2022 Year in Review: *Patents*

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Introduction

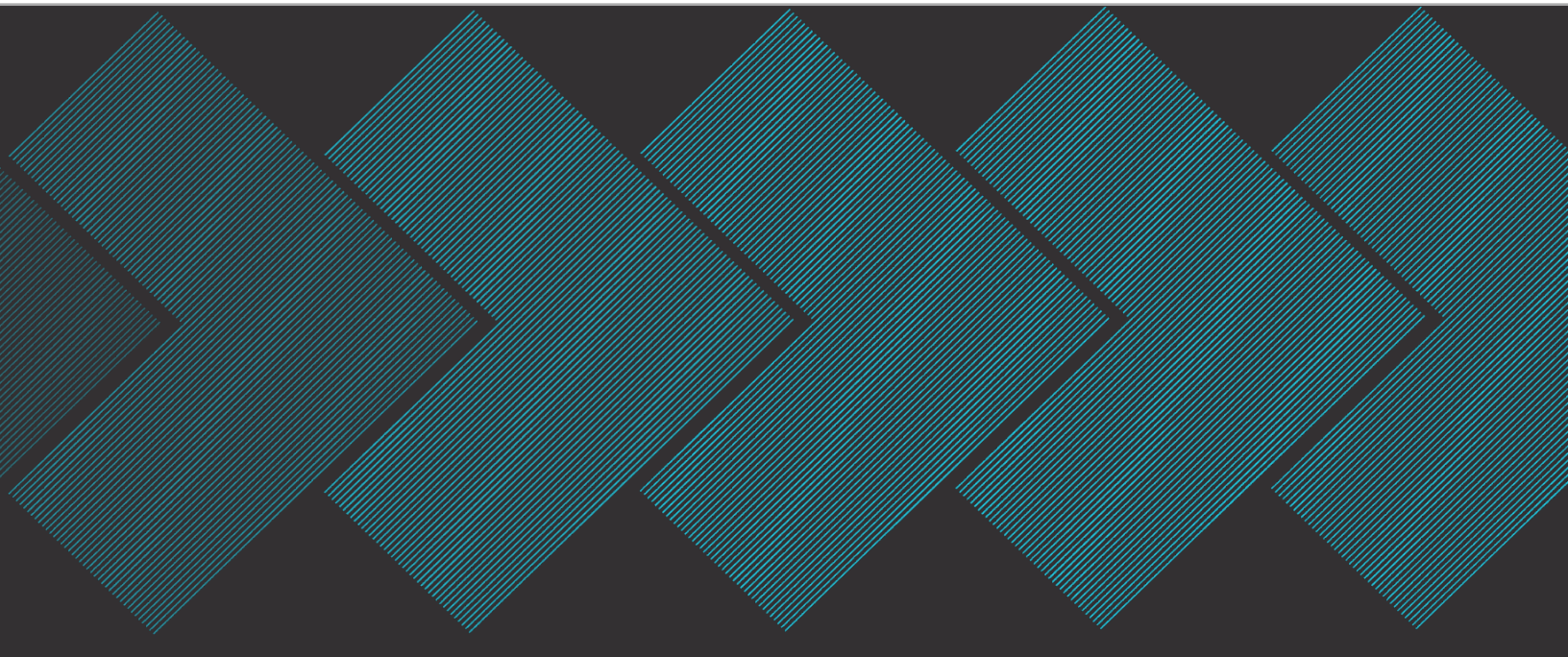
Welcome to 2022 Year in Review: Patents

This paper is divided into two main sections. The first section is "Commentary" and in it we discuss key patent caselaw developments in 2022. This section has three parts. In the first part we have chosen to focus our commentary on several key areas, namely: Claims Construction, Infringement, Validity, Patentable Subject Matter, Summary Proceedings, Relief and Entitlement, and Key Procedural Motions. The second part of the Commentary section provides a brief update on relevant patent related updates to Statutes, Regulations & Rules, and Practice Directions. Finally, the Commentary section includes some "Quick Hitters". This subsection provides some key takeaways from patent-adjacent (Patented Medicine Prices Review Board (PMPRB), data protection, etc.) decisions in 2022 and touches on other interesting topics worth noting.

The second section is "The Year in Data" and includes insights from the Lenczner Slaght Patent Appeals Project, which is a database of all Federal Court of Appeal ("FCA") cases from the last twenty years. This section sheds light on interesting trends from a data focused perspective. Thank you to Paul-Erik Veel and Samantha Hargreaves for their contributions to this section of the paper and for their data analysis and insights for the Lenczner Slaght Patent Appeals Project.

Case names are hyperlinked in the Commentary section to the decisions on the Federal Court and or CanLII websites. Other (non-2022) cases referenced are also hyperlinked to the decisions.

We hope you find it useful!



Commentary

Claims Construction

Claim Construction is a core tenet of patent law impacting both infringement and validity analyses. Claim construction analysis received some important guidance in 2022.

Recourse to the Disclosure is Always Permitted

In *Biogen Canada Inc. v. Pharmascience Inc.* 2022 FCA 143 ("Biogen FCA"), Gauthier JA held that in a claim construction analysis recourse to the disclosure is always permitted. Recourse to the disclosure is relevant whether or not a claim is ambiguous. Adherence to the claim language is also required. Purposive claim construction involves looking at words of the claims in context. This includes individual claim review and looking at the claims as a whole, as well as considering the description and the purpose of the patent. The inventor's objective intention is what the Court is trying to ascertain in the claim construction analysis.

The decision of Locke JA in *Betser-Zilevitch v. Petrochina Canada Ltd.* 2022 FCA 162 is dated shortly after the decision in Biogen FCA. In this decision the FCA held that more than a "gloss or stray mention" of a disputed term was present in the patent disclosure at issue. The patent describes characteristics of the invention with reference to its objects, and the disputed term was understood with reference to that aspect of the disclosure which spoke to the object of improved safety. It was not an error to rely on this part of the disclosure in construing the term. Locke JA held the Court below correctly concluded the term was ambiguous and appropriately had recourse to the disclosure to construe it.

In both decisions the FCA held recourse to the disclosure was appropriate, albeit with different approaches. Biogen FCA appears to seek to resolve the open question as to when recourse to the disclosure is permitted. The 2022 trend on claim construction leans into looking at the disclosure. In 2023 we will watch if the trend follows Biogen FCA's effort at closure.

Focus on Issues in Dispute

In *Swist v. MEG Energy Corp* 2022 FCA 118, Laskin JA held that the Court may focus its construction analysis on the issues in dispute between the parties, centering the analysis on "where the shoes pinches". The FCA further stated that the Federal Court was, at first instance, entitled to focus construction on certain disputed terms in the claims without explicitly construing other claims. To the extent the analysis implicitly required construction of other terms, there was no error. Where the parties have not provided expert evidence on how a skilled person would understand a term, or where that evidence is clearly not necessary, claim terms are to be given their plain and ordinary meaning. Leave to appeal to the Supreme Court of Canada ("SCC") sought (File No. 40363).

Infringement

A few interesting developments emerged in infringement decisions this year including as to indirect infringement, common design and attribution, the prior use defence, and the meaning of "use".

Inducement

In *Angelcare Canada Inc. v. Munchkin Inc.* 2022 FC 507 ("Angelcare"), Roy J found the Defendants infringed several patents owned by the Plaintiffs relating to their diaper disposal system sold under the brand name "Diaper Genie". The decision provides insights particularly relevant to inducement.

On the issue of inducement, the Court held the Plaintiffs established both direct and indirect infringement. In respect of inducement, the Court held that Munchkin encouraged consumers to use their products in a manner that infringes certain claims of the patents in issue. The Court further found that Munchkin's labels affixed on its Munchkin products encouraged consumers (i.e. the direct infringer) to use the Munchkin products with the diaper genie pails. The Court held there was no doubt that Munchkin knew its label was affixed on its cassette products and that those labels announced compatibility with the Diaper

Genie. The influence was deliberate. The Court further held that it was easily inferred from the evidence that the influence resulted in the completion of the act of infringement. All three prongs of the inducement test were satisfied in respect of some of the patented combinations. Decision under appeal (File Nos. A-106-22 and A-105-22 consolidated under File No. A-105-22).

Common Design and Attribution

Two appeals were heard consecutively in *Rovi Guides, Inc. v. Videotron Ltd* 2022 FC 981. *and Rovi Guides v. Bell* 2022 FC 979 by Brown J. The motions sought to strike allegations grounded in the doctrines of infringement by common design and infringement by attribution. The appeals involved similar arguments by the Defendants asserting that infringement by common design and infringement by attribution are not recognized in Canadian law and therefore the allegations disclose no reasonable cause of action. The Court dismissed the appeals and allowed the allegations to proceed.

Prior Use Defence

In *Kobold Corporation v. NCS Multistage Inc.* 2021 FC 1437, Zinn J provided the first judicial consideration of the prior use defence since the substantial amendments to section 56 of the *Patent Act* in 2018. The Court articulated the following test under s. 56(1). *First*, if the acts performed before and after the claim date are identical, then a prior use defence applies. *Second*, if the acts are not identical, determine whether the acts infringe the patent. *Third*, if the pre- and post-claim date acts are not identical, but both infringe the same claims, determine whether the changes between pre- and post-claim date acts relate to the inventive concept of the patent. If the changes do not relate to the inventive concept, then subsection 56(1) will provide a defence to infringement.

The Meaning of "Use"

In a summary trial in *Steelhead LNG (ASLNG) Ltd. v. ARC Resources Ltd.* 2022 FC 998, Manson J considered what constitutes infringing "use" in the context of s. 42 of the *Patent Act*. The Court held that the Defendants' conceptual design for purposes of future development of a liquified natural gas facility, and presentation of that design to third parties, did not constitute "use" of a patent claiming systems and methods of liquefying natural gas. The Court stated that the claimed invention is an actual physical apparatus, system, or method using such an apparatus, and that simply drawing the invention for promotional purposes would only constitute a "paper offer" that does not amount to infringement. The Court also found that, on the evidence, there was no commercial benefit obtained by the Defendants from the alleged "use". Decision under appeal (File No. A-210-22).

Validity

In 2022, as in most years, we saw ebbs and flows in the development of various validity issues. This section highlights some of the most interesting developments. Although patentable subject matter could properly be addressed in this section it is so topical it is addressed under its own heading.

