



Patents in the Knowledge-Based Economy

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Patent Quality Control: A Comparison of U.S. Patent Re-examinations and European Patent Oppositions¹

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ABSTRACT

We report the results of the first comparative study of the determinants and effects of patent oppositions in Europe and of re-examinations on corresponding patents issued in the United States. The analysis is based on a data set consisting of matched European Patent Office (EPO) and U.S. patents. Our analysis focuses on two broad technology categories—biotechnology and pharmaceuticals and semiconductors and computer software. Within these fields, we collected data on all EPO patents for

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which oppositions were filed at the EPO. We also constructed a random sample of EPO patents with no opposition in these technologies. We matched these EPO patents with the “equivalent” U.S. patents covering the same invention in the United States. Using the matched sample of U.S. Patent and Trademark Office (USPTO) and EPO patents, we compared the determinants of opposition and of re-examination. Our results indicate that valuable patents are more likely to be challenged in both jurisdictions, but the rate of opposition at the EPO is more than thirty times higher than the rate of re-examination at the USPTO. Moreover, opposition leads to a revocation of the patent in about 35 percent of the cases and to a restriction of the patent right in another 33 percent of the cases. Re-examination results in a cancellation of the patent right in only 10 percent of all cases. We also find that re-examination is frequently initiated by the patentholders themselves.

INTRODUCTION

Beginning in the 1980s, a series of administrative, judicial, and legislative actions strengthened the economic value of U.S. patents and extended their coverage in such areas as computer software and “business methods.” Although many of these actions were undertaken at the behest of the U.S. business community, concerns have been raised since the early 1990s about the potential economic burdens of low-quality patents in an environment of greater deference to the rights of the patentholder (Merges, 1999; Barton, 2000). A number of experts have suggested that the U.S. patent examination system does not impose a sufficiently rigorous review of patent and nonpatent prior art, resulting in the issuing of patents of considerable breadth and insufficient quality. Many of these critics advocate the reform or extension of procedures that would enable interested parties other than U.S. Patent and Trademark Office (USPTO) examiners to bring relevant information to bear on this process either before or shortly after the issue of a patent. However, much of this debate has occurred in an empirical vacuum. Little is known about the characteristics or effectiveness of existing procedures for such post-issue challenges within the U.S. patent system, and virtually no research has compared the characteristics or effects of U.S. post-issue challenge procedures with those available elsewhere in the industrialized world’s patent systems.

At present, the primary procedure for such a challenge to the validity of a U.S. patent is the re-examination proceeding, which may be initiated by any party during the life of the patent. A more elaborate and adversarial procedure in the European Patent Office (EPO) is the opposition process. This chapter uses new data in an exploratory comparative analysis of these post-issue challenge proceedings, pursuing two main questions:

1. What are the determinants of post-issue challenges via opposition or re-examination to the validity of patents in the United States and Europe?²
2. How do patents pertaining to the same invention fare in the two different administrative systems?

In answering these questions, we use data from both the EPO and the USPTO, including a newly created data set of “twin” patents, that is, patents taken out in both jurisdictions on the same invention.

The institutions that allow for post-grant challenges of patent validity differ considerably between the U.S. and Europe. An important feature of the proceedings at the EPO, the significance of which has been remarked upon widely by practitioners but only minimally analyzed, is the “opposition process.”³ For 9 months after the issue of a patent by the EPO, interested parties can contest its validity by filing an opposition. Typically, opponents argue that an issued patent is invalid because it fails to meet the standard requirements of patentability (novelty, inventive step, industrial application, nonprejudicial disclosures) or it does not disclose the invention with sufficient clarity or completeness.⁴ In response to an opposition, the EPO may reject the opposition, amend the patent, or revoke the patent entirely.⁵

Patents issued by the EPO designate the European states in which the applicants wish to patent their inventions. Although the EPO application costs roughly three times more than the typical national application, because an EPO patent grants the applicant a right to patent in any designated state, the EPO process affords significant cost advantages for inventions requiring protection in a number of European markets. However, the centralization of application and examination also allows a centralized legal challenge: Under the European Patent Convention (EPC), any third party can use an opposition proceeding to challenge the granted patent within 9 months after the granting date for all of the designated states, rather than having to pursue legal proceedings in each of the European nations designated in the patent. The EPO opposition process has been cited by Merges (1999) as a more effective means of ensuring “high-quality” patents, especially in novel technological areas, than those available in the United States.

²We use the terms “European patents” or “opposition in Europe” as shorthand descriptions for patent applications, grants, and challenges administered by/at the EPO. Strictly speaking, a European patent (that is, a patent valid throughout Europe) does not exist, because patent rights are defined within the respective national law. Despite some harmonization, these laws are still heterogeneous.

³The opposition process at the EPO resembles the opposition process at the German Patent Office. The frequency of opposition is also quite similar.

⁴Article 100 EPC

⁵Article 102 EPC

U.S. patents are issued on the basis of criteria that are broadly similar to those employed by the EPO. In newly patented or novel technologies a lack of patent-based prior art or the difficulty of accessing nonpatent prior art can result in the issuance of patents of dubious merit or quality. Furthermore, for examiner searches made in the nonpatent prior art, novel technologies create higher search costs that can pose added barriers to effective discovery of prior disclosures. If prior disclosures are missed by the examiner, interested third parties wishing to challenge a U.S. patent after issue have two options: (1) challenge the patent in federal court or (2) request a re-examination of the patent by the USPTO. In absolute terms, patent litigation grew significantly in the United States during the period from 1985 to 2000, although the rate of litigation relative to the number of issued patents remained constant. However, as we suggest below, litigation is a costly and time-consuming means for establishing the validity and/or claims of a patent. In addition, costly patent litigation may contribute to growth in “defensive” patenting, another resource-intensive process with limited social returns (Hall and Ziedonis, 2001).

The patent re-examination procedure was created by federal legislation during the 1980s.⁶ The number of annual re-examination requests grew from the mid-1980s through the early 1990s but has scarcely grown since 1994. Unlike litigation or oppositions, the re-examination process is not an adversarial proceeding in which advocates for each side introduce evidence and arguments in support of their position, and there are limits on the types of issues that can be raised within a re-examination. Moreover, Merges (1999) has suggested that the requirement that any opposition be filed within 9 months of the issue of an EPO patent may mean that the validity of EPO patents is determined at a much earlier point in their term than is true of the re-examination or litigation processes.⁷ Merges estimates that almost 7 percent of EPO patents trigger opposition proceedings, whereas only 0.3 percent of U.S. patents result in re-examination re-

⁶An alternative re-examination procedure, the *inter partes* re-examination, was enacted by the U.S. Congress in 1999 (see the American Inventors Protection Act, codified in 35 USC 311-318). Several commentators have questioned the efficacy of the *inter partes* re-examination on grounds that it allows the third-party requestor limited opportunities of involvement, prevents any adverse findings of the USPTO from being appealed to the courts, and also precludes the raising of any questions of validity on grounds that were, or may have, been raised during the *inter partes* re-examination from being litigated in the courts (Neifeld 2000). The USPTO reports no *inter partes* re-examination requests in 2000 and only one in 2001.

⁷Balanced against this is the fact that EPO patents take longer to issue than U.S. patents, so the median lag between patent application and opposition challenge could be and is in fact longer than the median re-examination lag in our data (see Table 1). Unfortunately, we were unable to obtain data on litigation outcomes in either Europe or the United States that were adequate for addressing the question of the total delay in either system.

quests.⁸ In addition, oppositions result in much higher rates of patent revocation than do re-examinations. According to Merges, more than 34 percent of oppositions filed in 1995 resulted in the revocation of the relevant EPO patent, considerably higher than the 12 percent of re-examination requests producing a similar result in U.S. patents during this period.⁹

In this chapter, we report the results of the first comparative study of the determinants and outcomes of patent oppositions in Europe and of re-examinations on corresponding patents issued in the United States. Our analysis focuses on two broad technology categories—biotechnology and pharmaceuticals and semiconductors and computer software.¹⁰ Within these fields, we collected data on all EPO patents for which oppositions were filed at the EPO. We then constructed a random sample of EPO patents in these technology classes that triggered no opposition proceedings. We matched these EPO patents with the “equivalent” USPTO patents covering the same invention in the United States. This approach allows us to compare the post-issue quality control processes for technologically identical patents. Using the sample of matched USPTO and EPO patents, we compared the determinants of either opposition or re-examination.

We explore issues related to the first main topic of the chapter by addressing the following questions:

1. How does the rate of opposition (number of oppositions/all issued patents) vary by patent class within the EPO data and, similarly, for USPTO re-examinations? Which EPO and USPTO patent classes exhibit the highest opposition and re-examination rates, respectively?

2. What are the outcomes of the opposition and the re-examination processes? Do the two procedures consistently lead to a large number of patent revocations or amendments? Do types of outcomes differ significantly with the characteristics of the patent or characteristics of the patent owner or the challenger? For example, is there any evidence suggesting that patents owned by “independ-

⁸Some of this difference in challenge rates may be due to the limited 9-month window available under EPO opposition rules: Because of uncertainty over the competitive threat posed by the new property right, challengers in Europe may be forced to purchase a challenge option by filing within the first 9 months after patent issue. In the United States, conversely, challengers are permitted to observe the development of the competitive landscape and technological trajectory, only filing a challenge when the threat justifies the added costs.

⁹See Merges (1999), pp. 612-614.

¹⁰The IPC classes included were A61K (except A61K/7), C07G, C12M, C12N, C12P, and C12Q (biotechnology/pharmaceutical) and G01R, G06F, G06K, G11C, H01L, H03F, H03K, H03M, and H04L (semiconductors/computers/software).

dent inventors” are more likely to be challenged than patents owned by corporations?¹¹

3. How do the lengths of the average opposition and re-examination processes compare? What is the total time lag between application date and resolution of legal disagreements? Do oppositions, for example, enable a faster resolution of issues of patent quality and/or validity?

Using our matched sample of patents, we address the second main topic (see above) by investigating the following questions:

1. Do EPO oppositions and U.S. re-examinations focus on relatively “important” patents, measured in terms of citations to these patents in subsequent patents? How do the U.S. patents that correspond to opposed EPO patents compare with the U.S. control sample (equivalents to unopposed EPO patents) in terms of the number of post-issue citations?

2. Do we observe significant differences in the probability that a U.S. patent corresponding to an EPO patent for which an opposition is filed will be challenged through a re-examination request, by comparison with patents in the U.S. “control samples”?

More broadly, we wish to use this preliminary analysis as one component of an assessment of the comparative cost and efficiency of the re-examination and opposition processes, including a comparison of the costs, outcomes, and duration of these processes with those of litigation. This more ambitious goal is beyond the scope of this chapter because of the lack of U.S. and European litigation data. Nevertheless, the results reported here provide a useful starting point for the broader analysis.

¹¹The U.S. re-examination process was altered considerably during congressional consideration in response to pressure from the “independent inventor” community within the United States, and there is some reason to believe that any effort to strengthen the re-examination process or institute an opposition proceeding would encounter considerable opposition from this group. Much of the group’s opposition to such changes stems from the belief of many independent inventors that stronger re-examination or opposition proceedings would significantly raise the costs of patenting, because of the added costs of defending patents within these proceedings. Accordingly, information on the incidence of re-examination and opposition proceedings among different classes of patentholders will shed light on the likelihood that a disproportionate share of any such increased costs would be borne by the independent inventor.

INSTITUTIONAL BACKGROUND

At present, the U.S. and European patent systems have similar aims and requirements for patentability but differ in the allowable subject matter and in their administrative procedures. In this and the next section of the chapter, we provide a brief overview of the operations of the two systems.

In the United States, an invention (“process, machine, manufacture or composition of matter”) must satisfy four requirements to be patentable: adequate disclosure, novelty, usefulness, and nonobviousness. In Europe, firms and individuals have been able, since 1978, to submit a single application to the EPO that specifies up to 24 national jurisdictions¹² in which they desire patent protection for an invention. Under the EPO regime, the patentability requirements—adequate disclosure, novelty, industrial application, and inventive step—are broadly similar but not identical to those of the United States. The last two requirements, “industrial application” and “inventive step,” map roughly onto the U.S. requirements of “usefulness” and “nonobviousness,” respectively.

Figure 1 shows a rough time line covering the period between patent application and grant in the two systems. During the period covered by our data set, the U.S. patent application was kept secret until the patent issued, which meant that the median time between application and publication was 18 months to 2 years, with a long tail. As part of the patent system harmonization legislated in the American Inventors Protection Act of 1999, the United States instituted a policy of publication 18 months after application in November 2000 for many patents with applications pending in jurisdictions outside the United States.¹³ In contrast, EPO applications have always been published with an 18-month lag, regardless of whether they have issued.

Both systems have a post-grant procedure through which the validity of the patent can be challenged by other parties, but the two patent systems’ post-grant challenge procedures differ significantly. In both systems, interested parties can also bring suit in court over infringement and validity (with some restrictions as to when a suit can be filed). We discuss these administrative processes for post-grant challenges in the following section.

¹²Including: Austria, Greece (Hellenic Republic), Belgium, Ireland, Switzerland, Italy, Cyprus, Liechtenstein, Germany, Luxembourg, Denmark, Monaco, Spain, the Netherlands, Finland, Portugal, France, Sweden, Turkey, United Kingdom, Bulgaria, Estonia, Czech Republic, and Slovak Republic.

