

PATENTS

ICLG

The International Comparative Legal Guide to:

Patents 2017

7th Edition

A practical cross-border insight into patents law

Published by Global Legal Group, in association with CDR, with contributions from:

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Published by

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Email: info@glgroup.co.uk
URL: www.glgroup.co.uk

GLG Cover Design

F&F Studio Design

GLG Cover Image Source

iStockphoto

Printed by

Ashford Colour Press Ltd
August 2016

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ISBN 978-1-911367-10-9

ISSN 2044-3129

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USA



Eugene Goryunov



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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?

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). Patents may be enforced in any state where an accused infringer engaged in continuous and systematic activities or committed a specific act of infringement. Patents may be enforced at the ITC where infringing “articles” are imported into the U.S. and a domestic industry exists for the patented product.

A patent owner may, subject to the above threshold requirements, select a tribunal to enforce its patent. Selection depends on many factors, including cost, pending time, and available remedies. Cases brought to the ITC are usually tried within eight to nine months. As a result, ITC cases are generally more expensive to try than those in a U.S. district court. Patent owners can obtain damages and injunctions in a U.S. district court. The ITC cannot award damages. It can, however, issue: (1) limited or general exclusion orders; and (2) cease and desist orders. These orders effectively prohibit importation of “articles” into the U.S.

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 U.S. district courts, patent owners may initiate an infringement action by serving the accused infringer with a summons and complaint. 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.

The ITC may act on its own accord to enforce patents, but more commonly, a patent owner must file a complaint. The pre-trial period is typically completed within five 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?

In general, a party cannot obtain documents or materials from its adversary before commencing a proceeding.

After a proceeding has been commenced, the parties must exchange initial disclosures. These disclosures require the parties to: identify each individual likely to have discoverable information; provide a copy of all documents which a party may use to support its case; disclose a computation of damages; and provide any insurance agreement that may satisfy all or part of a judgment. Local patent rules in a U.S. district court often require additional disclosures.

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; (2) the amount in controversy; (3) the parties' relative access to relevant information and the parties' resources; (4) the importance of the discovery in resolving the issues; and (5) whether the burden or expense of the discovery outweighs its likely benefit.

Non-parties to a proceeding may be compelled to provide discovery through *subpoena* practice.

If, after notice and an attempt to meet and confer, a party or non-party fails to provide requested discovery, the requesting party may move the court 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?

The sequence of pre-trial activities in 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 patent litigation begins at the pleading stage. This includes a complaint by the plaintiff (the patent owner), an answer and counterclaims, if any, by the defendant(s) (the accused infringer), and, if necessary, a reply to the counterclaims by the plaintiff.

The court then arranges a scheduling conference. The parties must discuss the nature of the case, submit a joint report addressing the scope and agreed-upon limitations on discovery, and exchange initial disclosures before the scheduling conference. The court generally issues a case management order with deadlines for the pre-trial stages at the conference.

The parties next engage in extensive 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. Expert discovery typically includes the exchange of expert reports and depositions of expert witnesses.

Courts are required, as a matter of law, to resolve the meaning of disputed claim terms. Claim construction proceedings typically begin within the first six months of litigation, even though the discovery stage may not have concluded, and include significant briefing and a specialised (*Markman*) hearing.

After a court issues its claim construction order, litigants often file summary judgment motions to resolve issues that can be decided as a matter of law where no genuine issue of material fact exists. Prior to trial, but after the close of discovery, the litigants may file additional summary judgment motions and motions to limit the evidence that can be heard by the jury.

As the trial nears, patent litigants submit individual or joint pre-trial statements that identify witnesses and exhibits. Patent litigants also 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 to the exhibit 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, the court may request a technical tutorial. It is not uncommon to hold a technology tutorial prior to the claim construction (*Markman*) hearing. The court may also appoint its own technical advisor. Indeed, this is common practice in the U.S. District Court for the Eastern District of Texas.

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

Parties to a patent infringement case in the U.S. district court have a right to a jury trial, and a jury may be requested by any one of the parties. Most parties request a jury and the trial begins with jury selection. There are some proceedings that do not involve a jury: (1) litigation concerning the right to sell generic drugs before final approval by the U.S. Food and Drug Administration (commonly called “ANDA litigation”); (2) ITC investigations; and (3) validity challenges at the Patent Office.

At the commencement of the trial, each party may present an opening statement. The opening statements are an opportunity to tell the judge and jury, if applicable, what each party expects the evidence will show.

The parties then present the evidence. The patent owner has the burden of proof on infringement and normally presents its case-in-chief first. The defendant(s) bears the burden on invalidity and presents its case-in-chief second. Both parties usually present both fact and expert witnesses. After a direct examination of a witness, the opposing party is permitted to hold a cross-examination. During witness examination, both parties may move exhibits into evidence.

Finally, each party may make 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 support a verdict in their favour.

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. The court 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?

Trials normally last from three trial days to several weeks. In a jury trial, the jury deliberates immediately after the trial is finished. This may last a few hours or a few days. If tried before a judge without a jury, the judge will typically issue a written opinion explaining his decision. These opinions are issued in the weeks or months following trial. Decisions on 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.

Administrative judges at the ITC have developed substantial patent expertise by hearing a large number of patent cases, but often the individual judges do not have a technical background. Administrative judges at the Patent Trial and Appeal Board (PTAB) are 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 infringement action in its own name without joining the patent owner. An ITC investigation requires the party filing the complaint to have an interest in the patent and an injury to a domestic industry.

