



# ICLG

The International Comparative Legal Guide to:

## Patents 2016

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A practical cross-border insight into patents law

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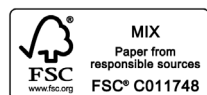
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# USA

Kirkland & Ellis LLP / Spence PC



## 1 Patent Enforcement

### 1.1 How and before what tribunals can a patent be enforced against an infringer?

Actions to enforce U.S. patents may be brought in U.S. district courts or, under more limited circumstances, at the U.S. International Trade Commission (ITC).

Claims for patent enforcement may be brought in a U.S. district court in any state where an accused infringer engaged in continuous and systematic activities or committed a specific act of infringement. Patent owners may initiate an infringement action by serving the accused infringer with a summons and complaint.

Where infringing products are being imported into the U.S., and a domestic industry exists for the patented product, patents may also be enforced by the ITC. The ITC may act on its own accord to enforce patents, but more commonly a complaint must be filed.

### 1.2 What are the pre-trial procedural stages and how long does it generally take for proceedings to reach trial from commencement?

The timing and sequence of pre-trial activities in U.S. patent litigation varies from court to court. Many U.S. district courts have adopted local patent rules to help standardise and streamline pre-trial procedure.

While pre-trial procedure may vary, all U.S. patent litigation begins at the pleading stage. This includes a complaint by the plaintiff, an answer and counterclaims, if any, by the defendant, and, if necessary, a reply to the counterclaims by the plaintiff. Next, the U.S. district court will schedule a scheduling conference.

Prior to the court-scheduled conference, the parties must meet to discuss the nature of the case and submit a joint report addressing the scope and agreed-upon limitations of discovery. The parties must also exchange initial disclosures. U.S. district courts then generally issue a case management order with deadlines for the pre-trial stages.

Next, the parties engage in extensive fact discovery. Some U.S. district courts may also require infringement, invalidity, or unenforceability contentions. Motion practice to resolve disputes that arise during fact discovery is common.

Generally, fact discovery is followed by expert discovery on technical and/or damages issues. Expert discovery typically includes the exchange of expert reports and depositions of expert witnesses. Because U.S. district courts are required, as a matter of law, to resolve

disputed claim terms prior to trial, claim construction proceedings typically begin within the first six months of litigation and include significant briefing and a specialised (*Markman*) hearing.

After the claim construction order, litigants often file summary judgment motions to resolve issues that can be decided as a matter of law. Prior to trial, the litigants may also file motions to limit the evidence that can be heard by the jury, if one has been requested. Depending on the U.S. district court, the pre-trial period may be as short as nine months but normally is closer to two years.

In ITC actions, the discovery period is typically completed within a year after the ITC initiates the proceeding.

### 1.3 Can a defence of patent invalidity be raised and if so how?

Any party with standing may initiate an action for declaratory judgment that a patent is invalid. Also, a patent defendant in a U.S. district court may bring an affirmative counterclaim for declaratory judgment of invalidity. Finally, a patent infringement defendant may be required to plead patent invalidity as an affirmative defence otherwise the defence may be waived.

### 1.4 How is the case on each side set out pre-trial? Is any technical evidence produced and if so how?

Prior to trial, patent litigants submit individual or joint pre-trial statements that identify witnesses and exhibits. Patent litigants next exchange objections to the same. If a litigant fails to disclose an exhibit, or fails to object to it, the litigant may waive its right to use or object at trial.

Prior to trial, patent litigants may also be required to submit joint proposed jury instructions or proposed modifications to standard jury instructions.

Depending on the nature and complexity of the issues to be litigated, a U.S. district court may request a technical tutorial. For example, it is not uncommon to hold a technology tutorial prior to the claim construction (*Markman*) hearing.

### 1.5 How are arguments and evidence presented at the trial? Can a party change its pleaded arguments before and/or at trial?

Most patent cases are tried by a jury. The trial begins with jury selection. After jury selection, each party is given the opportunity to present an opening statement.

The opening statements are an opportunity to tell the jury what each party expects the evidence will show during trial. Next, the parties present the evidence. The patent owner, with the burden of proof on infringement, normally goes first. Both parties present both fact and expert witnesses. After a direct examination of a witness, the opposing party is permitted cross examination. During witness examination, both parties may move exhibits into evidence and the non-moving party may object.

Finally, each party presents closing arguments. The closing arguments are an opportunity to tell the jury what the evidence has been, how it relates to the jury instructions, and why the evidence and the law require a verdict in their favour.

