

International **Comparative** Legal Guides



Patents **2021**

A practical cross-border insight into patent law

11th Edition

Featuring contributions from:

Bird & Bird LLP
Cedar White Bradley IP LLC
Chuo Sogo Law Office, P.C.
CPST Intellectual Property
Daniel Law
DDPV Studio Legale
Duane Morris LLP
Eric Silwamba, Jalasi and Linyama
Legal Practitioners
Gleiss Lutz
Gorodissky & Partners Ukraine

Gowling WLG
Haynes and Boone
Kadasa Intellectual Property
(in association with Rouse & Co. International)
Law Office of KRAdamo
LexOrbis
Mintz
Nestor Nestor Diculescu Kingston Petersen
Ofo Ventura Intellectual Property & Litigation
OLIVARES
Patrinos & Kilimiris

PETOŠEVIĆ Russia
Pham & Associates
Reinhold Cohn Group
Reising Ethington P.C.
Rouse
Setterwalls
Shook Lin & Bok
SyCip Salazar Hernandez & Gatmaitan
TIPLo Attorneys-at-Law

ICLG.com



ISBN 978-1-83918-066-8
ISSN 2044-3129

Published by

glg global legal group

59 Tanner Street

London SE1 3PL

United Kingdom

+44 207 367 0720

info@glgroup.co.uk

www.iclg.com

Consulting Group Publisher

Rory Smith

Publisher

James Strode

Editor

Jane Simmons

Senior Editor

Sam Friend

Head of Production

Suzie Levy

Chief Media Officer

Fraser Allan

CEO

Jason Byles

Printed by

Ashford Colour Press Ltd.

Cover image

www.istockphoto.com

Strategic Partners



International **Comparative** Legal Guides

Patents **2021**

11th Edition

Contributing Editor:

Katharine Stephens

Bird & Bird LLP

©2020 Global Legal Group Limited.

All rights reserved. Unauthorised reproduction by any means, digital or analogue, in whole or in part, is strictly forbidden.

Disclaimer

This publication is for general information purposes only. It does not purport to provide comprehensive full legal or other advice. Global Legal Group Ltd. and the contributors accept no responsibility for losses that may arise from reliance upon information contained in this publication.

This publication is intended to give an indication of legal issues upon which you may need advice. Full legal advice should be taken from a qualified professional when dealing with specific situations.

Expert Chapters

- 1** **The Relevance of Compulsory Licensing in the Fight Against the COVID-19 Pandemic**
Neil Jenkins & Georgina Straughan, Bird & Bird LLP
- 4** **A New Fault Line in the Modern Era of U.S. Patent Eligibility**
Corey M. Beaubien, Reising Ethington P.C.
- 8** **Ownership of Patent Rights and Standing to Sue in US Courts**
D. Stuart Bartow, Duane Morris LLP
- 12** **Appealing a PTAB Post-Grant Final Decision: The Need for Standing**
Kenneth R. Adamo & Eugene Goryunov, Law Office of KRAdamo | Haynes and Boone
- 17** **Gulf Co-operation Council Countries – Patent Landscape**
Sara Holder & Mohammad Jomoa, Kadasa Intellectual Property (in association with Rouse & Co. International)

