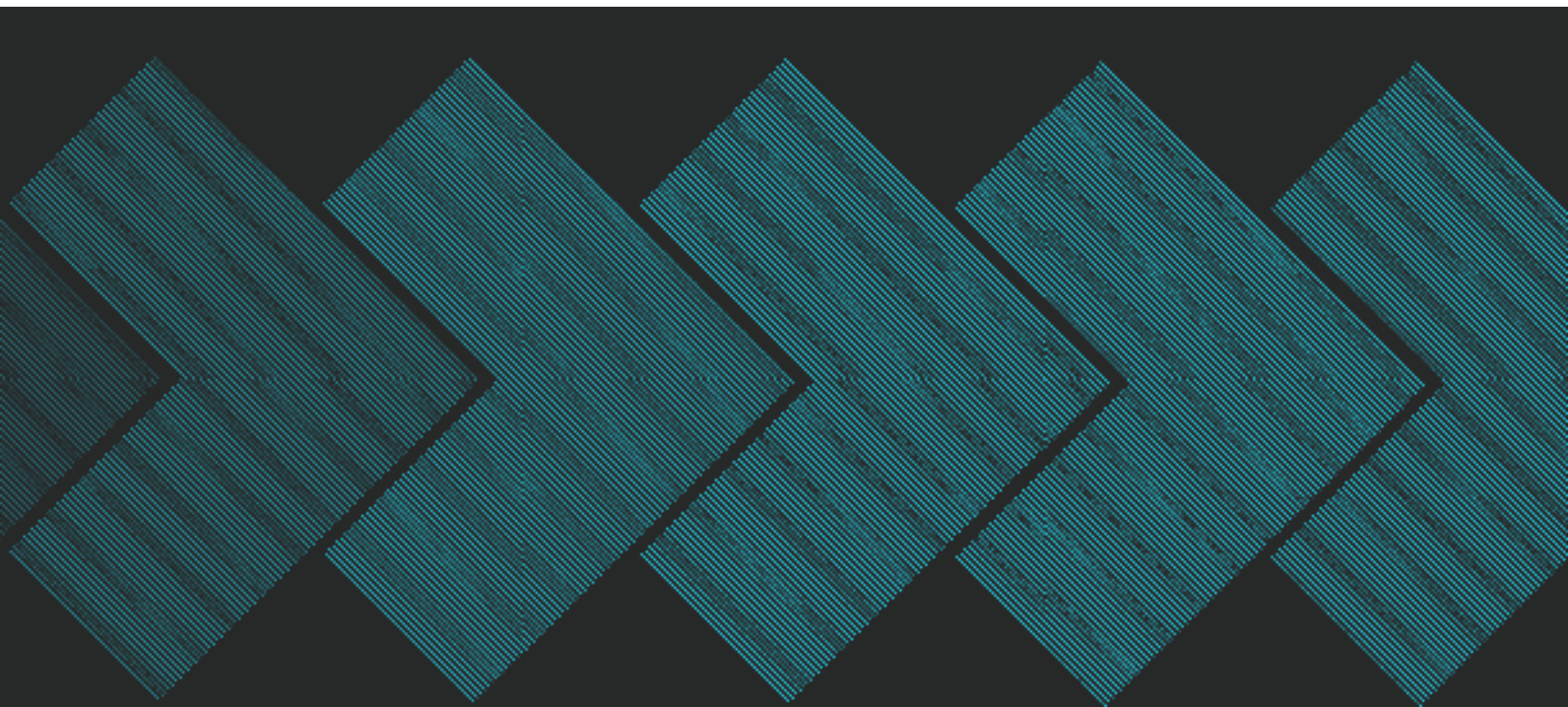


# IP Litigation in Canada 2021: *Patents*



# Introduction

This guide provides an overview of Canadian IP litigation, with a focus on patent litigation: the types of proceedings that can be brought and the possible venues for those proceedings, the stages of an action, an overview of *Patented Medicines (Notice of Compliance)* (“PM(NOC)”) proceedings, a summary of the key differences between Canadian and US proceedings, and finally, a review of recent notable patent law developments in Canada.



# Types of Proceedings

In Canada, a proceeding is commenced by way of an application or action.

## **Applications**

An application (informally known as a “paper trial”) is a streamlined procedure in which evidence is submitted by way of affidavits (sworn statements) and no pre-trial documentary or oral discovery is allowed. Cross-examinations of the affiants take place outside of court and the cross-examination transcripts, along with the affidavits, form the record.

While matters that proceed by application are generally not as long or expensive for the parties involved, not all disputes may be decided in this way. Eligible matters include judicial review of an administrative action, appeals from a decision of the Registrar of Trademarks, enforcement of a foreign judgment, and simple copyright or trademark infringement cases. Patent infringement cases are required to proceed by way of action.

## **Actions**

Actions are brought to address matters that are more complex. The stages of an action are set out in detail in [a later section](#) of this guide.

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# Venue

Two Canadian court systems are relevant to IP matters: the Federal Court and the provincial superior courts.

## Federal Court

For various reasons, most IP disputes are heard by the Federal Court:

- Though the Federal Court and the provincial superior courts have concurrent jurisdiction to decide IP infringement actions, only the Federal Court has the jurisdiction to impeach, invalidate or expunge IP.
- The Federal Court has national jurisdiction. This means the Court may assess and grant relief that is binding and enforceable across Canada, including national injunctions.
- Since most IP disputes are heard before the Federal Court, many judges have developed expertise in deciding complex IP matters.
- The Federal Court features a robust case management regime, with Case Management Judges (also known as Prothonotaries) assigned at the outset of complex cases to manage all interlocutory and procedural matters (see our section on [case management](#) below). Most cases can proceed to trial in two to three years, which is significantly faster than most proceedings before the provincial superior courts.

Over the course of the pandemic, the Federal Court has transitioned smoothly to fully virtual hearings. Moving forward, the Court has indicated it will remain flexible as to whether hearings will be fully in-person or in a “hybrid” style, with some witnesses appearing remotely. In the transition period back to “normal”, the parties will have significant input into the conduct of hearings.

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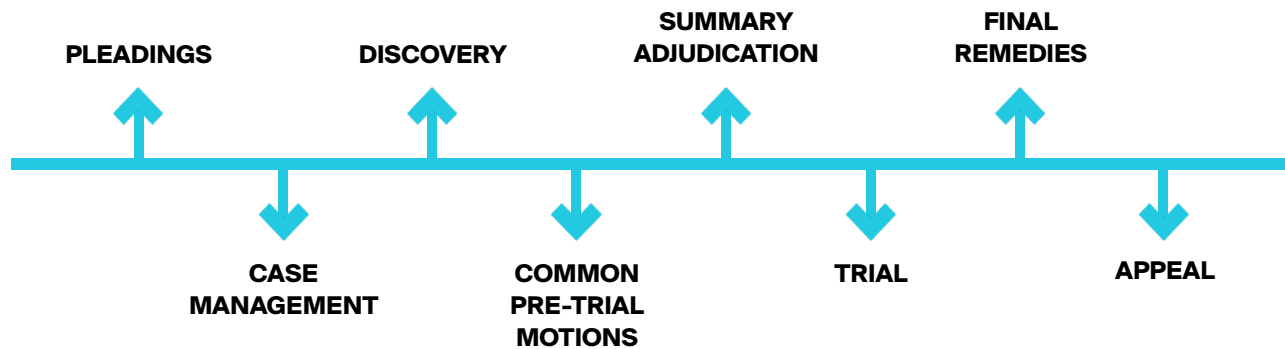
## Provincial Superior Courts

A claimant may bring a proceeding in the superior court of the province in which the infringement is said to have occurred, however any remedy granted by a provincial court will be limited to that province. Because the Federal Court only has jurisdiction over particular areas of the law (like IP) and does not have inherent jurisdiction, provincial courts — who do have inherent jurisdiction — may be the only option for disputes that are largely contractual or based on tortious activities, such as breach of confidence arising from a departing employee, ownership disputes based on employment contracts, breaches of non-disclosure or license agreements, or misappropriation of trade secrets.