Common General Knowledge and Prior Art

In *Janssen Inc. v. Sandoz Canada Inc.* 2022 FC 715, Palotta J states that the common general knowledge ("CGK") analysis is distinct from the state of the art analysis and they each play different roles. Identifying the CGK is the first step in the obviousness inquiry. A comparison of the inventive concept to the state of the art is the third step. The state of the art is the culmination of the relevant prior art and is understood by reading the prior art in light of the CGK of the skilled person. The Court further states that while in some cases there may be little practical difference between the CGK and the state of the art, in some cases, as in this one, it does matter. The Court found that the Defendant's position was inconsistent with the expert evidence and that the expert did not properly consider what would have formed part of the CGK of the skilled person. The Defendant did not establish that certain prior art references would have formed part of the CGK. Decision under appeal (A-128-22).

Prior art was also in issue before Zinn J in *Google LLC v. Sonos, Inc.* 2022 FC 1116. This decision is of interest for its discussion of obscure prior art. In this case, a key prior art document was obscure (i.e. it would not have been found in a

reasonably diligent search). The prior art reference was also not found by any of the experts in preparing their reports nor was it known to them prior to the litigation. Following the FCA's decision in *Hospira* (2020 FCA 30), Zinn J found that this obscure piece of prior art was eligible to be considered for the purpose of the obviousness analysis. However, Zinn J went on to find that given the difficulty in locating this particular prior art reference, the skilled person would not have been led directly and without difficulty to combine it in the obviousness analysis. The Court rejected any obviousness argument by the Defendant that involved using that obscure prior art reference in combination with other references. Decision under appeal (A-208-22).

This decision is similar to, and consistent with the decision of Locke JA in 2022 FCA 2 upholding Kane J in 2020 FC 1158.

Inventiveness

Several decisions in 2022 considered inventiveness issues beyond the CGK and prior art discussion above. These decisions provide useful guidance on, among other things, the inventive concept, the inventiveness of salt patents, and the interplay between obviousness and sound prediction.

One such decision is *Merck Sharp & Dohme Corp. v. Pharmascience Inc.* 2022 FC 417 ("Merck v. PMS"). In this case Furlanetto J held the patent in issue (the '400 Patent) was inventive. In coming to this conclusion, the Court considered the obviousness analysis as well as selection patent analysis. Further, in looking to the inventive concept, the Court did so on a claim-by-claim basis. The Court stated that inventive concept is distinct from claims construction, although it may be informed by it.

The Court held that the inventive concept of the asserted claims consisted of the same advantages that rendered the '400 Patent a selection patent. The Court made this finding even though the advantages were not claimed.

Furlanetto J held that the analysis of a salt patent does not have general rules that can be applied in all cases. The analysis will turn on the facts, issues, and evidence in each case. The patent was held to be inventive. Decision under appeal (A-91-22).

A selection patent analysis was also before the FCA in *Pharmascience Inc. v. Bristol-Myers Squibb Canada Co.* 2022 FCA 142. ("PMS v. BMS") The FCA held that:

1. There was evidence on which the Federal Court was entitled to and did rely to conclude that the patent in issue does disclose a special advantage of apixaban over the genus of compounds described in the prior genus patent;
2. The Federal Court did not err in considering the claims of the patent in determining how the skilled person would find the special advantage was disclosed by inference; and
3. An explicit comparison of apixaban to any other individual compound within the genus was not required.

Leave to appeal to the SCC sought (File No. 40400).

The Obviousness Squeeze Argument

In *Pharmascience Inc. v. Teva Canada Innovation* 2022 FCA 2 ("PMS. v. Teva"), the FCA held that the Court can find that there is enough in the CGK to support a sound prediction but not enough to find the invention obvious. According to this decision of Locke JA, it is not necessarily inconsistent to find on one hand that something is described sufficiently in the patent disclosure and the CGK to support that a sound prediction will be useful, and on the other hand the idea is not known enough in the prior art, including the CGK, to lead skilled person directly and without difficulty to the solution taught in the patent, but not enough to find the invention obvious.

Leave to appeal to the SCC dismissed (File No. 40100).

Sufficiency is Assessed on the Issued Patent

In PMS v. BMS 2022 FCA 142, Locke JA considered among other things, the issue of sufficiency. The FCA held the sufficiency assessment should be made based on the issued patent which includes the issued claims as part of the specification. The claims relevant to the determination are the issued claims, not

claims pending before the patent office at the claim date.

Further, the FCA held that there is nothing in the *Patent Act* or in the SCC decision of *Pioneer Hi-Bred Ltd v. Canada (Commissioner of Patents)* [1989] 1 SCR 1623 that indicates that a specification cannot be amended during prosecution to comply with the sufficiency requirement. In addition, in this case, the FCA held that the claims to the compound (apixaban) could be reasonably inferred from the original application. Leave to appeal to the SCC sought (File No. 40400).

Contemporaneous Testing May Be Available to Support Insufficiency Allegation

In another decision involving Pharmascience sufficiency was before the Court. In Merck v. PMS 2022 FC 417 Furlanetto J found the patent in issue was valid for sufficiency.

One of the allegations made by the Defendant was that the patent did not fully disclose the process for creating sitagliptin phosphate monohydrate. As part of this allegation the Defendant pointed to failed experiments conducted by the Plaintiffs at the relevant time. However, the Court found that there was also evidence put forward by the Plaintiffs of experiments where the salt was successfully created.

The Court held the allegation of insufficiency to be speculative. The Defendant could have had its experts conduct testing attempting to create sitagliptin phosphate monohydrate by following the disclosed process. According to Furlanetto J, if this process were shown to be insufficient as of the time of the proceeding it would be a challenge for the patentee to suggest the process would have been sufficient as of the patent filing date. Contemporaneous testing is not supportive in a defence against insufficiency allegations because contemporaneous testing would benefit from hindsight. Decision under appeal (A-91-22).

Utility: Sound Prediction

In PMS v. Teva 2022 FCA 2, a central issue on appeal was the disclosure requirement in the sound prediction test. The parties agreed that there is a "heightened" disclosure requirement applicable to inventions based on sound prediction. As such that issue was not considered by the FCA.

The Court held that the trial judge did not misunderstand the disclosure requirement. The trial judge recognized the distinction between disclosure generally per s. 27(3) of the *Patent Act* and disclosure regarding utility in s. 2 of the *Patent Act*. The trial judge further specifically discussed the disclosure requirement in the context of sound prediction.

Although the trial judge seemed to have erred in one aspect of her decision relating to "Small Studies", the FCA held that sound prediction is an issue of mixed fact and law and reviewed on a standard of palpable and overriding error. The FCA was not convinced this error was overriding, i.e. goes to the core of the outcome of the case. The FCA came to this result because the basis for the trial judge's finding on sound prediction is found in a paragraph in the reasons that makes no mention of "Small Studies". Nor was it clear to the FCA that the trial judge relied on the "Small Studies" elsewhere in the reasons to support the sound prediction finding. Further the FCA stated that it was not clear to the Court that the trial judge relied on other internal information to Teva Innovation as part of her reasons to support her decision. Leave to appeal to the SCC dismissed (File No. 40100).

Anticipation by Prior Disclosure

The issue of anticipation by prior disclosure arose in Angelcare 2022 FC 507. The allegation was that the inventor made a disclosure of the invention regarding the cassettes defined in the Angelcare patents in an email, relating to a prototype of the patented invention, to third-party manufacturers. The crux of the issue was whether that disclosure was a public disclosure and hence enabling, or whether it was subject to confidentiality and thus not an enabling disclosure.

The Court held that there was an implied obligation of confidentiality and as such this disclosure of the prototype was not an enabling disclosure, available to the public and was not anticipatory.

Further, the Court stated that there was an inherent suggestion that an obligation of confidence existed because the third-party manufacturers were in the business of making prototypes and because of the nature of the relationship between the parties. Decision under appeal (File Nos. A-106-22 and A-105-22 consolidated under File No. A-105-22).

Overbreadth

2021 saw the FCA confirm that overbreadth is an independent ground of invalidity. 2022 was a less dramatic year for overbreadth, but it was specifically considered in several trial decisions as discussed below.

In *Eli Lilly et al v. Apotex et al* 2022 FC 1398, the Court held that the claims, which related to the compound tadalafil "or a physiologically acceptable salt or solvate thereof" for the treatment of erectile dysfunction, were broader than the invention made. The Court construed "physiologically acceptable" to mean the salt was non-toxic, would not cause harm, and would be stable and pure rather than degraded.

It was admitted that the inventors had not actually made any salt of tadalafil prior to the filing date. The Court also accepted the Defendants' expert's opinion that the extremes of pH required to make salts of tadalafil would result in the degradation of tadalafil and any salts that could be made would therefore not be "physiologically acceptable", as they would not be pure and stable. The Court concluded that it was more probable than not that a physiologically acceptable salt of tadalafil cannot be made, such a salt was not invented, and the claims were invalid because they were broader than what was invented.

In Angelcare 2022 FC 507, the Court held that the claims were not invalid for overbreadth simply for being broader than the described embodiments. The Defendant argued that the asserted patents only disclosed one closing mechanism but claimed diaper disposal systems that used any closing mechanism. However, the Court stated that the specific closing mechanism was not an essential element of the invention disclosed; rather, the invention was focused on how aspects of the closing mechanism interacted with aspects of the cassette to solve the "incorrect orientation problem". Decision under appeal (File Nos. A-106-22 and A-105-22 consolidated under File No. A-105-22).

In *Rovi Guides, Inc. v. Bell Canada and Telus Corporation* 2022 FC 1388, the Court held that the "invention made" for the purpose of the overbreadth analysis is to be determined as of the filing date rather than the priority date. Decision under appeal (A-231-22 and A-233-22).

Patentable Subject Matter

One of the hottest topics in 2022 was patentable subject matter. In particular, the ongoing battle between the Courts and the Patent Office relating to this issue has caught the attention of most of the patent bar.

Gagné ACJ's decision in *Benjamin Moore & Co v Attorney General of Canada* 2022 FC 923 ("Benjamin Moore") is the second time that the Federal Court stated that the Commissioner was not applying the correct test for patentability of computer-implemented invention. The Court provided instruction on how the Commissioner ought to assess patentability of such inventions.

All parties involved in the appeal agreed that the Commissioner erred in her assessment of the patent applications at issue. The only question to be decided was as to the appropriate remedy.

In this case, Benjamin Moore & Co., asked the Court to send the matter back to CIPO with a direction to follow the leading SCC decisions on claims construction and non-patentable subject matter.