Q&A Chapters

- | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> 21 Australia Bird & Bird LLP: Jane Owen & Rebecca Currey 29 Brazil Daniel Law: Rana Gosain & Ricardo Nunes 37 Canada CPST Intellectual Property: Anthony Prenol & Brett Slaney 45 France Gowling WLG: Céline Bey & Clémence Lapôtre 61 Germany Gleiss Lutz: Dr. Matthias Sonntag & Dr. Herwig Lux 69 Greece Patrinos & Kilimiris: Constantinos Kilimiris 75 India LexOrbis: Joginder Singh, Varun Sharma & Rajeev Kumar 84 Israel Reinhold Cohn Group: Adv. Eran Bareket & Dr. Ronnie Benshafrut 93 Italy DDPV Studio Legale: Luciano Vasques & Chiara Sciarra 102 Japan Chuo Sogo Law Office, P.C.: Naoko Nakatsukasa 110 Malaysia Shook Lin & Bok: Michael Soo & Wendy Lee Wan Chieh 117 Mexico OLIVARES: Daniel Sanchez y Bejar & Sergio L. Olivares, Jr. 127 Myanmar Rouse: Fabrice Mattei & Moe Mynn Thu 134 Philippines SyCip Salazar Hernandez & Gatmaitan: Vida M. Panganiban-Alindogan & Anna Loraine M. Mendoza | <ul style="list-style-type: none"> 142 Romania Nestor Nestor Diculescu Kingston Petersen: Sorina Olaru, Daniela Savin (Ghervas) & Alina Tace (Dumitru) 150 Russia PETOŠEVIĆ Russia: Natalia Osipenko & Mayya Pak 157 Saudi Arabia Kadasa Intellectual Property: Mohammad Jomoa & Sara Holder 164 Sweden Setterwalls: Martin Levinsohn & Per Lidman 171 Taiwan TIPLo Attorneys-at-Law: J. K. Lin & H. G. Chen 180 Thailand Rouse: Fabrice Mattei & Manoon Changchumni 188 Turkey Ofo Ventura Intellectual Property & Litigation: Özlem Futman & Yasemin Aktas 197 Ukraine Gorodissky & Partners Ukraine: Oleg Zhukhevych & Maksym Bocharov 206 United Arab Emirates Cedar White Bradley IP LLC: David Harper 212 United Kingdom Bird & Bird LLP: Katharine Stephens & Audrey Horton 224 USA Mintz: Michael T. Renaud & Matthew A. Karambelas 232 Vietnam Pham & Associates: Pham Vu Khanh Toan 240 Zambia Eric Silwamba, Jalasi and Linyama Legal Practitioners: Joseph A. Jalasi & Andrew Simunyola |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

USA

Mintz



Michael T. Renaud



Matthew A. Karambelas

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?

Patent owners can bring actions in U.S. federal district courts, or at the U.S. International Trade Commission (ITC), or both. District courts offer money damage and injunctive relief, whereas the ITC offers exclusion orders and cease and desist orders against importation and further sale of infringing products.

Timing is a key factor – at the ITC, cases are often tried within a year of the filing of the complaint, and are usually completed in less than 18 months, whereas in the U.S. district courts, the time to trial can be over a year, or several years, after the complaint. Cases brought in district court take longer to complete than at the ITC (although in some districts, such as the Western District of Texas, trial dates are generally scheduled earlier on average than other districts).

To file at the ITC, there must be imports of infringing products into the United States, and the patent owner (itself or its licensees) needs to support a significant domestic industry protected by the patents. In district court, the patent owner can file in any U.S. state in which an infringer is subject to personal jurisdiction, and where venue is proper.

1.2 Can the parties be required to undertake mediation before commencing court proceedings? Is mediation or arbitration a commonly used alternative to court proceedings?

Unless the contractual relationship between the parties requires mediation or arbitration prior to commencing court proceedings, there is no requirement that parties must engage in mediation or arbitration before litigation. For some judges in U.S. federal districts (such as the Northern District of California), and at the ITC, there can be deadlines in the procedural schedule for the parties to meet and confer to discuss alternative dispute resolution (“ADR”), *i.e.*, mediation. Judges may also require the parties engage in settlement discussions.

1.3 Who is permitted to represent parties to a patent dispute in court?

Due to the complex nature of patent litigation, patent owners typically hire counsel experienced with the tribunal in which

the litigation is taking place. While it is strongly discouraged, individual patent owners are entitled to represent her/himself in court *pro se*.

1.4 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?

At the ITC, cases are often tried within a year of the filing of the complaint, and typically are completed between 14 and 18 months, whereas in the U.S. federal district courts, the time to trial can be over a year, or several years, after the filing of the complaint. However, as noted above, in some districts, such as the Eastern District of Texas, Western District of Texas, and others, trial dates are generally scheduled earlier on average in comparison to other districts. To commence proceedings in U.S. district courts, the patent owner is required to pay a court filing fee of about \$400, and is required to prove effective service on the accused infringers, which typically can be done by serving a summons to appear and a copy of the complaint.

To commence proceedings at the ITC, the patent owner is not required to pay a filing fee, and is typically not required to prove effective service on the accused infringers, but will in some instances collaborate with the ITC if needed.

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

Parties may obtain discovery on matters that are relevant to a claim or defense in the litigation, that are not privileged, and for which the burden and expense of the requested discovery does not outweigh its anticipated benefit and importance to the case. The scope of discovery, *i.e.*, relevant discovery, is broader than the scope of what ultimately will be admissible at trial. The Court's ground rules will also govern many aspects of conducting discovery.

