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The case of biotechnology and pharmaceuticals

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Determinants of Opposition against EPO Patent Grants – The Case of Biotechnology and Pharmaceuticals^{*}

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Abstract

We analyze the determinants of opposition to biotechnology and pharmaceutical patents granted by the European Patent Office between 1978 and 1996. Opposition can be considered an early form of patent validity challenge suit. In our sample, 8.6 percent of the patents are attacked in opposition proceedings. 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. We comment on the implications of these results for the design of the patent and litigation system. (100 words)

JEL Classification: K41, L00, L20

Keywords: patents, litigation, intellectual property rights, European Patent Office

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1 INTRODUCTION

Intellectual property rights constitute an important aspect of public policies trying to enhance the incentives for innovation. Patent systems frequently form the core of such policies, and appropriately, they have found considerable attention in the law and economics literature on innovation.¹ Yet, two important aspects of patent rights still require considerable attention. First, patents endow their holders with passive rights. 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 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 defended in court, or if the enforcement or defense is too costly. While this point is particularly relevant for the case of infringement, the principal problem also occurs when a patent is defended against the legal claim that it is invalid.

Second, some attacks on patents should clearly succeed. The patent system itself is not a flawless mechanism. Just as legal decisions in courts may be subject to erroneous decision-making, some decisions made by the staff of patent offices may turn out to be flawed. For example, some evidence on prior art may be available and relevant for the examination of the patent's extent of novelty. But the relevant document may have been overlooked or out of the immediate reach of the examiner. The information may surface only after the patent has been granted. Other errors may occur in the translation processes at supranational institutions, yielding patent rights that have an unintentionally broad scope.² The examination of patent rights can be interpreted as a design process in which the breadth and scope of the patent right is carefully designed such as to achieve an optimal tradeoff between R&D incentives and losses of static welfare due to the exclusion of competitors. Errors in the examination of patent applications can then have serious welfare consequences. The correct design of a patent right should matter particularly for highly valuable

¹ A survey of patents as economics indicators is provided by Griliches (1990). For recent theoretical contributions to the analysis of patent systems see Scotchmer (1991, 1996) and Merges and Nelson (1990).

² On December 8, 1999, the European Patent Office (EPO) granted patent EP 0695351. In its English translation, claim 49 of this patent refers to “a method of preparing a transgenic animal”. In English scientific language, the term animal also includes humans while the European Patent Convention explicitly rules out patents on humans. Thus, the English-language version of the patent did contain an error. But an EPO patent grant – once issued – cannot simply be revoked or amended by the European Patent Office itself. Instead, the validity of this patent must be challenged in the opposition process of the European Patent Office. This is currently the case for the said patent. For details see the press release 1/2000 (http://www.european-patent-office.org/news/pressrel/2000_02_22_e.htm as of June 1, 2001) of the European Patent Office. Our description follows the interpretation of the European Patent Office. Several public interest groups such as Greenpeace have published their own assessments which argue that the EPO is acting in the interest of commercial players.

patents (i.e., patents that grant the owner a very strong economic advantage). Hence, it should be particularly relevant (in a welfare-maximizing sense) to specify valuable patent rights correctly.

The opposition mechanism at the European Patent Office is of interest with respect to both questions. 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. The opposition process can be initiated by any third party. By its very nature the process allows opponents to threaten the position of a patent holder and may therefore undermine R&D incentives. At the same time, since it is frequently initiated by competitors of the patent holder, the opponents may be able to generate information about the appropriate specification of the patent which has not been available to the patent office's examiner. Thus, it may have the potential of generating information for those patents where a correct design of the patent right matters the most, i.e. for valuable patents.

Studying this mechanism is not just an academic exercise, since opposition is a relatively frequent event – on average, 8.2 percent of the patents granted by the EPO are subject to opposition.³ 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 this paper as a counterpart 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 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 (1999) has

³ This is computed from the number of opposition cases filed against patent grants of applications filed between 1978 and 1992. For data sources, see section 4 of the paper.

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 ten times more valuable than comparable patents which were not attacked.

⁵ See Lanjouw and Schankerman (2001) 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

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 (1999) 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.⁷ This proposal is currently being pursued in the U.S. House of Representatives where legislation HR 1332/1333 is pending under which an opposition system will be introduced into the U.S. patent code. While the overall setup of this system is remarkably similar to the one at the EPO, opposition would be limited to business method patents if the legislation were enacted as proposed.

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). We first apply the Priest and Klein (1984) model from the literature on litigation and settlement in order to formulate our hypotheses for a world of diverging expectations and idiosyncratic payoffs. These imply that the more valuable patents should be particularly prone to attacks. Moreover, a host of other models imply that the more asymmetrically the information is distributed between patent holder and opponent, the more likely is a case of opposition. We use these predictions to select appropriate regressors for our probability models, and we discuss issues of operationalization in some detail. We then use a multivariate probit model to test our hypotheses.

