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ARTICLE

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Patent Decisions

Order of prohibition granted in respect of crystalline form I ODV Succinate

Pfizer Canada Inc. v. Apotex Inc., 2017 FC 774

Drug: PRISTIQ o-desmethyl-venlafaxine ("ODV")

This is an application pursuant to the *Patented Medicines (Notice of Compliance) Regulations*. The Court began by noting a related decision in which a different second person sent a separate Notice of Allegation making different allegations. The Court issued an order of prohibition.

The patent relates to Form I ODV succinate, which the Court accepted is a novel composition of matter. Venlafaxine metabolizes into ODV, and was previously patented and approved to treat depression. The Court set out the invention story, including the experimentation with ODV fumarate and forming a pro-drug.

There were several disputes relating to claim construction, which the Court addressed and then found that Apotex's allegation of non-infringement was not justified, although some claims were not infringed by all Apotex's products. In terms of obviousness, the allegation was found not to be justified on the basis of a detailed analysis finding that, although "the new composition of matter being the crystalline Form I ODV succinate, was 'worth a try'", and "there were 'possibilities' that the Skilled Person would find the invention", this was not sufficient. With respect to utility, the Court had asked the parties for submissions in light of the Supreme Court of Canada decision in *AstraZeneca v Apotex*. The Court then indicated that it was applying the approach set out in that decision, proceeding on a claim by claim basis having regard to its previous construction of the claims.

The Court also addressed an argument made by Apotex relating to "overpromising" in relation to subsection 27(3) of the *Patent Act*. The Court noted:

I also observe that the alleged overpromises resemble the promise arguments advanced by Apotex, which are no longer valid having regard to *AstraZeneca*. If the Supreme Court intended to say, in effect, that the Promise Doctrine was not good law in terms of utility under s. 2, but was good law in terms of patent specifications under subsection 27(3) it could have done so; it did not.

The Court concluded by finding that the specification analysis pursuant to section 27(3) requires the patentee to define the precise extent of the exclusive property claimed. In terms of anticipation, although it filed evidence, Pfizer did not address anticipation in its memorandum of fact and law, arguing that Apotex had not filed evidence in this regard. The sections of the expert evidence that Apotex pointed to were submitted in respect of obviousness not anticipation, and no instructions relating to anticipation were given to Apotex's experts. The Court did not accept Apotex's arguments that it could rely on this evidence. However, the Court also did not agree that Pfizer could split its case by failing to deal with anticipation in its memorandum but addressing it in oral reply at the end of the hearing. The Court held that Pfizer could not proceed on the basis that anticipation was not in issue once Apotex filed its memorandum dealing with anticipation. The Court did not accept Apotex's expert evidence on anticipation. The Court also refused to accept Apotex's argument that its allegations of anticipation in its NOA were sufficient to displace the statutory presumption of validity. The presumption of validity was found to prevail in this case and the allegation of anticipation not justified. The Court also found Apotex's allegation of double patenting not to be justified. Costs were awarded to Pfizer.

Judicial review of the Minister of Health's decision to cancel reconsideration of abbreviated new drug submission dismissed

Apotex Inc. v. Canada (Health), 2017 FC 857

The Court dismissed Apotex's judicial review of the Minister of Health's decision to cancel the reconsideration of Apotex's submission in respect of its Apo-Omeprazole tablets. The underlying facts of this decision span a period of over ten years, in which Apotex had sought approval for its Apo-Omeprazole tablets. A brief overview of some of the background facts are as follows.

