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Contents

Rothwell, Figg, Ernst & Manbeck PC devotes more than half its work to intricate, multi-party patent litigation involving complex scientific and legal issues in district courts, before the International Trade Commission and in the US Court of Appeals for the Federal Circuit. As a single-office firm in Washington, DC dedicated solely to IP, its clients have the advantage of working with a patent litigation team that is housed under one roof and therefore works in a highly collaborative environment. The majority of attorneys in the firm's patent litigation practice earned undergraduate degrees in specialised fields – such as biology, chemistry, computer science, electrical engineering, biomedical engineering, mechanical engineering and biochemistry – and it has attorneys with PhDs and advanced degrees in areas such as electrical engineering, mathematics, chemistry, biotechnology and aeronautics. The team's higher education and prosecution experience means its attorneys understand the technical aspects of a client's IP at a deeper level.

Authors

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1. Types of Intellectual Property Rights & Grant Procedure

1.1 Types of Intellectual Property Rights

The United States (US) offers protection of inventions through the intellectual property rights associated with patents or trade secrets. Patents provide broad, time-limited rights to the patentee in exchange for public disclosure of the invention. In contrast, trade secrets are not publicly known, have narrower rights and in principle, an indefinite duration.

Patents arise from federal law. Congress created the US patent system based on its authority in the US Constitution, which grants Congress power "to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." Title 35 of the US Code contains the federal laws related to patents.

Trade secret law is primarily based on state laws. Specific definitions vary, but generally, a trade secret must not be known to the public, must confer economic benefit on its holder because it is not publicly known, and the trade secret-holder must take reasonable measures to keep such information secret. Most states have adopted the Uniform Trade Secrets Act, 1979, as amended, or a variation of it, so there is a measure of uniformity among the state laws. In addition to state law causes of action, the Defend Trade Secrets Act of 2016 provides a federal cause of action for trade secret misappropriation.

The statutory language creates a foundation for patents and trade secrets, but the law continues to evolve through case law as courts interpret legal terms and concepts.

1.2 Grant Procedure

The US Patent and Trademark Office (USPTO) conducts the patent approval process and grants any resulting patents. Applicants file either a provisional or non-provisional patent application with the USPTO.

Provisional applications provide a quick and inexpensive way for inventors to establish a US filing date for the invention, which can be claimed in a non-provisional application that is filed later. A provisional application must contain a description of the invention and may include drawings necessary to understand the invention. A provisional application has fewer requirements than a non-provisional application but cannot develop into a patent without a corresponding non-provisional application filed within twelve months.

A non-provisional patent application must include both a description of the invention and claims describing the scope of the protections sought in the patent. A non-provisional application may be filed without a prior provisional application. However, a non-provisional application may gain the benefit of the earlier filing date of a corresponding provisional application if filed within twelve months of the provisional application.

Non-provisional applications undergo substantive examination by the USPTO to ensure compliance with the legal requirements for a patent. As a preliminary matter, a patent must claim patent-eligible subject matter. At a minimum, the US Supreme Court has stated that laws of nature, natural phenomena and abstract ideas are not patentable. Patents must also describe an invention that is novel and non-obvious with sufficient detail that a person of ordinary skill in the art of the invention can make and use the invention without undue experimentation.

The interaction between patent applicants (or their representatives) and the USPTO is called patent prosecution. During patent prosecution, an examiner at the USPTO will review the patent application and information already available to the public to determine whether the patent application meets the requirements for patenting based on the laws found in title 35 of the US Code, the regulations listed in title 37 of the Code of Federal Regulations and the guidance provided in the USPTO Manual of Patent Examining Procedure. If the examiner finds evidence that the invention was already publicly disclosed or discovers another reason that the application does not comply with the patent requirements, the examiner may issue a rejection describing the deficiencies of the patent application. The applicant has an opportunity to respond to the rejection, which may include amending the claims in the application, having a phone conference with the examiner and presenting arguments that the rejection was improper. This process may be repeated until a final rejection or allowance of the application. If the patent application is allowed, the USPTO issues a patent creating enforceable rights for the patentee.

By their nature, trade secrets are not disclosed publicly or registered with any agency. Information becomes a trade secret when the holder takes affirmative action to keep the information secret. This can include physical protection of the information, use of non-disclosure agreements or lawsuits to recover for misappropriation of the trade secrets.