Provincial courts can make determinations regarding IP *in personam* (as against a party) but lack the power to make orders *in rem* (such as invalidating a patent). For example, in a patent infringement action, a finding of invalidity in a provincial court would be a defence to infringement, but would not invalidate a patent as against other parties. Plaintiffs opting to enforce a patent in a provincial court will often face an impeachment action in the Federal Court and a motion to stay the provincial court proceeding.

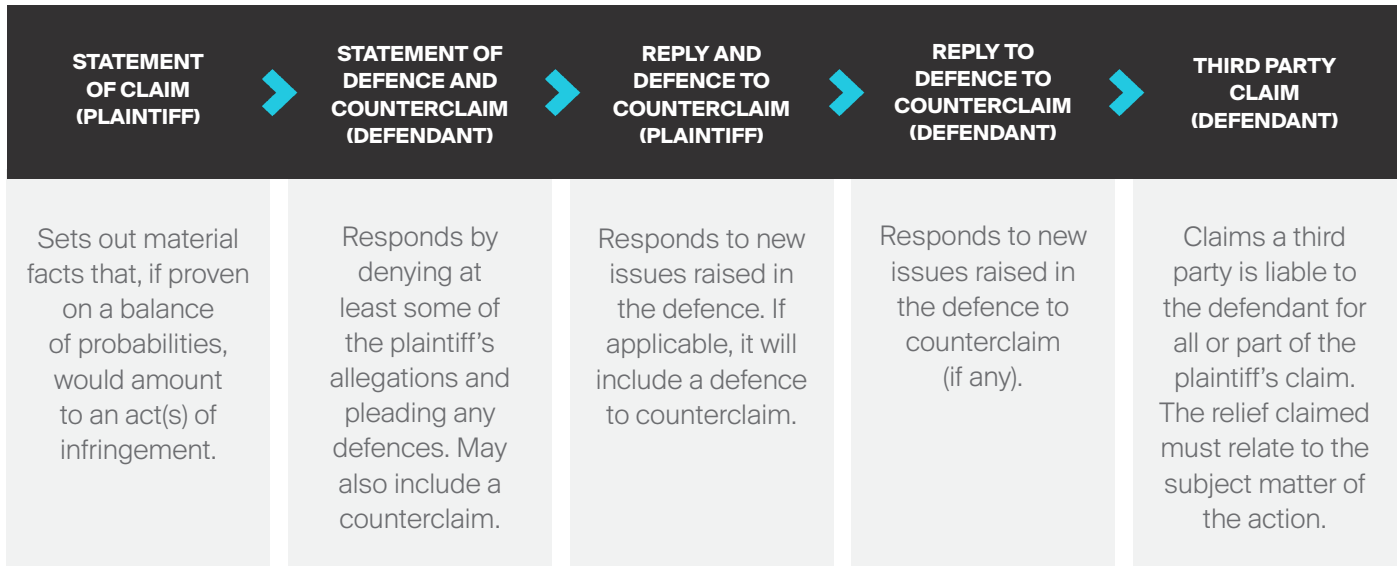
# Stages of an Action

Because IP proceedings are most often brought as actions in the Federal Court, this section along with our overview of the key differences between Canada and the US, will focus on Federal Court procedure.



# Pleadings

Actions start with pleadings, which set out the causes of action and relief sought by the plaintiff(s), as well as the defences and any counterclaims of the defendant(s). The flow of typical pleadings is as follows:



## Patent Pleadings

There are two main types of patent actions: infringement actions and impeachment actions. Typically, the same kinds of issues will arise in both types.

In a patent infringement action, the plaintiff (usually the patent owner) seeks a declaration of infringement and remedies in the form of injunctions, damages, delivery up, or an accounting of profits. The defendant (alleged infringer) typically pleads defences of invalidity and non-infringement, and often will counterclaim to impeach the patent.

In a patent impeachment action, the roles are reversed, with the action being initiated by a plaintiff (potential infringer) who wishes to clear the way for itself by invalidating a patent. In such a case, the defendant (patent owner) will often counterclaim for infringement.

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# Case Management

The Federal Court has an established and robust case management system. At the outset of any complex case, a case management judge (also called a prothonotary – a role analogous to a magistrate judge in US Federal Court) is assigned to deal with issues of scheduling, early dispute resolution, most pre-trial motions, and other matters. The case management judges are generally available on short notice to assist the parties by convening a case management conference to discuss issues informally, or to adjudicate a motion on procedural or interlocutory matters.

As a result, it is common for all steps in IP proceedings (or at least the steps through discovery) to be scheduled at the outset of the litigation. Trial is also often scheduled very early, particularly in *PM(NOC)* proceedings. While the schedule leading to trial can be and often is modified, the trial date itself, once fixed, is extremely difficult to move.

Appeals of a case management judge's decision are heard by a judge of the Federal Court. Absent a palpable and overriding error of fact or an error of law, great deference is granted to a decision of a case management judge.

The Court, in consultation with members of the Bar, regularly publishes guidance to the profession, such as the [Case and Trial Management Guidelines for Complex Proceedings and Proceedings under the \*PM\(NOC\)\* Regulations](#), which provides detailed directions on issues such as the conduct of discovery, expert evidence, and pre-trial preparation.

While mandatory mediation is not a feature of case management in the Federal Court, case management judges are available to conduct mediations at the request of the parties.

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# Discovery

## Documentary Discovery

Parties to an action have a continuing obligation to identify and disclose all documents that are relevant to any issue in the action. A sworn statement that lists these documents, known as the affidavit of documents, is produced to the other side, along with a copy (usually digital) of the non-privileged documents themselves.

If documentary production is perceived to be deficient, a motion can be brought to compel further and better productions.

In the context of IP trials, orders and/or agreements that serve to limit disclosure of produced documents to specific individuals, so as to maintain confidentiality, are common. These orders are discussed in more detail in the [next section](#).

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## Examinations for Discovery

After documentary discovery, oral discoveries begin in which a party may examine the adverse party or parties. Where a party is a corporation, partnership or unincorporated association, a representative is selected to be examined on its behalf. Prior to examination, this representative has an obligation to inform themselves on the matters at issue in the case. The evidence of a corporate representative at an examination for discovery binds the party and the transcript is admissible at trial as a “read-in” against that party.

In patent cases, the defendant may also examine named inventors. Such examinations are narrower than party examinations both in terms of the permissible topics of questioning and because the examination is limited to the witness’s personal knowledge. Although the defendant has the right to examine every named inventor, a plaintiff has limited obligations to produce non-employee inventors, and it is common for the parties to agree that only a key subset of inventors will be examined.

