



FENWICK & WEST LLP



Patent Litigation

for High Technology and Life Sciences Companies



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Introduction

This booklet is designed for those who wish to enforce their patents or who have been accused of infringing another's patent. It provides an outline of patent law in the United States, and an overview of the procedure of patent cases.

The companion booklet, *Patent Protection for High Technology and Life Sciences Companies*, goes into more depth about how patents are obtained and how patents differ from other forms of intellectual property, such as copyrights, trademarks and trade secrets.

What Is a Patent?

Patents are often described as limited monopolies. The U.S. government grants the exclusive right to make, use, sell or import an invention, but only for a limited time (usually 20 years from the filing of the patent application). Patents may also be thought of as a contract between the inventor and the U.S. government: in exchange for the disclosure of the invention to the public, the government permits the patent holder to prevent others from benefiting from the invention for a limited period of time. Finally, patents may also be thought of as property, in that the holder of a patent can sell (or "assign") the patent to others or give them a license to avoid infringing it.

No matter how patents are described, they remain powerful forms of protection. In general, no one else, without the patent holder's permission, may make, sell, offer to sell, import or even use a patented invention within the United States. Neither innocent infringement nor independent development are defenses to a claim of patent infringement.

There are several different types of patents. In the United States, we have utility patents, design patents and plant patents. Utility patents protect the functional aspects of an invention, design patents protect the ornamental aspects of a product and plant patents protect new varieties of flowers, trees and the like. As patent litigation cases more frequently involve utility patents than design or plant patents, the following sections, for the most part, discuss utility patents.

Utility patents consist of several parts: the claims, which outline the scope of protection the patent holder has, and the drawings and the specification, which teach the public about the invention.

What Are Patent Claims?

The claims of a patent define the scope of the invention. A patent usually has multiple claims. Thus, certain claims of a patent may be infringed, while others are not. Similarly, some claims of a patent may be invalidated in litigation, but not others. Not all of the claims in a patent need to be asserted in a lawsuit.

Consider a very simple patent to protect an electronic mousetrap. Two claims might read like this:

Claim 1: A mouse-trapping device, comprising a platform and a spring bar pivotally attached to the platform for engaging a mouse, responsive to the mouse stepping on the platform.

Claim 2: A mouse-trapping device as in Claim 1, wherein the platform comprises a capacitive detector circuit coupled to the spring bar, the capacitive detector circuit releasing the spring bar responsive to a change in nominal electrical capacitance representative of the mouse stepping on the platform.

Claim 1 is said to be an independent claim. Claim 2 is called a dependent claim that “depends from” Claim 1.

The claims are made up of limitations (also known as elements). Limitations are the components of the claim that define the invention. In the example above, Claim 1 contains the limitations of: (1) a platform, (2) a spring bar, (3) the spring bar’s pivotal attachment to the platform and (4) the spring bar’s responsiveness to the mouse’s stepping on the platform. Claim 2 has all those limitations, plus the additional limitations of (5) a capacitive detector circuit and (6) that circuit’s responsiveness to “a change in nominal electrical capacitance representative of the mouse stepping on the platform.” A claim is only infringed if each limitation is present in the infringing device or process, either literally or under the doctrine of equivalents.

A person who uses (or makes, sells, offers for sale or imports) a mousetrap with a platform and an attached spring bar but no capacitive detector circuit would infringe Claim 1 but not Claim 2. But if that mousetrap also used a capacitive detector circuit, then it would infringe both claims.

The reason Claim 2 is included is that it may be discovered that prior to this inventor’s work someone else already came up with the mousetrap described in Claim 1. As detailed on page 7, Claim 1 might then be invalid, leaving Claim 2 as narrower, but more certain, protection for the invention.

What Else Is in a Patent Other than claims?

Patents also contain a specification and typically a number of drawings. The first part of the specification usually details the state of the art prior to the invention. A brief summary of the invention follows, which often recites the ways in which the new invention improves upon the prior art. The rest of the specification describes the one or more “preferred embodiments” of the claimed invention, typically with extensive reference to the drawings.

The specification must teach a person “of ordinary skill in the art how to make and use the invention without undue experimentation.” It must also describe the best method of practicing the invention known to the inventor(s) at the time the patent application was filed.

