



# ICLG

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**General Chapters:**

1	<b>Preparing for the Unitary Patent and Unified Patent Court: What to Consider Before Opting Out or Opting to Stay In</b> – Katharine Stephens & Audrey Horton, Bird & Bird LLP	1
2	<b>Method Claiming in the United States: The Who, What, and Where of Enforcement</b> – Scott A. Hogan & Shannon K. Smith, Reising Ethington P.C.	7
3	<b>U.S. Supreme Court Agrees Upon Restricted Venue for Patent Cases</b> – D. Stuart Bartow & Terry Ahearn, Lewis Roca Rothgerber Christie LLP	11
4	<b>Review of the Eurasian Patent System</b> – Maxim Sobolev, Rouse & Co. International (UK) Limited (Moscow Branch)	15
5	<b>Gulf Co-operation Council Countries – Patent Landscape</b> – Sara Holder & Mohammad Jomoa, Rouse & Co. International/Kadasa & Partners	19

**Country Question and Answer Chapters:**

6	<b>Australia</b>	Bird & Bird LLP: Jane Owen & Rebecca Currey	22
7	<b>Brazil</b>	Daniel Legal & IP Strategy: Rana Gosain & André Bastos Venturini	28
8	<b>Chile</b>	PORZIO · RIOS · GARCIA: Cristóbal Porzio & Marcelo Correa	36
9	<b>China</b>	AnJie Law Firm: Steve Song & Ying Wang	42
10	<b>France</b>	Armengaud & Guerlain: Catherine Mateu	49
11	<b>Germany</b>	Gleiss Lutz: Dr. Matthias Sonntag & Dr. Herwig Lux	56
12	<b>India</b>	Subramaniam & Associates: Hari Subramaniam	62
13	<b>Ireland</b>	WhitneyMoore Solicitors: Aoife Murphy & Robin Hayes	70
14	<b>Israel</b>	Gilat, Bareket & Co.: Eran Bareket Reinhold Cohn & Partners: Ronnie Benschafut	77
15	<b>Japan</b>	Chuo Sogo Law Office, P.C.: Naoko Nakatsukasa	84
16	<b>Latvia</b>	Agency TRIA ROBIT: Vladimir Anohin & Voldemars Osmans	91
17	<b>Mexico</b>	OLIVARES: Alejandro Luna Fandiño & Sergio Luis Olivares Lobato	96
18	<b>Norway</b>	Wikborg Rein Advokatfirma AS: Gunnar Meyer & Lars Erik Steinkjer	104
19	<b>Philippines</b>	SyCip Salazar Hernandez & Gatmaitan: Enrique T. Manuel & Vida M. Panganiban-Alindogan	110
20	<b>Romania</b>	Nestor Nestor Diculescu Kingston Petersen: Ana-Maria Baciú & Sorina Olaru	116
21	<b>Russia</b>	Rouse & Co. International (UK) Limited (Moscow Branch): Maxim Sobolev & Andrey Cherkasov	121
22	<b>Saudi Arabia</b>	Rouse & Co. International/Kadasa & Partners: Sara Holder & Mohammad Jomoa	127
23	<b>South Africa</b>	De Beer Attorneys: Elaine Bergenthuin & Ntombovuyo Bungane	133
24	<b>Spain</b>	Elzaburu: Colm Ahern	140
25	<b>Sweden</b>	Advokatfirman Lindahl KB: Ludvig Holm & Annie Kabala	145
26	<b>Switzerland</b>	Gros & Waltenspühl: Pascal Fehlbaum	151
27	<b>Taiwan</b>	TIPLo Attorneys-at-Law: J. K. Lin & H. G. Chen	157
28	<b>Turkey</b>	Gün + Partners: Selin Sinem Erciyas & Tuğçe Avcısirt Geçgil	165
29	<b>Ukraine</b>	Gorodissky & Partners (Ukraine): Nina Moshynska	173
30	<b>United Arab Emirates</b>	Rouse & Co. International: Sara Holder	180
31	<b>United Kingdom</b>	Bird & Bird LLP: Katharine Stephens & Audrey Horton	185
32	<b>USA</b>	Finnegan, Henderson, Farabow, Garrett, and Dunner LLP: Mareesa A. Frederick & Clara N. Jiménez	195
33	<b>Vietnam</b>	Pham & Associates: Pham Vu Khanh Toan	202

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# USA

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## 1 Patent Enforcement

### 1.1 Before what tribunals can a patent be enforced against an infringer? Is there a choice between tribunals and what would influence a claimant's choice?