Revocation proceedings do not exist in the U.S. but certain entities can challenge the validity of a patent at the Patent Office in *ex parte* re-examination, *inter partes* reviews (IPR), covered business method reviews (CBMR), or post-grant reviews (PGR) proceedings. In a CBMR and PGR, a petitioner can challenge validity on any grounds, including patent-ineligible subject matter, lack of novelty, obviousness, or failure to meet the standards of 35 U.S.C. § 112. In *ex parte* re-examination and IPR, a petitioner 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; an *ex parte* re-examination may.

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

1.9 If declarations are available, 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. Declarations can also address market realities and hypothetical activities as they may relate to damages or harm to a patent owner.

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 35 U.S.C. § 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 35 U.S.C. § 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, 35 U.S.C. § 271(g) permits liability 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. It should be noted, however, that exceptions of § 271(g) are not available in ITC investigations.

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, however, may prevent a patent owner from recapturing, through the doctrine of equivalents, subject matter surrendered to acquire the patent.

1.13 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?

Any party with standing may initiate an action for declaratory judgment that a patent is invalid in a U.S. district court. A defendant may plead invalidity as an affirmative counterclaim and/or a defence. Failure to plead the defence may waive it.

A defendant may prefer to challenge the validity of a patent in a post-grant review proceeding: IPR; CBMR; or PGR. If such a proceeding is instituted and results in a decision affirming validity, the defendant (proceeding petitioner) is estopped from raising, in

court and at the ITC, arguments it actually raised (in a CBMR) or raised or reasonably could have raised (in IPR and PGR). Arguments raised in a petition requesting review that are rejected as redundant are not subject to estoppel.

1.14 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 unenforceable due to inequitable conduct before the Patent Office during prosecution of the patent.

1.15 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 review proceedings, courts typically consider 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; and (3) whether discovery is complete and a trial date has been set. The Federal Circuit has interlocutory appellate jurisdiction to review court decisions on CBMR-premised stay motions. Courts are more likely to stay actions in light of IPR, CBMR, or PGR proceedings, especially if a proceeding has been instituted.

1.16 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 a plaintiff's representation or conduct). Certain technical defences such as failure to keep patents together that are subject to a terminal disclaimer can also be raised.

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

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.

Generally, a court may issue an injunction only if the moving party gives security (in the form of a bond) in the amount the court considers sufficient to pay the costs and damages sustained by any party that is later found to have been wrongfully enjoined.

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

Damages are intended to compensate the patent owner for the infringement. Pursuant to 35 U.S.C. § 284, the damages may not

be less than a reasonable royalty. The amount of the reasonable royalty is based on a number of factors, normally known as the *Georgia-Pacific* factors, which 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 at the start of the infringement. A patent owner may also be able to obtain his lost profits if he can establish: (1) demand for the patented product; (2) no acceptable non-infringing substitutes; (3) that the patent owner had the manufacturing and marketing capacity to exploit the demand; and (4) the amount of profit the patent owner would have made absent the infringement (the *Panduit* test).

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

In addition to monetary damages, a patent owner may obtain: (1) an injunction to prevent 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 the facts show wilfulness or a case is exceptional is reviewed under the U.S. Supreme Court's precedent (*Halo/Highmark/Octane Fitness*).

The ITC cannot award damages. The patent owner may request 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.

1.20 How common is settlement of infringement proceedings prior to trial?

Settlement of an infringement case is very common, especially in view of the potential for a high adverse damages judgment. Some estimate that over 90% of patent infringement cases are settled.

1.21 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.

1.22 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, any party may appeal a reversible error committed by a U.S. district court, subject to waiver. 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).

1.23 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. 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 if the case is exceptional under 35 U.S.C. § 285.

1.24 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?

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 offer to 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. 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/invalidity 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?

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 (*Ericsson*).

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 or a method of using the drug, 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. Patent terms may also be extended for all patents for certain delays in processing the application caused by the Patent Office. 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 of Title 35 of the U.S. Code 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 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 or knowingly submitting misleading or false information may be deemed 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?

Any third party may submit any patent, unpublished patent application, 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 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, derivation proceedings allow a determination of whether the person who claims inventorship actually invented the subject matter or whether he learned of it from another and filed first.

5.6 Is there a "grace period" in your jurisdiction, 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 one-year grace period may exist 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 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. 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 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?

An accused infringer may assert an antitrust counterclaim if the patent owner 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, lessening competition through attempts to monopolise or improper agreements with third parties and, in some circumstances, patent misuse. 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.

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*), attorney’s fees (*Highmark/Octane Fitness*), wilful infringement (*Halo*), induced infringement (*Limelight/Commil*), claim construction (*Nautilus/Teva*), broadest reasonable construction in post-grant review proceedings and appellate review of institution decisions (*Cuozzo*), patent royalty payments (*Kimble*), natural products/genes (*Myriad*), and patent-eligible subject matter (*Mayo/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 more 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*). The Federal Circuit has also ruled on the scope of the ITC’s jurisdiction (*ClearCorrect*), foreign and domestic patent exhaustion (*Lexmark*), and patent-eligible subject matter (*Enfish/TLL*).

8.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction 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. However, even in view of the number of successful outcomes from post-grant review proceedings, the number of new patent cases in 2016 is on track to exceed those filed in 2015.

Note

This chapter reflects only the present considerations and views of the authors, which should not be attributed to Kirkland & Ellis LLP, SpencePC, or to any of their former or present clients.

Acknowledgment

The authors acknowledge, with great appreciation, the significant authorship contributions of their colleague Kenneth R. Adamo in the preparation of this chapter.

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