Life Sciences 2020 Year in Review

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2020 will always be remembered as the year of COVID, and we would be remiss not to discuss the impact of COVID in the Life Sciences field. From the interest in patenting the use of remdesivir in treating COVID (see Patenting Coronavirus (COVID-19) Treatments) and finding ways to rapidly diagnose a COVID positive patient, to the race to produce a vaccine (see The Race to Produce a COVID-19 Vaccine (Part I) and The Race to Produce a COVID-19 Vaccine (Part II)), COVID has definitely brought the incredible strength of medical research to the attention of us all, while showing that scientific collaborations and acceleration to market can still occur in conjunction with intellectual property protection (see Pooling Patent Rights to Combat COVID-19 and Canadians Ramping Up COVID-19 Collaborations and IP).

Recognizing this rapid need for COVID treatment, government, including intellectual property offices and regulatory bodies, developed programs to help accelerate research, examination and approval (see Ontario Government Unveils Intellectual Property Action Plan Along with COVID-19 Research Projects and The USPTO's Fast-Track Patent Program Spurs on COVID-19 Innovations).

Although COVID has dominated most discussions, there were many other developments of note in Life Sciences IP over the last year.

Prior Art: Anticipation and Obviousness

The Federal Court of Appeal considered both anticipation and obviousness in *Hospira Healthcare Corporation v. Kennedy Trust for Rheumatology Research*, 2020 FCA 30 [*Hospira*], in a decision relating to the infliximab biosimilar. With respect to the first requirement for anticipation, Justice Locke of the Federal Court of Appeal found that the disclosure requirement "is satisfied if performing what is described in the prior art reference would necessarily result in infringement". Justice Locke could not see how the two prior art references, which disclosed the idea of co-administration of methotrexate and the antibody, did not satisfy this requirement merely because the special advantage of the adjunctive therapy was not disclosed. Justice Locke also found that "in order for any particular results from the claimed combination treatment to be a basis for distinguishing over the prior art, it would be necessary to conclude that such results constituted an essential element of the claim in question". With respect to the second requirement for anticipation, Justice Locke similarly found that what must be enabled in the prior art is the essential elements of the claims, and not the experiments that were disclosed in the patent.

Regarding obviousness, Justice Locke clarified the obvious to try test, explaining that the determinative test is whether "it was more or less self-evident *to try to obtain* the invention" (emphasis added). The question of "whether it was more or less self-evident that what is being tried ought to work" is not part of the determinative test, but is a factor for consideration. Justice Locke also provided certainty over what prior art is citable for obviousness, confirming that prior art should not be excluded on the basis that it could not be found using a reasonably diligent search.

In *Biogen Canada Inc. v. Taro Pharmaceuticals Inc.*, 2020 FC 621 [*Biogen*], Justice Manson of the Federal Court provided a good reminder of the importance of carefully reviewing documents prior to making any disclosure, and to redact any data that may jeopardize the patentability of an invention. In this case, the claims were anticipated and found obvious in view of a single financial document. After completion of a small phase II study of fampridine SR, Acorda decided to go public in order to raise additional funds. Its registration statement included results from the first phase II trial and the design of a

second phase II trial. Justice Manson found some of the claims anticipated and all the claims obvious. With respect to anticipation and relying on *Hospira*, he held that the disclosure requirement was satisfied because performing what was described in the second phase II trial design would necessarily result in infringement, even in the absence of results. The enablement requirement was also met. Even if the second phase II trial ultimately failed, the skilled person would be willing to conduct routine trial and error experiments to get the invention to work. The decision is under appeal.

Selection patent

In *Eli Lilly Canada Inc. v. Mylan Pharmaceuticals ULC,* 2020 FC 816, Justice St-Louis of the Federal Court did not consider Lilly's patent to low dose (between 1 and 20 mg) tadalafil to be a patentable selection of an earlier tadalafil patent since the advantage was not found peculiar to the selected group. This led to findings of anticipation and obviousness. Lilly argued that the unexpected advantage was reduced facial flushing compared to higher dosages and compared to the competitor sildenafil. However, nothing in the specification, or the claims indicated such an advantage. In fact, reduced flushing compared to sildenafil was also observed in doses up to 100 mg tadalafil.