¹³The American Inventors Protection Act (1999) requires publication of all applications after 18 months but excepts applicants opting to make a declaration that a patent will not be sought in a foreign jurisdiction requiring 18-month publication. 35 USC §122.

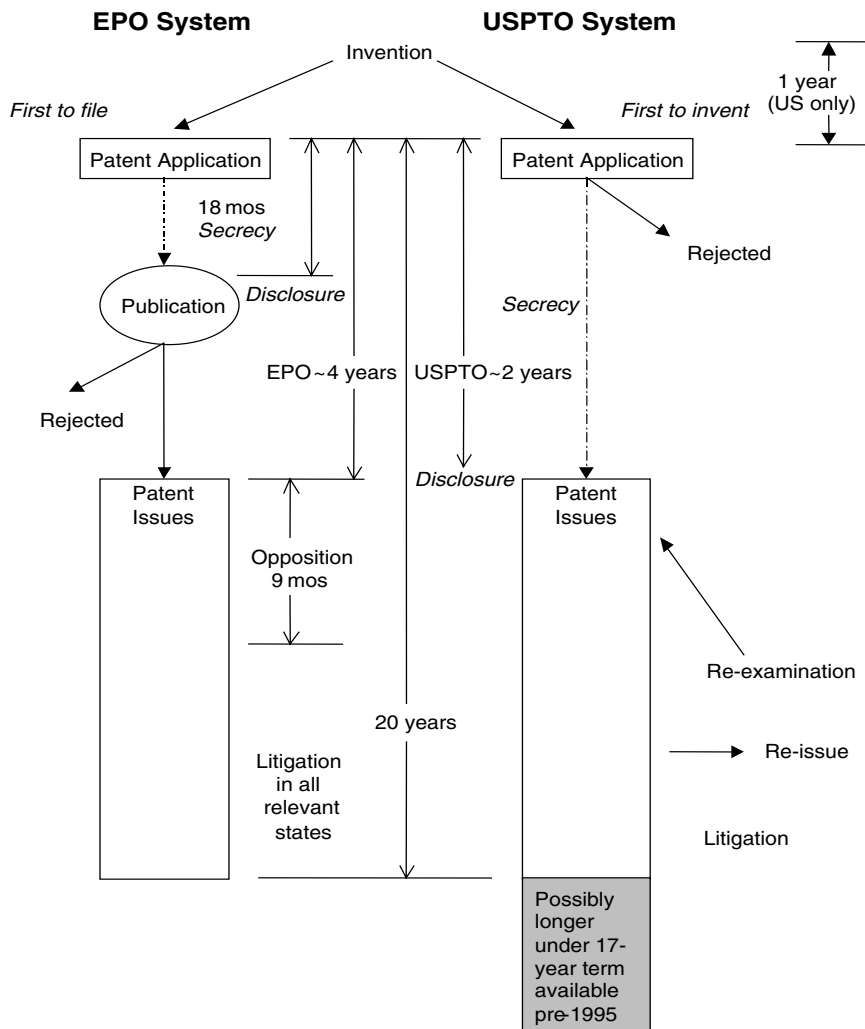


FIGURE 1 Time line of patent application process in the EPO system and USPTO system.

THE ADMINISTRATIVE PROCESSES AT THE USPTO AND EPO

USPTO Examination and Re-examination Procedures

In the United States, inventors may claim a utility patent¹⁴ by making application to the USPTO. Before a patent issues, the USPTO is charged with ensuring that the invention is adequately specified,¹⁵ covers patentable subject matter,¹⁶ and is useful,¹⁷ novel,¹⁸ and nonobvious.¹⁹ Procedurally, the application must be filed within 1 year of the invention's public use or publication,²⁰ contain an adequate description with one or more claims,²¹ and be accompanied by the payment of a fee.²²

The USPTO patent examiner is the arbiter of the patentability, novelty, usefulness, and nonobviousness requirements cited above, judging these standards against the "prior art," i.e., prior inventions, in the field. Prosecution of the patent has been characterized as a "give-and-take affair," with negotiation and renegotiation between the patentee and the examiner that ordinarily continues for 2–3

¹⁴Although the vast majority of U.S. patents—and the focus of this chapter—are the so-called utility patents authorized by 35 USC §101, patents are also available on plants (35 USC §161) and designs (35 USC §171).

¹⁵35 USC §112. See *O'Reilly v. Morse*, 56 US 62 (1854) (finding that a claim to all uses of electromagnetic waves did not adequately describe these uses).

¹⁶35 USC §101. See *Diamond v. Chakrabarty*, 447 US 303 (1980) (determining that man-made living microorganisms are patentable subject matter).

¹⁷35 USC §101. See *Brenner v. Manson*, 383 US 519 (1966) (upholding examiner's determination that the output of a chemical process was not useful if merely similar to a useful compound).

¹⁸35 USC §101, 102. See *Jamesbury v. Litton Industrial*, 756 F.2d 1556 (CAFC 1985) (finding that an invention was "novel" when no prior art was precisely equivalent).

¹⁹35 USC §103. See *Graham v. John Deere Co.*, 383 US 1 (1966) (finding an invention invalid on grounds that the improvement would have been obvious to a person of ordinary skill in the art).

²⁰35 USC §102(b).

²¹35 USC §112. Adequate description properly consists of four statutory requirements: enablement, written description, definite claims, and best mode. The "enablement" requirement is intended to allow any person skilled in the art to either make or use the invention. See *Flick-Reedy Corp. v. Hydro-Line Mfg.*, 351 F.2d 546 (7th Cir. 1965) (holding that withholding information from claims failed to adequately describe the invention). The closely-related "written description" requirement ensures that the invention is actually described. See *Permutit v. Graver Corp.*, 284 US 52 (1931) (finding the absence of any writing an insufficient description). The "definite claim" requirement ensures that the boundaries of the patent right are clearly marked. See *Halliburton Oil Well Cementing Co. v. Walker*, 326 US 1 (1946) (finding overbroad and indefinite claims invalid). The "best mode" requirement is intended to ensure that the applicant discloses the most effective method known. See *Chemcast Corp. v. Arco Industries*, 913 F.2d 923 (Fed. Cir. 1990) (finding that a failure to disclose the only known mode violates the best mode requirement).

²²USPTO regulations set the basic filing fee at \$710 for utility patents. 37 CFR §1.16(a). Additional claims may raise the fees payable, and all fees are generally lower for "small entities." 37 CFR §1.16(b),(c),(d).

years (Merges et al., 1997). The costs of prosecuting a patent through the USPTO range from \$5,000 to \$100,000 (including the USPTO issue fee), depending on the nature of the technology.²³

Re-examination, originally envisioned as an alternative to expensive and time-consuming litigation, was created by the 1980 Bayh-Dole Act.²⁴ The legislative history of this act suggests that the re-examination was intended to be a mechanism that would be less expensive and less time-consuming²⁵ than litigation. During the legislative process, however, the act²⁶ was purged of its intended adversarial characteristics, reducing the usefulness of the procedure for opponents of a given patent.

Procedurally, the re-examination proceeding permits the patent owner or any other party to notify the USPTO and request that the grounds on which the patent was originally issued be reconsidered by an examiner.²⁷ Initiation of a re-examination requires that some previously undisclosed “new” and relevant piece of prior art be presented to the agency. Under the statute, a relevant disclosure must be printed in either a prior patent or prior publication—no other source can serve as grounds for the re-examination.

After being initiated by the proponent through a notification and the payment of a fee to the USPTO,²⁸ the re-examination goes forward only if the USPTO finds a “substantial new question of patentability.”²⁹ Such a determination was intended by lawmakers to prevent the reopening of issues deemed settled in the original examination (Merges, 1997). The USPTO must make this determination within 3 months of the request and, having made the determination, must notify the patent owner.

When the owner is not the re-examination proponent, the patentee is allowed to file a response to the newly discovered prior art within 2 months. If the owner chooses to respond, the requester is afforded an opportunity to reply within 2 months. By choosing not to respond, the owner can limit the requester’s partici-

²³Gable and Montague (2001), although it is likely that most patent prosecutions cost less than \$10,000. Exclusive of variable costs, e.g., attorney time and search, the USPTO has set utility patent issue fees at \$1,240. 37 CFR §1.18(a).

²⁴Public Law 96-517 (12/12/80).

²⁵Our evidence suggests that the average re-examination takes less than 2 years, slightly shorter than the average duration of a patent lawsuit (31 months). But this difference is not large (especially in view of the high variance of the “average duration” estimate for a trial); some observers have criticized the re-examination system for not having provided a fast and cheap alternative to trial.

²⁶“Act to Amend the Patent and Trademark Laws,” Pub.L.No. 96-517, 94 Stat. 3015 (1980).

²⁷It is also possible for the USPTO Commissioner to request a re-examination. In our sample, approximately 80 of our 4,500 re-examination requests were initiated by the USPTO, a rate of slightly less than 2 percent.

²⁸\$2,520 in 2001. 37 CFR §1.20(c).

²⁹35 USC §303.

pation in the process. The re-examination is thus designed to be an *ex parte* proceeding between the patent owner and the USPTO, with limited opportunities for third-party involvement.

Any third party, such as a competitor or other opponent of the patent, thus has a limited role in the re-examination process. The requester is entitled to notify the USPTO of the triggering “prior art,” to receive a copy of the patentee’s reply to the re-examination (if any), and to file a response to that reply. The owner’s role in the process is much more involved: The re-examination statute contemplates a second examination, with the same type of “give-and-take” negotiation between owner and patent office that occurs during the initial issuance of a patent. The examiner remains the final arbiter of the process, and it is not uncommon for the original examiner to be assigned the follow-up re-examination, thus putting the question of whether prior art was overlooked in the hands of the same government official who was responsible for ensuring that no prior art was overlooked in the previous search.

Once the re-examination goes forward, however, the statute requires that the Commissioner make a validity determination.³⁰ The original patent is afforded no statutory presumption of validity in the proceeding, although the practice of assigning re-examinations to the original examiner may produce such a *de facto* presumption. The re-examination may be neither abandoned nor postponed to await the result of concurrent litigation proceedings.³¹ The result of the re-examination may be a cancellation of either all or some of the claims or the confirmation of all or some of the claims. Nothing in the re-examination procedure can expand the scope of the original patent’s claims, but claims may be amended or new claims added during the renegotiation between the patent owner and the examiner.

In summary, for parties seeking to invalidate an issued patent, the re-examination procedure involves considerable costs and risks. The filing fee for the re-examination is not insubstantial, and practitioners estimate the average costs of a re-examination at \$10,000-\$100,000 depending on the complexity of the matter. Although the costs of a re-examination are lower than those of litigation (\$1 million—\$3 million), the third-party challenger in re-examination is denied a meaningful role in the process, and the patentholder maintains communications with the examining officer, offering amendments or adding new claims during the re-examination. Re-examination may also impose additional costs on challengers seeking redress in court because juries tend to give added weight to re-examined patents and the Court of Appeals for the Federal Circuit (CAFC) has indicated that claims confirmed by the re-examining officer present, in practice, added bar-

³⁰35 USC §307. There is no time limit on the duration of a re-examination *per se*.

³¹However, re-examinations may be stayed during other USPTO proceedings, including re-issue or interferences.

riers to a successful contest.³² As a result, challengers face powerful incentives to forgo re-examination in favor of litigation, a process that may well be more expensive, more time-consuming, and less expert in testing post-issue validity.

Patent Litigation in the United States

In the United States, post-issue validity can also be tested in court. The U.S. federal courts obviously are a unified system operating under the same substantive legal requirements, in contrast to the multistate system facing litigants in Europe. Because patent suits are filed at the District Court (trial) level, litigants have considerable control, e.g., through their choice of District Court, over the manner in which litigation unfolds. This opportunity for control is partially mitigated by the existence of the CAFC, which hears all patent appeals. However, only a very small percentage of patent cases are appealed to the CAFC, which means that any differences in judicial philosophy among the many U.S. District Courts may influence the outcomes of litigation.³³

Procedurally, litigation differs markedly from the re-examination procedure. Unlike the re-examination procedure, litigation is an adversarial appeal to a court-arbiter in which the litigant has a choice over the final arbiter of the dispute and may elect to have the case heard by either a judge or a jury. Because patent suits generally arise from a charge of infringement by the patent owner, the patentee exerts considerable control over the timing of enforcement and litigation in a patent dispute.³⁴

Legal standards create a relatively hostile environment in the federal courts for challengers seeking to invalidate an issued patent. Under the statute, patents are “born valid,” enjoying a strong presumption of validity during the court proceedings.³⁵ Furthermore, the evidentiary standard for proving a claim invalid is “clear and convincing” evidence, a standard considerably higher than the mere “preponderance” of proof required in the typical civil suit. Because judges and juries may have limited technical expertise, these presumptions and evidentiary barriers create high costs for challengers. The propatent environment signaled by the creation of the CAFC has compounded these barriers: According to one study,

³²*Kaufman Company v. Lantech, Inc.*, 807 F.2d 970 (CAFC, 1986) (suggesting that evidentiary burdens are likely higher for challengers after re-examination).

³³However, it is likely true that more valuable patents are more likely to be the subject of an appealed trial verdict.