The incidence of opposition is surprisingly high: in our data, 8.6 percent of all biotechnology and pharmaceutical patent grants are opposed. Using indicators like citations and patent family size, we can show that valuable patents are particularly likely to be attacked. Moreover, opposition occurs frequently in areas with considerable technical or market uncertainty. In technical areas where a large number of patents exist, opposition is more likely to occur. The rights of patent holders appear to “collide” in this case quite frequently, possibly due to intense competition among the owners of the patent rights. While limitations of our data do not allow us to look at the interaction between holders of opposed patents and their opponents, we find that patents of firms with strong patent portfolios appear to be attacked less often than patents of their competitors with smaller portfolios. This result may suggest that the incidence of opposition is also determined by the firms’

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.

⁷ Other countries which have incorporated some type of opposition mechanism in their national patent code include Australia, China, Japan, South Korea, and New Zealand. Most of these mechanisms are post-grant opposition proceedings. Some pre-grant opposition systems appear to have been abused strategically by opponents seeking to delay the grant. Most post-grant opposition systems allow third parties to attack the validity within a short time period after the grant. Typically, there is a presumption that the patent is valid during the opposition proceeding until it is either declared invalid or amended in some form.

capability of deterring hostile acts in some unobserved way. The advantage of the firms with large portfolios is getting weaker, however, as a technical field gets more crowded. *Ceteris paribus*, patents held by independent inventors are not more likely than corporate-owned patents to be attacked. This is an important result, since it suggests that there is no first-hand evidence that independent inventors will suffer from strategically filed opposition. However, the result does not rule out completely that strategic behavior exists in opposition filings.⁸

We also discuss the implications of these results and possible extensions of our research in the paper. Most significantly, we confirm that patents with above-average values are more likely to be attacked. This conclusion is an indirect one, since we do not have access to direct measures of patent value. However, the indicators used in this study have repeatedly been shown to be reliable proxies for a patent's value. Based on our results we suggest that the opposition system in Europe may be quite efficient in resolving legal uncertainty, in particular for economically relevant patents. At this point, this is a mere supposition, since the opposition system in Europe is a slow-moving process in which cases get on average decided about four years after the opposition has been filed.

The remainder of the paper is structured in five sections. We first discuss the institutional elements of the European Patent Office and its associated procedures. 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.

2 Patent Systems in Europe

National legal systems in Europe display considerable heterogeneity which is a reflection of the diverse legal traditions. However, in the area of legal frameworks for patents, harmonization of legal institutions has had a long tradition. 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

⁸ There may be strategic effects at work which we cannot detect with our data. For example, large opponents may have an incentive to extend and delay opposition proceedings against independent inventors in order to drive the costs of the proceedings up. See section 6 for comments on the possibility of such effects.

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 EPO-granted 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.⁹ 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

⁹ For a definition of "novelty" and "inventive step" see section 2.3.

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.¹⁰

2.2 European Patents

The conclusion of the European Patent Convention in 1973 prepared the ground for the creation of a central European Patent Office which has its headquarter in Munich. Between 1978 and 1999, the European Patent Office has received 1.267,681 patent applications and has granted 479,133 patents.¹¹ It 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 1999.

Patent protection for European member states can be obtained by filing several national applications or one EPO patent application designating the states for which patent protection is requested. Considering the fees charged by the various patent offices in Europe, a European patent application costs approximately €29.800 and thus about three times as much as a typical national application.¹² 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 Application and Examination Process

European patents are granted for inventions which are novel, mark an inventive step, are commercially applicable, 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 is generated by EPO staff in the The Hague office and then transferred to the examining staff in the Munich office. It describes state of the art regarded as relevant according to

¹⁰ 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 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.

¹¹ See the European Patent Office Annual Report 1999, Table 7.6. The application and grant figures include so-called Euro-PCT applications.

¹² As in other patent systems, the official patent office fees are a relatively small part of the costs (in this case €4,300). Professional representation before the EPO amounts to €5,500 on average, while translation into the languages of eight contracting states requires €1,500. Renewal fees for a patent maintained for ten years amount to roughly €8,500.

EPO guidelines for the patentability of the invention. In particular, the examination report lists and classifies references to earlier patents or to documents in the non-patent literature according to the guidelines for substantive examination issued by the World Intellectual Property Organisation (WIPO). So-called A references simply describe the state of the art without posing a threat to the novelty claims in the application. Other classes of references (Y and X) are potentially harmful to the novelty claim and may therefore signal to the applicant (and to outsiders once the research report is published) that the patent application is weak. Category X is applicable when a referenced 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 referenced 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. 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. As we will argue later, a patent grant emerging from an application with a large number of X references may attract the attention of possible opponents.

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. If examination is not requested, the patent application is deemed to be withdrawn. Eighteen months after the priority date the patent application will be published. At this point, the application will normally still be under examination; thus, 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 ever 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 the reasons for the refusal to grant a patent right are reconsidered.¹³ After the grant, the European patent becomes a “bundle” of national patent rights. On average, the granting process for a European patent takes about 4.2 years from the date of filing the application.

¹³ This form of appeal has to be distinguished from appeals seeking to reverse the decisions rendered by the opposition division of the EPO.