1.3 Timeline for Grant Procedure

The time to obtain a patent can vary greatly depending on many factors, including the subject matter of a patent, the number of rejections and appeals during patent prosecution and the type of USPTO examination programme. The USPTO has several patent application initiatives that can expedite patent applications meeting the respective programme requirements. For example, applications qualifying for Accelerated Examination may have a final disposition within twelve months. According to statistics provided by the USPTO, the average time for a final decision on a patent application is about two years, but some take several years.

Patent applicants are not obliged to be represented by a lawyer. However, the USPTO cautions that the patent application process is an undertaking requiring knowledge of patent law and rules, USPTO practices and procedures, as well as knowledge of the scientific or technical matters involved in the particular invention. Because of the complexities involved, most inventors employ the services of registered patent lawyers or patent agents.

The cost associated with obtaining a patent varies with many factors. Administrative fees imposed by the USPTO depend on the type of entity (large, small, or micro), the number of claims in the application, the amount of time taken to respond to the USPTO rejections, the use of patent application initiative programmes and other procedural details. Lawyer fees in connection to the application may also vary depending on the complexity of the application and patent prosecution.

1.4 Term of Each Intellectual Property Right

Generally, a patent expires 20 years after its filing date, but this term can vary depending on the timing of the patent application and patent prosecution. Patents issued and applications filed before 8 June 1995 expire either 20 years from filing or 17 years from issue, whichever is later.

Patent applications filed after 8 June 1995 expire 20 years after the earliest effective US filing date. This may be earlier than the filing date of the patent application if it claims priority to an earlier provisional or international application.

Under limited circumstances, a patent term may be extended to account for administrative delays when acquiring the patent. For example, if the USPTO does not issue a patent within three years after its filing date, the patent-holder may obtain an extension of patent term equal to the period in excess of three years. For certain drug products and medical devices, a patent may be extended up to five years to account for the regulatory review conducted by the US Food and Drug Administration (FDA).

1.5 Rights and Obligations of Owner of Intellectual Property Right

A patent gives its owner the right to exclude others from making, using, selling and importing the patented invention. To maintain the enforceability of the patent, the USPTO must receive maintenance fees for the patent, due at 3.5, 7.5 and 11.5 years after the date of issue.

The remedies available to the patent-holder vary depending on the chosen forum of enforcement. In a district court, a patent-holder may seek equitable remedies in the form of a preliminary or permanent injunction and may seek monetary damages for both past and future infringement.

At the US International Trade Commission (ITC), a patent-holder may seek cease-and-desist orders and exclusion orders to prevent the importation of patent-infringing goods. The exclusion orders direct US Customs and Border Protection to exclude articles from entry into the US. A limited exclusion order prevents specified entities from importing the articles and a general exclusion order prevents any entity from importing the articles. The ITC cease-and-desist orders can direct infringers to stop importing infringing articles and to stop sales of infringing articles in US inventory. The ITC cannot award monetary damages.

1.6 Further Protection After Lapse of Maximum Term

The US allows certain extensions of patent terms for administrative delays. Delays by the USPTO in the issue of patents can receive patent-term extensions for the time of the delay. This extension does not apply to delays resulting from the patent applicant's actions, including requests for continued examination or appeals. The possible extension for USPTO delays is unlimited.

Certain drug products and medical devices can receive annual patent term extensions if the product is undergoing administrative review by the FDA. These extensions are renewable for up to five years.

1.7 Third-Party Rights to Participate in Grant Proceedings

Any third party may submit patents, published patent applications or other printed publications as part of a third-party pre-issuance submission. The submission must include a concise description of the asserted relevance of each submitted document. These submissions may be made online at the USPTO website. Submissions must be made before the later of six months after publication of the patent application or the date of a USPTO communication rejecting any claims in the application. However, a notice of allowance for the patent application immediately terminates the timeframe for third-party submissions.

1.8 Remedies Against Refusal to Grant Intellectual Property Right

During patent prosecution, the USPTO may issue a final rejection of the patent claims. If the applicant wishes to challenge the final rejection, the applicant may request continued examination or may file an appeal to the Patent Trial and Appeal Board (PTAB). The applicant may appeal PTAB decisions to the US Court of Appeals for the Federal Circuit. Further review may be sought from the US Supreme Court through a petition for writ of certiorari.

