

# Validity and Invalidity of Patent Claims

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## Introduction

An invalid patent claim cannot be infringed. This statement has far-reaching implications whether you are a patent owner or a party accused of infringement, albeit each situation involves very different analyses and results. As a patent owner, the validity or invalidity of patent claims provides a basis for whether the owner has any leverage in enforcing a patent against an infringer and negotiating or maintaining the terms of a license agreement.

However, this chapter will address validity or invalidity of patent claims in the context of finding yourself in the undesirable position of dealing with the possibility or even the reality of an infringement lawsuit naming your institution as a party.

Once issued, a U.S. patent is presumed valid, as mandated by the U.S. patent statutes (35 USC § 282). This means that courts will deem each claim of the patent as meeting the statutory requirements of novelty, nonobviousness, utility, written description, definiteness, enablement, and best mode, which places a heavy burden to overcome this presumption on those challenging issued patent claims.

It also means that each claim is presumed valid independently of any other claim, which, in most cases, means that, even if an independent claim is rendered invalid, a claim dependent therefrom may still be valid and enforceable. Thus, each claim of a patent requires a separate validity analysis.

The examiners at the U. S. Patent and Trademark Office (USPTO) cannot comment on the validity or invalidity of claims in a U.S. patent, unless it is necessary to do so in the context of a reissue request, a re-examination request, or an interference proceeding (MPEP § 1701). Re-examination and interference proceedings are proceedings available

through the USPTO under certain circumstances for challenging another party's claims, as discussed in more detail below. In some situations, however, the only venue available for challenging the validity of a patent that is or may be enforced against you is the courts. This chapter discusses the different options for addressing claim validity issues before getting to court, once before the court, and outside the court.

## Before Going to Court: Invalidity Opinion Letter

There are various ways in which your institution can become aware that it could be named as a party in an infringement lawsuit. In one scenario, a patentee (Company A) sends a registered or certified letter providing notice to you that it has one or more patents and extends an invitation to discuss licensing or other agreement options.

If Company A is savvy about its intellectual property rights, the letter (or at least the first letter sent) will not expressly accuse you of infringement or even threaten you with litigation, because to do so would allow you to file a *declaratory judgment action* with the court, wherein you as the plaintiff ask the court to declare that the claims of the patent are invalid or that the claims are not infringed. Declaratory judgment actions are discussed in more detail below.

It is more likely that Company A will word the letter carefully, providing notice of its patent(s) and documenting your receipt of the notice (by registered/certified mail or otherwise). This allows Company A to start the clock on calculating damages (i.e., monetary remuneration for the financial harm caused to the patentee by your institution's activities) if Company A brings a patent infringement lawsuit against your institution. This presuit notice to your institution will also be relevant to Company A's potential claim of willful infringement, which can result in a tripling of any damages award. Company A would likely base its willful infringement claim on the fact that your institution had notice of its patent(s) and, thus, was allegedly aware that it was infringing and continued to do so nonetheless.

An institution should not ignore such correspondence because it puts the institution in the position of having knowledge or places an expectation on the institution of having knowledge (i.e., the institution knew or should have known) of one or more patents it

may be infringing. A patentee could use this correspondence at trial to demonstrate that your institution was reckless in failing to avoid infringing a patent of which it was aware.

A different scenario whereby your institution may become aware that it is possibly infringing a patent is through a faculty member or other employee informing you or other administrative officials of a patent that he or she believes is related to activities he or she is carrying out. In either situation, whether by notice from a patentee or through information from an employee of potentially infringing activity at the institution, the institution needs to consult a patent attorney at this point.

In some situations, the best course of action by your institution may be a dialogue with the patentee to work out terms of a license or other agreement so that the patentee will not pursue litigation against your institution.

If this is not a feasible option for the institution or if your institution's patent attorney has provided you with reasons why the institution's activities may not be infringing, your institution may instead choose to have its outside patent counsel provide a letter providing a legal opinion letter addressing one or both of these positions.

After reviewing the facts and the patent(s) at issue, your patent attorney may propose either the preparation of a noninfringement opinion letter, which explains that the claims of the patent(s) involved are not infringed by the activities at the institution, or the preparation of an invalidity opinion letter, which explains that the claims of the patent(s) involved are invalid and, therefore, cannot be infringed.