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 granting decision, 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 amend¹⁴ or even revoke¹⁵ the patent. Patents are revoked in about one third of all cases.¹⁶ The decision affects all of the “designated states,” i.e., the states for which the patent applicant sought to obtain a patent

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.¹⁷

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 contested European patent.

¹⁴ 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. See Straus (1996) for a detailed discussion of the legal status of the patent rights during this process.

¹⁵ On average, the opposition procedure takes around 2.2 years if the patent is revoked and about 4 years if the patent is amended.

¹⁶ See EPO (1999), p. 17 and Merges (1999), pp. 612-614. For the sample used here, we did not have access to data on the frequency and extent of amendments, or the frequency of rejected oppositions.

¹⁷ EPO may, but will not necessarily pursue the opposition procedure after the opponent’s withdrawal from his attack.

The official fee for filing an opposition is €613; for filing an appeal against the outcome of opposition, the fee is €1022. But the total costs to an opponent or the patent holder are much higher. Estimates by patent attorneys range between €15,000 and €25,000 for an opposition case (for each party). Approximately the same amount would be due for an appeal against the outcome of the opposition proceedings.

Figure 2 displays the rate of opposition for the time period from 1980 to 1998.¹⁸ 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.¹⁹ The discrepancies between the U.S. and EPO figures may mainly be driven by cost differences.

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. The costs for litigation in any one of the national courts have been estimated to be between €50,000 and €500,000, depending on the complexity of the case. This cost structure makes an attack at the European level via the opposition procedure particularly attractive for a potential competitor of the patent holder. The litigation rate (computed as the number of cases for which a suit is filed divided by the number of patents) in most European countries is roughly one percent, slightly lower than in the United States (Stauder 1989, 1996). But there is not sufficient evidence at this point to conclude that the existence of the opposition mechanism leads to a reduction in litigation.

¹⁸ 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.

¹⁹ Lanjouw and Schankerman (2001) estimate the incidence of validity challenges to be at 1.05 percent of all patent grants in the drugs and health field (which in their case includes cosmetics). See Lanjouw and Schankerman (2001, Table 1). The authors of this study point out that many of the US challenge suits against patents arise as a consequence of infringement suits. A frequently observed move by the defendant is to assert that the infringed patent had no validity in the first place.

3 Theoretical Aspects - The Selection of Opposition Cases

3.1 *A Simple Theoretical Model*

In order to derive our hypotheses in a systematic manner, we briefly introduce a simple formal model of opposition which is based on the classical study by Priest and Klein (1984).²⁰ To simplify matters, we consider a world in which parties make imprecise assessments of case quality and decision standards, but where information is distributed symmetrically.²¹ The opponent and the patent-holder may have diverging subjective assessments of the outcome of the case, but the value of the patent (i.e., the profits in the duopoly or monopoly case) are given. To qualify for opposition, any case must satisfy the condition that the expected value for the opponent must dominate the expected cost of opposition. In other words, we rule out that the opponent “bluffs” and threatens to oppose in circumstances under which the true expected benefit from opposition is lower than the cost.²² If the suit is feasible, then the parties may still settle prior to the expiration of the opposition period, i.e. within nine months after the patent has been granted. We formulate these two conditions in the context of a simple model and then discuss some of the comparative statics in a stylized manner.

In the case of opposition proceedings, it is important to recall one distinct institutional feature. Once filed, the European Patent Office can pursue an opposition case even if the parties involved have achieved some kind of understanding. Suppose that the case has been filed, but the opponent has withdrawn after obtaining a license from the patent holder. Such a settlement would be attractive, since both firms will now enjoy patent protection (even if the patent has been assigned erroneously or if it grants too much scope to the owner and licensees). The European Patent Office may nonetheless pursue the case and subsequently revoke the patent. We would therefore assume that settlement negotiations tend to take place mostly prior to the filing of the opposition (if at all). Thus the following considerations are based on the assumption that once an opposition is filed, it is also tried. Settlement may take place, but it would occur prior to filing the case.²³ Thus unlike the case of litigation, where we observe the filing of suits even if they are settled before trial, we do not observe opposition cases that “settle.”

²⁰ Lanjouw and Lerner (1998) uses the Priest and Klein model to interpret conditions under which infringement cases will be brought to trial.

²¹ In Waldfogel’s terminology, this is the case of divergent expectations (DE) which he carefully distinguishes from the case of asymmetric information (AI). Since we cannot distinguish among the different theories in our data, we do not present the arguments in detail. See Waldfogel (2000) for an empirical test the results of which favor the DE hypothesis.

²² Frivolous suits are possible under asymmetric information, which we rule out (Bebchuck 1984).

²³ Our interviews with patent attorneys suggest that this is indeed the case - estimates of the settlement frequency range suggest that between 10 and 25 percent of disputes are not filed, but settled between the parties.

