Intellectual Property Weekly Abstracts Bulletin — Week Of June 13

June 15, 2016

Patent Decisions

Hearsay statements regarding the generic's ability to supply in the "but for" world should have been excluded
Pfizer Canada Inc. v. Teva Canada Limited, 2016 FCA 161
Drug: venlafaxine

A Judge of the Federal Court had previously awarded Teva section 8 damages under the *PM(NOC) Regulations*. The Court provided the key findings of fact in 2014 FC 248, previously summarized the week of April 7, 2014, and then issued an order providing the total damages accrued during the relevant period ($92 million in damages and $32 million in prejudgment interest — 2014 FC 634).

Pfizer appealed, alleging several errors were made, and the Court of Appeal has agreed with Pfizer on one of the alleged errors, namely that the Federal Court erred in admitting and relying upon hearsay evidence at trial.

The Federal Court held that Teva had to show on a balance of probabilities that it both could and would supply the market in the “but for” world. This meant that Teva had to identify its third-party supplier of the active pharmaceutical ingredient and show that that supplier had the capacity to supply the market over the relevant period.

The only evidence on this point was provided by a former executive of Ratiopharm, now Teva. Teva's witness testified as to the capacity of the third-party supplier to make venlafaxine for Teva. He relied upon emails he was not copied on and what colleagues had told him.

Pfizer had objected that this evidence was hearsay but it was allowed at trial. The Court of Appeal agreed that information told to Teva's witness by the third-party supplier was hearsay. Information routed from the supplier through other Ratiopharm employees to Teva's witness was held to be double hearsay.

The Court of Appeal found that this evidence should have been excluded and this error might have affected the outcome of the case. Thus, the Court of Appeal has remitted the proceeding back to the Federal Court for redetermination.

Application for prohibition is struck on motion after the Court construes the patent and finds no infringement
Janssen Inc. v. Celltrion Healthcare Co. Ltd., 2016 FC 525
Drug: infliximab

Celltrion has successfully struck a prohibition application brought by Janssen after Celltrion sought to add indications to its already approved drug.

Celltrion has an NOC to market infliximab for the treatment of indications including rheumatoid arthritis. At the time Celltrion filed its first drug submission, Janssen did not have any patents on the Patent Register. That meant that Celltrion did not have to address any patents.

However, Janssen subsequently filed an issued patent on the Patent Register for infliximab. Thus, when Celltrion submitted a SNDS for approval to also sell its infliximab product for the treatment of diseases related to various forms of inflammatory bowel disease, Celltrion needed to address this new patent.

Celltrion alleged it would not infringe the patent because none of the new intended uses relate to the patent. Rather, it was argued that the patent relates to the already-approved rheumatoid arthritis indications. Celltrion brought a motion to strike Janssen's prohibition application on this basis.

Janssen submitted that the Court needs to look at whether the drugs should be compared, not the uses of the drugs. The Court disagreed. Instead, the Court held it could construe the claims on a plain and ordinary construction, without any expert evidence. In doing so, the Court found the claims spoke specifically and directly to only rheumatoid arthritis. Thus, it was found that Celltrion's SNDS for the treatment of inflammatory bowel disease could not infringe the claims of the patent.

Janssen argued that if the Celltrion product were sold for both the rheumatoid arthritis and inflammatory bowel disease indications, then there would be direct infringement of the patent. However, the Court's view was that Celltrion's existing NOC for the rheumatoid arthritis indications does not come into play in this application.

The application was dismissed, with the order being stayed for 30 days to allow Janssen to take whatever steps they deemed appropriate.

Ontario Superior Court again refuses to strike claims pursuant to the *Statute of Monopolies* and the *Trade-marks Act*
Apotex Inc. v Schering Corporation, 2016 ONSC 3407

The defendant corporations sought to strike Apotex's claims to:

1. Treble damages pursuant to s 4 of *An Act concerning Monopolies and Dispensation with Penal Laws, etc*., R.S.O. 1897, c. 323 (the "*Ontario Monopolies Act*");

2. Treble damages pursuant to s. 4 of *An Act concerning Monopolies and Dispensation with Penal Laws and the Forfeitures thereof*, 1624, 21 Jac. 1, c. 3 (the "*UK Monopolies Act*", or, collectively the "*Monopolies Acts*")
3. Damages or an accounting of profits under the *Trade-marks Act*, R.S.C. 1985, c. T-13;
4. Disgorgement of revenues or profits on the basis of unjust enrichment; and
5. Other relief (the so-called "basket clause").

The Court noted that the last two prayers for relief (d and e) had been struck from a very similar Apotex statement of claim in prior litigation. Apotex did not oppose the striking of those claims.

But as to the remaining causes of action, the Court followed earlier jurisprudence and held that in light of the unsettled nature of the applicable law the objections should not be decided at the pleadings stage of the proceeding. Instead, the Court held that where the legal issues are as novel or unclear as they are here, the correct course is to have them resolved together on the merits.

