

Determinants of Opposition against EPO Patent Grants – The Case of Biotechnology and Pharmaceuticals

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Abstract

We use a newly developed data set covering all biotechnology and pharmaceutical patents granted by the European Patent Office. We analyze the determinants of opposition which can be considered an early form of patent validity challenge suit. In our sample, the validity of 8.6 percent of the patents are attacked in the opposition proceeding. Using citation and patent family indicators, we show that valuable patents are more likely to be attacked, and that opposition is particularly frequent in areas with strong cumulative patent numbers and with high technical or market uncertainty.

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1 Introduction

Over the last decades, economists have made considerable progress in coming to a detailed assessment of the role and implications of patents rights. Theoretical contributions have studied the breadth of patents and the nature of cumulative inventions.¹ Empirical studies have pointed out that patent rights vary considerably in their commercial importance.² Some progress has even been made in the notoriously difficult assessment of the monetary value of patent rights on the basis of citation indicators and other value correlates.³

Yet, two important aspects of patent rights are still under review. First, a patent holder may have to defend his patent against legal challenges seeking to cast doubt on the validity of the patent right as well as against infringement, e.g., via imitation of the patented technology. The efficacy of the legal mechanisms by which patents can be challenged or defended may have considerable impact on R&D and innovation incentives. Even the most comprehensive patent system cannot work well if the rights allocated to patent holders cannot be enforced or if the enforcement is too costly. Second, the patent system itself is not a flawless mechanism. Some decisions made by the staff of patent offices may later turn out to be erroneous. Some evidence on prior art – relevant in the patent examiner's assessment of an invention's extent of novelty - may surface after the patent has been granted. Legal implications of particular patent rights may not have been taken into account properly by patent office staff at the time of the granting decision. The well-known European patent EP 0695351 recently awarded to an Edinburgh research institution is such an example. Erroneously, the European Patent Office (EPO) granted a patent to an applicant although the patent right violates legal provisions in several countries which have signed the European Patent Convention. The patent grant – once issued – cannot simply be revoked by the European Patent Office, but the validity of this patent is now challenged by a number of opponents in the opposition process at the EPO.

This case has brought public attention to the opposition mechanism at the European Patent Office. Opposition can be considered an early form of litigation in which opponents may argue that a patent grant issued by EPO should be either revoked or amended. Opposition is not an infrequent event – on average, 8.5 percent of the patents granted by the EPO are subject to opposition. Despite its obvious importance, the economics of this institution are virtually unknown, and there have been no studies analyzing it in detail. To the best of our knowledge, this paper is the first study to put forth an econometric study of the determinants of opposition at the European Patent Office.⁴ We therefore see

¹ See for example Scotchmer (1991, 1996) and Merges and Nelson (1990).

² See Griliches (1990) for a survey of the use of patents as economic indicators. Scherer, Harhoff and Kukies (2000) discuss sources and potential implications of skewed value distributions in a simulation exercise.

³ Cf. Lanjouw and Schankerman (1999), Harhoff, Scherer and Vopel (1999).

⁴ Van der Drift (1989) is the only earlier study we are aware of in which opposition data are used to classify patents according to their importance. The role of opposition as a predictor of patent value is emphasized in Harhoff, Scherer and Vopel (1999). Their study shows that patents that survived opposition are on average 40 times more valuable than other comparable patents.

this paper as a complement to recent U.S. studies which have focused on patent litigation.⁵ The results of these studies cannot easily be transferred to the European context, since legal mechanisms and institutions differ considerably. Thus, there is an obvious motivation for undertaking a study of the European institutions, and in particular of the opposition procedure.

An analysis of post-grant opposition is not only relevant in the European context – the institution *per se* is of some interest, since it may offer a relatively efficient solution to a number of problems. Uncertainty about the validity and scope of patent rights can have considerable negative implications. Firms may delay investments if they expect another firm to enter a market under patent protection. But the patent holder himself may also delay the exploitation of a patent if the extent of legal protection against imitators is unclear. Moreover, in the case of objectively erroneous decisions by a patent office, it is quite obvious that a fast and inexpensive resolution of the legal disputes could improve the incentive properties of the patent system.⁶ Merges (1997) has recently argued that an inclusion of post-grant opposition may improve the efficiency of the U.S. patent system. He explicitly refers to the recent onslaught of patent grants protecting business models and software in the U.S. The re-examination procedure in the U.S. patent system does not appear to be an attractive early-stage litigation mechanism, and litigation in U.S. courts is costly and time-consuming. To correct possible errors made by the patent office relatively soon after the patent has been granted, Merges therefore suggests to introduce a post-grant system similar to the one present in Europe and a number of individual European countries, such as Germany.

In this paper, we concentrate on the biotechnology and pharmaceuticals industries, since legal disputes appear to arise quite often in these fields (Lanjouw and Schankerman 1999, Lerner 1995). The incidence of opposition is surprisingly high: in our data, 8.6 percent of all patents are opposed. Using citation indicators, we can show that valuable patents are more likely to be attacked, and that opposition occurs particularly often in areas with considerable technical or market uncertainty. Moreover, in technical areas where a large number of patents enter, opposition is more likely to occur. Patents of firms with strong patent portfolios appear to be attacked less often than patents of their competitors, but this advantage is weaker in crowded technical fields. We discuss the implications of these results and possible extensions of our research in the paper.

The remainder of the paper is structured in five sections. We first discuss the institutional elements of the European Patent Office and its associated routines. The institutional information provided in section 2 forms the background of our theoretical discussion in the subsequent section 3 in which we develop our hypotheses. Section 4 discusses data sources and the computation of key variables. In section 5, we first consider a number of descriptive statistics before setting up and estimating multivariate probit equations for the incidence of opposition in the sample studied here. In the subsequent discussion, we compare our theoretical expectations and the probit results. Section 6 concludes and discusses implications and extensions of this research.

⁵ See Lanjouw and Schankerman (1999) for an exploration of the determinants of patent litigation in the U.S., and Lanjouw and Lerner (1998) for a survey of the empirical literature.

⁶ Obviously, any institution that can correct errors may also be capable of introducing new ones. Moreover, the institution itself may introduce uncertainty for the participating actors. It will be very important to study if the opposition mechanism can be employed strategically, e.g., by financially strong firms which want to deter entrants from exploiting their patent rights. The current study is merely a first exploratory step towards more detailed studies.

2 Patent Systems in Europe

The difference between national legal systems in Europe is one reflection of its historical diversity. The advantages of a common European patent law were already acknowledged during the last century. Since then there has been a continuous effort to align the different forms of national patent legislation in Europe. Such processes of legal alignment in Europe are translated into action on a contractual basis. Thus, the national jurisdictions of the sovereign member states are not abolished and continue to exist in parallel to the new supranational contracts. It is for the same reason that Europe has reached a remarkable consensus on the patent filing and granting process reflected in a widespread use of supranational filing and granting mechanisms. At the same time, with regard to patent litigation before courts, the legal heterogeneity of Europe is still prevailing. The opposition procedure at the European Patent Office, however, can be regarded as a centralized "first-instance challenge suit" for European patents and can thus be compared to patent litigation in U.S. civil courts. In the following we try to set out important details of European patent legislation in a very condensed form.