How Is a Patent Obtained?

An invention is patentable if it is useful, new and nonobvious. Unlike copyrights, which arise automatically when pen is put to paper, patents can only exist by getting a patent application granted in whatever jurisdiction protection is desired. For U.S. patents, applications are filed with the U.S. Patent & Trademark Office (the “PTO”). A patent examiner is assigned to the application and ultimately determines if the patent should issue. The examiner typically makes an initial rejection of the application on various grounds. The applicant then generally amends the application or explains why they think the rejection was wrong. A record of the application process, called the “file wrapper,” is maintained at the PTO and is available for public inspection once the patent issues. Often, a patent applicant will have to revise the proposed claims, and the record of those revisions can be helpful in understanding the patent claims that ultimately are allowed.

Because the process of obtaining a patent is one of examination rather than merely registration, patents are presumed to be valid. However, an issued patent can be invalidated by a court if it fails to meet the standards for patentability.

What Strategic Considerations Are Involved in Patent Litigation?

Patent litigation is expensive and can take years to resolve. The decision to enforce or challenge a patent is an important one and must take into account the company's overall business goals and strategies.

A company wishing to enforce a patent should consider a number of issues in addition to whether there is infringement, including the nature of the remedies available for the infringement, the costs of pursuing the infringement versus the costs of not pursuing it and the possible counterclaims the defendant could raise. A company facing a possible patent lawsuit has a similar list of issues to consider in determining how to respond to that lawsuit. In either event, the early involvement of patent litigation counsel is vital to smart decision making.

Where Is a Patent Enforced?

The U.S. government grants a patent, but it is up to the patent holder to enforce the patent. Enforcement often starts with a letter to the possible infringer notifying them of the patent and possibly offering to negotiate a license. There is a real art to writing such demand letters; too strong a letter will allow the recipient to go to court on their own home turf to seek a declaration that the patent is not infringed or that the patent is invalid or unenforceable.

If negotiations are not successful, the patent holder must bring an action for infringement, usually before a United States District Court, or, in the case of the importation into the United States of infringing goods or goods made by an infringing process, before the United States International Trade Commission (the "ITC"). Accused infringers also have the option of requesting that the PTO reexamine the patent.

Courts

Patent infringement actions may be filed in federal district courts. The federal district courts can determine whether the patent is valid, if the patent is infringed and if the patentee's conduct prevents it from enforcing the patent. A federal district court can award damages for patent infringement and issue injunctive relief to prevent further infringement. It can also decide related claims concerning the same parties.

Patent cases are often decided by juries. Depending on the specific district chosen, there may be few or no jurors with background in the relevant technology area. Thus, a premium is placed upon counsel's ability to explain complex technology to the jury. At the same time, counsel must also be able to understand the technology to be able to work effectively with the client and with technical experts.

A patent holder can bring a patent case in any district in which personal jurisdiction exists over the defendant, which includes those districts in which an infringing item can be found.

As noted above, a party accused of patent infringement may also bring a lawsuit for “declaratory relief” — a declaration from the court that the patent is invalid, unenforceable or not infringed. A declaratory relief action may be brought in any district where there is personal jurisdiction over the patent holder, including districts in which the patent holder has licensees or distributors for the patented product, and in which it has threatened enforcement of its patent.

Appeals from decisions of each of the federal district courts are taken to the Court of Appeals for the Federal Circuit, located in Washington, D.C. The U.S. Supreme Court is the court of final appeal on patent matters. However, it has discretion whether to review appellate court decisions and takes very few cases.

International Trade Commission (ITC)

The ITC hears patent cases involving the importation of infringing products. It is an arm of the Department of Commerce, and its proceedings must conform to various international treaties, most notably the General Agreement on Trade and Tariffs (GATT). Proceedings before the ITC are similar to — but generally faster than — proceedings in federal district courts and have similar but not identical procedural rules.

One of the key distinctions between civil litigation in federal district court and ITC proceedings is that the ITC has discretion whether to institute a formal investigation based upon a complaint, while in federal district court the patent holder has sole discretion to decide whether to bring suit. If the ITC does initiate a formal proceeding, an administrative law judge (ALJ) is assigned. The ALJ makes an initial determination on whether the imported goods infringe the patent and recommends a remedy. The initial determination becomes the final determination of the ITC unless revised or reversed on administrative or judicial appeal. A final determination becomes effective after 60 days if not vetoed by the President.