1.9 Consequences of Failure to Pay Annual Fees

Patent-holders must pay maintenance fees to keep patents in force. The payments are due 3.5, 7.5 and 11.5 years after the date of issue. The USPTO allows payment of each fee six

months before the due date, but does not allow any other pre-payment of the maintenance fees. Payments that are less than six months past the due date have a surcharge of USD40-160 in addition to the normal fee.

Under some circumstances, a patent can be reinstated after not paying the maintenance fee in a timely manner. The USPTO requires a statement that the delay in payment was unintentional and submission of a petition fee of USD500–2,000 in addition to the required maintenance fees.

2. Initiating a Lawsuit

2.1 Actions Available Against Infringement

A patent-holder has several options when seeking enforcement of patent rights. District court litigation can provide injunctions, monetary remedies for infringement and declaratory judgments. As discussed above, the ITC can issue exclusion orders and cease-and-desist orders. If an applicable contract provides for alternative dispute resolution proceedings, such as mediation or arbitration, or the parties agree to alternative dispute resolution proceedings, they may be used in lieu of litigation. Alternative dispute resolution proceedings can allow more flexible solutions and a final resolution can often be reached faster and less expensively. Additionally, the ITC and many courts offer mediation programmes.

2.2 Third-Party Remedies to Remove Effects of Intellectual Property Right

A third party may challenge the validity of an issued patent through district court litigation or through post-grant proceedings at the USPTO. A party with standing may seek a declaratory judgment of patent invalidity in a district court. As a defendant in a patent infringement lawsuit, a party may argue patent invalidity as a counterclaim or affirmative defence. Patent invalidity may also be raised as a defence in an ITC investigation.

Challenges to patent validity at the USPTO take the form of post-grant review (PGR), inter partes review (IPR), ex parte re-examination and covered business method review (CBM). The timing and type of patent affect which of these proceedings is available to a third party.

PGR is available during the first nine months after the issue of a patent. Any party that is not the patent-holder and has not challenged the patent validity in a civil action may request PGR. PGR allows the broadest grounds for challenging patent validity.

After the nine-month window of PGR, a third party may challenge validity through an IPR proceeding. Similar to PGR, the IPR petitioner must not be the patent-holder and must not have challenged the patent in civil litigation, but there is an additional requirement that the petitioner must not have been served a complaint alleging infringement more than one year prior to the IPR petition. The IPR also has more limited grounds to challenge patent invalidity, only allowing arguments of obviousness and lack of novelty based on patents and printed publications.

A CBM review has the most restrictive requirements: at least nine months must have elapsed since the patent was issued; the patent must be a financial product or service patent, excluding technological inventions; the CBM petitioner must have been sued or charged with patent infringement; and the CBM review petition must be filed before 16 September 2020. The grounds for challenging patent validity in a CBM review are similar to those of PGR.

There are no actions available in the US for a compulsory licence.

2.3 Courts with Jurisdiction

Federal district courts have original jurisdiction over patent matters. Parties may appeal district court decisions to the US Court of Appeals for the Federal Circuit. Decisions of the Federal Circuit are subject to discretionary appeal to the US Supreme Court through a petition for certiorari.

In certain circumstances involving importation of patent-infringing articles, the ITC may have jurisdiction. In an ITC investigation, an administrative law judge makes an initial determination on liability. A party may petition the ITC to review the administrative law judge's initial determination. After the ITC's final decision, a party may appeal the decision to the Federal Circuit, with further discretionary appeal to the US Supreme Court.

2.4 Specialised Bodies/Organisations for the Resolution of Disputes

Two administrative agencies provide a review of patents before administrative law judges. The USPTO has the PTAB, which provides a review of patent application rejections and several post-grant proceedings discussed above. The ITC conducts investigations related to importation of patent-infringing articles. Both PTAB and ITC decisions may be appealed to the US Court of Appeals for the Federal Circuit, with further review available from the US Supreme Court.

2.5 Prerequisites to Filing a Lawsuit

There are no prerequisites to filing a lawsuit in a district court, unless the parties' contract provides otherwise. Lack of pre-filing notice may, however, limit recovery of monetary damages in certain instances.

2.6 Legal Representation

While individuals are not required to be represented by a lawyer, all federal courts require corporations to have legal representation. It is generally viewed as exceedingly unwise

for an individual to pursue patent litigation without experienced counsel. In proceedings before the PTAB, at least one representative of each party must be a registered practitioner of the USPTO.

