Intellectual Property Weekly Abstracts Bulletin — Week of January 16, 2017

January 18, 2017

Patent Decisions

Application for Prohibition Granted for Generic Version of Concerta
Janssen Inc. v. Actavis Pharma Company, 2016 FC 1361

The Court granted Janssen's application prohibiting the Minister of Health from issuing an NOC to Actavis for its generic version of Concerta. The patent at issue does not relate to the active ingredient in Concerta, but rather, to the use of compositions that release the active ingredient in a "sustained-ascending dose over time". The active ingredient, methylphenidate, had been used in other products (Ritalin IR and SR), but both products were problematic. The ascending dosage in the patent was shown to achieve equivalent behavioural improvements to Ritalin IR, with no significant elevation of side effects.

Actavis submitted that the patent at issue should be construed as claiming dosage form and a method of administering a drug that involves providing an increasing rate of release throughout the entire extended dosing period, not just some portion of it. The Court disagreed. The Court found that the skilled person would not interpret the words "over time" and "sustained" to mean an entire dosing period. Therefore, a drug that had a sustained-ascending release profile over a few hours (and not the entire dosing period) could continue to be effective for a few hours after the drug stopped releasing the active ingredient into the plasma.

The Court found Actavis' allegations of invalidity were unjustified. The Court also concluded that Actavis' allegations of non-infringement were not justified. Actavis' expert erroneously relied on Actavis' construction to conclude that since the Actavis tablets did not provide a sustained-ascending dose over an entire dosing period, they would not infringe the patent. Further, Actavis' expert relied on mean data, not the results from analyzing individual Actavis tablets. The Court noted that this approach told us only whether a batch of tablets might infringe, and therefore, could permit a large quantity of infringing material to enter the market.

Patent Validity and Infringement Upheld on Appeal; Limitation Period in *Patent Act* not Necessarily Applicable to Old Act Patents

Apotex Inc. v. Astrazeneca Canada Inc., 2017 FCA 9

In this case, the FCA considered an appeal and cross-appeal of a decision relating to omeprazole. The trial decision can be found here (2015 FC 322).. It was modified here (2015 FC 671). The Court dismissed the validity challenges and the cross-appeal. The appeal relating to limitation periods was allowed. The FCA considered validity allegations on appeal relating to sufficiency of disclosure, ambiguity, overbreadth and inutility.

The FCA reviewed construction on a correctness standard, holding that the objective intention of the inventor is to be found within the four corners of the patent. The FCA also held that it is trite law that a court will consider the disclosure when construing the claims, as it may help to determine if a particular meaning was provided for an expression in the claim. However, the disclosure cannot be used to enlarge or contract the scope of the claim.

With respect to ambiguity, the FCA held that simply because Apotex argued one construction issue over another, the language of the claim is not ambiguous. With respect to sufficiency, the FCA dismissed Apotex's argument that the patent was insufficient because it did not describe the particular process that Apotex was using (the *in situ* process), which only became known several years after the patent issued. The FCA held that in the *Teva* case at the SCC, the problem was that the inventor had not disclosed his invention because only one compound worked, and which compound that was was not disclosed. However, in this case, the experts agreed that if they followed the teachings of the patent, they would expect the formulation of Claim 1 to have the advantages set out for the patent. Furthermore, the FCA held that routine testing is acceptable as part of enablement. The inventor does not need to provide all methods to make a product and does not need to provide for detailed technical support in respect of new methods that are not discussed in the disclosure.

With respect to inutility, Apotex was making the same argument that the patent was invalid for inutility based on a lack of sound prediction to make the formulation through the *in situ* process. The FCA held that requiring an inventor to demonstrate the utility of the preparation made by a process that was not known when the claim was drafted makes no sense.

The FCA held that the Federal Court erred in holding that the 6-year limitation period in the *Patent Act* applied to all acts of infringement by Apotex when considering the old *Patent Act*. The FCA held that, under the old *Patent Act*, if a cause of action arises in a province, that cause of action may be subject to the applicable provincial limitation period. This issue was remanded to the Federal Court. The FCA also dismissed AstraZeneca's cross-appeal seeking punitive damages or solicitor/client costs.

Dismissed Motion for Interlocutory Injunction Upheld on Appeal
Tearlab Corporation v. I-Med Pharma Inc., 2017 FCA 8

This was an appeal against Justice Manson's unreported decision in 2016 FC 606, dismissing TearLab's motion for an interlocutory injunction to prevent the sale of the i-Pen by I-MED Pharma, pending the determination at trial of TearLab's patent infringement claim. The Court had previously dismissed TearLab's motion for an interim injunction on the basis that it failed to present qualified witnesses and cogent evidence

to satisfy the last two prongs of the tripartite test for granting injunctions (see 2016 FC 350 and our summary here).

Justice Manson dismissed the interlocutory injunction motion for similar reasons. Justice Manson found that TearLab failed to meet the second prong of the tripartite test and that the balance of convenience favoured I-MED. In respect of the second prong, Justice Manson determined that it would be reasonably possible to quantify the damages triggered by the alleged infringement as patent rights are economic in nature. In addition, Justice Manson found that TearLab could not claim it was susceptible to irreparable harm merely because of its difficulty or inability to quantify damages.

The Court of Appeal dismissed the appeal, finding that Justice Manson did not commit a reviewable error of law, a misapprehension of the facts or an inappropriate weighing of the evidence.

