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What do patent-based measures tell us about product commercialization? Evidence from the pharmaceutical industry

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ESMT Working Paper

WHAT DO PATENT-BASED MEASURES TELL US ABOUT PRODUCT COMMERCIALIZATION?

EVIDENCE FROM THE PHARMACEUTICAL INDUSTRY

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Abstract

What do patent-based measures tell us about product commercialization? Evidence from the pharmaceutical industry

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Patent-based measures are frequently used as indicators in empirical research on innovation and technology as well as on firms' strategies and organizational choices to characterize inventions or, more generally, innovative activities and the technological capabilities of organizations. A clear correlation between the value of an invention and a number of patent indicators such as the number of citations received has been established. However, there is much less evidence of what patent-based indicators tell us about outcomes beyond patent value. Using data from the pharmaceutical industry, we investigate the relationship between the most frequently used indicators and the outcomes from the product development process. Our findings draw a complex picture regarding the information content of various patent indicators that bear important implications for the use and the proper interpretation of these indicators in settings where they are employed to describe outcomes beyond the patent system itself.

Keywords: Patent indicators, patent system, product commercialization, pharmaceutical industry, drug development

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1. Introduction

Patent-based measures are among the most frequently used indicators in empirical research on innovation and technological change and have become increasingly popular in diverse topics such as studies of labor mobility, firms' strategies and organizational choices. Early work primarily relied on simple patent counts as a measure of innovation output (see Griliches 1990 for a survey). More recently, the availability of comprehensive micro-level data has enabled the construction of more refined indicators aiming at characterizing the patent as well as the underlying inventions on a large scale. These indicators are in general derived from information contained in publicly available patent documents such as patent references, technology classifications or inventors involved. Patent-based indicators constructed from this information have been widely applied to study the outcomes and the functioning of the patent system itself (see Hall and Harhoff, 2012 for a recent survey). Going beyond the patent system itself, patent indicators are increasingly used to study phenomena such as R&D productivity (Jaffe 1986), firm survival (Malerba and Orsenigo, 1999; Nerkar and Shane 2003; Wagner & Cockburn, 2010), investments in young companies (Sorenson and Stuart 2001; Cockburn and MacGarvie, 2009), entry in industries (Cockburn and MacGarvie, 2011), alliance formation (Mowery, Oxley, and Silverman, 1996; Stuart 1998), knowledge flows (Jaffe, Trajtenberg, and Henderson, 1993) among others.

It is important to establish that these patent-based measures actually reflect the more general facts that they are implicitly claimed to represent. Having a clear understanding of the relationship between these indicators and the underlying (and mostly unobserved) outcomes that they purport to measure is important not only for their construction but also for a meaningful interpretation of their effect on the dependent variable. As a consequence much work has been invested in the validation of various patent indicators. The correlation between the value of an invention that underlies a patent and the number of citations a patent receives

by subsequent applications has been clearly established (see Trajtenberg, 1990; Harhoff, Narin, Scherer and Vopel, 1999; Gambardella, Harhoff and Verspagen, 2008; Hall, Jaffe and Trajtenberg, 2005). Using citations derived from patent references is now widely accepted to proxy for the value of the underlying invention. Patent references have frequently been used to characterize knowledge flows and a broad literature discusses to what extent patent references are an informative proxy (Jaffe, Trajtenberg and Fogarty 2000; Henderson, Jaffe and Trajtenberg, 2005; Duguet and MacGarvie 2005; Thompson and Fox-Kean, 2005).

Nevertheless, despite these validation efforts, there is still little known which and to what extent patent indicators convey valuable information with regard to an invention's commercialization and hence the most immediate product market outcome possible. Since patent indicators are often used to describe firms' competitive situation on the product market, a clear understanding of how to interpret patent indicators in settings where they are used to derive conclusions that reach beyond the patent system is of utmost importance. This paper provides new insights into this important question by investigating the relationship between the frequently used patent indicators and the outcomes from product commercialization processes: how fast and how far that product proceeds through the product development process. This approach allows us to make statements about whether and how well patent-based indicators predict the likelihood of product development and ultimately market entry.

Rooting our study in the pharmaceutical industry has various advantages for achieving our objective. First, obtaining a clear and unencumbered patent position is essential for commercializing an innovation in the pharmaceutical industry (Cohen, Nelson and Walsh 2000). Patent rights in this industry are generally strong which should allow for an easier detection of correlations between patent indicators and outcomes of the product commercialization process. Second, the pharmaceutical industry is a discrete industry where

a relatively small number of patents (often only 1 patent) protect an entire product. This allows us to clearly link candidates for product development to patents protecting the underlying invention. Such an approach would be nearly impossible in complex technologies where a large number of patents is associated with a product. To the best of our knowledge, our study is the first attempt to combine fine-grained patent indicators with product market-outcomes (here success in commercializing new products) on a large scale.

Our findings draw a complex picture regarding the effect of patent indicators on product commercialization outcomes. Overall, the effect of most indicators is in line with expectations. Previous findings on the relation between patent indicators and outcomes within the patent system such as patent grants or opposition hold in our sample. More importantly, we find that strong intellectual property (IP) protection is related with increased hazards and higher speed of product commercialization, as are other frequently used value indicators such as forward citations or the number of countries in which a patent has been applied for. Interestingly, our data reveals that products associated to patents with a higher share of critical prior art reach earlier stages of the commercialization process slower while passing faster through later stages of the development process. We argue that once the IP protection has been clearly delineated which takes longer for these “difficult” patents firms speed up the commercialization process.

The remainder of the paper is structured as follows: In the next section (section 2), we briefly summarize how patent-based indicators have been used and interpreted in existing literature. In section 3, we describe our data set and the constructed variables used in our analysis. Section 4 links important patent-based indicators to outcomes in the product commercialization process in a descriptive way before we discuss our multivariate regression approach and present the results from duration models in Section 5. The paper concludes with a brief discussion in Section 6.

2. Patent-based indicators and pharmaceutical product commercialization

2.1 Patent-based indicators

A large volume of literature has used a range of patent-based measures to characterize aspects of inventions, innovative activities or firms and their strategies and organizational choices more generally. It is beyond the scope of this paper to provide a full survey of patent indicators and their use; we restrict ourselves to highlight the most important stylized facts. To start with, amongst the most accepted patent-based measures are indicators of patent value (or to be more precise indicators of the value of the inventions underlying patents). The most widely used patent-based variable used to proxy for the value of the underlying invention is the number of citations the focal patent receives from subsequent patents (Trajtenberg, 1990; Harhoff et al., 1999), commonly referred to as “forward citations”. Citation-based indicators have been frequently validated. The validation efforts include correlating them with responses from surveys of patentees with regard to the value they actually extracted from specific patents (Harhoff et al., 1999; Harhoff, Scherer and Vopel, 2003; Gambardella et al., 2008) and to other measures of value such as stock market valuations measured in Tobin’s q (Hall et al., 2005) or indicators of public surplus (Trajtenberg, 1990). The disadvantage of using citation-based indicators of patent value is that they are available only with a considerable lag as citations only arrive over time. It is common to use the number of citations that a patent has received within 5 years after its application. The number of years a patent has been renewed has also been used as a value indicator (Pakes and Schankerman, 1984; Pakes, 1986; Schankerman and Pakes, 1986; Lanjouw, Pakes and Putnam, 1998). To observe renewals, however, one has to wait even longer than for citation measures and information on the full renewal history is only available 20 years after their application. Alternative value indicators that are available already during the process of patent

examination or at patent grant include the number of countries in which protection is sought (Putnam, 1996; van Pottelsberghe de la Potterie and van Zeebroeck, 2008), whether it was applied under the Patent Cooperation Treaty (PCT) (Harhoff and Reitzig 2004; Harhoff and Wagner, 2009), and whether the patent has been upheld by the EPO following an opposition proceeding (Harhoff et al., 2003).

A related strand of work uses measures based on patent references to characterize the nature of inventions. These references document the state of the art that is relevant to judge the patentability of an invention seeking patent protection and are published by patent offices in a search report that accompanies published patent documents.¹ Henderson, Jaffe and Trajtenberg (1998) use the distribution of technology classes of patents that the focal patent refers to (backward references) or receives citations from (forward citations) to construct measures that describe the technological originality and generality (respectively) of new inventions. It can be argued that inventions that are applicable in more technologies (and hence are more general) are more valuable than other inventions. Various studies have also used the proportion of patent to non-patent references to characterize how close an invention is to basic science (Trajtenberg, Henderson and Jaffe, 1997; Narin and Noma, 1985; Narin, Hamilton and Olivastro, 1997; Meyer, 2000).