The federal district courts, located throughout the United States, are the trial courts in patent cases. Provided certain jurisdictional requirements are met, a party may also enforce their patent rights at the United States International Trade Commission (“ITC”). The ITC is a federal administrative agency that hears claims of patent infringement for imported goods accused of infringing U.S. patent rights.

Decisions from patent cases from district courts and the ITC are appealed to the United States Court of Appeals for the Federal Circuit (“Federal Circuit”).

Litigants have some flexibility in selecting the venue for their case. This selection depends on, for example, the facts and strategy of the case, compliance with personal jurisdiction and venue requirements, and the available remedies. For example, patentees can obtain damages and/or injunctions in a district court, but in the ITC, only injunctive relief prohibiting importation into the United States is available.

### 1.2 What has to be done to commence proceedings, what court fees have to be paid and how long does it generally take for proceedings to reach trial from commencement?

In district courts, patentees commence an infringement action by serving the accused infringer with a summons and complaint for patent infringement. The complaint must meet certain pleading requirements and requires a filing fee of \$400. Service of process requires additional, nominal fees. Depending on the court, the pre-trial period may be as short as nine months but is normally closer to two years.

In the ITC, a patentee must file a complaint to initiate an investigation. The pre-trial period is typically completed within eight to nine months after the ITC initiates the investigation.

### 1.3 Can a party be compelled to disclose relevant documents or materials to its adversary either before or after commencing proceedings, and if so, how?

Shortly after a lawsuit has commenced, the rules require parties to initially exchange information concerning individuals and repositories likely to have discoverable information, disclose a computation of damages, and provide any insurance agreement that may satisfy all or

part of a judgment. Local patent rules often require additional initial disclosures.

The parties may prepare and file a joint discovery plan ahead of the scheduling conference. The parties then exchange written discovery (e.g., interrogatories and requests for admission), documents, and depose witnesses.

Non-parties to a proceeding may be compelled to provide discovery (documents and deposition testimony) through subpoena practice.

If a party or non-party fails to provide requested discovery, the requesting party may move to compel such discovery.

### 1.4 What are the steps each party must take pre-trial? Is any technical evidence produced, and if so, how?

Pre-trial procedure specifics vary from court to court. Generally, the first phase includes an exchange of pleadings (e.g., complaint, answer and counterclaims). A scheduling order is typically issued within three months of the complaint being served.

The parties next engage in fact discovery. Some courts may also require that infringement, invalidity, or unenforceability contentions be exchanged. Motion practice to resolve discovery disputes is common. Generally, fact discovery is followed by expert discovery on technical and/or damages issues; this period includes exchange of expert reports and deposition of expert witnesses.

Courts are required, as a matter of law, to resolve the meaning of disputed claim terms. Claim construction proceedings include significant briefing and a hearing (“*Markman* hearing”). The average time from filing to a *Markman* ruling was 23 months (as of 2016). Depending on the complexity of the issues, the court may request or allow a technical tutorial.

After a *Markman* order, litigants often have an opportunity to file updated infringement and invalidity contentions. Once discovery ends, summary judgment motions and motions to limit the evidence available for trial, including motions to exclude expert witnesses, may be filed.

Before trial, litigants exchange pre-trial statements that identify witnesses and exhibits to be introduced at trial, and objections to the same. Failure to disclose an exhibit or objection may waive a party's right to use or object to the exhibit or witness at trial. Proposed jury instructions for the court to consider may also be submitted.

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

Generally, patent infringement cases in district courts are tried before a

jury. Jury trials, however, are not available in the following situations: (1) a trial regarding the right to sell generic pharmaceuticals before the expiration of the branded pharmaceutical patent; and (2) ITC investigations. A trial before a judge (without a jury) is called a “bench trial”.

Trials begin with opening statements that provide a road map of what each party will show through evidence. Parties then present the evidence through fact and expert witnesses, subject to cross-examination. The scope of expert testimony is limited to the scope of a written report provided ahead of trial. Depending on the issues being tried, the parties may reach agreement with the court as to the order in which the evidence is introduced. Each party ends its presentation with a closing argument. Because patent infringement cases may be highly technical, this is often an opportunity to explain to the jury how the evidence supports each party’s theories. Opening and closing statements themselves are not considered evidence.