We distinguish two cases. Our first case is one in which successful opposition to a patent grant transforms a monopoly to a duopoly. Suppose that a patent has been granted to one firm and the patent would allow the firm to earn monopoly rents Π^M . Another firm considers the benefits and costs from filing an opposition and letting it go to trial versus settlement of the dispute. The trial can only have two outcomes – the rejection of the opposition or the revocation of the patent right. Should the opponent prevail in having the patent revoked, both firms will be able to earn duopoly profits Π^D in the market.²⁴ If the opposition is rejected, the attacker will receive zero profits. Note first that the case will only qualify for opposition if

$$p_o \Pi^D - c_o > 0 \quad (1)$$

where p_o is the likelihood of successful opposition as perceived by the opponent, and the opponent's total cost of opposition proceedings is given by c_o which we treat as exogenously given for now. Cases that qualify for opposition may either be settled or tried. For our discussion of a pre-trial settlement solution, the threat point of the opponent is given by

$$p_o \Pi^D - c_o . \quad (2)$$

The threat point for the patent holder is given by its expected value from trial

$$(1 - p_p) \Pi^M + p_p \Pi^D - c_p \quad (3)$$

where p_p is the likelihood of successful opposition as subjectively perceived by the patent holder. The cost of opposition proceedings (including attorneys' and patent office fees) is given by c_p . The differences in the subjective probabilities simply reflect uncertainty – both parties may assess the quality of their case and the decision standard with some error, but no party has any privileged information. The trial value of the game is given by the sum of the threat points. The cooperative value of the game is the industry profit in case of settlement net of total settlement costs S , i.e., $\Pi^S - S$. We treat the profit level in the case of cooperation separately here, since it may exceed the industry profits of a duopoly if some collusive elements are present in the licensing or side-payment setup chosen by the firms. Hence, we assume that $\Pi^M \geq \Pi^S \geq 2\Pi^D$. Settlement will not occur (i.e., opposition will occur) if the trial value exceeds the cooperative value of the game. This comparison yields the inequality

$$(1 - p_p) (\Pi^M - 2\Pi^D) + (p_o - p_p) \Pi^D + (S - c_p - c_o) \geq (\Pi^S - 2\Pi^D) \quad (4)$$

The first term captures how attractive the monopoly position is as compared to the duopoly case from the patent-holder's perspective. The higher the wedge between monopoly and industry duopoly profits, the less likely the patent holder is to settle, in particular if he perceives the

²⁴ If entry is free, more firms may enter so that profits are driven to zero. Note that in this case the opponent may not wish to oppose the patent, since the opposing firm creates a public good for every other firm in the industry, but bears the full cost of trial. In this case the threat point is negative.

likelihood of successful opposition to be low. *Ceteris paribus*, we would expect this difference to grow with the level of monopoly or duopoly profits. The second term captures the effects of diverging expectations of case quality and decision standards. If the opponent is optimistic (i.e., if his subjective probability of winning is higher than the patent holder's assessment), then litigation will again become more likely, especially if the level of duopoly profits is high. The third term captures the cost disadvantage (or advantage) of the settlement solution – high trial costs will make settlement more likely, high settlement costs will drive the parties to a trial solution, *ceteris paribus*. One would usually assume that settlement is less costly than a trial. In the case of opposition against patent grants, this conclusion is not necessarily warranted. First, the costs of conducting the trial are born by the European Patent Office. The two parties involved have to take into account a fee for filing opposition and attorney costs. Since the filing fee is minor²⁵ and since settlement negotiations would also be conducted by attorneys, settlement may actually be more expensive to the parties than the trial. Finally, the term on the right-hand side of the inequality captures the effect of a cooperative solution. The higher the settlement profit is in comparison to the duopoly solution, the more likely settlement will be. This term will be zero if cartel authorities do not allow firms to enter arrangements that leave them more than the duopoly profits.

Now we consider another case in which successful opposition actually functions to *maintain* a monopoly. Suppose that a firm has received a patent that allows it to enter an industry dominated by an incumbent. The entrant's patent may, for example, protect a technology that neutralizes the former technological lead of the incumbent. In this case the incumbent may oppose the patent right, since it threatens the existing monopoly. The threat point of the ex ante monopolist (the opponent) is given by

$$(1 - p_o) \Pi^D + p_o \Pi^M - c_o \quad (5)$$

while the entrant views

$$(1 - p_p) \Pi^D - c_p \quad (6)$$

as her threat point. The condition for an opposition case to be filed and tried is then given by

$$p_o (\Pi^M - 2\Pi^D) + (p_o - p_p) \Pi^D + (S - c_p - c_o) \geq (\Pi^S - 2\Pi^D). \quad (7)$$

As a comparison of (4) and (7) show, ex ante asymmetries in the market positions may affect incentives to file an opposition case. Hence, a structural approach to estimation would also necessitate a careful operationalization of the market conditions. For our reduced form estimation, however, the conclusions for the two cases are similar. As the stakes increase and as the cost advantage of settlement decreases, opposition is more likely to occur.

²⁵ See section 2.4 for details.