In 2003, the examination of Apotex's submission was understood to have been completed but placed on patent hold. In 2008, Health Canada revoked approval because Apotex's abbreviated new drug submission ("ANDS") lacked a study showing bioequivalence to the Canadian reference product ("CRP") when the drug is taken with a high calorie/high fat meal. Apotex chose to challenge the Minister's decision but was unsuccessful before the Federal Court and Federal Court of Appeal. In 2013, Apotex refiled its ANDS and included its 15-year old high calorie/high fat study, but the Minister refused to issue a NOC because she was not satisfied with the results of the study and the study design. In 2015, Apotex pursued a reconsideration process offered by Health Canada. In Apotex's view, the reconsideration exercise ought to be about whether or not its new drug is safe and effective, whereas the Minister contends that the manufacturer of a new drug may file an ANDS that compares the CRP, such that the new drug is bioequivalent, based on the pharmaceutical and, when the Minister considers it necessary, bioavailability characteristics. Despite an exchange of correspondence about suggested questions for the reconsideration, the parties could not agree on a proper question to put to an external expert panel. The Director General ultimately refused reconsideration.

In its application for judicial review, Apotex raised two arguments: 1) the Minister fettered her discretion in deciding that the reconsideration exercise had to focus on bioequivalence instead of allowing it to establish safety and efficacy; and 2) the Minister had created expectations that she would follow a procedure that included working with a sponsor to draft the questions to be posed to the Reconsideration Panel that would address the issues in dispute.

The Court first reviewed the doctrine of legitimate expectations. The Court noted that Apotex's position treated the reconsideration process as an appeal any issue, including the issue of the safety and effectiveness of a new drug, using the short cut that is the ANDS. The Court concluded that this was not a legitimate expectation about procedure or practice that is clear, unambiguous and unqualified. Rather, the Court found that the reconsideration policy did not allow Apotex to circumvent the requirement for bioequivalence found in the *Food and Drug Regulations ("Regulations"*).

The Court also found that there was no was fettering of discretion. While it was completely clear what discretion was alleged to have been fettered, the Court concluded that there was no evidence that the Minister fettered her discretion through strict adherence to the guidelines. Rather, the Court found that the Minister did precisely what the Regulations required of her and focused the question on bioequivalence instead of safety and effectiveness. The Court also found that if the fettering was that the Minister had to agree to a question, the Minister would have had to have that discretion in the first place, which she did not. The Court concluded that a reconsideration exercise that would exclude bioequivalence in favour of safety and effectiveness, as argued for by Apotex, would be outside of the framework of the Regulations.

Patent Related Decisions

Motion for a protective order drafted and agreed to by the parties dismissed

Live Face on Web, LLC v. Soldan Fence and Metals (2009) Ltd., 2017 FC 858

The Court dismissed the parties' motion for a protective order. The underlying dispute is a patent infringement action and the Plaintiff made an informal motion for the issuance of a protective on consent of the Defendant. In dismissing the motion, the Court concluded:

[...] absent highly unusual circumstances, it is not necessary for the Court to incorporate in an order the specific or additional protective measures agreed by the parties for them to be effective, and that the Court ought no longer to routinely issue protective orders on consent of the parties.

The Court added that the majority of the provisions from typical protective orders are already covered by the common law doctrine of the implied undertaking rule. The Court dismissed the parties' arguments that the proposed order is necessary despite the existence of the implied undertaking rule. Specifically, the parties argued that the proposed order expanded on the rule in two ways: 1) it limits the number of individuals that may access the information; and 2) it provides that parties must give each other prior notice of their intention to file material in Court, to allow the disclosing party an opportunity to seek a confidentiality order to ensure the continued protection of the information.

In respect of the first argument, the Court noted that a breach of these limits will not necessarily constitute an improper use of discovery evidence, and that it was certainly not obvious that it should be punishable by contempt. In respect of the second argument, the Court agreed that such a provision was unquestionably useful. However, the Court did not consider that its incorporation into an order of the Court was necessary for it to be fully effective. The Court noted that it could not "conceive that anyone would think that a solicitor could, with impunity, breach such an undertaking simply because it has not been made part of an order of the Court".

The Court also dismissed the notion that that in the absence of a protective order, a separate agreement is needed to bind third parties to the implied undertaking rule. The Court found that this notion was simply incorrect in law.