Although the general theories must be developed and disclosed before trial, the court may allow a party to amend its pleadings before trial for good cause and in exceptional circumstances.

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

Trial length varies greatly depending on each case. Jury deliberations happen immediately after the trial is finished, and may last a few hours or several days. After a verdict, the judge entertains the parties’ post-trial motions. For bench trials, the judge will typically issue a written opinion explaining his decision in the weeks or months following trial. Judgments are entered after post-trial motions are decided.

Protective orders, agreed upon by the parties and approved by the court, that govern how confidential information is handled during the litigation, are common. Generally, trials in district courts are open to the public, but the parties may request to have the courtroom sealed to avoid disclosure of confidential information in special circumstances. Proceedings before the ITC are open to the public but can more easily be conducted in confidence than in a district court.

Judgments from district courts and the ITC are available to the public. The parties may request the judgment to be kept off the public record for some period of time after it is issued, to allow the parties a chance to redact confidential information. A redacted version is subsequently made available to the public.

#### **1.7 Are judgments made available to the public? If not as a matter of course, can third parties request copies of the judgment?**

Judgments from district courts and the ITC are available to the public. The parties may request the judgment to be kept off the public record for some period of time after it is issued, to allow the parties a chance to redact confidential information. A redacted version is subsequently made available to the public.

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

District court and ITC judges are not required to have technical backgrounds. Because patent litigation is concentrated in a small number of courts, however, it is common to appear before a judge with extensive experience in patent law. Administrative judges at the ITC, on the other hand, have developed substantial patent

expertise. At the appellate level, some of the judges at the Federal Circuit have technical backgrounds, and most have substantial patent law experience.

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

Patentees and their exclusive licensees have standing to bring infringement suits in district courts. Non-exclusive licensees may bring suit only by joining the licensor. To appear at the ITC, a party must have an interest in the patent and must establish that it has a domestic industry.

A party that is threatened with a patent infringement lawsuit or faces an immediate, realistic and substantial risk of being involved in an actual case or controversy, may preemptively file a declaratory judgment action in district court to have the patent declared invalid or not infringed.

The validity of U.S. patents may also be challenged at the U.S. Patent Office Patent Trials and Appeal Board (“PTAB”) through *ex parte* and *inter partes* proceedings including *ex parte* reexamination, *inter partes* review (“IPR”), post-grant review (“PGR”), and covered business method reviews (“CBM”). A petition for IPR, PGR or CBM may not be brought by the patentee. A patentee, however, may file a request for *ex parte* reexamination of a patent.

#### **1.10 If declarations are available, can they address (i) non-infringement, and/or (ii) claim coverage over a technical standard or hypothetical activity?**

During litigation, parties can provide declarations of fact and/or expert witnesses to support arguments concerning claim construction, liability, validity and damages issues. Such declarations are often used to support motions for summary judgment on infringement or validity. Declarants are generally subject to cross-examination.

#### **1.11 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?**

Induced infringement and contributory infringement are available in the United States.

To prove induced infringement, a patentee must show that the accused infringer actively encouraged infringement, knowing that the induced acts constituted patent infringement, and direct patent infringement actually resulted from the induced acts.

Liability for contributory infringement arises from the offer to sell, sale in the US or importation into the United States of a component of a patented device, article of manufacture, or a combination or composition or a material or apparatus for use in practicing a patented process, where the item at issue constitutes a material part of the patented invention and has no non-infringing uses.

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

A party infringes a process patent by importing a product made by the process even if the process was performed outside of the United States. In district court litigation, a party may avoid liability if the product is materially changed before importation or is a trivial part



of another unpatented product. Such an exception is not available in an ITC investigation.

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

The “doctrine of equivalents” extends infringement liability to products and processes that do not literally infringe on a patent’s claims, where there is equivalence between the elements. The “doctrine of prosecution history estoppel” may limit the equivalents available to the plaintiff, by precluding the recapture of subject matter surrendered during prosecution.

### 1.14 Can a defence of patent invalidity be raised, and if so, how? Are there restrictions on such a defence e.g. where there is a pending opposition?

A party may defend against patent infringement by challenging the validity of the patent. Invalidity can be raised as an affirmative counterclaim or in response to a plaintiff’s infringement claim.