Which type of letter to pursue is dependent on the circumstances of the institution's allegedly infringing activity or technology. If, after reviewing the patent(s) at issue, including their complete file histories, and gathering information and discussing the details of the allegedly infringing activity or technology with those involved in it, the patent attorney decides that reasonable legal arguments can be made that the institution does not infringe the patent(s), either literally or under the doctrine of equivalents, then an opinion of noninfringement would be appropriate.

If after such an analysis, however, the patent attorney is not able to reach this conclusion, generally no letter or other written record addressing infringement should be prepared. Instead, the patent attorney may suggest analyzing claim validity to establish a basis for writing a letter explaining why the patent claims at issue are invalid.

One should obtain an invalidity opinion letter before becoming involved in litigation and use outside patent counsel to prepare the opinion letter to avoid issues of conflict of interest and bias that could arise if such an opinion is prepared by an inhouse attorney or someone with a financial or other incentive to provide anything other than a fully objective analysis. The letter should provide an explanation of the legal standards for patentability and set forth the facts regarding the prosecution history of the patent under analysis, including rejections that were made and how they were overcome.

The letter should then provide a discussion of each claim and why a court would not consider each claim valid. Such reasoning can be based on various factors, such as disclosures in prior art references, particularly those that were not considered during the prosecution of the patent and that provide teachings that would anticipate or render obvious the claims of the patent (35 USC §§ 102, 103).

Other factors can include an analysis of the language and scope of each claim and a legal discussion of why the language of the claim is not in compliance with statutory written description requirements and/or why the scope of the claim is not adequately enabled (35 USC § 112). Arguments can also be presented explaining that the claims should be deemed invalid for failure of the specification to disclose the best mode for carrying out the invention at the time the application was filed. Although less common, an analysis can also be made regarding whether the claims meet the utility requirements set forth in the U.S. patent statutes (35 USC § 101).

If relevant, an invalidity opinion letter can also address other bases for invalidating claims of a patent or rendering the patent unenforceable, including such issues as incorrect inventorship or inequitable conduct before the USPTO. To raise these issues in an invalidity opinion letter, a detailed analysis of the facts surrounding these issues must be

included, as well as an explanation of how the legal standards for asserting invalidity or unenforceability due to such improper conduct have been met.

An invalidity opinion letter must be a competent and well-reasoned analysis of the facts and legal bases that lead to a conclusion of invalidity of the claims at issue. It does not provide any guarantee or assurance that your institution will not be sued for infringement or found by a court to be carrying out acts of infringement. What it does provide is a basis for the institution to believe in good faith that its activities are not infringing because there is no valid patent claim to infringe, which allows for a defense against a claim of willful infringement that is likely to accompany an infringement claim. Once such a defense against willfulness is raised, the opinion letter is no longer protected by attorney-client privilege and its contents become available to the opposing party and to the court. Accordingly, all such opinion letters should be written with this possible outcome in mind.

One final point on invalidity opinion letters is that, in some circumstances, this good faith belief of no infringement can also be used to improve your leverage in negotiating a license or other agreement. However, care must be taken to maintain the privileged status and confidentiality of the legal opinion.

## Once Before the Court

If it becomes necessary for your institution to use the court system to address the issue of whether a patent claim is invalid, there are typically two routes that can be pursued: that of a proactive plaintiff in a declaratory judgment suit or that of defendant in an infringement suit. Different ways to address claim validity in either of these situations are discussed below.

### Declaratory Judgment

Traditionally a patentee could wait to file a patent lawsuit at its convenience. The patentee could decide to sue customers of a competitor for the customer's infringement without suing the patentee's competitor itself. This allowed the patentee to pick the venue for the lawsuit. A patentee could target the competitor's customers to disrupt the relationship between the competitor and its customers. The competitor, however, could not force the

patentee to engage the competitor itself in litigation. Thus, the competitor could not know when, where, or even if the patentee would file an infringement suit.

To remedy this situation, Congress in the 1920s enacted the Declaratory Judgment Act, which gave the Federal Courts jurisdiction to hear cases brought by someone whose interests (i.e., a competitor or other potential infringer) were affected by threat of a patent suit. This provides a potential infringer or other interested party the opportunity to proactively seek a judgment from the court that the patent at issue is invalid and/or not infringed without having to wait for a lawsuit from the patentee.