³⁴This owner initiation occurs in many cases in which declaratory validity determinations are being sought by a challenger third party: These suits, which make the patentee the defendant, are often initiated only after a demand by the patentholder for the challenger to stop infringing the patent, thus putting the initial move in the hands of the patentholder.

³⁵35 USC §282.

successful challenges to patent validity fell from 50 percent to 33 percent in the years after the creation of the CAFC (Lemley and Allison, 1998).

Direct costs in litigation are also high compared with those of re-examination. Estimates of legal costs in patent litigation run from \$1 million to \$3 million per suit (AIPLA, 1999) to \$500,000 per claim at issue, per side (Barton, 2000). One important driver of these costs is the extensive use of pretrial discovery. The lag between filing a patent suit and reaching a resolution can also be considerable: One study estimates the average length of a District Court patent suit at 31 months (Magrab, 1993). These relatively high costs and long lags have led a number of scholars (e.g., Merges, 1999) to argue that a stronger post-grant challenge system could reduce uncertainty regarding the validity of individual patents and, arguably, contribute to higher patent quality in a less expensive and time-consuming manner. As we noted above, the adversarial elements originally contained in the legislation that established the U.S. re-examination system were largely removed from this procedure during congressional debate of the bill. In contrast, adversarial processes form the basis for the “opposition” procedure adopted by the EPO.

EPO Examination and Opposition Procedures³⁶

Patent protection for European member states can be obtained by filing several national applications at the respective national patent offices or by filing one EPO patent application at the European Patent Office. The EPO application designates the EPC³⁷ member states for which patent protection is requested. The total cost of a European patent amounts to approximately €29,800, roughly three times as much as a typical national application.³⁸ Thus, if patent protection is sought for more than three designated states, the application for a European patent is less expensive than independent applications in several jurisdictions. This cost advantage has made the European filing path particularly attractive for applicants selling goods and services in multiple European markets. Increases in the number

³⁶This section is largely based on the description of the EPO examination and opposition system by Harhoff and Reitzig (2001).

³⁷The Convention on the Grant of European Patents, also referred to here as the European Patent Convention (EPC) was enacted in October of 1973. It is the legal foundation for the establishment of the EPO. The full text of the convention is available at http://www3.european-patent-office.org/dwld/epc/epc_2000.pdf.

³⁸As 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, whereas translation into the languages of eight contracting states requires €11,500. Renewal fees for a patent maintained for 10 years amount to roughly €8,500. See “Cost of an average European patent as at 1.7.99,” http://www.european-patent-office.org/epo/new/kosten_e.pdf (Jan. 14, 2002).

of patent applications and grants have given the EPO a level of economic importance that now resembles that of the USPTO.

EPO patent grants are issued for inventions that are novel, mark an inventive step, are commercially applicable, and are not excluded from patentability for other reasons.³⁹ After the filing of an EPO application, a search report is made available to the applicant by the EPO. The search report is generated by EPO's search office in The Hague and then transferred to the examining staff in the Munich office. The search report describes the state of prior art regarded as relevant according to EPO guidelines for the patentability of the invention, i.e., it contains a list of references to prior patents and/or nonpatent sources.⁴⁰ Within 6 months after the announcement of the publication of the search report in the EP Bulletin, applicants can request the examination of their application. This request 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 is published. At this point, the application is normally under examination; thus the patent owner is generally required to reveal some information about his/her invention before the grant of the patent and even if no patent is ever issued.

After examination (if requested) has been performed, the EPO presents an examination report. At this point, the EPO either informs the applicant that the patent will be granted as specified in the original application or requires the applicant to agree to changes in the application that are necessary for the patent grant. In the latter case, a negotiation process similar to that in the U.S. system may ensue. Once the applicant and the EPO have agreed concerning the scope of the allowable subject matter, the patent issues for the designated states and is translated into the relevant national languages. If the EPO declines to grant a patent, the applicant may file an appeal.⁴¹ On average, the issue of a European patent takes about 4.2 years from the date of filing the application (Harhoff and Reitzig, 2001). Within 9 months after the patent has been granted, any third party can oppose the European patent centrally at the EPO by filing an opposition against the granting decision. The outcome of the opposition procedure is binding for all designated states. If opposition is not filed within 9 months after the grant, the patent's validity can only be challenged under the legal rules of the respective designated countries.

The EPO opposition procedure is thus the only centralized challenge process for European patents. An opposition to a European patent is filed with the EPO.

³⁹See Article 52 EPC.

⁴⁰It is important to note that applicants at the EPO are not required to supply a full list of prior art—as is the case in the U.S. system (see Michel and Bettels, 2001, 191ff).

⁴¹See Article 106 EPC. Any decisions made by the EPO in receiving, examining, and opposition sections and legal division can be appealed, and the appeal has suspensive effect.

The opponent must substantiate his opposition by presenting evidence that the prerequisites for patentability were not fulfilled, e.g., the opponent must show that the invention lacked novelty and/or an inventive step or that the disclosure was poor or insufficient. At the EPO, an opposition division determines the outcome. The examiner who granted the patent is a member of the three-person opposition chamber but may not be the chairperson. The opposition procedure can have one of three outcomes: The patent may be upheld without amendments, it may be amended,⁴² or it may be revoked.⁴³ As we pointed out above, revocation occurs in about one-third of all opposition cases.⁴⁴

Another interesting aspect of the opposition procedure concerns the restrictions imposed by this process on the opponent's ability to settle "out of court." Once an opposition is filed, the EPO can choose to pursue the case on its own, even if the opposition is withdrawn.⁴⁵ Thus the opponent and patentholder may not be free to settle their case outside of the EPO opposition process once the opposition is filed. This provision of the opposition proceeding may discourage its use by opponents seeking to force patentholders to license their patents.

Both the patentholder(s) and the opponent(s) may appeal the outcome of the opposition procedure.⁴⁶ The appeal must be filed within 2 months after receipt of the decision of the opposition division, and it must be substantiated within an additional 2 months. The Board of Appeal affords the final opportunity at the EPO to test the validity of the contested European patent. Both parties can bring expert witnesses into the proceedings, and there are various options for having deadlines extended. For the two technical fields considered in this chapter, the median duration of the challenge procedures (opposition and any appeal⁴⁷) is 3.07 years, although there is considerable variation in the duration of individual cases (the interquartile range is 2.8 years).

The official fee for filing an opposition is €613; for filing an appeal against the outcome of opposition, the fee is €1022. However, the total costs to an oppo-

⁴²See Article 99ff EPC. An amendment normally results in a reduction of the "breadth" of the patent by altering the claims that define the area for which exclusive rights are sought. See Straus (1996) for a discussion of the legal status of the patent under amendment.

⁴³On average, the opposition procedure takes around 2.2 years if the patent is revoked and about 4 years if the patent is amended. See Table 2 for similar information on our samples.

⁴⁴See EPO (1999), p. 17 and Merges (1999), pp. 612-614. There are no publicly available data as to the frequency and extent of amendments or the frequency of rejected oppositions. For the technical fields considered in this paper, we compute these figures below.

⁴⁵Rule 60 EPC: "In the event of the death or legal incapacity of an opponent, the opposition proceedings may be continued by the European Patent Office of its own motion, even without the participation of the heirs or legal representatives. The same shall apply when the opposition is withdrawn."

⁴⁶Article 99ff. EPC

⁴⁷For the two technical fields studied in this chapter, an appeal occurs in about one-third of all opposition cases.

ment or the patentholder are much higher. Estimates by patent attorneys of the costs of an opposition range between €15,000 and €25,000 for each party. Patent attorneys we interviewed agreed that there is not much room for the opponent to drive up the patent owner's cost of litigation, because attorney fees are regulated in most European countries, including Germany, where many patent lawyers who have the required EPO registration reside.

Patent Litigation in Europe

Although the EPO provides a centralized application and examination process, there is no supranational or centralized process of patent litigation in Europe. The attractiveness of the EPO opposition process stems in part from the fragmentation of patent litigation processes in Europe. Unfortunately, there have been very few systematic studies of patent litigation within the various European nations. We therefore confine ourselves to a brief review of the few facts that are known.

After the grant, the EPO patent becomes a bundle of national patent rights that are treated as "normal" national patents, which can be attacked by third parties through legal means allowed for in the respective national legislation. Outcomes in these "local" litigation cases are restricted to the "local" level, e.g., the patent may be invalidated in Spain, but this does not affect its validity in Italy. During the past decade, national patent courts have increasingly taken evidence and decisions from litigation in other European nations into account, but no systematic study has analyzed such legal "spillover" effects (Stauder, 1996; Stauder et al., 1999). Other spillover effects link the outcome of oppositions and those of subsequent litigation. The national authorities involved in the adjudication of these suits can refer to previous proceedings, which may make it more difficult for a plaintiff to win a national validity suit after having lost an EPO opposition proceeding. However, no systematic analysis of these spillovers has yet been undertaken.

The differences among national jurisdictions within Europe are enormous, requiring substantial investments in each national suit and driving up the costs of challenging the national patents emerging from an EPO grant in several of the designated states. The costs of litigation in any national court 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 with the opposition procedure particularly attractive for a current or potential competitor of the patentholder. 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 1 percent, slightly lower than the 1.9 percent reported for the United States (Stauder, 1996, 1989; Lanjouw and Schankerman, 2001). However, the quantitative evidence is too sparse to conclude from these figures that the existence of the opposition mechanism leads to a reduction in litigation.

EXTENT AND DETERMINANTS OF POST-ISSUE CHALLENGES

Aggregate Statistics

This section presents some aggregate statistics on EPO patent oppositions and USPTO re-examinations during the past two decades. First, we look at the rate at which these post-grant challenges are pursued for all granted patents. We then analyze the length of time until challenge occurs and until it is resolved. Finally, we examine the characteristics of patents that influence the frequency of post-grant challenges in our two technology classes.

Any comparison of opposition and re-examination must begin with a recognition of the fact that there are far more opposition cases (33,599 between 1980 and 1998) than re-examination cases (4,547) during the period of this analysis. This difference reflects the fact that the re-examination proceeding operates very differently from an opposition proceeding. Indeed, one salient difference between the re-examination and opposition procedures concerns the identity of the challengers in these processes. In nearly 40 percent of the re-examination cases during this period, the party initiating the proceeding is identified by USPTO as the patent's "owner." Obviously, there are virtually no circumstances under which the patentholder initiates an opposition proceeding in the EPO. Moreover, because many of the other parties initiating re-examinations are law firms that may be acting on behalf of patentholders, the share of re-examinations initiated by patentholders almost certainly approaches 50 percent.⁴⁸ In many cases, patentholders initiate re-examinations to address failures to properly cite prior art, to correct claims, or to repair other flaws in the issued patent. However, this difference between re-examinations and oppositions in the identity of the initiating parties highlights the very different roles of the re-examination and opposition procedures and underscores the need for caution in drawing analogies between these types of post-issue challenges.

Because our technology classes contain relatively few re-examination cases, much of our discussion of re-examinations in this section uses data for all U.S. re-examinations, rather than only those from our two broad technology classes. Figure 2 displays the opposition and re-examination "rates" in all technology sectors

⁴⁸Obtaining information on patent re-examinations is difficult. The USPTO makes no effort to supply this information on its website; any amendment of the claims or revocation that results from a re-examination would not be discovered in a search of the patent based on the public data, which seems to us a bit surprising. Therefore, our estimate of owner re-examination requests is based on a somewhat incomplete sample of all re-examination requests, drawn from the incomplete paper records at the USPTO. We identified some additional owner requests by a visual scan of the assignee and requestor for each patent, but for about one-quarter of the requests, the requestor is clearly a law firm or individual and we do not know whom they are representing, if anyone. However, the 40 percent figure is not inconsistent with the current rate of owner requested re-examinations reported by the USPTO, which is in the range of 40 to 50 percent (USPTO, private communication).

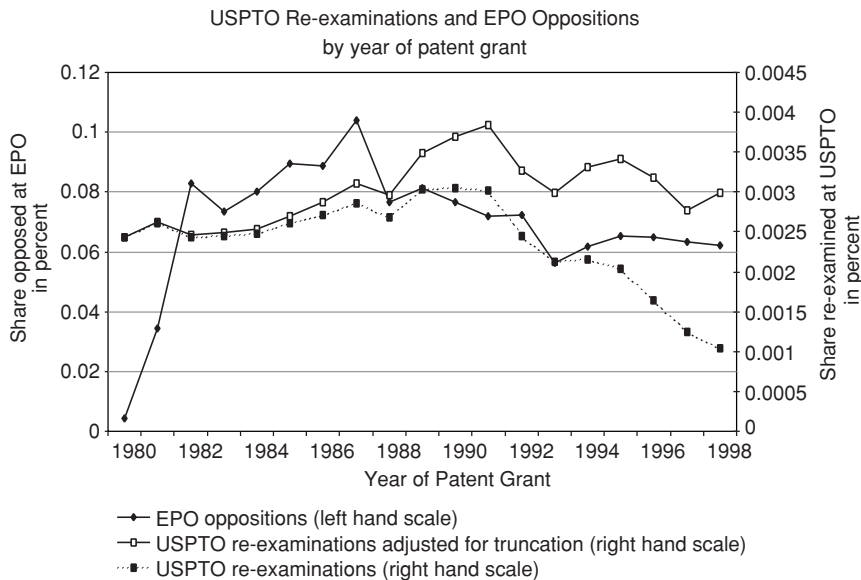


FIGURE 2 USPTO re-examinations and EPO oppositions by year of patent grant.

during 1980-1998 (based on the year of patent grant), whereas Figure 3 shows the rates for our two technology classes during 1980-1996. The opposition and re-examination “rate” is defined as the share of patents granted in a given year that are ultimately challenged through opposition or re-examination. Our measure of the re-examination rate is truncated because challenges can happen any time during the lifetime of a patent,⁴⁹ and we use a simple model of the re-examination lag to compute a minor correction for this truncation. Two facts are immediately apparent from Figures 2 and 3:

1. The opposition rate at the EPO is much higher than the re-examination rate at the USPTO for all technology classes (Figure 2), as has been noted previously by Merges (1999) and Harhoff and Reitzig (2001). The average re-examination rate during the 1981-1998 period was 0.3 percent and the average opposition rate during the period was 8.3 percent. Thus, during 1980-1998, oppositions were about 30 times more likely to be filed than re-examinations.