In an ITC action, private damages are not recoverable. The ITC can issue either a general or limited exclusion order, which is enforced by Customs; a temporary exclusion order under standards similar to those for preliminary injunctive relief in federal courts; and/or a cease and desist order, which can be enforced in federal district court and which can be the basis for civil penalties.

It is common for a complainant to combine an ITC proceeding with an action in federal district court, to obtain the benefits of both a potentially expedited proceeding before the ITC and an exclusion order, and money damages from the federal district court proceeding.

Appeals from decisions of the ITC are heard by the Federal Circuit, and final review may be accepted by the Supreme Court.

Reexamination in the PTO

Those accused of infringement have still another option available to them. By law, the public can request that the PTO reexamine an issued patent. Typically, such reexamination is based on prior art that the patent examiner did not consider during the initial examination.

Two types of reexamination are permitted: *ex parte* and *inter partes*. *Ex parte* reexamination does not permit the party seeking reexamination to do much more than submit the prior art with an explanation of its reference. In contrast, *inter partes* reexamination gives the requesting party more involvement in the process, but precludes them from re-arguing the same issues later in court.

One potential benefit of seeking reexamination is that if a lawsuit has already been brought, the court may issue a stay to halt litigation activities during the PTO's reexamination process, thus buying time for a company that could not at the moment afford ongoing litigation expenses.

What Must the Patent Holder Prove?

The patent holder must prove that the defendant either directly infringed a claim of the patent, contributed to another's infringement or induced another to infringe. In a district court proceeding, the patent holder must also prove the amount of damages that should be assessed for the infringement.

Varieties of Infringement

Direct Infringement: To prove direct infringement, the patent holder must prove that the defendant made, used, sold, offered for sale or imported a claimed invention. Direct infringement may occur either literally, meaning that a claim of the patent, when compared to the accused device or process, is an exact match. Alternatively, under a theory known as the doctrine of equivalents, infringement may be found where the accused device, while not literally identical to what is described in a claim of the patent, is interchangeable with what is claimed. This doctrine prevents would-be infringers from avoiding liability by making only trivial changes to their product.

Proving direct infringement is a two-step process. First, the court construes the patent claims to determine what they cover. To do this, both parties submit competing definitions of the terms of the claims, relying upon the patent specification, the prosecution history for the patent (*i.e.*, the record of proceedings before the PTO) and the other technical references that were before the PTO. In some cases, the parties may also try to use inventor testimony and expert opinion. The judge then rules on the meaning of the terms in the claim. Depending on

the district, this may be done at a separate court hearing, known as a claim construction or “Markman” hearing, prior to trial.

In the second step, the factfinder (which may be a judge or a jury) compares the accused product or process with the claims of the patent. If the accused product or process possesses each limitation of a single claim, the product or process literally infringes the patent. If this comparison does not show exact identity between the patent and the accused device or process, but the differences are insubstantial, the product or process infringes under the doctrine of equivalents.

Contributory Infringement: To establish liability for contributory infringement, the patent holder must prove that the defendant sold, offered for sale or imported a component that is a material part of a patented invention, and that the defendant knew that the component was especially made or adapted for use in the infringing product. An exception is made for the sale of “staple” products — those that have a substantial noninfringing use or uses.

Inducement of Infringement: To prove inducement, the patent holder must prove that the defendant actively induced another to directly infringe the patent holder’s patent.

Foreign Activities That Raise U.S. Infringement Issues

There are a number of activities that, if carried out overseas, can run afoul of American patent law. Patent law forbids persons within the United States from providing all or substantially all of the components of a patented invention to an overseas manufacturing facility with the intention of making the patented invention. The patent law also prevents anyone in the United States from importing into the United States a product that was made overseas using a process patented in the United States.

What Can Invalidate a Patent?

The court system makes the final determination as to whether a patent is valid. A defendant can prevail in a patent infringement action by proving a patent's invalidity if the defendant can show that the invention was not patentable, was not fully disclosed in the patent or was applied for too late.