2.7 Interim Injunctions

A patent-holder may seek a preliminary injunction to protect the rights of the parties while litigation is pending. Preliminary injunctions require showing a reasonable probability of success on the merits, irreparable harm to the party if the preliminary injunction is denied, the balance of the hardships favour issuing a preliminary injunction and the impact on the public interest favours the party bringing the motion. If a court determines that a preliminary injunction is appropriate, such an order will only be issued if the party seeking it posts a bond in an amount that the court considers proper to compensate the other party should the injunction be determined to have been improperly granted.

2.8 Protection for Potential Opponents

The potential opponent may oppose the preliminary injunction by arguing against the factors described above for granting a preliminary injunction — most particularly that monetary relief at the end of the case will adequately compensate the plaintiff for any injury it incurs. Alternatively, a potential infringer could seek a declaratory judgment of patent invalidity or non-infringement in a federal district court. A party could also seek to challenge patent validity through one of the post-grant proceedings available through the USPTO.

2.9 Special Limitation Provisions

US law limits patent infringement damages to six years prior to the filing of the complaint or counterclaim for infringement. Additionally, the patent-holder cannot recover damages for infringement prior to the point the infringer had notice of the infringement. Filing the lawsuit is notice of infringement, but the infringer could have earlier notice based on communications from the patent-holder detailing the infringement, or from constructive notice by marking the patented articles with their patent numbers.

2.10 Mechanisms to Obtain Evidence and Information

In general, a party cannot obtain relevant information and evidence from another party or any third parties before commencing a proceeding in a district court. However, once a lawsuit has commenced, the Federal Rules of Civil Procedure require the parties to exchange initial disclosures of information, including:

- the identity of each individual likely to have discoverable information;
- copies of all documents a party may use to support its case, a computation of claimed damages; and
- any insurance agreement that may satisfy all or part of a judgment.

Parties may then obtain non-privileged information that is relevant to any party's claim or defence and is proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues and whether the burden or expense of the proposed discovery outweighs its likely benefit. Parties may obtain discoverable information through depositions, requests for production of documents, written interrogatories or requests for admission.

Parties may subpoena third parties to provide discoverable information in the form of depositions or production of documents. Procedures are also available to obtain discovery from third parties located outside the US through applicable treaties or letters rogatory, formal requests for assistance sent to foreign courts.

2.11 Initial Pleading Standards

Patent litigation follows the same pleading standards as other civil cases. A complaint filed in district court must allege facts that state a claim to relief that is plausible on its face. At a minimum, a patent infringement complaint should identify the patent-holder, the relevant patent(s), the accused infringer and the requested relief sought. For claims of indirect infringement, more details are typically required. Preferably, the complaint will provide additional information about the accused infringement, including the claims and elements infringed.

The Federal Rules of Civil Procedure govern amended and supplemental pleadings. A party may amend its pleadings once as a matter of course within 21 days of serving. Other amendments require the opposing party's written consent or the court's permission. To account for occurrences after a pleading, a party may supplement its pleadings with the court's permission.

2.12 Representative or Collective Action

There are no class actions available in intellectual property cases. However, a patent-holder may join multiple accused infringers in a single federal lawsuit if the actions arise out of the same transaction, occurrence, or series of transactions. It is not sufficient to have unrelated defendants infringe the same patent.

In situations where joining all defendants in a single case is not possible, there are options to gain advantages of consolidated actions. Cases across several districts that share a common question of fact may be co-ordinated for pre-trial proceedings before a Judicial Panel on Multidistrict Litigation. Similarly, multiple cases in the same district may be consolidated to promote judicial efficiency when there is a common question of law or fact.

ITC investigations of patent-infringing articles often involve multiple respondents. Because the ITC only needs jurisdiction over the imported articles and not the infringers, it can be easier for a patent-holder to proceed against multiple infringers simultaneously.

2.13 Restrictions on Assertion of Intellectual Property Right

Some patent-holder actions can limit the ability to enforce a patent against others. Under patent exhaustion – also referred to as the first-sale doctrine – the patent-holder's right to control an individual article ends after an authorised sale. If the patent was procured through improper conduct before the USPTO, it could be unenforceable under the doctrine of inequitable conduct. A patent-holder that expands its rights beyond the statutory patent grant may commit patent misuse. Finally, when the patent-holder uses its patent impermissibly to gain market share or other anti-competitive behaviour, antitrust laws may limit the enforceability of the patent.