2.1 Historical Aspects

Three milestones in European patent legislation can be identified in retrospective: the passing of *the Paris Convention for the Protection of Industrial Property in 1883*, the rectification of the *Patent Convention of Strasburg in 1963*, and the conclusion of the *European patent Convention* in Munich in 1973. Before 1883, supranational arrangements did not exist in Europe in the field of intellectual property rights. Neither the premises nor the consequences of the different jurisdictions were recognized in other countries. It was due to growing international industrialization that a need for international validity of intellectual property rights was articulated at the end of the last century. As a consequence, in 1883 the leading European countries of the time agreed on treating foreign patent holders like domestic patent owners; besides, patent priorities could from now on be claimed internationally. After this first step no further need for legal harmonization was felt until the end of the second World War. The efforts of the European Economic Community (EEC) towards trade liberalisation and the establishment of a common market in Europe led to the Patent Convention of Strasburg in 1963. The significance of this treaty lies in the alignment of terms of material patent law, such as novelty or inventive step.⁷ This alignment of material right terms in the different national legislation was a necessary step towards the conclusion of the *European patent Convention (EPC)* in 1973. The EPC is nowadays the most important source of common European patent law. As a special agreement referring to the *Paris Convention for the Protection of Industrial Property in 1883* it regulates the filing and granting process of common European patents. It covers both, formal and material aspects of patent law. As of April 1998, nineteen European states had confirmed the treaty. By doing so they acknowledge that centrally examined and granted European patents are given the same validity as nationally granted patents. They also agree that granted European patents can be centrally attacked via opposition, i.e., in a procedure comparable to a "first-instance challenge suit". Traditional national litigation on infringement or the validity of the patent before national courts remains untouched, but loses importance.⁸

⁷ For a definition of "novelty" and "inventive step" see section 2.3.

⁸ In addition to the mentioned supranational contracts, two other treaties have assumed major significance for Europe, i.e. the *Patent Cooperation Treaty (PCT)* and the *Agreement on Trade-Related Aspects of*

2.2 European Patents

The conclusion of the European patent system in 1973 prepared the ground for the creation of a central European Patent Office, which has its headquarter in Munich. Since 1979 the European Patent Office has granted more than 400,000 patents and has therefore become one of the most important patent offices in the world. Figure 1 displays the number of EPO applications and patent grants from 1978 to 1998.

Patent protection for European member states can be obtained by filing national applications and/or European patent applications designating the states for which protection is desired. This dual system of seeking patent protection in Europe is a consequence of the national sovereignty described above. Considering the fees charged by the various patent offices in Europe, a European patent application costs approximately three times as much as a typical national application. Thus, if patent protection is sought for more than three designated states, the application for a European patent becomes cheaper than independent applications in several jurisdictions. This cost advantage has made the European filing path particularly attractive for applicants that are selling goods and services in international markets. Due to the increasing application and grant numbers, the European Patent Office has now gained a level of economic importance similar to that of the United States Patent and Trademark Office (USPTO). Moreover, the opposition procedure before the European Patent Office has become an important instrument for first-instance challenges to the validity of patents granted by the EPO.

2.3 The Filing Process

European patents are granted for inventions which are novel, mark an inventive step, are commercially useful, and are not excluded from patentability for other reasons. After the filing of the application, a search report is provided by the EPO and made available to the applicant. The search report describes state of the art regarded as relevant according to EPO guidelines for the patentability of the invention. Within six months after the announcement of the publication of the search report in the EP Bulletin, the applicant can request the examination of his application which is a compulsory prerequisite for the patent grant. Eighteen months after the priority date the patent application will be published. At this point, the application will normally still be under examination; thus, differing from the U.S. system, the patent owner will already reveal some information prior to the grant of the patent. Moreover, the content of the application is revealed even if no patent is issued.

If engaged with the examination, the EPO will present an examination report; either the EPO will inform the applicant that the patent will be granted in the way it was applied for, or the EPO will propose changes after which the patent could be granted if the invention was patentable at all. In the latter case it is up to the applicant to decide whether to accept the alterations proposed by the EPO, or to come up with a different proposal for alteration. Once the applicant and EPO have reached a consensus on the version of the application to be granted, the patent is centrally granted for all the designated states and then translated into the respective languages. If no such agreement is reached and if the EPO declines to grant a patent, the applicant may turn to the appeals proceeding in which

Intellectual Property Rights (TRIPS). However, since these two treaties are global treaties rather than inter-European agreements, they will not be discussed in detail in this paper.

the reasons for the refusal to grant a patent right are reconsidered.⁹ After the grant, the European patent becomes a “bundle” of national patents. On average, the granting process for a European patent takes about 4.2 years from the date of filing the application.

2.4 The Opposition Procedure

Once the European patent is granted, its national successors are treated like “normal” national patents that can be attacked by third parties through legal means allowed for by the respective national legislation. Outcomes of such national litigation cases are always restricted to the national level, e.g., the patent may be invalidated in Spain, but this does not affect its validity in Italy. Up to nine months after the granting date, however, third parties can attack the European patent centrally at the European Patent Office by filing their opposition against the granting decision. Comparable to the grant of the European patent, the outcome of the opposition procedure is again binding for all designated states. The opposition procedure is thus the only central “challenge suit” for European patents. After the expiration of nine months subsequent to the grant, a competitor will have to attack the succeeding national patents of the European patent in each jurisdiction separately.

Opposition to a European patent is again filed with the EPO. The opponent has to substantiate his opposition by presenting evidence that the prerequisites for patentability were not fulfilled, e.g., he has to show that the invention lacked novelty, and/or an inventive step, or that the disclosure was poor or insufficient. The opposition is formally admitted by the EPO where an opposition division decides on the case. At the end of the opposition procedure the chamber may uphold the patent without amendments, or it may amend¹⁰ or even revoke¹¹ the patent. The decision affects all of the designated states. A further interesting aspect of the opposition procedure that distinguishes it from a “real” litigation before civil courts concerns the possibility of settlement between the litigating parties. Once an opposition is filed, the EPO may continue to decide on the case even if the opponent does no longer actively pursue opposition. Thus, opponent and patent holder may not be free to settle their case outside of the EPO opposition process once the opposition is filed.¹²

Both the patent holder(s) and the opponent(s) may file an appeal against the outcome of opposition procedures. The appeal has to be filed within two months after the receipt of the decision of the opposition division, and it has to be substantiated within an additional two months. The Board of Appeal is the final instance at the EPO to decide on the validity of the European patents.

⁹ This form of appeal has to be distinguished from appeals seeking to reverse the decisions rendered by the opposition division of the EPO. We are leaving this issue aside for now, since our data on appeals are incomplete.

¹⁰ An amendment normally results in a reduction of the “breadth” of the patent by altering the claims which define the area for which exclusive rights are sought.

¹¹ On average, the opposition procedure takes around 2.2 years if the patent is revoked and about 4 years if the patent is amended.

¹² EPO may, but will not necessarily pursue the opposition procedure after the opponent’s withdrawal from his attack.

