Date: 20091118

Docket: T-780-08

Citation: 2009 FC 1179

Toronto, Ontario, November 18, 2009

PRESENT: The Honourable Mr. Justice Zinn

BETWEEN:

JANSSEN-ORTHO INC. and ALZA CORPORATION

Applicants

and

THE MINISTER OF HEALTH and NOVOPHARM LIMITED

Respondents

REASONS FOR ORDER AND ORDER

[1] This is an appeal by Novopharm Limited (Novopharm) from a decision of the case management Prothonotary dated October 29, 2009. This appeal was heard on November 16, 2009 at the commencement of the hearing of this proceeding which is an application for an Order under the *Patented Medicines (Notice of Compliance) Regulations* prohibiting the Minister from issuing a Notice of Compliance to Novopharm for its proposed product. After oral submissions, I indicated

that the appeal was being allowed and that Reasons would follow. These are those Reasons and formal Order.

[2] Dr. Quinn, an expert for the Applicants, swore an affidavit in which he makes the following assertion at paragraph 92:

> Along the same vein, I have been known to say that the clinical significance of the need for ascending plasma concentrations because of a possible side effect of acute tolerance is theoretical because it has not been quantified. That too is simply a comment on the problem of an inability to ethically test to rigorously prove such significance. The fact remains that psychiatrists generally do recognize that the prior RITALIN SR® formulation created acute tolerance and that the newer once a day CONCERTA® formulation due to its sustained ascending plasma concentration resolves or regulates that problem. On this topic, I note that the British group of child and adolescent psychiatrists accept the concept of acute tolerance to Methylphenidate (http://www.rcpsyh.ac.uk).

[3] It is accepted that the website referenced by Dr. Quinn is that of the Royal College of Psychiatrists in the United Kingdom (the College). No particular web pages were identified from this site or attached as an exhibit to Dr. Quinn's affidavit. Dr. Quinn was not cross-examined on paragraph 92 of his affidavit nor was he asked any questions concerning the website referenced by him.

[4] When the Applicants were cross-examining Dr. Kutcher, an expert witness of Novopharm, they asked questions of him relating to paragraph 92 of Dr. Quinn's affidavit and specifically put to him two pages from the College's website. Dr. Kutcher stated that he could neither identify the

pages nor authenticate them as he had not seen them. The pages were marked as Exhibit A for identification purposes only. The Applicants also asked Dr. McCracken, another Novopharm expert, about paragraph 92 of Dr. Quinn's affidavit. He responded that he had not gone to the website because he didn't see the relevance "of a group of community psychiatrists passing judgment on something that I think is determined by the weight of scientific evidence."

[5] The Applicants filed their Application Record which included Exhibit A marked for identification purposes on the cross-examination of Dr. Kutcher. Novopharm objected and brought a motion before the case management Prothonotary seeking an Order striking the web pages from the Record as well as any reference thereto. In this respect, it was noted that the Applicants refer to Exhibit A in paragraph 95 of their Memorandum of Fact and Law wherein they submit as follows:

> Dr. Quinn points out that the United Kingdom's Royal College of Psychiatrists' website has a training manual that specifically references the Swanson "Acute Tolerance" article that is also referenced in Novopharm's product monograph. On the basis of that authority the Association recommends that acute tolerance to methylphenidate be regulated by use of CONCERTA®'s ascending methylphenidate plasma attributes.

[6] The Applicants resisted the motion and brought a cross-motion seeking leave to serve and file the affidavit of Marie Mutchler, to which is attached as Exhibits the web pages that were marked as Exhibit A on the cross-examination of Dr. Kutcher.

[7] The learned Prothonotary held that Exhibit A on the cross-examination of Dr. Kutcher was not in evidence. No appeal was taken by the Applicants from this finding and I concur with her ruling on this issue which reads as follows:

> I am satisfied that the two web pages are not properly in evidence. They were not included in the affidavits and documentary exhibits filed by the Applicants pursuant to Rule 306, and they were not identified or authenticated by any witness on cross-examination. Reference to the domain or home page for the Royal College of Psychiatrists in the United Kingdom by Dr. Quinn at paragraph 92 of his affidavit does not give adequate or complete reference to the appropriate source. Providing the web address for the domain or home page without the balance of the path or address contained in the complete URL to the specific page would purport to make the entire site and all of its contents "evidence" in a proceeding, which cannot properly be the case. Moreover, and in any event, an opposing party is not required to go on a hunt to try and ferret out the evidence with the hope that they are correct in finding what might be referred to in an affidavit.

[8] The Prothonotary granted the Applicants' motion and permitted the late filing of the affidavit of Marie Mutchler, a clerk in the office of counsel for the Applicants, and the two web pages attached as Exhibits. Accordingly, the Prothonotary found that "the disposition of Novopharm's motion to strike the two web pages and references to them from the Applicants' Record is rendered moot by the disposition of the Applicants' motion for an order to file the two web pages as additional evidence through the affidavit of Ms. Mutchler."