The intervenor, the Intellectual Property Institute of Canada ("IPIC"), took similar positions but provided a framework with precise instructions to the Commissioner on the redetermination. The applicant agreed with the intervenor. The proposed framework requires examiners to:

1. Purposively construe the claim;
2. Ask whether the construed claim as a whole consists of only a mere scientific principle or abstract theorem, or whether it comprises a practical application that employs a scientific principle or abstract theorem; and
3. If the construed claim comprises a practical application, assess the construed claim for

the remaining patentability criteria: statutory categories and judicial exclusions, as well as novelty, obviousness, and utility.

Gagné ACJ held that determining the proper legal test to be applied is well within the purview of the Federal Court. The Court further held that the legal framework proposed by IPIC and endorsed by the applicant is in accordance with the SCC's teachings and the Federal Court of Appeal's decision in *Amazon* (2011 FCA 328).

The Court held that the framework was the proper procedure for claims construction and identifying patentable subject matter. Gagné ACJ stated, the framework "ensures consistency" between:

1. The law applied to patent applications by CIPO, and the law applied to issued patents by the Courts; and
2. The way patent law is applied to computer-implemented inventions and the way patent law is applied to all other types of inventions".

The applications in question were remitted to CIPO for a new determination along with a direction to follow IPIC's framework. Decision under appeal (A-188-22).

Patentable Subject Matter: Method of Medical Treatment

The issue of patentable subject matter was also before the Court in 2022 in relation to method of medical treatment. In *Janssen Inc. v. Pharmascience Inc.* 2022 FC 1218, Manson J comments on the dichotomy of case law that has developed in the area of method of medical treatment cases. The dichotomy identified is between:

1. Specific dosages and administration intervals contrasted with,
2. Ranges of dosages and schedules.

The former has been held to be patentable vendible products while the latter has been held, in some cases, to be unpatentable as requiring skill and judgment amounting to methods of medical treatment. Although Manson J states that there seems to be a questionable underpinning in the dichotomy of cases, he states that this is where we are under the current state of the law.

In this decision the Court finds the use claims provided for two possible dosing regimens. The Court also finds that once the physician chooses to use the products for the claimed purpose, each claim is directed to fixed dose amounts, fixed intervals, and fixed injection sites. The Court held that while there are elements where there are choices, those choices do not have clinical implications. Therefore, no skill or judgment is required that would interfere with or restrict a physician skill or judgment to prescribe the dosing regimen within the claimed invention. The patent was held to disclose patentable subject matter. Decision under appeal (A-205-22).

Summary Judgment and Summary Trial

There were several developments in summary proceedings this year, including:

1. The FCA "tapping the brakes" on summary judgment if credibility determinations are required;
2. Uncertainty regarding the burden in summary trial;
3. Summary trials in proceedings under the Patented Medicines (Notice of Compliance) Regulations ("PM(NOC)"); and
4. The range of outcomes from summary proceedings.

Summary Judgment and Credibility

Over the last several years there has been a trend towards increased adoption of summary proceedings for resolving patent cases in Canada, and the Federal Court and FCA had signaled a willingness to move away from the historic reluctance of those Courts to approve summary judgment for patent infringement actions. In August, the FCA released its decision in *Gemak Trust v Jempak Corporation* 2022 FCA 141 ("Gemak"), which "taps the brakes" on that trend.

In Gemak, the FCA held that summary judgment is not appropriate where there are serious issues with respect to the credibility of witnesses, and the Court observed more generally that "while patent infringement issues are not by definition

excluded from the ambit of the summary judgment process, they tend to raise complex issues of fact and law that are usually better left for trial".

Burden in Summary Trial

Summary trial permits *viva voce* evidence, which in light of the Gemak decision may make it a preferable procedure where credibility is a major factor. However, summary trial faced its own challenges in 2022, with conflicting Federal Court decisions relating to the burden of proof. It is uncontentious that the moving party bears the burden on the threshold question in a summary trial – whether it is an appropriate procedure for determining the issues raised in the motion. The jurisprudence is now divided relating to which party bears the burden on the merits.

In three separate decisions – *Janssen Inc. v. Pharmascience Inc.* 2022 FC 62, *Janssen Inc. v. Apotex Inc.* 2022 FC 107, and *Steelhead LNG (ASLNG) Ltd. v. ARC Resources Ltd.* 2022 FC 998 – Manson J held that the burden should reflect that of the underlying action, such that the respondent patentee bore the civil burden of proof on infringement.

However, in *Mud Engineering Inc. v. Secure Energy (Drilling Services) Inc.* 2022 FC 943 ("Mud Engineering"), St. Louis J held that the party asserting an issue in the summary trial bears the burden – i.e., the moving Defendant must prove non-infringement. The Court stated that this issue had been settled by the *Federal Court of Appeal* in *ViiV Healthcare Company v Gilead Sciences Canada, Inc* 2021 FCA 122 at para 44 (affirming 2020 FC 486).

Summary Trials in NOC Proceedings

In *Janssen Inc. v. Pharmascience Inc.* 2022 FC 62, the Court held that it was appropriate to determine infringement by way of summary trial in this PM(NOC) proceeding. The Court found infringement, the Defendant's motion was dismissed, and the case proceeded to trial on validity issues only. The trial was held eight months after the summary trial, and the patent was found valid (2022 FC 1218).

Similarly, *Janssen Inc. v. Apotex Inc.* 2022 FC 107, involved a summary trial motion in a parallel PM(NOC) proceeding, which related to the same patent and raised the same issues. This summary trial was heard separately, and involved different evidence, but the Court came to the same conclusions. Unlike *Janssen Inc. v. Pharmascience Inc.* 2022 FC 62, validity was not at issue in this PM(NOC) proceeding, and the infringement finding in the summary trial was case dispositive.

Range of Outcomes

In *Kobold Corporation v. NCS Multistage Inc.* 2021 FC 1437 (decision publicly available in 2022), the Court granted partial summary judgment, finding that certain issues could be resolved on the motion – the interpretation of s. 56 of the *Patent Act*; construction of the asserted claims; summary judgment in favour of the Defendant in respect of one tool that was admitted to be covered by the prior use defence; and summary judgment in favour of the (respondent) Plaintiffs by striking third party prior use defences pursuant to ss. 56(6) and 56(9) of the *Patent Act*. However, the Court found that there was insufficient evidence to determine whether the Defendant's other three tools were covered by the s. 56(1) prior use defence and ordered that this issue proceed to trial. This case is a helpful reminder that summary judgment motions do not necessarily have binary outcomes, in which the motion is either entirely successful (thereby ending the case) or dismissed entirely (thereby punting all issues to trial and resulting in a waste of time and money).

Mud Engineering is a reminder that a party should not assume it will get a second chance if its summary motion fails. In the underlying action, the Defendant alleged non-infringement, invalidity, and that it owned the patents asserted against it. In this summary trial, the Plaintiffs sought a declaration of ownership and dismissal of the Defendant's counterclaim of ownership of the patents. In response to the motion, the Defendant also sought a declaration of ownership. On the facts, the Court found that neither party met their burden to obtain a declaration of ownership, and the Plaintiffs' motion was dismissed. Moreover, since both parties must put their best foot forward on a motion for summary trial, the Court refused to allow the parties a "second kick at the can" to establish ownership at trial and dismissed both

the Plaintiffs' underlying action and the Defendant's counterclaim.

Relief and Entitlement

Accounting of Profits

The only SCC decision in the area of patent law in 2022 was *Nova Chemicals Corp. v. Dow Chemical Co.* 2022 SCC 43.

In this case, the SCC dismissed the appeal from the FCA and found that the lower Court calculated Nova's accounting of profits ("AOP") correctly. Further the SCC held that Dow is entitled to springboard profits. The SCC articulated a 3-part test to be used in calculating an AOP:

1. Calculate the actual profits earned by the infringer from the selling of the infringing product;
2. Determine whether there is a non-infringing option ("NIO") to help isolate the profits causally connected to the invention from those that are not;
3. If there is a NIO, subtract the profits the infringer could have made had it used the NIO from its actual profits, to determine the amount to be disgorged.

Some of the important takeaways from this decision are:

- The aim of the AOP equitable remedy is to ensure the infringer does not retain a benefit from the infringing act and is not to punish the infringer or make them worse off.
- The differential profits approach is the preferred way of calculating an AOP analysis.
- Focus on causal connection to invention.
- Take the alleged infringer as you found them.
- Not a "but for world" analysis.
- There was no reason to interfere with the factual findings of the Court below regarding the NIO.
- Springboard profits are available under Canadian law and are directed to the benefit that arose and not the timing of when the benefit arose

Statute of Monopolies

A significant decision was rendered in 2022 relating to actions seeking to recover damages under the Statute of Monopolies.

In *Apotex Inc. v Eli Lilly Canada Inc.* 2022 ONCA 587, the Ontario Court of Appeal ("ONCA") held that the PM(NOC) Regulations is a complete code. At the core of the appeal from the order of Schabas J of the Superior Court of Justice - Ontario was whether the invalidity of a patent owned by Eli Lilly for olanzapine gave rise to a claim by Apotex for damages for being kept off the market during the proceeding under the PM(NOC) Regulations, pursuant to the *Statute of Monopolies*, the *Trademarks Act*, and the tort of conspiracy. The ONCA denied each ground of appeal.

The key findings are:

I. COMPLETE CODE

Section 8 of the PM(NOC) Regulations provides the sole remedy for a generic manufacturer to seek relief if it has challenged a patent within the PM(NOC) regime. On the facts of the case, Apotex did not meet the requirements for section 8 damages and no other relief was available.

II. NO LIABILITY FOR ACTIONS AUTHORIZED TO TAKE BY LAW

Apotex's delay in bringing its generic drug product to market was caused by the statutory stay mechanism provided under the PM(NOC) Regulations and the Order that Apotex was not entitled to early market access or compensation pursuant to section 8 of the PM(NOC) Regulations. Further a patentee is not liable for actions it was authorized to take by law or for alleged harms that were caused by the operation of the patent regime that the generic, in this case Apotex, invoked.

III. THE STATUTE OF MONOPOLIES EXCLUDES LIABILITY

The *Statute of Monopolies* specifically excludes liability for patents for new inventions. At the time the patent was granted to Eli Lilly, it was granted for a new invention. The *Statute of Monopolies* does not distinguish between valid and

subsequently invalidated patents. This is in line with the historical purpose of the legislation.