Figure 2 displays the rate of opposition for the time period from 1980 to 1998.¹³ We plot here the number of opposed patent grants divided by the total number of patents granted in a particular year. Leaving aside the early period after the EPO commenced operations, the rate of opposition has initially been on the order of 8 percent. It has been declining to about 6.5 percent over time, but it is still extremely high in comparison to the likelihood of patent litigation in the U.S.. Lanjouw and Schankerman (1999) estimate the incidence of patent litigation to be around 1.07 percent of all patent grants, but this estimate includes cases of patent infringement.¹⁴ In the drugs and health fields, the incidence of challenge suits is somewhat higher with 2.01 percent, but still considerably lower than the opposition rate of 8.5 percent for our sample.¹⁵

2.5 National Litigation

In cases of unsuccessful opposition and appeal against commercially valuable patents, third parties may try to attack the national successors of the European patent in the designated states. As of today, this option is not touched by the harmonisation of the European patent laws. However, national authorities can refer to former trials, thus, the probability of winning a national trial after having lost at the European level may be reduced. The differences across national jurisdictions are still enormous. Economies of scale are therefore difficult to achieve, thus making it quite expensive to attack the national successor patents in all of the designated states. This cost structure makes an attack at the European level via the opposition procedure particularly attractive for a potential competitor of the patent holder.

3 Theoretical Aspects

3.1 Theoretical Background

Our paper is linked to two research areas: the economics of the patent system and the economics of litigation and legal disputes. Both areas have found considerable attention in the recent economics literature. As to the economics of patent systems, European national patent systems are quite well-understood with respect to the renewal system they employ.¹⁶ Traditional models of patent rights have focused on a limited set of features which characterize patent rights and national patent systems.¹⁷ The dominant view is that patent systems raise innovation incentives, since they allow inventors to appropriate a larger return to inventive activity than would be achievable without such an institution. The basic idea behind the design of a patent system is therefore to spur innovative activity by allowing inventors to “appropriate” the economic benefits of their contributions more fully. In early models,

¹³ Since opposition must be filed within nine months after a patent is granted, the application cohorts from 1978 to 1996 were attacked by opposition cases dated between roughly 1980 and 1998. The lag corresponds to the examination period between application and grant.

¹⁴ See Lanjouw and Schankerman (1999, Table 1).

¹⁵ These discrepancies may mainly be driven by cost differences between the U.S. system and the European context.

¹⁶ See Griliches (1990) for a survey of these studies.

¹⁷ For a summary see Kaufer (1987).

such as the one in Nordhaus (1967), a patent allows the inventor to enjoy a temporary, but iron-clad monopoly. The problem of designing a patent system involves the trade-off between welfare losses due to monopoly rights and welfare gains from improved innovation incentives. Nordhaus (1967) assumes that patents ensure perfect appropriation possibilities and that no competition between inventors would occur until the expiration of the patent. From the existing empirical evidence, it is clear by now that the effectiveness of patents differs across industries and technical fields.¹⁸ From an empirical point of view, this assumption is not a reasonable approximation. The effectiveness of patent protection varies across sectors. Some fields (such as pharmaceuticals) enjoy relatively strong protection. Others, such as engineering are characterized by relatively weak patents rights. The main policy instrument studied by Nordhaus is an adjustment of the duration of patent protection. More recent studies (e.g., Scotchmer 1991, 1996) have allowed patents to differ with respect to other characteristics.

With respect to the economics of litigation, most of the theoretical studies and – to the best of our knowledge – all of the empirical studies have focused on U.S. institutions.¹⁹ However, since the EPO opposition procedure is in essence an institution for “first-instance litigation”, some of the theoretical considerations prevalent in U.S. studies of patent litigation apply quite well to the context studied here. Studying litigation in the patent system is quite important, since the impact of patents on innovation and monopoly distortions depends on the extent to which patented inventions can be imitated by competitors without being threatened by legal sanctions. As Lanjouw and Schankerman (1999) demonstrate in their summary of the theoretical literature, the likelihood of litigation increases as

- (1) information is distributed more asymmetrically;
- (2) expectations with respect to the outcomes diverge;
- (3) the stakes increase, i.e., as profit implications become more important;
- (4) the cost of litigation rises.

All of these predictions should hold for patents with a comparable degree of legal "quality" or merit. We add a fifth hypothesis here which states that litigation is more likely if

- (5) the patent right is perceived to be a legally weak one, e.g. with respect to its degree of novelty or inventive step.

The next section derives hypotheses that will then be addressed in the empirical sections of the paper.

3.2 Testable Hypotheses

Predictions (1) and (2) suggest that rates of opposition will be particularly high for technical fields in which asymmetric information and diverging expectations are pronounced. This is likely to be the case in relatively new areas, such as special areas of biotechnology in which applicants seek patent

¹⁸ See Levin et al. (1987) for an early study on this issue.

¹⁹ See for details Lanjouw and Lerner (1997, 1996), Lanjouw and Schankerman (1997, 1999) and Lerner (1994, 1995). The only exception to this rule is Lanjouw (1998) who estimates the impact of litigation on patenting in Germany in a structural model.

protection for new microorganisms, enzymes and recombinant DNA processes. We use four-digit IPC classifications to test this hypothesis. The reference group for our tests are patents whose main IPC classification is C12M. We expect that there is relatively little uncertainty in this field, since it involves the patenting of machinery the working principles of which are well-known. Other IPC fields taken into account are C12N (microorganisms or enzymes), C12P (fermentation or enzyme-using processes), and classical pharmaceuticals (A61K, without cosmetics) for which we expect higher opposition rates than for the reference group, *ceteris paribus*.

Prediction (3) states that the likelihood of opposition will increase with the value of the patents in dispute. We do not have estimates of the monetary value of the patents considered here. But from earlier studies we know that there is a significant correlation between patent value and citation indicators.²⁰ Further below, we will present details on the operationalization of three different citation measures: forward citations (i.e., references made by subsequent patents to the patent at hand), backward citations (i.e., references to earlier patents as they appear in the examination report), and references to the non-patent literature, mostly to the scientific literature. Furthermore, an additional indicator of patent value is the size of the patent family, i.e., the number of jurisdictions in which patent protection has been granted for the invention. We use the number of designated states for which the applicant obtains patent protection once the European patent becomes a bundle of national patent rights.

Given that some technical fields are more attractive than others in terms of profit expectations, the attraction of the technical field should also have an effect on the litigation probability. Our hypotheses would be that the higher the attraction of the technical field, as measured by the cumulative number of patents in the field, the higher the rate of opposition. As to the patent holder's position, there are competing predictions. First, the more potent the position of the applicant is, the closer the patent will be to marketable products and the more likely it is to be attacked by opposition. However, patent holders with larger portfolios in a given field may also have more incremental patents of relatively little marginal value. In this case, we would expect a negative impact on opposition rates. These predictions are notoriously ambiguous, since patent value and (legal) strength of the patent are likely to be correlated.

Finally, given some value for a positive outcome of litigation, cost-benefit considerations should matter. Since the opposition procedure is relatively inexpensive in comparison to U.S. litigation cases, it is not clear whether this effect will be apparent in our data. Moreover, we will not be able to test this hypothesis directly, since we use data describing the patent under attack in a challenge suit, while Lanjouw and Schankerman (1999) mainly use data on patents that were infringed. Data on the challenged patent are not likely to cast much light on the cost-benefit tradeoff of the opposing party. Differences associated with the nationality of the owner (one of the variables which Lanjouw and Schankerman associate with cost differences) could therefore be attributed to variations in the average quality of patent applications filed with the EPO or to other unobserved sources.