3. Infringement

3.1 Necessary Parties to an Action for Infringement

Generally, the party bringing an infringement action must be the patent-holder, although an exclusive licensee that owns "all substantial rights" in the patent may bring an infringement action in its own name without joining the patent-holder. An ITC investigation requires the party filing the petition to have an interest in the patent and an injury to a domestic industry.

3.2 Direct and Indirect Infringement

Direct infringement occurs when a person makes, uses, offers to sell, sells, or imports in the US a patented invention without authority. Usually, the patent-holder demonstrates this by showing every claim element, or its equivalent, is present in the accused article. When more than one party infringes the patent, there can still be direct infringement if one party directs or controls the actions of another.

A party induces infringement when it actively and knowingly aids and abets another's direct infringement. The inducer must have knowledge of the patent and actively encourage the acts that result in direct infringement. Induced infringement can result in both parties being jointly and severally liable for the infringement.

Contributory infringement involves supplying a component of a patented invention to another that performs the direct infringement. The component must not be a staple article or commodity of commerce suitable for non-infringing use, nor can it have substantial non-infringing uses.

There are also rules primarily directed to the pharmaceutical industry. A party may engage in activities (such as testing) to support an Abbreviated New Drug Application (ANDA) for a generic version of an FDA-approved drug – even if that drug is patented – without incurring patent infringement liability. However, filing an ANDA is considered an act of "artificial" infringement if the ANDA applicant seeks approval to engage in the commercial manufacture, use or sale before the patent expiration.

The available remedies for patent infringement are discussed below.

3.3 Scope of Protection for an Intellectual Property Right

The scope of protection of a patent is determined by its claims, which describe the extent of the protection sought in a patent application. Often, significant dispute arises when determining the precise meaning of terms or phrases in the patent claims.

In 2018, the standard for claim interpretation became more uniform, whether in a district court, the ITC, or in a post-grant proceeding at the USPTO. The "Phillips" standard seeks to interpret the claims from the perspective of a person having skill in the relevant art of the invention based on intrinsic and extrinsic evidence. Intrinsic evidence includes the patent's description of the invention, including the claims themselves and the patent prosecution history. This means arguments and statements made to the USPTO during patent prosecution may limit how claims are interpreted later. Extrinsic evidence includes dictionaries, treatises and expert testimony. Extrinsic evidence can aid the decision-maker's understanding of how a skilled person would have understood the claims at the time of the invention.

During patent prosecution, the USPTO uses a slightly different standard for analysing patent application claims. Generally, the USPTO uses the same types of information described above, but seeks to determine the "broadest reasonable interpretation" of the claims for purposes of issuing patents.

3.4 Defences Against Infringement

An accused patent infringer may seek to avoid liability by proving that no infringement occurred, the patent is invalid, or the patent is unenforceable.

Several defences to patent infringement do not require challenging the patent itself, either by showing the accused article does not infringe or showing the use of the patent was lawful. For example, direct infringement requires all the elements of the patent claim be present, so demonstrating missing elements in the article can avoid liability by direct infringement. Showing an implied or express licence can negate the infringement requirement of unauthorised use

of a patented invention. In the medical field, gathering data to support an ANDA for a generic version of a patented and FDA-approved drug does not create patent infringement liability — although the filing of the ANDA may. The courts also recognise a more general experimental use exception to liability, but it is a very narrow exception, requiring no commercial motive in the experimental use. Under certain circumstances, prior commercial use of an invention occurring more than a year before the patent application can avoid infringement liability. Finally, infringement damages are limited by law to the six years prior to the filing of the complaint, so infringement before this period would not incur liability.

The accused infringer may also challenge the validity of the patent because there will be no liability for an invalid patent. The grounds for challenging the patent may include lack of patent-eligible subject matter, lack of novelty, lack of enablement or written disclosure, obviousness of the invention, public knowledge or prior offers to sell.

The patent-holder's actions can also be the basis of a defence against infringement. Inequitable conduct can result from improper conduct before the USPTO. Relying on a patent-holder's conduct and representations may create equitable estoppel if the patent-holder later acts inconsistently with the reliance. A patent-holder that impermissibly expands its rights beyond the statutory patent grant may commit patent misuse. Under patent exhaustion – also referred to as the first sale doctrine – the patent-holder's right to control an individual article ends after an authorised sale. In some circumstances, a patent-holder's failure to keep patents together that are subject to a terminal disclaimer may be used as a defence to patent infringement.