⁴⁹Figure 4 depicts the distribution of the lag between patent *application* and challenge. Roughly three-fourths of the re-examination requests are filed within 8 years of the application date. Because the average pendency period for a U.S. patent application is 2 years, this lag corresponds to approximately 6 years after the grant date.

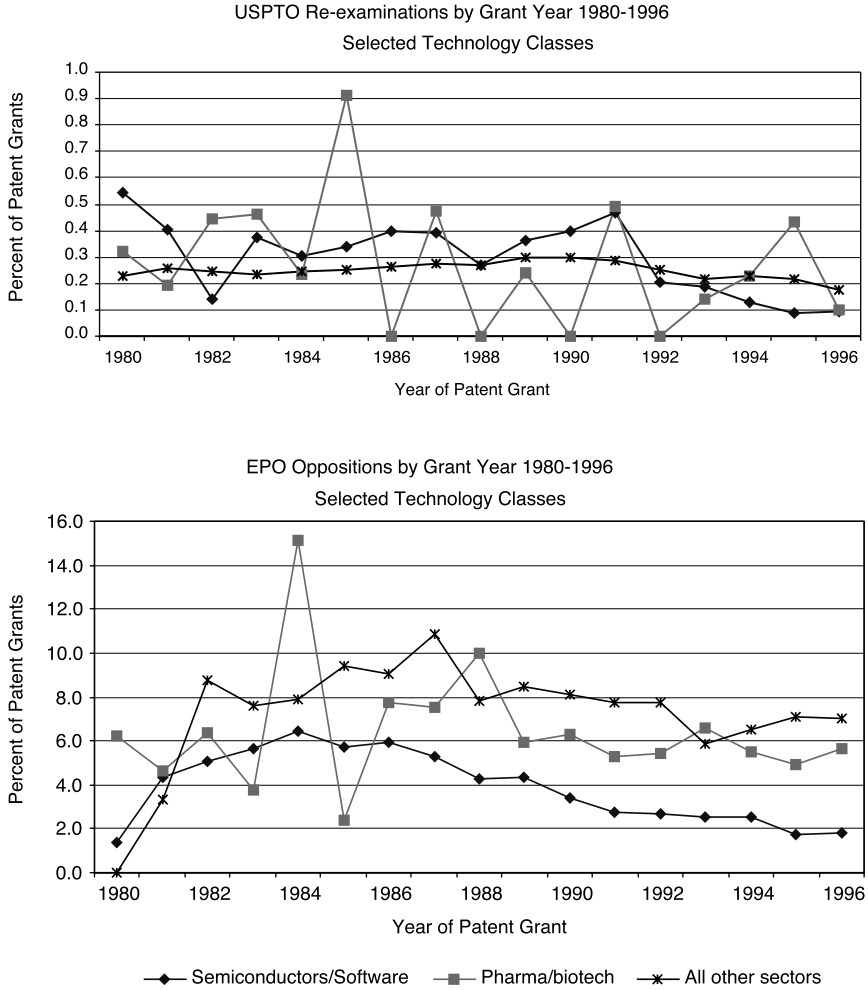


FIGURE 3 USPTO re-examinations and EPO oppositions by grant year, 1980-1996, by selected technology class.

2. The opposition rate for patents in the semiconductor, computing, and software sector is substantially lower than that for patents in the biotechnology/pharmaceutical sector and for patents in all sectors. Our two technology classes display far smaller differences in their re-examination rates, and their re-examination rates do not differ very much from those for patents in other sectors. The lower opposition rates in semiconductors and software may reflect technological differences, but it is also plausible that firms in the semiconductor and computing industries have developed a pattern of private negotiations (e.g., cross-licensing

negotiations) for resolution of some emerging disputes (Hall and Ziedonis, 2001). The relatively modest interclass differences in re-examination rates reflect the limited utility of this process for use by patent opponents or competitors.

Figure 4 displays the distribution of the average lag between applying for a patent and the filing of a re-examination or opposition request. Because opposi-

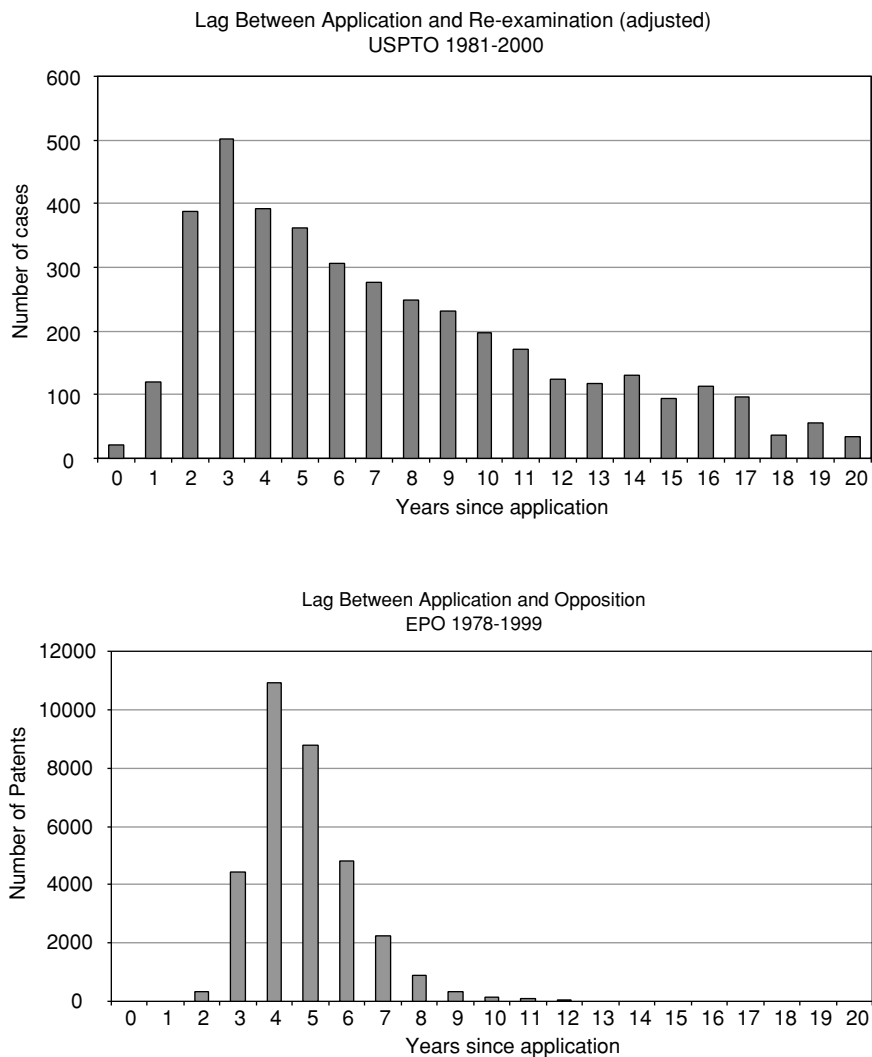


FIGURE 4 Lag between USPTO application and re-examination (adjusted), 1981-2000, and lag between EPO application and opposition, 1978-1999.

tions must be filed within 9 months of a patent grant, the lag distribution for EPO opposition cases is much tighter than that for re-examinations. However, the grant lag itself in Europe is longer, making the mean lag between application and the filing of an opposition or re-examination action relatively similar for the two proceedings: 4.8 years elapse between the application date and initiation of an EPO opposition, somewhat less than the average lag of 6 years between patent application and a re-examination request in the United States.

Figure 5 depicts the distribution of the time lag between a patent application and final resolution of the post-grant challenge in the two systems. Because prompt resolution of uncertainty over patent validity is one potential source of welfare gain from an efficient system for post-issue challenges, the length of time from patent application to final resolution is an important criterion for evaluating the respective benefits of oppositions and re-examinations. The distributions of the duration of these proceedings differ considerably, and it is clear that the European opposition system takes somewhat longer to resolve patent disputes. The median length of time between application and final outcome of the challenge proceeding is 7.0 years at the EPO and 6.6 years at the USPTO (for re-examinations requested by a nonowner). Confining our analysis to patents applied for before 1991, to minimize the effects of lag truncation, changes the picture slightly: The median lag at the EPO is 7.2 years whereas the resolution of cases takes 7.9 years at the USPTO. The large interquartile ranges for the USPTO cases reflect the more diffuse distribution of these lags at the USPTO. The duration of the period from application to resolution is thus slightly shorter for EPO oppositions than is true of re-examinations.⁵⁰

Table 1 summarizes the characteristics of the lag distributions that were shown in Figure 5 for the two systems. The final panel of the table confines the analysis to USPTO patents with at least one nonowner re-examination request. These cases take one-quarter to one-half year longer to resolve, but the difference is not very significant. For re-examinations requested by a nonowner, the median lag between patent application date and final opposition outcome at the EPO is 0.35 years greater than for re-examination at the USPTO for the overall time period. For pre-1991 applications, this lag is 0.3 years smaller in the EPO system. The interquartile range is 2.7 years smaller within the EPO data for the entire time period and more than 3.3 years smaller for pre-1991 applications. The total durations from application to the outcome of EPO challenge proceedings are slightly shorter on average, but the variance of the lags is greater within the U.S. re-examination proceedings. Because the re-examinations can be initiated at any time during the life of a U.S. patent, this greater variance in the distribution of the “procedural lags” for U.S. re-examinations is hardly surprising.

⁵⁰The lag effect may be exacerbated over time in the U.S. system, particularly in certain sectors. In biotechnology, for instance, there is evidence that application pendency increased through the 1990s (Wright, 1997) and that this effect may have been evident before our 1991 cutoff (Rader, 1990).

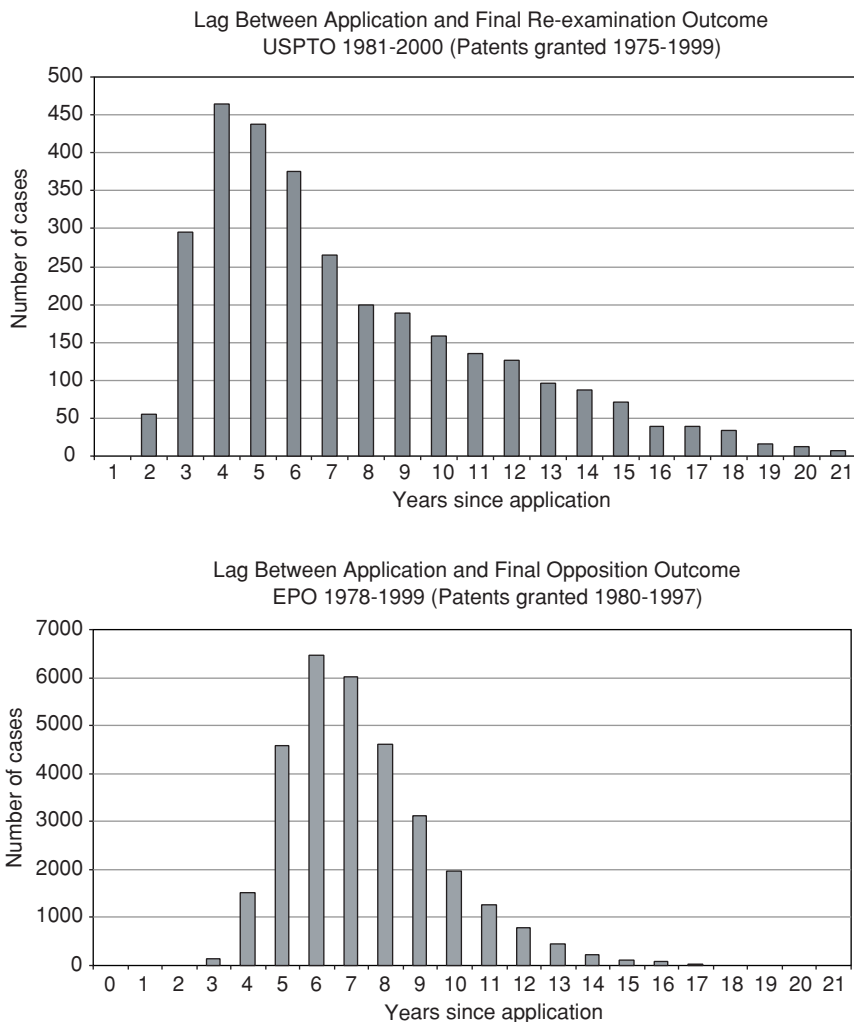


FIGURE 5 Lag between USPTO application and final re-examination outcome, 1981-2000 (patents granted 1975-1999) and EPO application and final opposition outcome, 1978-1999 (patents granted 1980-1997).