Prediction (5) has not been tested empirically in the literature. We argue that the likelihood of opposition will increase to the extent that the opponent feels confident to win the legal dispute. When filing his opposition the opponent will plausibly have at his disposal comparable information to the

²⁰ See, e.g., Harhoff, Narin, Scherer and Vopel (1998), Lanjouw and Schankerman (1999), and Trajtenberg (1990).

examiner at the time the latter sees the patent application for the first time. Thus, information that seem to signal a weak patent right will enhance the opponent's inclination to enter into opposition. As will be explained below, the likelihood of opposition should therefore increase with the share of so-called X documents presented by the examiner who prepares the initial search report.²¹ These documents are a signal that previous patents may to some extent be harmful to the novelty claim of the opposed patent.

The next section discusses data-specific issues, before we elaborate on the variables used to operationalize the hypotheses.

4 Data Issues

4.1 Data Sources

We use three different data sources for our study. The ELPAC data bank contains information on European patents and Patent Applications filed between 1979 and 1996. The data include the names of the inventors, applicants and opponents, designated states, process dates, international patent classifications and decisions of granting and opposition procedures. Our version of ELPAC contains 813,979 observations. We also use information from the ESPACE databank to add observations where ELPAC is not complete. The ESPACE databank basically contains the same information as ELPAC; however, ESPACE covers the filing and granting process more completely than ELPAC whereas ELPAC is more complete with respect to the opposition procedure. Finally we draw information on citations from the REFI database. REFI contains data on patent citations for 712,315 European patent applications as well as references to the non-patent literature for 424,962 European documents.

From these databases, we select pharmaceuticals and biotechnology patents on the basis of the main IPC classification. We can identify 13,389 granted European patents in the biotechnology and pharmaceutical fields between 1979 and 1996. Of these, 1,158 patent grants (8.6 percent) were opposed.

4.2 Variables

In the following sections, we briefly describe the variables computed from our three data sources.

Opposition. We create a binary variable to distinguish between patents that were opposed from those that were not opposed. This variable reflects the endogenous outcome we want to model.

Backward Citations. The search report of the EPO yields information on the state of the art relevant for the patentability of the application. State of the art is mostly described by patent or non-patent literature. Relevant references are cited (backwards) by the examiners during the examination of the patent application. Furthermore, the cited references are pre-classified by the EPO office in The Hague which composes the search report prior to examination. The citations are pre-classified into different categories according to the guidelines for substantive examination issued by the World Intellectual Property Organisation (WIPO). The definitions of the dominating three categories A, X, and Y are

²¹ The detailed meaning of the share of X documents cited by the first examiner will be explained explicitly in section 4.2.

briefly summarised. Where a document cited in the European search report is particularly relevant, it should be indicated by the letters X or Y. Category X is applicable when a document is such that (even) when taken alone, a claimed invention could possibly not be considered novel or could not be considered to involve an inventive step. Category Y is applicable when a document is such that a claimed invention could possibly not be considered to involve an inventive step when the document is *combined* with one or more other documents of the same category, such combination being obvious to a person skilled in the art. Where any document cited in the European search report is not considered to belong to either of the two categories X and Y but defines the general state of the art, it should be indicated by the letter A. Documents are classified by the EPO staff members in Den Hague who prepare the search report. The classifications therefore have pre-examinatory status, i.e., they are re-evaluated during the material examination in Munich. However, they serve as indicators of the quality of the citation to the examiners. In particular, a high share of X documents should put the patent right at risk in post-grant opposition procedures, since possible concerns about novelty are already reflected in the research report and may resurface in the opposition proceeding.

For our analysis we construct several variables referring to backward citations. At first, we count the overall number of backward citations to relevant patent literature. We also include the share of A and the share of X documents in the analysis. We expect that as the share of X documents increases, the patent will face a higher likelihood of opposition, *ceteris paribus*. Conversely, as the share of A documents increases, the reverse effect should become apparent.

References to the Non-Patent Literature. Patents may be based in part or fully on new scientific knowledge.²² Since published research results can be used to document the state of the art against which the application has to be evaluated, patent examiners will then search for relevant references in the scientific literature. As in the case of references to the patent literature, a relatively high number of references to the scientific literature may therefore indicate patents of relatively high value. Following our main hypothesis, these should be particularly likely to encounter opposition.

The fact that not all non-patent references refer to scientific sources is well-known. Thus, the number of non-patent references is not a direct measure of the strength of a patent's science linkage. This problem has been studied in some detail by Schmoch (1993). A survey of the literature on this topic is contained in Meyer (1999). However, the number of non-patent references is considerably easier to compute than the number of explicit links to the scientific literature. Moreover, we also expect that "science-based" patents contain a relatively high number of non-patent references. This is actually borne out by the data (see below). Thus, we maintain the easily available indicator which simply counts the references to the non-patent literature.

Forward Citations. If a patent receives citations from other future patents, this is an indication that it has contributed to the state of the art. Earlier studies have shown that forward citations are positively correlated with the monetary value of the patent (Harhoff, Scherer and Vopel 1999; Lanjouw and Schankerman 1999; Trajtenberg 1990). In our paper, forward citations are computed within the EPO system only, i.e.m we only identify how many future citations a patent received from subsequent European patents. We count the number of references to the patent under consideration in patents filed within four years of the filing date of the original patent.

²² The growing importance of the linkage between private patenting activities and scientific knowledge has been documented by Narin, Hamilton, and Olivastro (1997).

Number of Designated States. Putnam (1991) and other authors have argued out that information on family size (the number of jurisdictions in which patent protection is sought) may be particularly well suited as an indicator of the value of patent rights. Studies by Putnam (1996) and Lanjouw et al. (1998) have shown that the size of a patent family and the survival span of patents are highly correlated. While we do not observe the global size of the patent family in our data, we can construct variables for the designation of the patent in the different member states of the European patent Convention. In essence, this reflects the European family size. Given the fee schedule of the EPO, it is clear that firms seeking to designate the patent right for a large number of EPC member countries face a considerable increase in total patenting expenses. However, there are some economies of scale in that some types of fees (e.g., for translation) are fixed. In our multivariate analysis, we therefore use the logarithmic transformation of the number of designated states to reflect the declining marginal cost of patenting in another EPC country.

Ownership. An invention can only be made by individuals. The applicant (and later on patent-holder) may be either an individual, a firm or a group of individuals and firms. We construct a variable for the type of ownership (corporate or individual) for each patent by comparing the inventor's and the applicant's name. The patent is assigned individual ownership if the inventor's name and the applicant's name are the same. We also create binary variables for owners from the U.S., Germany, Japan, France, Great Britain, Switzerland and all remaining countries.

International Patent Classifications (IPC) Assignments. During the EPO research and examination process, patents are assigned to 9-digit categories of the IPC system. Patented inventions may belong to diverse technological fields, i.e. they may be assigned different IPC codes. The broader the relevance of the patent, the more potential opponents it may therefore have. The number of different IPC classifications may therefore be positively correlated with the likelihood of opposition. This argument is related to Lerner (1994) who suggests that broader patents are more valuable ones. An opposing argument would suggest that the likelihood of opposition should decrease with an increasing number of different IPC codes, since the invention is more general and therefore has less immediate relevance for market outcomes.

Previous Patents - Cumulative EPO Patent Grants by Firm. We construct a further variable that counts the number of previous EPO patent grants the applicant has already received. It is plausible to assume that the greater the number of patents he holds, the higher the market share will be. Moreover, a larger patent portfolio should reduce the impact of a successfully opposed patent, both on the applicant's and the opponent's profits. We therefore expect that the likelihood of opposition decreases as the number of previous patents increases.