Successful Defendant Awarded Costs Elevated by 50% for Most Issues and on Solicitor-and-Client Basis for Withdrawn Punitive Damages Claim
Mediatube Corp. v. Bell Canada, 2017 FC 6

In this infringement action, the Court held the patent at issue valid and not infringed. The Court noted that there were unusual developments over the course of this litigation, which had the effect of morphing this patent infringement matter to one of allocation of costs. As a result, the Court devoted more discussion to costs than would normally be warranted.

In awarding costs, the Court considered the factors as listed in Rule 400(3) of the *Federal Courts Rules*, and particularly Rules 400(3)(i) and (k). As a general rule, Bell having successfully defended itself from the patent infringement allegations, was entitled to have its costs. However, the Court addressed various arguments that might suggest straying from the general rule.

One unusual development in this case included a series of changes to Bell's discovery answers following the second round of discoveries, referred to as the “Corrected Information”. The Court declined to make any special award of costs against Bell for the Corrected Information, First, the Court found that Bell acted in good faith in answering discovery questions and in providing the Corrected Information. Furthermore, the Court noted that the timing of Bell providing the Corrected Information made no difference between proceeding with the trial and reaching a settlement before trial. The case for non-infringement was so compelling that the Court was unprepared to accept that the Plaintiffs had a reasonable belief that they had a good arguable case before receiving the Corrected Information.

The Court also declined to award cost consequences against Bell for the allegation in its Statement of Defence that the Plaintiffs are patent trolls, or for citing 753 prior references and waiting until about three months prior to trial (after the exchange of expert reports) to identify references on which it intended to rely at trial.

In respect of cost consequences against the Plaintiffs, the Court awarded costs elevated by 50% to reflect the weakness of the Plaintiffs' case for infringement. The Court found that the Plaintiffs commenced and pressed forward with their infringement allegations against Bell Aliant in the face of information indicating that Bell Aliant was

not infringing. Furthermore, the Plaintiffs commenced the action against Bell Canada without a clear theory of infringement, and the eventual theory they did form was weak.

The Court also awarded Bell its costs on a solicitor-and-client basis in relation to the punitive damages claims. The Court noted that a considerable amount of time was spent during the trial, and in preparation for trial, on the Plaintiffs' claim for punitive damages. The Plaintiffs withdrew their punitive damages claim based on its own evidence, and before Bell adduced any evidence on the issue. This indicated to the Court that the Plaintiffs had access to information that Bell was neither dishonest nor fraudulent prior to commencement of this action.

Supreme Court Updates

Teva Canada Limited v. Pfizer Canada Inc. (F.C.) (Civil) (By Leave) (37162)

The Supreme Court of Canada announced that judgment in this application for leave to appeal will be delivered on Thursday, January 19, 2017. The Supreme Court's website provided the following summary:

Intellectual property — Patents — Medicines — Section 8 damages action remitted to Federal Court for redetermination based on non-hearsay evidence — Does proving compensatory damages, which are based upon restoring the plaintiff to a hypothetical position in a “but for” analysis, require evidence demonstrating that "nothing made it impossible" for the plaintiff to be in that hypothetical position?

The respondent, Pfizer Canada Inc. ("Pfizer") is the corporate successor to the original patentee and innovative manufacturer of venlafaxine hydrochloride, a drug marketed under the name Effexor XR. The Canadian Patent 1,248,540 related to it was set to expire on January 10, 2006. In 2005, Ratiopharm, the corporate predecessor to the applicant, Teva Canada Limited ("Teva"), wanted to market its generic version of venlafaxine hydrochloride and filed an abbreviated new drug submission. Health Canada informed Ratiopharm that it would not issue a notice of compliance until the requirements under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 were met. On the eve of the expiry of the '540 Patent, Canadian Patent 2,199,778, covering the extended release formulation of venlafaxine was issued and Pfizer listed it on the Patent Register against Effexor XR. On the same day, Ratiopharm (Teva) served a notice of allegation, accepting that its notice of compliance would not issue until after the expiry of the '540 Patent but alleging that the newly-listed '778 Patent was invalid or would not be infringed by its generic version of venlafaxine. Pfizer applied for an order of prohibition preventing the Minister from issuing a notice of compliance to Ratiopharm (Teva), and triggering the automatic twenty-four month stay. Ratiopharm (Teva) filed a motion to dismiss Pfizer's prohibition application, submitting that the '778 Patent was not eligible for listing on the Patent Register. That motion was granted and Pfizer's prohibition application was dismissed. On August 2, 2007, the Minister granted Ratiopharm (Teva) a notice of compliance for its generic version of venlafaxine. Teva then commenced an action for damages under s. 8 of the Regulations for having been improperly kept off the market during the period of the statutory stay.

Industry Updates

In January 2017, sections 17.07 and 17.08 in chapter 17 of the Manual of Patent Office Practice (MOPOP) were revised to reflect antibody practice. A comprehensive list of the changes is available online on the MOPOP Revision History web page.

Health Canada has released a Notice — Applications for Investigational Testing Authorization (ITA), for Medical Devices, in the "Non-eCTD Electronics-Only" Format. The website indicates that as of January 1st, 2017, applications for ITAs for Medical Devices will be accepted in the "non-eCTD electronic-only" format.

Health Canada has released a Notice — Mandatory Requirements for using the Common Electronic Submissions Gateway (CESG). The website indicates that effective January 1st, 2017, the CESG will be mandatory for all regulatory transactions under 10GB in size (including first transactions) prepared in the eCTD format.

Health Canada has released a Notice — The Regulatory Enrolment Process (REP) Functional Pilot. The website indicates that the deadline for submitting a request for participation is January 20th, 2017.

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