

GETTING THE DEAL THROUGH

Patents

in 27 jurisdictions worldwide

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Charles R Brainard, Stuart J Sinder, Michelle Carniaux, and Shawn W O'Dowd

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Patent enforcement proceedings

1 Lawsuits and courts

What types of legal or administrative proceedings are available for enforcing patent rights against an infringer, and are there specialised courts in which a patent infringement lawsuit can or must be brought?

Two types of civil proceedings are available by which a patentee can enforce patent rights against a potential infringer, one legal and one administrative. A patentee may institute an infringement suit in a federal court by filing a complaint against a potential infringer. Where potentially infringing goods are being imported into the United States, a patentee may alternatively, or in addition, request that the US International Trade Commission (ITC) institutes an investigation of the potential infringement. The two types of proceedings differ primarily as to the remedies that are available in the event that infringement is proven. A prevailing patentee in a court proceeding may be entitled to both monetary damages and an injunction against future infringement, whereas in an ITC proceeding the primary remedy is an order excluding future importation of the infringing goods into the United States and monetary damages are not available.

A patent infringement suit may be filed in any federal district court that can properly exercise personal jurisdiction over the defendant. There are no specialised patent trial courts. In general, an infringement suit may be brought in any forum with which the defendant has the minimum level of contacts such that it could reasonably have anticipated being sued there. Patent infringement suits are typically filed in a forum where the defendant resides, or where allegedly infringing activity took place.

In contrast to the trial courts, since 1982 all appeals of federal district court decisions in patent cases are heard in the first instance by the US Court of Appeals for the Federal Circuit in Washington, DC. The Federal Circuit was given exclusive jurisdiction over patent appeals for the purpose of promoting uniformity in the development and application of the patent laws. Appeals from decisions of the Federal Circuit may be heard by the US Supreme Court on a permissive basis, but it is relatively rare that the Supreme Court accepts a patent case.

2 Trial format and timing

What is the format of a patent infringement trial, to what extent are documents, affidavits and/or live testimony relied on, is cross-examination of witnesses permitted, are experts (court appointed or private) utilised, are disputed issues decided by a judge or a jury, and how long does a trial typically last?

Patent infringement cases may be tried before a judge or before a jury. Either the plaintiff or the defendant may demand a jury trial, but only if the case involves a claim for monetary damages. In a

jury trial, the judge is responsible for deciding all disputed issues of law, while the jury is responsible for deciding all disputed issues of fact and for applying the law to the decided facts in order to resolve issues of liability and damages. Of course, in a trial to a judge, called a bench trial, the judge resolves all disputed issues.

The primary vehicle for introducing evidence in an infringement trial, whether to a judge or a jury, is through live testimony of witnesses. Counsel for the party offering the witness first questions the witness to elicit direct testimony, after which counsel for the opposing party has the opportunity to cross-examine the witness on matters within the scope of the direct testimony. Typically the offering party is thereafter permitted to conduct re-direct examination (re-examination). The judge on occasion may ask a question to clarify a particular point of interest, but this is relatively uncommon (and particularly so in a jury trial). Documents and other physical items, such as a sample of an allegedly infringing device, may also be received into evidence, but this is typically also done through a witness.

Each party in a patent infringement case will usually present one or more expert witnesses to testify on technical matters relating to infringement and validity, or financial matters relating to damages. In contrast to fact witnesses, experts are permitted to testify as to their opinions on matters within their recognised area of expertise. A trial judge may appoint an expert or a special master to advise the court in especially complex cases, particularly in bench trials.

A significant development in US patent trial practice occurred in 1995 when the Federal Circuit ruled in *Markman v Westview Instruments* that the interpretation of patent claims is an issue of law for the judge to decide, not the jury. As a result, it has become common for courts to conduct so-called 'Markman hearings' prior to trial, during which the judge receives evidence and argument on disputed claim interpretation issues. Some judges believe that claim construction issues should be resolved early in a case, while others believe it makes more sense to wait at least until fact discovery has been largely completed in order to develop the issues as completely as possible. In a jury trial, the result of a *Markman* hearing will be a set of jury instructions by which the judge tells the jury how they are to interpret the patent claims in resolving issues of infringement and validity.

The length of patent infringement trials varies dramatically depending on the number and nature of the issues to be tried, ranging anywhere from a few days to many weeks or even months. Some judges have adopted a practice of imposing strict time limits on the parties at the beginning of the trial, while others take a more lenient approach while exhorting the parties to try the case as efficiently as possible.

HATCH-WAXMAN ACT

A special statutory provision (known as the Hatch-Waxman Act) entitles the owner of a patent covering an approved drug product to sue someone who applies for regulatory approval of the equivalent generic drug even before the generic drug has been marketed. A party seeking to obtain approval from the federal Food and Drug Administration (FDA) to market a new drug must file a New Drug Application (NDA), including a full report of the investigations of the drug's safety and effectiveness. The NDA applicant must provide notice of any of its patent rights covering the drug or the method of using the drug, through an FDA publication entitled *Approved Drug Products With Therapeutic Equivalence Evaluations* (commonly called the Orange Book).

A party who wishes to obtain approval from the FDA to market a generic drug, which is essentially an equivalent to an FDA-approved new drug, may file an Abbreviated New Drug Application (ANDA) including test data sufficient to establish equivalence to the FDA-approved new drug. As part of an ANDA filing, the applicant must certify that either (i) no patent information has been filed by the NDA holder, or (ii) the listed

patent has expired, or (iii) the generic drug will not be marketed until after the listed patent expires, or (iv) the listed patent is invalid, unenforceable, or will not be infringed by use or sale of the proposed generic drug. If a certification of invalidity, unenforceability or non-infringement is made, the ANDA holder is required to provide the patent owner and NDA holder with notice of the ANDA filing and the certification, and provide a detailed statement of the reasons for the certification. The filing of an ANDA and associated certification seeking approval to market the generic drug prior to the expiry of any of the patents listed in the Orange Book for the approved drug product entitles the patent owner to bring an infringement suit within 45 days of the receipt of the notice from the ANDA filer. Upon filing of the suit within the 45 days, approval of the ANDA is automatically stayed for the shorter of 30 months from receipt of the notice from the ANDA filer or until the suit is resolved in favour of the ANDA filer.