Crowdedness - Cumulative EPO Patent Grants within Technical Field. The more attractive a technical field, the higher should be the cumulative number of patents. This form of "crowding" is likely to raise the likelihood of opposition. Our measure for "crowdedness" is the cumulative number of patents within a four-digit IPC classification.

5 Empirical Specification and Estimation Results

5.1 Descriptive Statistics

Our empirical analysis is based on data covering all European patents in the biotechnology and pharmaceutical industry with application years from 1978 to 1996. The data include information on the filing date, the date of opposition, the number of designated states, the IPC codes assigned, the nationality of the patent owner and the type of ownership; furthermore they comprise forward and backward citations and references to the non patent literature for each European patent. The complete data set contains 13,389 European patents and 1,158 opposition cases (8.64 %).

Summary statistics for these patents are given in Table 1. Forward citations range from 0 to 36 citations per patent at an average of about one citation per patent; backward citations range from 0 to 29 citations at an average of about two citations per patent. The average share of X documents is below 10%, the share of A documents around 20% of the cited documents. On average, the applicant designates 10 EPC member states when filing his application.

Tables 2 to 5 display the relationships between the incidence of opposition and four of the exogenous variables, i.e., forward citations, backward citations, references to the non-patent literature, and the number of designated EPC states. In these tables we present data on the distribution of the exogenous variables as well as data on the bivariate relationship between these variables and the incidence of opposition. We present these statistics for the total number of patents in the sample, and separately for the dominating national groups of patent owners. The most important non-European owner nations are the U.S., accounting for approximately 34 percent, and Japan accounting for roughly 19 percent of the total number of patents, respectively.

As is evident from Table 2, forward citations are highly correlated with the likelihood of opposition in the overall sample and in each of the national groups. The rate of opposition increases monotonically with the number of forward citations. The group of patents receiving more than 9 forward citations is in fact attacked in 44.6 percent of all cases, nearly twice as often as the group of patents which is referenced 7 to 9 times. It is also clear from Table 2 that Japanese patents are attacked far less frequently than those of U.S. and other owners, but it is not clear whether this is driven by differences in patent quality (in the sense that Japanese patents are legally "stronger"), or by differences in patent value (in the sense that Japanese patents tend to be more incremental).

Table 3 reveals that there is also a significant relationships between backward citations and the incidence of opposition, although the relationship appears to be weaker than in the case of forward references. This result also holds for the sub-samples of Japanese owned patents and those mainly held by European owners. However, backward citations are not significantly correlated with the likelihood of opposition when restricting the sample to U.S. owners.

Table 4 summarizes the relationship between opposition and the number of references to the non-patent literature. Again, in the overall sample we find a significant relationship ($p=0.029$), but this correlation is mainly driven by the U.S. sub-sample. References to the non-patent literature are not significantly associated with the likelihood of opposition for Japanese owned patents and for patents owned by mostly European patent holders. These two results are somehow plausible considering the practical aspects of filing in the two countries. In the U.S. the "best-mode" requirement not only

oblige the applicant to disclose the optimal method of carrying out his invention, but he is also forced to protect himself against any possible objections of state of the art in possible legal disputes by quoting any kind of literature that could at all be related to the patentability of his invention²³. Thus, whereas citations of European applicants and examiners refer to the important relevant literature, U.S. owner may by habit reveal additional information that is correlated with the incidence of opposition.

Finally, the results summarized in Table 5 confirm that the likelihood of opposition is correlated positively with the number of designated states in our univariate analysis. However, the relationship does not appear to be a monotonic one. The relationship is also insignificant in the Japanese patent sub-sample, suggesting again that there may be important heterogeneity effects across owner nations. Obviously, the decision to seek patent protection in a particular country may also be driven by variables that we have considered before, e.g., the patent's anticipated legal strength. It will therefore be important to study the effects of all variables described before in a multivariate analysis.

5.2 Multivariate Specification and Results

We now discuss the results from our multivariate probit specifications which are summarized in Table 6 and Figure 3. We report both the probit coefficients (columns 1a and 2a) and the marginal effects (columns 1b and 2b) which are computed for the sample means. Columns 1a and 1b refer to the full sample of 13,389 patents. In columns 2a and 2b, we restrict the sample to patent holders with at least 10 patents. This probit regression therefore excludes firms and individuals which do not participate on a regular basis in the patenting process. However, the differences between the results are quite small, and we will focus in our discussion on columns 1a and 1b.

First, family size displays the expected effect on the likelihood of opposition. Per logarithmic unit, the likelihood of opposition increases by 3.3 percent (S.E. 0.70). The effect is precisely estimated and indicates a strong relationship. Using a dummy variable approach as a nonparametric alternative specification, we confirm these estimates. Taking patents with fewer than 5 designated states as the reference group, the likelihood of opposition increases by 5.23 (S.E. 1.40) percentage points if the number of designated states is between 5 and 11. It increases by 6.0 (S.E. 1.1) percentage points (relative to the reference group) for the group of patents with 11 to 14 designated states and by 9.3 (3.3) percentage points for patents with more than 15 designated states.

As in the study of U.S. patent litigation by Lanjouw and Schankerman (1999), we find that the effect of the scope variable (number of different four-digit SIC codes) is negative and quite small. Moreover, the effect is barely significant in column 2b, and not significant in column 1b. This result is apparently in contrast with Lerner's study who reports a positive correlation between scope and the market value of the biotechnology firms owning the respective patents. A previous study by Harhoff, Scherer and Vopel (1999) did not find any significant relationship between this variable and the value of individual patents. Indirectly, we confirm this result here using a sample that is much closer to Lerner's biotechnology data than the previously used ones.

We have argued that interactions between patent holders in "crowded" fields with a large cumulative number of patents should lead to an increase in the rate of opposition, since competitors are more

²³ A flouting of this rule can be considered an inequitable conduct and possibly lead to the total loss of the patent.

likely to pursue similar research paths. At the same time, opposition by competitors is likely to be a function of the patent holder's portfolio. We model these effects by including a measure for “crowdedness”, a measure for the size of the patent portfolio of the firm holding the opposed patent, and the interaction term. The results for these variables are not easy to interpret. “Crowdedness” has the anticipated positive marginal effect on opposition, but it is quite small and only works through the interaction term. For firms with the average number of patents (26,8 patents), an increase in the number of patents in the field by 1000 patents raises the likelihood of opposition by 0,14 percentage points. For firms with strong patent portfolios (e.g. 300 patents), the effect is on the order of 0.4 percentage points. Since the differences between our IPC groups are quite large in terms of “crowdedness”, we can explain a difference on the order of about 1 percentage point in the likelihood of opposition. The effect of the firm's own portfolio is much larger. Adding 100 patents to the average portfolio of 26.8 patents reduces the rate of opposition by 2.7 percentage points. Again, the effect is highly significant. This effect is reduced in crowded areas – for most “crowded” fields it is on the order of 1 percentage point. These results parallel the evidence in Lanjouw and Schankerman (1999) who find in their study of U.S. patent litigation cases that litigation is more likely to occur whenever patents appear to form the basis of a sequence of technologically linked inventions. Unfortunately, we do not have data on self citations available, hence a direct comparison with the U.S. study cannot be provided at this point.