At a more aggregate level, several authors have constructed measures of the similarity between firms based on the distribution of patent applications across technology fields as an explanatory variable for other analyses (Jaffe, 1986; Mowery et al., 1996). Similarly, Ziedonis (2004) uses patent references to measure the fragmentation of ownership in the technological space on which a firm's R&D activities draw. Meanwhile, numerous papers starting with Jaffe, Trajtenberg and Henderson (1993) have used patent references to

¹ Both patents as well as non-patent literature documenting the state of the art at a given point in time are included in the search report.

characterize the flow of knowledge between inventions and across organizations triggering a whole stream of research both in the economics and management literature. The use of patent references to trace knowledge flows has been intensely discussed in the literature (see Henderson et al., 2005; Thompson and Fox-Kean, 2005; Alcácer and Gittelman, 2006). Results from surveys of inventors suggest that references might be noisy measures of knowledge flow but are not systematically biased (Jaffe et al., 2000; Duguet and MacGarvie, 2005).

Some more recent literature has exploited the “X” and “Y” classifications given by the European Patent Office (EPO) to prior art identified in its review of the patent application (Michel and Bettels, 2001; Webb et al., 2005) to characterize weaknesses in patents and patent portfolios. Documents implying that a claimed invention cannot be considered novel or cannot be considered to involve an inventive step are called X references. In case a document has to be combined with one or more other documents to imply a lack of novelty or inventiveness they are called Y reference.² A series of papers have used X and Y references to identify patents that may prevent subsequent patents from being exploited – so-called blocking patents (Grimpe and Hussinger, 2008; Czarnitzki, Hussinger and Leten, 2011; Guellec, Martinez and Zuniga, 2012). von Graevenitz, Wagner, and Harhoff (2011) use X and Y-type references to construct a network-based measure of the density of patent thickets, and find a clear relationship between these measures of patent thickets and firms’ patenting strategies as well as the way they resolve conflict (von Graevenitz, Wagner and Harhoff, 2013; Harhoff, von Graevenitz & Wagner, 2013). A series of papers have demonstrated that an increasing number of X and Y references not only decreases the likelihood that an application ultimately leads to a patent grant (Harhoff and Wagner, 2009) but also increases

² See EPO Guidelines for Examination, Part B, Chapter X, Section 9.2.1, available at http://www.epo.org/law-practice/legal-texts/html/guidelines/e/b_x_9_2_1.htm, latest access on 30th of December 2013

the likelihood that a patent will be opposed conditional on grant (Harhoff and Reitzig 2004; Harhoff, von Graevenitz and Wagner, 2013). However, given that X and Y-type references are an input into the patent approval process and do not relate directly to the patent that is actually granted, it is an open question whether these measures provide any information beyond whether the patent is likely to be granted and/or upheld after a patent opposition proceeding.

We attempt to shed some light into this question and also aim to contribute to a more-refined understanding of the relationship between the indicators described above and the outcomes not only within the patent system but also beyond. More specifically, we relate patent-based indicators to outcomes of product commercialization on the level of individual products.

2.2 Product commercialization in the pharmaceutical industry

The pharmaceutical industry is characterized by a high R&D intensity and developing new drugs is expensive. Estimates of the average cost of development generally exceed \$US800 million (DiMasi, Hansen and Grabowski, 2003; Adams and Brantner, 2006) and research active pharmaceutical companies (originator companies) spend about 17% of their revenues from prescription drugs on R&D (European Commission 2009).³ The commercialization process of inventions in this industry can be divided in three different phases: (i) the pre-launch period where R&D, clinical trials and clinical tests take place, (ii) the marketing and sales period during which the originator company sells its product under exclusivity usually derived from patents and (iii) a post-exclusivity period where competition by generic companies copying the initial invention is possible (European Commission, 2009). We focus on the pre-launch period, and specifically the duration between the invention of a

³ Note that 1.5% of the revenues made from prescription drugs is spent on basic research while the remaining fraction is spent on clinical trials and tests (European Commission 2009).

product and its market launch is of utmost importance for companies commercializing pharmaceutical inventions. Initial patents relating to a drug are typically filed during the stage of basic R&D and have a fixed duration of 20 years. Hence, the length of the period during which a drug can be sold by the originator company under exclusivity granted by the primary patent right is directly determined by how much time lapses between patent filing and the market launch of a product. The shorter the duration of the pre-launch stage, the more time an originator company has to enjoy exclusivity from patent protection and has a chance to recoup the investments made during drug discovery and testing within facing competition from companies selling drugs based on the same substance.

The pre-launch phase contains the search for molecular targets associated with a disease and the identification of novel pharmaceutically-active substances that interact with the target. Once a substance has been identified, various preclinical and clinical tests will be carried out to ascertain toxicity and efficacy of the new molecule. Finally, national regulators have to approve the drug before it can be sold on the market. The overall duration of the pre-launch period is of significant length. Sternitzke (2010) reports an average duration of about 11.5 years, while the European Commission (2009) reports a shorter period of only 8.6 years for a selection of 144 substances. After the initial discovery of pharmaceutically active substances companies will usually file first patent applications related to the active molecules themselves.⁴ Depending on the actual duration until a substance is first sold on the market originator companies are generally left with a period of 8 to 12 years during which they enjoy exclusivity arising from a granted patent right.

⁴ These applications, and the resulting patents, are generally referred to as "primary patents" because they relate to the first patents for the active molecules. Companies often file further patent applications for different aspects of the active molecules. These are usually related to dosage forms (e.g. tablets, capsules or solutions for injection) or for particular pharmaceutical formulations (mixtures of active agents and other substances which promote the activity of the medicine) –referred to as “secondary patents” (European Commission 2009).

We examine the relationship between the range of patent-based measures and the progress through the pharmaceutical commercialization process of the underlying inventions to which the patents relate. Although the literature discussed above has clearly established a relationship between forward citations and the value of inventions in general, it also shows that citations only explain a small proportion of variation in the value (Gambardella et al., 2008). Hence we cannot assume that all value-increasing aspects of an invention will be positively correlated the number of citations. In particular, in the pharmaceutical industry, the value of an invention depends on technological, clinical, and commercial aspects. While we might reasonably assume that patent citations are positively related to the technological aspects (i.e., whether the invention enters clinical trials), it is an open question whether patent citations provide any information about the likelihood that the invention will progress through clinical trials or whether it will be a commercial success once approved.

Similarly it is also worth examining whether the number of countries in which a patent was filed provides any information about the likelihood of success during the product commercialization process. Although we do not have any information on the commercial success of the product, our data enables us to distinguish between the technological and clinical aspects and examine the relative impact of forward citations, family size, etc. on these different aspects of commercialization.

At the same time, we are able to validate the relationship between some of the other reference-based measures and non-patent-based outcomes. In particular we examine whether the existence of X or Y-type references in the prior art tells us whether the product will enter clinical trials or make it through the clinical trials process, conditional on the patent being granted. In addition, we look at what the reference-based measures that have been used to characterize other aspects of an invention indicate about product commercialization. We examine how the originality and generality of the patent (as defined by Henderson et al.,

1998) are related to the underlying product's success at both the technological (i.e., preclinical) and clinical stages of commercialization.

Finally, we also look at the relationship between product commercialization and the number of claims included by the patent applicant in the filing that marks the boundaries of the patent. It should be stressed that the arguments about how the number of claims is related to value are not uncontroversial: Each additional claim might raise the probability of an infringement and therefore the value of a patent. On the other hand, however, additional claims make the description of the claimed invention more specific and might narrow the scope of the protected area and hence the value of the property right (Lanjouw and Schankerman, 2004b).