Although the general theories must be developed and disclosed before trial, the U.S. district court may allow a party to amend its pleadings before trial for good cause and in exceptional circumstances, may even allow an amendment based on the facts shown at trial.

#### **1.6 How long does the trial generally last and how long is it before a judgment is made available?**

For most patent infringement matters in the U.S., there is a right to a jury trial if one is requested by one of the parties. Exceptions are cases before the ITC and litigation concerning the right to sell generic drugs before final approval by the FDA (commonly called "ANDA litigation"), which are bench trials to a judge.

Trials normally last from three trial days to several weeks. In a jury trial, the jury deliberates immediately after the trial is finished: that may last a few hours or a couple of days. If tried before a judge without a jury, the judge will typically offer a written opinion explaining his decision. Post-trial motions and appeals can take around two additional years.

#### **1.7 Are there specialist judges or hearing officers and if so do they have a technical background?**

On June 7, 2011, 14 U.S. district courts were selected to participate in a 10-year patent pilot programme designed to enhance expertise in patent cases. When a new patent case is filed, it will be assigned randomly to any judge in a district. If the randomly assigned judge is not designated under the programme, the judge may decline to accept the case, and the case will be reassigned.

The U.S. Court of Appeals for the Federal Circuit (Federal Circuit), hears all patent-related appeals and its judges have thus developed substantial patent expertise.

The administrative judges at the ITC have developed substantial patent expertise by hearing a large number of patent cases, but often the individual ITC judges do not have a technical background.

It is the exception that any of those judges have technical backgrounds.

The administrative judges at the Patent Trial and Appeal Board (PTAB) do not hear "infringement actions"; only *inter partes* reviews (IPR), covered business method reviews (CBMR), or post-grant reviews (PGR) challenges to patent validity. Generally speaking, these judges are all patent attorneys with technical backgrounds.

#### **1.8 What interest must a party have to bring (i) infringement (ii) revocation and (iii) declaratory proceedings?**

Generally, a party bringing the infringement action must be the patent owner. Some U.S. district courts have allowed an exclusive

licensee to bring an action in its own name without joining the patent owner.

Revocation proceedings do not exist in the U.S. but certain entities can challenge the validity of a patent in *ex parte* re-examination, IPR, CBMR, or PGR proceedings. In a CBMR and PGR proceeding a non-patent owner petitioner can challenge validity on any grounds, including unpatentable subject matter, lack of novelty, obviousness, or failure to meet the standards of § 112 of the patent statute. In *ex parte* re-examination and IPR proceedings a party can challenge validity only on lack of novelty or obviousness over patents or printed publications. An IPR, CBMR, or PGR may not be brought by a patent owner.

Any party may also bring an action seeking declaratory judgment that a patent is invalid in U.S. district court so long as the facts show there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant relief.

An ITC action requires that the party bringing suit has an interest in the patent (the patent owner is likely to be required) and there must be a showing of injury to a domestic industry.

#### **1.9 Can a party be compelled to provide disclosure of relevant documents or materials to its adversary and if so how?**

Parties may obtain discovery regarding any non-privileged matter that is relevant to a claim or defence so long as it is proportional to the needs of the case, taking into account five factors: (1) the importance of the issues at stake in the action; (2) the amount in controversy; (3) the parties' relative access to relevant information, the parties' resources; (4) the importance of the discovery in resolving the issues; and (5) whether the burden or expense of the proposed discovery outweighs its likely benefit.

Third parties may be compelled to provide discovery through subpoena practice.

If, after notice and an attempt to meet and confer, a party fails to provide requested discovery that falls within scope of permitted discovery, the requesting party may move the court.

#### **1.10 Can a party be liable for infringement as a secondary (as opposed to primary) infringer? Can a party infringe by supplying part of but not all of the infringing product or process?**

A party that aids or abets a direct infringer may be liable for two forms of secondary (or indirect) infringement. A party that actively induces infringement is liable as an inducer of infringement under § 271(b). A party that offers to sell, or sells, a component of a patented invention constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use, may also be liable as a contributory infringer under § 271(c).

#### **1.11 Can a party be liable for infringement of a process patent by importing the product when the process is carried on outside the jurisdiction?**

Yes, § 271(g) allows a claim for infringement for a product imported into the U.S. made by a process patented in the U.S., unless the product is materially changed before importation or it is a trivial part of another product.