The parties may also bring a motion for leave to examine non-parties who might have information on a question in issue that cannot be obtained from the parties. Examinations of non-parties (other than inventors) are not common, and if leave is granted, the scope of the examination is usually circumscribed. The difficulties in obtaining non-party discovery are compounded if the witness to be examined is located outside of Canada, and even more so if outside the US. Canada is not a signatory to the Hague Convention on the taking of evidence abroad.

# Common Pre-trial Motions

## Interlocutory Injunctions

Interlocutory injunctions (sometimes referred to as preliminary injunctions) are difficult to obtain in IP disputes. The party seeking an interlocutory injunction (“moving party”) must bring a motion or application.

The three-stage test for an interlocutory injunction is as follows:

### 1. STRONG *PRIMA FACIE* CASE / SERIOUS ISSUE TO BE TRIED

The first stage depends on whether the moving party is seeking a *mandatory* interlocutory injunction (the court directing the other party to undertake a positive course of action) or a *prohibitive* interlocutory injunction (the court staying a party’s hand until trial).

To obtain a mandatory injunction, the court will undertake “an extensive review of the merits” at the interlocutory stage to see if the moving party’s case has a strong likelihood of success at trial (i.e., “a strong *prima facie* case”). This is a heightened standard as compared to that of a prohibitive interlocutory injunction where the court will take an “extremely limited review of the case” and move on to the next stage of the test unless the claim is “vexatious or frivolous” (i.e., a “serious question to be tried”, a low threshold).

The judge will examine the practical consequences of the injunction and determine whether, in substance, the overall effect would be to “do something” (mandatory) or to “refrain from doing something” (prohibitive).

### 2. IRREPARABLE HARM

The moving party must demonstrate that irreparable harm will result if the relief is not granted. Irreparable refers to the nature of the harm suffered rather than its magnitude – it is harm which “either cannot be quantified in monetary terms or which cannot be cured”.

Canadian courts take varying approaches to the evidence required to prove irreparable harm. In some provincial superior courts, clear proof of irreparable harm is not required and doubt as to the adequacy of damages may suffice.

The Federal Court takes a stringent view, requiring clear and non-speculative evidence which demonstrates irreparable harm and how such harm will occur if the

relief is not granted. A finding that irreparable harm is likely to occur will not suffice. As the threshold for establishing irreparable harm is very high, the outcome in many interim injunction decisions turns on this stage of the three-stage test.

In the patent infringement context, interim injunctions are difficult to obtain in the Federal Court. Practically, a moving party will need to act quickly and persuade the Court that the resisting party will not be able to pay damages following trial. Accordingly, where infringement is taking place in a single province, that province’s superior court may be a better venue in which to seek an injunction for patent infringement.

### 3. BALANCE OF CONVENIENCE

The moving party must show that the balance of convenience favours granting the injunction. The court will consider which of the parties will suffer the greater harm from the granting or refusal of the interlocutory injunction, pending a decision on the merits.

Whether the moving party has (i) acted equitably (has clean hands), (ii) acted without delay, and (iii) given an undertaking as to damages (i.e., undertaken to pay the resisting party’s damages should the moving party be unsuccessful at trial) are all factors the court considers at this stage. The court may also consider the impact of the interlocutory injunction on third parties.

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### Confidentiality Orders & Protective Orders

In Canada, documents and information exchanged during discovery are received subject to an implied undertaking that such documents and information will not be used or disclosed for any purpose other than the proceeding in which it is disclosed. This implied undertaking rule arises even in the absence of any order of the court.

Notwithstanding the implied undertaking rule, formal protective orders, confidentiality orders and hybrids of the two are available in Canada to protect a litigant's information. A protective order governs the way in which parties may designate information as confidential and the handling of each other's sensitive information during the pre-trial disclosure phase of an action. If the court will not issue an order to this effect, the parties may enter into a protective agreement instead.

A confidentiality order allows parties to file confidential information under seal with the court. The Federal Court has acknowledged the sensitive nature of the issues that are often at the core of IP trials, and commonly grants these orders on consent.

Absent agreement from all parties, these orders may prove difficult to obtain. Before issuing a protective order, the court must be satisfied that "the moving party believes that its proprietary, commercial and scientific interests would be seriously harmed by producing information upon which those interests are based". In practice, this requires the moving party to advance fact evidence and potentially submit to cross-examination.

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The test to obtain a contested confidentiality order is stringent, because such an order engages the Canadian open-court principal, a “hallmark of [the Canadian] judicial system” that provides members of the public the right to attend court hearings and access the records of the court. To grant a confidentiality order, the court must be satisfied that:

- Such an order is necessary to prevent a serious risk to an important interest, including a commercial interest, in the context of litigation because reasonable alternative measures will not prevent the risk; and
- The salutary effects of the confidentiality order, including effects on the right of civil litigants to a fair trial, outweigh its deleterious effects, including effects on the right to free expression, which in this context includes the public interest in open and accessible court proceedings.

The elements of this test are difficult to satisfy. For example, in the context of the first element:

- The court will require that the risk in question be real and substantial, in that the risk is well grounded in the evidence and poses a serious threat to the commercial interest in question. The “important commercial interest” in question cannot merely be specific to the party requesting the order; the interest must be one which can be expressed in terms of a public interest in confidentiality; and
- The phrase “reasonable alternative measures” requires the judge to consider not only whether reasonable alternatives to a confidentiality order are available, but also to restrict the order as much as reasonably possible while preserving the commercial interest in question.

Accordingly, a party seeking an order shielding information from public view must overcome the strong presumption in favor of open access by demonstrating compelling reasons supported by specific factual findings.

### **Motion for Particulars/Motion to Strike**

A pleading must clearly and precisely define the questions and controversy between the litigants. Every pleading must contain particulars of the allegations and a concise statement of the material facts on which the plaintiff relies. Sufficient material facts are the foundation of a proper pleading. Material facts frame the discovery process and allow counsel to advise their clients, prepare their case, and plan a trial strategy.

The party responding to a pleading is entitled to understand the case it has to meet in sufficient detail to allow it to deliver a responsive pleading that gives some level of precision to the issues for discovery and trial.

Where a party delivers a bare-bones pleading with limited material facts or that simply denies all allegations, the party pleading in response can serve a demand for particulars or bring a motion to strike.

The threshold to strike a statement of claim is high – it must be plain and obvious that the pleading discloses no reasonable cause of action or is frivolous, vexatious or an abuse of process. More often, a court will grant leave to amend a pleading (by adding additional facts) or will strike certain paragraphs rather than the pleading in its entirety.

### **Motion for Bifurcation**

In the context of complex IP litigation, it is not uncommon for a party to bring a motion to divide the issues into two (or more) phases, particularly in patent infringement actions.

The most common request is to bifurcate issues of liability and entitlement to an injunction in a first proceeding from issues of quantum of monetary remedies in a second proceeding.

The onus is always on the party requesting a bifurcation order to establish that bifurcation is more likely than not to result in the just, expeditious and least expensive determination of the proceeding on its merits. However, the court will typically bifurcate a proceeding on consent.

Practically, the parties may consent to bifurcation to avoid producing commercially sensitive documents that have no bearing on liability but might be relevant to the quantification of remedies. Similarly, bifurcation may reduce costs, in that settlement often follows an adjudication on liability.

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The case law is divided on the advantages and disadvantages of bifurcation, such that there is room for argument on the merits of bifurcation in any given case. A party favouring bifurcation will leverage case law that notes savings of time or resources resulting from bifurcation (e.g., fewer issues being tried, less discovery, fewer experts or less expert evidence, or a shorter trial time). A party resisting bifurcation will point to case law acknowledging that bifurcation carries with it inherent and significant duplications and delay.