3. Data and variables

The data used for our analysis is derived from two major sources: IMS Lifecycle R&D Focus database ("R&D Focus") – as of April 2011 – and PATSTAT. R&D Focus is a proprietary database that contains extensive information on just under 30,000 development projects (i.e., product candidates) in the pharmaceutical and biotech industry until the end of 2009. It is organized by product, and each product record contains information such as the developing company, the Anatomical Therapeutic Chemical (ATC) classification of the product, and a detailed history of the major clinical development and commercialization events.⁵ For about 30% of the products, R&D Focus lists the primary patent (or patents) covering the products. The primary patent covering a given product may be filed in any jurisdiction. In order to construct patent indicators that are comparable across products we

⁵ Whether a product is included in the R&D Focus dataset prior to product launch depends to a large extent on voluntary disclosure by the product owner. Requirements for publicly listed companies to disclose "material" information often mandates disclosure of information about products in later-stage clinical trials, and in recent years new regulations have required more trials to be registered and disclosed (e.g., through clinicaltrials.gov). However, typically we only observe products that have reached a pre-clinical development milestone.

use the patent family information provided by PATSTAT to identify the EP equivalent (if the primary patent is not filed in the EPO) of the primary patents listed in R&D Focus. Our sample includes all products contained in R&D Focus which are (1) either covered by a patent filed at the EPO or by a patent that has an EP equivalent filing and (2) have priority dates greater or equal to 1980 for our study.

In total, we identify 5,923 products with an average of 1.12 primary patents associated to them in R&D Focus (see Table 1). Since some of the non-EP primary patents have more than one EP equivalent filing, this results in a total of 8,247 unique EP patents with application dates ranging from 1980 to 2007. It is worth noting that some of the identified EP patents are associated to more than one product. Our final sample therefore contains 9,229 unique product-EP patent-pairs. For each of the 5,923 products, we observe whether and when certain stages in the (pre-)clinical development process were achieved before end of 2009. As Figure 1 shows, these products are subject to the severe attrition along the various stages that is characteristic for the drug development: Only 10.6% of the products are launched on a European market after an average duration of slightly more than 11 years. These figures are broadly in line with earlier statistics derived from a comparably yet much smaller dataset in Sternitzke (2010).

INSERT FIGURE 1 ABOUT HERE

In our multivariate analyses we will employ duration models which exploit as dependent variable the duration (i) between the invention of a product and reaching a particular stage and (ii) each particular stage in the development process. This allows us to relate various patent indicators to the hazard that a given stage of the development process will be reached and what their effect on the duration of the development cycle is. We obtain comprehensive data on the characteristics of the patents covering these products from PATSTAT which

allows computing the patent-based indicators of interest. We focus on EP patents as there is more fine-grained information available as for patents filed at other offices. For each of these patents we compute the following indicators.

Legal status of the patent application

For each patent application we observe important features of its examination history: In addition to the date when the application was filed at the EPO subsequent stages in the patenting process including whether and when a *patent grant (0/1)* was issued as of October 2011 are covered by our data. Based on this information we compute the *grant lag* as the difference between the date of the patent grant and its application date. Moreover, we also observe whether granted patents are challenged in an *opposition (0/1)*. (See Harhoff & Reitzig, 2004, for a detailed information on the opposition procedure at the EPO.)

Characteristics of the patent document

We compute the number of patents belonging to a patent family (*family size*) as an indicator of the scope of international protection sought by the applicant. An indicator variable for whether the application was filed under the *Patent Cooperation Treaty PCT (0/1)* is included in the analyses. The PCT provides a unified procedure for filing patent applications to protect inventions in up to 147 contracting states within 30 months of the filing date. PCT applications allow the expansion of patent protection to a large number of countries without incurring the full costs and complexity of national application path and hence have greater option value. It allows applicants to delay the choice of countries for which they designate the application for up to 30 months after the priority date compared to only 12 months for national or regional patent applications. Our data also contains the *number of claims* of a patent that marks the boundaries of the patent (van Zeebroeck, van Pottelsberghe de la Potterie and Guellec 2009). Finally, we derive the technology

classification an application has been assigned to by the patent office in order to capture structural difference across technologies using the *IPC classification* on the 2-digit level.

Reference-based measures

Along with the publication of a patent application 18 months after its filing, the EPO also publishes the search report which contains information on prior art relevant for the patentability of an application by referencing previous patents or non-patent literature (mostly scientific publications). We compute various indicators from these (backward) references including the *number of patent references* and the *number of non-patent references* contained in a patent's search report.

In addition to the mere count of patent references contained in the search report we also account for their composition. At the EPO, references contained in a patent's search report are classified into different categories: Most importantly, X-type references indicate that a single prior patent is in conflict with the applications claims. Y-type reference may do the same in combination with other references. We compute the *share of X-references* and the *share of Y-references* (relative to the total number of references). Finally, we exploit the technology classification of the patent references to compute the *originality* index. The originality index is a Herfindahl-based index and defined for patent i as

$$originality_i = 1 - \sum_k^{N_i} \left(\frac{Nreferences_{ik}}{Nreferences_i} \right)^2, \text{ where } k \text{ is the index of technology classes and } N_i \text{ is the}$$

number of different classes to which the referred patents belong. Since $Nreferences_{ik}$ is the number of references contained in patent i that point to technology k and $Nreferences_i$ is the total number of references, originality is bounded between 0 and 1. Higher values represent less concentration and hence more originality of the invention in the sense that it draws on a wider set of different technologies (Henderson, Jaffe and Trajtenberg 1998).

Citation-based measures

The citations a patent receives are – just citations of scientific publications – are a signal that the cited patent contributed to the state of the art in a technology field and hence bear value. For the patents in our sample we compute the *number of forward citations* these patents receive from subsequent EP patents within a period of 5 years excluding self-citations.⁶ In order to get a fine-grained measure of the impact a patent has on a technology we compute the *share of citations from X-type references* and the *share of citations from Y-type references* relative to the total number of citations. It can be assumed that the higher the share of X- or Y-type citations, the higher the likelihood is that a patent poses an obstacle for patenting subsequent innovations that are related. Finally, we also account for the distribution of the technology classification of the patents citing a focal patent by computing the *generality* index analogous to the originality index. Generality of patent i is defined as

$$generality_i = 1 - \sum_k^{N_i} \left(\frac{N_{citations_{ik}}}{N_{citations_i}} \right)^2$$
, where k is the index of technology classes and N_i is the

number of different classes to which the citing patents belong. Generality is bounded between 0 and 1 with higher values indicating that a focal invention is relevant for a wider set of different technologies and hence is more general (Henderson, Jaffe, Trajtenberg 1998).

Applicant characteristics

Patent documents contain information on the patent applicant including its identity and its country of origin. The ECOOM-EUROSTAT-EPO PATSTAT Person Augmented Table (EEE-PPAT) provides a harmonization of the applicant names listed on EP patents.⁷ We use

⁶ We compute the number of forward citation received within a 5 year period to avoid bias arising from the fact that “older” patents have a longer period over which they can receive citations compared to “younger” patents.

⁷ We use the applicant names provided by the ECOOM-EUROSTAT-EPO PATSTAT Person Augmented Table (EEE-PPAT) which provides harmonized applicant names for the PATSTAT database. See Magermann et al. (2010) for a full description.

these harmonized names to compute the *cumulative number of patent applications* filed by a patent applicant on annual basis as a coarse proxy of size. We also characterize applicants by their *country of origin* and distinguish between applicants located in Europe, in the US, in Japan or in ‘the rest of the world’ (ROW). Finally, the EEE-PPAT data classifies applicants according to their *organizational form* as companies, Government/non-profit, University/hospital and individuals. This information allows us to control for organizational form.

4. Descriptive statistics

Our sample consists of 8,247 unique EP patents corresponding to 5,923 products. In addition to Figure 1 we report a breakdown of the different stages these products achieved distinguishing entering pre-clinical trials, Phase 1/2/3 clinical trials, and market launch in at least one major European country. Most notably, products reaching higher stages seem to be characterized by stronger patent protection than products that did not. Successful products are not only associated to a higher number of primary patents in R&D Focus, but also the EP equivalent applications corresponding to the R&D focus priorities have been granted at a higher frequency. We interpret this finding as an indication that organizations put more effort in commercialization if they are able to get strong patent protection. When interpreting Table 1, however, it must be taken into account that these findings might partly be influenced by censoring as products that reached advanced stages are older than the average product. As a consequence, the lengthy process of patent examination is more likely to have been completed for more advanced products. This is one of the major reasons we employ duration models in our multivariate analysis as they are able to properly account for this censoring of the data. It should be noted, however, that the number of priority patents associated to a product are not affected by censoring but are a result of an organization’s patenting strategy that is carried out in a relatively short time-period after invention. Taken together, Table 1

suggests that stronger patent protection is correlated with products moving further ahead in the development process.