That an accused infringer has its own patent does not, by itself, provide a defence to an infringement claim.

3.5 Role of Experts

Parties may submit expert reports in connection with the claim construction process to assist the court in construing disputed terms. Parties almost always rely on expert reports and expert testimony in connection with infringement, invalidity and damages issues. Experts are especially effective when a case involves a jury because a good expert can explain complicated information in a clear and understandable fashion.

3.6 Procedure for Construing the Terms of the Patent's Claim

Courts use specialised claim construction hearings called "Markman" hearings to examine evidence from the parties on the appropriate meaning of the relevant terms in a patent claim. In a district court, patent claim interpretation is performed by the judge, even if there is a jury trial.

4. Revocation/Cancellation

4.1 Reasons and Remedies for Revocation/Cancellation

In the federal court system, a final judgment of invalidity effectively revokes the invalidated claims of the patent. A decision that the patent-holder committed some other actions that prevents liability for patent infringement, such as equitable estoppel or antitrust violations, may make a patent unenforceable.

The ITC makes similar decisions about patents, but its decisions are not binding on district courts. For example, an ITC decision of patent invalidity does not require a district court to treat the patent as invalid, but the district court may reach the same decision based on the persuasive influence of the ITC decision.

In post-grant proceedings, the USPTO may cancel some or all of the claims of a patent.

4.2 Partial Revocation/Cancellation

Patent invalidity is examined on a claim-by-claim basis. The remaining claims of a patent remain valid, even if some claims are found invalid.

4.3 Amendments in Revocation/Cancellation Proceedings

During some post-grant proceedings before the USPTO, the patent-holder can amend claims, but may not enlarge the scope of the claims. During ex parte re-examination, the patent-holder may amend claims to respond to the USPTO's findings of substantially new questions of patentability. In the adversarial proceedings — IPR, PGR and CBM — the patent-owner may file a motion to amend claims.

4.4 Revocation/Cancellation and Infringement

In district court actions, patent infringement claims and defences may be heard together. Courts have broad discretion to control proceedings to promote judicial efficiency and avoid prejudice to the parties, so some issues may be "stayed". Typically, a judge rather than a jury will determine equitable defences such as inequitable conduct or laches.

ITC investigations hear all infringement and defences together. The ITC has a shorter timeline than district courts and no juries to consider.

Proceedings challenging patent validity must be heard separately from infringement claims at the USPTO because the USPTO does not determine infringement. Often, there is a related district court case claiming infringement during post-grant proceedings at the USPTO. The district court may stay its proceeding to await the patent invalidity decision of the USPTO.

5. Trial & Settlement

5.1 Special Procedural Provisions for Intellectual Property Rights

In district court proceedings, patent litigation is subject to the same rules as other civil litigation: the Federal Rules of Civil Procedure and Federal Rules of Evidence. Most courts (and some individual judges) that hear a large number of patent cases, such as the District of Delaware or the Northern District of California, have their own supplemental procedures that apply in patent cases.

ITC investigations and post-grant proceedings at the USPTO each have their own procedures, but many of the rules are similar to those in district courts. One notable exception is the right to a jury. Unlike district court proceedings, there is no jury at the ITC or the USPTO.

5.2 Decision Makers

With respect to federal district court litigation, beyond choosing the particular forum in which to file suit, parties have little ability to influence who will be the decision-maker – unless they agree to waive their rights to a jury trial (which patentees almost never do). In a district court, unless a judge decides an issue in a pre-trial (eg, a summary judgment) or post-trial motion, issues of infringement, invalidity and damages are decided by a jury. Juries do not have technical expertise. There is no requirement that a judge have a technical background to preside over a patent case in district court and most district court judges do not have technical backgrounds.

In 2011, 14 district courts began a ten-year Patent Pilot Program to enhance expertise in patent cases. New patent cases in those districts are assigned to a random judge. If the randomly assigned judge is not a designated judge in the program, the judge may transfer the case to a participating judge in the district.

ITC investigations proceed before an administrative law judge. Because a large proportion of ITC investigations involve patents, many administrative law judges have developed substantial experience with patent cases and many also have technical expertise. The ITC randomly assigns an administrative law judge to new investigations, and assignment is not based on any particular technical background of the administrative law judge.