The Hatch-Waxman Act also creates a limited exemption from infringement claims for the use of a patented invention solely for purposes reasonably related to, for example, obtaining approval from the FDA for a generic drug.

3 Proof requirements

What are the respective burdens of proof for establishing infringement, invalidity, and unenforceability of a patent?

There are two different burdens of proof applied in patent infringement litigation, depending upon the issue. A patentee bears the burden of proving infringement by a preponderance of the evidence, whereas a party challenging a patent bears the burden of proving invalidity or unenforceability by clear and convincing evidence. Proof by a preponderance of the evidence requires a finding that what the party seeks to prove is more probably true than not. The clear and convincing standard imposes a higher burden, and requires a finding that it is highly probable that what the party seeks to prove is true. The higher burden for invalidity reflects the fact that all US patents enjoy a statutory presumption of validity.

In one limited circumstance, a patentee can be relieved of the burden of establishing infringement and a burden of establishing *non*-infringement is placed on the alleged infringer. This occurs only in cases involving a product alleged to have been made by a process patented in the United States, regardless of where the process is actually practised. The burden of proof will shift to the alleged infringer if a court finds there is a substantial likelihood that the product was made by a patented process *and* the patentee has made a reasonable effort to determine the process actually used, but has been unable to do so. This provision reflects the difficulties that a domestic patentee may face in trying to obtain fact discovery from a foreign manufacturer.

4 Standing to sue

Who is entitled to sue for patent infringement (patent owner, exclusive licensee, non-exclusive licensee, distributor), and under what conditions, if any, can an accused infringer bring a lawsuit to obtain a judicial ruling or declaration on the accusation?

The Patent Statute provides that a 'patentee' is entitled to bring an action for infringement, and it defines 'patentee' as including not only the party to whom a patent was issued but also any successors to title in the patent. Where rights in a patent have been conveyed to another, a court will examine the agreement to determine

whether all or substantially all of the significant rights in the patent have been conveyed, such that the conveyance will be deemed an assignment of the patent. Any conveyance of rights in a patent must be in writing to be effective.

In general, an exclusive licensee will also have standing to bring an action for infringement of a licensed patent, but only as a co-plaintiff with the patent owner. Someone with a lesser interest in a patent, such as a non-exclusive licensee or a mere distributor of patented goods, does not have standing to sue for infringement.

Under certain circumstances, an accused infringer can bring an action for declaratory relief without having to wait for the patentee to bring an infringement action. The general requirements for such a declaratory judgment action are twofold: the patentee must have done something to cause the party seeking relief to reasonably fear that it will face an infringement suit, and that party either must have engaged in activity that could constitute infringement or have made meaningful preparations to engage in such activity. Mere knowledge of a patent that might someday be asserted against the party is insufficient; there must be an actual controversy between the parties at the time the action is initiated. Assuming the conditions for bringing an action are met, the plaintiff may seek a declaratory judgment of non-infringement, invalidity and/or unenforceability. A patentee facing a declaratory judgment claim typically will assert a counterclaim for infringement. Conversely, a party sued for infringement typically will assert a counterclaim for a declaratory judgment of non-infringement and/or invalidity.

5 Inducement/contributory infringement

To what extent can someone be liable for inducing or contributing to patent infringement by someone else?

A person who actively induces someone else to infringe a patent can likewise be liable as an infringer. The inducer must have specifically intended that the person induced engage in the infringing acts, and also must have known, or at least should have known, that its actions would induce infringement.

A person can be liable for contributory infringement as a result of offering to sell or selling in the United States, or importing into

the United States, a component of a patented device, article of manufacture, combination or composition, or a material or apparatus for use in practising a patented process, where the item at issue constitutes a material part of the patented invention. To be a contributory infringer, the person must have known that the item was especially made or especially adapted for use in an infringing manner. Moreover, the item must not be a staple article of commerce suitable for substantial non-infringing use.

6 Infringement by foreign activities

To what extent, if any, can activities which take place outside of the country support a charge of patent infringement?

Infringement generally requires making, using, offering to sell, or selling a patented invention in the United States, or importing a patented invention into the United States, without authority. In certain limited circumstances, however, the reach of the patent laws can extend to extraterritorial activity.

It is an act of infringement to import into the United States, or offer to sell, sell or use within the United States, a product made by a process patented in the United States even though the patented process may be practised outside the country. Nevertheless, a product will not be deemed to have been made by the patented process if it is materially changed by subsequent processes, or it becomes a trivial, non-essential component of another product. Likewise, it is an act of infringement to supply from the United States all or a substantial portion of the components of a patented invention even though the components are combined to 'make' the patented invention only outside the United States. Liability requires that the components be supplied in such a way as to induce their combination outside the United States in a manner that would infringe the patent if the combination occurred within the United States. Similarly, it is an act of infringement to knowingly supply a component of a patented invention that is especially made or adapted for use in the invention, intending that the component will be combined outside the United States in a manner that would infringe the patent if the combination occurred within the United States, unless the component is a staple article of commerce suitable for substantial non-infringing use.

7 Infringement by equivalents

To what extent, if any, are 'equivalents' of the claimed subject matter (not literally covered by the claims) liable for infringement?

A product or process that does not literally include all of the elements of a patented invention may still be found to infringe under the 'doctrine of equivalents'. This is an equitable doctrine developed by the courts in an effort to avoid the inherent unfairness of someone obtaining the benefit of a patented invention but avoiding infringement liability owing to unimportant and insubstantial substitutions for one or more claim elements. Infringement under the doctrine of equivalents requires that each element of a claimed invention be found in the accused product or process, either literally or by a substantial equivalent. Thus, the doctrine of equivalents is applied separately to each individual claim element, not to the invention as a whole.

The classic test for determining infringement by equivalents looks to whether the asserted equivalent performs substantially the same function in substantially the same way to achieve substantially the same result as the corresponding claim element. In recent years a more straightforward test has been developed that looks to whether a person of ordinary skill in the art would view the differences between the element of the invention as claimed

and the corresponding element of the accused product or process as insubstantial, in which case the accused product or process is deemed equivalent.