The strongest predictor of opposition are forward references to a patent. In order to model the impact of this variable in a flexible way, we have included dummy variables for the number of forward references. The joint test of these variables in Table 6 reveals that they are highly significant. The size of the coefficients and the standard errors are plotted in Figure 3. Increasing the number of citations from zero to one raises the likelihood of opposition by 2.5 (S.E. 0.7) percentage points; increasing the number from zero to ten citations yields an increment in the rate of opposition of 20.2 (S.E. 9.8) percentage points. In general, these multivariate results are consistent with the descriptive statistics in Table 2. They confirm our view that more valuable patents face a much higher likelihood of opposition. Thus, the result is also consistent with the positive effect of family size.

The number of backward references has no significant impact on the likelihood of opposition. However, the composition of the backward references does matter considerably. We noted before, that X documents among the cited patents pose a particularly strong threat to patent validity, while A documents merely summarize the state of the art. Consistent with this view, we find that increasing the share of X documents from, e.g., zero percent to fifty percent would lead to a direct increase in the opposition rate of about 1.2 percent. Moreover, since the share of A documents may be reduced, there is an additional effect of similar order. Our results demonstrate that the WIPO classification of cited documents in the research report could become an interesting variable for empirical researchers interested in modelling litigation or the value of patent rights. To the best of our knowledge, this information has not been used before.

Somewhat surprisingly, we cannot find any significant correlation between the likelihood of opposition and the number of references to the non-patent literature. In Harhoff, Scherer and Vopel (1999), there is clear evidence for German patents that a strong correlation exists between these references and patent value. A possible explanation of our result in Table 7 would be that the increase in value documented by a large number of non-patent literature references is accompanied by an increase in the legal “robustness” of the patent right. While increased value may help to make opposition look attractive to competitors, the links to scientific results may reduce the chances of a successful outcome of the challenge. We will investigate this explanation in future work.

We hypothesized that patents in fields with higher economic, legal or technical uncertainty and subsequently higher asymmetry of information should attract opposition more frequently. These expectations are confirmed in our estimates. The joint test for significance of those variables characterizing the IPC classification of the patent yield a strong result – clearly, there are important differences across these groups. Taking the group C12M (apparatus for enzymology or microbiology) as our reference case, we would expect all other IPC groups included in our study (see Table 2 for a description) to display higher opposition rates. After all, the C12M classification refers to patented machinery which may be much closer in terms of the patented inventions to mechanical engineering fields than to recombinant DNA biotechnology. Our estimates show that the strongest increment in opposition rate occurs in the IPC fields C12N (microorganisms or enzymes – 9.2 percentage points, S.E. 2.9) and C12P (fermentation or enzyme-using processes – 7.6 percentage points, S.E.3.1). Classical pharmaceuticals (A61K, without cosmetics) face an opposition rate that is only 6.0 percentage points (S.E. 2.0) higher than in the reference group. The other IPC classes have an even lower coefficient.

Finally, we do not find robust evidence that patents held by individual inventors are more or less likely to be challenged. Moreover, the coefficients for the nationality of the owner do not display a clear pattern. Taking German applicants as the reference group, applicants from the U.S., Switzerland and a residual group of smaller countries do not face incrementally different opposition rates. Japanese owners have a significantly lower rate of opposition (by 3.8 percentage points, S.E. 0.9), and UK owners face higher opposition rates (by 2.5 percentage points, S.E. 1.1). However, these variations may very well reflect differences in technical sub-fields which we have not controlled for sufficiently.

6 Conclusions and Further Research

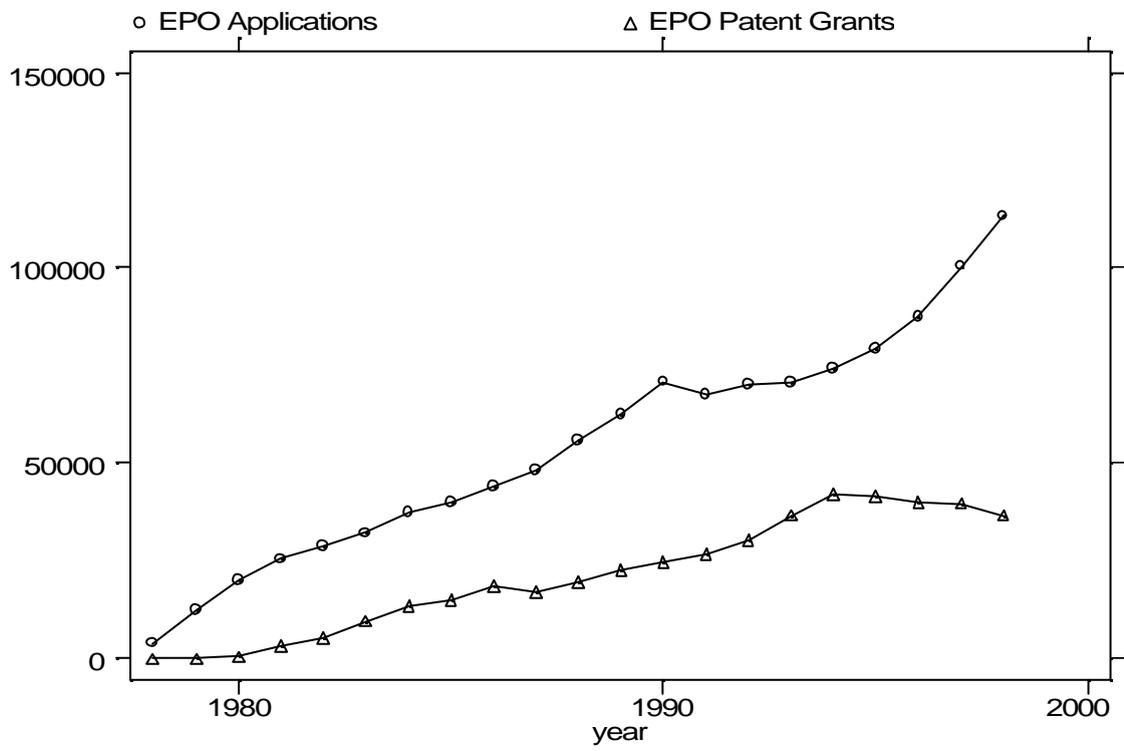
This paper has presented an exploratory analysis of the opposition procedure at the European Patent Office. To the best of our knowledge, this is the first econometric study of this kind. The previous lack of interest cannot be attributed to the fact that the topic is unimportant – the EPO grants about 40,000 patent rights per year, and 8 percent of these are opposed. Hence, opposition may not only affect the incentives for patenting and R&D, it may also serve a valuable function in weeding out weak patents and resolving legal uncertainty with regard to particularly valuable inventions. Given our results, the latter interpretation appears to be the most relevant one. Naturally, this study is merely a first glimpse at an important institution, and more structured attempts, both for particular technical fields and the population of patents, should follow. We should also emphasize that the opposition procedure is not only used by competitors of patent applicants. In particular in the field of biotechnology, a large number of public interest groups is trying to influence European patenting practice by filing opposition cases against certain patents. It should be interesting to study the political economy of this process as well as the detailed structure of the institution in further work.