The USPTO has administrative patent judges. These judges are typically experienced patent lawyers with technical backgrounds. If possible, the USPTO assigns cases to judges based on their technical background.

Appeals from all patent cases at the district courts, ITC or USPTO go to the US Court of Appeals for the Federal Circuit. The judges in the Federal Circuit have significant patent law experience from the many patent-related appeals, but do not necessarily have a technical background.

5.3 Settling the Case

Settlement of patent disputes is quite common (except in pharmaceutical patent cases). Parties may reach a settlement through a variety of possibilities, such as negotiation, alternative dispute resolution or mediation. Some courts require parties to attempt a resolution before proceeding with a trial. Settlement agreements can terminate the proceedings in a district court, usually without disclosure of the settlement details to the court.

The ITC has a non-mandatory mediation programme to aid resolution of disputes before pursuing a full investigation. After the investigation begins, parties may request termination of the investigation upon reaching a settlement, but a copy of any agreement will be submitted to the ITC in the process. Procedures are available to protect information within the settlement from public disclosure.

Post-grant proceedings before the USPTO follow similar settlement disclosure procedures as the ITC when seeking termination of a trial. The USPTO may continue a proceeding despite the parties' settlement agreement. This is more likely if the proceeding is nearly completed when the settlement occurs.

5.4 Other Court Proceedings

Federal courts have inherent authority to control their dockets, including the power to stay proceedings when there are co-pending matters in another forum. The courts may consider several factors when deciding to stay, including the progress of the court proceeding, whether the stay will simplify issues before the court, or whether a stay would unduly prejudice a party. When there is a co-pending post-grant proceeding, courts are more likely to stay proceedings if the USPTO proceeding has been instituted.

Generally, decisions reached in different forums are not binding on each other. This means a district court is not obliged to agree with a USPTO decision on patent validity, but the court may find the USPTO decision very persuasive because of its perceived expertise on patents. Similarly, the USPTO may consider the progress and findings of district court litigation or ITC investigations in its own proceedings.

6. Remedies

6.1 Remedies for the Patentee

In federal district courts, the patent-holder may seek damages for patent infringement and injunctions to prevent ongoing infringement. By statute, damages for infringement should be adequate to compensate for the infringement, but not less than a reasonable royalty. A jury verdict will typi-

cally include a damages award, which is then reviewed by the district court judge (if a party files a motion requesting such a review) for compliance with certain legal standards regarding damages. Patent damages are limited to no more than six years before commencement of the lawsuit. In cases of wilful infringement, the courts may award three times the damages. Generally, each party pays its own lawyers' fees, but in "exceptional" cases, courts may impose fee-shifting to the losing party. In addition to monetary damages, a party may seek an injunction to prevent continued infringement.

The ITC cannot impose monetary damages for infringement, but can issue exclusion and cease-and-desist orders. The exclusion orders direct US Customs and Border Protection to exclude infringing articles from entry into the US. The ITC cease-and-desist orders can direct infringers to stop importing infringing articles and to stop sales of infringing articles in US inventory.

6.2 Rights of Prevailing Defendants

In the US legal system, each party typically pays its own lawyers' fees and costs. Similar to the description above for successful patent-holders, a prevailing defendant may request lawyers' fees and costs if the case is determined to be "exceptional". Under US Supreme Court precedent, "an 'exceptional' case is simply one that stands out from others with respect to the substantive strength of a party's litigating position (considering both the governing law and the facts of the case) or the unreasonable manner in which the case was litigated."

6.3 Types of Remedies

The available remedies do not vary based on the technical area of a patent.

6.4 Injunctions Pending Appeal

A successful patent-holder in an infringement proceeding does not automatically get an injunction against the infringing party. Similarly, if the district court issues an injunction, its effect is not automatically stayed during appeal. Ordinarily, a permanent injunction is effective upon issue, but a court has broad equitable authority to modify relief. The defendant may seek a stay of the injunction by filing a motion with the issuing court or the appellate court — the US Court of Appeals for the Federal Circuit. When deciding to stay an injunction, the courts balance the likelihood of success on the merits against the equities of the parties and the public.

7. Appeal

7.1 Special Provisions for Intellectual Property Proceedings

The appellate procedure for patent litigation is the same as for other civil litigation, except that all appeals in patent cases go to the US Court of Appeals for the Federal Circuit. This includes patent cases from district courts, ITC investigations and USPTO proceedings.