There is an inherent tension between use of the doctrine of equivalents to broaden claims beyond their literal scope and the basic function of patent claims, which is to provide notice to competitors of what is and is not covered by a patent. Accordingly, the courts have developed a number of limitations on application of the doctrine of equivalents. For instance, the doctrine of prosecution history estoppel bars a patentee from using the doctrine of equivalents to recapture subject matter that was surrendered in order to secure the grant of a patent. Indeed, where a claim element was narrowed during prosecution for a reason substantially related to patentability, it is presumed that the doctrine of equivalents is not available for that claim element, and the presumption can only be overcome by showing that, at the time of the amendment, a person of ordinary skill in the art could not have reasonably drafted a claim that would have encompassed the alleged equivalent. The prior art imposes another significant limitation on the doctrine of equivalents. The doctrine cannot be used to expand the claims to encompass what was already in the public domain.

8 Discovery of evidence

What mechanisms are available for obtaining evidence from an adverse party, from third parties and/or from outside the country, for proving infringement, damages or invalidity?

Under the Federal Rules of Civil Procedure, the scope of permissible pre-trial discovery is extremely broad, with a primary goal being the elimination of trial by surprise. In general, a party is entitled to discover any non-privileged information that is relevant to any claim or defence of any party in a suit. A privilege against disclosure attaches to attorney-client communications and an attorney's work product. The information sought need not be admissible at trial, so long as the discovery appears to be reasonably calculated to lead to the discovery of admissible evidence. On the other hand, in an effort to curb discovery abuse, the Federal Rules also impose limitations on the number and timing of the various forms of discovery that are available.

The Federal Rules provide a variety of mechanisms for obtaining evidence from adverse parties in a lawsuit. Indeed, the parties in a patent case are required to disclose a substantial amount of information through 'initial disclosures' without even waiting for the opposing party to request discovery, including the identification of each individual likely to have discoverable information that the disclosing party may use to support its claims or defences. Other discovery mechanisms include written interrogatories, requests for production of documents and things, depositions by oral testimony, requests for admissions, and requests for inspection of premises. Special rules are also provided for expert discovery, including a requirement that each expert serve a report well in advance of trial containing a complete statement of all opinions to be expressed at trial and the bases for those opinions. Experts are also required to submit to a deposition by the opposing party.

The Federal Rules permit discovery to be taken from third parties, but with additional limitations designed to protect against imposing undue burden or expense. The most common mechanisms for taking third-party discovery are document requests and depositions, but a subpoena must be duly served on a person or entity from whom such discovery is sought in order to impose on them a legal obligation to respond.

Discovery may also be taken from people or entities outside

the United States pursuant to the Convention on the Taking of Evidence Abroad in Civil or Commercial Matters (the Hague Convention), an international treaty to which the United States is a signatory. Taking discovery under the Hague Convention is cumbersome and time-consuming compared to the liberal discovery approach embodied in the Federal Rules of Civil Procedure. In general, where a party seeks discovery from a resident of another signatory country, the party must ask the court in which the case is pending to issue a letter of request (also called a letter rogatory) to the appropriate authority in the other country setting forth the discovery sought. In executing a letter of request, the receiving authority will apply its own laws with respect to the discovery methods and procedures to be followed.

9 Litigation timetable

What is the typical timetable for a patent infringement lawsuit in the trial court and in the appellate court?

The average duration of a patent infringement suit from filing of a complaint to entry of judgment varies widely depending upon the court in which the case is filed. Some federal district courts, such as the Eastern District of Virginia and the Eastern District of Texas, have garnered well-earned reputations as 'rocket docketed'. In those courts, it is not uncommon for an infringement suit to be resolved within a year. On the other hand, there are courts where durations of two or three years are not uncommon.

All appeals from judgments in patent cases are taken to a single appellate court, the US Court of Appeals for the Federal Circuit, and that court has long demonstrated a commitment to resolving appeals with reasonable dispatch. Typically, briefing on an appeal will be completed within three to four months of the appeal being docketed, oral argument will be held within three months after briefing, and a decision will be issued within three to six months of oral argument. Thus, the typical pendency of an appeal is often less than one year from docketing to decision.

10 Litigation costs

What is the typical range of costs of a patent infringement lawsuit before trial, during trial and for an appeal?

The costs associated with patent infringement litigation vary widely depending upon many different factors, including the complexity of the technology, the amount of damages at stake, and even the part of the country in which the case is brought. According to the *Report of the Economic Survey 2005* published by the American Intellectual Property Law Association, for an infringement case where less than US\$1 million is at stake, the average estimated cost through to the end of discovery was US\$350,000, and the total average estimated cost inclusive of trial and appeal was US\$650,000. For cases where between US\$1 million and US\$25 million is at stake, the average estimated cost through to the end of discovery increased to US\$1.25 million, and the total average estimated cost increased to US\$2 million. Finally, where more than US\$25 million is at stake, the average estimated cost through to the end of discovery was US\$3 million, and the total average estimated cost was US\$4.5 million. Since these amounts are only averages, many lawsuits naturally involve much greater cost. This is especially so for cases involving multiple patents, or cases involving very complex technology. The actions of the opposing party and the requirements of the judge can also have a considerable impact on the total costs.

11 Court appeals

What avenues of appeal are available from an adverse decision in a patent infringement lawsuit?

As noted in question 1, all appeals of final judgments in patent cases are heard exclusively by the US Court of Appeals for the Federal Circuit in Washington, DC. This is true whether the appeal is from a US Federal District Court or from the US International Trade Commission.

The aggrieved party may appeal to the Federal Circuit for relief from a judgment adverse to it. To be appropriate for appeal, a judgment must be final in the lower trial court. Quite often, this occurs when all issues, such as patent validity, patent infringement, patent enforceability and damages and other remedies have been determined by the court. Interlocutory appeals are appropriate before the conclusion of the lower court trial in certain circumstances (eg when a preliminary injunction has been granted or denied before a final determination of patent infringement and validity). In special circumstances, the lower court may certify an issue for immediate appeal, though whether such an appeal is heard is within the discretion of the Federal Circuit. Appeals from decisions of the Federal Circuit may be heard by the US Supreme Court on a permissive basis, though the review of patent cases by that court is relatively rare.