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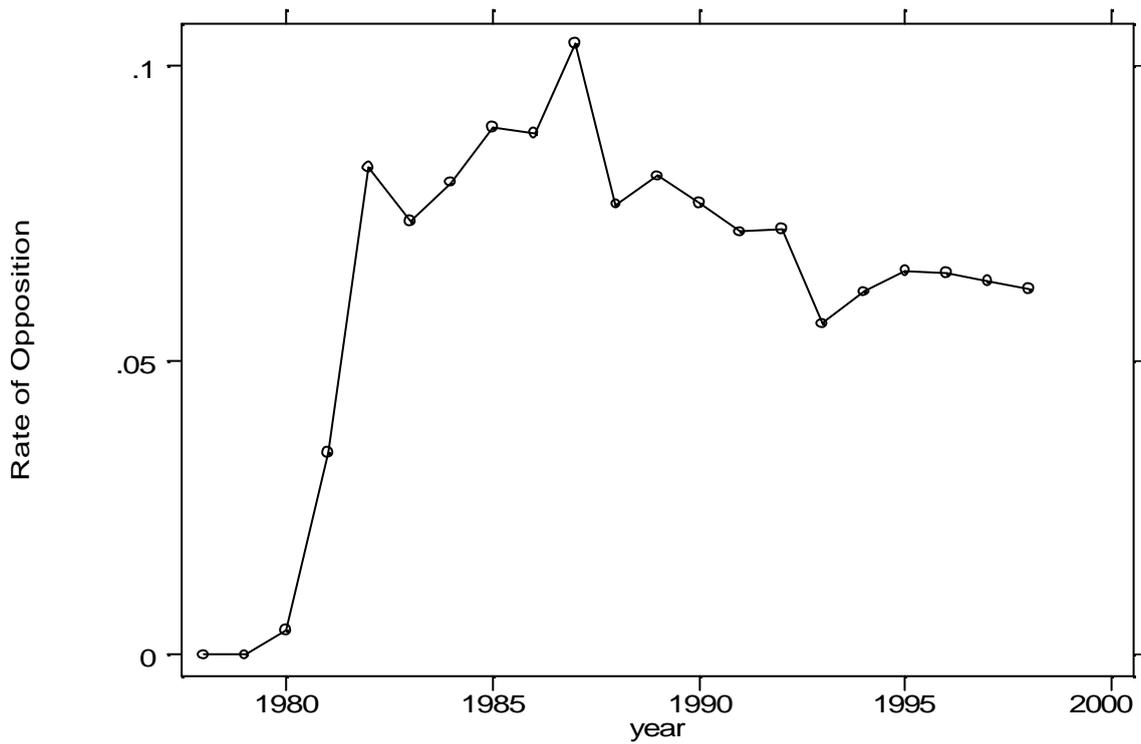
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Figure 1
EPO Applications and Patent Grants
1978-1998



Source: European Patent Office Annual Report 1998, Table 7.6

Figure 2
Opposition Rate 1978-1998
(All EPO Patent Grants and Opposition Cases)

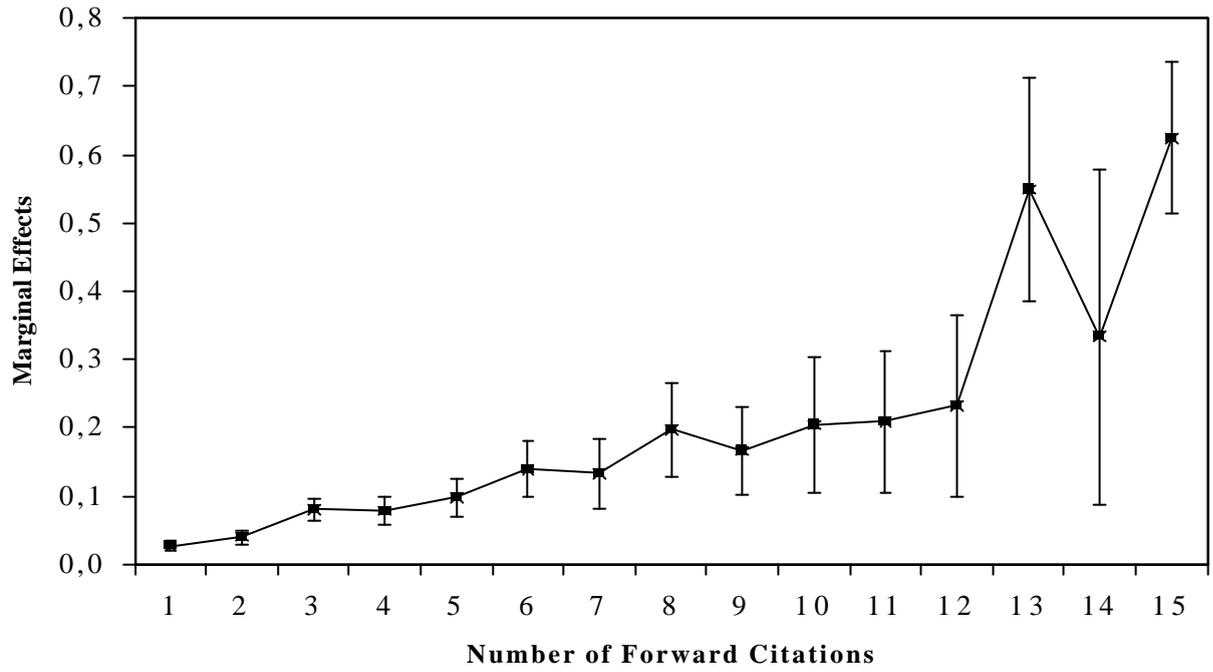


Note: Opposition rate is defined as number of patent grants opposed divided by the number of all patents granted in a given year. The first EPO patent grants were issued in 1980.

Source: European Patent Office Annual Report 1998, Table 7.6

Figure 3

Forward Citations and the Likelihood of Opposition
Probit Marginal Effect Estimates and Standard Errors



Note: The figure displays marginal effects (plus and minus one standard error of the estimate). The estimates are obtained from the probit specification in column 1b of Table 6.

Table 1
 Descriptive Statistics for the Biotechnology
 and Pharmaceuticals Sample
 (N=13,389)

Variable	Mean	S.D.	Min.	Max.
Opposition case	0.0864		0	1
Forward citations (received within 4 yrs after filing of application)	0.914	1.800	0	36
References to the non-patent literature	1.749	1.995	0	29
Backward citations (references to the patent literature)	2.159	2.203	0	19
Share of X documents among backward citations	0.086	0.229	0	1
Share of A documents among backward citations	0.196	0.338	0	1
Number of designated states	10.445	3.437	1	17
Cumulative number of patents within four-digit ipc/1000	2.486	2.144	0.001	7.394
Cumulative number of patents by patent holder/1000	0.027	0.043	0.001	0.322
Scope (number of 4-digit IPC classifications)	1.934	1.936	1	23
IPC A61K – Preparation for Medical, Dental, or Toilet Purposes	0.552		0	1
IPC C07G – Compounds of Unknown Constitution	0.009		0	1
IPC C12M – Apparatus for Enzymology or Microbiology	0.030		0	1
IPC C12N – Microorganisms or Enzymes; Composites thereof	0.215		0	1
IPC C12P – Fermentation or Enzyme-Using Processes	0.110		0	1
IPC C12Q – Measuring or Testing Processes Involving Enzymes	0.083		0	1
Individual owner	0.065		0	1
Owner from U.S.	0.338		0	1
Owner from U.K.	0.074		0	1
Owner from France	0.067		0	1
Owner from Japan	0.191		0	1
Owner from Switzerland	0.025		0	1
Owner from other country	0.115		0	1