INSERT TABLE 1 ABOUT HERE

As has been demonstrated in prior literature, patent-based indicators contain information regarding the strength of a patent as they predict whether an application results in a patent grant and also whether granted patents are opposed. Before we move on in describing how patent indicators correlate with product commercialization, we relate important patent-based indicators to outcomes *within* the patent system. This allows us to validate whether stylized facts regarding patent indicators also hold within our sample. In Table 2, we report descriptive statistics for the patents underlying the products in our sample and compare them to the respective value of the underlying population of all EPO patents. For this purpose we created a sample of roughly 50,000 EPO that match the composition of the original 8,247 patents along the dimensions application year and IPC4 classification. Overall roughly two thirds of the patents in our sample have been granted by the EPO while the share of granted patents that are opposed subsequently is 6.5% (see Table 2). The grant rate in our sample is significantly higher than the grant rate in the underlying population which indicates the importance of patent protection for the commercialization of pharmaceutical products. However, we don't see a significant difference between our sample and the population of patents in the occurrence of opposition against granted patents.

INSERT TABLE 2 ABOUT HERE

The descriptive statistics presented further clearly indicate strong correlations between numerous patent-based indicators and patenting outcomes, as anticipated. For instance, we observe that valuable indicators such as the number of citations received, and family size are higher in the group of granted applications. Moreover, our descriptive findings are also

consistent with prior evidence in Harhoff and Reitzig (2004) and Harhoff, von Graevenitz and Wagner (2013) that more valuable patents are more likely to be opposed subsequently (see right panel of Table 2). It should be noted that patents associated to inventions that were developed for commercialization seem to be more valuable than the average patent from the underlying population. The value indicators in our sample of IMS patents are all significantly higher than for the EPO population.

The number of backward references and their composition are also related to patenting outcomes: We find that patents that have been granted are characterized by a smaller number of references than those not granted with a similar pattern for opposed patents. More importantly, and in line with previous findings in Harhoff and Wagner (2009), we find that granted patents are characterized by a fewer critical references. In particular, the share of X-references is more than 10 percentage points lower for granted patents when compared to non-granted patents. This is not surprising as X-references indicate the existing of prior art that limits the patentability of an application under scrutiny. Opposed patents are characterized by a higher share of critical references but the difference is less pronounced when compared to grants vs. non-grants. Harhoff and Reitzig (2004) find similar results.

Finally, and most importantly, we relate patent characteristics which have been shown to impact outcomes within the patenting process to outcomes beyond the patent system. In Table 3 we report descriptive statistics of the patents indicators broken down by the stage in the development process a product reached. Most value indicators correlate with a product's commercialization success. In particular, the average family size, and the number of forward citations are correlated with the product's stage in the development process. One notable exception, however, is the PCT filing path: The share of patents that have been filed under the PCT treaty decreases for products that are at higher stages of the development process. Regarding backward references, we observe that products that have reached the later

development stages are characterized by fewer backward references and a lower share of X-references. We interpret this as an indication that firms are more likely to advance the development of products which are covered by patents at less risk of being invalidated by existing prior art in opposition proceedings or litigation in court.

INSERT TABLE 3 ABOUT HERE

Our descriptive statistics suggest there is a positive correlation between value indicators and successful product commercialization. At the same time, the descriptive statistics suggest that patent strength also is related to successful commercialization. In the following, we analyze which of these patent-based indicators contain most information with regard to the commercialization of products in a multivariate context. This allows us to draw conclusions to what extent patent-based indicators are informative beyond the patenting process and are reliable proxies for outcomes in the product market.

5. Multivariate analyses

5.1 Methodology

In order to analyze the explanatory power of the patent-based indicators described above, we employ multivariate regressions to relate them to the duration of reaching a particular stage in the patenting process and – beyond the patent system itself – also in the product development process. In the absence of censoring, standard regression models such as Ordinary Least Squares (OLS) and Probit would be suitable to model the effect of patent indicators on whether and when the underlying product reaches a particular stage. However, with the exception of opposition proceedings, which must take place within 9 months after the grant of a patent,⁸ for a subset of the observations in our dataset we do not know the final

⁸ We extracted the information of whether an opposition was filed more than 9 months after the most recent grant date observed in our data. Therefore, this information is not affected by potential censoring.

outcome of the dependent variables due to censoring. In particular, our data on product commercialization includes only information until the end of 2009 and, given the long process of commercialization in the pharmaceutical industry, it is likely that a large share of the observations is censored. In the presence of censoring, pending cases have to be excluded from the standard regression analyses despite conveying information on process durations if standard models were employed. Censoring, however, can be addressed by employing duration models.

The class of duration models includes both the Cox proportional hazards model and the Accelerated Failure Time (AFT) model. We believe the AFT model is more appropriate than the Cox model in our setting as it allows interpreting the estimated coefficients directly as changes of duration.⁹ Kalbfleisch and Prentice (2002) and Kiefer (1988) contain a good overview of AFT models. In AFT models, the logarithm of time until a particular stage is reached is expressed as a linear function of covariates X to be included in the model with $\ln T = X\beta + \varepsilon$. If ε follows a logistic distribution, the log-logistic regression model is obtained and will be used in the following (Cleves et al. 2010). The underlying survival function in log-logistic models is given by $S(t) = [1 + (\lambda t)^{1/\gamma}]^{-1}$. In this specification, λ is in general parameterized as $\lambda = \exp(-X\beta)$ and γ is a scale parameter. β and γ have to be estimated from the data. In this specification, the β coefficients can easily be interpreted as proportional change of survival time associated to an increase in the underlying variable x since $\frac{\partial \ln(T)}{\partial X} = \beta$. Positive coefficients β imply an increase in the expected waiting time until an event takes place. AFT models imply parametric assumptions about the underlying hazard function. In contrast, the semi-parametric Cox proportional hazards model is not based on parametric assumptions with regard to the underlying hazard function (Cox, 1972;

⁹ In unreported robustness tests we also estimated Cox proportional hazards models and found similar results.

Kalbfleisch and Prentice, 2002). It should be noted, however, that an acceleration of the waiting time until an event is reached implies an increased hazard that the event is reached (Kalbfleisch and Prentice, 2002; Cleves et al., 2010).

We present three different sets of regressions performed using AFT models. In the first set of regressions we relate outcomes within the patent system (patent grant and patent opposition) to various patent indicators (see Table 4). For patent grants we compare the results from probit regressions with the results from duration models in order to evaluate the role of censoring. A second set of regressions specifies the time between invention and reaching a particular stage in the product development process as a function of the patent indicators described above employing AFT models (Table 5). In these regressions, we treat products that reached a given stage in the commercialization process as completed spells. Products that did not reach a given stage are included in these regressions but are treated as censored (Kalbfleisch and Prentice, 2002; Cleves et al., 2010). Finally, we model the duration of each stage in the product development process conditional on having completed the preceding stage to get a refined understanding at what stage in the development process particular characteristic accelerate or decelerate progress towards the ultimate market launch (Table 6).

In our regressions, we treat patents without a grant decision before October 2011 as censored. The same applies to products that did not reach a given stage of the development process before the end of our observational period (December 2009).¹⁰ Finally, our regressions account for the fact that products often are protected by more than one EP patent. In these cases, we keep each patent-product combination in the regression but weight it by the

¹⁰ For some observations we do not observe the dates of every stage. If we do not observe when a product entered a given stage we treat these observations as censored. In cases where we can infer that a product reached a given stage based on its observed entry into a subsequent stage, we treat them as censored and take the difference between the date they entered the next subsequent stage and their date of invention as their time at risk.

inverse of the number of patents per product so all products are weighted equally. All regressions include fixed effects for the year of invention and the technology class (using the IPC level 2 classification). For reasons of brevity we do not report these results here.

5.2 Results

We report the results relating the patent-based indicators described above to outcomes *within the patent system* – the patent grant and the filing of a subsequent opposition – in Table 4. The first four columns of Table 4 focus on the likelihood that a patent application leads to a patent grant. Column 1A contains the marginal effects from a probit estimation and column 2A the coefficients from an AFT duration model. As discussed above, the AFT model is more appropriate as it accounts for pending cases and we report marginal effects of the probit model only to show the impact of censoring. The AFT coefficient of a patent grant incorporates both whether the patent is granted and also the time to patent grant. In columns 1B and 2B we report the effects from a one-standard-deviation change in the underlying variable in order to enable comparison across the various patent-based measures.