The Appendix to this chapter presents two brief case studies of USPTO and EPO patents covering similar inventions that were opposed in the EPO system (in our terminology, these are “twin” patents). The cases, both of which cover biomedical inventions, indicate that parties opposing patents in the EPO may well pursue litigation simultaneously against the EPO patentholder’s U.S. patent. The cases also underscore the point made above about the lengthy duration of the

TABLE 1 Lags Between Application, Grant, Challenge, and Final Outcome

	EPO ^a			USPTO ^b			USPTO (Non-owner Requested)		
	# Obs.	Median	IQ Range	# Obs.	Median	IQ Range	# Obs.	Median	IQ Range
Lag between application & grant	36,491	3.89	1.65	3117	1.73	0.90	1885	1.75	0.90
Lag between grant & first challenge	36,479	0.75	0.03	3117	2.68	4.62	1885	2.73	4.81
Lag between first challenge & final outcome	31,389	2.10	1.91	3117	1.31	0.97	1885	1.42	1.15
Total lag	31,389	6.96	2.80	3117	6.29	5.40	1885	6.61	5.71
Pre-1991 Applications Only									
Lag between application & grant	24,202	3.99	1.953	2425	1.79	0.92	1506	1.80	0.90
Lag between grant & first challenge	24,200	0.74	0.03	2425	3.52	5.48	1506	3.45	5.68
Lag between first challenge & final outcome	23,401	2.22	2.20	2425	1.30	1.04	1506	1.42	1.22
Total lag	23,401	7.23	3.11	2425	7.34	6.07	1506	7.54	6.54

^aThe numbers in the upper panel are for all oppositions against patents granted from 1980 to 1997.

^bThese numbers are for all re-examined patents (requests 1974-2000; duplicates removed).

NOTE: Neither set has been adjusted for truncation.

EPO opposition system—one lawsuit in the United States over Ortho Pharmaceuticals ‘799 patent was settled 5 years before the opposition proceeding on the corresponding EPO patent reached a conclusion. The other U.S. lawsuit involving this patent, however, was not settled for 2 years after the conclusion of the opposition process for the EPO “twin.” The other case study of the Liposome Corporation’s U.S. and EPO patents reveals a similarly complex interaction between the processes of post-grant review or litigation in the U.S. and European systems. In this case, as in the Ortho Pharmaceuticals case, a defendant in an

infringement suit filed in the United States by Liposome Corporation was engaged as an opponent to the Liposome Corporation's EPO patent. This case also highlights the strategic use by a patentholder of the U.S. re-examination process to (apparently) strengthen its claims and weaken the position of a competitor. The cases thus indicate considerable interdependence between the EPO opposition process and post-grant challenges in the United States. The dimensions and timing of this interdependence are an important topic for future research.

Summarizing our descriptive findings, the EPO opposition system does not reach a conclusion much more rapidly than the U.S. re-examination procedure when this procedural duration is estimated as the length of time from patent application date to final resolution. The average lag between application date and the initiation of a challenge is substantially greater within the U.S. re-examinations than in the EPO oppositions, but this difference reflects the different time limits on the initiation of such proceedings (the EPO requirement that opposition be filed within 9 months of patent grant). Should we conclude from these comparative data that the longer lags in the EPO opposition system imply a lengthier period of uncertainty, legal expense and, therefore, a higher welfare burden within the innovation systems of these economies? Such a conclusion is unfounded, because it relies on a characterization of the re-examination and opposition proceedings as analogous in their characteristics, rigor, and outcomes. The data presented above on the identity of the parties initiating re-examinations, as well as the abundant evidence discussed above of significant procedural differences between the re-examination and opposition processes, should dispel any such analogies. Any such comparison of challenges also must incorporate data on the next stages of these challenges, which in both Europe and the United States involve litigation. Unfortunately, the analysis of litigation data is beyond the scope of this chapter.

Analyzing the Determinants of Re-examination at the USPTO

What are the characteristics of the U.S. patents that undergo re-examination? Do they differ from the characteristics that have been identified as determinants of EPO opposition challenges in the study by Harhoff and Reitzig (2001)? To address these questions, we analyzed the characteristics of re-examined patents by analyzing patents issued between 1975 and 1999 in all patent classes for which re-examinations were requested by a nonowner between 1981 and 1999 (a total of 2,462 patents), comparing the characteristics of these patents against those in a 1 percent sample of all U.S. patents issued during this period (yielding a "control sample" of 20,359 patents). To deal with truncation issues, we also analyzed a sample of pre-1991 patents from each system (a sample including 1,513 re-examined patents and 10,099 control patents).

The results for our probit regressions analyzing the determinants of re-examinations of all U.S. patents, which use variables similar to those used by

Harhoff and Reitzig (2001), are shown in Table 2. The first panel shows results for the whole 1975-1999 sample, whereas the second panel restricts the sample to patents granted before 1991, because our measure of forward citations (those during the first 9 years of patent life) is truncated for patents issued in the 1990s. The variables have fairly high predictive value, with a pseudo-R-squared of about 0.13 and an error rate of about 13-17 percent compared with 23 percent for random assignment.

Similar to the findings of Harhoff and Reitzig in their analysis of oppositions, we find that re-examination requests are more likely for patents that are cited more frequently by other patents after their issue. The effects are large and monotonic: A patent cited more than 20 times in the 10 years after its application date is more than 50 percent more likely to be re-examined. Patents owned by individual inventors are about 2 percent more likely to be re-examined than those held by corporations.⁵¹ Patents held by government entities are about 6-9 percent less likely to be re-examined, *ceteris paribus*.

As we noted above, our data include re-examinations in all technology classes, in contrast to the analysis of oppositions by Harhoff and Reitzig. Our analysis of re-examinations of patents in the classes examined by Harhoff and Reitzig indicates that biotechnology/pharmaceutical patents are no more likely to be re-examined and patents in the semiconductor, computer hardware, and software classes are less likely to be re-examined, compared with patents overall.⁵² For patents granted before 1991, both biotechnology/pharmaceuticals and semiconductor/computer hardware have re-examination rates that are approximately the same as those for other industries. Only the rate for software is lower, by about 8 percent, although sample sizes are small.

The nationality of the patentholder has little effect on the likelihood of re-examination, although patents held by British, U.S., Canadian, Australian, or Israeli assignees are slightly more likely to be re-examined. Finally, the results for dummy variables indicating the number of claims in the patent suggest that the probability of re-examination rises monotonically with the number of claims; more complex patents are more likely to be re-examined.

⁵¹Unfortunately, it is difficult to be precise about this statement. Removing owner-requested re-examinations, but leaving in those requested by patent law firms, may bias the coefficient of this dummy if independent inventors and individuals are less likely to have their ownership concealed when requesting a re-examination. When the same estimations are performed on the whole sample, whether the patent is assigned to an individual is insignificant.

⁵²Looking at the detailed classes, the following are less likely to be re-examined: C12P (fermentation or enzyme-using processes), G06F (electronic digital processing), and H01L (semiconductor devices). More likely to be re-examined are H03K [electronic switching (pulse) devices], G11C (static information storage), and H03F (amplifiers).

TABLE 2 Probability of a Re-examination Request by Other Than the Patent Owner (Binary Probit Estimation)

	All Observations (22,821; 2,462 Re-exams)						Patents Granted Before 1991 (11,612; 1,513 Re-exams)					
	No. of re-exams ^a	Dprob/dx ^b	Std. Error	Dprob/dx ^b	Std. Error		Dprob/dx ^b	Std. Error	Dprob/dx ^b	Std. Error		
Bio/pharma	26	-0.0063	0.0179	-0.0094	0.0167	13	0.0070	0.0358	-0.0038	0.0327		
Semiconductor/hardware	144	-0.0231	0.0065	-0.0188	0.0066	87	-0.0044	0.0128	0.0002	0.0129		
Software	42	-0.0593	0.0061	-0.0578	0.0056	19	-0.0625	0.0132	-0.0612	0.0127		
Cites (10yr) = 1 or 2 ^a	407	0.0505	0.0080	0.0410	0.0077	232	0.0853	0.0153	0.0773	0.0149		
Cites (10yr) = 3 to 10 ^a	982	0.1266	0.0087	0.1074	0.0083	642	0.1641	0.0137	0.1466	0.0134		
Cites (10yr) = 10 to 20 ^a	518	0.3226	0.0174	0.2745	0.0170	361	0.4010	0.0254	0.3591	0.0255		
Cites (10yr) > 20 ^a	338	0.5375	0.0222	0.4623	0.0236	223	0.6164	0.0277	0.5486	0.0308		
Claims = 6 to 9 ^a	481			0.0165	0.0063	320			0.0220	0.0091		
Claims = 10 ^a	130			0.0225	0.0104	92			0.0369	0.0157		
Claims = 11 to 15 ^a	455			0.0332	0.0072	283			0.0408	0.0106		
Claims > 15 ^a	1010			0.0595	0.0068	579			0.0880	0.0108		
Claims missing ^a	38			-0.0056	0.0133	5			0.3658	0.1591		
Individual assignee	536	0.0310	0.0054	0.0206	0.0051	330	0.0340	0.0080	0.0256	0.0078		
Government assignee ^c	13	-0.0566	0.0094	-0.0562	0.0084	6	-0.0878	0.0101	-0.0850	0.0096		
U.S. inventor	1906			0.0498	0.0039	1166			0.0479	0.0061		
Inventor from non-US English-speaking country ^d	87			0.0532	0.0144	45			0.0408	0.0218		
Pseudo R-squared			0.109		0.130			0.107		0.127		
Log likelihood			-6954.31		-6794.75			-4013.26		-3922.83		
Chi-squared (dff) ^d			1301.07 (9)		1620.18 (16)			911.06 (9)		1091.93 (16)		

^aThe number of re-exams that have the characteristic described.

^bThis is the increase in probability for a unit change to the dummy (all variables are dummy variables).

^cUK, Australia, Canada, New Zealand, Israel

^dGrant year dummies are included in all estimations; the null hypothesis is these dummies only.

NOTE: The left-out category is a corporate-owned patent granted in 1975/76 with fewer than 6 claims and no citations within 10 years after grant.

Re-examination Outcomes

Table 3 summarizes the results of re-examinations conducted by the USPTO between 1981 and 1998. Where there are two or more re-examination requests and outcomes for a particular patent, we have combined them to produce a final outcome in the following way: Patent revocation replaces any other outcome; claims added, amended, and or cancelled cumulate over re-examinations and replace any earlier no-change result.⁵³ The first set of columns shows all 3,000 re-examinations for which we have outcome information, and the next two columns show the results for our two main technology classes.⁵⁴ The proportions are similar, although claim amendment appears to be more likely than the mere addition or cancellation of claims in our two technology classes, both of which cover relatively new areas of inventive activity. A likelihood ratio test for similarity of the two distributions passes easily.

About 24 percent of the patents are confirmed in full on re-examination, whereas only about 10 percent are revoked in full, a number similar to the 12 percent reported by Merges (1999) for 1995. For the newer technologies, confirmation in full is less likely and revocation more likely. When we confine the sample to re-examinations initiated by nonowners (the third and fourth sets of columns), we find that both revocation in full and no change to the patent are more likely, and that the distribution of outcomes is significantly different for owner-requested re-examinations as compared to the others. The next section compares the results of re-examination to those achieved by the EPO opposition system for these two technology classes.

Sampling Strategy for U.S.-EPO Equivalents

Thus far, we have examined data on the determinants of re-examinations at the USPTO. We now examine the similarities and differences between the U.S. and European challenge systems, both in terms of the characteristics of patents that trigger challenges and in terms of the outcomes of these challenges. This analysis requires that we control for possible differences between U.S. and EPO patents. To that end, we assembled a data set that includes “twins,” i.e., EPO patents that are also issued in the United States or vice versa.

Assembly of this data set of “twin” patents relied on a sampling strategy that could produce a set of U.S.-EPO “twins” and control samples that are similarly

⁵³Unfortunately, we were unable to find outcomes for a number of re-examinations, because of the problems mentioned above with USPTO paper records. We are missing about 200 outcomes before 1992 (approximately 13 percent) and about 700 from 1992 and later (approximately 30 percent). Some of the later re-examinations are probably not yet completed.

⁵⁴The sample of outcomes is slightly larger than the sample of re-examinations used in Table 2 because a few observations were deleted from the sample used in Table 2 because of problems with missing data.