### **Motion for Security for Costs**

Unlike other jurisdictions, successful litigants in Canada can expect to recover some portion of their legal fees and disbursements (known as costs) from the unsuccessful party. Under certain circumstances (including if a plaintiff is seeking to impeach a patent and if a plaintiff is a corporation with minimal Canadian assets), a defendant can ask the court to order a plaintiff to deposit money as “security” for costs that would be payable in the event its action is unsuccessful.

A motion for security for costs can be brought anytime after the delivery of a statement of defence. A successful motion puts the action on hold until the plaintiff pays the ordered security into court.

# Summary Adjudication

The below discussion focuses on summary adjudication in the Federal Court. All provincial superior courts have summary adjudication procedures, but the rules and procedural details vary.

Prior to a trial date being fixed, a party may bring a motion for summary judgment or summary trial as of right. Once a trial date is set, leave of the court is required. It is common for such a motion to take at least six months to get to a hearing, so a moving party should consider the impact of the motion on the overall schedule in the action to address potential concerns about delay.

## Summary Judgment

Summary judgment allows the Court to summarily dispose of cases which ought not to proceed to trial because there is no genuine issue to be tried. It proceeds by way of a standard motion involving the exchange of affidavit evidence, out-of-court cross-examinations, written argument, and then a hearing on the paper record.

In principle, a party may seek partial summary judgment, but in practice the Court is reluctant to hear non-dispositive motions absent compelling procedural arguments.

Summary adjudication is more common in the context of trademark and copyright infringement than patent infringement. Recently, however, several decisions from the Federal Court and Federal Court of Appeal signal a willingness to use summary judgment in patent cases in the right circumstances. Those circumstances might include if neither party proffers expert evidence, and the Court does not require expert assistance to understand and construe the claims at issue. Or if there is conflicting expert evidence, but that conflict can be easily resolved without the need for live evidence.

During any summary judgment motion, the responding party cannot rely on what might be adduced as evidence at a later stage in the action. Instead, the responding party must set out specific facts and adduce evidence showing that there is a genuine issue for trial.

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These obligations allow, for example, a party to bring a summary judgment motion on its best evidence before documentary discovery or oral examinations and require the opposing party to respond. The Federal Court of Appeal has confirmed that “a party responding to a motion for summary judgment cannot be faulted for the absence of evidence if that evidence is in the exclusive control of the moving party.” However, the Court still expects a responding party to marshal evidence, including expert evidence (if necessary), to respond to the moving party’s case. As such, a plaintiff with limited resources may be unable to marshal such evidence, and may abandon their claim in the face of such a motion by a defendant.

## Summary Trial

Summary trial differs from summary judgment in several key ways:

- There is a hybrid record consisting of affidavits and live evidence. Although there is considerable flexibility in summary trial procedure, typically the key witnesses will appear for in-court cross-examination at the hearing.
- There is a different burden. Whereas summary judgment involves a high burden (no genuine issue requiring a trial), summary trial only requires the moving party to: (a) prove their case on a balance of probability; and (b) demonstrate that there is sufficient evidence for adjudication and that it would not be unjust to decide the issue by way of summary trial.



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Where the parties agree, the Federal Court has readily resolved patent infringement disputes by way of summary trial. The Federal Court may also resolve disputes using a summary trial procedure when faced with major opposition from one of the parties.

The Court will consider several factors in determining whether a case is suitable for summary trial:

- The amount involved and the cost of taking the case forward to a conventional trial in relation to the amount involved;
- The complexity and urgency of the matter, and any prejudice likely to arise by reason of delay;
- Whether the summary trial involves a substantial risk of wasting time and effort, and producing unnecessary complexity;
- Whether credibility is a crucial factor; and
- Whether the motion will result in litigating in slices.

In patent cases, there have been proposals among the bench and bar to use summary trial for an early determination on claims construction (akin to a Markman hearing in the US), but to-date the procedure has not been used in this manner.

Considering the Federal Court and Federal Court of Appeal’s recent decisions, it is prudent for litigants considering summary trials to:

- Advance expert evidence as one would during a trial;
- Advance the necessary fact evidence as one would during a trial;
- Pursue issues that are unlikely to require duplicative consideration in the event the summary trial is not determinative (e.g., claims construction and straightforward non-infringement issues, with complex validity issues being left for trial if necessary); and
- Bring the motion for summary trial as soon as possible.

Summary adjudication (both summary judgment and summary trial) is still relatively rare in Canadian IP cases because of the burden on the moving party, the time and expense involved, and the potential for a substantial adverse cost award against an unsuccessful party. However, in the last few years there appears to be an increase in the use of summary adjudication in IP cases, and there are examples of these procedures being successfully used to resolve issues (such as obviousness) which traditionally were considered to be unsuitable for summary adjudication. Parties should always consider whether summary adjudication is appropriate for their case, but such motions are not brought as a matter of course.

# Trial

A trial in the Federal Court is heard by a single judge, not a jury. The Federal Court strives to schedule trials within three years of the issuance of a statement of claim.

Trials in the Federal Court are generally set down for 10 to 20 days, absent unusual circumstances, such as a large number of patents or the need for numerous fact witnesses. Parties provide a joint schedule to the court ahead of trial setting out when witnesses are going to appear and be cross-examined.

## Conduct at Trial

A trial typically proceeds in the following order:

- Opening statements – opportunity for the parties to outline the theory of their case, the evidence to be relied upon, the witnesses to be called, and what each will say. Openings often include slide presentations and/or written outlines. Defendants may open immediately after plaintiffs, or at the beginning of their case.
- Examinations-in-chief and cross-examinations of the plaintiff's witnesses on all issues (both fact and expert witnesses).
- Examinations-in-chief and cross-examinations of the defendant's witnesses on all issues (both fact and expert witnesses).
- Closing arguments – either immediately after the close of evidence, or a few days to a few weeks later. Oral closing arguments are usually accompanied by written submissions (not more than 50 pages without leave of the court).

## Expert Witnesses

Expert witnesses play an important role in IP trials and should be retained early in the proceeding. Expert reports are often at the core of a case, and cases often turn on which expert is preferred by the court.

Experts have a duty to the court to be fair, objective and non-partisan. Experts may assist the court in understanding complex technology, or in quantifying damages, and may provide opinion evidence within their area of expertise. For instance, in patent cases, experts often educate the court as to the state of the art or common general knowledge at the relevant date,

how the inventions work, any similarities and differences between the invention and the allegedly infringing product and other details of the art.

Expert reports are exchanged before trial, and are generally admitted as evidence at trial and taken as read. Despite this manner of proceeding, experts are usually examined in chief before being cross-examined.

When selecting an expert, it is preferable that the witness is not employed by the party retaining them. For patent cases where the validity of a patent is called into question, an expert will need to be able to provide evidence from the perspective of the ordinary person of skill in the art, as of the priority, filing, and/or publication date of the patent. The expert's ability to speak from this perspective is an important consideration in selecting an expert.

In some patent cases, scientific analysis or experimental testing may be required to obtain evidence of infringement or invalidity. If a party wishes to rely on the results of such testing at trial, notice of the time and location of the testing (technically, a notice of "*inter partes* testing") must be served on the adverse parties no later than two months before delivery of expert reports in chief. The purpose of the notice is to give the adverse parties (and their experts, if desired) the opportunity to attend and observe the testing.