A party can be compelled to disclose relevant documents, usually after proceedings begin. At the ITC, once the Investigation is instituted, which is about 30 days after the filing of the complaint, the parties can serve discovery requests. In the U.S. federal district courts, the parties typically will first exchange initial disclosures which require that each party identify sources of discoverable information.

If a discovery dispute arises, the parties are encouraged to meet and confer in an attempt to resolve the issues, but may seek the assistance and guidance of the presiding judge, including by means of a motion to compel the discovery.

Importantly, third parties may also be compelled to provide discovery, if one of the named parties seeks a subpoena.

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

Patent cases begin with pleadings, *i.e.*, the patent owner's complaint, followed by an answer, counterclaims, or any responsive pleadings by the accused infringer. Usually, once the initial pleadings are in, and the parties have made their appearances of counsel, the Court will schedule an initial case management conference, where the parties discuss proposed procedural schedules, and any issues that might likely arise in discovery. Parties typically will submit a joint proposed procedural schedule, discovery stipulation, and protective order governing the production of, and reasonable access to, confidential information. The Court will then enter a scheduling order to govern the sequence of the pre-trial events, which are highly dependent on the particular ground rules involved for that particular Court.

In fact discovery, the parties will serve written interrogatories, requests for production of documents, and requests for admission, as well as notices of depositions of fact witnesses. Technical evidence is produced during fact discovery, *e.g.*, if electronics or semiconductor technology is involved, circuit layout files may need to be produced, or for a microbiology case, genetic sequences and complex protein analyses may need to be produced. During the fact discovery period, parties will also exchange preliminary infringement, invalidity, and/or unenforceability contentions.

In expert discovery, the experts prepare technical and economic expert reports. After the reports are exchanged, the parties depose the experts in depositions.

In the claim construction process, the Court may set a *Markman* hearing date to resolve disputed claim terms before trial, sometimes with a technical tutorial from the parties.

Then, the parties may file any motions for summary judgment, based on the facts produced, and the Court's claim construction, so that there are no genuine issues of material fact, and there are only issues of law for the Court to decide. These motions can serve to substantially limit the scope of the trial.

Some pre-trial motions, called motions *in limine*, can allow the parties to limit, or exclude, evidence or arguments by the opposing party prior to the trial commencing.

After that, parties provide their pre-trial statements that identify witnesses and exhibits, proposed jury instructions (if there is to be a jury trial) and any objections they have concerning the opposing side's exhibits or proffered testimony.

These pre-trial stages are common at both the ITC and U.S. federal district courts.

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

Depending on the preferences of the judge presiding over the case, arguments can first be presented in an opening statement, which gives the parties the opportunity to tell their story and theories of the case.

Factual evidence (including exhibits) is then presented initially through either (i) written witness statements (followed by live cross examination), or (ii) live direct witness testimony (followed by live cross examination). The patent owner has the burden of proof on infringement, and accused infringers bear the burden on invalidity. Depending on the judge's preferences, there may be closing arguments.

The audience will be the judge in a bench trial, such as at the ITC, or a jury such as at the district court. While district court actions typically involve a jury in patent infringement cases, some proceedings, such as ANDA litigation involving generic drugs pending final U.S. FDA approval, do not involve a jury.

Parties can generally alter arguments before or at trial, if there is good cause for doing so, *e.g.*, late production of evidence by an opposing party.

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

A typical patent trial is one week (five weekdays), but the length can be shorter or longer depending on the number of issues, or number of patents, in the case.

In U.S. district courts, with juries, an infringement verdict can issue soon after trial, but a Court's ruling on other post-trial issues could take a few weeks or months after trial.

At the ITC, the ALJ typically issues an initial determination two or three months after the evidentiary hearing, which is then affirmed or overturned by the Commission at a time before the initial target date for completion of the Investigation, typically 14 to 18 months after the filing of the complaint.

The appeal process usually takes between one and two years after the trial concludes.

1.9 Is there any alternative shorter, flexible or streamlined procedure available? If so, what are the criteria for eligibility and what is the impact on procedure and overall timing to trial?

Generally, the ITC is the most expedited infringement forum available, and as described again in question 1.21, it is exceedingly rare for the ITC to stay proceedings pending a validity challenge elsewhere. Aside from the ITC's expedited schedule for having a patent infringement trial in usually less than one year after filing the complaint, other Courts do not usually provide shorter procedures for ultimate determinations of patent infringement. However, some U.S. district courts with procedural schedules that are faster than most other districts, such as the Western District of Texas, which usually involves a *Markman* hearing less than one year after the complaint.

