007/2009) removed because the cells were too small.

Table 3: Regression sample by accession state

Country	*Number of observations*	*Share*	*Number of firms*	*Number of patenting firms*		
				Total	*Pre-accession*	*Post-accession*
Bulgaria	11,489	5.2%	5,270	40	14	32
Croatia*	8,595	3.9%	1,337	27	(27)	na
Czech Republic	24,141	10.9%	5,619	209	62	183
Estonia	1,058	0.5%	451	1	0	1
Hungary	2,817	1.3%	1,873	27	2	25
Iceland	281	0.1%	117	3	1	3
Latvia	1,209	0.5%	232	16	13	7
Lithuania	925	0.4%	221	10	2	8
Norway*	53,768	24.3%	10,906	438	(438)	na
Poland	32,050	14.5%	8,034	349	192	238
Romania	77,932	35.2%	29,163	106	54	65
Slovakia	4,861	2.2%	766	31	34	67
Slovenia	2,370	1.1%	1,150	76	2	30
Total	221,496	100.0%	65,139	1,333	376**	659

* Joined the EPC only in 2008.

** Excludes Croatia and Norway.

Table 4: Firm level estimates of the post-accession impact

Dependent variable	*Number of patent applications in the year*					
	Total		*National Office*		*EPO*	
	[1]	[2]	[3]	[4]	[5]	[6]
Post-accession	-0.126	-0.130	-0.287	-0.268	1.437***	1.151***
	(0.183)	(0.183)	(0.188)	(0.197)	(0.454)	(0.415)
Log (total assets	0.625***	-0.303	0.554***	-0.185	0.746***	-0.642
per employee)	(0.043)	(0.231)	(0.045)	(0.183)	(0.063)	(0.437)
Log (employment)	0.939***	0.137	0.887***	0.070	1.070***	0.019
	(0.036)	(0.275)	(0.037)	(0.335)	(0.050)	(0.254)
D (subsidiary)	-15.0***		-16.3***		-10.5***	
	(0.3)		(0.3)		(0.4)	
Firm FE	*No*	*Yes*	*No*	*Yes*	*No*	*Yes*
12 Country Dummies	*Yes*	*No*	*Yes*	*No*	*Yes*	*No*
7 Year Dummies	*Yes*	*Yes*	*Yes*	*Yes*	*Yes*	*Yes*
Log likelihood	-32,991.4	-10,365.4	-22,361.1	-7,150.6	-8,535.2	-2,584.5
Observations	221,496	7,852	221,496	7,137	221,496	2,362

Standard errors clustered on firm and adjusted for heteroscedasticity.
The method of estimation is maximum likelihood on a Poisson model.

Table 5: Firm level estimates of the post-accession decision to patent

Dependent variable	*Decision to patent*		*Homogeneity testing#*	
	EPO	*National Office*	*Individual*	*Joint*
	[1]	[2]	[3]	[4]
Post-accession	0.304***	0.009	(0.000)	
	(0.069)	(0.033)		
Log (total assets per employee)	0.277***	0.187***	(0.000)	
	(0.016)	(0.010)		
Log (employment)	0.289***	0.281***	(0.563)	(0.000)
	(0.015)	(0.010)		
D (subsidiary)	-3.66***	-4.54***	(0.000)	
	(0.11)	(0.09)		
7 Year Dummies	*Yes*	*Yes*		
12 Country Dummies	*Yes*	*Yes*		
Log likelihood	-12,185.5			
ρ (s. e.)	0.674 (0.017)			
Wald test of ρ=0 (p-value)	691.9 (0.000)			
Observations	221,496			

Standard errors clustered on firm and adjusted for heteroscedasticity.

The method of estimation is maximum likelihood on a bivariate probit model.

ρ indicates the interrelatedness of the two probit models estimated jointly.

#We test the null of parameter homogeneity one by one in the column labelled "Individual." The "Joint" column shows a test for equality of all but the post-accession coefficient

AIPLA QUARTERLY JOURNAL

VOLUME 33, NUMBER 2 Page 153 SPRING 2005

PATENT FILING STRATEGIES FOR PHARMACEUTICAL PRODUCTS: A SIMPLE COST-BENEFIT ANALYSIS BASED ON FILING COSTS AND PHARMACEUTICAL SALES

Robert Silverman[*]

 The author is an associate general counsel at Millennium Pharmaceuticals, Inc. He has a B.A. in biology from Lehigh University, a Ph.D. in chemistry from the University of New Mexico, and a J.D. from the Rutgers School of Law, Camden. The author thanks the following for their review of the manuscript and helpful discussions: Scott Brown and Harriet Winter of Millennium Pharmaceuticals, David Reed of Procter & Gamble, and Dr. Herwig von Morze of Heller Ehrman. Comments from others are welcome and can be sent to Robert.Silverman@mpi.com.

LIST OF TABLES

LIST OF CHARTS

I. INTRODUCTION

Global patent filing strategies to protect pharmaceutical products are generally shaped by two basic considerations: the need to protect a broad geographic market and the long development time prior to commercialization. For most pharmaceutical products there are potential sales in almost every country. Though market size will differ depending on the country and the nature of the disease, therapeutic products are sold virtually everywhere. Consequently, patent protection for pharmaceutical products is typically sought in a relatively large number of countries. Second, there is a long development and clinical testing period required for regulatory approval. According to the Pharmaceutical Research and Manufacturer's Association, only one in five compounds that enter Phase I clinical trials ultimately obtain FDA approval, and the average time to discover and develop a new drug is twelve to fifteen years.[1] As a result, one or more patents covering a pharmaceutical product are usually granted well before the product reaches the market. In fact, patents often issue even before it is known whether there will be FDA or other regulatory approval.

Because of the long delay and uncertainty in getting to the market, it is advantageous to defer, as long as possible without risking any loss of rights, patent filing decisions and patent prosecution.[2] Over time, the prospects of success may become clearer, and better informed decisions can be made on whether to incur or continue to incur patent expenses. Unfortunately, inventors in highly competitive pharmaceutical research do not have the luxury of waiting too long to file for patent protection. Most applicants strive to file a priority application early, usually before a drug candidate has even entered pre-clinical testing. This means that costly global filing decisions usually need to be made at a fairly early stage in a drug's development, well before commercialization is certain. In terms of geographical coverage and expense, the two biggest decisions occur at the national stage of the Patent Cooperation Treaty ("PCT") and at the validation phase after the grant of a European patent.

---

1 PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA, WHY DO PRESCRIPTION DRUGS COST SO MUCH?, *at* http://www.phrma.org/publications/publications/brochure/questions/questions.pdf (Mar. 1, 2001).

2 Notable exceptions to this rule of thumb include patents relating to products that are either already on the market or close to regulatory approval. Examples include patents for a new use or process improvement.

The PCT is designed to serve those who seek broad protection early while wishing to defer most of the global patent procurement expense until a later time.[3] A PCT application is an international application, making it possible to simultaneously protect an invention in as many as 125 PCT contracting states.[4] The 125 PCT member countries account for almost 98 percent of the world pharmaceutical market.[5] Notable non-PCT countries are Argentina, Pakistan, and Taiwan.

In addition to providing early and broad coverage, the PCT also provides a mechanism for deferring expensive global filing decisions. Under the PCT, the procedure for seeking national (or regional) patents may be postponed up to thirty months from the first priority date claimed.[6] Pharmaceutical companies typically take advantage of the full thirty-month period before entering the PCT national stage.[7] Usually the PCT application claims priority to a national application filed one year earlier, such as a U.S. provisional patent application, so the deadline for entering the PCT national stage is eighteen months after filing the PCT application. The national procedure requires

---

3 *Yearly Review of the PCT: 2003* 1, World Intellectual Property Organization (WIPO) Pub. No. 901(E) (2004), *available at* http://www.wipo.int/pct/en/activity/pct_2003.pdf.

4 One hundred and twenty-five states had acceded to the PCT as of January 3, 2005. *Id.*

5 *See infra* Table 1.

6 Patent Cooperation Treaty, *done* June 19, 1970, art. 39, 40 (as in effect in 1970) (amended to include a 30 month time limit on Apr. 1, 2002), 28 U.S.T. 7645, 7685-86, *available at* http://www.wipo.int/pct/en/texts/pdf/pct.pdf [hereinafter PCT].

7 *Id.* Note that a PCT application can enter the European phase within thirty-one months from the priority date under the Convention on the Grant of European Patents (European Patent Convention) and the Implementing Regulations to the Convention on the Grant of European Patents. Convention on the Grant of European Patents, *done* Oct. 5, 1973, art. 150, 1065 U.N.T.S. 199, 298, *available at* http://www.european-patent-office.org/legal/epc/e/ar150.html [hereinafter European Patent Convention]; Implementing Regulations on the Convention on the Grant of European Patents, done Oct. 5, 1973, rule 107 (last amended June 18, 2001), *at* http://www.european-patent-office.org/legal/epc/e/r107.html.

furnishing a translation, where necessary, of the application into the official language of the designated national patent office and paying to it the usual fees.[8]

While designating many countries in a PCT filing is a nominal expense, perfecting the filing in numerous individual countries at the PCT national stage becomes a large expense for the patent applicant. For a pharmaceutical patent application of one hundred pages and twenty-five claims, it would cost over $400,000 to file national applications in all 125 PCT countries.[9] This dollar figure assumes that translation efficiencies will be employed by using a single translation, such as Spanish, for countries requiring the same language. It also assumes that filings will be made in regional patent offices, such as the European Patent Office, rather than in each of the individual countries that are part of the regional convention.