The [Federal Courts Rules](#) and the [Canada Evidence Act](#) limit the number of experts to five per case, while Ontario's [Evidence Act](#) limits that number to three. This limit also applies to bifurcated actions, which are treated as a single "trial" or "proceeding". The limit can be waived with leave of the court.

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**“The Federal Court strives to schedule trials within three years of the issuance of a statement of claim.”**

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# Final Remedies

The available remedies in IP matters heard by the Federal Court typically fall into three categories: compensatory, preventative, and declaratory. Courts have broad discretion to grant appropriate relief pursuant to the common law and equity.

## Compensatory

The successful plaintiff in an infringement action may elect to be compensated in damages or by an accounting of profits. Damages compensate a plaintiff for loss caused by the defendant's infringement, whereas an accounting of profits requires the defendant to disgorge the profits it earned as a result of that wrongful activity. Pre-judgment and post-judgment interest may also be awarded on any monetary award granted.

## Preventative

A permanent injunction prohibiting further infringing activities is usually awarded to a successful rights-holder in IP trials. An injunction may be accompanied by an order to deliver up or destroy infringing materials. Such orders are discretionary and typically are granted only to the extent necessary to ensure the effectiveness of the injunction.

## Declaratory

A successful litigant may obtain a declaration from the court, the terms of which will depend on the subject matter in issue. For example, the court may declare that certain claims of a patent are invalid and that no infringement has occurred, or, conversely, that the claims are valid and have been infringed.

As discussed in our section on [Venue](#) above, the provincial and federal courts have the power to make a binding declaration regarding the rights of the litigants, but only the Federal Court may expunge or vary an entry in the various Canadian IP registers.

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## Punitive

Punitive damages are rarely awarded in IP trials in Canada. The purpose of this category of damages is not to compensate the rights-holder, but rather to punish, deter and denounce the actions of the infringing party. These damages are awarded only in cases where a party's misconduct has been so malicious, oppressive and high-handed that the court's sense of decency is offended.

## Costs

Ordinarily, the losing party is ordered by the court to pay a portion of the successful party's legal costs. In the Federal Court, the quantum of costs will be determined by a tariff set out in the [Federal Courts Rules](#) (the tariff lists amounts of recoverable costs by step in the proceeding, which tend to be much lower than actual costs) or fixed as a lump sum (based on a percentage of actual costs) plus reasonable disbursements. Lump sum awards are usually made on a party-party scale in complex IP cases (typically about 25 to 50% of actual costs). Certain factors – such as divided success, the conduct of the parties, or offers to settle – may lead the court to award costs on a higher or lower scale.

The court has complete discretion to decide whether and how to allocate costs, and in what amount.

# Appeal

An order of a case management judge may be appealed to a judge of the Federal Court. Final and interlocutory judgments of the Federal Court may be appealed to the Federal Court of Appeal (“FCA”).

Appeals to the FCA are commenced by the issuance of a notice of appeal that sets out the grounds intended to be argued and a precise statement of the relief sought. The notice of appeal must be filed within the time specified by the applicable statute. A respondent who intends to participate in the appeal will then serve and file either a notice of appearance or a notice of cross-appeal.

In the FCA, appeals are argued before a panel of three judges. The FCA has the power to:

- Quash the proceedings;
- Dismiss the appeal;
- Overturn the trial judgment and substitute the judgment that should have been rendered;
- Order a new trial; or
- Declare the conclusions that the Federal Court should have reached and refer the matter back for continuation of the trial on the issues that remain to be determined in light of that declaration.

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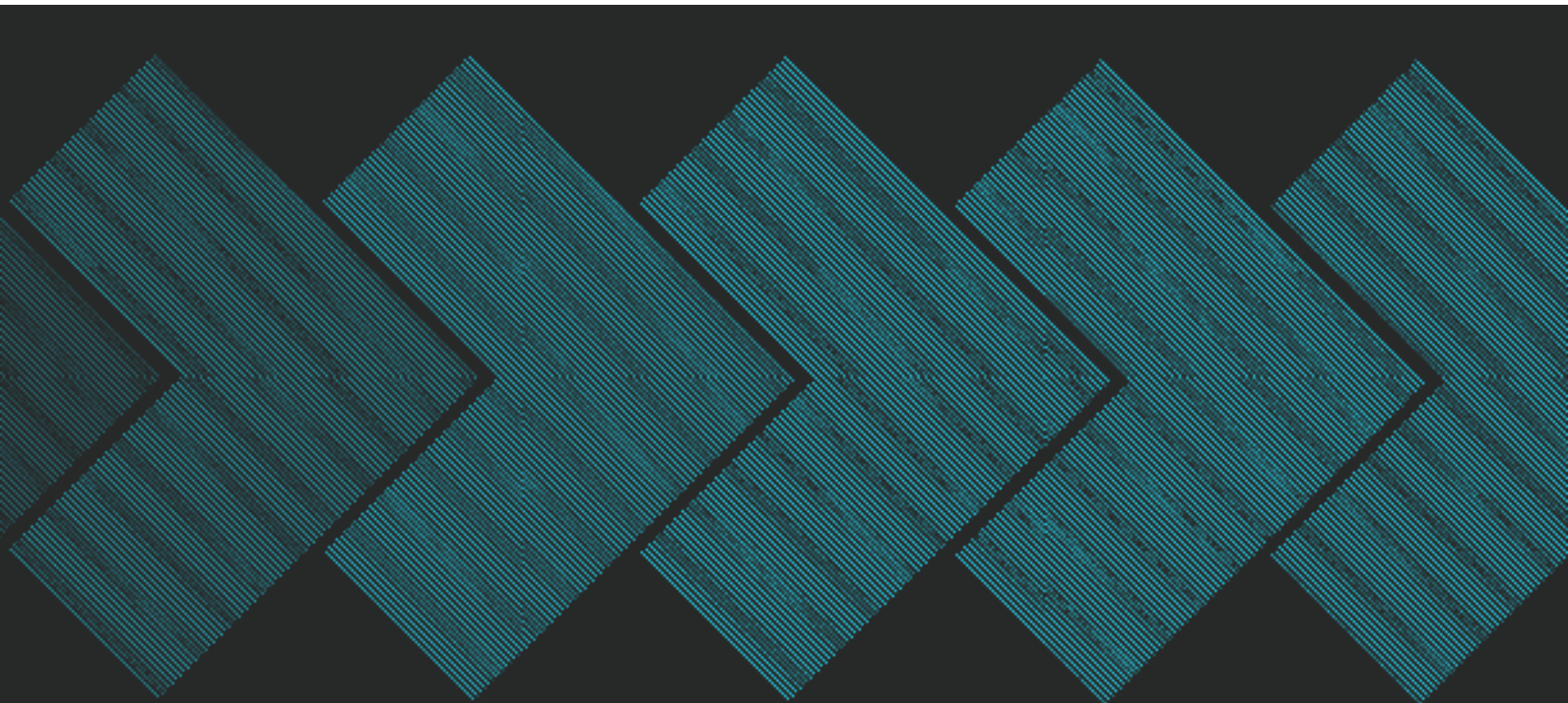
The applicable standard of review depends on the issues raised on appeal. Pure questions of law are reviewed on the standard of correctness, meaning that the FCA is free to replace the decision of the trial judge with its own. Findings of fact are accorded a much higher degree of deference and may not be reversed unless the trial judge made a “palpable and overriding error”. Questions of mixed fact and law involve applying a legal standard to a set of facts. These are also subject to a standard of palpable and overriding error unless it is clear that the trial judge made an extricable error of law, in which case the standard of correctness will apply.