IV. FORM IV WAS NOT A MISREPRESENTATION

The information that Eli Lilly supplied at the time of listing its patent on the Patent Register, including the brand name of the drug and that it held a valid patent, was not a misrepresentation. It was not an error for the Court below to find that a granted patent is presumed valid as per section 43(2) of the *Patent Act*. Eli Lilly did not make a misrepresentation when it completed the Form IV and stated it held a valid patent to be listed on the Patent Register.

V. NO CONSPIRACY

There was nothing unlawful in Eli Lilly applying for and protecting a registered patent under the *Patent Act* and PM(NOC) Regulations, even though the patent was later held to be invalid. There was also no failure in the factual finding that there was no evidence to support a claim for conspiracy.

Leave application to Supreme Court of Canada filed (File No. 40420).

Section 8 Damages

In *Apotex Inc v Janssen Inc.* 2022 FC 1473, Southcott J held that multiple actions for section 8 damages should not have common issues heard together.

The issue before the Court was whether the Court should grant an order under the *Federal Courts Rules* Rule 105(a) directing that portions of the trials in three separate actions commenced under section 8 of the PM(NOC) Regulations be heard together. Rule 105(a) allows for consolidation of all or part of two or more proceedings. The purpose is to avoid multiplicity of proceedings, find efficiencies, and result in more expeditious and less expensive proceedings. Factors to be considered in assessing whether consolidation is appropriate include commonality of parties, issues, facts, and relief requested as well as potential prejudice. As to the factor of commonality the Court held:

I. PARTIES

Although there is a common Defendant across the section 8 actions, each action has different Plaintiffs.

II. ISSUES AND FACTS

As a matter of law, the Court will be required to assess different factual aspects of the But For World ("BFW"). The Court accepted this argument but also stated that Rule 105(a) does not require identical questions of fact or law.

III. REMEDIES

The differences as to the BFW were most compelling to Southcott J. These differences involve a combination of different time periods and different product dosages. The impact of hypothetical notices of compliance for each Plaintiff is also a factor to be considered in the BFWs. There may also be an impact on evidence of non-parties because of the different factual parameters of each action and the BFWs.

The Court was not satisfied that the level of commonality justifies ordering a common trial.

Southcott J then considered four main assertions of prejudice raised by the Defendant:

1. Evidence of several non-parties needs to be tendered in all three actions at different times;
2. Inconsistent burdens of proof in different actions addressing the same facts;
3. Expense of having the same witnesses testify on multiple occasions; and
4. The risk of inconsistent findings.

The Court held that prejudice did not weigh in favour of granting the Defendants' motion.

Liability of Parent Corporation

In Angelcare 2022 FC 507, the Court found the parent entity liable in addition to finding the Canadian subsidiary liable for the infringing activities. Roy J found that the parent entity made design and marketing decisions. Those decisions directly impacted the resulting infringing activity that gave rise to liability. As such

the parent and subsidiary were held liable. Decision under appeal (File Nos. A-106-22 and A-105-22 consolidated under File No. A-105-22).

Entitlement

In *Rovi Guides Inc. v. Videotron Ltd* 2022 FC 874, the Court dismissed Rovi Guides Inc.'s infringement action against Videotron Ltd. with respect to four patents pertaining to interactive television program guide technology. Videotron's counterclaim was granted. In *obiter* the Court held that Rovi would not have been entitled to an AOP if its patents were found to be valid and infringed.

Lafrenière J stated that an AOP is not obtained as of right, but that the Court should not refuse it without good reason. The Court further stated that a patentee bears the burden to establish its entitlement to an AOP.

The Court considered the patentee's conduct and the speculative nature and complexity of the AOP as factors weighing in favour of denying the remedy.

The Court found that the appropriate remedy would have been a reasonable royalty. The Court adopted Videotron's proposed royalty which was based on the amount it would have cost Videotron to remove or design-around an infringing feature (i.e., an NIO) in its system if Rovi's patents were found to be valid and infringed. Decision under appeal (A-186-22).

In a related decision, Lafrenière J made similar statements in *obiter* on entitlement in *Rovi Guides, Inc. v. Bell Canada and Telus Corporation* 2022 FC 1388. Despite Rovi operating within the provisions of the *Patent Act*, the Court took the perspective that Rovi had unclean hands by "failing to diligently prosecute its patents".

The Court appeared to be concerned with the patentee's ability to amend claims over the period of prosecution to encompass products and or services of others. The Court further raised concerns about licensing negotiations and whether those were carried out in good faith, which contributed to the refusal to grant equitable relief. It is unusual for the Court to consider licensing and settlement negotiations in the entitlement analysis.

The Court was further worried about a perceived "patent holdup" problem and expressed concern that granting equitable relief in this case could incentivize licensing entities to follow similar conduct. Decision under appeal (A-233-22 and A-231-22).

Key Procedural Motions

Confidentiality/ Protective Orders

Confidentiality orders and agreements, implied undertakings and protective orders are procedural issues that continued to appear before the Court in 2022.

In *FibroGen, Inc v Akebia Therapeutics, Inc.* 2022 FCA 135, the FCA set aside an order requiring a party to make certain fact witness statements from a discontinued action public. Two key concepts were at play:

1. Confidentiality agreements; and
2. The implied undertaking rule.

The FCA held that Akebia was bound by the implied undertaking rule, and the rule survived the discontinuance of the action. An applicant seeking to be relieved from the implied undertaking must demonstrate, on a balance of probabilities, a public interest of greater weight than the values that the implied undertaking protects privacy, candor, and the efficient conduct of the litigation.

The confidentiality designations made during the action remained valid at the time the action ended. Akebia failed to preserve its rights to contest the designations having consented to the discontinuance of the action. In the alternative, Akebia should have made a reservation to this effect prior to the discontinuance.

The FCA provided practical advice in stating that in many cases a party seeking to be relieved from the implied undertaking rule does not need to file the documents in question with the Court. A generic description of the situation that does not disclose confidential information is usually sufficient to allow a Court to determine if the party should be relieved of its obligations under the implied undertaking rule.

In *Janssen Inc. v. Apotex Inc.* 2022 FC 1746, the Plaintiffs brought a motion to vary the Protective and Confidentiality Order issued previously by the Court on consent of the parties. Janssen's proposed amendments would have allowed materials that were marked "Confidential" pursuant to the Order to be used in four subsequent actions involving the same parties.

An issue before the Court was whether this motion was procedurally defective because Janssen failed to seek relief from its implied undertaking. Manson J found that it would be inappropriate to vary the Confidentiality Order until Janssen sought relief from its implied undertaking, nevertheless the parties agreed to a more limited variance of the Confidentiality Order at the hearing of the motion.

Samples Motion

In *Gilead Sciences, Inc. v. Apotex Inc.* 2022 FC 1460, the Plaintiffs in a PM(NOC) action brought a motion for production of samples. A request for samples may be brought before the Court on a motion under Rule 249. Samples may be ordered where it is "necessary or expedient for the purpose of obtaining information or evidence in full."

A motion for production of samples turns on its own facts. In order to obtain such an order, the moving party is not required to lead evidence that that the proposed tests are the only means to establish their case, or at least that the facts present an exceptional case where such testing is a solution of last resort. Important statements from the Court on evidence for a Rule 249 motion included:

- While the moving party bears the burden of demonstrating that samples should be produced, expert evidence is not required.
- The moving party is not required to particularize the testing it intends to conduct beyond what its apparent on the face of the pleadings and the patent.
- The moving party is not required to produce information from a related foreign proceeding.

The Court ordered the production of samples of the drug product, the active pharmaceutical ingredient, and associated Material Safety Data Sheets; but not samples of excipients.

Motion to Strike/Amend

Bayer Inc. v. Sandoz Canada Inc. is an infringement action under the PM(NOC) Regulations 2022 FC 1187. On a motion the case management judge was asked to grant leave for the Defendant to amend its statement of defense 13 months before trial. While the Plaintiff consented to certain amendments, it conceded that the new allegations relating to the improper priority claim, anticipation, and the clarifications to the Gillette defence could, despite the lateness of the amendments, be briefed and ready to proceed to trial on the currently scheduled dates. The Defendant did not dispute that amendments which necessitated the adjournment of a trial in an action under the Regulations are inherently prejudicial to the first person, unless there is a concomitant extension of the 24-month period. However, the Defendant argued that there was sufficient time before the scheduled trial to take all the steps required.

The Court found that the contested amendments are lengthy and raise complex arguments. Thirteen months before trial is not sufficient time to be prepared to plead, conduct discovery, and prepare for trial on those issues. The Court granted the motion on the conditions that if the Defendant made some of the proposed amendments the trial dates would be adjourned, and the 24-months stay would be extended.

Bifurcation Motions

While in some, if not many cases, parties may agree to bifurcate patent actions, bifurcation motions continue to appear before Associate Judges at the Federal Court. In 2022 some of the bifurcation motions sought interesting formats to the proposed bifurcation orders:

On this motion in *Farmobile, LLC v. Farmers Edge Inc.* 2022 FC 22 the Defendant proposed an atypical bifurcation, not simply a divide of liability and damages. Given that there had been an update to the allegedly infringing system, the infringement issues were proposed to be divided between the first and second phases (phase 1 would also include validity and inventorship/ownership issues). Although an

interesting example, the Court determined that the proposed bifurcation in this case would result in duplication of resources and found no reason to bifurcate. Appeal dismissed (2022 FCA 116).

In *Wi-Lan Inc. v. Apple Canada Inc.* 2022 FC 276 the Defendants brought a motion to bifurcate in which part of the relief sought was to defer the issue of the Plaintiff's right to an injunction to the second phase. Interestingly the Plaintiff provided a concession that if the matter is not bifurcated, it will forego its claim for an AOP and limit its claim to damages. The Court found that the Defendants' proposed bifurcation only results in savings if it is entirely successful at the liability phase. The Court did not find that the Defendants met their onus, and the motion was dismissed.

Appealing Interlocutory Orders to the FCA

Section 6.11 of the PM(NOC) Regulations requires that leave be sought for an interlocutory appeal and that such leave is sought no later than 10 days from the date of the Order. In *Janssen Inc. v. Apotex Inc.* 2022 FCA 185, the parties neglected to follow section 6.11 of the PM(NOC) Regulations.

In this decision the FCA states that no fewer than three judges sitting together are required to hear a leave application before the FCA. In contrast, a Direction from the FCA may be made by a single judge. A Direction is not leave.

Locke JA held the Court denies leave and refuses the appeal for failure for a formal and timely request for leave. The Court further dismissed the appeal on the merits.