There is a presumption that patents are valid. The invalidity of a patent must be established by "clear and convincing evidence," which is a more rigorous standard than the more common "preponderance of the evidence" standard in most civil actions.

The Invention Was Not Patentable

An invention is patentable only if it is useful, new and nonobvious. Therefore, a claim of patent infringement can be defeated if the defendant can show that the invention is anticipated by an earlier invention, was obvious in light of the state of the prior art or is useless.

Anticipation: A patent is said to be anticipated if the same invention was first made by another or was known or used by others or described in a printed publication before the invention date. For a claim of a patent to be anticipated, each limitation of the claim must be found in the prior art.

Obviousness: An invention must not be obvious to "one of ordinary skill in the art" given the state of the art at the time of the filing of the patent application.

Uselessness: The government will not go to the trouble of granting protection for inventions that do not benefit the public.

The Invention Was Not Fully Disclosed

A claim of patent infringement can be defeated if the defendant can show that the specification or claims of the paper do not meet certain standards.

Enablement: The patent must describe the invention well enough to enable a person of ordinary skill in the art to make and use the patent.

Best Mode: The inventor must also describe what he or she believes is the best way to carry out the invention—the "best mode."

Definiteness of the Claims: The claims cannot be overly broad and vague.

The Application Was Not Timely

In order to encourage rapid disclosure of the invention, U.S. law requires the inventor to file a patent application no later than one year after the first time the invention was publicly used, offered for sale or sold—and not necessarily by the inventor. These defenses are known as the “public use bar” and the “on-sale bar.”

Public Use Bar: The use does not have to be very public. For example, a demonstration of a beta version of software to a third party may suffice, unless that demonstration was subject to a nondisclosure agreement.

On-Sale Bar: The invention need not have been actually reduced to practice—just ready for patenting when it was offered for sale or sold.

What Makes a Patent Unenforceable?

A patentee's bad faith acts can render an otherwise valid patent unenforceable. The following may render a patent unenforceable:

Defrauding the PTO: The patent applicant has an obligation to disclose to the PTO all of the information that is "material to patentability." A defendant must prove that the applicant intentionally failed in this duty, and that the omission was not cured.

Misusing the Patent: A patent holder may misuse a patent by extending the legal monopoly of a patent beyond what is allowed by law. If so, it may be guilty of patent misuse, which renders the patent unenforceable until the misuse is redressed. For example, a patent holder that "ties" the sale of a patented technology to the sale of nonpatented technology may have misused its monopoly.

Laches: A laches defense requires a showing that a patentee delayed in bringing the lawsuit, that the delay was unreasonable and inexcusable and that alleged infringer was materially prejudiced by the delay. When the alleged infringer is able to successfully invoke a laches defense, the patentee is precluded from recovering damages from any infringement that occurred before the patentee filed suit. Laches is a partial defense, however; it does not bar post-filing damages nor injunctive relief.

Equitable Estoppel: Equitable estoppel applies where a patent holder has misled the alleged infringer into reasonably believing that that patentee no longer intends to enforce the patent against the alleged infringer, who relies on that misleading conduct to his or her detriment.

Standards Activity: In many instances, representatives on industry committees work together to develop standards regulating technology for that particular industry. Failure to follow the patent policies of the standards body may give rise to defenses to a claim of patent infringement.

What Are the Remedies for Patent Infringement?

A patent holder that prevails in a patent infringement case in federal district court is entitled to two main remedies: an injunction, and money damages. In addition, under certain circumstances, the patent holder may also receive increased damages and attorneys' fees.

Injunctions

Permanent Injunctions: A patent holder who prevails at trial can ask the court to prevent (“enjoin”) the defendant from further infringing upon the patent. Such post-trial injunctions are commonly granted, unless a matter of public interest (such as a medical treatment) is involved or unless the case presents serious appellate issues. An injunction is only available during the lifetime of the patent.