7.2 Type of Review

The Federal Circuit can review factual and legal determinations of the proceedings in a lower court, if the errors were properly preserved in its record. The level of deference given to the decision-maker in a lower court varies depending on the type of error. For purely legal issues, such as statutory interpretations and judgments as a matter of law, the Federal Circuit applies a "de novo" standard where the court examines the record to form its own opinion, with no deference to the previous decision-maker. Factual determinations receive more deference, either "clearly erroneous" if the judge made factual determinations, or "substantial evidence" if the jury was the fact-finder. Equitable determinations, such as inequitable conduct, injunctions, or lawyer fees, are left to the discretion of the trial court judge, so a review of these decisions gets the highest deference, only being reversed for "abuse of discretion".

8. Costs

8.1 Costs Before Filing a Lawsuit

Pre-litigation costs vary depending on the complexity of the issues and the amount in controversy between the parties. A patent-holder may require legal and technical research for claim charts, warning letters to potential infringers and analysis of potential enforcement options. An accused infringer may accrue legal fees to weigh its options for challenging the alleged infringement through an affirmative defence in a lawsuit, a declaratory judgment of invalidity or non-infringement, or a USPTO proceeding challenging patent validity.

8.2 Calculation of Court Fees

In district courts, the fee for filing a federal civil complaint is fixed by statute, but the Judicial Conference of the United States may prescribe additional fees. Currently, the filing fee is USD350, plus a USD50 administrative fee.

The fee to file an inter partes review (IPR) at the USPTO is USD30,500, and a PGR or CBM request is USD38,000.

8.3 Responsibility for Paying Costs of Litigation

The traditional rule in the US is that each party bears its own costs, but there are limited exceptions to this default rule. The Federal Rules of Civil Procedure allow a party to seek reasonable expenses, including lawyers' fees, incurred when an opposing party makes improper representations to the court or commits discovery misconduct. These sanctions do not award all costs and lawyers' fees, only the expenses associated with the violation. In patent litigation, a court may award all costs and reasonable lawyers' fees to the prevailing party if the case is determined to be "exceptional", that is "one

that stands out from others with respect to the substantive strength of a party's litigating position (considering both the governing law and the facts of the case) or the unreasonable manner in which the case was litigated."

9. Alternative Dispute Resolution

9.1 Type of Actions for Intellectual Property

Alternative dispute resolution is common in civil cases, and its use in intellectual property disputes is becoming increasingly common. Parties may use alternative dispute resolution as an alternative to litigation either by mutual agreement, contractual agreement or court order (although a court cannot force the parties to agree to a mediator's ruling). Some courts offer mediation or special masters for settlement purposes. Parties may prefer alternative dispute resolution to take advantage of its improved flexibility, confidentiality and cost effectiveness. Additionally, a patent owner can avoid a court's judgment of patent invalidity.

10. Assignment and Licensing

10.1 Requirements or Restrictions for Assignment of Intellectual Property Rights

Assignments of all or part of the rights in a patent must be in writing. The assignee or assignor may record the assignment with the USPTO, but recordation is not required to enforce the assignment.

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10.2 Procedure for Assigning an Intellectual Property Right

Generally, the procedure to assign patent rights involves the same type of negotiations as other contract rights. The parties negotiate the terms of the agreement and execute a written assignment contract. An employer's employment contract may require its employees to assign rights to the employer for inventions developed during employment. Although not required, any assignments should be recorded with the USPTO.

10.3 Requirements or Restrictions to License an Intellectual Property Right

An intellectual property licence must describe the terms of the licence agreement in writing and clearly identify all parties and the intellectual property involved. The licence may be exclusive or non-exclusive. In an exclusive licence, the licensee receives all rights in the patent except ownership of title. This allows an exclusive licensee broader rights, such as the ability to sue for patent infringement. A non-exclusive licence can be granted to more than one party, but a licensee cannot enforce the patent against others. For public policy reasons, a patent licence cannot require payment of royalties beyond the term of the patent. The USPTO allows recording of licences, but recording is not required for a licence to be valid. No approval from the USPTO is necessary for a licence.

10.4 Procedure for Licensing an Intellectual Property Right

Licence agreements are contractual rights; the parties agree to the terms and execute the agreement in writing. Unlike an assignment of a patent, the rights assigned by licence revert to the licensor after the agreed time period.