Also, accused infringers can seek expedited relief at the Patent Trial and Appeal Board ("PTAB") to challenge validity, *e.g.*, in *inter partes* reviews ("IPRs"), post-grant reviews ("PGRs"), and covered business method reviews ("CBMs").

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

Generally, yes, due to a presumption of public access to judicial records. However, depending on the confidential nature of the material, and the risk it may impose on a party if it were disclosed, some documents filed with the Court in the case may be redacted, or be filed under seal.

1.11 Are courts obliged to follow precedents from previous similar cases as a matter of binding or persuasive authority? Are decisions of any other jurisdictions of persuasive authority?

All jurisdictions are subject to binding authority (from its own

jurisdiction, the U.S. Court of Appeals for the Federal Circuit, and the Supreme Court) or persuasive authority (from others).

At the PTAB, whose decisions in IPRs, PGRs, and CBMs are not binding on other forums, like the ITC, will sometimes issue decisions as “precedential” or “informative” which affects the level of precedential value.

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

At the ITC, all administrative law judges have developed an acute patent expertise given their case experience.

In U.S. district courts, when a patent case is filed, it is randomly assigned to a judge in the district, who in some circumstances may decline to accept the case, and it would then be reassigned.

The Justices at the U.S. Court of Appeals for the Federal Circuit, as well as administrative judges at PTAB, have all developed patent expertise.

Many judges have a technical background, but not always.

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

To bring a patent infringement action, the “complainant” (at the ITC) or the “plaintiff” (at the U.S. district courts) will need to either be the patent owner, or an exclusive licensee with standing. In addition, as noted earlier, complainants at the ITC also need to be supported by a significant domestic industry based on their own (or their licensees’) in the patented products or technology.

U.S. patent tribunals do not have revocation proceedings *per se*, but accused infringers can challenge the validity of a patent at PTAB through IPRs, PGRs, or CBMs. *Ex parte* re-examinations may also be brought by the patent owner. In IPRs and *ex parte* reexaminations, petitioners can challenge validity only on novelty (35 U.S.C. § 102) or obviousness (§ 103) grounds. With PGRs or CBMs, additional challenges are available, including patentable subject matter (§ 101) and indefiniteness (§ 112).

Any party may seek a declaratory judgment that a patent is either not infringed, and/or invalid, in U.S. district court, if there is an “immediate” and “real” substantial controversy between the parties as to patent infringement.

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

Declarations are available. They can be used to support a parties’ arguments on how the patent claims should be interpreted, or factual background describing, *e.g.*, (i) a patent owner’s earlier conception and reduction to practice of an invention, (ii) how the accused products work, (iii) relevant aspects of the prior art, or (iv) economic, financial, or market data relating to damages or other economic issues.

1.15 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?

Yes, a party may be liable for indirect infringement if it contributes to, or induces, infringement by a direct infringer (35 U.S.C.

§ 271(b), (c)). With contributory infringement, liability may apply where the indirect infringer makes a component constituting a material part of the invention, knowing it to be made or adapted for use in a directly infringing manner.

1.16 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, process patents have started playing a larger role in patent enforcement cases, particularly at the ITC where foreign manufacturing processes are at issue. Under 35 U.S.C. § 271(g), a party is liable for importing products into the U.S. made abroad by a process patented in the U.S., with the following two exceptions: (i) the product is materially changed before importation; or (ii) is a trivial part of another product. Notably, those two exceptions are not applicable at the ITC.

1.17 Does the scope of protection of a patent claim extend to non-literal equivalents (a) in the context of challenges to validity, and (b) in relation to infringement?

The scope of patent protection extends to non-literal infringing embodiments (i.e., equivalent embodiments), under the doctrine of equivalents. The doctrine may be limited if the patent owner surrendered a particular scope in prosecuting the patent (which cannot be recaptured for subsequent allegations of infringement) or if the accused infringer can show that the “equivalent” in question would have been covered by prior art.

1.18 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? Are the issues of validity and infringement heard in the same proceedings or are they bifurcated?

Yes, as stated above, an accused infringer can raise a defense or counterclaim of invalidity in a patent suit, or a potential accused infringer can file a declaratory judgment action in a U.S. district court asserting invalidity. Also, a party can challenge validity at the PTAB, through an IPR, CBM, or PGR. However, that party should carefully consider the potential that it will be estopped from raising, at both the ITC and district court, arguments it actually (or could have) raised before the PTAB.