Costs

The issue of costs in *Janssen Inc. v. Teva Canada Ltd*. 2022 FC 269 arose in the context of an infringement action under the PM(NOC) Regulations. Prior to the judgement being rendered, the parties agreed to a costs framework of 35% of legal fees and 100% of disbursements subject to reasonableness of the fees and disbursements. In the judgement the Court determined that the asserted claims were valid; certain claims would be directly infringed, while others would not, if the product came to market; and that the Defendant did not induce infringement. Costs were awarded to the Plaintiffs however the parties were unable to agree on a quantum. The Court awarded the Plaintiff costs in the amount of $2,697,671.79 with post-judgment interest at a rate of 2%. This included 80% of disbursements and 35% of legal fees.

Jamp brought a motion in writing under Rule 369 seeking costs arising out of two applications for judicial review (*AbbVie Corporation v. Canada (Health)* 2022 FC 1538). As part of its request for costs, Jamp sought a lump sum cost award. The Court considered this request and stated that a lump sum award is specifically contemplated in Rule 400(4), and may serve to promote the objective of the Rules of securing "the just, most expeditious and least expensive determination" of proceedings. The Court further stated that a lump sum award may be particularly appropriate in complex matters where a precise calculation of costs would be unnecessarily complicated and burdensome. The burden is on the party seeking increased costs to demonstrate why its particular circumstances warrant an increased award. In this case the Court was not persuaded that a lump sum award of costs was warranted. While the applications raised complex questions of statutory interpretation in relation to the PM(NOC) Regulations, the procedural steps preceding the short hearing were largely consistent with what one would expect in applications for judicial review. The high end of Column IV was the appropriate benchmark in this case.

Janssen Inc. v. Pharmascience Inc. 2022 FC 1218 is a noteworthy cost award in regard to recovery of expert fees. The Court reduced fees of two experts by 25% because the Court held the experts provided inconsistent evidence having regard to their previous testimony in related proceedings. The Court also held that at times their testimony was not forthcoming when it should have been. Further there were no fees awarded for an expert who was not called at the last minute. Moreover, the Court awarded costs thrown away to the other party as a result of the last-minute cancellation of the witness. Decision under appeal. (A-205-22)

Pharmascience Inc. v. Teva Canada Innovation 2022 FCA 207 is of interest because the FCA reinforced the importance of settlement offers—even when the offer is not a formal Rule 420 offer. Costs awards are determined by the facts of the case, and the Court must be sensitive to the

circumstances before it. A settlement proposal or offer is a circumstance to consider when determining cost awards.

Statutes, Regulations & Rules

Several legislative changes relating to patent law or patent adjacent areas were introduced or came into effect in 2022.

Statutes

The Budget Implementation Bill (C-19): provides changes of interest to the patent bar including changes to the *College of Patent Agents and Trademark Agents Act* (Division 17); and replaces the term "Prothonotary" with "Associate Judge" for the Federal Court (Division 22).

Regulations

Regulatory amendments to the Patented Medicines Price Review Board ("PMPRB") were made on June 24, 2022. Rights holders are required to begin reporting price information to the PMPRB based on the new basket of countries as of July 1, 2022.

Although the government repealed certain aspects of the proposed amendments in June 2022, the balance of the Amendments came into force on July 1, 2022.

New Guidelines will be needed to address the new regulations. However, on December 16, 2022, the PMPRB announced that the New Guidelines will not be implemented on January 1, 2023. The interim Guidance issued on August 18, 2022, will remain in place until further notice.

The challenge to the proposed 2020 PMPRB Guidelines that was pending in the Federal Court was discontinued following the government's announcement that it would not proceed with the 2020 proposed PMPRB Guidelines.

Rules

In 2022, we saw amendments to the *Patent Rules* under the *Patent Act* and amendments to the *Federal Courts Rules*.

The amendments to the *Patent Rules* have the goal of streamline the examination process in anticipation of the CIPO's obligation to introduce Patent Term Adjustment ("PTA") provisions into Canadian patent law under the Canada-United States-Mexico Agreement ("CUSMA"). The amendments include a change to current practice before CIPO including:

- Introduction of excess claims. Fees of $100 per claim for any claim over and above 20. Multiple dependencies and claims in the alternative will still be counted as a single claim for the purpose of calculating claims fees.
- Introduction of a Request for Continued Examination ("RCE") procedure after three office actions.
- Introduction of Conditional Notice of Allowance ("CNOA") where the examiner considers the application to be allowable subject to minor defects and providing four months to correct the defect.
- Amendments to correct obvious errors in translation.
- Reference to Patent Cooperation Treaty sequence listing standards.
- Extension of time for having paid the incorrect fee due to incorrect information given by the Commissioner.

Amendments to the *Federal Courts Rules* came into force on January 13, 2022. The amendments relate to miscellaneous changes including expansion of Rule 3 to focus on 'outcome' and proportionality rather than 'determination', explicit powers to limit examinations (Rule 87.1), and a rule specifically for motions in writing at the Federal Court of Appeal (Rule 369.2), among other things. The amendments also pertain to enforcement of foreign judgments and arbitral awards and limited-scope representation.

Practice Directions

There were two important Practice Directions from the Federal Court in 2022 that impact patent litigation.

In June 2022, the Consolidated General Practice Guidelines were introduced. This Practice Direction consolidates and replaces several previous Practice Directions. Key aspects of this Direction include:

- Parties should be prepared to inform the Court as to whether they have agreed on the disposition and/or quantum of costs, otherwise they should be prepared to make submissions on those issues at the end of the hearing.
- Articling students may appear in the Federal Court where they are permitted to do so in the province or territory in which the hearing takes place.
- Parties are encouraged to file books of authorities containing copies of the authorities to which the parties intend to refer at the hearing in addition to the requirements applicable to electronic documents.

In September 2022, the Pilot Project for Online Access to Court Records was introduced. To allow for greater public access, and to enhance the open Court principles, the Court is introducing an online platform to access electronic Court records. In the pilot project, pleadings, written arguments and court-generated documents for matters commenced on or after September 12, 2022 in Maritime and Admiralty, Class Actions, Indigenous Law, and Intellectual Property matters that are not subject to confidentiality or sealing orders will be made available online.

Quick Hitters

In this section, we provide some of the key take-aways from patent adjacent decisions rendered in 2022. Because of the significance of some of these decisions the comments are not always "quick". This section also provides key take-aways on issues of interest that arose in the context of patent motions, applications, and actions.

A. Patent Adjacent Decisions

I. FEDERAL JURISDICTION OVER PATENTS

The Quebec Court of Appeal ("QCA") determined that several proposed amendments to the PMPRB Regulations were *ultra vires.* The QCA considered the purpose of the PMBRB Regulations, the purpose of the proposed amendments, as well as the purpose of the powers conferred on the PMPRB in the *Patent Act*.

The QCA held that federal jurisdiction over patents could not extend beyond the ex-factory price; and extends only to protect against excessive pricing that arises because of a patent monopoly.

As a result:

- The proposed amendments that compelled drug manufacturers to disclose discounts or rebates to third parties were held to be *ultra vires*, as this information extended beyond ex-factory pricing.
- The proposed amendments to the list of comparator countries used to determine whether prices are excessive was held *intra vires*. The objectives in selecting comparator countries are to promote research and development within Canada while controlling excessive pricing resulting from the patent monopoly. Both considerations are objectives within the federal jurisdiction over patents.
- The new factors introduced to assess whether a medicine was excessively priced were held *ultra vires*, as they imposed arbitrary price reductions unrelated to patent monopoly. *Merck Canada inc. c. Procureur général du Canada* 2022 QCCA 240.

II. AMENDMENTS TO THE PATENTED MEDICINES REGULATIONS

In the spring of 2022, Innovative Medicines Canada and several pharmaceutical companies sought a declaration that the same provisions of the proposed amendments challenged in QCA decision (discussed above) were invalid as *ultra vires* the *Patent Act*.

The key issue that remained before the FCA was to amendments to the PMPRB Regulations that change the list of comparator countries for which pricing information must be filed.

The Court held that Vavilov applies to all administrative decisions, regardless of differences in their content and applies to decisions to make regulations. The standard of review under Vavilov is reasonableness.

The FCA agreed with the Federal Court that the Governor in Council reasonably enacted the regulation changing the list of comparator countries, and that the decision to enact the amendment changing the list of comparator countries is based on a reasonable interpretation of the regulation-making power in subsection 101(1) of the *Patent Act*, a power that, on an analysis of text, context and purpose, can be viewed as relatively unconstrained.

The FCA further found it was reasonable to conclude that it is consistent with section 85 of the *Patent Act* and its purposes, as shaped by subsection 91(22) of the *Constitution Act, 1867*. Reasonableness is enhanced by the consistency with judicial decisions on those matters. *Innovative Medicines Canada v. Canada (Attorney General),* 2022 FCA 210.

III. CONTROL PATENT ABUSE

The PMPRB's mandate is to control patent abuse, not regulate reasonable pricing. In 2022 the SCC dismissed the leave application in *Alexion Pharmaceuticals Inc v Canada (Attorney General).* The Board was intended to rehear the case in Fall 2022, however the parties reached a

settlement in June 2022. As such this matter has come to an end.

IV. DRUG IDENTIFICATION NUMBERS

Fothergill J dismissed an application for judicial review and found it was reasonable for the Minister of Health to interpret section 5(1) of the *PM(NOC) Regulations* as applying only to the drug identification number ("DIN") specific to the version of the innovator's drug that is marketed in Canada. *AbbVie Corporation v. Canada (Health)* 2022 FC 1209. Decision under appeal (A-203-22).

V. NEW DRUG SUBMISSIONS

In a judicial review application relating to a decision of the Minister of Health regarding issuance of a notice of compliance, the Court held that a New Drug Submission ("NDS") may be deemed to have been made on the basis of a comparison at any time up to its approval, regardless of whether an innovative drug was on the Register at time the NDS was filed. Further the Court held the threshold for "reliance" on data relating to the innovative drug, and hence what amounts to a "comparison", is ostensibly low. *Catalyst Pharmaceuticals, Inc. v. Canada (Attorney General)* 2022 FC 292. Decision under appeal (A-78-22).

VI. EVIDENCE ON JUDICIAL REVIEW

The Court held the motion to strike three affidavits filed in a judicial review proceeding relating to a PMPRB decision was allowed in part, striking the affidavit of the Applicant's patent expert in full and the other regulatory expert affidavit in part. The Court allowed the affidavit of the Applicant's fact witness, which provides non-controversial background information. *Galderma Canada Inc. v. Canada (Attorney General)* 2022 FC 19.