### 1.12 Does the scope of protection of a patent claim extend to non-literal equivalents?

Under the doctrine of the equivalents, a product or process that does not literally infringe a patent claim may nonetheless be found to infringe if there is equivalence between the elements of the accused product or process and the claimed elements of the patented invention. The doctrine of prosecution history estoppel may prevent a patent owner from recapturing, through the doctrine of equivalents, subject matter surrendered to acquire the patent.

### 1.13 Other than lack of novelty and inventive step, what are the grounds for invalidity of a patent?

Patent claims may be held invalid for: (1) lack of enablement; (2) inadequate written description; (3) indefiniteness; and (4) failure to claim patentable subject matter. In addition, a patent may be found to be unenforceable due to inequitable conduct before the Patent Office during prosecution of the patent. (A patent applicant must disclose best mode, but failure to do so is no longer a defence to patent infringement.)

### 1.14 Are infringement proceedings stayed pending resolution of validity in another court or the Patent Office?

A U.S. district court has the inherent power to control its own docket, including the power to stay proceedings. In deciding whether to stay litigation pending post-grant proceedings, courts typically consider the following three non-exclusive factors: (1) whether a stay will unduly prejudice or present a clear tactical disadvantage to the non-moving party; (2) whether a stay will simplify the issues in question and trial of the case; and (3) whether discovery is complete and whether a trial date has been set. The Federal Circuit has interlocutory appellate jurisdiction to review U.S. district court decisions on CBMR-premised stay motions. U.S. district courts are more likely to stay actions in light of the new IPR, CBMR, or PGR procedures.

### 1.15 What other grounds of defence can be raised in addition to non-infringement or invalidity?

Additional defences in a patent infringement litigation include inequitable conduct (intentionally misleading the Patent Office), patent misuse (typically shown through improper licensing practices), laches (undue delay in bringing suit), and equitable estoppel (reliance on plaintiffs' representation or conduct). Certain technical defences such as failure to keep patents together that are subject to a terminal disclaimer can also be raised.

### 1.16 Are (i) preliminary and (ii) final injunctions available and if so on what basis in each case?

Both preliminary and permanent injunctions can be sought. Preliminary injunctions require that the moving party show substantial likelihood of prevailing on the merits, irreparable harm, balance of hardship in its favour and that the grant of the injunction will further the public interest. Similar standards are used for a permanent injunction, although there must be a final ruling on the merits.

### 1.17 On what basis are damages or an account of profits estimated?

Damages are intended to compensate the patent owner for the infringement. Pursuant to § 284, the damages may not be less than a reasonable royalty. In addition, a patent owner may be able to obtain his lost profits in the proper case. The reasonable royalty is based on a number of factors, normally known as the *Georgia-Pacific* factors; they include comparable licences, scope of the infringement, exclusivity, duration of patent term, profitability of products made under the patent and other similar factors. The *Georgia-Pacific* factors also include a hypothetical negotiation between the patent owner and the infringer, determined at the start of the infringement.

### 1.18 What other form of relief can be obtained for patent infringement?

In addition to monetary damages, a patentee may obtain: (1) injunctive relief to address issues of ongoing infringement; (2) increased damages (up to treble damages, if wilful infringement is found); and (3) reasonable attorney fees, if the case is exceptional. Whether a case is exceptional is reviewed under the U.S. Supreme Court's recent precedent (*Highmark/Octane Fitness*).

### 1.19 Are declarations available and if so can they address (i) non-infringement and/or (ii) claim coverage over a technical standard or hypothetical activity?

Declarations can be used to support arguments regarding how patent claims should be interpreted. They can also be used to support motions regarding non-infringement and/or invalidity. In such cases, the subject matter of the declaration may extend to any subject that is relevant to the motion, including background regarding technical standards.

### 1.20 After what period is a claim for patent infringement time-barred?

There is no statute of limitations for patent infringement actions, but damages are not recoverable for infringement committed more than six years before the filing of a pleading alleging the infringement. The equitable doctrines of laches, prosecution laches, and estoppel may also limit liability for past infringement.

### 1.21 Is there a right of appeal from a first instance judgment and if so is it a right to contest all aspects of the judgment?

Generally speaking, subject to waiver, any party may appeal a reversible error committed by a U.S. district court. The Federal Circuit has exclusive jurisdiction over such appeals so long as the jurisdiction is based, in whole or part, on the patent laws. Decisions by the Federal Circuit cannot be appealed by right but can be reviewed by the U.S. Supreme Court on petitions for *certiorari* (if granted).