Motion to amend in light of SCC's decision in AstraZeneca allowed in part; amendments for allegation of fraud without particular facts dismissed

Apotex Inc. v. Shire LLC, 2017 FC 831

In this motion, Apotex sought to amend its statement of claim in light of the Supreme Court's decision in AstraZeneca Canada Inc. v Apotex Inc., 2017 SCC 36. The Court found that the majority of the amendments proposed by Apotex did not introduce new facts, but simply "recast" the same factual allegations underlying Apotex's inutility plea. In describing the proposed amendments, the Court noted that:

[...] The amendments are slipshod, inconsistent and confusing. Although Apotex portrays its amendments as being made in accordance with the Supreme Court's teachings on the correct approach to utility, they reflect, in my view, an obtuse application of selected passages of the Supreme Court's decision, a refusal to come to terms with and embrace the essence of the Supreme Court's teachings, and a fairly desperate attempt to shoehorn Apotex's promise allegations into each and every ground of invalidity known to law. The resulting pleading remains haunted by the ghost of the now defunct promise doctrine and is neither particularly helpful nor illuminating.

Notwithstanding the foregoing, the Court concluded that the factual allegations of the statement of claim relating to inutility should not be struck as disclosing no reasonable cause of action.

The Court also allowed Apotex's proposed amendments that alleged new facts, with the exception of the amendments found to be "a bare pleading that "the applicant was aware" that the inventors had not demonstrated or had no sound basis to predict a particular utility". The Court noted that pleadings of fraud are a serious matter and the proposed pleading contained no particular facts upon which a Court might find any particular state of mind or knowledge in any particular persons at any particular time.

Appeal of order adjourning applicant's motion for confidentiality order dismissed

Innovator Company v. Canada (Attorney General), 2017 FC 864

The Court dismissed the appeal of the Prothonotary's Order adjourning the Applicant's motion for a confidentiality order until after such time that the Other Innovator is served with the Notice of Application, among other things. The underlying proceeding is an application seeking judicial review of the Minister's decision requiring that the Applicant address patents listed against the Other Innovator's product. The Prothonotary had found that the Other Innovator is a person directly affected by the order sought in the underlying application, and that it ought to have been named as a Respondent.

Copyright Decision

Copyright in registered plans of survey belongs to the Crown

Keatley Surveying Ltd. v. Teranet Inc., 2017 ONCA 748

Land surveyors brought a class action alleging copyright infringement through the digitizing, storing and copying of the plans of survey created by the surveyors and registered in Ontario's electronic land registry system, Teranet.

Teranet sought summary judgment on the issue of the impact of registration or deposit of plans of survey under the Teranet system on Crown copyright as described in section 12 of the Copyright Act. The motion judge held that copyright in the plans of survey registered or deposited under the ELRS belonged to the Province of Ontario, and not to the surveyor who created the plan.

The Ontario Court of Appeal has upheld the decision of the motion judge, albeit from a slightly different reasoning.

The Court recognized copyright in plans of survey, noted they are artistic works, and the land surveyor is the author of said work. The Court further noted that surveyors do not have to register a plan with the province of Ontario, and that there are measures that can be taken to prevent that from happening. However, the Court did state that if the surveyor owned copyright then there is a breach of copyright regardless of whether a government employee or a third-party retained by the government makes a copy.

After reviewing the whole of the statutory scheme for plans of survey, the Court held that the Crown has complete control over registered or deposited plans of survey and complete control over the "publication" of those plans of survey within the meaning of the *Copyright Act*. However, the Court did not find that the legislation transfers "ownership" of the copyright to Ontario. Instead, Ontario's publishing of plans of survey, making those copies available

to the public, is done under the "direction or control of Her Majesty", thus section 12 of the *Copyright Act* provides that copyright in the registered plans of survey belongs to the Crown.

On this basis, the decision on summary judgment to dismiss the class proceeding was upheld.

Industry Update

Health Canada released a Notice: Consultation on proposals for prescription drug transparency. The website indicates that the consultation is available online between September 28, 2017, and October 28, 2017, and that feedback is to be submitted exclusively through the consultation document.

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