With the high number of PCT applications that a pharmaceutical company files each year,[10] it is not economically feasible to perfect filing in all of the PCT countries at the national stage. Nevertheless, if the application covers a potential commercial pharmaceutical product, a broad PCT national stage list

---

8 *Basic Facts about the Patent Cooperation Treaty* 6-7, WIPO Pub. No. 433(E) (Apr. 2002), *available at* http://www.wipo.int/pct/en/basic_facts/basic_facts.pdf.

9 There are no typical page and claim numbers; they vary greatly. The numbers used for this study were based on a random selection of PCT applications with claims to small molecule composition of matter (n = 100, median number of pages = 91, median number of claims = 25).

10 Pharmaceutical companies were listed among the most frequent PCT users based on the number of PCT applications published in 2003. Merck was the first named applicant on 197 PCT applications published in 2003, followed by AstraZeneca (193); Novartis (187); Glaxo Group Limited (178); Bristol-Myers Squibb (143); Isis Pharmaceuticals (130); Eli Lilly (113); Pfizer (113); Pharmacia (100); Smithkline Beecham Corp. (99); Wyeth (96); F. Hoffmann-LaRoche (94); Abbott (91); Boehringer Ingelheim (87); Pharmacia & Upjohn (84); Aventis (77); Millennium Pharmaceuticals (74); Incyte (72); Schering (70); Smithkline Beecham Plc. (58); and Warner-Lambert (57). For some companies the number of PCT publications is actually higher because their affiliates or acquired companies are listed separately on the Most Frequent PCT Users list. *Most Frequent PCT Users*, 7-12, PCT NEWSLETTER (WIPO), NO. 06, June 2004, at 7-12, *available at* http://www.wipo.int/edocs/pctndocs/en/2004/pct_news_2004_6.pdf.

will typically cover about fifty to seventy countries.[11] While the cost will vary depending mostly on the countries selected, the size of the application, and the number of claims, the PCT national stage will be one of the largest single expenses the applicant incurs. Furthermore, the applicant still faces future expenses associated with patent prosecution, issue fees, and annuities as well as a large expense to validate national patents in Europe after the European patent is granted.

If it is not feasible to seek patent protection in all countries, how much of the pharmaceutical market should be protected, and what countries should comprise the protected market? To answer this question, we adapted methodology used in a 1995 study by Michael Bednarik,[12] and focused our attention first on the PCT national stage, where one of the largest single expenses is incurred. The Bednarik study was not specific to pharmaceutical patents. There, the value of a patent was measured in two ways: by the country's population and by its gross domestic product.[13] The value was then compared to the cost of getting a patent to reveal which national patents provided the most "bang for the buck."[14]

II. RETURN VALUE SCORE ("RVS") METHODOLOGY

In this study, we calculated a measure called the "Return Value Score" ("RVS"), which is the return on the dollars spent to file a patent application in a country based on the country's total annual pharmaceutical sales. We used 2002 and 2003 sales figures provided by IMS Health Services.[15] Patent costs for filings in non-PCT countries and at the PCT national stage were calculated using Global IP Estimator software, based on a one-hundred-page application having twenty-

---

[11] Based on private communications with patent departments at pharmaceutical companies.

[12] Michael K. Bednarik, *Planning a Global Patent Strategy to Maximize Value: Where to Get the Most "Bang for Your Buck,"* 77 J. PAT. & TRADEMARK OFF. SOC'Y 381 (May 1995).

[13] *Id.* at 382.

[14] *Id.* In the Bednarik study, the top ten countries providing the best values for patent protection were the United States, India, United Kingdom, Canada, Japan, Germany, Brazil, France, South Africa, and Australia. *Id.* at 387.

[15] Available from IMS Health, 660 West Germantown Pike, Plymouth Meeting, PA 19462-0905 (U.S.), and IMS Health, 7 Harewood Avenue, London, NW1 6JB, U.K. (worldwide).

five claims and two drawings.[16] It assumes that the original PCT application was filed in English and includes the cost of translation and fees for the patent office and foreign agent. The cost of a Spanish translation was only included once, for a filing in Mexico.[17]

III. PHARMACEUTICAL SALES AND FILING COSTS

Table 1 shows the ranking of countries based on the size of their pharmaceutical markets. For this calculation, the total pharmaceutical sales in a country were taken as a percentage of 2002 total worldwide sales of approximately $417 billion.[18] Member countries of the European Patent Organization ("EPO") and the extension states were grouped together.[19] Filing in the EPO rather than in separate European countries is an option that is almost always selected by pharmaceutical companies desiring to cover Europe at the PCT national stage. Note that a separate analysis for the validation phase after the grant of a European patent is discussed below. Table 1 also includes the market-size rankings for non-PCT countries. The non-PCT filings, if any, would

---

16 Available from Global I.P. Net, 564 Kaiola Street, Kihea, Hawaii, 96753 (U.S.), and Global I.P. Net Europe, 363, Rue de l'Eolienne, 83260 La Crau, France (worldwide).

17 The practitioner should not assume that the use of a Spanish translation that was prepared for an equivalent Mexican application will be acceptable automatically in another country requiring a Spanish translation. For example, the Spanish Patent and Trademark Office requires that the translation be prepared by a Spanish patent attorney or a sworn interpreter appointed by the Spanish government. Nevertheless, it should be expected that the prior translation will help to greatly reduce costs.

18 Available from IMS Health, *supra* note 15. In 2003, total worldwide sales were about $464 billion. *Id.*

19 As of December, 2004, the European Patent Convention consisted of the following contracting states: Austria, Belgium, Bulgaria, Switzerland, Cyprus, Czech Republic, Germany, Denmark, Estonia, Spain, Finland, France, United Kingdom, Hellenic Republic (Greece), Hungary, Iceland, Ireland, Italy, Liechtenstein, Lithuania, Luxembourg, Monaco, Netherlands, Poland, Portugal, Romania, Sweden, Slovenia, Slovakia, and Turkey. EUROPEAN PATENT OFFICE, EPO MEMBER STATES, *at* http://www.european-patent-office.org/epo/members.htm (last updated Dec. 1, 2004). Extension states include Albania, Bosnia and Herzegovina, Croatia, Latvia, the former Yugoslav Republic of Macedonia, and Serbia and Montenegro (formerly known as the Federal Republic of Yugoslavia). *Id.*

be made in accordance with the Paris Convention, within one year after the priority application was filed and usually eighteen months before the PCT national stage. An interesting observation is that the U.S., Europe, Japan, and the other top seven countries alone account for greater than 92 percent of the world pharmaceutical market.[20]

Table 1 also shows the cost of filing a national patent application at the PCT national stage or earlier for the non-PCT countries. From the side-by-side comparison of market share versus cost, it becomes readily apparent that some countries (e.g., Norway) are disproportionately expensive. The last column of Table 1 shows the cost of translation as a percentage of the PCT national stage cost in the previous column. The variability of translation costs and their significance in the cost-benefit analysis are discussed below.

Table 1

Ranking of Countries Based on 2002 Pharmaceutical Sales

Rank	Country	Percent of World Market	PCT National Stage Cost (USD)	Translation Costs[21] (percentage)
1	USA	45.83	3,287	0
2	EPO (+ Extension States)	25.05	13,623	0
3	Japan	12.35	17,382	66
4	Canada	1.87	2,440	0
5	Mexico	1.76	7,351	57
6	China	1.44	8,032	64
7	Brazil	1.18	4,842	48
8	South Korea	1.11	12,386	65
9	India	0.92	1,963	0
10	Australia	0.87	3,006	0
11	Taiwan (non-PCT)	0.61	6,932	66
12	Saudi Arabia (non-PCT)	0.36	10,974	51
13	Venezuela (non-PCT)	0.35	2,650	*

[20] *See infra* Table 1.

[21] An asterisk indicates a translation efficiency due to multiple countries requiring the same language. In such cases, translation costs are not included in the calculation of PCT national stage costs or in the calculation of filing costs for non-PCT countries.