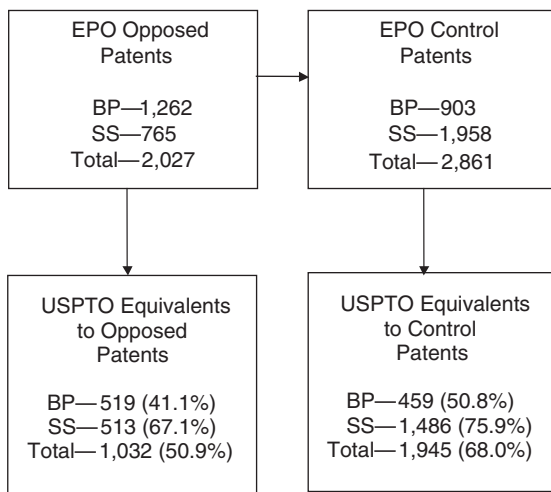
TABLE 3 Re-examination outcomes, 1981-1998 (patents granted 1975-1998)

Final outcome	Excluding Owner-Only Re-exams			
	All Re-exams	Bio/pharma & Computer Hardware/Software	All Re-exams	Bio/pharma & Computer Hardware/Software
No outcome noted	902	77	472	37
No change to patent	716	57	476	41
Patent revoked	291	30	209	17
Claims added only	133	12	86	6
Claims cancelled only	144	15	93	8
Claims amended only	440	47	259	32
Claims added and amended	362	32	213	19
Claims added and cancelled	148	5	90	2
Claims amended and cancelled	369	28	208	17
Claims added, amended, & cancelled	397	32	202	16
Total	3902	335	2308	195
Test for differences in outcomes		BioPh/Comp versus other technologies	Owner-only versus other re-exams	BioPh/Comp versus other technologies
Chi-squared (degrees of freedom)		11.49 (9)	69.57 (9)	11.45 (9)

Each re-examination appears only once. In the cases where there is more than one re-examination request, the outcomes have been combined. The shares are computed relative to the total for which we have outcomes, except for the first row, which is relative to all re-examinations in the column.

distributed among years and technology classes within the U.S. and EPO patent data. We used the International Patent Classifications (IPC) for our patents, because it is employed by both the USPTO and the EPO. We based our sampling strategy on the IPC classifications done at the EPO, because these assignments are more reliable than the IPC assignments done after the fact at the USPTO.⁵⁵ We began by drawing a sample of approximately 2,000 EPO patents that met the following criteria (Figure 6 provides a graphic depiction of this sampling strategy):

- They were granted between 1980 and 1997 (applied for between 1978 and 1995).
- They were classified in one of our two broad technology classes (62 percent in biotechnology/pharmaceuticals and 38 percent in semiconductors/computers/software).
- An opposition was filed against them after grant.



BP = biotechnology/pharmaceuticals
SS = semiconductors/software/computers

FIGURE 6 EPO-USPTO twin study sampling strategy.

⁵⁵This conclusion is based on private communications from more than one U.S. patent examiner. The search system at the USPTO is based on the U.S. patent classification system, and IPCs are assigned only after the fact, based on a rough concordance.

These patents are shown in the upper left corner of Figure 6. Using these 2,027 patents as our sampling frame, we then drew an 8 percent sample of unopposed EPO patents in these technology classes to use as controls in our analysis of oppositions, stratifying on the filing date (month and year) and IPC class, yielding a total of 2,861 patents. These are shown in the upper right corner of Figure 6. Because biotechnology/pharmaceutical patents are opposed at a higher rate, our 8 percent sample of unopposed patents yields a smaller control sample.⁵⁶

U.S. equivalents for these two samples of patents (equivalents are members of the same patent family that have exactly the same priority or priorities in common) were then collected, yielding the patents in the two bottom panels.⁵⁷ In about 2-3 percent of the cases, an EPO patent has more than one U.S. equivalent; three patents have more than three US equivalents.⁵⁸ The likelihood that an EPO patent has a USPTO equivalent is higher for semiconductor/software than for biotechnology and pharmaceuticals. We have no definitive explanation for this difference at present. It may reflect a greater tendency for patent applicants to pursue national rather than global intellectual property protection strategies in biotechnology and pharmaceuticals, or it may reflect a greater presence of nonindustrial assignees (universities and government laboratories, both of whom are less likely to pursue global filings) in the biotechnology and pharmaceuticals patent databases. However, these possibilities are purely speculative, and additional analysis of our data is needed.

The probability that an EPO patent has a U.S. equivalent is also higher for the controls than for the opposed patents, even when we control for broad technology class. It is possible that this result reflects interdependence between the EPO oppositions and patent filings in the U.S. system. For example, an applicant collecting information—through either patent issue or *ex parte* discussions with the examiner—that the USPTO patent is likely to be relatively “weak” may be less likely to pursue a “strong” EPO patent, simply because of the nonzero prob-

⁵⁶Sixteen patents in the EPO opposed sample and three in the control sample described above had twins that encountered re-examination requests, implying re-examination probabilities of 1.6 percent and 0.15 percent, respectively. This means that the re-examination probability is ten times as high for opposed patents, but still very small overall.

⁵⁷See <http://gb.espacenet.com/espacenet/gb/en/help/161.htm> for definitions of patent families and equivalents. Equivalents can be identified by using the ESPACENET service of the EPO. This database is available at <http://ep.espacenet.com>.

⁵⁸This may result because the U.S. and EPO standards for the patenting of embodiments differ, the USPTO permitting a larger number of applications than the EPO's Unity of Invention standard would allow. Article 82 of the European Patent Convention states: “The European patent application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept.” This international distinction would tend to be exacerbated in the case of pharmaceutical and biotechnology patents, however, the applicants for which have long been recognized to pursue of strategy of “serial patenting” (Merges, 1997).

ability that an opposition to the EPO patent could result in the revocation or significant amendment of the EPO patent. However, this issue requires additional analysis.

Incidence of Opposition

Table 4 displays the results of a series of probit regressions that relate the probability that a patent is opposed in the EPO system to the characteristics of the patent, its assignee, and the U.S. twin, if there is one. All of the right-hand variables are dummies, and the estimates shown are the change in the probability if the dummy changes from 0 to 1. The first data column of the table gives the number of observations for each variable for which its respective dummy variable was equal to 1.

When we included only grant year dummies, the biotech/pharma dummy, and the U.S. twin dummy in the probit, we obtained the following estimate:

$$\begin{aligned} \text{Prob(opposition)} = & \\ \text{year effects} + 0.290 \text{ D(biopharm)} - 0.117 \text{ D(U.S. twin exists)} & \\ (0.015) (0.016) & \end{aligned}$$

This result essentially summarizes the results of our sampling strategy: Biotechnology/pharmaceutical patents are 30 percent more likely to be opposed, and patents with U.S. twins are approximately 12 percent less likely to be opposed. Including only these variables along with grant year dummies yielded an R-squared of 0.09.

Columns (1) and (2) relate opposition to a number of characteristics of the patent and its holder. In column (2) we replace the biotech/pharma dummy by a full set of dummies for the 15 four-digit IPC classes we are considering. These dummies are clearly significant [$\chi^2(12) = 99.5$], but they have little effect on the estimate of the other coefficients.⁵⁹ The other variables in the regression are the following:

- A set of dummies for the number of EPO citations received by the patent between its issue date and 1999. One additional forward cite raises the opposition probability about 3-5 percent, with some diminishing returns, a result that is consistent with the Harhoff-Reitzig results cited above.

⁵⁹The degrees of freedom are lowered by the fact that some cells are sparse and therefore not identified in the regression. Those that had much lower opposition probability than average were G06F, G11C, H01L, H03K, H03M, and H04L, which are most of the semiconductor/computing classes. Those that were higher were C07G and C12M. This result essentially confirms the fact that the biopharm dummy captures most of the difference in opposition rates for these technologies.

TABLE 4 Probability of an Opposition, Binary Probit Estimation (4868 Observations; 2021 Opposed), Part 1

	No. of obs equal to 1	Dprob/ dx ^a	(1) Std. Error	Dprob/ dx ^a	(2) Std. Error
EPO characteristics					
Biotech/pharma technology	2,157	0.159	0.020	Full 14 tech dummies ^b	
No. of forward EPO cites = 1	974	0.060	0.022	0.064	0.023
No. of forward EPO cites = 2/5	1,311	0.163	0.021	0.173	0.021
No. of forward EPO cites = 6/10	258	0.229	0.035	0.224	0.036
No. of forward EPO cites >10	80	0.400	0.051	0.418	0.050
No. of designated states 6-10	1,082	0.137	0.022	0.128	0.023
No. of designated states >10	1,733	0.175	0.024	0.169	0.025
No. of EPO claims 6-9	1,192	0.015	0.024	0.010	0.025
No. of EPO claims = 10	580	0.044	0.030	0.022	0.030
No. of EPO claims 11-15	1,068	0.051	0.026	0.033	0.026
No. of EPO claims >15	1,244	0.118	0.026	0.105	0.026
Independent inventor (EPO ass.)	220	0.028	0.036	0.016	0.036
Accelerated search requested	86	-0.136	0.054	-0.140	0.054
Accelerated exam requested	140	0.243	0.045	0.240	0.046
PCT application	937	0.122	0.023	0.131	0.024
Nationality of patentholder					
U.S.	1,642	-0.012	0.049	0.000	0.049
Germany	713	0.101	0.053	0.096	0.053
Other West European	1,240	0.075	0.050	0.072	0.050
Japan	1,154	0.042	0.051	0.045	0.051
Chi-squared (4) for region dummies		29.50		20.30	
Chi-squared (2) for US,JP		5.96		3.85	
U.S. Twin characteristics					
U.S. Twin exists	2,893	-0.089	0.016	-0.094	0.016
More than one U.S. twin	95				
No. of U.S. forward cites = 1 or 2	571				
No. of U.S. forward cites = 3/10	1,327				
No. of U.S. forward cites = 10/20	512				
No. of U.S. forward cites >20	271				
No. of U.S. claims 6-9	751				
No. of U.S. claims = 10	157				
No. of U.S. claims 11-15	555				
No. of U.S. claims >15	846				
U.S. app. date prior to EPO	1,495				
Independent inventor (USPTO ass.)	124				
Log likelihood		-2864.89		-2810.72	
Pseudo R-squared		0.133		0.148	
Chi-squared (df)		877.9 (37)		977.4 (49)	

^aThis is the increase in probability for a unit change to the dummy.

^bOne of the dummies predicts opposition perfectly, so the increase in degrees of freedom is only 12 = 13-1.

NOTE: All equations include a complete set of 18 grant year dummies; the left-out category is a corporate patent in semiconductor/software with number of states <6, number of claims <6, zero forward cites, and with holder from a country other than the "triad."

TABLE 4 Probability of an Opposition, Binary Probit Estimation (4868 Observations; 2021 Opposed), Part 2

	Dprob/ dx ^a	(3) Std. Error	Dprob/ dx ^a	(4) Std. Error
EPO characteristics				
Biotech/pharma technology	0.165	0.020	0.181	0.020
No. of forward EPO cites = 1	0.063	0.022	0.053	0.023
No. of forward EPO cites = 2/5	0.168	0.021	0.144	0.021
No. of forward EPO cites = 6/10	0.236	0.035	0.194	0.037
No. of forward EPO cites >10	0.397	0.051	0.365	0.056
No. of designated states 6-10	0.129	0.022	0.130	0.022
No. of designated states >10	0.165	0.024	0.164	0.024
No. of EPO claims >15	0.084	0.018	0.074	0.019
Accelerated search requested	-0.132	0.055	-0.132	0.055
Accelerated exam requested	0.242	0.045	0.239	0.046
PCT application	0.119	0.023	0.100	0.023
Nationality of patentholder				
Germany	0.091	0.023	0.091	0.024
Other West European	0.068	0.018	0.069	0.020
U.S. Twin characteristics				
U.S. Twin exists	-0.088	0.016	-0.141	0.038
More than one U.S. twin			0.007	0.055
No. of U.S. forward cites = 1 or 2			0.008	0.040
No. of U.S. forward cites = 3/10			0.090	0.036
No. of U.S. forward cites = 10/20			0.171	0.042
No. of U.S. forward cites >20			0.180	0.048
No. of U.S. claims 6-9			-0.025	0.028
No. of U.S. claims = 10			0.000	0.027
No. of U.S. claims 11-15			-0.071	0.045
No. of U.S. claims >15			-0.037	0.029
U.S. app. date prior to EPO			-0.041	0.021
Independent inventor (USPTO ass.)			0.077	0.049
Log likelihood	-2870.21		-2848.92	
Pseudo R-squared	0.131		0.138	
Chi-squared (df)	867.2 (31)		909.8 (42)	
Chi-squared for U.S. patent vars.			42.6 (11)	

^aThis is the increase in probability for a unit change to the dummy.

- A set of dummies for the number of EPO states in which the patent was taken out (1-5, 6-10, and more than 10). Designating more states raises the probability of opposition, which again is consistent with Harhoff and Reitzig (2001).

- A set of dummies for the number of claims (1-5, 6-9, 10, 11-15, more than 15). Having more claims raises the probability of opposition, but only if the number of claims exceeds 10.⁶⁰ The meaning of this result is ambiguous, because the number of claims in a patent is itself subject to multiple interpretations. On the one hand, patents with a large number of claims could be seeking protection for a very narrowly defined invention. In other words, these patents are occupying a space in a relatively “crowded” field populated by many similar inventions, raising the probability of an opposition. On the other hand, patents with large numbers of claims may be broader, rather than narrower, and may therefore face a lower probability of opposition (i.e., they could be early occupants of a less crowded invention space). The coefficient implies that the “crowding” effect, which raises the probability of an opposition, becomes significant as the number of claims in the patent exceeds 10.