The Declaratory Judgment Act gives standing (i.e., the legal right to bring a lawsuit) to sue a patentee where the plaintiff (i.e., the potential infringer) has a threat of injury from a patent infringement accusation. This occurs in a situation where the plaintiff wishes to take action but taking that action may subject it to a patent infringement lawsuit.

For example, standing can arise if the plaintiff has been accused of infringement or threatened with legal action by the patentee. Another example is where the plaintiff is operating under a license agreement for the patent but believes it should not have to be bound by the license or pay royalties due to noninfringement or invalidity of the patent claims.

Formerly, where there was no risk of suit (e.g., a covenant not to sue was in place), the plaintiff lacked standing to bring a declaratory judgment suit against the patentee. As noted above, a patentee will typically try to insulate itself from the threat of declaratory judgment suits by couching its communications with a potential infringer in terms of offering a license under the patent as opposed to accusing the recipient of infringement.

The Supreme Court, however, recently altered the law in this area (see *Medimmune Inc. v. Genentech Inc.*, 127 Supreme Court 764 (2007)), with the result that, arguably, even a letter giving a patent number and suggesting that there will be licenses available may give a potential infringer standing to file a declaratory judgment suit. Similarly, even a promise or intent not to sue may be insufficient to avoid a declaratory judgment suit. In circum-

stances where the patentee still has the right to sue, even if it indicates its unwillingness to, grounds for a declaratory judgment suit may exist. Thus, this change in the law lowers the threshold required to have standing to pursue a declaratory judgment action in certain circumstances.

Further, it likely does not matter whether the potential infringer has yet to engage in the allegedly infringing activity. A recipient of an infringement charge, even under the guise of an offer to license, likely can file a declaratory judgment suit to remove any cloud over its ability to engage in activity in light of the patent(s) at issue. Previously, a plaintiff would have had to engage in the arguably infringing activity before it had standing to bring such a suit. Recent court decisions are more favorable for standing where the plaintiff has not actually engaged in the allegedly infringing activity but has intentions or plans to engage in the activity.

In sum, as courts interpret the law, a potential infringer can file a declaratory judgment suit before a threat or without a threat of suit as long as a patentee states that an activity or technology of a potential infringer is covered by its patent(s). A declaratory judgment action can ask the court to decide not only whether the patent claims are valid, but also whether specific activity constitutes infringement.

In such a declaratory judgment suit, the patentee has the burden to show that the plaintiff's activity is infringing and the plaintiff has the burden of proving that the patent is invalid and/or unenforceable (if alleged). In other words, the same burdens exist as in a normal infringement suit filed by the patentee, as described below.

## **Infringement Suit**

Given the numerous requirements for the grant of a patent by the USPTO, any patent is subject to attack on the basis that it violated or did not meet one or more of the legal requirements for patentability. Thus, in an infringement lawsuit, the accused infringer can raise a defense that the patent did not meet the requirements for patentability, i.e., the patent is invalid. The accused infringer then has the burden of showing that the patent is invalid.

Each accused infringer also has the defense of denying that the scope of the patent claims covers the accused activity, i.e., that the patent claims are not infringed. It is the patentee who then has the burden to prove infringement of one or more claims. An accused infringer can also defend the suit by alleging that the patent is not enforceable under the principles of equity including unclean hands and certain other specific defenses relating to enforceability, such as inequitable conduct arising out of the patentee's conduct before the USPTO. These defenses, some of which are more accurately described as counterclaims, typically are directed to individual claims in the patent. Some defenses, such as enforceability, can affect the entire patent.

As noted above, when the USPTO issues a patent, by statute it is presumed to be valid, which includes the presumption that the patent claims have met all of the legal requirements for patentability. Discussed below are the more commonly occurring bases for invalidity. Specific fact situations could give rise to more or different invalidity allegations than described here.

### *Invalidity Due to Prior Art*

In examining the patent, the USPTO makes a determination of whether the subject matter claimed in the patent application meets the requirements of being new (novel) relative to what was known in the art before the application was filed (the prior art). Likewise, the subject matter of the patent claims must be nonobvious in light of the state of the prior art.