We demonstrate these points graphically for the first case in which the opponent can gain a duopoly position if the opposition case is successful. In Figure 3, we consider a profit-probability space and characterize parameter regions in which opposition would occur. To simplify matters, let us assume that diverging expectations are not present. Hence, in equation (4) the second term would vanish. We also assume that the settlement solution duplicates the duopoly solution, i.e., antitrust authorities can prevent firms from engaging in collusive licensing agreements. Hence, the right-hand side term in equation (4) is zero. Furthermore, let the monopoly profit Π^M be equivalent to $(2 + \alpha)\Pi^D$ where $\alpha > 0$ measures the attractiveness of the monopoly position as compared to the industry profit in a duopoly. Equation (4) implies that for opposition to occur we need

$$(1 - p)\alpha\Pi^D \geq -(S - c_p - c_o) \quad (8)$$

Moreover, recall that for opposition to be feasible in a world without bluffs, we have to have

$$p\Pi^D - c_o > 0. \quad (9)$$

In Figure 3, we plot parameter combinations of p and Π^D that satisfy these conditions. As can be seen from this figure, higher settlement costs $\bar{S} > \underline{S}$ make opposition more likely, since the locus of equation (8) shifts downwards. Similarly, higher costs of opposition (to the opponent) $\bar{c}_o > \underline{c}_o$ make opposition less likely to occur, and an increase in the level of profitability (as measured by the level of duopoly profit Π^D) will tend to enlarge the range of p -values for which opposition occurs. Moreover, equation (8) demonstrates that larger values of α will also shift the locus of the settlement curve downwards – the likelihood of opposition (non-settlement) increases as the monopoly position becomes more attractive.

These simple considerations neglect the possibility of asymmetric information. In the model developed by Bebchuk (1984), the defendant knows the probability of winning while the plaintiff only knows the distribution of that probability. The less well-informed plaintiff makes a take-it or leave-it settlement offer which in some cases turn out to be unacceptable to the better-informed defendant. These offers will therefore be rejected and a trial ensues. Thus, the likelihood of trial versus settlement should increase in the extent of informational asymmetries. Similar conclusions emerge from other models with asymmetric information between plaintiff and defendant.²⁶ We do not specify these models in detail, but simply take from them the prediction that as information is more asymmetrically distributed, the likelihood of an opposition case increases.

²⁶ See, for example, Png (1983). Waldfogel (1998) provides an empirical test of the diverging predictions of AI (asymmetric information) and DE (diverging expectations) models.

3.2 Hypotheses

While there is no single model that captures all possible situations in which opposition cases may occur, some conclusions can be drawn from the above and the literature. In particular, we would predict that the likelihood of observing opposition increases as

1. expectations increasingly diverge;
2. information is distributed more asymmetrically;
3. the stakes increase, i.e., as the level of profits rises;
4. the costs of trial (opposition proceedings) decrease in comparison to the costs of settlement.

We do not offer a structural test of these predictions here, since that would require considerably more detailed data than were available for this paper. However, a reduced-form test of some of the predictions is feasible. To perform such a test, we first need to identify variables that can serve as proxies for the variables implicit in the theoretical models.

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. Increasing uncertainty would therefore be associated with higher rates of opposition against patent grants. This is likely to be the case for relatively new technical areas, such as special areas of biotechnology in which applicants seek patent 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 comparatively little uncertainty in this field, since it involves the patenting of machinery and process equipment. The working principles of the equipment 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*.

Other features of the EPO research and examination system allow us to capture situations of asymmetrically distributed information. Recall that the process of communication between patent applicant and patent examiner is a kind of negotiation. By and large, we would expect the patent-holder to be well-informed about this process while the potential opponent has no direct knowledge of the information exchanged. This is particularly relevant when novelty and inventive step of the patented invention are assessed in comparison to the state of the art. As described in section 2.3 of the paper, the patent examiner receives a research report from EPO office staff at the The Hague office in which the research branch of the EPO has collected prior art and has labelled these

references – X-labeled references indicate prior art that is a potential threat to the novelty claims of the patent. The research report is published at some point by the EPO – we therefore assume that similar information will be available to the potential opponent, but that the result of the communication process will only be known to the patent applicant and the examiner. Thus, to the extent that the discussion resolves disputes between examiner and patent applicant, the opponent will find itself disadvantaged with respect to the information she has about the examination and granting process. While this is generally the case, we consider patents with a large number of X-labelled references to be particularly exposed to informational asymmetries.²⁷

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 strong relationship between patent value and the number of citations that a patent receives from subsequent patents.²⁸ 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 as an additional proxy for patent value. The number of references to prior patents and to the non-patent literature²⁹ have also been found to be positively related to patent value (see Harhoff, Scherer and Vopel 1999). These measures have also been constructed for the present dataset, but their sign is not unambiguous. For example, references to prior art described in the scientific literature may be correlated positively with patent value, but may also strengthen the patent against legal attacks such as opposition. In our empirical estimates both effects may be present, and on theoretical grounds alone it is not clear which effect will dominate.