- Whether the patentholder is an independent inventor,⁶¹ a dummy variable for which the coefficient is insignificant.

- Whether an accelerated search was requested by the patent applicant at the EPO, which lowers the probability of opposition by about 14 percent.⁶² Accelerated search is often requested when the applicant is unsure of the state of the art or of whether the invention is patentable. We therefore interpret this result as indicating a relatively “low-quality” (or less important) patent that is less likely to trigger an opposition.⁶³

- Whether an accelerated examination was requested by the patent applicant, which raises the probability of opposition by 24 percent. This request indicates that the applicant attaches high value to the patent, e.g., because a patent race is under way. As a result, it is more likely that there will be a competitor that wishes to oppose the patent.

- Filing a Patent Cooperation Treaty (PCT) application, something that enables the applicant to file for protection later in up to 80 countries at the World

⁶⁰The focal point at 10 claims is apparently caused by the fact that EPO charges a separate claims fee of €40 for the eleventh and each subsequent claim (Rule 31, 51 and 101 EPC).

⁶¹This variable disagrees with the U.S. assignment code for the twin in about one-third of the cases, which seems unlikely to us. Some of the differences occur because the EPO records multiple owners for the same patent, both individual and corporate, whereas the USPTO records only the corporation (or university, in many of these cases). We include both the U.S. and the EPO independent inventor variable in the regression to cover all possibilities.

⁶²A detailed assessment of this and the next two variables is given by Reitzig (2002).

⁶³Accelerated searches may be pursued in the case of commercial necessity, i.e., an applicant’s need for a quick patent. In such a circumstance, we can determine no reason why opposition rates would be lower, and indeed these rates might be expected to be higher.

Intellectual Property Organization (WIPO). A PCT application raises the probability of an opposition by about 10-12 percent, which may reflect the higher value of an invention for which broad international patent protection is sought. The PCT also allows strategic delay: A PCT filing gives a patentee up to 31 months in which to make a patent application in a foreign jurisdiction. A PCT filing motivated by such delay would also likely reflect a patent of higher value.

- A set of dummies for the country of the patentholder. Although they are jointly significant, none are significant individually. Because those for Germany and the rest of Western Europe are marginally significant, we retain them.

- A dummy for the presence of one or more U.S. twins. Once we control for other patent characteristics, the relative probability that a patent with a twin is opposed increases slightly, from minus 12 percent to minus 9 percent. This finding is puzzling and requires further analysis. We speculate that this result may once again reflect some interdependence between the information an applicant collects regarding the “weakness” of the USPTO patent and the perceived “strength” or quality of the “twin” EPO patent. The EPO “twins” of patents that survive USPTO review may be viewed as stronger by potential opponents, and therefore are less likely to trigger an opposition. Obviously, this speculative interpretation requires additional analysis of the timing of filings and oppositions in the U.S. and EPO systems.

In general, the results from the regressions in columns (1) and (2) confirm the findings by Harhoff and Reitzig (2001) that variables positively correlated with the value of a patent increase the probability that the patent will be subject to opposition. It is suggestive that patents held by independent inventors are no more likely to be opposed than other patents, other things being equal. If we do not control for patent characteristics, however, patents held by independent inventors are 11 percent *more* likely to be opposed; the main reason seems to be that they are more likely to be biotechnology/pharmaceutical patents. This result may reflect the greater presence of European university inventions within the biotechnology/pharmaceutical patent class, ownership of many of which remains with the individual faculty member.

Column (3) presents our preferred specification. Eliminating the insignificant variables does not affect the remaining coefficient estimates substantially. Patents held by German and Western European assignees are about 7-9 percent more likely to be opposed than patents held by residents of other countries. We explored the identity of the opposers, finding that they are more likely to come from countries that share a language with Germany or are in close proximity to a country that does. This suggests that the opposition system is more heavily used by those who are familiar with the language and culture of the country in which it is operated. It is natural, therefore, that the opposed patents also come from nearby countries, either because the (potential) opposers are more informed about them or simply because they are more likely to be in the same narrow line of business.

On the other hand, this finding may be caused by the choice of designated states for patent coverage, with Germany being the most favored choice. Inventors and corporations in European countries for which patent protection is not sought will have lower incentives to challenge patents that are not valid in their home country.

Finally, in column (4), we add the following variables concerning any U.S. twins for these patents:

- Whether the patent has more than one U.S. twin, a variable that is insignificant.
- A set of dummies for the number of USPTO citations received by the patent in the first 10 years of its life. One additional forward cite of this type raises opposition probability 1 percent, with some diminishing returns at high citation levels. The slightly lower coefficient for U.S. citations relative to EPO citations may reflect the fact that USPTO patents have many more citations per patent than EPO patents. Although the EPO citation variables fall slightly in the presence of USPTO citation variables, both enter the equation significantly.
- A set of dummies for the number of claims in the U.S. patent (1-5, 6-9, 10, 11-15, more than 15). Unlike citations, these variables are not significant in the presence of the dummy variable for the number of claims in the EPO patent application. When we exclude the dummies for EPO claims, the dummies for the U.S. claims become slightly significant and *negative*. This result may well reflect the difficulty, noted above, of interpreting the meaning of the number of claims in a patent.
- Whether the U.S. application date was before the EPO application date. This reduces the probability of opposition by about 4 percent, possibly reflecting the fact that more of the value of these patents relies on their exploitation in the U.S. market, making opposition in Europe less important. However, the finding also is consistent with the “signaling” interpretation of U.S. patent issue noted above.
- Whether the USPTO coded the inventor as an independent inventor. This increases the probability by about 8 percent, but the coefficient is insignificant. Measuring this more accurately is of some concern, given the reluctance of the U.S. independent inventor community to embrace an opposition system.⁶⁴ Controlling for grant year and nothing else, the raw difference in probability is 9.4 percent with a standard error of 4.8 percent.

The set of variables that describe the U.S. twin are jointly significant, with a $\chi^2(11) = 42.6$. Adding them has little effect on the other coefficients beyond a

⁶⁴As we indicated above, there are many cases for which the U.S. variable is coded as unassigned that are currently (and perhaps, erroneously) included in the independent inventor class. In EPO applications, the listing of the applicant and of the inventors is compulsory.

reduction in the size of the coefficient for the “U.S. twin” dummy to minus 14 percent.

Opposition Outcomes

The outcomes of the oppositions for our sample are shown in Table 5. The category “opposition closed” refers to cases in which either the opponent withdraws the opposition and the patent office does not pursue the case on its own behalf, or the patent holder does not renew patent protection, which causes the patent to lapse into the public domain. It is therefore not clear how many of these cases reflect a successful challenge to the patent’s validity. Two facts are particularly striking: First, oppositions against patents with U.S. equivalents are more likely to be rejected. This may be due to the fact that patents from non-European applicants are selected carefully for patenting in Europe and are therefore more robust against the opposition challenge. It is also consistent with the argument that USPTO review does have a “quality-enhancing” effect on the issued patent. This result may also be a plausible explanation for the previously discussed negative impact of the “twin status” variable on the likelihood of opposition.

Second, the probability of outright revocation of a patent subjected to opposition is much higher than for re-examination: A total of 35.1 percent of the patents are revoked, and the category of “opposition closed” may contain additional cases which reflect a successful challenge (recall that only 9-11 percent of re-examined U.S. patents are revoked in full). Presumably, these results reflect the wider grounds allowed for opposition and the presence of a third party in the opposition process.

Table 6 explores the relationship between patent characteristics and outcomes with a simple logit model of the following form:

$$P_j = Pr(\text{outcome } j|X_i) = \exp(X_i\beta_j) / \sum \exp(X_i\beta_k)$$

where j = outcome of the opposition (still pending, rejected, amended, closed, or revoked) and X_i are various characteristics of the i th patent. In Table 6 we show the change in probability of each outcome type induced by a one-unit change in the right-hand side dummy variable, holding all other variables constant:

$$\Delta P_j (\Delta X_i^l = 1) = P_j [\beta_j^l - \sum \beta_k^l \exp(X_i\beta_k) / \sum \exp(X_i\beta_k)]$$

where l indexes the right-hand side variables. All effects are measured relative to the opposition pending outcome, so the rows in Table 6 sum to zero.

The results in Table 6 support the following conclusions:

1. Oppositions to patents with more citations or wider European coverage, or where there are multiple oppositions or multiple U.S. twins, tend to take longer to resolve, in the sense that the outcomes are more likely to be pending.

TABLE 5 Final Outcome of Oppositions

	Total	With U.S. Twin	Percent with U.S. Twin	Share of Outcomes	With U.S. Twin
Opposition rejected	266	173	65.0%		
Opposition rejected on appeal	85	47	55.3%		
Opposition rejected—total	351	220	62.7%	17.4%	21.4%
Patent amended	355	207	58.3%		
Patent amended on appeal	163	81	49.7%		
Patent amended—total	518	288	55.6%	25.6%	28.0%
Patent revoked	366	181	49.5%		
Patent revoked on appeal	184	92	50.0%		
Patent revoked—total	550	273	49.6%	27.2%	26.6%
Opposition closed	150	81	54.0%	7.4%	7.9%
Opposition case pending	190	72	37.9%		
Appeals case pending	262	94	35.9%		
Case pending—total	452	166	36.7%	22.4%	16.1%
Total	2021	1028	50.9%	100.0%	100.0%
Summary					
Share of Outcomes					
Outcome	Total	Total	Biotech/ Pharma	Computer Hardware/Software	With U.S. Twin
Opposition rejected—total	351	22.4%	19.1%	26.8%	25.5%
Patent amended—total	518	33.0%	38.1%	26.1%	33.4%
Patent revoked—total	550	35.1%	31.5%	40.0%	31.7%
Opposition closed	150	9.6%	11.3%	7.1%	9.4%
Total with an outcome	1569	100.0%	100.0%	100.0%	100.0%
Opposition pending	452	22.4%	27.7%	13.6%	16.1%
Total	2021				

2. Oppositions to biotech/pharma patents and/or highly cited patents, or where there are many claims, tend to result in amendment rather than a simple yes or no decision. Amendment is less likely when there are multiple oppositions or the inventor is an individual. More important patents or patents in relatively new, dynamic areas of inventive activity appear on this evidence to be more likely to be amended rather than revoked in an opposition.

TABLE 6 Multinomial Logit for Opposition Outcomes (2,021 Observations)

	Change in Probability Going from Dummy=0 to Dummy=1 (#obs.)				Change in Probability Going from Dummy=0 to Dummy=1 (#obs.)					
	Opposition Rejected (351)	Pending (452)	Patent Amended (518)	Opposition Closed (150)	Patent Revoked (550)	Opposition Rejected (351)	Pending (452)	Patent Amended (518)	Opposition Closed (150)	Patent Revoked (550)
Biotech/pharma	-2.9%	1.7%	10.3%	1.4%	-10.5%	-3.9%	2.8%	11.7%	0.6%	-11.2%
EPO Citations 6/10	-3.2%	3.0%	5.5%	-0.6%	-4.6%					
EPO Citations >10	-15.5%	14.1%	11.3%	4.7%	-14.6%	-14.6%	11.1%		3.9%	-13.0%
Designated states 6/10	-1.1%	3.9%	1.1%	-1.0%	-2.9%	0.6%			0.4%	-1.7%
Designated states >10	-0.2%	8.2%	-3.9%	-0.5%	-3.7%		-5.0%			
No. of EPO claims 6-9	-1.7%	-3.9%	7.4%	-2.4%	0.6%					
No. of EPO claims = 10	-5.1%	-2.4%	8.2%	-5.5%	4.8%					
No. of EPO claims 11-15	-2.3%	-5.4%	13.2%	-4.4%	-1.0%	-0.2%	8.1%		-2.2%	-3.0%
No. of EPO claims >15	-2.5%	-1.0%	13.5%	-0.8%	-9.2%	-0.4%	2.1%	8.4%	1.4%	-11.5%
Accelerated search requested	4.5%	0.8%	3.7%	1.8%	-10.8%					
Accelerated exam requested	-5.4%	5.2%	7.3%	-1.0%	-6.2%	-5.3%	5.3%		-0.7%	-6.6%
PCT filing	-2.6%	2.4%	-0.2%	1.3%	-0.9%					
U.S. patentholder	2.4%	-0.2%	2.0%	-3.1%	-1.1%					
German patentholder	7.0%	-2.5%	-1.3%	-4.1%	0.9%	6.5%	-2.3%	-2.6%	-2.7%	1.1%
Japanese patentholder	-0.3%	-1.4%	10.5%	-5.1%	-3.7%	-0.6%	-2.3%	9.1%	-3.5%	-2.7%
Same patent & opposer country	-2.2%	-3.2%	4.1%	5.0%	-3.8%	-2.1%	-3.1%	4.4%	4.9%	-4.1%
Multiple oppositions	-10.7%	9.6%	-6.4%	-10.3%	17.9%	-10.9%	10.1%	-5.8%	-10.6%	17.3%
U.S. twin exists	4.2%	-1.6%	3.2%	1.8%	-7.6%	4.8%	-1.7%	3.2%	1.5%	-7.8%
Multiple U.S. twins	1.1%	5.5%	2.8%	-1.0%	-8.4%	0.6%	5.4%	2.8%	-0.3%	-8.5%
USPTO—Indep. Inventor	7.2%	0.2%	-3.8%	-0.6%	-3.1%					

NOTES:

Entries in bold are significantly different from the rejection effects at the 5 percent level.
 Entries in bold italics are significantly different from the rejection effects at the 10 percent level.
 Bi-annual year dummies are included.
 Only one (final) outcome per EPO patent included.