Preliminary Injunctions: In some circumstances, a patent holder can obtain an injunction before the trial begins — a preliminary injunction. Despite its temporary nature, a preliminary injunction may essentially determine the outcome of a case, because the defendant cannot sell the product(s) at issue until either the district court or appellate court removes the injunction, which may take months or years. In deciding whether to grant a preliminary injunction, courts weigh the following four factors: (1) the likelihood of success on the merits (that the patent holder will likely prove infringement at trial and that its patent will likely withstand validity challenges at trial); (2) the relative rights and hardships of the parties; (3) the possibility of irreparable harm; and (4) the public interest. Obtaining a preliminary injunction is not without its costs to the patent holder; the patent holder must post a bond to cover any damage done to the defendant in the event the defendant wins later at trial.

Temporary Restraining Orders (TRO): These are emergency preliminary injunctions. Under extraordinary circumstances, a court can enjoin a defendant from allegedly infringing activities for a short period, at which point a full hearing — usually for a preliminary injunction — must be had.

Money Damages

Courts have the power to award money damages to fully compensate the patent holder for any damages it has suffered as a result of the infringement. There are two forms of money damages: lost profits, and a reasonable royalty. The patent statute provides that if a patent holder is entitled to damages, then the damages award cannot be less than a reasonable royalty. Therefore, if a patent holder cannot prove lost profits or can show only some lost profits, it may seek damages in the amount of a reasonable royalty on the remainder of its sales.

Reasonable Royalty: A reasonable royalty is a calculation of how much the patent holder would have received from the defendant in a hypothetical license negotiation at the time of

the infringement. The amount of the reasonable royalty depends upon royalties the patent holder charged its actual licensees, the going - rate of similar licenses in the industry, the importance of the patent to the infringing product or process, the defendant's anticipated profit on the infringing product and a number of other factors relating to the commercial relationship between the patent holder and the defendant.

Lost Profits: Lost profits are the profits the patent holder would have made but for the defendant's infringement of the patent. To recover lost profits, a patent holder must show: (1) there are no acceptable noninfringing substitutes; (2) the product is in demand during the relevant time period; (3) the patent holder had the manufacturing and marketing capability to meet the demand for the product; and (4) a detailed calculation of the lost profits. Lost profits are easier to calculate in a two-player market—the patent holder and the infringer—than when there are multiple players, because it is easier to show that had the infringer not been in the market, the patent holder would have made the infringer's profits. However, it is also possible to obtain lost profits in a multiple-player market under a “market share” theory, by calculating a percentage of the infringer's revenue based on the patent holder's market share. In addition, a patent holder may be able to recover for price erosion that occurred as a result of the infringer's competition.

Marking

While a defendant that was unaware of a patent prior to receiving a lawsuit may still be liable for patent infringement, its damages may be limited. In order to recover money damages, a patent holder that makes or licenses others to make a patented apparatus must have those patented articles marked with the patent number, to give notice to the public of the patent protection. If the patent holder fails to mark, damages may only be recovered for the time period after the infringer was notified of the patent infringement (*e.g.*, by a cease-and-desist letter or the complaint itself). There is no marking requirement when only method claims are asserted (as opposed to apparatus claims or method and apparatus claims).

Treble Damages and Attorneys' Fees

The Court may order the infringer to pay up to three times the money damages if the patent holder can show that the defendant's conduct was “willful.” In determining whether a party found to have infringed acted willfully, the jury is allowed to consider a number of factors, including: when infringement began relative to the patent's issuance; any deliberate copying by the defendant; any efforts by the defendant to design around the patent; the defendant's investigation of patent and any consequent belief that the patent is invalid or not infringed; the defendant's litigation conduct; the defendant's size and financial condition; the closeness of the case; the duration of defendant's conduct; any remedial actions taken by defendant; the defendant's motivation for harm; and the extent to which the defendant attempted to conceal its conduct.

Often businesses that are accused of infringing a patent seek advice from independent patent counsel and introduce evidence of patent counsel's opinion on the infringement and validity of the patent.

The American Rule is that generally each party bears its own attorneys' fees and expenses. However, in a patent case attorneys' fees may be granted against the defendant when the patent holder prevails on at least part of his infringement claims, and the defendant has willfully infringed the patent and has litigated in bad faith. Similarly, attorneys' fees may be assessed against the patent holder for bringing a lawsuit in bad faith or for fraud during patent prosecution, if the defendant prevails.

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