For example, the construction of claims in a patent is considered a question of law. The assessment of expert evidence as to how particular words would be understood by a person skilled in the art is a question of fact, reviewable on the standard of palpable and overriding error. Anticipation and obviousness are usually considered to be questions of fact or mixed fact and law.

A judgment of the Federal Court of Appeal may be appealed to the Supreme Court of Canada with leave. In a typical year, leave to appeal is granted in approximately ten percent of the leave applications filed and very few are IP cases.

## *PM(NOC) Proceedings*

The *Patented Medicines (Notice of Compliance) Regulations* (“*PM(NOC) Regulations*”) link the patent protections provided by the *Patent Act* with the regulatory approval process for generic drugs set out in the *Food and Drugs Act* and the *Food and Drug Regulations*. The *PM(NOC) Regulations* are similar to the Hatch-Waxman regime in the United States.





In Canada, the Minister of Health issues a Notice of Compliance (“NOC”) when a prescription medicine has met regulatory requirements and is approved for market. To obtain an NOC for an innovative drug, the manufacturer files a New Drug Submission (“NDS”). To obtain an NOC for a generic product, the manufacturer files an Abbreviated New Drug Submission (“ANDS”) for a “small molecule” drug, or an NDS for a biosimilar drug.

The Minister of Health maintains a register of patents (“Register”) that relate to approved innovative drugs. A drug manufacturer who has filed an NDS for an innovative drug (a “first person” under the *PM(NOC) Regulations*) may submit to the Minister a list of patents in respect of the drug. A patent will be eligible for listing on the Register if it contains a claim for the approved medicinal ingredient, dosage form, formulation, or use of the medicinal ingredient.

The *PM(NOC) Regulations* are engaged when:

- A submission makes a direct or indirect comparison to a drug marketed in Canada, regardless of whether that submission is an ANDS (e.g., generic drug) or NDS (e.g., biosimilar); and
- There are patents listed on the Register in respect of the comparator drug.

In such cases, a follow-on manufacturer who has filed a submission (a “second person” under the *PM(NOC) Regulations*) has two options: it must await expiry of the listed patent(s) before an NOC can be issued for its product; or it must allege that each patent is invalid, not infringed, and/or improperly listed on the Register. The legal and factual grounds for the allegation(s) must be detailed in a Notice of Allegation (“NOA”), which is served on the first person.

The first person has 45 days after service of the NOA to commence an action in the Federal Court seeking a declaration of infringement against the second person. The second person may counterclaim seeking a declaration that the patent is invalid or void. If such an action is commenced, a statutory stay is triggered that prohibits the Minister from issuing an NOC for the follow-on medicine to the second person for up to 24 months, unless the first person renounces the stay. The stay is lifted as soon as the action is discontinued or dismissed (so long as the NOA has not been withdrawn); the patent

is declared invalid; the second person is found not to infringe; the patent expires; or the first person consents to allow the second person to market the drug. If the Federal Court finds the patent valid and infringed, then the Minister is prohibited from issuing an NOC until patent expiry.

If no action is commenced by the first person within 45 days after service of the NOA, then an NOC for the generic medicine can issue and the first person is precluded from ever asserting that patent against the second person (i.e., with limited exceptions, the first person cannot wait to commence a regular infringement action once the follow-on product is on the market).

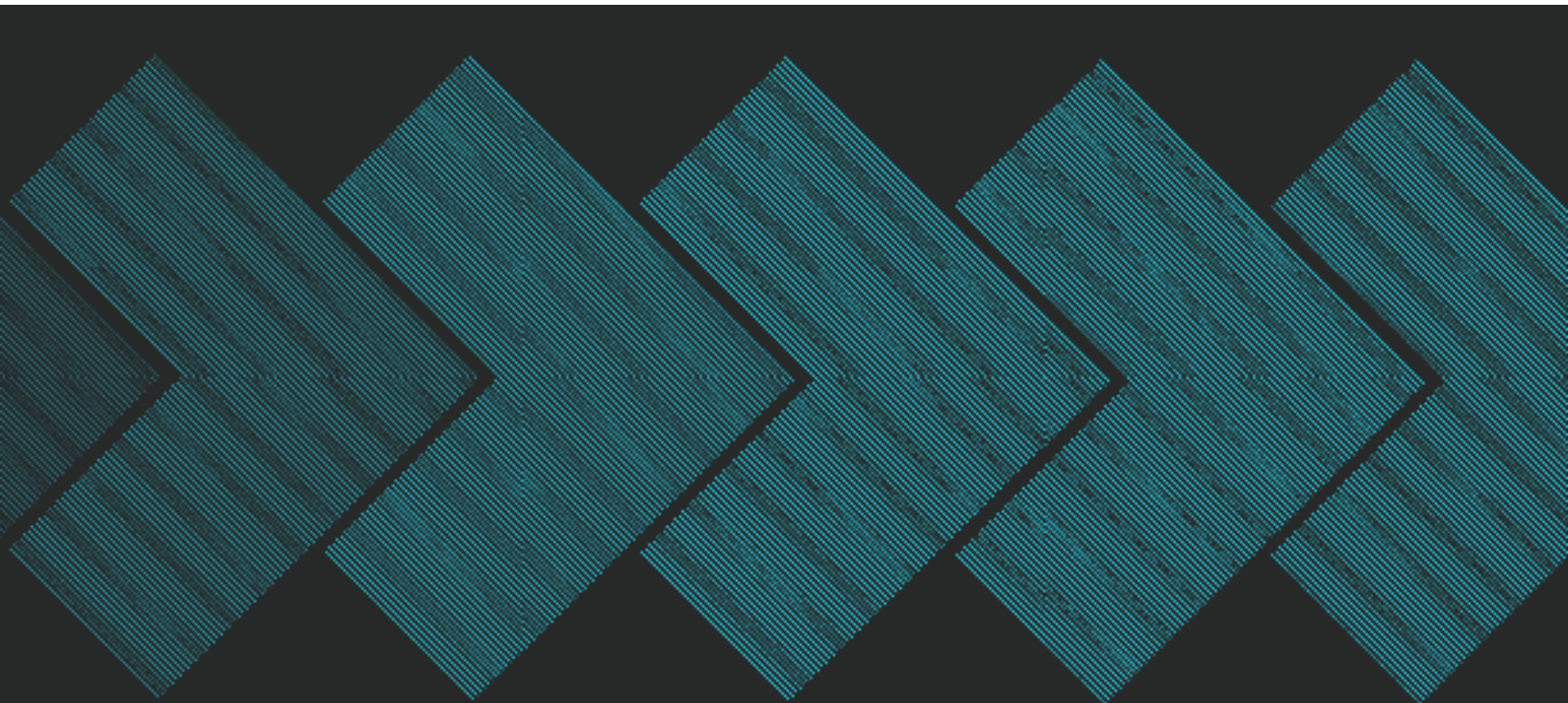
Actions commenced pursuant to the *PM(NOC) Regulations* are generally similar to regular actions in the Federal Court, although there are some important differences, including as follows:

- **Rigid scheduling** – A case management judge is appointed immediately after the action commences, a full schedule through trial is set at an early stage (usually within the first month), and there is little flexibility for schedule adjustments that threaten the trial date.
- **Early disclosure of key documents** – A second person must deliver relevant portions of its regulatory submission at the same time as serving its NOA, and a first person must deliver key invention documents (e.g., lab notebooks or reports relating to certain allegations in the NOA) at the same time as commencing the claim. These early disclosure requirements are in advance of, and in addition to, ordinary documentary and oral discovery.
- **Trial dates** – Trials take place within 21 months and a written judgment and reasons must be released within 24 months of commencing the action (i.e., within the statutory stay period).
- **Trial length** – No more than 10 days unless there are very unusual circumstances.