Patentable Subject Matter

Patentees were pleasantly surprised by the decision of Justice Zinn of the Federal Court in the appeal of Yves Choueifaty against the rejection of his application by the Commissioner of Patents (*Yves Choueifaty v. Attorney General of Canada*, 2020 FC 837 [*Choueifaty*]). In this decision, the Federal Court held that the Canadian Intellectual Property Office's (CIPO) approach to claim construction was "incorrect in law". Justice Zinn found that the Commissioner had indeed "erred in determining the essential elements of [Choueifaty's] claimed invention by using the problem-solution approach". Although the ruling in *Choueifaty* has implications in all cases where purposive construction is to be used during examination, it has particular importance with respect to the question of patentable subject matter. For the Life Sciences community, CIPO's problem-solution approach created great difficulty for medical diagnostic inventions, where patent examiners often determined that the innovation was directed to the discovery of a correlation between a genetic alteration, or a level of an analyte, and a disease or other medical condition. Once the elements of measuring or detecting the genetic alteration or analyte were disregarded, the claim was alleged to be directed to a disembodied idea (i.e., a mental process or having no practical application) and excluded from patentability.

In response to *Choueifaty*, CIPO published a guidance document for patent examiners on purposive construction and patentable subject matter. In the guidance document, CIPO explicitly states that all elements set out in a claim are presumed essential, unless it is established otherwise or is contrary to the language used in the claim. Furthermore, where an invention consists of a combination of elements cooperating together, all of the elements of the combination must be considered as a whole when considering whether there is patentable subject matter. Patent examiners will now have to consider all steps identified in a claim to be essential, unless the language indicates otherwise and suggests that for diagnostic methods, the data acquisition and the correlation steps will both be considered when assessing patentable subject matter. This guidance on diagnostic method claims is bolstered by the examples provided.

The guidance document also goes on to consider the patentable subject matter in relation to medical uses. In Canada, it is well established that methods of medical treatment are not patentable, but medical uses are. Patentees, however, must be aware that claims directed to a dosage range may be construed to be a method of medical treatment if professional skill and judgment is required to determine the dosage. Justice Locke in *Hospira* commented on the issue of what constitutes a method of medical treatment, noting the need for a "deep analysis" and questioning the distinction between fixed dosages vs. dosage ranges. In *Biogen*, Justice Manson, following *Hospira*, also held that claims limited to fixed dosages and intervals of administration are not invalid as methods of medical treatment.

PMPRB Update

Amendments to the *Patented Medicines Regulations* were first announced in August 2019 and are now expected to come into force July 1, 2021. The *Regulations*, through the Patented Medicine Prices Review Board (PMPRB), regulate prices of patented medicines in Canada. The changes include updating the reference countries for which patentees need to report

pricing information, introducing a new price calculation, and changing reporting requirements, including increasing the reporting requirements with respect to three new economic factors to determine whether the price of a patented medicine is excessive. One of the controversial requirements is found in subsection 4(4) of the *Regulations*, which require price and revenue reporting to include reporting of third party discounts and rebates.

Innovative Medicines Canada and 16 pharmaceutical companies brought an application for judicial review of the amendments (see Recent Amendments to the Patented Medicines Regulations Declared Unconstitutional), alleging that the changes fell outside the scope of the *Patent Act*. Although Justice Manson of the Federal Court found that the majority of the changes were within the scope of the *Patent Act*, he held that the subsection 4(4) amendments that require patentees to report rebates went beyond the scope of the *Act*. This decision is under appeal. Justice Picard of the Quebec Superior Court also considered the amendments in *Merck Canada inc. c. Procureur général du Canada*, 2020 QCCS 4541, and found that the subsection 4(4)a) and 4(4)b) amendments are unconstitutional. Consistent with Justice Manson, Justice Picard found the rest of the *Regulations*, including the other amendments, and the relevant sections of the *Patent Act* constitutionally valid. This decision is also under appeal.