Rank	Country	Percent of World Market	PCT National Stage Cost (USD)	Translation Costs[21] (percentage)
14	Russia	0.34	7,895	55
15	Indonesia	0.33	5,942	46
16	Argentina (non-PCT)	0.32	3,160	*
17	Colombia	0.29	5,417	*
18	Philippines	0.27	2,252	0
19	Norway	0.26	19,088	55
20	Pakistan (non-PCT)	0.23	2,350	0
21	Thailand (non-PCT)	0.21	7,735	68
22	Egypt	0.20	6,185	47
23	South Africa	0.19	2,014	0
24	Israel	0.17	2,208	0
25	Chile (non-PCT)	0.15	2,962	*
26	Ecuador	0.12	4,427	*
27	Morocco	0.11	9,976	72
28	New Zealand	0.10	1,972	0
29	Hong Kong (non-PCT)	0.10	2,687	*
30	Bangladesh (non-PCT)	0.10	1,596	0
31	Peru (non-PCT)	0.09	5,548	*
32	Malaysia (non-PCT)	0.08	2,362	0
33	Dominican Rep. (non-PCT)	0.07	2,912	*
34	UAE	0.07	5,227	*
35	Lebanon (non-PCT)	0.06	2,336	*
36	Ukraine	0.06	7,023	*
37	Singapore	0.06	1,684	0
38	Tunisia	0.05	3,505	*
39	Uruguay (non-PCT)	0.05	3,496	*
40	Belarus	0.04	5,932	*
41	Kuwait (non-PCT)	0.03	2,066	*
42	Jordan (non-PCT)	0.02	18,229	*
43	Paraguay (non-PCT)	0.01	3,276	*
44	Bolivia (non-PCT)	0.01	3,419	*

IV. Relative Cost-Benefit Analysis at the PCT National Stage

For a cost-benefit comparison at the PCT national stage, each country was scored based on the size of the pharmaceutical market covered per dollar-patent cost. A raw score for each country was calculated by dividing its pharmaceutical sales by its filing cost (for non-PCT applications or at the PCT national stage). The raw scores were then normalized based on Japan having an RVS of one hundred. Table 2 shows the normalized RVS for each country.[22]

Table 2
Value of Patent Spending per Country at PCT National Stage Based on Size of Pharmaceutical Market

Rank	Country	Return Value Score (normalized)	Rank	Country	Return Value Score (normalized)
1	USA	1963	12	Argentina	14.1
2	EPO[23]	250	13	Pakistan	13.9
3	Canada	108	14	South Africa	13.3
4	Japan	100	15	South Korea	12.6
5	India	65.6	16	Taiwan	12.5
6	Australia	40.7	17	Israel	11.1
7	Brazil	34.2	18	Bangladesh	8.4
8	Mexico	33.7	19	Indonesia	7.8
9	China	25.2	20	Colombia	7.6
10	Venezuela	18.5	21	New Zealand	7.3
11	Philippines	16.8	22	Chile	7.0

[22] Return Value Scores may be normalized based on any country without altering the results of the analysis. Normalization based on Japan provided numbers that were relatively easy to compare.

[23] Includes extension states.

Rank	Country	Return Value Score (normalized)		Rank	Country	Return Value Score (normalized)
23	Russia[24]	6.1		29	Lebanon	4.3
24	Hong Kong	5.0		30	Thailand	3.9
25	Singapore	4.9		31	Ecuador	3.8
26	Malaysia	4.8		32	Dominican Rep.	3.7
27	Saudi Arabia[25]	4.6		33	Tunisia	2.5
28	Egypt	4.6		34	Peru	2.4

[24] The Eurasian Patent Organization ("EAPO") is a regional patent system which comprises Russia, Azerbaijan, Armenia, Belarus, Georgia, Kazakstan, Kyrgyz, Moldova, Ukraine, Turkmenistan, Belarus, and Tajikistan. EURASIAN PATENT ORGANIZATION, STATES PARTY TO THE CONVENTION, *at* www.eapo.org/eng/information/about.html (last visited Mar. 20, 2005). Comparative world pharmaceutical sales figures were only available for Russia, Ukraine and Belarus. A Eurasian patent may be granted on the basis of an international application filed in accordance with the PCT. *See* Eurasian Patent Convention, *done* Sept. 9, 1994, art. 20, *at* http://www.eapo.org/eng/documents/konvenci.html (last visited Mar. 20, 2005). At the PCT national stage, the filing of a one hundred page EAPO patent application costs $13,980, about 46 percent of which is due to the cost of a Russian translation. Using the Global IP Estimator software, *see supra* note 16 and accompanying text.

[25] The Gulf Cooperation Council ("GCC") has a regional patent system which comprises United Arab Emirates, Kingdom of Bahrain, Kingdom of Saudi Arabia, Sultanate of Oman, State of Qatar, and State of Kuwait. PATENT OFFICE OF THE COOPERATION COUNCIL FOR THE ARAB STATES OF THE GULF, ABOUT GCC PATENT OFFICE, *at* www.gulf-patent-office.org.sa/about_GC.htm (last visited Feb. 12, 2005). The GCC requires documents in the Arabic language. PATENT OFFICE OF THE COOPERATION COUNCIL FOR THE ARAB STATES OF THE GULF, GUIDELINES FOR FILLING OUT A PATENT REQUEST FORM, *at* http://www.gulf-patent-office.org/sa/directions.htm (last visited Feb. 12, 2005). Comparative world pharmaceutical sales were only available for Saudi Arabia, UAE, and Kuwait. The patent cost for each of these countries was based on a direct filing in the national patent office. The filing of a one-hundred-page GCC patent application costs $15,573, about 50 percent of which is due to the cost of an Arabic translation. Using the Global IP Estimator software, *see supra* note 16 and accompanying text.

Rank	Country	Return Value Score (normalized)	Rank	Country	Return Value Score (normalized)
35	Uruguay	2.1	40	Kuwait[26]	1.1
36	UAE[27]	2.0	41	Belarus[28]	0.8
37	Norway	1.9	42	Paraguay	0.6
38	Morocco	1.6	43	Bolivia	0.3
39	Ukraine[29]	1.3	44	Jordan	0.2

Table 2 shows the relative benefit of spending a patent dollar to protect a pharmaceutical product in various countries based on filing costs up to the PCT national stage. In other words, it shows the "bang-for-the-buck" comparison. For example, it is not surprising that the United States would rank number one, but the scores reveal how much more value United States patent spending provides at this stage. The U.S. score is almost eight times greater than for Europe and twenty times greater than for Japan. The disparity between the U.S. and Europe, in the value of patent dollars spent, will be even greater down the road. As discussed below, this is because validation in individual European countries will require costly translations after the European patent is granted.

As expected, countries that accept patent applications in English and do not require translations generally score well. India, Australia, Philippines, Pakistan, and Israel all accept English translations and rank higher in Table 2 than they do in Table 1. In fact, the rankings of India (score = 65.6) and Pakistan (13.9) were surprisingly high.[30] On the other hand, Russia (6.1) and particularly Norway (1.9) notably were on the low end.

---

[26] *See supra* note 25.

[27] *See supra* note 25.

[28] *See supra* note 24.

[29] *See supra* note 24.

[30] Pakistan became a member of the Paris Union on July 22, 2004. Paris Convention for the Protection of Industrial Property, *done* Mar. 20, 1883, Paris Notification No. 211 (entered into force on July 22, 2004), *at* http://www.wipo.int/edocs/notdocs/en/paris/treaty_paris_211.html (notification occurred Apr. 22, 2004).

V. COMPARISON OF FILING STRATEGIES

The cost-benefit analysis can be used to develop and evaluate various global patent filing strategies. The data in Tables 1 and 2 can be employed to evaluate a potential filing in any grouping of the countries. By taking the percentage of the world market and filings costs for the entire group, an RVS can be calculated for the group in the same manner as described above for the individual countries. Using an Excel spreadsheet, we were able to evaluate a number of scenarios representing different countries for patent filings. The following examples illustrate how various filing strategies compare using this analysis.

Option A. All Countries in Table 2

A filing in all of the countries in Table 2 would cost an estimated $283,000 and would cover countries that represent about 99 percent of the pharmaceutical market, based on 2002 sales figures. The Option A group has an RVS of 1.6.

Option B. All Countries with a score of 10 or better

From Table 2, the EPO and sixteen other countries have a score of ten or better: United States, EPO (and Extension States), Canada, Japan, India, Australia, Brazil, Mexico, China, Philippines, South Africa, South Korea, and Israel (at the PCT national stage), and the non-PCT countries Argentina, Taiwan, Venezuela, and Pakistan. These countries represent almost 95 percent of the world pharmaceutical market. At an estimated filing cost of $96,000, this group would cost about 34 percent of the cost of filing in all the Table 2 countries. The Option B group has an RVS of 138.

Option C. PCT Countries with a score of 10 or better

This group includes the same countries as in Option B, but without the four non-PCT countries. The Option C countries represent about 93 percent of the world pharmaceutical market. At an estimated filing cost of $81,000, this group would cost an estimated 29 percent of the cost of filing in all the Table 2 countries. The Option C group has an RVS of 161.

Option D. All Countries with a score of 20 or better

The countries that have a score of 20 or higher include the United States, EPO (and Extension States), Canada, Japan, India, Australia, Brazil, Mexico, and China. These are all PCT countries that represent about 91 percent of the world

pharmaceutical market, at about 22 percent of the cost of filing in all the Table 2 countries. The cost for this group is an estimated $62,000. The Option D group has an RVS of 206. By selecting Option D over Option B, the applicant sacrifices exclusivity in 4 percent of the world market, but the filing costs decrease by about 35 percent.