[9] The test under Rule 84(2) for granting leave to file evidence after having cross-examined the opposite parties' deponents is the same as under Rule 312: *Pfizer Canada Inc. v. RhoxalPharma Inc.* [2006] 36 C.P.R. (4^{th}) 550 (F.C). As the Prothonotary correctly observed, the filing of

additional evidence may be permitted but only if four requirements are met. The first three requirements are not relevant, however, the fourth requirement as stated by her is "whether the further evidence was available and/or could not be anticipated as being relevant at an earlier date." The Court of Appeal in *Atlantic Engraving Ltd. v. Lapointe Rosenstein,* 2002 FCA 503 at para. 9 stated that this requirement is included because the Rule permitting the filing of additional evidence "is not there to allow a party to split its case and a party must put its best case forward at the first opportunity…"

[10] The Prothonotary found and the parties are agreed that the two web pages at issue were available to the Applicants prior to the cross-examination.

[11] The Prothonotary states that while the web pages were available, "it appears that the Applicants may have erroneously thought that they had properly referenced them through the web address to the home page of the Royal College of Psychiatrists, noting that the site has an effective search function." I can only conclude that the Prothonotary was of the opinion that due to this erroneous view, the Applicants could not have anticipated that these pages were relevant at an earlier date; otherwise the fourth requirement was not met and the Order permitting the late filing of evidence should not have issued.

[12] I have concluded that the Prothonotary acted on a misapprehension of the facts or erred in law in her application of the fourth requirement of the test. In order to find that a party requesting leave to file additional evidence could not have anticipated that the evidence it now wishes to tender

was relevant, one must make that determination by examining the circumstances as they existed when the party requesting leave first filed its evidence. The question is whether the moving party knew or ought to have known then that the evidence was relevant. Here the Applicants knew when it filed its evidence that these pages were relevant; they were indirectly referenced in an affidavit they filed. The Applicants tried, without success, to pull themselves up by their bootstraps by tendering these pages as evidence through Novopharm's experts but they were unable so to do. They cannot now tender evidence that was available and known by them to be relevant when Dr. Quinn swore his affidavit; to permit this would be to permit the Applicants to split their case.

[13] Novopharm also made submissions that the evidence that was to be tendered by Ms. Mutchler was hearsay evidence and that there was no way the Court could know that these were the pages that Dr. Quinn was referencing in his affidavit or that they constituted all of the pages from the College on the issue or that they reflected the opinion of the College. It was further submitted that they had not had the opportunity to cross-examine Dr. Quinn on this "new" evidence. The Applicants submitted that the Court was able to assign whatever weight it saw fit to the pages after they were allowed into evidence.

[14] I share the view of Novopharm that the purported evidence that is now being tendered by a clerk and not by an expert who is relying on it, is hearsay and had it been allowed in I would have given it virtually no weight for the reasons advanced by Novopharm, especially as it had not had an opportunity to cross-examine on this evidence.

[15] The Applicants submitted that Novopharm did have an opportunity to cross-examine Dr. Quinn on paragraph 92 of his affidavit (and by inference these pages) but asked him no questions relating to paragraph 92. In my view, it is disingenuous for the Applicants to suggest that Novopharm had any meaningful opportunity to cross-examine on two specific pages of a web site when it only mentions the home page and not the specific pages being relied upon. Perhaps the Applicants tried to hide the two pages in the forest of the home webpage rather than attaching them as an Exhibit to the affidavit, which would have been the proper procedure, or perhaps they merely failed to be more specific when drafting their expert's affidavit. Regardless, they are bound by the choices they made and cannot at this late date tender that evidence.

[16] Accordingly, the appeal is allowed and considering Novopharm's original motion afresh, it is granted.

ORDER

THIS COURT ORDERS that:

1. The Order of Madam Prothonotary Milczynski, dated October 29, 2009, is set aside;

2. Exhibit A to the cross-examination of Dr. Stanley L. Kutcher and the affidavit of Marie Mutchler are struck from the Application Record;

3. Paragraph 95 of the Applicants' Memorandum of Fact and Law is struck as are any other references to the web pages in the Applicants' Record;

4. Novopharm is granted its costs of this appeal and of the motion below.

"Russel W. Zinn"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-780-08
STYLE OF CAUSE:	JANSSEN-ORTHO INC. and ALZA CORPORATION v. THE MINISTER OF HEALTH and NOVOPHARM LIMITED
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	NOVEMBER 16-19, 2009
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DATED:	NOVEMBER 18, 2009

APPEARANCES:

Mr. Neil Belmore Ms. Lindsay Neidrauer Mr. Greg Beach Ms. Marian Wolanski	FOR THE APPLICANTS
Mr. Jonathan Stainsby Mr. Julian Worsley Mr. Andrew Skodyn	FOR THE RESPONDENT NOVOPHARM
No Appearance	FOR THE RESPONDENT MINISTER OF HEALTH

SOLICITORS OF RECORD:

Belmore McIntosh Neidrauer LLP Toronto, Ontario	FOR THE APPLICANTS
Heenan Blaikie LLP Toronto, Ontario	FOR THE RESPONDENT NOVOPHARM
John H. Sims, Q.C. Deputy Attorney General of Canada	FOR THE RESPONDENT MINISTER OF HEALTH