1.19 Is it a defence to infringement by equivalence that the equivalent would have lacked novelty or inventive step over the prior art at the priority date of the patent (the “*Formstein* defence”)?

The U.S. does not have a direct equivalent to the *Formstein* defense. However, as noted earlier, a patent owner’s assertion of infringement under the doctrine of equivalents may be limited in certain circumstances.

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

Other grounds include lack of enablement, indefiniteness, claims unsupported by a written description, and claiming unpatentable subject matter.

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

U.S. district courts have the discretion to stay proceedings pending resolution of validity before the PTAB, considering whether the stay will be prejudicial to the patent owner, and the stage of both proceedings. Some districts with relatively faster schedules, such as the Western District of Texas, will be less likely to stay proceedings.

At the ITC, because of its expedited proceedings, it is exceedingly rare for the ITC to grant a stay pending a PTAB decision, and will typically only consider a stay in the rare circumstance in which an ITC case is pending when a final written decision from PTAB has already been issued.

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

Other equitable defenses, such as inequitable conduct, patent misuse, and equitable estoppel may be raised, depending on the specific factual circumstances of the case.

1.23 (a) Are preliminary injunctions available on (i) an *ex parte* basis, or (ii) an *inter partes* basis? In each case, what is the basis on which they are granted and is there a requirement for a bond? Is it possible to file protective letters with the court to protect against *ex parte* injunctions? (b) Are final injunctions available? (c) Is a public interest defence available to prevent the grant of injunctions where the infringed patent is for a life-saving drug or medical device?

Yes, preliminary and permanent injunctions are available, *ex parte*, through temporary restraining orders, and *inter partes*. For a preliminary injunction, the moving party must show: (i) a substantial likelihood of prevailing on the merits (such as the patent infringement allegations); (ii) irreparable harm if a preliminary injunction were to not issue; (iii) the balance of hardships weighs in favour of an injunction; and (iv) an injunction will further the public interest. There are similar elements for permanent injunctions, plus requiring a final ruling on the merits. If a preliminary injunction is granted, the Court may require the moving party post a bond in the amount the Court deems sufficient to cover costs if the enjoined party later prevails.

As discussed, the public interest is a factor (and therefore considered in the analysis) for injunctions. If the Court finds an injunction will harm the public, it may decline to grant one.

1.24 Are damages or an account of profits assessed with the issues of infringement/validity or separately? On what basis are damages or an account of profits assessed? Are punitive damages available?

Damages in the district court are typically tried with the other merits (unless the court or the parties request a bifurcation of the proceedings), and can be accounted for using an number of approaches, including an analysis of (i) a reasonable royalty, (ii) a hypothetical negotiation between the parties, (iii) any of the fifteen *Georgia-Pacific* factors that may be relevant, (iv) cost

savings (particularly with patented methods), (v) any acceptable non-infringing alternatives, and (vi) lost profits by the patent owner due to the infringement. Triple damages are available if the infringement is willful. Damages are not available at the ITC, where the remedy of an exclusion order is the relief provided to a prevailing patent owner.

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

Either actions for contempt of a court order (in U.S. district courts) or enforcement actions brought before the ITC or U.S. Customs (for ITC cases). The USPTO enforces the cancellation of claims if ordered by PTAB. Due to the increasing difficulty in obtaining an injunctive relief in a district court over the past decade, the ITC has increasingly become a preferred forum for patent owners seeking injunctive relief.

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

In exceptional cases, parties can recover reasonable attorneys' fees.

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

Settlement is very common before trial. Some IP data services such as Lexology estimate that over 90% of patent infringement actions in the U.S. settle before trial.

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

Damages are not recoverable for infringement occurring more than six years before the complaint.

1.29 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?

Parties may appeal final judgments on the merits with the Federal Circuit. In some cases, a party may move for permission to file an interlocutory appeal before the conclusion of the case.

1.30 What are the typical costs of proceedings to a first instance judgment on (i) infringement, and (ii) validity? How much of such costs are recoverable from the losing party?

Costs vary depending on the complexity of the case, but there are some services that periodically collect survey data on how much parties spend in their own cases. See <https://www.aipla.org/detail/journal-issue/2019-report-of-the-economic-survey>. Under the American rule, each party must bear its own litigation expenses, although as noted earlier, reasonable attorneys' fees can be recovered in exceptional cases.