B. Noteworthy Patent Decisions

I. INVENTOR EVIDENCE NOT HEARSAY

The Court held that an inventor's supervisory role enabled the inventor to provide evidence at trial as to the work of his co-inventors and the team working on the invention. The Court further held that because the Defendant had already accepted the documents for the truth of their contents and had accepted this inventor's evidence on discovery as binding, the hearsay objection could not stand. *Merck Sharp & Dohme Corp. v. Pharmascience Inc.* 2022 FC 417.

II. EXPERT BLINDING

Expert Blinding is not necessarily given greater weight. Kane J stated:

> *"I note that the jurisprudence is mixed on the treatment of blinded evidence. I favour the approach noted in Janssen Inc v Apotex Inc, 2019 FC 1355 at paras 58-59 . . . that blinded opinions are not necessarily given greater weight just because they are blinded."*

Allergan Inc. v. Apotex Inc. 2022 FC 260.

III. EXPERT STRATEGY

Practical statements on strategy regarding expert evidence was provided by Locke JA when stated:

> *"A final reason that I would be hesitant to interfere with the Trial Judge's conclusion on utility is that Pharmascience adduced no evidence from its own experts on this issue, an issue on which it had the burden of proof. Pharmascience relies principally on the evidence of Teva's experts and their testimony during cross-examination. However, the reports submitted by these experts discussed the issue of obviousness, not utility. Teva's experts were not instructed on the law concerning utility and were never asked directly for their opinions on the issue."*

Pharmascience Inc. v. Teva Canada Innovation 2022 FCA 2.

IV. CONTEMPT HEARING

In a rarely seen contempt hearing, the Plaintiffs alleged that the Defendants were in contempt of the Court's infringement judgement. The Court determined that the Plaintiffs had not established beyond a reasonable doubt that the Defendants were in contempt of the Court's judgement and the contempt proceeding was dismissed. *Deeproot Green Infrastructure, LLC v. Greenblue Urban North America Inc.* 2022 FC 709. Decision under appeal (A-116-22).

V. REPLY REPORTS

The Defendants brought a motion to exclude the reply expert report of the Plaintiffs. The expert provided a report that supports the Plaintiffs' infringement allegations and defends against allegations of invalidity. The contentious reply report addresses infringement and constructions issues—and is over 240 paragraphs in length with several annexes. Despite the Plaintiffs withdrawal of about two thirds of the contentious reply report, the Court found that the Plaintiffs had not satisfied its burden that this reply report was permissible, and any new evidence constituted case splitting. The Court determined that the report was long and unduly argumentative, inadmissible. *T-Rex Property AB v. Pattison Outdoor Advertising Limited Partnership* 2022 FC 1008.

In another matter, the Defendants brought a motion seeking leave to file a reply report in a patent infringement action with a trial commencing on January 9, 2023. Pallotta J conducted a tight analysis of the reply report permitting specific paragraphs and sentences to be filed. The permitted sections of the reply report responded to a reference that was not previously at issue: it was not pleaded, asserted as prior art, cited in the patent at issue, or mentioned in any previous expert report. *Medexus Pharmaceuticals Inc. v. Accord Healthcare Inc.* 2022 FC 1734.

VI. REPRESENTATION BY NON-LAWYER

In a motion under Rule 120, a Plaintiff sought leave to be represented by a non-lawyer. Of the four factors for the Court to consider on such a motion, the Court stated that three factors did not favour the Plaintiff: the non-lawyer acting as a witness, the complexity of the action and the non-lawyer's ability to deal with the complexity, and the ability of the matter to proceed expeditiously. While the Court determined that it would be difficult for the Plaintiff to pay for counsel on this action, this was not an overriding consideration. The Court was not persuaded that the Plaintiff demonstrated the special circumstances required by Rule 120 to be granted leave. *Glycobiosciences Inc. v. L'Oreal Canada,* 2022 FC 1517.

VII. MOTION REQUESTING DETERMINATION OF LAW

In a Rule 220 motion the Plaintiff brought a question of law to the Court to be determined prior to trial in a section 8 action. The question was:

> *Under the PM(NOC) Regulations, when a patentee has exercised its right to a section 7 statutory stay against generic entry, and never resolved or renounced that right in relation to certain generics in the real world, does that same obstacle to entry by those generics prevail in the section 8 but-for world (other than the section 8 claimant)?*

The Court must first determine whether it is appropriate for the proposed question to be addressed before trial, then the Court will determine the legal question. This motion only dealt with the first stage. The Court arrived at a conclusion on the discretionary analysis, taking into account the factors considered, that the factors do not favour granting the first stage of the Rule 220 motion.

While the Court found certain factors to be neutral, it determined that three factors militated against making this determination on the motion and not in the context of the full trial. These factors were:

1. The possibility that the determination of the question before trial might save neither time nor expense;

2. The difficulty and importance of the proposed question; and
3. The desirability of answering the question in a vacuum.

On this basis, the Court dismissed the motion. The issue remains available to the Plaintiff to advance at trial. *Dr. Reddy's Laboratories Ltd. v. Janssen Inc.* 2022 FC 1672.

VIII. NORWICH ORDER

A Norwich Order under is an extraordinary request for equitable relief. On this motion the Plaintiff sought to compel the president of the Defendant to provide information regarding the Defendant's clients.

The Court dismissed the Plaintiff's motion finding that it was not persuaded that it was just and equitable to grant a Norwich Order. Significantly the Court was not able to find that the president of the Defendant was the only practical source of the information sought. The Defendant held the necessary information in its corporate records, and the Plaintiff had asked for this information on discovery. The Plaintiff had also sought the identification of the Defendant's clients at a refusals motion. The request was not granted, but the Plaintiff did not appeal the decision.

The Court stated that a Norwich Order is not intended to circumvent the normal discovery process. The Court concluded that a Norwich Order was not appropriate. *Worthware Systems International Inc. v. Raysoft Inc.* 2022 FC 1492.

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The Year in Data: 2022 Cases at a Glance

Insights from the Lenczner Slaght Patent Appeals Project

Introduction

Patent disputes are high-stakes, complex matters. While trials and summary judgments are a milestone, they are seldom the end of the road. Whether it's a patent infringement action, a patent impeachment action, or a proceeding under the PM(NOC) Regulations, an appeal is always likely. Understanding how those appeals unfold is important to the IP bar and to parties.

That's why we maintain a database of every substantive decision of the FCA in patent disputes from 2000 onward. For present purposes, a substantive appeal includes any appeal from a trial, application, or summary judgment motion that decides whether a patent is valid or infringed, or that adjudicates an issue of remedy. This includes both prohibition proceedings under section 6 of the PMNOC Regulations as well as damages claims under section 8. This data does not include appeals of decisions on interlocutory motions or costs decisions.

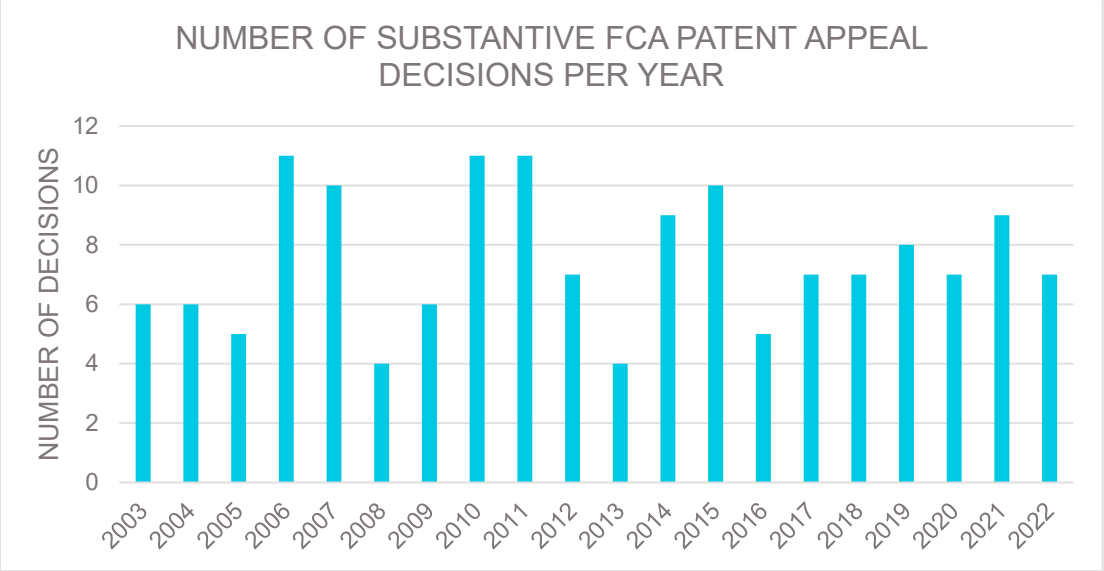
Our database includes approximately 30 characteristics of every appeal decision. This dataset allows us to provide benchmarks for the likelihood of success on different types of appeals and the timelines for resolution of appeals, among other things.

The database is intended to include every substantive appeal decision from the FCA in an appeal of a final decision pertaining to a patent-related dispute from January 1, 2000 onward.

Below we present various insights from this project.

Number of Appeals

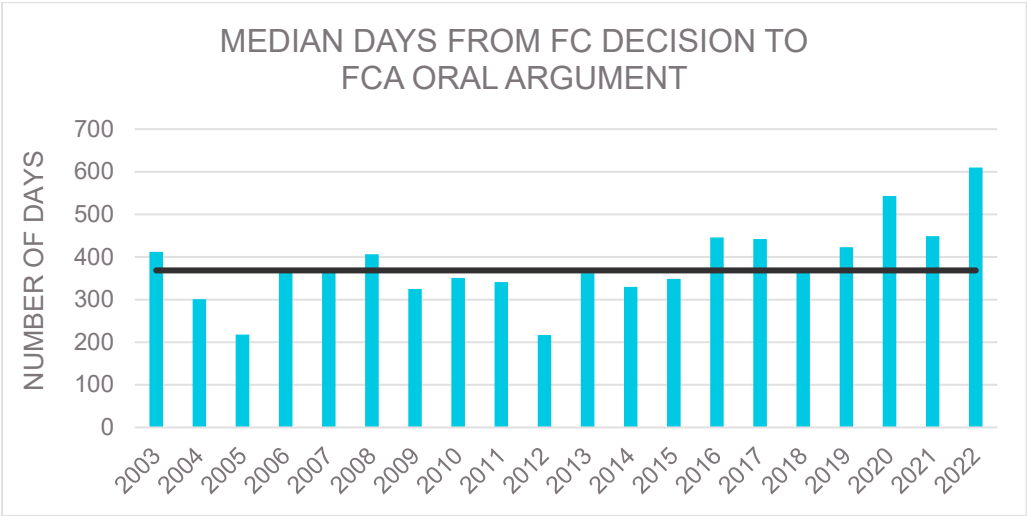
The number of substantive appeal decisions per year ranges from four to eleven, and there does not appear to be a trend in the number over the last twenty years. 2022 was consistent with the usual range, with the FCA rendering seven decisions.