### 1.22 What are the typical costs of proceedings to first instance judgment on (i) infringement and (ii) validity; how much of such costs are recoverable from the losing party?

Patent litigation costs are dependent upon a variety of factors such as the complexity of the case, law firms involved, geographic location, and amount in controversy. The American Intellectual Property Law Association conducts a survey of law firms and corporations and releases a biennial report on the average costs of patent litigation through the end of discovery and through the end of trial. Validity challenges filed with the PTAB may be significantly less expensive.

The traditional American rule requires that each party bear its own litigation expenses, but reasonable attorneys' fees may be awarded to a prevailing party in an exceptional case under § 285.

### 1.23 For countries within the European Union: What steps are being taken in your country towards ratification, implementation and participation in the Unitary Patent Regulation (EU Regulation No. 1257/2012) and the Agreement on a Unified Patent Court? For countries outside of the European Union: Are there any mutual recognition of judgments arrangements relating to patents, whether formal or informal, that apply in your country?

There are no formal or informal mutual recognition arrangements related to patents from outside the U.S.

## 2 Patent Amendment

### 2.1 Can a patent be amended *ex parte* after grant and if so how?

Minor corrections that do not affect the scope of the claims may be made by filing a Certificate of Correction. Substantive changes/corrections can only be made through a reissue of the patent, *ex parte* re-examination, or supplemental examination that, if granted, is converted into an expanded *ex parte* re-examination. Reissue requires the patent owner to state that the patent is wholly or partly inoperative or invalid and surrender the original patent. *Ex parte* re-examination can only be based on patents or printed publications that raise a substantial new question of patentability. The supplemental examination can seek to correct any error and the resulting expanded *ex parte* re-examination is not limited to patents and printed publications.

### 2.2 Can a patent be amended in *inter partes* revocation proceedings?

A patent can be amended by a narrowing amendment in an IPR, CBMR, or PGR by cancelling or proposing a reasonable number of substitute claims.

### 2.3 Are there any constraints upon the amendments that may be made?

As a general rule, an amendment cannot add new subject matter not contained in the original patent application as filed. A broadening reissue – the only exception to the general rule – can only be filed within two years of the issue date.

## 3 Licensing

### 3.1 Are there any laws which limit the terms upon which parties may agree a patent licence?

The U.S. Supreme Court has recently held that parties may not contract for patent royalties that run beyond the end of a patent's term (*Kimble*). The Federal Circuit has also clarified that U.S. district courts should consider any Fair, Reasonable, and Non-Discriminatory (FRAND) obligations attached to a particular patent.

### 3.2 Can a patent be the subject of a compulsory licence and if so how are the terms settled and how common is this type of licence?

Compulsory licences are disfavoured in the U.S., but may be required if necessary to further the public interest.

## 4 Patent Term Extension

### 4.1 Can the term of a patent be extended and if so (i) on what grounds and (ii) for how long?

For a patent claiming a new drug product or a method of using the drug product, the term of the patent may be extended for up to five years to restore a portion of the patent term that is shortened by regulatory review of the drug product. Patent terms may also be extended for all patents for certain delays in processing the application caused by the USPTO. There is no limit to patent term extensions based on delay in processing.

## 5 Patent Prosecution and Opposition

### 5.1 Are all types of subject matter patentable and if not what types are excluded?

Section 101 states that: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof" is entitled to a patent. The U.S. Supreme Court has clarified that laws of nature, natural phenomena, and abstract ideas are not patentable. Naturally occurring substances, such as genes, have been held to be patent-ineligible.

### 5.2 Is there a duty to the Patent Office to disclose prejudicial prior disclosures or documents? If so, what are the consequences of failure to comply with the duty?

Yes, the duty of disclosure extends to documents, information, and facts that a reasonable Patent Examiner would consider material to the examination of the patent application. The duty of disclosure applies to the inventor, his employer, and anyone else involved in the preparation or prosecution of the patent application, including the attorneys.

Failure to comply with the duty of disclosure or knowingly submitting misleading or false information may be deemed to be inequitable conduct, the consequence of which is that the patent becomes unenforceable against the world.

### 5.3 May the grant of a patent by the Patent Office be opposed by a third party and if so when can this be done?

Under the America Invents Act, any third party may submit a patent application, any patent, published patent application, or other printed publication to the Patent Office. The submission must be made before the earlier of the date of a notice of allowance or the later of six months after the patent application is first published or the date of the first rejection of any claim by the Patent Examiner. The submission must be of potential relevance to the Patent Examiner and include a statement of the asserted relevance of each submitted item.