Our results are consistent with previous analyses of the outcome of patent examination reported in Harhoff and Wagner (2009). First, patent grants are negatively correlated with both the number of claims and the total number of references. A one-standard-deviation increase in the number of claims and the number of backward references increases the duration until a patent is granted by 7.2% and 10% respectively (see Table 4, column 2B). This is not surprising as these variables indicate more complex examination tasks that require more effort by the patent examiner. The composition of backward references matters too. An increase in the share of critical (X- and Y-type) references lowers (or slows down) the likelihood of patent grant significantly. Similarly, greater originality of an invention is associated with a lower likelihood of patent grant. Arguably this is because more original

applicants are more complex and hence are harder to examine because prior art from a more diverse field of relevant technologies has to be researched.

Regarding correlates to patent value, our results are again in line with existing studies of patent examination at the EPO. We find that the likelihood and speed of obtaining a patent increases significantly with the size of the patent family to which a patent belongs and the generality of patent. However, we do not find a significant effect of the number of forward citations on patent grants. While the reason for the insignificance of forward citations is not intuitively clear in this case, Harhoff and Wagner (2009) found similar effects. In their examination on of the population of all EP patents, the number of forward citations had only a weak (and even positive) effect while other value indicators including family size and generality considerably decreased the pendency leading to a patent grant.

Comparing the various patent-based measures against each other, we find that family size is the best predictor of whether the patent is granted, followed by whether the applicant is from the US. However, whether the applicant files in additional countries (including Europe if it is from the US) will be endogenous to whether the patent is – or is likely to be – granted. Among the ‘more’ exogenous measures (i.e, those based on information added by the patent examiner), both originality and references to the non-patent literature appear to provide the best information about the likelihood of grant.

INSERT TABLE 4 ABOUT HERE

We also find that patent-based indicators are good predictors of opposition against granted patents taking place. Column 3A of Table 4 reports marginal effects from a probit regression relating patent-based indicators to the likelihood that a granted patent is opposed by a third party within 9 months after its grant and Column 3B the effect of a one-standard-

deviation increase in the underlying variable.¹¹ Our results are again in line with prior evidence in Harhoff and Reitzig (2004) and Harhoff, von Graevenitz and Wagner (2013). Most notably, we find that value correlates such as the number of forward citations or family size are positively related to the likelihood that an opposition takes place. We also find that patents that are characterized by a higher share of critical references are more likely to be opposed than other patents. Harhoff and Reitzig (2004) argue that a higher share of X- and Y-type references indicate “weaker” patents. Attacking “weak” patents should have a higher probability of success and hence drive up opposition rates. Column 3A also shows that the type of applicant matters with patents granted to universities and individuals being significantly less likely to be opposed, relative to patents granted to companies. In line with previous work, our results find a significant – albeit only the 10% level – effect of the cumulative number of patent applications filed by the same applicant (Harhoff and Reitzig, 2004; Lanjouw and Schankerman, 2001; Lanjouw and Schankerman, 2004a). Column 3B shows that in absolute terms none of the patent-based measures is a very strong predictor of whether a patent will be opposed – that is, a one-standard-deviation increase leads at most to a 2% increase in the likelihood of opposition (for forward citations).

Having replicated the findings reported in earlier literature with respect to the predictive power of patent-based indicators *within* the patent system we now turn to the separate regressions on the product level that scrutinize the information content of these indicators regarding events *beyond* the patent system. The results from AFT models relating patent-based indicators to the speed of a product reaching a particular stage in the development process are reported in Table 5 and results regarding the duration of particular stages within the development process in Table 6. We run separate regressions for whether a product has

¹¹ For all 5,647 patents that have been granted by October 2011, we have collected opposition information through to the end of 2012. Therefore, these observations do not suffer from censoring, thus allowing us to employ probit models instead of duration models.

entered preclinical trials, Phase 1, 2 or 3 clinical trials, and whether it is ultimately launched in a European country.¹² We do so to test whether patent-based indicators provide additional information about commercialization beyond proxying for whether the associated patent has been granted or not.

Overall, we find that patent-based indicators are informative with regard to outcomes beyond the patent system and therefore allow drawing inferences with regard to product market outcomes. However, their predictive power is reduced and the patterns that emerge are less clear when compared to outcomes within the patent system. Below we discuss their effect on overall durations until a particular stage is reached as well as their differential effect on the duration of single stage separately.

INSERT TABLE 5 ABOUT HERE

Table 5 reveals that indicators known to be correlated with patent value are significantly correlated with outcomes of the product development process. Products that are protected by patents with a larger family size and with a larger number of forward citations have a significantly higher hazard of ultimately being commercialized (see Column 5 of Table 5). Similarly products for which the patent has already been granted and which are protected by more patents are more likely to be commercialized.

The positive relationship between the value indicators and the likelihood of advancing through the commercialization stages is relatively stable across different stages preceding actual market launch. However, we find that products with higher values of those value

¹² In unreported robustness tests, we included the information whether patent grant/upheld in a time-varying way so that the indicator is one only for the periods after the actual patent grant. Additionally, we ran the regressions reported in Tables 5 and 6 without patent grant/upheld. In both cases, our findings remain qualitatively unchanged.

indicators enter preclinical tests later (or equivalently with lower likelihood) than products associated with less valuable patents.

We find a similar pattern for the composition of the references contained in patent documents: While the number of backward references is not related to the likelihood and speed of reaching a particular stage in the development process, products protected by patents that exhibit a higher share of X- and Y-type references have a higher hazard of ultimately being commercialized. However, the share of X- and Y-type references is negatively correlated with the hazard and speed of being put in preclinical trials. We hypothesize that is because companies will only invest in further development of inventions once they have obtained some certainty regarding the strength and scope of IP protection available for the invention. X and Y references indicate the existence of prior art that limits the patentability of the underlying invention. This means that the negotiations between the patent applicant and the patent examiner regarding the exact formulation (and hence the scope and value) of a patent will be lengthened as the patentee works to resolve the conflict with existing prior art. Only once the uncertainty of whether a patent will be granted and its exact delineation are resolved, will the companies be willing to invest in further development and hence entering preclinical trials will be delayed. Products protected by patents with a larger number of critical references reach subsequent stages faster, however. We hypothesize that this is because once these potential issues (as documented by X and Y-type references) have been resolved, the granted patent is more likely to be “legally stable” and provide strong protection, which in turn increases the incentives to invest in speedy development.

The number of patents protecting the product and the family size are the best predictors of market launch. Specifically, a one-standard-deviation increase in the number of patents/product and the family size decreases the likelihood of failure by 28.2% and 40.8% respectively. However, as above, the number of jurisdictions in which the patent has been

filed (i.e., family size) is likely to be endogenous to information about how the product is progressing through clinical trials. Similarly, the product owner may pursue more patents if the product has a higher likelihood of success. An alternative explanation is that X and Y references arise in more “popular” or “congested” patent spaces, possibly because the technological area is “hot”. Hence once a clear path has been found through there are greater rewards to be had.

Of those patent-based measures over which the applicant has no (or limited) control, the share of Y references appears to be the best predictor. Meanwhile the generality index is a strong predictor of failure at the final stage - a one-standard-deviation increase in the generality index increases the time until reaching market launch by 8.2% - although it is one of the better predictors of progress through the first three stages. (A one-standard-deviation increase in the generality index decreases time until entering preclinical, Phase 1, and Phase 2 trials by 2.3%, 7.1%, and 6.1% respectively.) We also see that products covering underlying patent whose applicant is an individual or based in Japan are much less likely to be launched (15.0% and 17.2% increase in waiting times respectively).

INSERT TABLE 6 ABOUT HERE

Finally, Table 6 reports the effects of patent indicators on the duration of individual stages of product commercialization process. These regressions allow us to identify how the observed effects of patent indicators on overall durations until a given stage is reached are resulting from accelerations/decelerations of individual stages. Note that the estimates for the different stages in Table 6 are based only on these products that have successfully completed the preceding stage.¹³ In these specifications we again find a strong correlation between the speed

¹³ The estimates in Table 5 are based on all products. Products that did not reach a particular stage are treated as censored but are not excluded from the dataset.

of commercialization and both the strength of patent protection and selected value indicators. In particular, products protected by larger number of patents and with larger international scope of protection (family size) complete all of the stages significantly faster than other products. The generality index is a good predictor of progress through the preclinical and clinical stages, but says nothing about likelihood of progressing from regulatory filing to market launch.