The Federal Circuit applies several different standards of review for lower court decisions. In general, the Federal Circuit will only reverse a lower court's finding on a question of fact if the finding was clearly erroneous. A jury's verdict will be reversed only if there was insufficient evidence for any reasonable jury to have reached the finding in question. As to remedies imposed by the lower court during fact discovery or at the end of the patent case, the Federal Circuit will reverse only if there was an abuse of discretion by the lower court. For questions of law, such as claim interpretation, the Federal Circuit reviews those issues de novo. If the Federal Circuit reverses all or part of the lower court's judgments, the case is remanded to the lower court either for a new trial or for a new ruling commensurate with the Federal Circuit's decision.

12 Antitrust considerations

To what extent can enforcement of a patent expose the patent owner to liability for an antitrust violation, unfair competition, or a business-related tort?

An issued US patent gives its owner the right to exclude others from exploiting the patented invention without authorisation. However, in certain cases actions taken pursuant to enforcement of a patent can expose the patentee to a number of different claims ranging from tortious interference with business relations to antitrust violation.

There are two different theories under which the filing of a patent infringement suit can support an antitrust counterclaim by the accused infringer. First, a patentee may be liable for an antitrust violation as a result of bringing an infringement suit knowing that the asserted patent was obtained through material fraud on the US Patent and Trademark Office. Second, a patentee may face antitrust liability if an infringement suit is objectively baseless, such as where the patentee knows the asserted patent is invalid or unenforceable, and is subjectively motivated to impose anti-competitive injury on the defendant. In either case, the other requirements for antitrust liability must still be established, such as market power and intent to monopolise. Patent-related antitrust liability can also arise as a result of attempts to improperly extend the scope of the patent grant through licensing, such as where a patent licence requires the licensee to purchase unpatented goods. Such licensing issues are discussed further in question 26.

Efforts to enforce a patent may also lead to claims against the patentee for any of a variety of state and federal business-related causes of action, such as unfair competition or tortious interference with business relations. Claims of this type have become increasingly common, particularly where a patentee sends a cease-and-desist letter or other notice of patent rights to customers of a manufacturer of allegedly infringing goods. However, since the federal patent laws bar imposition of liability for publicising a patent in the marketplace in good faith, in order to avoid pre-emption, any cause of action based on a communication of patent rights must include bad faith as one of its elements. Facts tending to support the requisite showing of bad faith include threatening infringement suits without any intention of ever filing a suit, sending indiscriminate infringement notices to all members of a trade, and publicising a patent without a good-faith belief in its validity or enforceability.

13 Alternative dispute resolution

To what extent are alternative dispute resolution techniques (eg, mediation, arbitration) available to resolve patent disputes?

Mindful of the tremendous costs and substantial delays inherent in seeking to resolve patent disputes in the federal courts, many parties have looked to alternative dispute resolution (ADR) techniques as a potentially more palatable option. Indeed, the local rules of many district courts now include a requirement that the parties engage in some form of ADR as a routine part of their pre-trial procedures, with the obvious goal of helping to ease the heavy caseload being carried by most federal judges. The most common forms of ADR for resolving patent disputes in the United States are mediation and arbitration, with mediation being the more commonly employed of the two. Both mediation and arbitration can take on a variety of different forms. In general, the techniques differ primarily as to their level of structure and formality, with mediation being the looser and more informal approach. In both cases, however, the purpose is to resolve a dispute more quickly and more cheaply than is possible through litigation, primarily by eliminating or greatly reducing formal discovery and trial.

Arbitration is a process whereby the parties contractually agree to refer a dispute to a neutral arbitrator or panel of arbitrators for an objective determination. Arbitration can be either binding or non-binding, depending upon whether the parties agree to be bound by the decision. Because of its finality, binding arbitration is typically more formal than non-binding arbitration, often involving a structured presentation of each party's case by counsel through live witnesses, depositions, affidavits, and documentary evidence, though generally not subject to formal rules of evidence. A variant of non-binding arbitration is the so-called 'mini-trial', in which the case is not only presented to a neutral, but also to the chief executive officers or other top management representatives of the respective parties, who thereafter attempt to negotiate a settlement with the neutral facilitator serving as a mediator. At the election of the parties, an arbitration proceeding may be overseen by an independent agency, such as the American Arbitration Association (AAA). In fact, the AAA has published a detailed set of rules specifically directed to arbitration of patent disputes. Patent licences will often include an arbitration clause by which the parties agree to refer later disputes over any or all issues relating to the licence to arbitration, and the Patent Statute expressly recognises the enforceability of such contractual provisions.

Mediation is typically far less structured than arbitration, and usually involves each party presenting its case to a neutral mediator in a very informal, narrative-style presentation. The presenta-

tions are usually made by counsel and/or representatives of the parties, and generally do not involve extensive use of evidence. Following the parties' presentations, the mediator engages in 'shuttle diplomacy', alternately meeting with each party in an effort to bring them together in a negotiated settlement. In contrast to arbitration, the mediator does not render a decision. Indeed, while a good mediator will probe the parties on the weaknesses in their respective cases, he or she will rarely pass judgment on the ultimate issues in dispute. The goal is simply to help the parties settle their dispute, and for that reason the emphasis is often on the costs and risks of resolving the dispute in court.

Scope and ownership of patents

14 Types of protectable inventions

Can a patent be obtained to cover any type of invention, including software, business methods and/or medical procedures?

The US patent laws establish the categories of subject matter eligible for patent protection. Any new and useful process, machine, manufacture, or composition of matter, and any new and useful improvement thereon is protectable as a utility patent. New, original and ornamental designs for articles of manufacture are protectable as design patents. Asexually reproduced, distinct and new varieties of plant, including cultivated sproutings, mutants, hybrids, and newly found seedlings, other than a tuber-propagated plant or a plant found in an uncultivated state, are protectable by a plant patent.

Software, business methods and medical procedures are all eligible for patent protection, providing they meet the other requirements of the patent laws (eg utility, novelty and unobviousness). With respect to patents related to medical procedures and business methods, there are certain limitations as regards to enforcement. For example, remedies against patent infringement do not apply to medical practitioners and related health entities for performance of a medical activity. Additionally, in some cases, there are limits on liability for infringement of a patent claiming methods of doing business for an infringer who: (i) reduced the subject matter to practice at least one year before the effective filing date of the patent; and (ii) commercially used the subject matter before the effective filing date of the patent.

Laws of nature, printed matter, abstract mathematical algorithms, and mental processes are not eligible for patent protection.