A party may also seek to invalidate the asserted patent at the PTAB during or before litigation, subject to certain time bars post-service of the complaint on the defendant. PTAB proceedings may be preferred to district court invalidation actions because of their speed and relative cost-efficiency. Arguments raised at the PTAB may have an estoppel effect in later litigation.

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

In litigation, the validity of a U.S. patent can also be challenged for failure to claim eligible subject matter and/or for failure to provide adequate description (i.e., written description support, definiteness, and enablement).

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

District courts may stay litigation pending PTAB proceedings or related litigations involving the patent. To determine if a stay is appropriate, district courts consider: whether a stay will unduly prejudice or present a clear tactical disadvantage to the non-moving party; whether a stay will simplify the issues; and whether discovery is complete and a trial date has been set.

If an ITC investigation is ongoing, an accused infringer can request, as a matter of right, a stay of the parallel district court action. Due to the rapid pace of ITC proceedings, stays pending PTAB proceedings are not routinely granted at the ITC.

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

Additional defences in a patent infringement litigation include defences that render the patent unenforceable, those being inequitable conduct (misleading the Patent Office) and patent misuse (typically through improper licensing practices), as well as equitable estoppel (reliance on a plaintiff’s conduct). Certain defences, such as failure to keep patents that are subject to a terminal disclaimer together, can also be raised.

### 1.18 Are (i) preliminary, and (ii) final injunctions available, and if so, on what basis in each case? Is there a requirement for a bond?

A party may receive a preliminary injunction if it establishes a substantial likelihood of prevailing on the merits, irreparable harm, a balance of hardship favouring the moving party, and that the injunction will further the public interest.

A permanent injunction is available when a party establishes that it will suffer an irreparable injury, that damages are inadequate to compensate for that injury, that the balance of hardships between the parties favours the movant, and that the public interest would not be disserved.

Generally, a court may issue an injunction only if the movant posts a bond sufficient to pay the costs and damages sustained by any party that is later found to have been wrongfully enjoined.

### 1.19 On what basis are damages or an account of profits assessed?

If a patent claim is found to be valid and infringed, a court awards the patentee damages adequate to compensate for the infringement. A patentee may obtain lost profits if it can prove a demand for the patented invention, an absence of acceptable, non-infringing substitutes for the patented invention, that the patentee had the capacity to exploit the demand, and the amount of profit the patentee would have made but for the infringement. The factors to determine lost profits are known as the *Panduit* factors. A reasonable royalty is calculated using a set of 15 considerations aimed at determining a rate that reasonable parties would have agreed upon at the time of the infringement, commonly known as the *Georgia-Pacific* factors.

### 1.20 How are orders of the court enforced (whether they be for an injunction, an award of damages or for any other relief)?

If a party fails to comply with a court order, including an injunction or award of damages, it may be held in contempt by the court upon motion by an opposing party. Upon holding a party in contempt, the court has the power to levy a fine on that party and/or order the United States Marshals Service to enforce the order through, for example, asset seizure.

At the ITC, exclusion orders, preventing the importation of the accused products into the United States, are enforced by the U.S. Customs and Border Protection agency.

### 1.21 What other form of relief can be obtained for patent infringement? Would the tribunal consider granting cross-border relief?

District courts have the power to grant a patentee damages (reasonable royalty or lost profits) upon a ruling that at least one asserted patent claim is valid and infringed. The court may enhance damages as a punitive measure for willful infringement. In rare circumstances, reasonable attorneys’ fees may be granted.

The ITC also has the power to issue exclusion orders that prevent the sale for importation, importation, or sale after importation of infringing products into the United States. It may also issue cease and desist orders preventing, among other things, the sale of accused products from existing inventory in the United States.

### 1.22 How common is settlement of infringement proceedings prior to trial?

Settlements of patent infringement proceedings are very common. Roughly 75% of patent infringement cases terminated in 2016 were settled.

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

Claims for patent infringement are not time-barred in the United States. A patentee, however, may not recover damages for acts of infringement which occurred more than six years before the filing of an infringement action.

### 1.24 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?

If a party raised an issue during proceedings at a district court or the ITC, the judgment may be appealed to the Federal Circuit. The Federal Circuit has exclusive jurisdiction over patent appeals. Federal Circuit decisions are not appealable as a matter of right, but are reviewed on a discretionary basis by a full panel of the Federal Circuit or, rarely, by the U.S. Supreme Court.