Novelty of an invention refers to whether the subject matter in a patent claim is described in or known from a single piece of prior art, e.g., a single document, prior patent, public disclosure, etc. The question of obviousness usually rises in the context of combining more than one prior art reference to determine if the subject matter of a claim would have been obvious to one of ordinary skill in the art at the time of the invention.

During the application process, the USPTO examines the claims of an application for novelty and nonobviousness in light of the prior art available to the examiner. The examination process at the USPTO, however, has its limitations; the examination of the claims is only as good as the information available to the examiner handling a given application.

The prior art search conducted by the examiner typically consists mostly of a review of other patents and printed publications available in various patent collections and publication databases. In addition to overlooked patents and patent publications, an accused infringer may be aware of other public disclosures, such as journal articles, theses/dissertations, or other documents not included in the examiner's review that nonetheless constitute prior art to the patent claims.

The accused infringer can also rely on prior art activities, including, e.g., the sales of devices or public uses of processes. Such new prior art, which may not have been available to the examiner during review of the patent claims, is available to the accused infringer for use in meeting its defense burden of demonstrating the invalidity of the patent claims at issue in the lawsuit. Specifically, on the basis of these sources of new prior art, the accused infringer can argue that the patent was improperly granted because these materials show that the invention (what is claimed) does not meet the statutory requirements that the invention be new or nonobvious over what was known or available to the public before the patentee's invention.

### *Other Invalidity Defenses*

Besides novelty and nonobviousness over the prior art, other legal requirements of patentability mandate that the patentee fully disclose the invention in a patent application to fulfill the patentee's part of its bargain with society of getting the benefit of exclusivity of the patented subject matter in return for contributing to the body of knowledge involved in making and using the claimed invention. Thus, the patentee's disclosure of the invention as set forth in a patent application must be sufficient so that the public gets the full benefit of the invention at its expiration.

These other legal criteria include (a) enablement, which requires that the patentee teach one of ordinary skill in the art enough to be able to make and use the invention (35 USC § 112); (b) utility, which requires that the patentee disclose a specific, substantial, and credible use for the claimed invention (35 USC § 101); (c) written description, which requires that the patentee provide adequate written details of the full scope of the claimed invention in its patent application (35 USC § 112); and (d) best mode, which

requires that the patentee disclose the particular embodiment of the claimed invention the inventor believes to be the most useful or best way of using the invention at the time of filing (35 USC § 112).

As these are legal criteria for patentability, the claims of an issued patent presumptively meet all of these requirements. This presumption of validity, as with the presumption of validity based on novelty and nonobviousness, is rebuttable by the accused infringer. It is not uncommon that once a litigation has commenced, there is often much more evidence available on these issues than that which was before the examiner during prosecution of the application. For example, inventor testimony, the court's definitions in interpreting the patent's scope and other information revealed during pretrial discovery may provide new evidence that was not available to the USPTO and the accused infringer can use such evidence to rebut the presumption of claim validity.

### *Unenforceability*

Other defenses to a patent infringement charge include certain equitable defenses along the lines of inquiring whether the patentee has unclean hands due to failure to deal honestly with the USPTO while obtaining its patent(s). These defenses deal with the patentee's state of mind during patent prosecution.

The patent applicant has a duty to deal honestly with the USPTO during the prosecution of patent claims. Patent prosecution is known as an *ex parte* procedure between the applicant and the USPTO with no direct representation by the public or any competitors. The examiner's role is to protect the public by seeing that the conditions for patentability are met before any patent issues. The examiner, however, has limited resources and, therefore, the applicant has a duty to interact honestly with the examiner and provide certain information that may be material to the patentability of the applicant's invention.

The issue of inequitable conduct can arise in the context of whether an applicant has met its obligation to disclose material prior art or other information to the examiner or has misled the examiner during prosecution. In some situations, failure to meet this obligation is referred to as fraud on the USPTO, though the legal standards for inequitable conduct are not as limited as for common law fraud.

