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2021 Year in Review & 2022 Trends to Watch: Pharmaceutical Patents

In 2021, the Canadian pharmaceutical and life sciences industries were once again at the forefront of innovation, developing and commercializing new vaccines, drugs, and medical devices. The media continued to shine a light on the advances made to protect the public from COVID-19, including regulatory approvals for new mRNA and adenovirus vector vaccines. In the pharmaceutical patent litigation arena in particular, we saw some new trends develop. There were important developments in proceedings relating to pharmaceutical patents, advances in cases and legislative developments relating to the Patented Medicine Prices Review Board ("**PMPRB"**) as well as judicial review applications and appeals in patent-related fields.

In this blog, we recap the top developments in the pharmaceutical patent space in Canada from 2021 and identify trends to watch for in 2022.

1. PMPRB

One of the biggest trends in 2021 was the focus on drug prices in Canada and the PMPRB. Not only were there important developments before the courts relating to excessive pricing and challenges to amendments to the *PMPRB Regulations* and *PMPRB Guidelines*, but there were also updates to legislative changes.

***Alexion Pharmaceuticals Inc v Canada (Attorney General)*, 2021 FCA 157**

In July 2021, the Federal Court of Appeal ("**FCA**") held that the PMPRB's decision regarding the alleged excessive pricing of the drug SOLARIS was unreasonable. The FCA reversed the finding of the Federal Court and granted Alexion's application for judicial review. The FCA held that the PMPRB's mandate is to control patent abuse, not regulate reasonable pricing. The FCA remitted the matter back to the PMPRB for redetermination. Alexion was awarded its costs on the appeal and below. On September 29, 2021, the Attorney General of Canada sought leave to appeal to the Supreme Court of Canada. Whether the SCC will grant leave is something to

watch for in 2022.

Merck et al c Le Procurer General du Canada, 2020 QCCS 4541

In December 2020, the Quebec Superior Court held that two recent amendments to the *PMPRB Regulations* are unconstitutional and of no force and effect. The impugned amendments relate to ss. 4(4)a) and 4(4)b), which require patentees to account for discounts and rebates provided to third parties when reporting to the PMPRB. The Court held that the other amendments and the rest of the *PMPRB Regulations* were constitutionally valid. An appeal was filed to the Quebec Court of Appeal in January 2021. In December 2021 oral submissions were made to the Quebec Court of Appeal as per the Rolls - Appeals on Merits session December 13-17, 2021. A decision on this appeal is something to watch for in 2022.

Innovative Medicines Canada et al v AGC et al., A-215-20

This matter relating to amendments to the *PMPRB Regulations* is currently pending before the FCA. In the underlying decision, reported at 2020 FC 725, Manson J. held that ss. 3(4) of amended *PMPRB Regulations*, which would expand the price calculation requirement in ss. 4(4) of the *PMPRB Regulations* to encompass information beyond the first point of sale, including confidential third-party rebates, was invalid. Manson J. found the balance of the provisions valid. In late 2020, an appeal was filed to the FCA. Over the course of 2021, procedural steps took place including the filing of memoranda of fact and law and requisitioning a hearing of the appeal. The appeal hearing of this matter is something to watch for in 2022.

Innovative Medicines Canada et al v AGC, T-1419-20

This proceeding relating to proposed new *PMPRB Guidelines* is currently pending before the Federal Court ("**FC**")**.** Most recently in 2021 an Order issued setting the schedule for the service and filing of the parties' records, which steps are due to be completed by April 2, 2022. The hearing of this application is something to watch for in 2022.

Coming into Force of Regulations Amending the Patented Medicines Regulations

On December 23, 2021, the Minister of Health once again deferred the coming into force of the *PMPRB Regulations*. The *PMPRB Regulations* were most recently expected to come into force on January 1, 2022. The revised date is July 1, 2022. According to the Government's announcement, the delay provides additional time for impacted stakeholders to continue to focus their efforts in responding to unprecedented challenges

presented by the COVID-19 pandemic. The statement also says that the delay allows the Government to further engage stakeholders on the application of these amendments within the changing pharmaceutical landscape.

Additionally, on December 20, 2021, the PMPRB announced that it will not proceed with changes to its new *PMPRB Guidelines* that had been proposed in July 2021. The PMPRB maintains that the new *PMPRB Guidelines* will come into effect with the coming into force of the amendments to the *PMPRB Regulations*. Will the amendments to the *PMPRB Regulations* and *PMPRB Guidelines* come into effect in 2022? That is something to watch for in 2022.