### 1.25 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 including technical complexity, number of parties involved, law firms involved, geographic location, and amount in controversy. The American Intellectual Property Law Association releases a biennial report on the average costs of patent litigation. Each party bears its own litigation expenses, but reasonable attorneys' fees may be awarded to a prevailing party if the case is deemed exceptional under the relevant statute.

### 1.26 For jurisdictions within the European Union: What steps are being taken in your jurisdiction towards ratifying the Agreement on a Unified Patent Court, implementing the Unitary Patent Regulation (EU Regulation No. 1257/2012) and preparing for the unitary patent package? For jurisdictions outside of the European Union: Are there any mutual recognition of judgments arrangements relating to patents, whether formal or informal, that apply in your jurisdiction?

This is not applicable.

## 2 Patent Amendment

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

Corrections that do not affect the scope of the claims may be made through a certificate of correction. Substantive changes/corrections can only be made through a reissue, *ex parte* reexamination, or supplemental examination. Reissue requires the patentee to state that the patent is wholly or partly inoperative or invalid, and offer to

surrender the original patent. *Ex parte* reexamination can only be based on patents or printed publications that raise a substantial new question of patentability. Supplemental examination can seek to correct any error and the resulting expanded *ex parte* reexamination is not limited to patents and printed publications.

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

Patentees may be able to replace a claim that has been deemed unpatentable during *inter partes* post-grant challenge (IPR, PGR, CBM), by filing a contingent motion to replace the claims. Thus, while the motion must be made before a final decision on patentability is reached, the PTAB will not consider the motion unless a claim has been deemed unpatentable.

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

In *inter partes* challenges, proposed claims in a motion to amend must not be broader than the original claims, must have written description support, and be patentable over the prior art.

Patents under *ex parte* reexamination can be amended in response to an Office Action. Although amendments will be entered for purposes of examination, the amendments are not legally effective until the reexamination certificate is issued and published.

Patentees may only add new subject matter to their patents through *reissue* within two years of the issue date. After this two-year mark, no new subject matter may be added to an issued patent through amendments.

## 3 Licensing

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

Patent licensing is policed through federal common law and antitrust statutes. Licensors of patents must offer fair, reasonable, and non-discriminatory rates. Courts have limited licensing agreements to prevent anti-competitive practices (product tying, price fixing, etc.). The United States Federal Trade Commission ("FTC"), charged with enforcing federal antitrust laws, has issued additional guidelines on its expectations of licence agreements.

### 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 rarely granted by U.S. courts. They may be granted in cases of bad faith. Additionally, inventions made with U.S. Government resources or funding are subject to a non-exclusive, non-transferable, irrevocable, paid-up licence to practise, or have practised for or on behalf of the United States, the invention throughout the world.

## 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?

In the United States, patent term *adjustment* refers to additional time

added to the patent term due to processing delays caused by the USPTO. The amount of time added is determined by the USPTO and is not limited by statute.

The U.S. Food and Drug Administration (“FDA”) may also grant patent term *extension* by up to five years for certain pharmaceuticals or medical devices whose market entry has been delayed by the FDA’s safety review of the patented products.

## 5 Patent Prosecution and Opposition

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

Generally, the United States grants patents to new and useful processes, machines, manufactures, and compositions of matter. It does not grant patents directed to laws of nature, natural phenomena, or abstract ideas. While subject matter eligibility is codified in the patent statute 35 U.S.C. § 101, its interpretation by the courts is a hot topic in the United States these days. Recent major decisions in this area include *Mayo v. Prometheus* and *Alice Corp. v. CLS Bank*.

### 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?

All individuals associated with the prosecution of a patent application have a duty to disclose information material to patentability to the USPTO. Failure to comply with the duty of disclosure may result in the USPTO’s refusal to grant a patent, or give rise to an inequitable conduct challenge in litigation.

### 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?

Third parties may submit *observations* 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 examiner. The submission must be of potential relevance to the examination of the application and include a statement of the asserted relevance of each submitted item. After the patent is granted, the PTAB proceedings described in the answer to question 1.9 may be brought.

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

There is a statutory right to appeal of USPTO decisions. Applicants may seek review of an examiner’s decision within the PTAB. In turn, PTAB decisions may be appealed to the U.S. District Court for the Eastern District of Virginia, or to the Federal Circuit.