6. Discussion and Conclusion

This paper contributes in various ways to our understanding of what can be concluded from refined patent-based indicators. First, it provides further evidence of the relationship between a broad range of patent-based measures and the outcomes of the patenting process. In particular we find that value indicators are positively correlated with both patent grant and opposition. Meanwhile, the share of X- and Y-type references is negatively correlated with patent grant and positively with opposition against granted patents. Second, and more importantly, this paper shows patent-based indicators are also informative with regard to outcomes that lie beyond the patent system. Analyzing the relation between patent-based measures and product commercialization shows that the relations are nuanced and need careful interpretation. Whether a patent has been granted and family size (indicators generally considered to be positively associated with value) and the share of X- and Y-type references (indicators generally considered to be negatively associated with value) follow similar patterns: they are positively correlated with the speed of product launch, but negatively correlated with entering pre-clinical trials. At this stage, we can only speculate what is driving the apparent contradiction. One potential explanation could be related to the uncertainty of the patenting process with regard to whether a patent is granted and what its final specification will be, which is only resolved after a patent is granted (and any opposition proceedings are completed). For products with higher value and/or greater uncertainty about

their final specifications, it is crucial to know the exact specification of the patent rights (and for the applicant to form expectations on how easy imitation by inventing around the patent will be) before it proceeds with clinical development. In these cases, the applicant might postpone decisions regarding product development until uncertainty has been resolved. This pattern would explain the observed pattern of the share critical references which makes an early patent grant less likely. Our empirical setting, however, does not allow for disentangling these effects.

In interpreting our findings, it is important to note when and how the various measures are generated. In general, it is possible to construct reference-based measures immediately on the publication of a patent application as well as whether the patent was filed through the PCT, the number of claims and the family size. Value-related measures, on the other hand, are generally not observable immediately. In particular, citation-based indicators can be computed only several years after patent applications.

Moreover, some of the measures will be endogenous to private information the applicant has about the underlying product or what it learns during the patent prosecution process. If the patentee has private information regarding the probability that an invention will successfully pass through the clinical trials and/or has high market potential he will be willing to invest more in obtaining a strong patent position. An applicant has 12 months to designate additional countries on a patent filed through the PCT so may add (or remove) additional countries based on new information it receives about the likely success of the patent application or the underlying product. It may also adjust the number of claims during that time depending on the examiner's feedback given during the examination procedure. Meanwhile, the likelihood of being cited is likely to be affected by the product's success in preclinical and clinical trials, so is not an exogenous indicator of success, although given the

average product enters preclinical trials only 5 years after priority filing, focusing on the first five years of citations limits the distortion.

If firms want to use patent-based indicators in order to derive conclusions regarding their own or their competitors' product pipelines, they need to take these differences in availability of information into account. Indicators that largely depend on patenting strategies of the applicant (e.g., the number of patents covering the product, family size, etc.) will not be very informative to the applicant itself. However, they might be useful for competitors and independent observers (e.g., researchers). Citation-based as well as reference-based indicators, on the other hand, can be assumed to be independent of patentee behavior as they largely depend on references gathered by independent patent examiners.¹⁴

¹⁴ Citation-based indicators might be weakly endogenous if patent examiners tend to cite patents associated to products that advance further in the development funnel. There is no evidence that this is the case, however.

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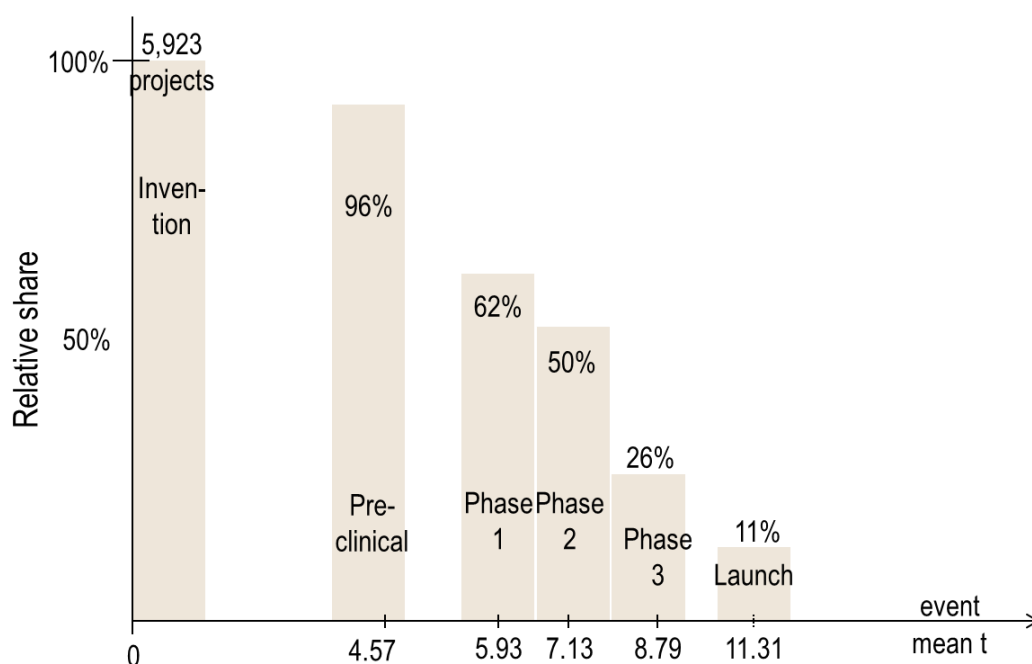
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Figure 1: Product attrition by stage of clinical development



Note: Clinical development of 5,923 pharmaceutical products for which we identified at least one European patent application. The vertical axis denotes the average share of products starting a given event during development. The horizontal axis denotes the average duration until a product reaches that stage.

Table 1: Number of products by stages in the product development process.

Development stage started	# Products	Reaching stage	Year of invention (estimated)	Age at reaching stage (years)	# Primary patents/product	# of EP patents	Granted	Opposed
Total	5,923	100%	1991.4	-	1.12	1.58	68.7%	7.05%
<u>Stage reached:</u>								
Preclinical	5,685	96.0%	1991.3	4.57	1.12	1.58	69.4%	6.83%
Phase 1	3,653	61.7%	1990.8	5.93	1.16	1.66	73.7%	7.93%
Phase 2	2,953	49.9%	1990.5	7.13	1.18	1.69	75.1%	8.50%
Phase 3	1,565	26.4%	1989.7	8.79	1.24	1.82	78.0%	11.43%
Launched in EP country	630	10.6%	1988.5	11.31	1.30	1.92	82.0%	17.66%

Note: The summary statistics regarding the patents related to the products are per product.

Table 2: Patent-based indicators and outcomes within the patent system.

	Patent grant			Patent opposition		
	No	Yes	Total	No	Yes	Total
Observations	2,600	5,647	8,247	5,280	367	5,647
Share	31.5% (47.3%)*	68.5% (52.7%)*	100% (100%)	93.5% (93.8%)	6.5% (6.2%)	100% (100%)
Filed through PCT	61.2% (56.0%)*	54.6% (47.8%)*	56.7% (51.7%)*	53.8% (47.8%)*	65.9% (48.1%)*	54.6% (47.8%)*
Family size	9.67 (7.16)*	18.30 (12.11)*	15.58 (9.87)*	18.09 (11.97)*	21.36 (14.26)*	18.30 (12.11)*
# Claims	24.21 (18.04)*	19.79 (15.60)*	21.18 (16.76)*	19.43 (15.44)*	24.99 (18.08)*	19.79 (15.60)*
# Forward citations w/i 5 yrs	1.50 (1.04)*	2.04 (1.22)*	1.87 (1.13)*	1.93 (1.16)*	3.53 (2.08)*	2.04 (1.22)*
Generality	0.15 (0.11)*	0.24 (0.15)*	0.21 (0.13)*	0.24 (0.15)*	0.25 (0.19)*	0.24 (0.15)*
# References to non-patent literature	1.63 (1.24)*	1.01 (0.93)+	1.20 (1.08)*	0.97 (0.93)	1.53 (0.92)*	1.01 (0.93)+
# References to previous patents	3.64 (3.35)*	3.01 (3.08)+	3.21 (3.21)	3.03 (3.06)	2.83 (3.48)*	3.01 (3.08)+
Share X refs	34.7% (39.5%)*	23.5% (29.6%)*	27.0% (34.5%)*	23.3% (29.0%)*	26.8% (36.9%)*	23.5% (29.6%)*
Share Y refs	12.1% (15.5%)*	10.5% (14.3%)*	11.0% (14.9%)*	10.4% (14.4%)*	11.5% (14.1%)*	10.5% (14.3%)*
Originality	0.41 (0.39)*	0.41 (0.36)*	0.41 (0.38)*	0.40 (0.36)*	0.50 (0.38)*	0.41 (0.36)*

Note: We report the descriptive statistics for 8,247 unique patents in our sample. Some of these patents, however, are associated to more than one product yielding 9,229 unique product-EP patent pairs. Statistics regarding opposition taking place are computed relative to the total number of granted patents. The number in parentheses relate to the average values of the population of EPO patents (matched by year and IPC4 classification), with asterisks indicating a significant difference: + p<0.10, * p<0.05, ** p<0.01

Table 3: Patent-based indicators and outcomes beyond the patent system.