15 Patent ownership

Who owns the patent on an invention made by (i) a company employee, (ii) an independent contractor, or (iii) multiple inventors, and how is patent ownership officially recorded and transferred?

The presumptive owner of patentable subject matter is the inventor, in the case of sole invention, or the joint inventors (ie jointly), in the case of joint invention. With respect to patent rights that arise out of an employment relationship, the general rule is that the sole or joint inventors own the patent rights, in the absence of express contractual arrangements to the contrary. However, an employer may own the patent rights if the employee(s) was/were hired to invent. Most large companies require their employees to sign an explicit agreement transferring patent ownership to the company.

Even if the employer does not own the patent rights, the employer may still have a non-exclusive and non-transferable royalty-free licence ('shop right') to use the invention, when the employee uses the time or facilities of his or her employer to

conceive an invention or to reduce it to practice.

A patent owner may assign or convey his or her patent rights; such an assignment must be in writing. The assignment should be recorded in the US Patent Office. An assignment is void against any subsequent purchaser or mortgagee for a valuable consideration, who does not know of the prior transfer, unless the assignment is recorded within three months from its date or prior to the date of such subsequent purchase or mortgage.

In the case of joint owners of a patent, in the absence of any agreement to the contrary, each of the joint owners may make, use, offer to sell, or sell the patented invention within the United States, or import the patented invention into the United States, or transfer his or her rights in or to the patent, without the consent of, and without accounting to, the other owners.

Defences

16 Patent invalidity

How and on what grounds can a patent be invalidated?

In patent litigation, an accused infringer may use invalidity as a defence to a charge of infringement, and may ask the court to declare that the claim is invalid. An accused infringer may also initiate a declaratory judgment action (asking a court to declare that the claim is invalid), under certain circumstances. In particular, there must be both: (i) an explicit threat or other action by the patentee which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit; and (ii) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity.

A patent claim can be invalidated by a court on any ground that would have barred issuance of the claim in the first instance. These grounds include:

- lack of utility (for a claim in a utility patent);
- subject matter not capable of being patented;
- anticipation by or obviousness in view of the prior art;
- the claimed invention was in public use or on sale in the United States more than one year prior to the date of the application for the patent;
- the inventor abandoned the claimed invention;
- the claimed invention was first patented or was the subject of an inventor's certificate, by the inventor (or the inventor's legal representative or assigns) in a foreign country prior to the date of the application for patent in the United States on an application or inventor's certificate filed more than 12 months before the filing of the patent application in the United States;
- the inventor did not, him(her)self, invent the subject matter of the claim; in other words, someone else was the true inventor;
- prior to the inventor's date of invention, the invention was made in the United States by someone else who had not abandoned, suppressed or concealed it;
- the patent specification does not adequately convey that, at the time the patent application was filed, the inventor had intellectual possession of the claimed invention;
- the patent specification does not adequately describe the claimed invention so as to enable a person of ordinary skill in the art to make and use the claimed invention; and
- the patent specification fails to describe the inventor's best mode of carrying out the claimed invention; in other words, what the inventor thought at the time of filing was the best way he or she knew of making or using the invention.

17 Absolute novelty requirement

Is there an 'absolute novelty' requirement for patentability, and if so, are there any exceptions to the requirement?

In the United States, there is no 'absolute novelty' requirement for patentability. The United States provides a one-year grace period for filing a patent application on subject matter that has previously been made public, placed on sale, or has been commercialised.

18 Obviousness or inventiveness test

What is the legal standard for determining whether a patent is 'obvious' or 'inventive' in view of the prior art?

A patent claim is 'obvious', and thus invalid, if the claimed subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the said subject matter pertains.

In evaluating the question of obviousness, the scope and content of the prior art, differences between the prior art and the claim at issue, and the level of ordinary skill in the pertinent art should be considered. Secondary considerations such as commercial success, long felt but unsolved needs, failure of others, etc, may be considered indicia of non-obviousness.

19 Patent unenforceability

Are there any grounds on which an otherwise valid patent can be deemed unenforceable due to misconduct by the inventors or the patent owner, or for some other reason?

Under certain circumstances an otherwise valid patent can be deemed unenforceable. These include fraud in the procurement of the patent (inequitable conduct), misuse, and unreasonable and/or inexcusable delay in the filing of a lawsuit against the infringer (laches and equitable estoppel). In such cases, the patent is not declared invalid but the patent owner is precluded from any remedy against the alleged infringer.

The US patent laws impose a duty of candour and good faith on all those involved in the prosecution of a patent application, including applicant(s) and their attorney(s) and assign(s). A breach of this duty, eg by misrepresentation or omission of material information to the US Patent Office, coupled with an intent to deceive, could result in a finding of inequitable conduct. Particular areas of concern include misnaming of inventors, withholding information regarding prior art, and submission of false or misleading affidavits.

A court may also withhold any remedy for infringement if a patent owner attempts to exploit a patent in an improper manner by, for example, violating the antitrust laws, or expanding the patent beyond its legal physical or temporal scope. Typical examples involve: (i) requirements for the purchase of unpatented goods for use with a patented apparatus or process in the case where the patentee has market power; (ii) covenants not to deal in products that compete; and (iii) coercive package licensing of patents.

A court may also withhold remedies for infringement under the doctrines of laches and equitable estoppel. Laches may bar liability for damages on infringing activities which occurred prior to bringing the lawsuit where: (i) the patent owner unreasonably and inexcusably delays bringing suit; and (ii) the accused infringer suffers material prejudice (either financial or evidentiary prejudice) attributable to the delay. Equitable estoppel will bar the entire lawsuit where: (i) a patent owner, through misleading conduct (statements, action, inaction, or silence where there was an obligation to speak) leads the accused infringer to reasonably infer that the patent owner does not intend to enforce its patent against the accused

infringer; (ii) the accused infringer relies on that conduct; and (iii) owing to its reliance, the accused infringer will be materially prejudiced if the patent owner is allowed to proceed with its claim.

Remedies

20 Monetary remedies for infringement

What monetary remedies are available against a patent infringer (reasonable royalty, lost profits, or some other basis), when do damages start to accrue, and do damage awards tend to be only nominal, provide fair compensation or be punitive in nature?