Time from Federal Court Decision to Appeal Oral Argument

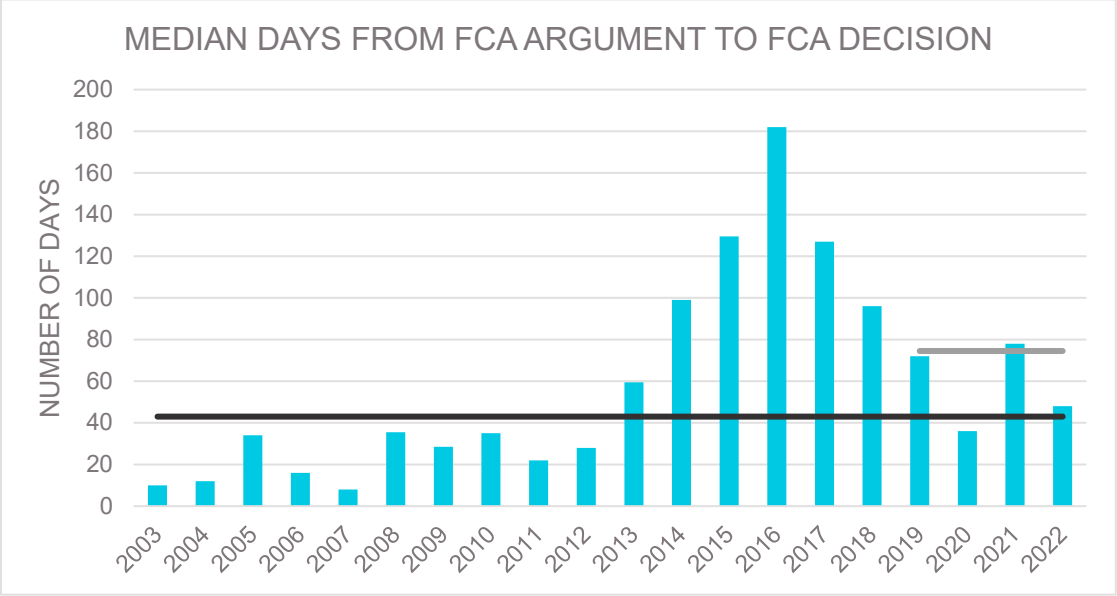
In general, the time from Federal Court decision to appeal oral argument has been fairly constant over the last twenty years. The black line at 368.5 days represents the median number of days from Federal Court decision to appeal oral argument across the entire twenty-year period from 2003 through 2022.

The time from Federal Court decision to appeal oral argument was higher than typical in 2022, rising to an average of 610 days. This is likely due to lingering effects from the COVID-19 pandemic, rather than evidence of an upward trend.

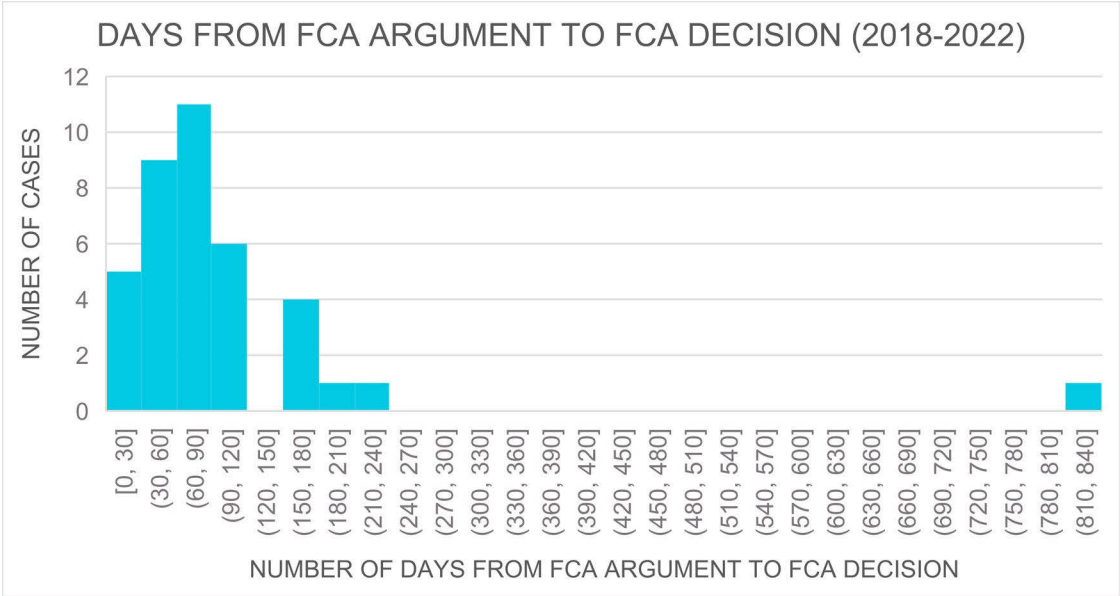


Time from Appeal Oral Argument to Decision

The time from appeal oral argument to decision was quite low for the first decade in our dataset. However, it increased year-over-year from 2013 through 2016, peaking in 2016. Since then, it has been trending downward again. The black line at 43 days represents the median days from argument to decision across the entire twenty-year period from 2003-2022. The grey line at 74.5 days represents the median days from argument to decision in the last five years only (2018-2022). The median time in 2022 of 48 days from FCA oral argument to decision represents a regression to the long-term median (black line).



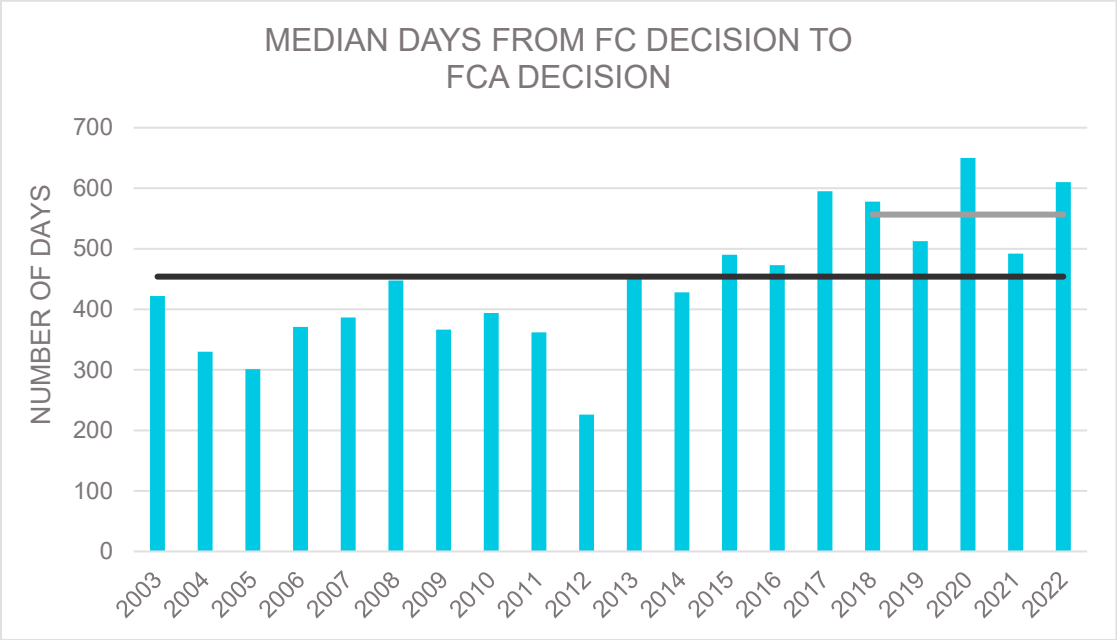
The vast majority of appeals in the last five years were decided in four months or less, and all but one appeal was decided in less than one year. One appeal took more than two years to be decided (*Nova Chemicals Corporation v Dow Chemicals Company* 2020 FCA 141), but this was due to the decision being held in abeyance to allow for settlement discussions, which were unsuccessful.



Time from Federal Court Decision to FCA Decision

The time from Federal Court decision to FCA decision has been trending slightly upwards in the last decade. That there would be a steady but only slight upward trend might initially seem surprising, in light of the fluctuation in days from FCA argument to FCA decision. However, the fluctuation in days from FCA argument to FCA decision is muted by the higher and more constant number of days from Federal Court decision to FCA argument.

The black line at 454 days represents the median number of days from Federal Court decision to FCA decision across the last twenty years (2003-2022). The grey line at 556.5 days represents the median number of days from Federal Court decision to FCA decision in the last five years (2018-2022).



Appeal Outcome Data

Below we present data relating to the success rates on appeal of particular issues (validity and infringement) by particular parties (patentee vs infringer).

It is important to clarify at the outset what the data below shows so that it can be interpreted accordingly. In the following sections, a "patent appeal" relates to an appeal of an issue relating to one particular patent by one particular party. In this terminology, there can be several "patent appeals" that are decided in a single decision of the Federal Court of Appeal, each with different possible outcomes. In most cases, there are only one or a handful of patents at issue in a particular decision, so the success rates pertaining to patent appeals are not particularly different from how we would conventionally think about success in appeals. However, there are outliers. For example, in *Eli Lilly and Company v. Apotex Inc.,* 2010 FCA 240, there were appeals by each side relating to the extent of infringement in respect of eight separate patents, all of which were dismissed. In our methodology, this counts as 16 separate patent appeals. Consequently, data pertaining to infringement appeals that includes 2010 should be assessed with this in mind.