2. INVENTIVE CONCEPT

An important development in Canadian pharmaceutical patent law in 2021 was an evolution in the continuously changing landscape of the inventive concept. In *Apotex Inc v Shire LLC* ("**Shire Decision**"), the FCA reaffirmed inventive concept in Canadian patent law as part of the obviousness analysis and set out three basic principles on how to determine a patent's inventive concept. While the FCA attempted to provide guidance, this decision raises questions on how to effectively apply the three principles articulated by the Court. The FCA's renewed interest in the inventive concept significantly differs from the view it stated in 2017 in both *Bristol-Myers Squibb Canada Co v Teva Canada Limited* and *Ciba Specialty Chemicals Water Treatments Limited v SNF Inc*. In these decisions, the FCA discussed the challenges of identifying the inventive concept, the confusion it creates and signalled that it may be best to avoid the inventive concept altogether. As the SCC denied leave to appeal the Shire Decision, we are left with an open debate on inventive concept. How this area of the law will unfold before the Federal Courts is something to watch for in 2022.

3. OVERBREADTH

Overbreadth was another area of patent law that took centre stage in 2021 with the decision of *Seedlings Life Science Ventures, LLC v Pfizer Canada ULC*. Although overbreadth is grounded in ss. 27(3) and (4) of the *Patent Act*, some commentators had raised doubts about whether a patent could be invalidated based on overbreadth alone. In this decision, the FCA held that it is a stand-alone basis for invalidating a patent. The FCA discussed the interplay between overbreadth and sufficiency. The FCA held that a claimed invention must be sufficiently disclosed such that a person of skill in the art can work the invention without undue experimentation (i.e., sufficiency). On the other hand, if the patent teaches the person

of skill in the art ways to practice the invention that requires a particular element, and some claims omit that element, then those claims that omit the element are overbroad as they are broader than the invention disclosed (i.e., overbreadth). How sound prediction will be seen to interact with overbreadth across the scope of a claim and whether courts will indeed make findings of patent invalidity based on overbreadth in the absence of another ground of invalidity such as sufficiency or obviousness are things to watch for in 2022.

4. STATUTE OF MONOPOLIES

2021 provided key insights into the availability of a claim for relief under the *Statute of Monopolies*. In Apotex Inc v Eli Lilly Canada Inc, the Court denied relief under the *Statute of Monopolies* for any harm suffered because of the adjudication of rights under the *PMNOC Regulations* and *Patent Act*. The Court held that the *PMNOC Regulations* and *Patent Act* were a legislative scheme that constitute a complete code. Accordingly, an innovative pharmaceutical company can only be liable for damages relating to assertion of its patents in accordance with the *PMNOC Regulations* and the *Patent Act*. A similar result was obtained on summary judgment motion in *Apotex Inc v Pfizer Ireland Pharmaceuticals*. These decisions may bring an end to efforts to seek additional relief for patent assertion outside of the relief provided for under the complete code of the patent regime. Both matters have been appealed. As such the continued exploration of this avenue for relief is something to watch for in 2022.

5. JUDICIAL REVIEW

In 2021 judicial review applications and appeals were once again trending, with cases pertaining to data protection (e.g., *Janssen Inc v Canada (Attorney General)*), patent listing and the strict applications of the timelines in the *PMNOC Regulations* (e.g., *Merck Canada Inc v Canada (Health),* aff'd 2021 FCA 224, and Certificates of Supplementary Protection (e.g., *Canada (Health) v GlaxoSmithKline Biologicals SA*). Early efforts to protect and defend patent-related rights is becoming increasingly popular. Whether the trend will continue is something to watch for in 2022.

6. SUMMARY PROCEEDINGS

The courts continued the recent trend of promoting the use of summary judgment and summary trials in 2021, even in complex matters in the patent and pharmaceutical space. In the case of *ViiV Healthcare Company v Gilead Sciences Canada Inc*, the FCA seized the opportunity to clarify when and how motions for summary judgment and summary trials should

proceed. The view from the FCA appears to be that—although not always the right approach—summary proceedings in some cases increase efficiency and save the parties and the court resources. The FCA also approved of summary judgment to resolve a patent dispute, not in the pharmaceutical space, in *Canmar Foods Ltd v TA Foods Ltd*. With the FCA opening the door to summary proceedings in patent infringement and validity actions, when and how often these proceedings will be pursued is something to watch for in 2022.

Conclusion

2022 is bound to be an interesting year in Canadian pharmaceutical patent law with these trends and other new developments on the horizon.