Inequitable conduct most often occurs where the patentee, as applicant, did not reveal to the USPTO examiner the most relevant prior art of which the applicant knew. Without this knowledge of material prior art, the examiner is prevented from making a decision on patentability on the best record. Similarly, if the applicant made misleading representations regarding what is or is not in the prior art, that too can constitute inequitable conduct. This is especially true when the examiner is not in a position to independently ascertain the true state of affairs or test the accuracy of the patentee's representations. Thus, inequitable conduct can take the form of misleading arguments made by the applicant, misleading affidavits filed in connection with the prosecution, or other misleading or incomplete assertions to the USPTO made in the course of obtaining a patent.

An inequitable conduct defense has two primary elements: materiality and intent. First, an inequitable conduct defense requires the patent challenger to show that the information not given to the patent examiner or the misleading nature of the arguments to the patent examiner were material to the examination of the patent claims. This is usually evaluated under the test of whether a reasonable examiner would have considered the information important in assessing patentability.

Second, the party asserting inequitable conduct has the burden of showing that the relevant prior art was withheld or that relevant representations were made with intent to deceive the USPTO. If the patent challenger is successful in proving that material prior art was withheld from the USPTO with intent to deceive, the result is unenforceability of the patent at issue. The patent is not technically invalid (for example, the claimed invention may still have been otherwise patentable), rather the patentee can no longer enforce the patent against any alleged infringers. The unenforceability of a patent due to inequitable conduct cannot be cured after the fact, so the patentee will never be able to enforce the patent against competitors, third parties, etc., after such a holding by the court. Also, an inequitable conduct determination usually affects the entire patent even if the inequitable conduct was limited to certain claims.

### *Invalidity or Unenforceability Due to Incorrect Inventors*

As a further requirement to obtain a patent, the applicant is also required to identify the proper inventors of the subject matter of the patent claims. There are technical rules for

determining who should be named as an inventor. For example, in some situations, persons assisting the main inventor may have made a conceptual contribution that rises to the level of inventorship and must be named in the application or patent. Conversely, a technician who carried out experiments at the direction of another, or a senior-ranking individual in an organization, either of whom may have been involved in discussions about the invention but who did not make a conceptual contribution, may not necessarily qualify as inventors.

Inventorship is normally correctable, even after a patent has issued or after a potential infringer has raised an allegation of incorrect inventorship. Inventorship is not correctable, however, where inventors were listed or not listed with deceptive intent. For example, in a situation where the patentee had something to gain or lose by listing or not listing inventors, the court may hold that the incorrect inventorship was stated with deceptive intent and, thus, cannot be corrected, resulting in an invalid patent.

Compare, for example, a situation where an inventor was not listed on a patent because he or she was otherwise entitled to a royalty that would increase the cost to the patent owner verses the situation where an inventor was omitted who was under a preexisting obligation to assign the patent to the patent owner who would divide a set royalty among all the inventors regardless of how many there were.

### *Raising Invalidity or Unenforceability Defenses in Litigation*

A determination of whether or not a patent is valid is separate and distinct from a determination of whether or not an accused process or product infringes the patent.

Sometimes the outcome of only one of the two determinations can end the case.

However, if the case goes to trial, the court may be required to render a decision on both questions.

One possible outcome when both questions are considered is a finding by the court that the claims of the patent do not meet the requirements for patentability and are, therefore, invalid. This is evaluated on a claim-by-claim basis. Once the claims are rendered invalid, they cannot be infringed, as there is nothing left to infringe. The accused

infringer or third parties no longer need to be concerned about infringing the claims of an invalid patent, as the patentee will no longer be able to assert these claims. Invalidity cannot be subsequently cured. There may, however, be other patents owned by the patentee or even third parties that contain valid claims directed to similar subject matter.

A second possible outcome is a finding by the court that the patentee's claims are valid but that they are not infringed by the accused product or process. This outcome reflects that the patent does meet the requirements for patentability or, more technically, any challenge to the patent's validity did not meet the burden of showing that the USPTO incorrectly issued the patent with its claims. While the patent may be valid, the decision of not infringed means that the accused product or process does not come within the scope of the patent's claims.

While these products and/or processes do not create liability for the accused infringer under this patent, it does not mean that the products or processes may not infringe other patents owned by this or another patentee. It must also be kept in mind that a different product or process, for example, a change in the accused product or process, may bring the product or process within the patent scope, i.e., result in infringement, thereby subjecting the accused infringer to liability.