### 5.4 Is there a right of appeal from a decision of the Patent Office and if so to whom?

Decisions of a Patent Examiner may be appealed first to the PTAB, and then to the Federal Circuit. Decisions from the PTAB in IPR, CBMR, PGR, derivative proceedings, and re-examinations may be appealed directly to the Federal Circuit.

### 5.5 How are disputes over entitlement to priority and ownership of the invention resolved?

For pre-AIA patents, interference proceedings that determine who first invented the subject matter, are still in effect. For post-AIA patents, a new derivation procedure allows a determination of whether the person who claims inventorship actually invented the subject matter of the invention or whether he learned of the invention from another and filed first.

### 5.6 Is there a “grace period” in your country and if so how long is it?

For pre-AIA patents, any actions by the inventor or others after the date of invention are not deemed prior art if they occurred less than one year before the patent application was filed. For post-AIA patents, a similar one-year grace period exists from the first disclosure by the inventor or someone who obtained the subject matter from the inventor to the filing date of the patent application.

### 5.7 What is the term of a patent?

A patent issuing from an application filed on or after June 8, 1995, has a term of 20 years from the earliest filing date of the U.S. utility (or PCT) application, subject to the patent term adjustments or patent term extension. For applications filed before June 8, 1995, the patent term is the longer of 17 years or 20 years from the earliest priority date.

## 6 Border Control Measures

### 6.1 Is there any mechanism for seizing or preventing the importation of infringing products and if so how quickly are such measures resolved?

A party may request from the ITC an exclusion order and/or a

cease-and-desist order if infringing products are being imported into the U.S. and a domestic industry exists for the patented product. An exclusion order requires U.S. Customs to block entry of the infringing products into the U.S. A cease-and-desist order blocks further sale of infringing products that have already been imported. The ITC administrative judges will typically render a final decision within 12 to 15 months of an action being initiated. The final decision may then be reviewed by the full Commission, and then, after Presidential Review, potentially by the Federal Circuit.

## 7 Antitrust Law and Inequitable Conduct

### 7.1 Can antitrust law be deployed to prevent relief for patent infringement being granted?

An accused infringer may assert an antitrust counterclaim if the patentee violates the antitrust laws in connection with the use of its patent. Some of the bases for antitrust counterclaims include tying, baseless enforcement, improper patent pooling, and lessening competition through attempts to monopolise or improper agreements with third parties. If an antitrust violation is found to be related to the patent, the patent will be deemed unenforceable.

### 7.2 What limitations are put on patent licensing due to antitrust law?

Improper licensing practices can render a patent unenforceable under patent misuse concepts. These may include tying the licence of a patented product to the purchase of an unpatented product, attempting to extend the term of the patent by requiring payments after patent expiration, requiring grant backs, and so-called “reverse payments” to a licensee. See § 271(d).

## 8 Current Developments

### 8.1 What have been the significant developments in relation to patents in the last year?

The U.S. Supreme Court has rendered a number of important decisions on patent exhaustion (*Bowman*), attorneys’ fees (*Highmark* and *Octane*), induced infringement (*Limelight/Commil*), claim construction (*Nautilus/Teva*), patent royalty payments (*Kimble*), natural products/genes (*Myriad*), and patent-eligible subject matter (*Alice*).

### 8.2 Are there any significant developments expected in the next year?

The next year will likely see a new phase of patent reform bills. It will also see the Federal Circuit deciding appeals from the PTAB’s decisions in IPR, CBMR, and PGR proceedings. So far, the Federal Circuit has confirmed the application of the broadest reasonable claim interpretation standard (*Cuozzo/Versata*), jurisdiction to review various issues related to the PTAB’s ability to decide CBMR petitions (*Versata*), and interlocutory appellate jurisdiction to review decisions of U.S. district courts on motions requesting a stay of proceedings pending resolution of a CBMR proceeding (*VirtualAgility/JPMC*).

### 8.3 Are there any general practice or enforcement trends that have become apparent in USA over the last year or so?

The rise of post-grant review proceedings and the likelihood that a challenged patent will be held invalid have impacted the number of cases filed by patent assertion entities. But, even in view of the number of successful outcomes from post-grant review proceedings,

the number of new patent cases in 2015 is on track to exceed those filed in 2014.

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