1.31 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? Will your country host a local division of the UPC, or participate in a regional division? 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?

For patents outside the U.S., the U.S. does not currently have mutual recognition arrangements.

2 Patent Amendment

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

Yes, a patent can be corrected or amended by: (1) reissue; (2) certificate of correction; (3) disclaimer; and (4) reexamination.

A reissue is available when a patent is deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or the patentee claiming more or less than it had a right to claim in the patent. To file a broadening reissue, a patent owner must seek correction within two years of the issue date, and identify at least one error in the original patent.

A certificate of correction is available for clerical or typographical mistakes that occurred in good faith, and the change would not constitute new matter or require reexamination.

A disclaimer is available when the patentee determines to disclaim individual claims.

Reexamination can be filed by anyone, including the patent owner. When the patent owner asks for re-examination, the procedure is an *ex parte* consideration of prior art. If the patent owner wants wider consideration of issues, including prior public use or on-sale, it may file a reissue application.

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

Yes, patent claims can be amended during an IPR, CBM, or PGR.

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

A patent can be amended during IPR, but only in one motion (which may cancel a challenged claim or propose a reasonable number of substitute claims), after conferring with the Board, and generally no later than the filing of a patent owner response. The motion could be denied where it: (1) does not respond to a ground of unpatentability involved in the trial; or (2) seeks to enlarge the scope of the claims of the patent or introduce new subject matter. An additional motion to amend may be authorised for good cause, or on a joint request of the petitioner and the patent owner to materially advance a settlement.

3 Licensing

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

Parties cannot contract for royalties that run after a patent

expires (see *Kimble v. Marvel Entm't, LLC*, 576 U.S. 446 (2015)) and district courts will consider fair, reasonable, and non-discriminatory obligations (FRAND) with standard essential patents ("SEPs").

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 generally disfavoured and not common in the U.S.

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?

Patents are eligible for an unlimited number of extensions caused by certain delays in processing applications by the USPTO. Patents claiming a new drug may be extended up to five years caused by regulatory review of the drug.

5 Patent Prosecution and Opposition

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

35 U.S.C. § 101 defines patentable subject matter as any new and useful process, machine, manufacture, or composition of matter. Courts have introduced the *Alice/Mayo* test to exclude abstract ideas and laws of nature from patentable subject matter, sometimes impacting diagnostic inventions and software inventions.

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 USPTO places a duty of candor and good faith upon each individual associated with the filing and prosecution of a patent application, including an obligation to submit any known information that is material to patentability (*i.e.*, not cumulative of the record, and would establish a *prima facie* case of unpatentability of a claim, or would materially refute or be inconsistent with a position of the applicant in arguing patentability). There is no affirmative duty to search for material information, only to disclose known information. The duty of disclosure continues after a patent has been issued. Failure to satisfy the duty of disclosure can be considered fraud and therefore result in a finding of inequitable conduct, which may result in the patent being unenforceable.

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?

Yes, a grant of a patent by the USPTO may be opposed by a third party, by (i) *ex parte* re-examination, (ii) PGR or CBM within nine months of issuance, or (iii) IPR within one year of service of a complaint alleging infringement. Absent the filing of a complaint alleging infringement, there are no time limits on filing *inter partes* review proceedings. There are no restrictions on the filing of an *ex parte* reexamination.

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

Yes, the applicant has the right to appeal a decision by an Examiner to a three-member panel of PTAB, whose decisions can then be appealed to the Federal Circuit, whose decisions can then be appealed to the United States Supreme Court.

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

For applications filed prior to March 16, 2013, interference proceedings, *i.e.*, resolution of inventorship thus ownership, may be available.

For applications filed on or after March 16, 2013, interference proceedings are no longer available, and the first inventor to file is presumed to have priority. However, in cases where a party files an application on another's invention, derivation proceedings are available.

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

For applications filed prior to March 16, 2013, any disclosure that occurred within one year prior to the application filing may be removed as prior art if the applicant can prove that it invented the invention prior to the disclosure.

For applications filed on or after March 16, 2013, a disclosure made one year or less before the effective filing date of a claimed invention is not considered prior art to the claimed invention if the disclosure was made by the inventor or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or the subject matter disclosed had, before such disclosure, been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor.