Pleadings amendments are allowed to particularize what a party would have done in the "but for" world
Apotex Inc. v. Astrazeneca Canada Inc., 2016 FC 552

This is an action where Apotex has claimed section 8 damages against AstraZeneca. The Court had previously ruled on a motion to determine objections arising out of discoveries. In that ruling, it was noted that the pleadings of both parties were deficient as it relates to what they would have done in the "but for" world. AstraZeneca sought particulars from Apotex and in response sought to amend its pleading by way of motion.

AstraZeneca's motion sought to particularize what it would have done in the “but for” world, including the authorization of a generic product. Apotex opposed, saying the pleading had no air of reality.

Leave was granted to amend the statement of defence. But, AstraZeneca was told to make better particularized amendments alleging what it would have done if Apotex had launched in the manner set out in its particulars, including that AstraZeneca would have launched an authorized generic sooner than it in fact did and would not have opposed other generics coming onto the market.

Court disallows pleading amendments that are found to have no reasonable prospect of success
Teva Canada Limited v. Gilead Sciences Inc., 2016 FCA 176

Teva has lost both of its appeals seeking to amend its pleading to add in a claim that the patent at issue had been fraudulently obtained by misleading the Patent Office, contrary to subsection 53(1) of the *Patent Act*.

Teva said that on discovery, the inventors and the representative of Gilead admitted that they had not made and did not believe they could make any predictions of utility across the broad class of compounds claimed in the '619 Patent. In light of this, Teva took the view that Gilead has committed a material misrepresentation by filing the '619

Patent without a factual foundation to prove or to soundly predict utility. Thus, Teva sought to amend its statement of claim.

The Federal Court had found that the amendments improperly added allegations tantamount to fraud without sufficient evidence, and that the allegations had no reasonable prospect of success.

The Federal Court of Appeal agreed. Teva's proposed amendments were not found to have a reasonable prospect of success. The standard to be applied by the Court was described as being "more than just assessing whether there is just a mathematical chance of success. In deciding whether an amendment has a reasonable prospect of success, its chances of success must be examined in the context of the law and the litigation process, and a realistic view must be taken."

Trademark Decisions

Decision staying an application pending the outcome of an appeal in a related decision is upheld
Dallevigne S.P.A. v. Constellation Brands Québec, Inc., 2016 FC 610

Constellation appealed from a procedural order of a Prothonotary staying this application until a determination on the merits is made in the related proceeding in Court File T-1104-15. The main appeal was dismissed, but the Court set aside the costs award and granted Dallevigne its costs based on Column III of Tariff B.

In staying this proceeding the Prothonotary noted that this proceeding was in its early stages while the expungement appeal from T-1104-15 is more advanced, such that it was reasonable to believe that it would be heard on its merits well before the opposition appeal. In the absence of an error, the Court upheld the stay.

However, costs were awarded based on Column V, but it was held that elevated costs are not normally awarded when the facts and legal issues are not complex as in the appeal of the stay order. Thus, costs were awarded under Column III.

Supreme Court Leaves to Appeal

Britton Low v. Pfizer Canada Inc., et al. (SCC #36848) — leave dismissed

The Supreme Court has dismissed Britton Low's appeal from a decision of the Court of Appeal for British Columbia (2015 BCCA 506). We had previously summarized that decision the week of December 14, 2015, wherein the Court of Appeal had overturned the certification of a class action relating to the drug Viagra, dismissing the action.

Industry News

The PMPRB has published CompassRx, 2 nd Edition; Annual Public Drug Plan Expenditure Report, 2013/14.

Health Canada has announced the Adoption of International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH) Guidance Document: S1C(R2): Dose Selection for Carcinogenicity Studies of Pharmaceuticals and Limit Dose.

Health Canada has announced the Adoption of International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH) Guidance: E14 Questions & Answers (R3): The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs.

Health Canada has announced the Adoption of International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH) Guidance: Q7 Questions & Answers: Good Manufacturing Practices Guide for Active Pharmaceutical Ingredients.

Health Canada has announced the Release of Draft (Step 2) ICH Guidance Document: S3A Q&A: Note for Guidance on Toxicokinetics: The Assessment of Systemic Exposure — Focus on Microsampling.

By

Chantal Saunders, Beverley Moore, Adrian J. Howard

Expertise

Intellectual Property, Copyright, Patents, Licensing, Trademarks

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Montréal

1000 De La Gauchetière Street West
Suite 900
Montréal, QC, Canada
H3B 5H4

T 514.954.2555
F 514.879.9015

Toronto

Bay Adelaide Centre, East Tower
22 Adelaide Street West
Toronto, ON, Canada
M5H 4E3

T 416.367.6000
F 416.367.6749