The remaining option is for a court to find that the patentee's claims are indeed valid and infringed by the accused party's process or product. This result reflects that the patentee meets the requirements for patentability and the accused product or process comes within the scope of the patent's claims. In this situation, the patentee is entitled to a remedy for this infringement, for example, reimbursement of economic damages incurred as a result of the infringement and/or an injunction to prevent the infringer from continuing its infringing activities. At this point, the court may also consider the issue of whether infringement of the patentee's claims was willful, a finding of which can result in a tripling of the previously calculated damages. As discussed above, should an accused infringer find itself in this situation, a previously prepared invalidity or noninfringement letter should be considered as a possible defense, with consideration of the associated advantages and disadvantages as described above.

## Outside the Court: Options to Invalidate Claims within the USPTO

Although as noted above, a USPTO examiner cannot publicly discuss the validity of an issued claim, there are certain situations that arise in which the USPTO can be the venue for addressing claim validity, which can occur either before or after a patent issues. These opportunities include: (1) an interference proceeding, (2) a third-party request for re-examination, and (3) a submission of relevant prior art to the USPTO by a third party, each of which is discussed below. One should note that as of September 2007, Congress was considering legislation that could provide additional avenues for challenging the validity of a patent even after issuance.

### Interference Proceeding

The USPTO's Board of Patent Appeals and Interferences (BPAI) conducts interference proceedings to determine which of two competing applicants or patentees is entitled to a patent. When the USPTO determines that a patent and a pending application claim the same invention or that two pending applications claim the same invention, the USPTO uses an interference proceeding to determine who is technically the first inventor and is thus entitled to a patent. The successful party gets or retains its patent and the patent of the unsuccessful party is rendered invalid or, in the case of an application, the losing party loses the ability to receive a patent on the claims at issue in the interference proceeding.

An advantage of pursuing an interference proceeding as a venue for invalidating claims is that the BPAI functions within the USPTO as a specialized court that is well-versed in the law regarding patentability. Likewise, the BPAI is not afraid to immerse itself in the technology of the invention. This is in contrast to a District Court proceeding involving a jury whose understanding of the law and technology may be suspect, leading to much greater unpredictability as to the outcome. Also, in most cases (but not all), an interference proceeding may be less costly and time-consuming in comparison to a litigation and an appeal of an unfavorable BPAI decision to the court remains an option.

A disadvantage of an interference proceeding is that you need to have your own application pending or a patent issuing during the pendency of the other party's application. Your application must include a description of your invention in sufficient detail to allow

you to claim subject matter that the USPTO will determine to be the same as or obvious in view of the subject matter claimed in the other party's application or patent. The timing of when claims are presented for the purpose of provoking an interference proceeding is critical (See 35 USC § 135), and if this requirement is not met, the opportunity to get an interference declared will be lost.

As noted above, the USPTO must also determine that the claims presented in the applications of the respective parties are for the same invention. Before an interference can be declared, each party must have subject matter in the claims that is in condition for allowance pursuant to the criteria for patentability as described above. That is, all other issues that must be resolved before patent issuance, such as utility, novelty, nonobviousness, etc., must have been decided in favor of patentability. Only then will the USPTO consider whether to declare an interference.

Once it declares an interference, the USPTO sets a tight calendar of due dates in the interference proceeding that are not easily extended.

The first stage (approximately the first half of the interference calendar) is directed to the filing of preliminary motions that deal with every possible issue except the actual priority issue. Preliminary motions involve the raising of questions such as whether the applicant is entitled to particular priority dates of any other patent applications, whether the subject matter of the interference count (the same invention) should be redefined or restated, etc.

For purposes of invalidating the claims of the other party, preliminary motions can be filed on matters directed to the unpatentability of the invention by the opponent, employing all of the arguments discussed above for invalidating a claim during a court proceeding. Some preliminary motions directed to unpatentability can result in a suicide squeeze play, in that, if granted by the BPAI against the opponent, the same evidence will stand as a determination that the movant's application is likewise unpatentable.