Chart 1 illustrates how sharply costs increase when coverage of the world pharmaceutical market increases only a few percentage points above 90 percent. The country groups comprise the countries described above for Options A through D. When above 90 percent, the slope for the cost line is much steeper than the slope for the percentage of market coverage line. The cost line slope increases dramatically when market coverage gets above 95 percent.

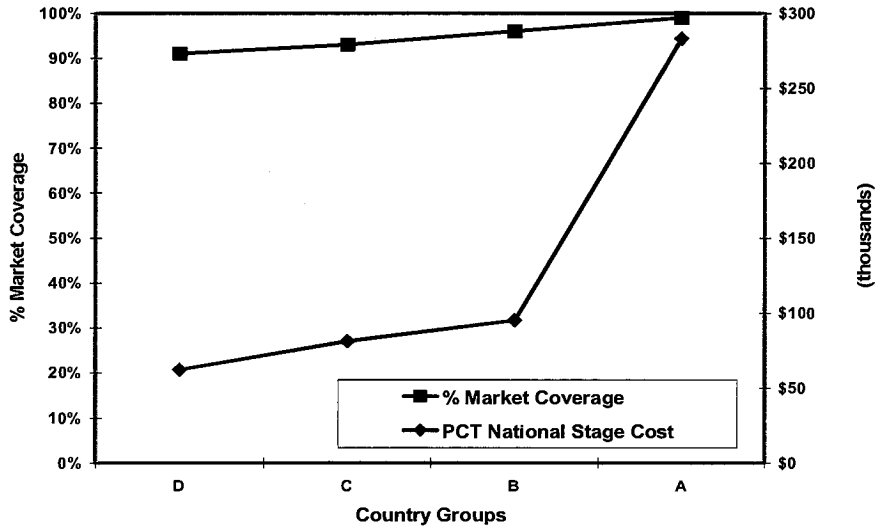


Chart 1

Percent Pharmaceutical Market Coverage versus PCT National Stage Cost

VI. IMPACT OF TRANSLATION COSTS

As expected, a significant cost component at the PCT national stage is the cost of translation. This cost is shown in the last column of Table 1 and ranges from about 46 percent to 72 percent of the total cost for the translation of one hundred pages. As a percentage of the total cost, the cost of translation will go up or down in a manner that is roughly proportional to the number of pages. In

practice, reducing the number of pages in the specification or negotiating a lower fee for the translation service or both will lower the cost. However, an interesting finding is that the translation cost is not likely to matter when the RVS is well below the minimum RVS that is selected as the basis for foreign filing.

To illustrate this point, consider a strategy to file in all countries that have an RVS of ten or better. Those countries would represent 94.5 percent of the world pharmaceutical market. Would it matter if one were able to obtain large savings on translation costs for countries that have an RVS of five or less? The answer is no, as shown using the calculations for Thailand and Norway. If the translation for a Thailand application could be obtained for only $2,500, which is less than half of the estimated cost, the RVS would only improve from 4.5 to 6.8. Likewise, a 50 percent cost savings on a Norwegian application puts that translation cost in line with a French or German translation, but only improves the RVS from 2.2 to 3.1. The large cost savings in each of these examples would have little impact on the RVS scores, which remain well below ten. This finding makes sense when one considers that Thailand and Norway each represent only less than 0.3 percent of the world market. Generally, a translation cost savings does not matter when the RVS (and market size) drops well below the desired cut-off.

VII. RELATIVE COST-BENEFIT ANALYSIS FOR VALIDATION OF EUROPEAN PATENT

The EPO is a centralized patent grant system that was established in 1973 as a result of the European Patent Convention ("EPC"). It consists of thirty contracting states and six extension states.[31] Under the EPC, a European patent can be obtained by filing a single patent application in French, German, or English.[32] The European patent application then undergoes substantive examination in a unitary procedure that is binding on all the member states.[33] When the European patent is granted, it still must be validated in each

---

[31] EUROPEAN PATENT OFFICE, *supra* note 19.

[32] European Patent Convention, *supra* note 7, at art. 14(1), 1065 U.N.T.S. at 262, *available at* http://www.european-patent-office.org/legal/epc/e/ar14.html.

[33] *Id.* at art. 2(2), 1065 U.N.T.S. at 259, *available at* http://www.european-patent-office.org/legal/epc/e/ar2.html.

designated state for which patent protection is sought.[34] Under EPC article 65, any member state can require a translation, which has to be provided within three months after the European grant as part of the validation process.[35] Only Luxembourg and Monaco do not require translations.

The EPO Web site touts the European patent application as "[a] cost-effective and time-saving way of *applying for* patent protection in several different countries."[36] The emphasis is added because the efficiency and cost savings pertain only to the European application and examination process. Broad European patent protection still requires a large expense after the European patent is granted. With the EPC countries using twenty separate official languages, most of the expense is in translation. Cost is particularly an issue in the pharmaceutical field, where a typical product patent tends to be much lengthier than average, requiring more pages of translation. For a patent containing twenty-five claims and requiring one hundred pages of translation, validation of the patent in all thirty-five European countries, including the extension countries, would cost an estimated $180,000.[37]

The EPO and the European Union ("EU") have recently expanded to include several countries that are very small markets. The pharmaceutical market in Spain is larger than that of the eleven Central and Eastern European countries ("CEE") combined.[38] In descending order of 2003 market size, the CEE countries are Poland, Hungary, Czech Republic, Slovakia, Slovenia, Bulgaria, Ukraine, Lithuania, Belarus, Latvia, and Estonia.[39] Eight of these countries, along

---

[34] *See id.* at art. 67, 1065 U.N.T.S. at 275, *available at* http://www.european-patent-office.org/legal/epc/e/ar67.html.

[35] *Id.* at art. 65, 1065 U.N.T.S. at 274-75, *available at* http://www.european-patent-office.org/legal/epc/e/ar65.html.

[36] EUROPEAN PATENT OFFICE, THE ADVANTAGES OF A EUROPEAN PATENT, *at* http://www.european-patent-office.org/gr_index.htm (last updated Sept. 1, 2003) (emphasis added).

[37] Using the Global IP Estimator software, *see supra* note 16 and accompanying text.

[38] *See infra* Table 3.

[39] *Id.*

with Malta and Cyprus, joined the EU on May 1, 2004.[40] Bulgaria, Ukraine, and Belarus are not yet members, although Bulgaria along with Croatia, Romania, and Turkey are candidates to join the EU.[41] With this expansion and the increase in patent cost for covering the EU, a somewhat selective patent strategy would seem to make sense. However, a simple cost benefit analysis, as described above for the PCT national stage, does not account for the economic dynamics of the EU as a whole. A suitable strategy for obtaining adequate patent protection at a reasonable cost should consider not only the individual European countries, but also the interplay of markets within Europe. Individual markets within Europe are interdependent due to the free movement of goods (or parallel imports) and the price disparity among the countries. Because of this interdependence, a patent decision in one EU country may affect the return on a patent investment in another EU country.

In addition to the market complexities within Europe, another important consideration is that the CEE countries represent emerging markets that may grow at a faster rate than the pre-expansion EU market.[42] In light of these factors, most pharmaceutical companies probably would take a conservative approach and seek patent protection in all of the EU countries for a promising development candidate. While broad coverage might make sense for one or perhaps two patents that protect a product, it might not be cost effective for additional patents on the product. Patents that cover various formulations, polymorphs, particular uses, or processes for making the product, especially when they do not extend in time beyond a base patent, would probably only require a more selective or "European-lite" strategy. In devising a European-lite strategy, applying the cost-benefit methodology described above to the European countries would be useful.

---

40 EUROPEAN UNION, THE HISTORY OF THE EUROPEAN UNION, *at* http://europa.eu.int/abc/history/2004/index_en.htm (last visited Mar. 20, 2005).

41 EUROPEAN UNION, THE MEMBER STATES, *at* http://www.eurunion.org/states/home.htm (last visited Mar. 20, 2005).

42 *See Enhancing Income Convergence in Central Europe after EU Accession* 81, *compiled in* OECD ECONOMIC OUTLOOK NO. 74, Organisation for Economic Co-operation and Development (OECD) (June 2004), *at* http://www.oecd.org/dataoecd/5/16/31920392.pdf (last visited Mar. 20, 2005). The OECD monitors economic growth patterns on a regular basis. *See* OECD Economic Projections *at* http://www.oecd.org.

Table 3 shows the RVS for each of the European countries, their percent of the 2003 world pharmaceutical market, and European patent validation cost. The translation cost as a percent of the European patent validation cost and the non-translation component of the European patent validation cost are also shown. The asterisks show countries where efficiency in the translation is possible. For example, a French translation can also be filed in Belgium and Switzerland; a German translation is acceptable in Austria and Switzerland; an Italian translation is acceptable in Switzerland; a Greek translation can be used for both Greece and Cyprus; and a Czech translation can be used for both the Slovak and Czech Republics. Where the asterisk appears, the European patent validation cost was adjusted lower to account for the translation savings.