The *PM(NOC) Regulations* also prohibit the formal consolidation of actions against different second persons, but in practice, various steps of parallel proceedings may be scheduled jointly.

## Key Differences Between Canadian and US Litigation

Although Canadian and US IP litigation are similar in many ways, there are a number of key differences, which are outlined in this section.



## General

DIFFERENCE IN CANADA	DESCRIPTION
No forum shopping	<ul style="list-style-type: none"> <li>➤ Federal Court judges travel to hear cases, so there is no local counsel advantage. As a result, forum shopping is rarely a factor.</li> </ul>
No International Trade Commission	<ul style="list-style-type: none"> <li>➤ No equivalent to ITC litigation.</li> </ul>
More detailed pleadings	<ul style="list-style-type: none"> <li>➤ Pleadings tend to be longer and more detailed than in the US.</li> </ul>
More speculative pleadings	<ul style="list-style-type: none"> <li>➤ No requirement to distinguish between allegations based on knowledge versus belief.</li> <li>➤ Although speculative pleadings may be struck (with cost consequences), there is no analogous requirement to FRCP Rule 11 sanctions for failure to make diligent inquiries.</li> </ul>
Limited examinations for discovery	<ul style="list-style-type: none"> <li>➤ Oral discovery is generally shorter and less expensive.</li> <li>➤ Discovery is typically limited to a single corporate representative for each party, whose answers bind the corporation.</li> <li>➤ Non-parties can be examined for discovery only with leave of the court, and such examinations are not common.</li> <li>➤ Counsel is permitted to refuse questions during examinations for discovery on the basis that they lack relevance, and not just on privilege grounds. If a question is refused, the witness does not provide an answer in the examination but may be compelled to do so if the court later determines that the objection was improper.</li> <li>➤ Discoveries are transcribed but there is no video recording.</li> </ul>
Undertakings	<ul style="list-style-type: none"> <li>➤ If a corporate representative witness does not know the answer to a question at discovery, they may be asked to give an undertaking to make inquiries and provide the answer later in writing. This is similar to US written interrogatories practice but occurs after examinations for discovery rather than before.</li> </ul>
Narrower document productions	<ul style="list-style-type: none"> <li>➤ Documentary discovery is typically much more streamlined.</li> <li>➤ There are no written interrogatories exchanged prior to documents being produced.</li> <li>➤ Limited consultation or collaboration between the parties on productions.</li> <li>➤ The relevance standard is higher in the Federal Court: documents are considered relevant only if (1) a party intends to rely on the document at trial or (2) the document tends to adversely affect the party's case or to support another party's case.</li> </ul>
No expert discovery	<ul style="list-style-type: none"> <li>➤ Expert reports are exchanged ahead of trial but an expert will be examined for the first time at trial.</li> <li>➤ The ability for experts to testify beyond the contents of their expert reports is very limited.</li> </ul>

Cross-examination on affidavits	<ul style="list-style-type: none"> <li>➤ Parties typically cross-examine any witness who provides a substantive affidavit in support of an interlocutory motion.</li> <li>➤ Failure to cross-examine can lead to the court accepting an affiant's evidence as unchallenged, even if the responding party has led contrary evidence from its own witness(es).</li> <li>➤ This practice necessitates careful consideration about the identity of affiants. For example, parties may be hesitant to file affidavits on interlocutory motions from trial experts.</li> </ul>
Longer trials	➤ It is not unusual for infringement actions to be heard over several weeks. Live in-chief testimony is still commonplace, and experts often testify for several days.
No jury trials	➤ IP disputes are heard by a judge alone.
No treble damages	➤ Treble damages are not available, though punitive damages may be awarded in rare cases.
Loser-pays system	➤ Successful litigants are generally entitled to a cost award.

## Patent Litigation

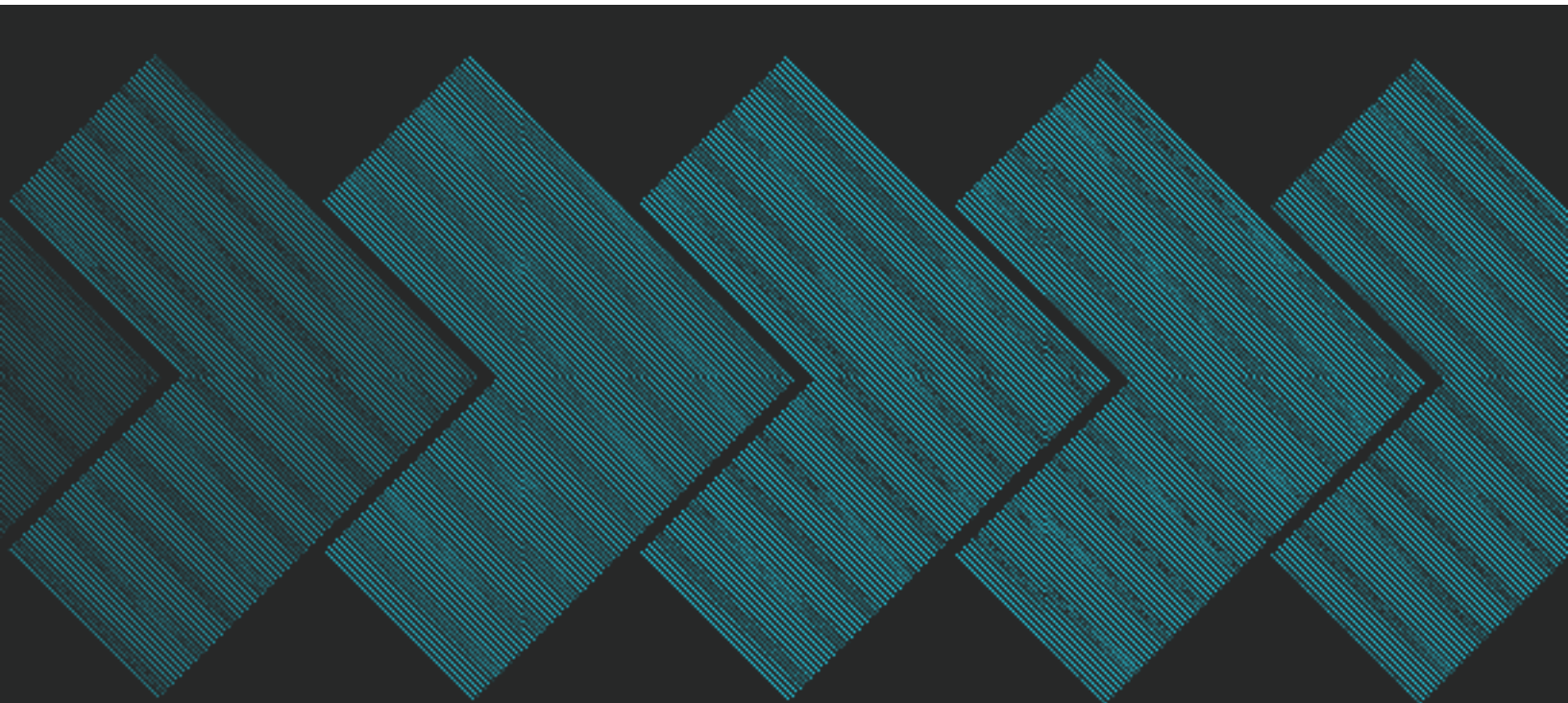
DIFFERENCE IN CANADA	DESCRIPTION
No notice requirement	<ul style="list-style-type: none"> <li>➤ No requirement that a patent owner provide notice to an infringer.</li> <li>➤ Liability for infringement of an issued patent may run from the date the patent application was published (pre-issuance) in the form of reasonable compensation (usually a royalty).</li> </ul>
Fewer patents asserted	➤ Few cases involve more than three or four patents.
Inventor discovery	➤ While non-party discovery is unusual, there is an exception – defendants have a right to examine inventors and usually do.
Order of evidence	<ul style="list-style-type: none"> <li>➤ Unless agreed to by the parties, plaintiffs must present and close their entire case (subject to a very limited reply right) before the defendants present their case.</li> <li>➤ This means that the plaintiff must present its evidence on validity before the defendant presents its evidence of invalidity, despite the defendant bearing the burden on that issue. Although this may seem counter-intuitive, by the time of trial the parties will have exchanged expert reports, responding expert reports, and sometimes reply expert reports (all of which are usually tendered as evidence), so the issues will be well-canvassed.</li> </ul>
Limited ability to oppose patent applications	➤ There is a limited opportunity to oppose another party's patent or co-pending application, but an opposer can file prior art with the Patent Office.