	# Products	Filed through PCT	Family size	# Forward citations (w/i 5 yrs)	# References to non-patent literature	# References to patents	Share of X-type references	Share of Y-type references
Total	5,923	56.3%	15.59	1.94	1.21	3.22	27.41%	11.07%
<u>Stage reached:</u>								
Preclinical	5,685	55.5%	15.78	1.93	1.19	3.21	26.81%	10.91%
Phase 1	3,653	53.0%	17.28	1.93	1.16	3.16	26.67%	11.06%
Phase 2	2,953	51.5%	17.07	1.97	1.15	3.14	26.17%	11.02%
Phase 3	1,565	48.2%	18.53	2.02	1.12	3.07	25.79%	11.81%
Launched in EP country	630	39.3%	21.00	2.33	1.10	2.86	22.53%	10.50%

Table 4: Regression of patenting events on patent-based measures

	Patent grant				Opposition	
	Probit		Duration Model		Probit	
	(1A)	(1B)	(2A)	(2B)	(3A)	(3B)
	MFX	+/- 0.5 S.D.	AFT coeff.	+/- 0.5 S.D.	MFX	+/- 0.5 S.D.
Patent characteristics						
Filed through PCT	0.117** (0.015)	0.058	-0.108** (0.022)	-0.054	0.030** (0.008)	0.015
Family size	0.018** (0.001)	0.206	-0.019** (0.001)	-0.218	0.001** (0.000)	0.011
Number of Claims	-0.001** (0.000)	-0.018	0.004** (0.001)	0.072	0.000** (0.000)	0.000
Citation-based measures						
# Forward citations w/i 5 yrs (log)	-0.011 (0.010)	-0.008	0.017 (0.013)	0.013	0.024** (0.004)	0.019
Share of X citations	0.006 (0.019)	0.002	-0.025 (0.027)	-0.009	0.011 (0.009)	0.004
Share of Y citations	0.046+ (0.024)	0.012	-0.107** (0.033)	-0.027	0.023* (0.010)	0.006
Generality index	0.160** (0.028)	0.037	-0.267** (0.038)	-0.062	-0.035** (0.013)	-0.008
Reference based measures						
# References to non-patent literature (log)	-0.041** (0.008)	-0.028	0.141** (0.013)	0.098	0.021** (0.004)	0.014
# References (log)	-0.017+ (0.009)	-0.013	0.025* (0.013)	0.019	-0.011* (0.005)	-0.008
Share of X-type references	-0.084** (0.017)	-0.031	0.168** (0.024)	0.061	0.019* (0.009)	0.007
Share of Y-type references	-0.043+ (0.023)	-0.011	0.103** (0.033)	0.026	0.015 (0.012)	0.004
Originality	-0.125** (0.017)	-0.046	0.224** (0.024)	0.083	0.031** (0.008)	0.012
Applicant characteristics						
Cumulative # applications (log)	-0.023** (0.004)	-0.037	0.022** (0.005)	0.036	-0.003+ (0.002)	-0.005
Government/non-profit	0.039 (0.024)	0.008	-0.002 (0.037)	0.000	-0.010 (0.011)	-0.002
University/hospital	-0.075 (0.046)	-0.010	0.104 (0.064)	0.013	-0.038** (0.008)	-0.005
Individual	0.055** (0.016)	0.017	-0.023 (0.027)	-0.007	-0.018* (0.007)	-0.005
From the US	-0.094** (0.013)	-0.047	0.243** (0.019)	0.121	0.005 (0.006)	0.002
From Japan	0.080** (0.019)	0.027	-0.093** (0.025)	-0.031	-0.018+ (0.010)	-0.006
From ROW	-0.017 (0.023)	-0.004	0.091** (0.032)	0.024	0.002 (0.011)	0.001
IPC2 dummy variables	YES		YES		YES	
Year dummy variables	YES		YES		YES	
Observations	8248		8248		5618	
Log-Likelihood	-3799.76		-46641.00		-1180.09	
Chi2	2682.649		2324.898		351.917	
p-value	0.000		0.000		0.000	

Note: For the probit regressions we report marginal effects (MFX) obtained from using Stata's margins command. For the duration model we report coefficients from a log-logistic parametric accelerated failure time (AFT) model. Standard errors are reported in parentheses. + p<0.10, * p<0.05, ** p<0.01

Table 5: Regressions of duration between first priority filing and stages of the product development process on patent-based measures

	Priority filing to entering preclinical trials		Priority filing to entering Phase 1 clinical trials		Priority filing to entering Phase 2 clinical trials		Priority filing to entering Phase 3 clinical trials		Priority filing to market launch	
	(1A)	(1C)	(2A)	(2B)	(3A)	(3B)	(4A)	(4B)	(5A)	(5B)
	AFT Coeff.	+/- 0.5 S.D.	AFT Coeff.	+/- 0.5 S.D.	AFT Coeff.	+/- 0.5 S.D.	AFT Coeff.	+/- 0.5 S.D.	AFT Coeff.	+/- 0.5 S.D.
Patent characteristics										
Patent granted/upheld after opposition	0.094** (0.023)	0.044	-0.200** (0.050)	-0.094	-0.258** (0.047)	-0.121	-0.307** (0.058)	-0.143	-0.195** (0.073)	-0.091
# Primary patents/product	0.121** (0.019)	0.061	-0.255** (0.031)	-0.130	-0.375** (0.028)	-0.190	-0.642** (0.035)	-0.326	-0.555** (0.041)	-0.282
Filed through PCT	0.020 (0.025)	0.010	0.092+ (0.052)	0.046	0.075 (0.050)	0.037	0.059 (0.066)	0.029	0.119 (0.078)	0.059
Family size	0.000 (0.001)	0.003	-0.030** (0.002)	-0.343	-0.032** (0.002)	-0.364	-0.034** (0.002)	-0.391	-0.036** (0.003)	-0.408
# Claims	-0.000 (0.001)	-0.006	-0.003** (0.001)	-0.055	-0.002* (0.001)	-0.043	-0.002 (0.001)	-0.029	-0.002 (0.001)	-0.040
Citation-based measures										
# Forward citations w/i 5 yrs (log)	-0.002 (0.016)	-0.001	0.006 (0.031)	0.004	-0.003 (0.029)	-0.002	-0.002 (0.037)	-0.001	-0.087* (0.044)	-0.068
Share of X citations	0.027 (0.032)	0.009	0.065 (0.064)	0.022	0.060 (0.060)	0.020	-0.025 (0.077)	-0.009	-0.065 (0.092)	-0.022
Share of Y citations	-0.025 (0.040)	-0.006	0.001 (0.078)	0.000	-0.143* (0.071)	-0.036	-0.191* (0.090)	-0.048	-0.143 (0.107)	-0.036
Generality index	-0.100* (0.047)	-0.023	-0.307** (0.090)	-0.071	-0.263** (0.086)	-0.061	0.090 (0.113)	0.021	0.354* (0.140)	0.082
Reference based measures										
# References to non-patent literature (log)	0.022 (0.015)	0.015	0.025 (0.030)	0.017	0.028 (0.029)	0.019	-0.024 (0.037)	-0.017	-0.052 (0.043)	-0.036
# References (log)	-0.008 (0.015)	-0.006	0.019 (0.030)	0.014	0.060* (0.029)	0.045	0.024 (0.037)	0.018	0.029 (0.046)	0.022
Share of X-type references	0.070* (0.030)	0.025	-0.114* (0.056)	-0.042	-0.209** (0.055)	-0.076	-0.198** (0.070)	-0.072	-0.100 (0.085)	-0.036
Share of Y-type references	0.124** (0.043)	0.031	-0.150* (0.077)	-0.038	-0.178* (0.073)	-0.044	-0.517** (0.092)	-0.129	-0.302** (0.114)	-0.076
Originality	-0.008 (0.029)	-0.003	-0.067 (0.056)	-0.025	-0.082 (0.054)	-0.030	-0.129+ (0.069)	-0.048	-0.078 (0.083)	-0.029
Applicant characteristics										
Cumulative # applications (log)	-0.016**	-0.025	0.011	0.017	0.019	0.030	0.056**	0.090	-0.007	-0.012