Table 3

Ranking of European Countries Based on Return Value Score[43]

Country	Percent of World Market	EP Validation Cost (USD)	Translation Cost Percentage	Non-Translation Cost (USD)	Return Value Score (Normalized)
US	*47.3*	-	-	-	*2229*
UK	3.54	1,012	0	1012	610
Germany	5.67	9,065	84	1464	109
France	5.21	8,395	84	1337	108
Japan	11.3	-	-	-	100
Belgium	0.80	1,491	*	1211	94.1
Italy	3.56	8,279	85	1276	75.0
Switzerland	0.61	2,274	*	1274	47.1
Spain	2.51	9,854	73	2615	44.5
Ireland	0.20	1,349	0	1349	26.1
Turkey	0.80	6,766	78	1456	20.6
Greece	0.53	5,892	71	1692	15.8
Austria	0.53	5,873	*	4873	15.6
Poland	0.74	11,035	0	1035	11.6
Netherlands	0.74	11,140	91	1005	11.6
Slovak Rep.	0.11	2,060	*	1060	9.7
Slovenia	0.09	1,695	35	1095	9.5
Portugal	0.49	9,147	77	2147	9.3

[43] The countries shown are those for which pharmaceutical sales data are available.

Country	Percent of World Market	EP Validation Cost (USD)	Translation Cost Percentage	Non-Translation Cost (USD)	Return Value Score (Normalized)
Czech Rep.	0.25	5,705	81	1105	7.6
Bulgaria	0.07	1,921	41	1141	6.7
Luxembourg	0.03	902	0	902	6.0
Hungary	0.35	11,185	70	3342	5.5
Lithuania	0.06	1,851	19	735	5.5
Finland	0.34	14,331	67	4678	4.2
Latvia	0.02	1,451	41	861	2.8
Estonia	0.02	7,942	87	1065	0.5
Sweden	0.49	15,631	70	4650	5.5
Denmark	0.24	13,954	78	3001	3.0

The European countries listed in Table 3 represent over 27 percent of the world pharmaceutical market based on 2003 retail and hospital sales figures. The United States and Japan are included for comparison. The five major European markets are Germany, France, Italy, United Kingdom, and Spain. Together, these five countries represent 73 percent of the European market, at only 22 percent of the overall cost. As previously described, the RVS can be used as a guide to select and evaluate groups of countries. For example, a grouping consisting of Ireland (RVS = 26) and the seven countries with a higher RVS would represent nearly 79 percent of the European market, at 25 percent of the total cost. A grouping consisting of Portugal (RVS = 9.3) and the fifteen higher countries would represent 93 percent of the European market at a little more than 50 percent of the total cost. The problem countries for the patent owner are Sweden, Denmark, Hungary, and Finland. These four countries together represent only 5 percent of the European market, yet because of the translation requirement they account for almost one-third of the total cost of validation. Therefore, omission of these four countries might make sense in a European-lite strategy.

VIII. NET PRESENT VALUE ("NPV") OF PATENT PROTECTION

The cost-benefit analysis described above is useful for comparing the various countries and country groups in a relative sense. The Return Value Scores show, for example, that a patent dollar spent at the PCT national stage in Australia will protect three times more pharmaceutical sales than a patent dollar

spent in Taiwan, and will protect twenty times more sales than a dollar spent in Norway. The IMS Health pharmaceutical-sales data in combination with the IP Global Estimator cost data can also be used to show patent costs for various scenarios of market coverage. By selecting countries with the highest Return Value Scores, one can readily identify groups of countries that provide the greatest market coverage for the patent dollar spent.

This comparative analysis is a useful tool, but it only provides a relative cost-benefit evaluation. It tells us that a patent dollar in some countries has greater or lesser value than in other countries, but it does not tell us if we should actually spend the patent dollar anywhere. For example, consider two hypothetical countries: In the first country, patent protection is worth $100 for every dollar spent; in the second country, the return is two to one. In relative terms, a patent dollar spent in the first country provides fifty times more bang for the buck. In absolute terms, however, the second country still may be a good investment. To know whether patent protection is worth the investment, we need to know how the cost compares to the present value of the expected future revenues that result from patent protection. Present value ("PV") is the discounted value of future cash flows that can be attributed to patent protection.[44] Net present value ("NPV") is the discounted value minus the patent cost.[45]

What follows is our initial effort to estimate the value of patent protection in various countries. Attention was first directed to the smaller markets of the expanded EU, especially the CEE countries. Before EU and EPO expansion, we considered all of the EPO countries to be priority countries for the patent protection of a promising compound. This is consistent with the general consensus that such protection is desirable. However, should this assumption hold after EU expansion? Is it desirable to spend patent dollars in the new EU member states where the cost is relativity high and the market is relatively small? To address this question, we were aided in our analysis by the fact that there is or will be patent and regulatory uniformity within the EU, as discussed more fully below.

The key valuation component to be determined is the future revenue (or more specifically, profit) that results from patent protection. Where a patent

---

[44] RICHARD A. BREARLEY AND STEWART C. MYERS, PRINCIPLES OF CORPORATE FINANCE 14-15 (7th ed. 2003).

[45] *Id.* at 15.

exists, not all revenue can be attributed to patent protection. Even in the presence of generic competition some revenue will be realized, and this portion is not included in the NPV calculation. Also, revenue is not attributed to patent protection during periods of data or market exclusivity. Data exclusivity prevents regulatory authorities from accepting applications for generic drugs during the period of exclusivity. The five year data exclusivity period in the United States is relatively short compared to the EU.[46] New EU pharmaceutical legislation, enacted in 2004, applies the so-called 8+2+1 formula for new chemical entities ("NCEs").[47] Under this formula, a generic application cannot be submitted until eight years after marketing authorization of the NCE, and the generic drug cannot be marketed for another two years.[48] This effective ten-year market exclusivity can be extended by an additional year if the innovator company obtains authorization for a significant new therapeutic indication during the first eight years.[49] If one adds the ten-year period of market exclusivity to the average of ten or more years it takes to get European marketing authorization after the PCT application is filed, a twenty-year patent term would not provide any additional exclusivity with respect to generic competition in Europe. Therefore, for the most part, revenue attributable to a European patent generally is produced during the period of a Supplementary Protection Certificate ("SPC").

---

[46] Federal Food, Drug, and Cosmetic Act §§ 505(c)(3)(D)(ii), 355(j)(4)(D)(ii), 21 U.S.C. §§ 355(c)(3)(E)(ii), 355(j)(5)(F)(ii) (2004). Pursuant to the Act, no § 355(b)(2) application (Abbreviated New Drug Application, hereinafter ANDA) may be submitted by a generic manufacturer during the five-year exclusivity period which is granted to new drug applications for products containing chemical entities, except that an ANDA may be submitted after four years if it contains a certification of patent invalidity or non-infringement.

[47] *See generally* Commission Regulation 726/2004 of 31 Mar. 2004 Laying Down Community Procedures for Authorization and Supervision of Medicinal Products for Human and Veterinary Use and Establishing a European Medicines Agency, art. 14(11), 2004 O.J. (L 136) 1, 10; *see also* EUROPEAN GENERIC MED. ASSOC., DATA EXCLUSIVITY, *at* http://www.egagenerics.com/gen-dataex.htm (last visited Mar. 20, 2005).

[48] Commission Regulation 726/2004, *supra* note 47.

[49] *Id.*

The SPC is a legal title that extends the duration of the exclusive patent right with respect to the drug.[50] The purpose of the SPC is to compensate for the patent term that is lost while the drug is under regulatory review before marketing authorization.[51] The SPC is analogous to a patent term extension in the U.S. under the Hatch-Waxman Act, though there are some important differences.[52] An SPC lasts for a maximum of five years after the basic twenty-year patent term expires, and up to fifteen years after the product is authorized to be placed on the market.[53] Therefore, for the NPV calculation in a country where there is an SPC and a ten-year marketing exclusivity period, we need only consider the revenues that are realized in years twenty-one to twenty-five after the PCT application is filed. This approximate window of time when product revenue can be attributed to patent protection corresponds approximately to years fifteen to nineteen after the European patent is granted.[54]

Calculating the revenue due to patent protection requires the following inputs: (a) the amount of drug sales during the window of patent-only exclusivity; (b) the royalty (or margin) derived from the drug sales; (c) the probability of success, which is based on the likelihood that the European patent

---

50 Council Regulation 1768/92 of 18 June 1992 Concerning the Creation of a Supplementary Protection Certificate of Medicinal Products, art. 4, 1992 O.J. (L 182) 1; Commission Regulation 1610/96 of 23 July 1996 Concerning the Creation of a Supplementary Protection Certificate for Plant Protection Products, art. 4, 1996 O.J. (L 198) 30.

51 *See* Council Regulation 1768/92, *supra* note 50; Commission Regulation 1610/96, *supra* note 50.