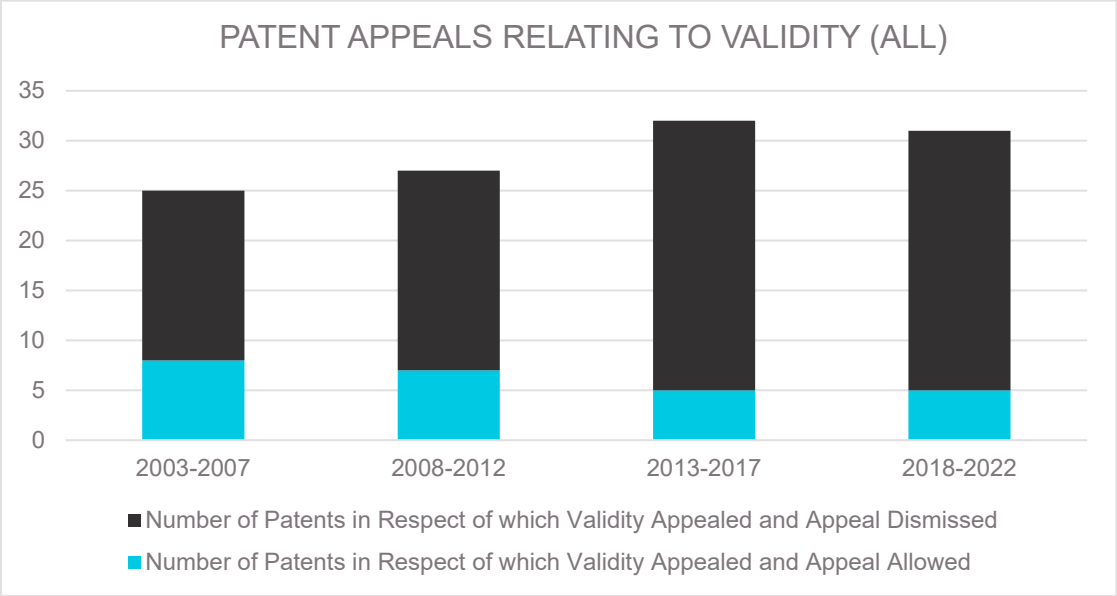
When we say that a patent appeal relating to either validity or infringement is successful, that means that the Federal Court of Appeal decided the appellant's appeal on that particular issue in favour of appellant. It does not necessarily mean that the appellant was successful overall on the appeal. For example, in our database coding, if a patentee appealed findings of invalidity and non-infringement and was successful in overturning the finding of non-infringement but unsuccessful in overturning the finding of invalidity, they would be coded has having been successful in their appeal relating to infringement and unsuccessful in their appeal relating to validity.

Below we present data on appeals being allowed or dismissed on both validity and infringement. The data below does not include circumstances where a party appealed on an issue, but the Court decided not to address it. For example, where the Federal Court of Appeal held that it was unnecessary to consider an appeal of non-infringement because it dismissed an appeal finding that a patent was invalid, the infringement appeal is not included in the data below (but the validity appeal is). We collected data on this, but it is less informative because it is unclear what the Court's decision not to render a decision on that issue means, so we exclude that from the data.

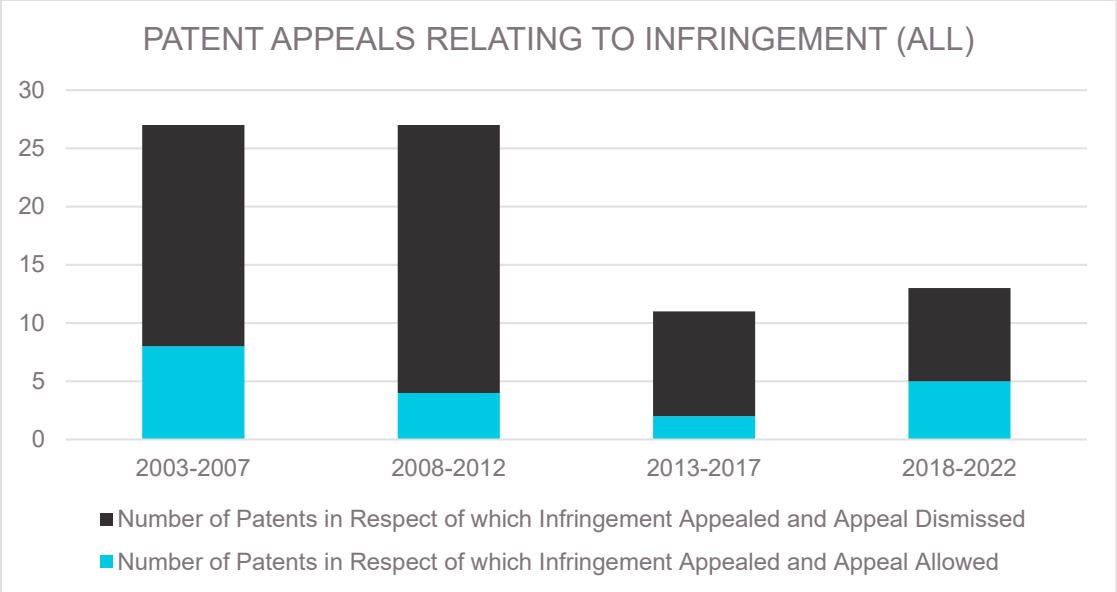
Given the relatively small number of patent appeals pertaining to either validity or infringement in any given year, we group decisions into five-year blocks below. This generates larger sample sizes so that we can more easily see whether there are any long-term trends.

Finally, as a note about terminology, we use the term "patentee" to mean any entity seeking to enforce rights under a patent, and "infringer" to mean any entity alleged to have infringed rights under a patent. Given the prevalence of claims and counterclaims, this language is more precise than "Plaintiff" or "Defendant".

Patent Appeals Relating to Validity



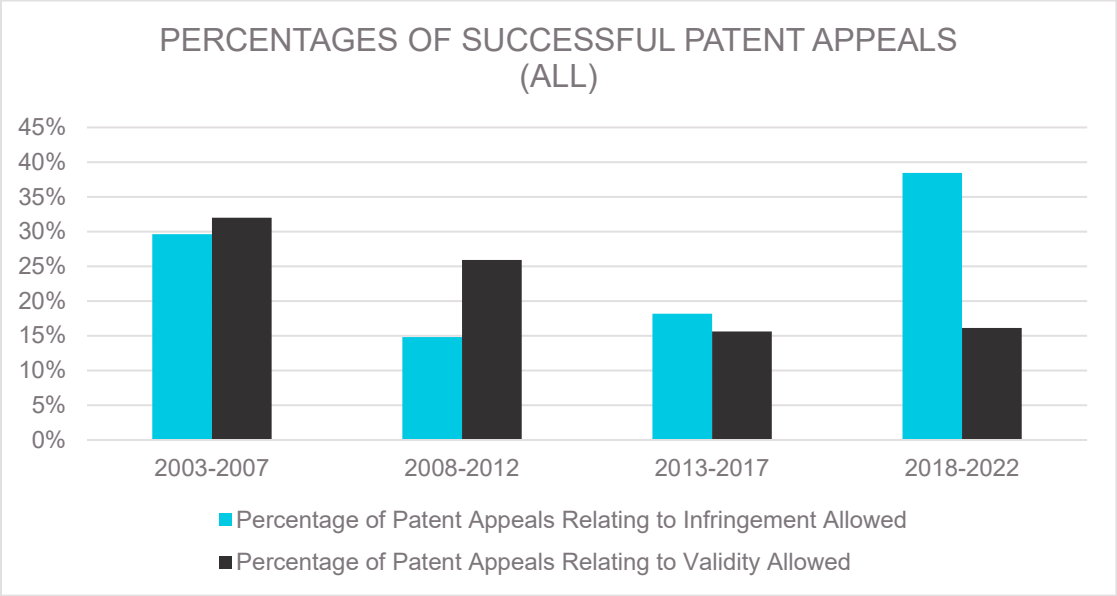
Patent Appeals Relating to Infringement



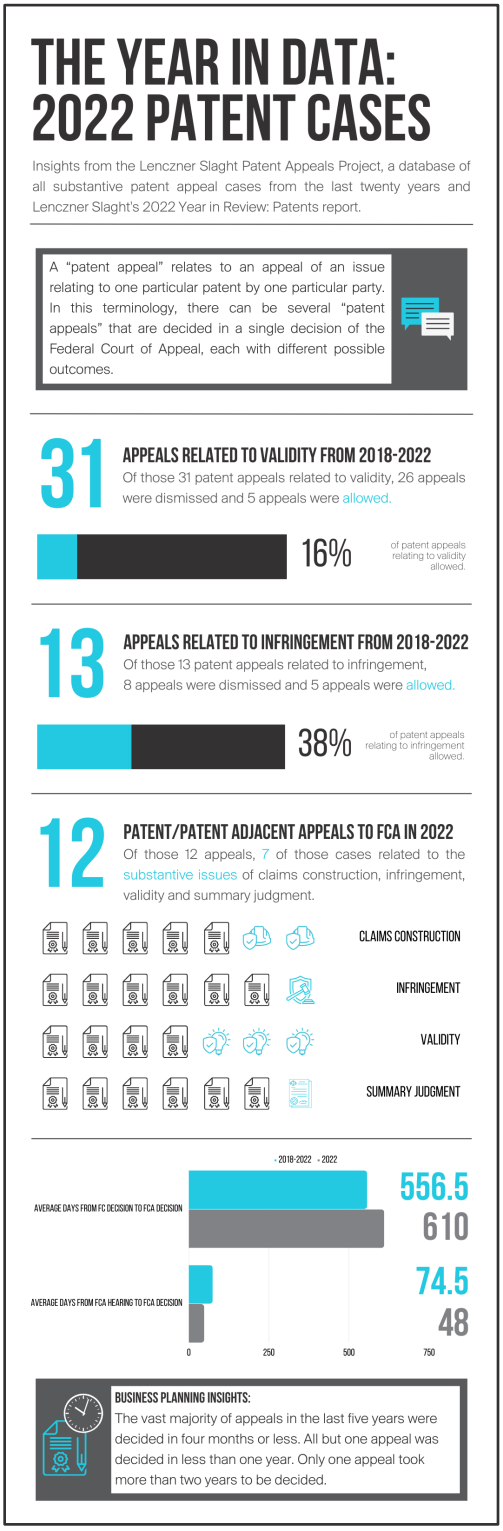
Success Percentages on Patent Appeals

This section presents data on success rates on different types of patent appeals, broken down in various ways.

We first look at the percentage of successful patent appeals over time. For validity appeals, that success rate has trended down, while for infringement appeals that success rate has trended up. Over the last five years, approximately 38% of patent appeals on infringement have been allowed, while just 16% of patent appeals on validity have been allowed.



The Year in Data: 2022 Patent Cases Infographic



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