Monetary damages are commonly awarded to a patentee when its patent is found to be valid and infringed. These damages awards are intended to fairly compensate the patentee for losses incurred as a result of infringement. A damages award may be increased to be punitive if the infringement is found to be wilful (see question 23). A patentee will be awarded its profits on all lost sales resulting from the infringement if the patentee can show that ‘but for’ the infringement, the patentee would have made the sales of the infringer. Accordingly, the patentee must show marketplace demand for the product, a lack of non-infringing substitutes, and sufficient capacity to make these sales. In the absence of such a showing, a patentee is entitled to a reasonable royalty. Such a royalty is usually reflected as a percentage of revenue for the infringing sales. The determination of the amount of such a royalty in the trial court tends to rely heavily on expert testimony, and takes into account a whole host of factors set forth in the *Georgia-Pacific* case.

Damages start to accrue from the time the alleged infringer is put on notice of the alleged patent infringement. Properly marking the patented product with the patent number will be sufficient notice to start the accrual of damages (see 25 below). Notice may also be accomplished by sending an appropriate letter to the infringer identifying the patent number. Until recently, a patentee could not obtain damages for infringement prior to issuance of the patent. Since the introduction of patent application publication in the United States, reasonable royalty patent damages may start accruing when the alleged infringer is notified of the published application. In such a case, the invention as claimed in the patent application must be substantially identical to the invention as claimed in the issued patent.

21 Injunctions against infringement

To what extent is it possible to obtain a temporary injunction or a final injunction against future infringement, and is an injunction effective against the infringer’s suppliers or customers?

Prior to a final determination by a trial court, it is possible to obtain a temporary injunction against future infringement. A temporary restraining order (TRO) may be obtained by the patentee in an ex parte proceeding (ie without the alleged infringer’s participation in court), though extraordinary circumstances must be present for such relief to be granted. If a patentee has a strong case for patent validity and infringement, a preliminary injunction may be granted and would be in effect until a final determination of the issues is made. To obtain a preliminary injunction, the patentee must show a likelihood of success on the merits for the issues of validity and infringement. In deciding whether to grant a preliminary injunction, the court must take into consideration the balance of hardships between the parties, the effect on the public interest, and the prospects of irreparable harm to either party. As noted in question 11, the grant or denial of a preliminary injunction is

immediately appealable to the Federal Circuit.

At the close of trial, and assuming that the patent is found to be valid, infringed, and enforceable, the court has the discretion to grant a permanent injunction against the infringer. An injunction will be effective against suppliers and customers if the products supplied or purchased have been determined to infringe the patent. In such a case, and after appropriate notice of the court’s injunction, the supplier or customer could be in contempt of the court order and subject to sanctions by the court if it violates the injunction.

22 Attorneys fees

Under what conditions can a successful litigant recover its costs and/or attorneys fees?

In the United States, although the prevailing party in patent infringement litigation can ordinarily recover certain limited costs (deposition transcript fees, filing fees, photocopies, etc) from the losing party, each party is ordinarily responsible for its own attorneys fees. However, attorneys fees may be awarded to a prevailing party (paid by the losing party) in certain exceptional cases. To obtain such an award, it must be shown that either: (i) the losing party participated in a wilful, excessive abuse of the judicial system; (ii) the patent owner engaged in inequitable conduct in dealing with the Patent Office; or (iii) the infringement was wilful. Even with such a showing the awarding of attorneys fees is left to the discretion of the district court. An award of attorneys fees and/or costs will be reversed only if, on appeal, the Federal Circuit determines that the trial court award was an abuse of discretion.

23 Wilful infringement

Are additional remedies available against a deliberate or wilful infringer?

If an accused infringer has notice of the patent and acts unreasonably after being given such notice, then a court may make a determination that the accused infringer has acted wilfully. In such a case, the court has the discretion to award up to triple the amount of monetary damages, as well as attorneys fees incurred by the patentee in the litigation. It is generally accepted that a competent opinion of counsel that the patent is either invalid or not infringed is a sufficient defence to an accusation of wilful infringement. If the accused infringer seeks to rely on such an opinion, then all facts surrounding the opinion would be subject to discovery during the litigation and no longer protected by the otherwise applicable attorney-client privilege. In a 2004 decision, the Federal Circuit held that a defendant’s failure to rely on such an opinion does not give rise to an inference that no opinion was obtained or that any opinion was unfavourable to the defendant.

24 Time limits for lawsuits

What is the time limit for seeking a remedy for patent infringement?

Unreasonable delay in filing a patent infringement suit may reduce the amount of damages, and in some cases, prevent relief of any type. US courts provide a general rule that a delay of six years from the time that the patentee knew or should have known of the infringement creates a presumption of the equitable defence of laches. It is noted that all relevant factors concerning the delay and the accused infringer’s reliance on that delay are considered in determining whether laches is present, and laches has been found in situations where the delay is less than six years. The effect of laches is to bar recovery of damages prior to filing the suit. In more egregious circumstances, unreasonable delay in filing a pat-

ent infringement suit may result in a court determination of equitable estoppel. In such a case, the patentee would be estopped from obtaining any relief against the alleged infringer.

25 Patent marking

Is a patent holder obligated to mark its patented products in any way, and if so, how must the marking be made, and what are the consequences of a failure to mark?

A patentee is not obliged to mark its patented products with the US patent number. However, proper patent marking effectively puts all potential infringers on notice of the patentee's rights for purposes of starting the clock on the accrual of patent damages. For notice purposes, when a patent includes any apparatus claims, the patentee is required to mark its products and require its licensees to mark their products covered by those claims with the US patent number. No marking is required for notice purposes if no products covered by the patent are sold by the patent owner or by a licensee. No notice is required for a patent containing only process claims. As explained under 20 above, however, in the absence of marking, providing actual notice by the patentee to the alleged infringer, such as by sending a cease-and-desist letter or by filing an infringement lawsuit, will begin the accrual of patent damages.

Licensing

26 Voluntary licensing

Are there any restrictions on the contractual terms by which a patent owner is permitted to license a patent?

Tying arrangements are licences which tie the licensing of a patent to the purchase of an unpatented item or component. If a patent gives the patentee monopolistic control of a market, then use of that patent to create a tying arrangement is considered to violate the US antitrust laws. This 'misuse' can be used as a defence against a charge of infringement and render the patent unenforceable, so that the trial court may deny relief, unless and until the misuse ceases. Tying arrangements are not per se illegal in the absence of a showing of market power in the relevant market in view of the circumstances.