Also related to the PMPRB is the PMPRB decision regarding Galderma's medicines containing adapalene. In this decision, the sole issue was whether Galderma was required to file financial information related to its product DIFFERIN®. According to Galderma, the patent at issue relates to the use of 0.3% adapalene (known as DIFFERIN XP®), whereas DIFFERIN® uses 0.1% adapalene. Galderma argued that the different concentrations affect effectiveness, tolerance and side effects and are treated as different medicines. The PMPRB held, however, that as both contain the same medicinal ingredient, are indicated for the same disorder and work in the same way, disclosure is required. The PMPRB concentrated on whether the invention "pertains to a medicine" i.e., whether the invention of the patent pertains to DIFFERIN®, rather than whether the invention "encompasses the medicine". The PMPRB ultimately found that the patent that discloses one strength of a drug pertains to a medicine that contains a different strength of the same active ingredient and thus is subject to the PMPRB pricing. Judicial review is being sought.

File Wrapper Estoppel

In *Janssen Inc. v. Teva Canada Ltd.,* 2020 FC 593, a PMNOC infringement action relating to paliperidone palmitate, Justice Manson considered the issue of file wrapper estoppel pursuant to section 53.1 of the *Patent Act*. The patent claimed dosing regimens for long-acting paliperidone palmitate depot formulations for treatment of schizophrenia. The issue was whether the term "continuous schedule" required ongoing administration of maintenance doses or required a single maintenance dose. During prosecution, Janssen stated, in response to a patentable subject matter objection, for administration on a fixed dosing schedule of "day 1, one week +/- 2 days, continuous schedule having a monthly +/- 7 days dosing interval". This position was inconsistent with the position that Janssen offered at trial, and was considered admissible for the construction of the claim language "continuous schedule".

Overbreadth / Utility

In *Seedlings Life Science Ventures, LLC v. Pfizer ULC*, 2020 FC 1, Justice Grammond found that all claims were overbroad on the basis that at least three essential elements of the invention were not mentioned in the claims. While overbreadth overlaps with other grounds of invalidity, Justice Grammond noted that it sometimes has an independent role to play, and reaffirmed that it indeed finds statutory basis in s. 27(4) of the *Patent Act*.

With respect to utility, Justice Grammond reaffirmed that the threshold for utility is low and that a scintilla will do. The use of computer-aided design software to design Seedlings' auto-injector prototype device and to stimulate the functioning, as well as successful firing of the prototype (despite failure on a subsequent attempt) was found to constitute a demonstration of utility.

Claim construction

In *ViiV Healthcare Company v. Gilead Sciences Canada Inc*, 2020 FC 486, the Federal Court rendered its first contested

summary trial decision in a patent infringement action. Gilead brought a motion for summary trial asserting a construction and accordingly seeking a declaration of non-infringement in respect of its BIKTARVY® product. At issue on construction was the purposive construction of Ring A in the relevant claims, and whether the bridged bicyclic ring in bictegravir sodium, a medicinal component of BIKTARVY®, fell within the scope of the claims. While Justice Manson of the Federal Court observed that on its face the claim language appears to be clear and unambiguous, he considered that recourse to the disclosure was necessary to understand the intended scope of this claim language. Justice Manson observed that there are only three ways in which rings can be joined – bridged (as in bictegravir), "spiro" and "fused" – and favoured Gilead's Ring A interpretation, as the patent disclosure made specific reference to spiro and fused rings, but never to bridged rings. Bictegravir was accordingly found to fall outside of the scope of the claims, and Gilead's motion for summary trial was granted. The decision is under appeal.

Certificate of Supplementary Protection (CSP)

The CSP regime provides certain pharmaceutical drugs up to an additional two years of protection upon expiry of the patent. Since its implementation in 2017, Health Canada has received 73 applications (57 issued, 7 refused, 6 pending and 1 withdrawn).