52 Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified in scattered sections of 15, 21, 28, and 35 of U.S.C.) [hereinafter Hatch-Waxman Act]. For the calculation of a patent term extension, *see* 37 C.F.R. § 1.775 (2004). Under the Hatch-Waxman Act, a patent term extension is equal to one-half of the time of the investigational new drug (IND) period, IND approval to the filing of a new drug application (NDA), plus the NDA period, the period during the NDA review. The maximum extension is five years and the total market exclusivity time cannot exceed fourteen years.

53 *See* Council Regulation 1768/92, *supra* note 50, at art. 13, preamble; *see also* Commission Regulation 1610/96, *supra* note 50, at art. 13, preamble.

54 The actual window may be slightly greater or less than five years, but five years is a reasonably conservative estimate that errs on the side of obtaining patent protection.

will protect a drug that makes it to the market; and (d) the percent loss in drug sales due to generic competition. The window of patent-only exclusivity (input (a)) extends from the end of marketing or data exclusivity to the end of the patent term, including any extension or supplemental protection. From the expected future revenue, during patent-only exclusivity, the PV can be calculated using a standard discount rate, which in turn can be obtained from the company's finance department. The NPV calculation can be illustrated using various European countries that have a low RVS value. To start, let's assume the following: (a) a drug with $1 billion in annual worldwide sales; (b) a 20 percent royalty on sales of the drug in each of the countries;[55] (c) a 3 percent probability of success; (d) an 80 percent loss in sales due to generic competition; and (e) a 12 percent discount rate.[56] Based on these assumptions, the NPV of patent protection at the European patent validation phase was determined for various countries for a drug with worldwide sales of $1 billion. The NPV was calculated based on revenues earned in the five-year period starting in year fifteen after the European patent validation phase.[57] The results are shown in Chart 2. Under this scenario, Denmark, Finland, Slovakia, Latvia, and especially Estonia have a negative NPV.

---

[55] A 20 percent royalty rate is a reasonable approximation for a company that expects to license its rights in the product. The margin may be higher for a company that markets its own product.

[56] A drug that averages $1 billion in annual worldwide sales, five to ten years after the first commercial sales, would be a blockbuster. The average pioneer drug has a total life-cycle of fourteen to sixteen years, with significant sales-decay during the last six to nine years. *See* Hans H. Bauer & Marc Fisher, *Product Life Cycle Patterns for Pharmaceuticals and Their Impact on R&D Profitability of Late Mover Products*, 9 INT'L BUS. REV. 703, 709 (2000).

[57] All EU accession countries must comply with the entire body of EU pharmaceutical legislation; however, some countries are given limited time to bring their national legislation into compliance under transitional arrangements or derogations. *See* EUROPEAN COMMISSION, CHAPTER 1 – FREE MOVEMENT OF GOODS, *at* http://europa.eu.int/comm/enlargement/negotiations/chapters/chap1/index.htm (last updated Dec. 17, 2004). With respect to marketing exclusivity, the NPV analysis assumes that there will be harmonization by the time revenue is realized from an EP patent that is granted today.

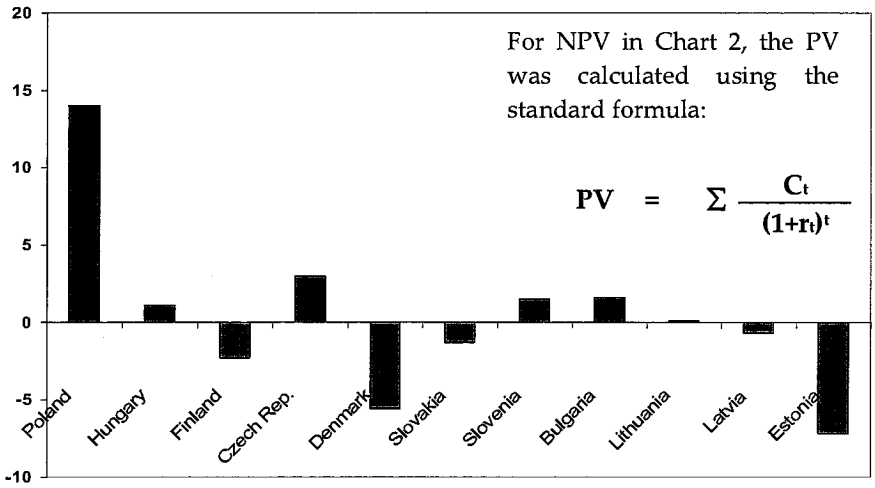


Chart 2

Net Present Value (in $ Thousands) of Patent Investment at the EP Validation Phase for a Worldwide Billion-Dollar Drug[58]

where PV is present value, C_t is the cash flow in year t, and r_t is the discount rate for year t. In other words, PV is equal to the sum of the discounted cash flows. Referring to the inputs for Chart 2, PV can be readily approximated using an Excel spreadsheet as follows: (Expected 5-YR Revenue)*(1.12)^-17, where 1.12 is 1.0 plus the discount rate, and 17 is the average of the years 15 through 19, which corresponds to the window of patent-only exclusivity when the revenues from patent protection are being realized.[59] Note that the 17 is preceded by a minus sign because the $(1+r_t)$ term is in the denominator. The expected five-year revenue in a country is equal to 5 x (average annual sales) x (probability of success) x (percentage of royalty on sales) x (percentage loss in market share from generic competition). The NPV for a country is the PV for the country minus the cost of European patent validation. Note that this scenario is

[58] Key inputs are a five-year window of patent-only exclusivity starting at year fifteen; a 3 percent probability of success; and a 20 percent royalty of sales.

[59] The PV value is an "approximation," because 17 is used as the average of years 15 through 19. This average would be accurate if revenue over the time period is linear. However, there is usually a non-linear decay in sales over the time period. *See* Bauer & Fisher, *supra* note 56, at 709. The "^" symbol is used in an Excel spreadsheet to indicate an exponential term.

conservative in the sense that it is based on a blockbuster drug.[60] By the time patent-only exclusivity in Europe commences, the product is probably more than halfway through its product life-cycle, which averages fourteen to sixteen years. At this point, sales are beginning to decay from the competition of new drugs.[61] Thus, sales tend to be in substantial decline throughout the period of patent-only exclusivity.

IX. SENSITIVITY ANALYSIS

Using the above PV formula, the inputs can be varied, and one can determine how sensitive the NPV calculation is to changes in our assumptions. For example, one can arrive at a more conservative scenario that would favor broader patent protection by making the following adjustments: (a) greater worldwide sales; (b) a higher probability of success in bringing the drug to the market; (c) a higher royalty or margin on sales; (d) a greater loss due to generic competition; (e) a lower discount rate; (f) a greater period of patent-protected revenue; and (g) a shorter time period between patent expense and market authorization. Because Slovakia is a country that had a slightly unfavorable NPV in Chart 2, it is good for illustrating the effect on NPV when changing some of the inputs. Chart 3 shows what happens to the Slovakian NPV when we change the probability of success, royalty rate, and period of time variables for patent-protected revenue.

---

60 Patent managers tend to be more comfortable with a conservative approach. For this reason, we exemplify the NPV for patent investments protecting a blockbuster drug. The methodology is equally applicable if one were to assume lower average sales.

61 *See* Marc Fisher, Michel Clement, & Venkatesh Shankar, International Market Entry Strategy: A Source for Late Mover Advantage? 11 (unpublished seminar paper), *at* http://www.gsb.stanford.edu/facseminars/events/marketing/pdfs/S2004_Mktg_Sem_Marc_Fischer.pdf (Mar. 2004).

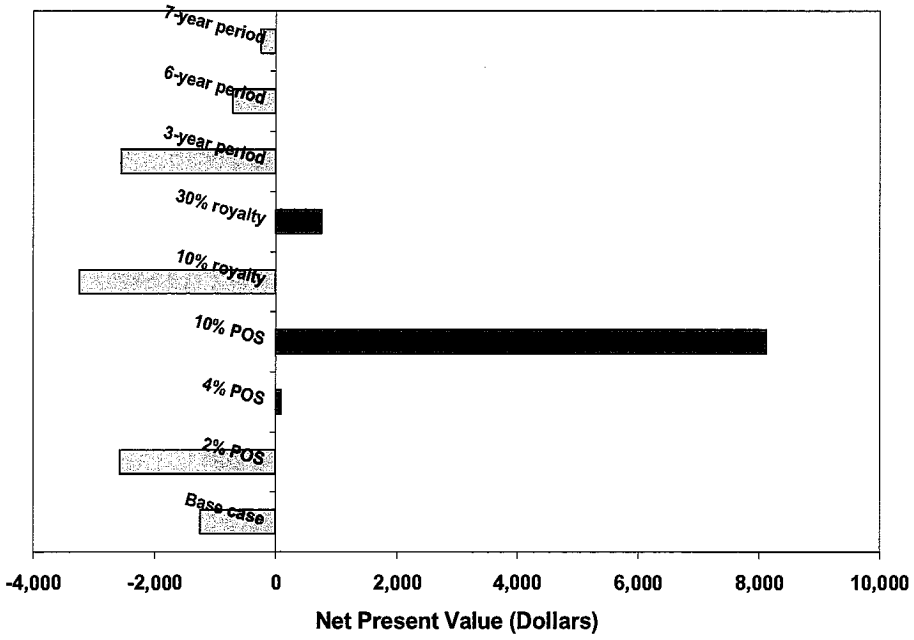


Chart 3

Sensitivity Analysis for Net Present Value of EP Patent in Slovakia[62]