The unconditional sale of a patented device exhausts the patentee's right to control the purchaser's use of the device thereafter. The exhaustion doctrine does not apply to an expressly conditional sale or licence. An example of a conditional licence would be a single-use licence (ie the licensee is authorised to use the patented product once). In such a case, the limitations of the expressly conditional licence are factored into the cost of the purchase.

There are other restrictions on voluntary licences for patents. For example, the term of a patent licence cannot extend beyond the expiry date(s) of the licensed patent(s). Also, for public policy reasons, it is impermissible for a patentee to prevent a licensee from contesting the validity of one or more licensed patents.

27 Compulsory licences

Are any mechanisms available to obtain a compulsory licence to a patent, and how are the terms of such a licence determined?

Under current US law there are no mechanisms for obtaining a compulsory licence to a patent. However, by virtue of involvement in an industry standards-setting organisation, a patent owner can be obliged to grant a licence to all interested parties on fair, reasonable, and non-discriminatory terms when the patent covers an established industry technology standard. Aside from compulsory

licences, US law does provide for 'intervening rights' in certain circumstances. When a patent is subjected to reissue or re-examination proceedings (see question 33), the resulting claims may be of a different scope than those in the original patent. If an accused infringer has a product that does not infringe a claim of the original patent but does infringe a claim of a reissue patent, for example, then the accused infringer will obtain intervening rights. The result is that products of the accused infringer already existing on the date of the reissue patent do not infringe. In certain such cases, a court may even allow an accused infringer to maintain a certain level of production volume during the term of the reissue patent.

Patent Office proceedings

28 Patenting timetable and costs

How long does it typically take, and how much does it typically cost, to obtain (and maintain) a patent?

Legal fees for preparing and filing a patent application typically depend on the subject matter sought to be patented. A typical cost for preparation and filing of an application can range from US\$5,000 to US\$7,500 for a very simple invention to US\$10,000 to US\$15,000 for more complex inventions, to US\$25,000 or more for very involved biotechnology or software inventions (excluding filing fees).

Most patent applications require drawings to illustrate the invention. Since the drawings must conform to specific requirements, these drawings should generally be prepared by a professional draftsman. Typical fees for the preparation of drawings are in the range of US\$60 to US\$120 per drawing sheet.

US Patent Office fees were raised significantly as of 8 December 2004. The exact amount of the filing fee charged by the US Patent Office varies with the number of claims filed, and the type of application that is filed. Costs for filing a non-provisional application currently begin at US\$1,000 for applications with 20 claims including three independent claims. Patent applicants which are 'small entities' (having fewer than 500 employees) and have not licensed the invention to a large entity receive a 50 per cent discount on most fees.

Additional legal fees are typically incurred during prosecution of the application for attending to such tasks as responding to actions by the Patent Office.

After an application is approved for issuance, an issue fee must be paid. The issue fee is currently US\$1,400.

After issuance of a patent, maintenance fees must be paid in order to maintain the patent. These maintenance fees are due at 3.5 years, 7.5 years and 11.5 years after issuance of the patent, and are currently US\$900, US\$2,300 and US\$3,800 respectively.

US patent applications, on average, take about 24 months to issue. However, the actual pendency time is highly dependent on the subject matter of the application. For example, patent applications that relate to business methods typically take significantly longer than 24 months to issue because of the Patent Office's backlog of applications in this area. The pendency time is also highly dependent on the extent to which the patent examiner finds reasons to reject the claims of the application.

29 Prior art disclosure obligations

Does an inventor have an obligation to disclose prior art to the Patent Office examiner?

US patent laws impose a duty of complete candour and good faith on all those involved in the prosecution of a patent application,

Update and trends

The most significant development in US patent laws could be the adoption of major changes to the US patent system. Legislation is currently pending in the US Congress to convert the United States from its present first-to-invent model to a first-to-file priority system like the rest of the world. The legislation would also institute a post-grant opposition procedure and adopt an absolute novelty standard for patentability – again, like almost all other countries – with a grace period exception only for the inventor's own disclosures, to replace the current one-year grace period for all prior art. A number of other changes, such as the elimination of the best mode requirement, are also being proposed. It is unclear whether these proposed major changes will be enacted, and if they are, when that would occur.

A number of significant patent law issues have also been developing in the US courts. One issue concerns the extraterritorial effects of US patents. In *NTP Inc v Research in Motion Ltd*, the US Court of Appeals for the Federal Circuit addressed the issue of infringement liability for a company practising part of the claimed invention in Canada. This case concerns e-mail services provided by RIM's system supporting its BlackBerry® devices. An 'interface' or 'interface switch' is provided by RIM in Canada that provides relay functions for customers' e-mail messages. The Federal Circuit held that system claims which include an interface or interface switch element could be infringed by RIM because the use of RIM's system is in "the place where control of the system is exercised and beneficial use of the system is obtained", which is the place where Blackberry devices are used in the United States. Conversely, the Federal Circuit held that the method claims of

the patent which include steps performed by the RIM relay system located in Canada would not be infringed.

Another seminal issue concerns what is and what is not patentable subject matter. In *Metabolite Inc v Laboratory Corp*, the Federal Circuit upheld a patent claim to a diagnostic method of measuring elevated levels of homocysteine in human patients (a potential link to cardiovascular disease and other ailments), and "correlating" that finding with a deficiency of two particular B vitamins. Though the claim arguably covers a natural phenomenon (the relationship between homocysteine levels and vitamin deficiencies), and though the claim includes a mental 'correlating' step, the Federal Circuit did not question that the claim fell within the statutory limits of patentable subject matter. The US Supreme Court has agreed to hear this case in 2006, and for the first time in a quarter century, will most likely provide guidance on the limits of patentable subject matter under United States patent laws.