3. Amendment is also more likely when an accelerated examination was requested for the patent. Recall that accelerated examinations are associated with a 25 percent higher probability of opposition in the first place. The two facts together suggest that these patents are in relatively new areas that are characterized by higher uncertainty about the technology, prior art, novelty, etc.

4. Revocation is more likely when there are multiple oppositions or few claims and substantially less likely when the patent is in the biotech/pharma area, when the patent is heavily cited by subsequent patents, when an accelerated search was requested, or when there are U.S. twins.

CONCLUSIONS AND FURTHER QUESTIONS

The determinants and characteristics of patent challenge procedures are an important issue in any assessment of the U.S. or other industrial economies' intellectual property systems. In a "knowledge-based" economy, intellectual property systems are constantly challenged by the advance of technology, a process that among other things creates new artifacts to which the necessarily backward-looking patent system must respond. A "knowledge-based" economy also is one in which the high political salience of national and global intellectual property systems means that they are the focus of political lobbying to strengthen, adapt, or weaken specific features of intellectual property regulation, administration, and law to favor particular interests. Both of these forces have been at work within the U.S. intellectual property system during the past quarter-century; a period of significant strengthening of patentholder rights has triggered a debate over the appropriate level and limits of such rights. Moreover, this debate has important trans-Atlantic and global echoes and analogues.

This chapter has explored one dimension of the operations of the post-issue systems for challenging patent validity in the U.S. and European intellectual property systems. The analysis presented here is preliminary, and many issues remain open for further research. One of the most important gaps in our current data is the lack at present of data on rates of litigation for U.S. patents that are re-examined and EPO patents (and their U.S. "twins") that are opposed. The lack of these data prevents us from examining whether the use of oppositions results in lower rates of litigation, lowering costs and resolving uncertainty more rapidly. Any such conclusion requires that we extend the analysis to incorporate post-challenge litigation, which we hope to do in future research.

Nonetheless, the analysis in this chapter (which itself needs to be extended to cover a broader array of patent classes and to incorporate the length and costs of litigation in the United States and Europe) highlights several interesting features of the patent challenge systems of the U.S. and EPO systems. First, the U.S. re-examination procedure differs dramatically from the EPO opposition procedure in virtually all of its features. Perhaps the most significant of these contrasts is the identity of the party requesting a re-examination, which our data indicate is the

patent owner in more than 40 percent of the cases. This characteristic of re-examination hardly qualifies it as the sort of adversarial procedure that EPO oppositions represent. With this fact in mind, comparisons of U.S. re-examinations and EPO opposition proceedings must be treated with great caution.

Keeping in mind the significant differences between the re-examination and opposition processes, our comparative analysis suggests that EPO oppositions do not resolve validity challenges much more quickly than USPTO re-examination proceedings. In other words (and keeping in mind the incomplete nature of our data), for any given patent the EPO opposition process does not resolve uncertainties over the quality and breadth of patents more rapidly than the re-examination process. Indeed, opposition proceedings in some cases (and almost certainly in important, complex cases with numerous opponents, appeals, etc.) may well take as much time to be resolved as litigation in the U.S. system. Nonetheless, the higher frequency of opposition (which is presumably due to the lower cost associated with opposition as compared to the cost of litigation in the United States) within the EPO system is at least consistent with the hypothesis that the opposition process handles many more legal disputes over patent validity than are addressed by the U.S. re-examination process.

Our analysis also indicates that patent amendment, rather than revocation, is more likely for oppositions in relatively new fields of inventive activity, for more “complex” patents, or for oppositions in which numerous opponents participate. Because we lack evidence on the extent to which oppositions are followed by litigation in the European patent system, we cannot determine whether the lack of any “speed advantage” for oppositions in resolving patent disputes quickly is offset by a reduction of litigation rates associated with oppositions. The EPO system may offer few advantages over the U.S. system for post-issue patent challenges, but we cannot address this issue without analyzing litigation data for both the U.S. and European systems. Any comprehensive assessment of the social costs and benefits of the two challenge systems requires that we consider both the “patent office” processes of post-grant challenge (opposition or re-examination) and litigation.

The analysis of EPO oppositions and USPTO re-examinations also indicates that more “valuable” or technologically important patents, based on the usual indicators of such characteristics, are more likely to trigger challenges. This conclusion is consistent with prior research, and if the private and social values of patent rights are correlated, higher levels of scrutiny for more important or valuable patents are welfare-enhancing. Misspecifications of the claims or other characteristics of important patents are likely to produce relatively large welfare losses, e.g., deviations from an optimal trade-off between market power allocated to the patent owner and incentives for R&D (Harhoff and Reitzig, 2001).

Our analysis of “twin patents” also suggests a complex interdependence between the probability of an EPO challenge and the issuance of a U.S. “twin” patent. This interdependence must be explored further, but at least some evidence

is consistent with the interpretation that “twin status” reflects selection issues that we have not addressed in this chapter. There also appear to be some interesting issues of the timing of applications and issue of USPTO and EPO patents within these data, and we intend to analyze these issues in greater detail. The existence of such interdependence is hardly surprising in an integrated global economy, but these linkages have received little scrutiny from scholars of intellectual property policy.

The heading for this section thus is used advisedly, because we have raised as many questions as conclusions in this analysis. But this highlights the richness of the agenda for further research.

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APPENDIX

Liposome Corporation—Patent No. 4,880,635 (EPO Publ. No. 190,315)

In July 1985, the Liposome Corporation (LC) submitted an application in the U.S. Patent and Trademark Office (USPTO) for a patent on their “dehydrated liposome” innovation, enabling the use of liposomes—fatty bubbles—that carry drugs to concentrate at the site of an infection. Within a month, the firm submitted an application to the European Patent Office (EPO) to secure patent rights in Europe. The European application was published in August 1986, based on LC’s claimed international priority date of August 1984.

After pending in the USPTO for 4 years and 4 months, the U.S. patent issued on November 14, 1989 (patent number 4,880,635—hereafter ‘635 patent), with nine claims. During the next several years, LC began distributing its drug Abelcet, an antifungal treatment used for AIDS-related infections based on technology disclosed in its ‘635 patent. Rival Nexstar, Incorporated (formerly known as Vestar) developed a competing liposomal drug, AmBisome, prompting LC to notify Nexstar that the antifungal AmBisome infringed its ‘635 patent. On May 17, 1993, Nexstar sued LC in the Federal District Court in Delaware, seeking a declaration that the ‘635 patent was invalid, and LC counterclaimed, charging AmBisome with infringement.

Presented with new prior art that created some likelihood that Nexstar would prevail in court, LC decided on July 13, 1993 to request an “owner-initiated” re-examination on its ‘635 patent, thus gaining for itself an ex parte proceeding with the USPTO to determine the impact of the new prior art. This re-examination enabled LC to reenter negotiations with the USPTO over the patent’s claims. If the USPTO upheld the suspect claims, the presumption of validity of the ‘635 before the court would be strengthened.

LC was awarded its equivalent European Patent, EP 190315, on October 17, 1993. LC designated Austria, Belgium, Switzerland, Germany, France, Great Britain, Italy, Liechtenstein, Luxembourg, and Sweden as states in which it intended to patent. Nexstar opposed LC’s EPO patent on April 6, 1994, and was joined in opposition by Daiichi Pharmaceutical Company on September 21. On December 21, 1994, the Delaware U.S. District Court found that LC’s patent was invalid and that Nexstar’s product was not infringing. As of this date, no decision has been delivered in the Nexstar/Daiichi opposition proceedings, thus suggesting that the cases are essentially closed.

Legal maneuvers kept the U.S. litigation alive through 1995 and on June 7, 1996 LC announced that it had been “upheld” by the USPTO in its re-examination. Company officials declared that the patent’s “presumption of validity [was] enhanced” and threatened Nexstar with an injunction to prevent it from selling AmBisome. LC shares were up 3.4 percent on the news that day, whereas

Nexstar's shares dropped 21.5 percent. (Marc Monseau, "Patent Office upholds Liposome patent," *Denver Rocky Mountain News*, June 7, 1996).

The news also appears to have scuttled Nexstar's plans for a \$60 million new share offering in June 1996 that would have financed the firm's acquisition of new drugs, marketing its newest product, and research and development. (David Algeo, "Nexstar may kill offering," *The Denver Post*, D:1, June 8, 1996). Nexstar officer said that LC's announcement of the outcome of its patent re-examination had harmed the firm (Jesse Eisinger, "Patent ruling may hamper Nexstar offering," *Denver Rocky Mountain News*, 5B, June 11, 1996).

The USPTO certificate on the re-examination of the '635 patent finally issued on July 2, 1996, and the facts did not entirely support LC's press releases of a month earlier. In reality, B1 Certification 2,937 stated that 3 claims had been cancelled, 6 claims had been amended, and 19 new claims were added to the '635 patent. Nexstar returned to federal court in May of 1997, claiming that LC had purposefully misrepresented the re-examination results to gain advantage and injure Nexstar, and argued that the '635 patent was invalid.

EP 190315 was opposed at the EPO on Feb. 1, 1994 by Nexstar and Daiichi Pharmaceutical. The case is still pending on appeal, and we do not know the preliminary outcome. It is probable, based on the events discussed immediately below, that they are not waiting for the final outcome and the case is essentially closed.

The two competitors ultimately reached a settlement in their U.S. court case on August 11, 1997, jointly stipulating to a dismissal. In the settlement, LC granted Nexstar immunity from future suits in connection with its worldwide manufacture and marketing of AmBisome. The firms agreed to grant reciprocal options to take licenses to the other's patented technologies, whereas Nexstar agreed to unspecified payments to LC. The following day, Nexstar's AmBisome was approved by the Food and Drug Administration for marketing in the United States.

Ortho Pharmaceuticals—U. S. Patent 4,363,799 (EPO Publ. No. 17,381)

By the early 1980s, monoclonal antibodies had been recognized as a remarkable advance in medical science. The discovery, which allows the identification of so-called T cell subsets of lymphocytes, a type of white blood cell, showed promise for enabling advancements in the treatment of infectious disease, cancer, infertility, autoimmune disorders, heart disease, and other maladies. In 1984, sales of diagnostics and therapies using the technique grossed U.S. \$500 million, with projections of annual sales of U.S. \$2 billion by 1990 (Lawrence Altman, "A Discovery and Its Impact: Nine Years of Excitement," *New York Times*, C:3, Oct. 16, 1984). The founders of the technique were awarded the 1984 Nobel Prize in "Physiology or Medicine," signaling its path-breaking nature.

On March 20, 1979, the Ortho Pharmaceutical Corporation (Ortho) applied for a U.S. patent on its invention entitled "Monoclonal antibody to human T cells, and methods for preparing same." On March 19, 1980, presumably taking advantage of the 1-year application window allowed in the EPO, Ortho applied for its equivalent European patent, application number EP1980030082, using the U.S. application date as its priority date. On the basis of the application's March 1979 international priority date, the EPO published the application on October 15, 1980, signaling the existence of the pending patent. Ortho designated its European states of interest on that date as Austria, Belgium, Switzerland, Germany, France, Great Britain, the Netherlands, Italy, and Sweden.

On December 14, 1982, after some 2 years and 9 months pending in the USPTO, the U.S. patent issued (number 4,363,799), with 11 claims. Approximately 2 years later, on September 20, 1984, Ortho filed a complaint alleging patent infringement against Becton Dickinson Monoclonal Center, Inc. in the Federal District Court in Wilmington, Delaware. The complaint also covered 12 other patents owned by Ortho. Within 10 months, the European equivalent patent (No. 17381) issued, on July 10, 1985.

During 1986, legal maneuvering on both sides of the Atlantic tested the validity of the Ortho patent. On June 4, 1986, an EPO opposition was filed by Behringwerke AG and Sandoz AG. Within a week, on June 11, a second opposition was filed by Becton, Dickinson & Company and by Boehringer Mannheim GmbH. On July 24, 1986, Ortho's U.S. infringement action against Becton Dickinson, an opponent to Ortho's EPO patent, was transferred to the U.S. Federal District Court in Northern California. On September 26, Ortho again asserted its patent in an infringement action against Coulter Corporation and Coulter Electronics Corporation in the Southern District of Florida.

By October 3, 1986, Ortho and Becton Dickinson had settled their California litigation. Each party stipulated to a voluntary dismissal of the case and the Court announced that the parties had "resolved their differences." But the EPO opposition proceedings continued, and after the two pending oppositions were consolidated, the EPO patent was revoked on October 17, 1986. Ortho immediately appealed the adverse decision to the EPO, but the appeal was finally rejected on January 8, 1991, 5 years after settlement of the firm's infringement suit against one of the EPO patent opponents.

Ortho's suit against Coulter Corporation and Coulter Electronics Corporation in the Southern District of Florida was finally settled in November 1993, with a consent judgment and a dismissal. Ortho's U.S. patent remains in force but has not been asserted in court since. The patent number is not withdrawn, although the patent is close to expiration.