If a recently granted European patent protects a small molecular NCE that is in preclinical or clinical development, some of the inputs will be available as estimates from the company's project team manager. The project team for that NCE will have at least rough estimates of potential market size and the development timelines for the NCE and its estimated regulatory approval. From this information, the patent attorney can calculate the date that data and market exclusivity will end and how much patent exclusivity remains. Also, the project team manager can often provide a probability of success for the NCE. As can be seen in Chart 3, PV is very sensitive to probability of success. Among the inputs, probability of success is perhaps the least accurate of the estimates and depends

---

[62] The base case for Slovakia assumed a 3 percent probability of success; a 20 percent royalty on sales; and a five-year period of patent-only exclusivity. With patent costs of $5,260 at the EP validation phase, the NPV of the base case was a negative $1,248. The chart shows the effect of changing the probability of success, royalty rate, and the period of patent-only exclusivity.

greatly on where the NCE is in development. Because of this sensitivity, a filing decision probably should not turn solely on whether an NPV is slightly negative or slightly positive.

When performing the NPV calculation for PCT countries outside the EU, it should be noted that most countries either have a shorter data- or marketing-exclusivity period or no data-exclusivity at all. For example, under the North American Free Trade Agreement, there is a minimum requirement of five years of data exclusivity that applies to the United States, Canada, and Mexico.[63] Iceland and Norway currently have a six-year period.[64] Other countries, including some that are members of the World Trade Organization ("WTO"), have no period of test data exclusivity.[65] This lack of data exclusivity runs counter to article 39(3) of the Trade-Related Aspects of Intellectual Property Rights ("TRIPs") Agreement, which requires that the data be protected against unfair commercial use.[66] Some of the notable countries that provide for no or very limited test data exclusivity include Israel, India, Argentina, and Egypt.[67]

---

[63] *See* North American Free Trade Agreement, Dec. 8-17, 1992, U.S.-Can.-Mex., art. 1711, para. 5, 6, 32 I.L.M. 605, 675.

[64] EUROPEAN GENERIC MED. ASSOC., *supra* note 47, *at* http://www.egagenerics.com/gen-dataex.htm (last visited Mar. 20, 2005).

[65] *See* U.S. TRADE REPRESENTATIVE, 2004 SPECIAL 301 REPORT (2004), *at* http://www.ustr.gov/assets/Document_Library/Reports_Publications/2004/2004_Special_301/asset_upload_file16_5995.pdf (last visited Mar. 20, 2005). [hereinafter 2004 SPECIAL 301 REPORT].

[66] The concept of data exclusivity is embodied in article 39(3): "Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use." Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPs Agreement].

[67] Letter from L. Val Giddings, Vice President for Food and Agriculture, Biotechnology Industry Organization, to Mark Wu, Director for Intellectual Property, & Sybia Harrison, Staff Assistant to the Section 301 Committee, Office of the U.S. Trade Representative 2, 3, 6, 10, 11 (Feb. 13, 2004), *at* http://www.bio.org/ip/action/3012004.pdf (last visited Mar. 20, 2005).

A shorter period or no period of data exclusivity causes the window of patent-only exclusivity to shift to an earlier date. This shift is favorable to the NPV since the discount rate is applied over fewer years. In other words, the patent investment brings more value when it starts paying off earlier, and it pays off earlier when there is no other mechanism for exclusivity. There are other factors, however, that tend to make the NPV less favorable for many PCT countries outside the EPO. For one, patent investments at the PCT national stage occur earlier than at the European patent validation phase by about three to four years. In Norway, for example, a six-year period of marketing exclusivity does not improve the value of patent protection relative to the EPO countries. This is because the four fewer years of marketing exclusivity are offset by having to make the patent investment about four years earlier at the PCT national stage. Another factor to consider is that many countries do not provide for patent term extension beyond the typical twenty years. Countries where the patent term cannot be extended beyond twenty years include, among others, Thailand, Canada, China, Mexico, New Zealand, and Turkey.[68]

Finally, the probability of success is likely to be lower at the PCT national stage than at the European patent validation phase for a pre-clinical or clinical candidate that is continuing to show promise. After entering the PCT national stage, another three to four years of preclinical and/or clinical information may result in a substantial change in probability of success for the compound, and consequently a substantial change in NPV.[69]

As mentioned earlier, pharmaceutical companies tend to file patents claiming a promising product in about fifty to seventy countries. Some companies file in over ninety countries. This means that within the industry there are considerable differences regarding filing in at least fifteen to twenty countries. To determine whether it makes sense or is a good investment to seek patent protection in this group of lower priority countries, the NPV methodology described above can be useful.

---

[68] WORLD INTELLECTUAL PROP. ORG., HANDBOOK ON INDUSTRIAL PROPERTY INFORMATION AND DOCUMENTATION app. 3, at 3, 4, 10, 11, 15 (1996), *at* http://www.wipo.int/scit/en/standards/pdf/03-09-02.pdf (last visited Mar. 20, 2005).

[69] An interesting side note here is that there should be no rush to get a quick allowance of the European patent application during examination.

X. OTHER CONSIDERATIONS

While the cost-benefit analysis based on pharmaceutical sales and patent costs is a useful tool for designing a global filing strategy, there are other considerations that should be kept in mind. These considerations may impact the value of the patent or the desirability of seeking protection in a particular country. Some of these other considerations are discussed below.

A. Projecting Future Sales

The 2003 pharmaceutical sales figures may be a close approximation of sales in 2005, but today's patent filings cover new pharmaceutical products that will not reach the market for many years. What will the pharmaceutical markets look like far in the future when the product is first commercialized and during the subsequent years of the remaining patent term? Such projections can be estimated using IMS Health, as it provides sales trends for many countries.[70] With these numbers, it may be advisable to file in a country that has an RVS somewhat below the cut-off for the group that was selected, if robust sales growth for the country appears likely.

B. Specific Disease Indications

The pharmaceutical sales figures used above represent the total for all disease indications. However, market sizes will vary depending on the disease. For example, an obesity drug or cholesterol-lowering drug may not sell as well in Southeast Asia compared to a drug that treats infectious diseases. Also, the probability of success will differ depending on the disease. For example, the probability of success in going from the "IND" (investigation of a new drug) filing stage to market is about 28 percent for an anti-infective, but is roughly 15 percent for a central nervous system drug.[71] The cost-benefit analysis can be refined by using sales figures and other inputs that are more applicable for

---

[70] Available from IMS Health, *supra* note 15. More information on the services IMS Health provides *available at* http://www.imshealth.com/ims/portal/front/indexC/0,2478,6599_1825,00.htm (last visited Mar. 20, 2005).

[71] Troy Norris, Using Valuation for Real-World Decisions, Presentation before the 2004 Licensing Executive Society Annual Meeting in Boston (Oct. 17, 2004).

certain diseases or types of diseases. Annual pharmaceutical sales figures for selected diseases are usually available.[72]

C. Enforceability of a Patent

Enforceability is difficult to factor into the analysis.[73] The cost-benefit analysis, above, does not consider whether a country's patent laws are strong or weak. There is a good argument to be made for simply ignoring this consideration. A country with weak patent protection today may have stronger patent laws in ten or twenty years. If globalization and an influential WTO fulfill their promise of strengthening weak economies, more robust patent protection may follow. Nonetheless, enforceability probably will not be a decisive factor unless the market size is small and other reasons for filing in the country are not that compelling.

D. Parallel Trade in Europe

How should parallel trade be factored into patenting decisions within the EU? Under EU law, parallel imports are permitted, so that a purchase of goods from the patent owner or licensee gives the buyer the right to import the goods into another EU country without the patent owner's permission.[74] For

---

[72] Available from IMS Health, *supra* note 15.

[73] The World Economic Forum publishes two quantitative indexes that may be helpful for assessing whether a country has the stable political, legal, and social institutions necessary for patent protection. The indexes are the Growth Competitiveness Index, developed by Professors Jeffrey Sachs and John McArthur, and the Business Competitiveness Index, developed by Professor Michael Porter. For the 2004 indexes results, *see* http://www.weforum.org/pdf/Gcr/Executive_Summary_GCR_04 (last visited Mar. 20, 2005). An additional source is the U.S. Trade Representative (USTR). Pursuant to the Trade Act of 1974, as amended, the USTR issues an annual "Special 301 Report," which examines "in detail the adequacy and effectiveness of intellectual property protection in approximately 85 countries." For the 2004 SPECIAL 301 REPORT, *see supra* note 65.