Prediction (4) cannot be tested using our data, since we do not observe the costs of opposition or settlement. Nor do we have proxy variables at hand which we can utilize to this purpose. But we hypothesize that patent holders with relatively large portfolios will be able to offer settlement offers to attackers more easily than other patent holders, e.g., via cross-licensing contracts. The value of such agreements should be particularly high in technical fields that are not “densely populated” by patents. One can argue alternatively that in industries with substantial licensing, an attack on a patent holder with a large portfolio may trigger a non-cooperative response. Large patent portfolios may therefore allow the patent holder to retaliate in some fashion against the attacker. We would therefore expect a negative effect of patent portfolio size on the incidence of opposition. Again, if there are a large number of patents in a technical field in any case, then

²⁷ An alternative interpretation of this variable is that it does indeed indicate patents for which opposition will be more successful. Note that in equation (4) the likelihood of observing opposition is increasing the success probability, while the reverse holds for equations (7). We cannot measure the correlation between the incidence of X-labeled references and outcomes, but intend to do so in the future.

²⁸ See, e.g., Harhoff, Narin, Scherer and Vopel (1998) and Trajtenberg (1990).

²⁹ See Meyer (1999) for a survey.

bilateral implicit collusion may not be valuable. The effect of a large portfolio is therefore likely to diminish as the total number of patents in a field increases.

Finally, we include a large number of control variables in our probability model. These do not have a clear interpretation, but are likely to control for additional sources of variation. First, we introduce dummy variables for the most important owner nations. Differences associated with the nationality of the owner may be correlated with variations in the average quality of patent applications filed with the EPO. To give a simple example: a Japanese firm which has already received several patents for its domestic market will not necessarily patent all of its domestically protected inventions in Europe, since the additional costs will induce a selection of particularly valuable patents.³⁰ Hence, we expect that the quality (and value) of patents owned by European patent owners will on average be lower than the quality of Japanese and US patents filed in Europe.

4 Data Issues

4.1 Data Sources

We use three different data sources for our study. The ELPAC data base contains information on European patents and Patent Applications filed between 1978 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.

³⁰ See Putnam (1990) for an analysis of foreign filings.

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 as we described in section 2.2.

However, they serve us as indicators of the extent of asymmetric information between patent holder and examiner. In particular, a high share of X documents should go along with significant informational advantages on the side of the patent holder.

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.³¹ 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-

³¹ The growing importance of the linkage between private patenting activities and scientific knowledge has been documented by Narin, Hamilton, and Olivastro (1997).

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. 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.

Number of designated states. Putnam (1991) and other authors have argued 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 classification (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 pharmaceuticals 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 than patents from other owner nations).

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 obliges 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 be related to the patentability of his invention. 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 bivariate 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 some heterogeneity 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 4. 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 which had received at least 10 patent grants by 1998. This probit regression therefore excludes firms and individuals which do not participate on a regular basis in the patenting process. We will focus in our discussion on columns 1a and 1b and then consider the differences between the results in column 1a and 1b, and columns 2a and 2b, respectively.

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. The following figures come from separate estimates not reported in Table 6. 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.

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 4. 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.

As in the study of U.S. patent litigation by Lanjouw and Schankerman (2001), 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 conclude that

the scope variable may not carry much explanatory weight once other proxies for the patent's value are included in a regression.

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 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 (2001) 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.

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 results in Table 6 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 empirical analysis of the opposition procedure at the European Patent Office. To the best of our knowledge, this is the first econometric study of its 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 roughly 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. We find that correlates of patent value such as received citations and the number of countries for which the EPO patent is designated are relevant predictors of the likelihood of opposition. Moreover,

uncertainty and asymmetric information appear to play a role as suggested by theoretical models of case selection for trial: in certain new technical areas as delineated by the IPC classification, the likelihood of opposition is considerably larger than in more mundane areas. Patents which are presumably characterized by intensive discussions between examiners and applicants also face a much higher risk of opposition – we attribute this to the pronounced informational asymmetries facing the opponent of one of these patents.

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. The expected probability of successful opposition plays an important role in such models, hence that analysis will have to await the arrival of reliable outcome data. Moreover, it will be important to study the duration of the opposition process – if the process is used strategically by some opponents to create legal uncertainty about the status of a patent right, we should be able to detect a pattern in which these cases take longer to be resolved, even after accounting for observable differences in the potential value of the patent rights. The question of who opposes whom is of similar interest – again, a pattern of frequent attacks of small or young firms by established players would be a worrisome result. If cases are indeed selected strategically, we may be able to find an analogue of Lerner's (1998) observation who finds that "patenting in the shadow of infringement" leads start-up firms in the biotechnology sector to patent in niches in which a legal conflict with large players is unlikely to occur. Again, this result would not be encouraging, since it points to a strategic mechanism by which large players can affect the direction of research chosen by new entrants. Currently, however, there is no evidence to that avail.

Finally, 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.