Table 2
Forward Citations and Incidence of Opposition

Number of Forward Citations	Number of Observations	% of Total Observations	Incidence of Opposition –	Incidence of Opposition – Patents of U.S. Owners		Incidence of Opposition – Patents of JP Owners		Incidence of Opposition – Patents of Other Owners	
			All Patents	Obs.	Mean	Obs.	Mean	Obs.	Mean
0	8,178	61.08	0.066	2,840	0.077	1,312	0.022	4,026	0.073
1-3	4,319	32.26	0.101	1,303	0.111	1,062	0.060	1,954	0.116
4-6	651	4.86	0.160	245	0.159	146	0.096	260	0.196
7-9	158	1.18	0.234	77	0.195	31	0.161	50	0.340
>9	83	0.62	0.446	54	0.481	5	0.200	24	0.417
Total	13,389	100	0.087	4,519	0.098	2,556	0.044	6,314	0.095
χ^2			275.30		123.98		43.81		126.01
(p-value)			(0.000)		(0.000)		(0.000)		(0.000)

Note: The χ^2 statistics (and p-values) refer to a Pearson test of the hypothesis that there is no relationship between the number of forward citations and the incidence of opposition within the indicated group of patents.

Table 3
Backward Citations and Incidence of Opposition

Number of Backward Citations	Number of Observations	% of Total Observations	Incidence of Opposition –	Incidence of Opposition – Patents of U.S. Owners		Incidence of Opposition – Patents of JP Owners		Incidence of Opposition – Patents of Other Owners	
			All Patents	Obs.	Mean	Obs.	Mean	Obs.	Mean
0	4,056	30.29	0.085	1,428	0.096	492	0.045	2,136	0.087
1-3	6,134	45.81	0.080	2,050	0.100	1,448	0.039	2,636	0.085
4-6	2,628	19.63	0.095	836	0.096	519	0.044	1,273	0.116
7-9	467	3.49	0.122	167	0.090	81	0.086	219	0.160
>9	104	0.777	0.173	38	0.158	16	0.250	50	0.160
Total	13,389	100	0.087	4,519	0.098	2,556	0.044	6,314	0.095
χ^2 (p-value)			23.67 (0.000)		1.87 (0.759)		20.26 (0.000)		23.96 (0.000)

Note: The χ^2 statistic (and p-value) refer to a Pearson test of the hypothesis that there is no relationship between the number of backward citations and the incidence of opposition within the indicated group of patents.

Table 4
References to the Non-Patent Literature and Incidence of Opposition

Number of References to the Non-Patent Literature	Number of Observations	% of Total Observations	Incidence of Opposition –	Incidence of Opposition		Incidence of Opposition		Incidence of Opposition	
			All Patents	– Patents of U.S. Owners	– Patents of JP Owners	– Patents of Other Owners	Mean	Obs.	Mean
0	3,618	27.02	0.099	1,132	0.082	656	0.052	1,830	0.101
1-3	7,719	57.65	0.084	2,670	0.096	1,417	0.046	3,632	0.091
4-6	1,630	12.17	0.086	558	0.116	404	0.032	668	0.093
7-9	318	2.38	0.132	113	0.221	67	0.015	138	0.116
>9	104	0.78	0.125	46	0.130	12	0.000	46	0.152
Total	13,389	100	0.087	4,519	0.098	2,556	0.044	6,314	0.095
χ^2			10.78		25.35		4.29		4.00
(p-value)			(0.029)		(0.000)		(0.368)		(0.406)

Note: The χ^2 statistic (and p-value) refer to a Pearson test of the hypothesis that there is no relationship between the number of references to the non-patent literature and the incidence of opposition within the indicated group of patents.

Table 5
European Family Size and Incidence of Opposition

Number Designated States	Number of Observations	% of Total Observations	Incidence of Opposition – All Patents		Incidence of Opposition – Patents of U.S. Owners		Incidence of Opposition – Patents of JP Owners		Incidence of Opposition – Patents of Other Owners	
			Mean	Obs.	Mean	Obs.	Mean	Obs.	Mean	Obs.
1-4	1,154		0.030	277	0.039	659	0.023	1,154	0.041	
5-10	4,109		0.083	1,165	0.104	1,115	0.056	4,109	0.085	
11-14	7,334		0.100	2,832	0.104	715	0.048	7,334	0.101	
>14	792		0.062	245	0.065	67	0.015	792	0.067	
Total	13,389	100	0.087	4,519	0.098	2,556	0.044	6,314	0.095	
χ^2			1779		15.498		12.710		19.539	
(p-value)			(0.000)		(0.001)		(0.005)		(0.000)	

Note: The χ^2 statistic (and p-value) refer to a Pearson test of the hypothesis that there is no relationship between the number of designated states and the incidence of opposition within the indicated group of patents.

Table 6
Probit Results

Independent Variable	Full Sample (1a)	Full Sample (1b)	Firms with >9 Patents (2a)	Firms with >9 Patents (2b)
European family size	0.234	0.033	0.220	0.031
ln(number of designated states)	(0.049)	(0.007)	(0.062)	(0.009)
scope (number of 4-digit IPC classes)	-0.012 (0.009)	-0.0017 (0.0012)	-0.022 (0.011)	-0.003 (0.0015)
crowdedness (cum. number of patents in four-digit IPC/1000)	-0.007 (0.022)	0.0014 (0.0006)	-0.009 (0.030)	0.0016 (0.007)
previous patents (cum. number of patents held by applicant/1000)	-3.733 (0.927)	-0.273 (0.126)	-4.160 (1.067)	-0.291 (0.143)
crowdedness * previous patents	0.630 (0.205)	-	0.751 (0.237)	-
forward references (dummy variables – see Fig. 3) – χ^2 (df)	162.51 (15) (p<0.001)		115.02 (15) (p<0.001)	
backward references	0.011 (0.008)	0.0015 (0.0011)	0.009 (0.010)	0.001 (0.001)
share of X documents	0.166 (0.068)	0.024 (0.010)	0.212 (0.086)	0.030 (0.012)
share of A documents	-0.109 (0.054)	-0.015 (0.007)	-0.150 (0.068)	-0.021 (0.010)
ref. to non-patent literature (dummy variables) – χ^2 (df)	5.02 (3) (p=0.171)		3.93 (3) (p=0.269)	
individual owner	-0.112 (0.070)	-0.015 (0.009)	-0.250 (0.281)	-0.029 (0.027)
Dummy Variables for Four-Digit IPC Groups – χ^2 (df)	26.91 (5) (p<0.001)		29.58 (5) (p<0.001)	
Dummy Variables for Application Years – χ^2 (df)	22.50 (15) (p=0.095)		17.77 (15) (p=0.278)	
Dummy Variables for Ownership Variables – χ^2 (df)	58.34 (4) (p<0.001)		54.36 (4) (p<0.001)	
log L	3705.97		-2413.89	
χ^2 (df)	469.86 (53)		384.14 (53)	
Pseudo-R-Squared	0.0596		0.0737	
N	13,389		8,644	

Notes: Dependent Variable: Patent Opposition (0/1). Column 1a and 2a contain coefficient estimates (standard errors) unless a chi-squared statistic is given. Columns 1b and 2b show marginal effects (standard errors). All probit equations contain dummy variables for the application year and for the nation of the owner. See the text for explanations.