[74] Commission Communication on Parallel Imports of Proprietary Medicinal Products for which Marketing Authorisations Have Already Been Granted, COM(03)839 final at 3, 6 [hereinafter Commission Communication]; *see also* Consolidated Version of the Treaty Establishing the European Community, Dec. 24, 2002, O.J. (C 325) 47, art. 28 (2002) [hereinafter EC Treaty].

example, drug prices are relatively low in Spain.[75] A portion of the drugs purchased from the patent owner or licensee in one of these countries can be resold at a higher price in England and Germany. Patent rights in England and Germany will not prevent parallel imports into these countries, because the principle of patent exhaustion applies throughout the EU; a patent owner exhausts his rights upon the first sale of goods anywhere within the EU.[76] It is important to keep in mind, however, that patent rights can be asserted against an importer who did not buy the drug from the patent owner or licensee.[77]

Patent protection does not prevent parallel imports; such importation works to the detriment of the patent owner when the price is relatively low in a country of first sale, and there is enough supply of the low-priced drug to be moved elsewhere within the EU.[78] Price differentials and the volume of drug supply in the low-priced country are the main drivers of parallel trade.[79] This begs the question, whether the lack of a patent in a country of first sale will indirectly stimulate parallel imports. This could happen, for example, if the absence of a patent in one EU country invites competition and forces a lower price. The goods bought at this low price could be moved to a higher-priced country despite having patent protection there.

Because parallel imports depend largely on market factors that are unrelated to the patent situation in a low-priced country, it is not clear whether the absence of a patent in this country would cause an increase in parallel imports. An essential factor for parallel trade is having a sufficient volume of drug supply in the low-priced country.[80] In 2003, parallel trade growth slowed

---

75 IMS HEALTH, PARALLEL TRADE – THE NUMBER ONE CONCERN IN EUROPE, *at* http://www.ims-global.com//insight/news_story/0210/news_story_021030.htm (Oct. 29, 2002).

76 Commission Communication, *supra* note 74, at 10-11.

77 *See* TRIPs Agreement, *supra* note 66, at art. 28.

78 *See* Keith E. Maskus, Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries 16, *at* http://www.wipo.int/about-ip/en/studies/pdf/ssa_maskus_pi.pdf (Apr. 2001) (final report to the World Intellectual Property Organization under terms of special service agreement).

79 *See id.* at 11-12.

80 *See id.*

considerably in both England and Germany after years of high growth.[81] This has been attributed to more effective supply-chain management by pharmaceutical companies.[82] Companies that can limit supplies flowing into countries like Spain can stem the tide of rising parallel trade.[83] In two recent European cases,[84] pharmaceutical companies withstood challenges by wholesalers who claimed that the companies' supply-management systems were anti-competitive.[85] At least for now, it appears that an effective supply-management system can mitigate substantially the loss in revenue due to parallel trade.

E. Other Costs

The cost-benefit analysis described above is based only on patent filing costs at the PCT national stage and the European validation phase. These are the largest expenses for the applicant who desires broad coverage of a

---

81 NEIL TURNER, IMS HEALTH, PRICING & REIMBURSEMENT REPORT: PRICING CLIMATE HEATS UP IN U.S. AND EUROPE 4, *at* http://www.imshealth.com/vgn/images/portal/cit_40000873/35/60/56695191PE_PriceClimateHeatsUp_Aug04.pdf (July 2004).

82 *Id.*

83 Note, however, that article 81(1) of the EC Treaty prohibits agreements that have the purpose or effect of restricting competition. EC Treaty, *supra* note 74, at art. 81(1).

84 Joined Cases C-2/01 P & C-3/01 P, Bundesverband der Arzneimittel-Importeure eV v. Bayer AG, [2004] 4 C.M.L.R. 13 (2004). The European Court of Justice (ECJ) dismissed an appeal by the European Commission from an earlier ruling that there was no abuse of dominant position by Bayer when it restricted the supply of its anti-hypertensive drug Adalat in Spain. *Id.* at para. 141. The European Commission had ruled that Bayer's practice was a violation of article 85(1) (now article 81(1)) and fined Bayer €3 million. *Id.* at para. 10, 12. The Court of First Instance annulled the fine. *Id.* at para. 16.

85 *Id.* In a case before the French Competition Council, Phoenix Pharma, a pharmaceutical products wholesaler, alleged that ten pharmaceutical companies, including GlaxoSmithKline, Pfizer, and Eli Lilly, had a supply system designed to freeze market share and competition. The Council dismissed the challenge by Phoenix Pharma. *France: Abuse of Market Power*, EC Nat'l Competition Report (Cleary Gottlieb, Brussels), at 3, *at* http://www.cgsh.com/files/tbl_s47Details%5CFileUpload265%5C167%5CNational%20Competition%20Report%201Q%202004.pdf (Jan.-Mar. 2004).

pharmaceutical product, but they are not the only expenses. For example, maintenance fees in countries can vary quite a bit.[86] It should be noted that the analytical method presented here can be adapted to consider these costs as well.

F. Additional Patent Protection

The cost-benefit methods described above are applied to a single patent application covering a single pharmaceutical product; however, most promising pharmaceutical products are protected by more than one patent or application.[87] Typically, a company will build a patent estate around a product rather than rely on a single patent for protection. For example, the patent estate may include two applications covering the composition of matter for an NCE, where the first application claims the structure generically and the second claims it specifically. Furthermore, the method-of-use claims may or may not be in the same application as the composition-of-matter claims. The estate may also include patent applications that are directed, for example, to a particular polymorph, a manufacturing process, picket-fence chemistry, a combination therapy, a formulation, or a new use. Not only will a product usually be protected by different patents, but the patents may expire at different times. Obviously, not every patent or patent application in the patent estate will have the same value.

Since the RVS method compares countries and groups of countries in a relative sense, different patent applications covering the same product can be treated independently. This means that for a particular patent application, the RVS analysis itself will be unaffected by the presence of other applications in the patent estate. Consider, for example, a first application having generic claims to a product composition and a second application claiming the same product specifically. For each of these applications, the RVS analysis would be the same. There will always be more "bang for the buck" when countries are selected based

---

[86] *E.g.*, USPTO Fees and Payment of Money, 37 C.F.R. § 1.20(e)-(h) (2004); IP Australia, Patent Fees, *at* http://www.ipaustralia.gov.au/patents/fees_index.shtml#roughguide (2004); CANADIAN INTELLECTUAL PROPERTY OFFICE, COMPARISON OF FEES CHARGED BY CIPO FOR TRADEMARK AND PATENT ACTIVITIES IN COMPARISON TO OTHER JURISDICTIONS, *at* http://strategis.ic.gc.ca/sc_mrksv/cipo/con_dis/fee_review3-e.html (last modified Dec. 31, 2002).

[87] *See, e.g.*, Pfizer, Inc., Annual Report for the Fiscal Year Ending December 31, 2004, at 8-9 (Feb. 28, 2005), *available at* http://www.sec.gov/Archives/edgar/data/78003/000095012305002379/y06124e10vk.htm#112.

on having a higher RVS score.[88] This does not mean, however, that the same RVS threshold should be chosen for each application. Most likely, the RVS threshold for selecting countries will be chosen on a case-by-case basis, depending on the type of invention, the expiration date of the patent, and consideration of the overall patent estate.

The NPV of a patent application, on the other hand, may be affected by other patent applications that relate to the same product. However, the NPV analysis is simplified by assuming that the most important or key patent application accounts for almost all of the value of the patent estate. The key application is the one that provides the most protection against generic competition. This is usually the application that would be chosen for patent-term extension or supplementary protection, if available. Assigning almost all of the value of a patent estate to a single application is a conservative assumption that errs on the side of broad geographic coverage. This does not mean that the other patent applications have zero value, but they will probably be much less valuable than the one or two most important applications in the patent estate. Knowing the PV of the key application helps to put the value of the others into perspective. The PV analysis of the key patent application, together with a sense of the relative value of each of the remaining applications, is a useful guide for determining whether a particular patent cost is justified, in view of the other assets in the patent estate.

XI. CONCLUSION

Annual worldwide pharmaceutical sales figures and commercial software for estimating patent costs were used to develop a simple cost-benefit analysis tool. This cost-benefit analysis is useful for evaluating and developing global patent filing strategies for pharmaceutical products, enabling the applicant to maximize the value of the patent dollars it spends. What is most revealing from the analysis is the significant additional cost it requires to gain a few more percentage points of market coverage, beyond the countries that already represent about 91 percent to 95 percent of the world market. After about 90 percent of the market is protected by patent filings in the largest countries, incremental market coverage comes at a steep increase in cost. At Millennium Pharmaceuticals, we have used this type of analysis in devising our

[88] Pharmaceutical sales data in a particular country may not be relevant for some inventions, such as a manufacturing process. For example, this analysis does not address the value of a patent in a manufacturing country that is not the intended market for a product.

global patent filing strategy. We have also begun to model the value of patent protection in various countries where the RVS score is low, especially the smaller markets of the expanded EU. Future efforts will be directed toward refining the cost-benefit model by focusing on some of the considerations discussed above.