5.7 What is the term of a patent?

The term of a U.S. patent is 20 years from the earliest filing date of the application on which the patent was granted, and any prior U.S. or Patent Cooperation Treaty (PCT) applications from which the patent claims priority, excluding provisional applications. In certain circumstances, the term of the patent can be increased (*e.g.*, due to administrative delays) or reduced (*e.g.*, as a result of a terminal disclaimer in which the applicant disclaims the term of a patent extending beyond the term of another patent).

For U.S. design patents, the term is either 15 years from the issue date (for design applications filed on or after May 13, 2015), or 14 years from the issue date (for design applications filed before May 13, 2015).

5.8 Is double patenting allowed?

Double patenting is allowed subject to certain restrictions. Statutory-type double patenting (where two patents claim exactly the same subject matter) is not allowed.

Non-statutory obviousness-type double patenting (where two commonly owned patents claim subject matter that, while different, are obvious variants), is allowed if overcome by filing a terminal disclaimer, which can impact patent term.

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?

The most effective mechanism for seizing or preventing the importation of infringing products is by filing a complaint at the ITC for an exclusion order blocking imports and/or cease and desist order blocking further sales of infringing products. Initial determinations typically are issued within nine to 12 months after institution, and may be reviewed, in whole or in part, by the full Commission, followed by a 60-day Presidential Review period before the orders are issued.

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 against the patent owner, and seek a ruling that the patent is unenforceable.

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

Patent misuse theories may render patents unenforceable for improper licensing, *e.g.*, requiring payments after patent expiration.

7.3 In cases involving standard essential patents, are technical trials on patent validity and infringement heard separately from proceedings relating to the assessment of fair reasonable and non-discriminatory (FRAND) licences? Do courts grant FRAND injunctions, *i.e.* final injunctions against patent infringement unless and until defendants enter into a FRAND licence?

Generally, patent infringement and validity trials involve damages issues, including FRAND licensing issues for SEPs. U.S. courts have discretion in the methodology and factors used in its FRAND analysis, with most courts using some combination of the "top down" and "comparative licensing" approaches. Although it is uncommon for a court to grant an injunction against an alleged infringer of an SEP, some trial courts have issued them, where, *e.g.*, the standard setting organization's patent policy agreement is found to be unenforceable. See <https://www.essentialpatentblog.com/2020/04/itc-avoids-sep-frand-issues-by-finding-patents-not-infringed-netlist-v-hy-nix-337-ta-1089/>.

8 Current Developments

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

In a ruling that may make it more difficult for district court defendants to seek a stay in the district court pending PTAB proceedings, *Apple v. Fintiv* was made "precedential" in May 2020, establishing factors for deciding whether to deny a petition where a co-pending district court action would resolve the same issues: (i) overlap of issues; and (ii) time to trial.

Also this year, the Supreme Court held that PTAB's decision whether an IPR petition is time-barred is not judicially reviewable (*Thryv*).

In another notable case (*In re: Google LLC*), the Federal Circuit found that Google's servers cannot suffice for establishing venue for purposes of filing suit against Google in the Eastern District of Texas, further clarifying the evolving law on the required "place of business" for venue purposes.

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

Many hoped the U.S. Supreme Court would provide guidance on patent eligibility (*Athena*), retroactive application of American Invents Act reviews (*Celgene Corp.*) and doctrine of equivalents (*CJ Cheiljedang*) in 2020. While the Court rejected cert petitions in these areas, there are several cases that many have a big impact on U.S. patent law: whether PTAB judges are unconstitutionally appointed (*Arthrex*); juries' ability to decide royalty rates for standard essential patent (SEP) cases (*TCL*); patent eligibility claiming a natural law (*American Axle*); approval pathway for

biosimilars (*California v. Texas*); and how narrowly inventors must claim antibody-based inventions to meet enablement requirements (*Amgen*). More broadly, as to SEPs, Courts in the U.S. will be closely monitoring decisions by Courts in other countries (such as the UK Supreme Court) regarding which tribunals can set FRAND terms and rates for SEP licences, *e.g.*, in the recent *Unwired Planet* decision.

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

Generally, with the onset of the COVID-19 pandemic, many Courts have considered providing virtual or telephonic hearings, where they typically had previously conducted those hearings in-person. In addition, parties have explored options for taking depositions remotely. Also, Courts have started to consider alternative protective order review protocols for discovery, whereby the reviewing party could, *e.g.*, review source code produced in a case remotely, as opposed to reviewing the code at a third-party review computer site.