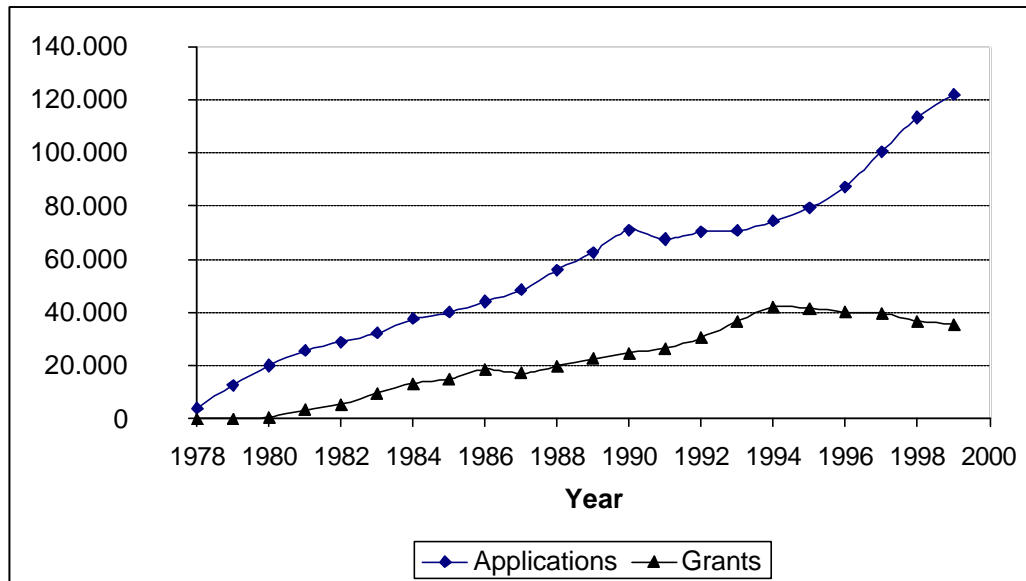
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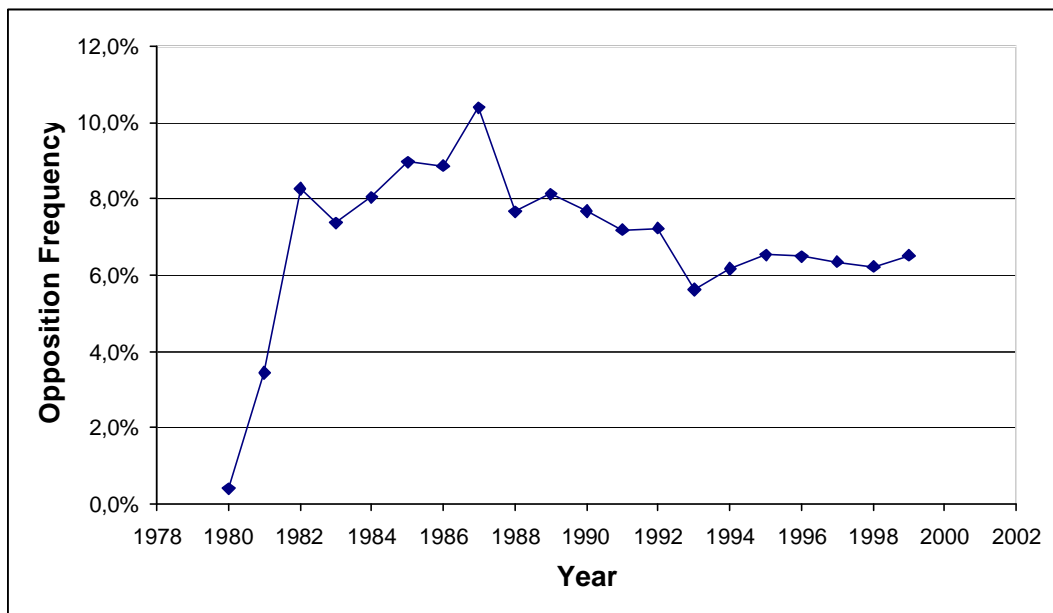
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Figure 1
EPO Applications and Patent Grants
1978-1999



Source: European Patent Office Annual Report 1999, Table 7.6

Figure 2
Opposition Frequency
1978-1999



Note: Opposition frequency is computed as the 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 1999, Table 7.6