	(0.006)		(0.012)		(0.011)		(0.015)		(0.017)	
Government/non-profit	0.057	0.012	0.111	0.023	0.153+	0.032	0.173+	0.036	0.065	0.013
	(0.048)		(0.088)		(0.083)		(0.102)		(0.125)	
University/hospital	0.114	0.015	0.357*	0.047	0.263+	0.034	0.139	0.018	0.529+	0.069
	(0.076)		(0.153)		(0.145)		(0.180)		(0.292)	
Individual	0.078*	0.024	0.184**	0.057	0.181**	0.056	0.421**	0.131	0.481**	0.150
	(0.033)		(0.064)		(0.064)		(0.089)		(0.125)	
Applicant ROW	-0.031	-0.008	-0.066	-0.017	-0.143*	-0.037	-0.251**	-0.064	-0.140	-0.036
	(0.041)		(0.077)		(0.073)		(0.093)		(0.114)	
Applicant from the US	-0.092**	-0.046	-0.130**	-0.065	-0.041	-0.020	-0.137*	-0.068	-0.012	-0.006
	(0.023)		(0.045)		(0.043)		(0.055)		(0.064)	
Applicant from Japan	-0.053+	-0.018	-0.252**	-0.083	-0.349**	-0.115	-0.204**	-0.068	0.525**	0.173
	(0.028)		(0.057)		(0.053)		(0.071)		(0.104)	
IPC2 dummy variables	YES		YES		YES		YES		YES	
Year dummy variables	YES		YES		YES		YES		YES	
Observations	9229		9229		9229		9229		9229	
Log-Likelihood	-1409.54		-3664.98		-3293.34		-2326.93		-1195.99	
Chi2	716.416		804.006		1062.569		1059.882		779.807	
p-value	0.000		0.000		0.000		0.000		0.002	

Note: Results from a weighted log-logistic accelerated failure time (AFT) model relating the log of the total duration between invention and a given state in the product development process to various patent-based indicators. Standard errors in parentheses. + p<0.10, * p<0.05, ** p<0.01

Table 6: Regressions of duration of individual stages of the product development process (conditional on having completed the preceding stage) on patent-based measures

	Entering preclinical trials to entering Phase 1 clinical trials		Entering Phase 1 clinical trials to entering Phase 2 clinical trials		Entering Phase 2 clinical trials to entering Phase 3 clinical trials		Entering Phase 3 clinical trials to regulatory filing		Regulatory filing to market launch	
	(1A) AFT Coeff.	(1B) +/- 0.5 S.D.	(2A) AFT Coeff.	(2B) +/- 0.5 S.D.	(3A) AFT Coeff.	(3B) +/- 0.5 S.D.	(4A) AFT Coeff.	(4B) +/- 0.5 S.D.	(5A) AFT Coeff.	(5B) +/- 0.5 S.D.
Patent characteristics										
Patent granted/upheld after opposition	-0.508** (0.121)	-0.238	-0.073 (0.123)	-0.034	-0.204 (0.126)	-0.095	0.193+ (0.111)	0.090	-0.090 (0.267)	-0.042
# Primary patents/product	-0.610** (0.092)	-0.310	-0.546** (0.078)	-0.277	-0.851** (0.065)	-0.432	-0.361** (0.052)	-0.183	-0.472** (0.143)	-0.240
Filed through PCT	0.140 (0.136)	0.070	0.034 (0.122)	0.017	0.200 (0.123)	0.099	-0.041 (0.100)	-0.020	0.093 (0.267)	0.046
Family size	-0.032** (0.005)	-0.361	-0.015** (0.004)	-0.167	-0.028** (0.004)	-0.324	-0.020** (0.003)	-0.225	-0.045** (0.008)	-0.512
# Claims	-0.011** (0.003)	-0.203	-0.005* (0.002)	-0.093	-0.005 (0.003)	-0.088	-0.003 (0.002)	-0.053	-0.000 (0.006)	-0.001
Citation-based measures										
# Forward citations w/1 5 yrs (log)	-0.010 (0.086)	-0.008	-0.005 (0.074)	-0.004	-0.009 (0.075)	-0.007	0.048 (0.063)	0.038	-0.148 (0.156)	-0.115
Share of X citations	0.052 (0.163)	0.018	0.155 (0.151)	0.053	0.057 (0.157)	0.020	-0.136 (0.135)	-0.046	-0.129 (0.364)	-0.044
Share of Y citations	0.141 (0.207)	0.035	0.042 (0.181)	0.010	0.052 (0.188)	0.013	0.091 (0.151)	0.023	0.415 (0.387)	0.104
Generality index	-0.949** (0.239)	-0.220	-1.289** (0.221)	-0.299	-0.716** (0.221)	-0.166	-0.888** (0.190)	-0.206	-0.335 (0.466)	-0.078
Reference based measures										
# References to non-patent references (log)	0.040 (0.079)	0.028	0.080 (0.072)	0.056	0.041 (0.077)	0.028	0.084 (0.067)	0.059	-0.094 (0.168)	-0.066
# References (log)	0.063 (0.080)	0.048	0.074 (0.072)	0.056	0.064 (0.073)	0.049	0.074 (0.062)	0.056	0.040 (0.171)	0.030
Share of X-type references	-0.260+ (0.153)	-0.095	0.119 (0.140)	0.043	-0.147 (0.141)	-0.054	-0.005 (0.120)	-0.002	0.112 (0.322)	0.041
Share of Y-type references	-0.299 (0.202)	-0.075	0.138 (0.190)	0.034	-0.611** (0.178)	-0.153	-0.067 (0.146)	-0.017	0.100 (0.399)	0.025
Originality	-0.384* (0.151)	-0.142	-0.272* (0.138)	-0.101	-0.233+ (0.140)	-0.086	-0.058 (0.121)	-0.022	0.112 (0.305)	0.041
Applicant characteristics										
Cumulative # applications (log)	0.158**	0.254	0.045	0.073	0.027	0.044	-0.047+	-0.075	-0.325**	-0.522

	(0.033)		(0.029)		(0.029)		(0.025)		(0.062)	
Government/non-profit	-0.083	-0.017	-0.411+	-0.085	-0.043	-0.009	0.223	0.046	0.284	0.059
	(0.233)		(0.227)		(0.209)		(0.187)		(0.475)	
University/hospital	0.873*	0.114	0.669+	0.087	0.340	0.044	0.987**	0.128	0.642	0.084
	(0.381)		(0.365)		(0.363)		(0.272)		(0.911)	
Individual	0.004	0.001	-0.386*	-0.120	0.199	0.062	0.273	0.085	0.897+	0.279
	(0.165)		(0.156)		(0.178)		(0.188)		(0.538)	
From the US	-0.229+	-0.098	-0.263*	-0.096	-0.382**	-0.096	-0.313**	-0.084	0.263	-0.183
	(0.120)		(0.109)		(0.114)		(0.097)		(0.229)	
From Japan	-0.497**	-0.040	-0.416**	-0.036	-0.381**	-0.038	-0.562**	-0.032	3.221**	-0.076
	(0.158)		(0.140)		(0.138)		(0.112)		(0.358)	
From ROW	-0.343+	0.000	-0.159	0.000	-0.141	0.000	-0.127	0.000	0.598	0.000
	(0.197)		(0.192)		(0.192)		(0.168)		(0.367)	
IPC2 dummy variables	YES		YES		YES		YES		YES	
Year dummy variables	YES		YES		YES		YES		YES	
Observations	8874		5592		4822		2696		1691	
Log-Likelihood	-5608.15		-4344.33		-2658.64		-1022.88		-1556.19	
Chi2	285.33		265.19		330.69		327.21		440.67	
p-value	0.000		0.000		0.000		0.000		0.000	

Note: Results from a weighted log-logistic accelerated failure time (AFT) model regressing the log of the duration of the given stage in the product development process (conditional on having completed the preceding stage) on various patent-based indicators. Standard errors in parentheses. + p<0.10, * p<0.05, ** p<0.01

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