In the past year, the Federal Court released its first two decisions where it considered the eligibility requirements for a CSP. In *Glaxosmithkline Biologicals S.A. v. The Minister of Health*, 2020 FC 397, Justice Barnes of the Federal Court interpreted the meaning of "medicinal ingredient" and considered whether a vaccine may be eligible for a CSP. The patent for the SHINGRIX® vaccine relates to an immunogenic composition comprising a Varicella Zoster Virus antigen in combination with an adjuvant. Health Canada denied a CSP on the basis that the patent does not cover a "medicinal ingredient" *per se* and that adjuvants, although biologically active, are not "medicinal ingredients" within the meaning of the *Patent Act* and *CSP Regulations*. GSK argued that both of the claimed ingredients are medicinal in the sense that both are biologically active and the antigen will not produce the desired immune response without the adjuvant. Justice Barnes found Health Canada's decision unreasonable. In considering the meaning of "medicinal ingredient", Health Canada had failed to take appropriate account of Canada's obligations under CETA, intended to have supplementary protection available for "active ingredients" and to cover vaccines. The case was sent back to Health Canada for reconsideration.

In *ViiV Healthcare ULC v. The Minister of Health*, 2020 FC 756, Justice Fuhrer of the Federal Court also found unreasonable Health Canada's decision to deny a CSP for JULUCA®, a combination therapy comprising dolutegravir and rilpivirine. Health Canada's position was that the patent for JULUCA® was not an eligible patent. Relying on the Regulatory Impact Analysis Statement (RIAS) of the *CSP Regulations* and its own guidance document, Health Canada's view was that if the approved drug contains a combination of medicinal ingredients, the patent must also include a claim for that combination. ViiV argued that the CSP provisions had to be interpreted in light of Canada's obligations under CETA, that Canada's *sui generis* regime is intended to provide protection for single medicinal ingredients or combinations of medicinal ingredients contained in new drug "products" protected by a "basic patent", and that a "basic patent" includes a patent containing a claim to at least one medicinal ingredient contained in a combination drug because that patent protects the product "as such". Justice Fuhrer favoured ViiV's argument in finding Health Canada's decision unreasonable and remitting the matter to Health Canada for redetermination.

Data Protection

Under section C.08.004.1 of the *Food and Drug Regulations*, an innovative drug may be eligible for a period of 8 years of market exclusivity from the date of issuance of a Notice of Compliance (NOC). The data protection regime prevents a subsequent-entry manufacturer who is submitting an abbreviated new drug submission (ANDS) from making any direct or indirect comparison to an innovative drug by relying on its clinical data.

In *Natco Pharma (Canada) Inc. v Canada (Health)*, 2020 FC 788, Justice McHaffie of the Federal Court affirmed that an indirect comparison to an innovative drug triggered data protection measures. Natco filed an ANDS for its new drug containing tenofovir alafenamide hemifumarate (TAF). The ANDS relied on Gilead's DESCOVY® drug, which contains TAF but was not considered an innovative drug, in contrast to Gilead's other drug, GENVOYA®, which was the first drug containing TAF to receive an NOC. Justice McHaffie held that Health Canada properly rejected Natco's ANDS because it

made an indirect comparison to GENVOYA® by including bioavailability studies for DESCOVY® compared to GENVOYA®, therefore engaging the data protection measures.

In *Janssen Inc. v. Canada (Attorney General)*, 2020 FC 904, Justice Zinn of the Federal Court found reasonable Health Canada's refusal to grant data protection to Janssen's drug SPRAVATO®, which contains an enantiomer of a previously approved medicinal drug. Under the *Food and Drug Regulations*, variations of previously approved medicinal ingredients such as enantiomers do not qualify as an "innovative drug" eligible for data protection. Janssen submitted that one should "look beyond" when assessing data protection eligibility and consider other factors such as the fact that SPRAVATO® is a lifesaving drug for a serious illness, that it was granted a priority review status and Janssen provided its own clinical data. Justice Zinn disagreed. To "look beyond" would require Health Canada to depart from *Takeda v Canada (Minister of Heath)*, 2013 FCA 13, which held that the correct interpretation of the *Food and Drug Regulations* was that no enantiomer of a previously approved medicinal ingredient is entitled to data protection. Janssen has since appealed the decision.

We will continue to monitor the cases that are under appeal and look forward to seeing how IP in the Life Sciences evolves in 2021.