Figure 3

Parameter Combinations (p, Π^D) in the Theoretical Model

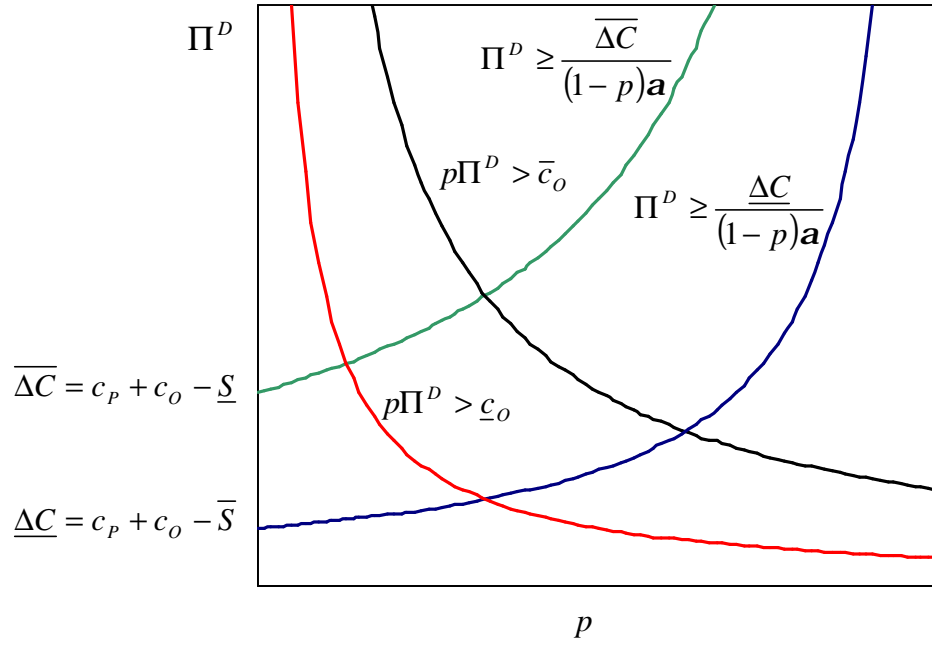


Figure 4

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

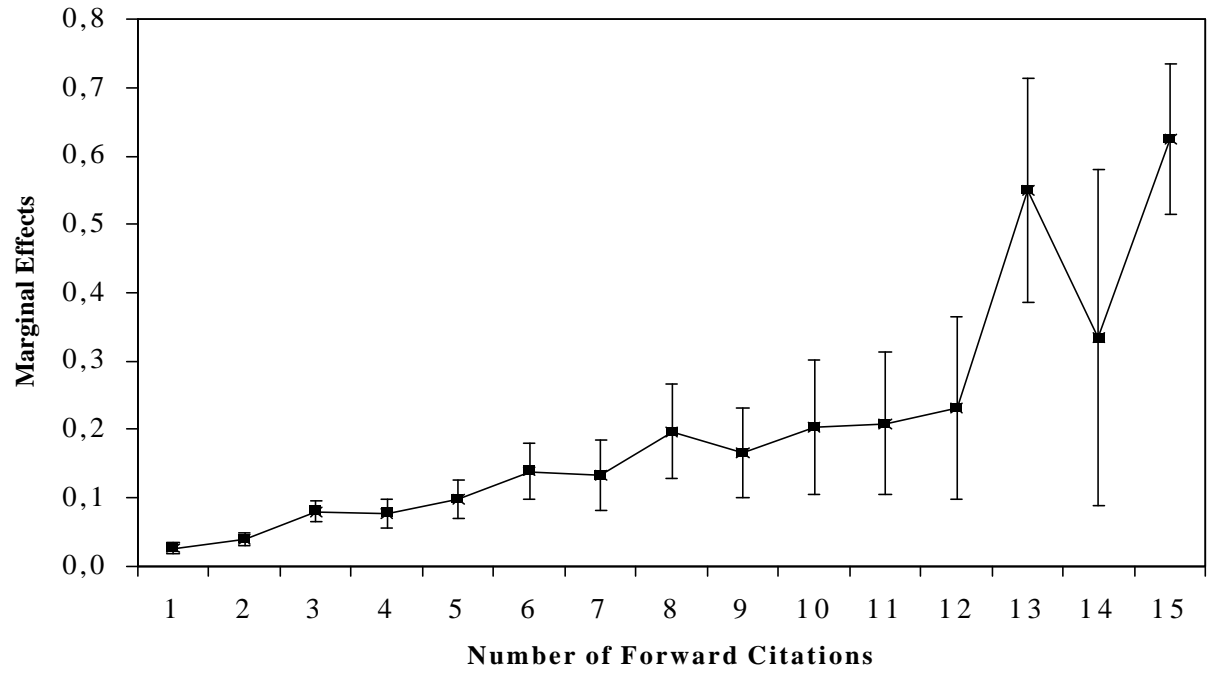


Table 1
Descriptive Statistics for the Biotechnology
and Pharmaceuticals Sample
(N=13,389)

Variable	Mean	S.D.	Min.	Max.
opposition cas	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 – 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
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 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 – 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
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			23.67		1.87		20.26		23.96
(p-value)			(0.000)		(0.759)		(0.000)		(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 – 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
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 (p-value)			10.78 (0.029)		25.35 (0.000)		4.29 (0.368)		4.00 (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 of 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
1-4	1,154	8.62	0.030	277	0.039	659	0.023	1,154	0.041
5-10	4,109	30.69	0.083	1,165	0.104	1,115	0.056	4,109	0.085
11-14	7,334	54.78	0.100	2,832	0.104	715	0.048	7,334	0.101
>14	792	5.92	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 (p-value)			1779 (0.000)		15.498 (0.001)		12.710 (0.005)		19.539 (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	Full Sample	Firms with >9 Patents	Firms with >9 Patents
	(1a)	(1b)	(2a)	(2b)
European family size ln(number of designated states)	0.234 (0.049)	0.033 (0.007)	0.220 (0.062)	0.031 (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.