Though patent suits are not often heard by the Supreme Court, that court will hear a second patent case in 2006. In *eBay Inc v MercExchange LLC*, the court will take up the issue as to whether, in the absence of exceptional circumstances, a court must issue a permanent injunction in favour of a prevailing patentee in litigation. The current US patent law provides that courts may grant injunctions against infringement "in accordance with the principles of equity". However, the courts have nearly automatically issued permanent injunctions against adjudicated infringers. The US legislature is also considering whether to change the law so that injunctive relief may only be obtained if the patent owner is itself practising the patented invention in the marketplace.

including applicant(s) and their attorney(s) and assign(s). The duty requires each individual involved in the prosecution of an application to disclose to the patent examiner all information known to them to be material to the patentability of any pending claim, eg prior art affecting novelty and/or obviousness, or information refuting or inconsistent with positions taken by the applicant on patentability during prosecution. This duty is ongoing throughout the entire pendency of the patent application, right up until the patent is issued. There is no obligation on the applicant to search for prior art, but any known prior art must be disclosed. Once the patent is issued, there is no obligation to submit later discovered prior art. Failure to meet the duty of candour and good faith may lead to unenforceability of any patent issuing from the patent application and could result in an award of attorneys fees against the patent owner who brings an infringement lawsuit (see questions 19 and 22).

30 Patent Office appeals

Is it possible to appeal an adverse decision by the Patent Office in a court of law?

An applicant who has received a second or final office action from an examiner may make an appeal before the Board of Patent Appeals and Interferences (BPAI). After the filing of a notice of appeal, the applicant (now appellant) and the examiner prepare briefs on the disputed issues. A panel of three administrative patent judges within the Patent Office will then review the briefs and hear

oral arguments if requested by the appellant. The BPAI may reverse the examiner, affirm the examiner, or enter new grounds for rejection. If the BPAI enters new grounds for rejection, a rehearing may be requested. After proceedings are completed before the BPAI, the case is then returned to the examiner for further proceedings.

If the BPAI affirms the examiner or enters new grounds for rejection, the appellant may appeal to the US Court of Appeals for the Federal Circuit. Alternately, the appellant may file a de novo civil lawsuit against the Patent Office commissioner in the district court for the District of Columbia requesting the court to order the Patent Office to grant the patent.

31 Oppositions or protests to patents

Does the Patent Office provide any mechanism for opposing or protesting the grant of a patent?

A protest may be filed by any member of the public against a pending patent application. However, a protest will be considered only if, among other things, the protest is submitted prior to the date the application was published or the mailing of a notice of allowance in connection with the application, whichever occurs first. Active participation by the protester, however, ends with the filing of the protest. It is up to the patent examiner whether, and how, to act on the protest.

A member of the public may also file a petition for the institution of a public use proceeding. A public use proceeding may be instituted when the petition, supported by affidavits or declara-

tions, makes a prima facie showing that the invention claimed in an application had been in public use or on sale more than one year before the filing of the application. In the United States, if an invention was in public use or on sale more than one year before the filing of the application, patent protection for that invention is barred.

Like a protest, a petition for institution of public use proceedings must be submitted prior to the date the application was published or the mailing of a notice of allowance in connection with the application, whichever occurs first.

32 Priority of invention

Does the Patent Office provide any mechanism for resolving priority disputes between different applicants for the same invention, and what factors determine who has priority?

The United States has a first-to-invent patent system, rather than a first-to-file system as in most other countries. Thus, an applicant who is second to file an application can establish priority by showing an earlier date of invention.

Priority of invention is generally awarded to the party who can show an earlier reduction to practice of the invention (the filing of a patent application is considered to be a constructive reduction to practice). However, the second party to reduce the invention to practice will prevail if that party can show: (i) a conception date earlier than the conception date of the other party; and (ii) reasonable diligence in reducing the invention to practice, from a time prior to conception by the other party.

The US Patent Office has jurisdiction to conduct 'interference' proceedings to determine priority of invention between a pending application and one or more pending applications or issued patents. Such a proceeding is conducted before the Board of Patent Appeals and Interferences.

The US Patent Office does not have jurisdiction to conduct interference proceedings which involve only patents. Instead, a civil court action must be filed in the federal courts to resolve such a dispute.

33 Modification of patents

Does the Patent Office provide procedures for modifying, re-examining and/or revoking a patent after it has been granted, and can a court amend the patent claims during a lawsuit?

After a patent has been granted, a patentee may file an application to 'reissue' a patent to correct an error in the patent which was made without any deceptive intention, where, as a result of the error, the patent is deemed wholly or partly inoperative or invalid.

A common basis for filing a reissue application is that the claims are too narrow or too broad. A patentee seeking to broaden the scope of the claims of the original patent must apply within two years from the grant of the original patent. However, a reissue will not be granted to 'recapture' subject matter which was surrendered to obtain the original patent.

The patent owner, or any member of the public, may also file a request for 're-examination' of a patent any time during the period of enforceability of the patent. Prior art considered during re-examination is limited to prior art patents or printed publications, and a substantial new question of patentability must be present for re-examination to be ordered.

Re-examination proceedings can be either ex parte, where a third party re-examination requester has very limited involvement in the proceedings, or inter partes, where the requester participates in the entire proceedings (including, for example, providing comments in response to office actions). However, when the requester participates, it is bound by the result in any later court proceeding.

34 Patent duration

How is the duration of patent protection determined?

In the case of patents (except design patents) based on applications filed on or after 8 June 1995, the patent term is 20 years measured from the date the application for the patent was filed. If the patent claims the benefit of the filing date of an earlier filed US (non-provisional) application or applications, the term is 20 years from the earliest filing date of such applications from which priority is claimed.

In the case of patents (except design patents) based on applications filed before 8 June 1995, the patent term is the greater of: (i) 17 years measured from the date the patent is issued; or (ii) 20 years measured from the filing date of the application or from the earliest filing date of any US (non-provisional) application from which the application in question claims priority.

In the case of design patents, the patent term is 14 years measured from the date the patent is issued.

In certain very limited circumstances, the patent term may be extended. The circumstances under which the term may be extended generally relate to: (i) failure by the US Patent Office to act promptly; (ii) proceedings (eg an interference, a secrecy order, and appellate review) which delay issuance of a patent; and (iii) patents which involve products or methods that have been subject to regulatory delays (such as delays in approving drugs by the Food and Drug Administration).

Kenyon & Kenyon

Contact: Stuart J Sinder

One Broadway
New York
NY 10004
USA

Tel: +1 212 425 7200
Fax: +1 212 425 5288
e-mail: ssinder@kenyon.com
Website: www.kenyon.com