Michael T. Renaud, recognised as one of the World's Leading IP Strategists by *IAM magazine* in its annual *IAM 300* publication, is the central tactician in developing and implementing multinational litigation and enforcement strategies, coordinating counsel across the globe.

As firmwide Chair of the Intellectual Property Division, Mr. Renaud leads an international team of IP prosecutors, litigators and transaction specialists. As an engineer with 20 years' experience in intellectual property, Mr. Renaud achieves success both in and out of the courtroom stemming from his uncommon combination of sound legal judgment, strong business acumen, and experience with, and sensitivity to, changing market conditions.

In the past year, he has led multiple teams of attorneys in U.S. Federal District Courts, the International Trade Commission, and German and Chinese courts, to successfully enforce patents for companies like GlobalFoundries, the largest semiconductor foundry in the U.S., against the largest semiconductor foundry in the world.

Mintz
One Financial Center
Boston, MA 02111
USA

Tel: +1 617 348 1870
Email: MTRenaud@mintz.com
URL: www.mintz.com



Matthew A. Karambelas is an experienced patent litigator who has represented clients, and organised trial teams, spanning several Investigations at the U.S. International Trade Commission, cases in the U.S. District Courts, and appeals in the U.S. Court of Appeals for the Federal Circuit. In addition, Mr. Karambelas has significant experience in evaluating patent portfolios, offering clients useful advice on assessment and valuation of key aspects of their U.S. patent holdings.

Mr. Karambelas's clients are focused on technologies ranging from high tech and software, to life sciences and medical products. He has recently worked on cases for clients with patents in semiconductor technology, microbiology and genetic engineering, graphics processing, telecommunications, medical-quality flocked swabs, and healthcare information systems. In the past year, he has played key roles on cases at the International Trade Commission to successfully enforce patents for semiconductor companies like GlobalFoundries, the largest foundry in the U.S., against the largest semiconductor foundry in the world.

Mintz
One Financial Center
Boston, MA 02111
USA

Tel: +1 617 348 1831
Email: MAKarambelas@mintz.com
URL: www.mintz.com

Mintz is an AmLaw 100 firm with an Intellectual Property practice of more than 135 professionals, including 40+ PhDs, which emphasises the development, protection and exploitation of strategic patent portfolios. We represent clients in the automotive, biotechnology, cloud computing, medical device, pharmaceutical, semiconductor, and telecommunications industries. The patent enforcement and licensing team has generated close to \$1 billion for clients in the past 10 years through strategic negotiations, brokered sales, and global enforcement proceedings in U.S., Chinese and German jurisdictions. Our patent litigators have achieved significant wins in U.S. District Courts, the International Trade Commission, the U.S. Patent Trial and Appeal Board, and in the Court of Appeals for the Federal Circuit. Our patent prosecution and strategic counselling professionals represent clients of all sizes, including numerous Fortune 1000 corporations, working alongside them to chart the course – using landscape analysis, opinions and strategic portfolio assessment to build optimised portfolios.

www.mintz.com



ICLG.com

Current titles in the ICLG series

Alternative Investment Funds
Anti-Money Laundering
Aviation Finance & Leasing
Aviation Law
Business Crime
Cartels & Leniency
Class & Group Actions
Competition Litigation
Construction & Engineering Law
Consumer Protection
Copyright
Corporate Governance
Corporate Immigration
Corporate Investigations
Corporate Tax
Cybersecurity
Data Protection
Derivatives
Designs
Digital Business

Digital Health
Drug & Medical Device Litigation
Employment & Labour Law
Enforcement of Foreign Judgments
Environment & Climate Change Law
Environmental, Social & Governance Law
Family Law
Fintech
Foreign Direct Investment Regimes
Franchise
Gambling
Insurance & Reinsurance
International Arbitration
Investor-State Arbitration
Lending & Secured Finance
Litigation & Dispute Resolution
Merger Control
Mergers & Acquisitions
Mining Law
Oil & Gas Regulation

Outsourcing
Patents
Pharmaceutical Advertising
Private Client
Private Equity
Product Liability
Project Finance
Public Investment Funds
Public Procurement
Real Estate
Renewable Energy
Restructuring & Insolvency
Sanctions
Securitisation
Shipping Law
Telecoms, Media & Internet
Trade Marks
Vertical Agreements and Dominant Firms