No <i>inter partes</i> review	<ul style="list-style-type: none"> <li>➤ There is no equivalent of <i>inter partes</i> review.</li> <li>➤ Though a third-party (or the patentee) may initiate re-examination of an issued patent, the procedure is rarely used because the scope of re-examination is very narrow. Submissions are limited to filing the initial request for re-examination; there is no right to participate further in the event that re-examination is granted.</li> <li>➤ If the Patent Office determines that re-examination is not necessary, the requesting party has no right of appeal.</li> </ul>
No Markman hearings	<ul style="list-style-type: none"> <li>➤ Except in the context of a summary trial, claims construction is not determined until trial, along with all other issues.</li> <li>➤ This means that experts must provide opinions on validity and infringement without the benefit of the court's construction.</li> </ul>
No doctrine of equivalents	<ul style="list-style-type: none"> <li>➤ The court considers the extent to which equivalents fall within the scope of the claims as part of its claims construction – rather than its infringement – analysis.</li> <li>➤ Generally, a claim element can be understood broadly based on purposive construction to include a variant, or it can be considered non-essential such that variants are within the scope of the claim.</li> <li>➤ Since claims construction does not need to be pleaded, parties' positions on construction tend to crystallise later in a proceeding than in the US.</li> </ul>
Common general knowledge	<ul style="list-style-type: none"> <li>➤ Common general knowledge is similar to "common sense" in the US, except a patent can be invalidated for obviousness based on the common general knowledge alone. That is, validity of a patent can be attacked based solely on expert testimony regarding the common general knowledge, without referencing any prior art.</li> </ul>
No developed joint or contributory infringement doctrine	<ul style="list-style-type: none"> <li>➤ Case law recognizes direct and indirect (including induced), but not contributory, infringement. There is a developing doctrine of infringement by common design, but the boundaries of that doctrine are still unclear.</li> </ul>



# Recent Developments in Canadian Patent Law

In this section, we review some recent and notable patent law developments in Canada.



## Patentable Subject Matter

For several years, the courts and the Canadian Patent Office have been at odds in their approach to patentable subject matter. Most recently, on November 3, 2020, the Canadian Patent Office released new guidelines, along with a set of examples, such as computer-implemented inventions, medical diagnostic methods and medical uses. The guidelines set out a three-step process for assessing whether patentable subject matter has been claimed:

1. Determine the subject matter defined by the claim by identifying the elements of the claimed invention that are either essential elements or non-essential elements (“purposive construction”).
2. Determine whether that subject matter complies with all of the requirements of the *Patent Act* by identifying an “actual invention” of the claim, where this “actual invention” “may consist of [...] a combination of elements that cooperate together to provide a solution to a problem”. Of particular significance, the “actual invention” does not necessarily include every element identified to be essential in step one above. This approach is contrary to established case law; the conflict will be addressed in an upcoming appeal to the FCA.
3. Determine if the “actual invention” of the claim has physical existence or discernible physical effect or change. Compared to the test under Canadian case law, the requirement that a claim covers discernible *physical* effect or change to be patentable subject matter may be more rigid.

## Successful Summary Adjudication in Patent Proceedings

As noted above, summary adjudication is increasingly being granted by the Federal Court in patent proceedings. In 2020, summary judgment was granted in three cases on substantive patent law grounds:

1. Claims construction;
2. Invalidity (obviousness); and
3. Non-infringement.

In one case, [\*ViiV Healthcare Company v Gilead Sciences Canada\*](#), the Court held that the completion of discovery was not necessarily required to conduct a summary trial, further demonstrating that summary proceedings may be brought at an early stage and may be a good strategy for early disposition in an appropriate case.

## Admissibility of Prosecution History

Following amendments to the *Patent Act* on December 13, 2018, an evidentiary provision, similar to file-wrapper estoppel in the US, was introduced into Canadian patent law. According to new section 53.1, written communications between an applicant or patentee and the Commissioner, the Patent Office or the re-examination Board during the prosecution of a Canadian patent application may now be admitted as evidence during any patent proceeding to rebut representations made by the patentee with respect to claims construction.

The Federal Court in [\*Allergan Inc v Sandoz Canada Inc\*](#) exposed a loophole in the scope of section 53.1: the reference to “patentee” was found not to include a licensee. Thus, a patent’s prosecution history is not admissible to rebut a licensee’s statements in a patent proceeding and a licensee is not bound by statements made by a patentee during prosecution.

There is also uncertainty as to whether statements made in the prosecution histories of foreign counterparts may be admissible as evidence under the new section. Following conflicting trial level decisions, the Federal Court of Appeal in [\*Canmar Foods Ltd v TA Foods Ltd\*](#) ruled that a foreign prosecution history was inadmissible on the facts of that case, but declined to decide that foreign prosecution histories could never be considered pursuant to section 53.1.

# Lenczner Slaght's IP Litigation Expertise

At Lenczner Slaght, we recognize the vital importance of intellectual property in a complex and fast-moving global marketplace.

Our lawyers have acted on some of Canada's leading patent trials. Our lawyers have also litigated IP cases in the US, and we regularly represent US-based corporations on the Canadian aspects of disputes that span multiple jurisdictions.

We're successful advocates not just because our lawyers have the scientific backgrounds necessary to understand the most complicated innovations. It's also that we know how to simplify those complicated concepts for judges.

# IP Litigation Practice Areas

We have extensive courtroom experience representing clients in all types of intellectual property matters in proceedings before the Federal Court, the Federal Court of Appeal, the Ontario Superior Court, the Ontario Court of Appeal and the Supreme Court of Canada.

Our clients include national and multinational companies from a wide array of industries and sectors, including pharmaceuticals, biotechnology, information technology and software, communications and the Internet, agriculture and aquaculture, manufacturing, nutraceuticals, fashion and design, music recording/distribution, broadcasting and internet communications, medical devices and mining.

15

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