Once the preliminary motion phase concludes, the BPAI can render an opinion that the claims of one party are invalid, ending the proceeding at this point. If the BPAI fails to

find the claims of either party invalid at this point, the next phase of the interference proceeding is initiated. In this second phase, each party introduces evidence demonstrating when the claimed invention was conceived to determine who was first to invent what is claimed. The outcome of this phase of the proceeding is an opinion by the BPAI that one party made the claimed invention before the other party and is, therefore, the only party entitled to a patent on the invention.

### **Re-examination Request**

A third party can challenge the validity of an issued patent directly through the USPTO by filing a request for re-examination and paying the requisite fee (which is currently more than \$2,500). A re-examination proceeding essentially reopens the prosecution of claims on the basis of new information brought to the attention of the USPTO.

However, the only grounds for challenging validity via this route is a demonstration that the claims of the patent at issue are unpatentable because they are anticipated and/or obvious in view of subject matter in the prior art that was not already considered by the examiner during prosecution of the allowed claims. Generally, issues related to other patentability criteria, such as enablement, written description, best mode, utility, or inequitable conduct, cannot form the basis for requesting re-examination.

Therefore, this route is only practical to consider if one has relevant public disclosures (which must be prior art, i.e., publicly available before the priority date of the patent) that have not been considered by the examiner in determining patentability of the patent claims and that provide a reasonable basis for the USPTO to consider reopening the case for further examination. In some circumstances, evidence that an invention does not work as claimed may be presented for consideration in a re-examination request.

If such art or evidence is available, the benefit of requesting re-examination is that it allows for the possibility that the claims of the patent at issue could be rendered invalid or at least narrowed in scope, such that the patent is no longer a problem for the third party.

The potential disadvantages of requesting re-examination of another party's patent is that the opposite outcome is possible; i.e., the original claims can be upheld and the relevant art or evidence is now on the record, invoking a strong presumption of validity in view of this information. In addition, under current law, a challenger may be estopped from raising in a subsequent challenge defenses it could have raised in a re-examination proceeding. In other words, if the claims are upheld, the re-examination may have the unintentional effect of actually strengthening the patent that is being challenged.

### **Third-Party Submissions to the USPTO**

As an additional mechanism for the USPTO to minimize the issuance of claims that do not meet the criteria for patentability and allow the public to assist in the patent process, there are procedures in place at the USPTO whereby a third party can submit relevant information (typically public disclosures or prior art) to allow an examiner to consider such information during prosecution of a patent application. As noted above, the examiners are limited in their access to public information and, even with the duty to disclose what an applicant knows, there are times when information material to the patentability of claims in an application is only known by a third party, which is typically a competitor or other party with an interest in the outcome of the examination of a particular patent application.

Such submissions can be sent anonymously, and they can be sent during examination of claims of a patent application that has been published by the USPTO (37 CFR § 1.99). Alternatively, the submission can be made before a patent application is published, in the form of a protest (37 CFR § 1.291), but this latter option requires specific knowledge of a patent application that is not yet publicly available and the submission must include an explanation of the relevance of the submitted documents. In contrast, a third-party submission during examination of claims in a published application cannot include any written comments or explanation of the relevance of the submitted documents.

The USPTO has discretion over whether the submissions are included in the record of a patent application and the applicant must be given notice of the submission. If a submission is entered into the record of a pending application, it is up to the examiner handling

that application to decide if the information provided impacts on the patentability of the pending claims. Thus, there is no guarantee that a third-party submission will have any invalidating effect on a pending application and may have the consequence of allowing the applicant to amend the claims to get around any such submitted art.

An alternative way to get information into the record of a pending application is to send the information directly to the applicant, thereby triggering the applicant's duty to disclose such information to the USPTO. It is best to send such information to the applicant or the applicant's attorney by registered mail or other means to document that it was received, along with a statement regarding why the information is material to the patentability of the applicant's claims. This enhances the burden on the applicant to disclose the information to the USPTO to avoid the appearance of failing to disclose material information, which can be the basis for a charge of inequitable conduct, thereby rendering any resulting patent unenforceable.

## Conclusion

In summary, if your institution is facing a possible patent infringement lawsuit or if you are aware of patent applications that may become problematic should claims issue, this chapter sets forth many of the avenues available to you to address such situations. Identifying these situations early and implementing some of the strategies described above gives you options for protecting your institution or at least minimizing any negative effects.