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

The America Invents Act (“AIA”) moved the U.S. patent system from first-to-invent to first-to-file. Thus, under the AIA when two parties independently invent the same subject matter, the one who files first gets the patent. Post-AIA, derivation procedures are used to resolve disputes when two parties claim the same invention, and there is a dispute as to whether the first to file was the actual

inventor, or whether the invention was “derived” from another party (i.e., independence of invention is questioned). Pre-AIA patents and applications may still be subject to interference proceedings at the USPTO. In these proceedings, the question is which of the parties claiming the subject matter invented it first (i.e., independence of invention is presumed).

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

For applications filed on or after March 16, 2013, a one-year grace period exists from the first disclosure by the inventor (or someone who learned of the invention from the inventor) to the application’s filing date. For applications filed before March 16, 2013, the grace period is one year before the patent application is filed.

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

In general, the term for utility patents, filed after June 8, 1995, is 20 years from the earliest filing date of the application to which the patent claims priority. For utility applications filed before June 8, 1995, the patent term is either 17 years from the issue date or 20 years from the filing date, whichever is longer.

Extensions, as explained in question 5.1, can enlarge the patent term. The term of a patent can also be shortened by prosecution terminal disclaimers (often filed to obviate double-patenting rejections), or when the maintenance fees are not timely paid.

## 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 seek an exclusion order from the ITC. When an exclusion order goes into effect, U.S. Customs and Border Protection will bar the infringing product from entering the United States. The ITC administrative judges will typically issue an initial determination within 12 months of an investigation 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?

Patent misuse is an affirmative defence based on a patentee’s abuse of the exclusive rights conferred by a patent. Patent misuse can only be used by an alleged infringer if and when the patentee seeks to enforce the exclusive right of the patent in a patent infringement suit. If a party is found to have committed an antitrust violation in connection with the exercise of its patent rights, the patent may be deemed unenforceable, and preclude the patentee from asserting infringement of it.

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

Antitrust violations are often committed when a patentee attempts to extend the exclusionary rights granted by the patent through the

imposition of additional contractual restrictions on the invention's use. The courts have restricted a number of such anti-competitive restrictions, including tying, patent pooling, and post-expiration royalties.

## 8 Current Developments

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

*TC Heartland* limited the forums in which patent litigation may be brought, by limiting the venue to where the accused infringer is incorporated, or where the infringement occurred and the accused infringer has a regular place of business.

In *SCA Hygiene Products*, the Court held that the equitable doctrine of laches cannot be invoked as a defence against a claim for damages incurred within the six-year statutory limitation period.

In *Lexmark*, the Court held that, when a patentee sells a product, the sale exhausts all patent rights in the item being sold regardless of any restrictions the patentee attempts to impose on the location of the sale.

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

In *Oil States v. Greene's Energy Group*, the Supreme Court will decide whether IPRs violate the constitutional rights of patentees by extinguishing their private property rights without a jury. Although the patent review proceedings are relatively new, the PTAB has become a preferred venue to challenge the validity of patents outside of district courts. A decision holding IPRs unconstitutional could alter the current landscape of patent litigation by shifting the bulk of invalidity challenges back to the courts.

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

The year 2016 showed a 20% decline in patent infringement cases when compared with 2015. The Eastern District of Texas, the District of Delaware, and the Central District of California handled the highest number of patent infringement cases. It is expected that in the wake of *TC Heartland*, the number of patent cases litigated in the Eastern District of Texas, a sought-after venue for its efficient docket, may decrease.

Opinions of counsel on non-infringement as a defence to allegations of willful infringement, in the wake *Halo v. Pulse Electronics*, which relaxed the standard patentees need to meet to make allegations of willful infringement, have become more popular and relied-upon at trial to defend against willfulness allegations.

The filing of IPRs and PGRs has increased since 2015. Overall, the majority of PTAB proceedings settle, with only about 18% proceeding to completion. The Federal Circuit has reversed and remanded more IPR decisions over the past year. Through March 1, 2017, the Federal Circuit decided 172 PTAB appeals from IPRs and CBMs. The Federal Circuit affirmed the PTAB on every issue in 76% cases and reversed in about 8%. A mixed outcome on appeal, where at least one issue was affirmed and at least one issue was vacated or reversed, occurred in 9% of cases.

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