CANADA / JUDGMENT

Pfizer Canada Inc. v. Rhoxalpharma Inc.

2004 FC 1685

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Federal Court	1 December 2004

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Pfizer Canada Inc. v. Rhoxalpharma Inc. Court (s) Database Federal Court Decisions Date 2004-12-01 Neutral citation 2004 FC 1685 File numbers T-807-03 Notes Digest Decision Content Date: 20041201 Docket: T-807-03 Citation: 2004 FC 1685 Ottawa, Ontario, this 1st day of December, 2004 Present: THE HONOURABLE JUSTICE von FINCKENSTEIN BETWEEN: PFIZER CANADA INC. AND PFIZER INC. Applicants and RHOXALPHARMA INC. AND THE MINISTER OF HEALTH Respondents REASONS FOR ORDER AND ORDER

[1] Canadian Patent 1,314,876 (the "876 patent") is with regard to crystalline azithromycin dihydrate and is owned by Pfizer Canada Inc. ("Pfizer"). The parties agree that the main point of contention in the within proceeding is whether Rhoxalpharma Inc.'s ("Rhoxal") azithromycin product contains azithromycin dihydrate ("dihydrate") or azithromycin monohydrate ("monohydrate"). The 876 patent claims cover dihydrate.

[2] On March 31, 2003, Rhoxal sent Pfizer a Notice of Allegation in which Rhoxal claims that Rhoxal's product would not infringe Pfizer's 876 patent because the product would not contain dihydrate. Pfizer served its Notice of Application on May 20, 2003, claiming that the dihydrate crystalline form of azithromycin was more stable than the monohydrate form and that conversion of monohydrate to dihydrate occurs during large-scale manufacturing of azithromycin tablets. On request from Pfizer, Rhoxal provided samples of its bulk azithromycin and azithromycin tablets to Pfizer's counsel on July 23, 2003.

[3] Pfizer filed two affidavits in support of its application. One by a Dr. Byrn states on paragraph 30 This would not be surprising considering that azithromycin dihyrate is a very stable form. Indeed, thermodynamic principles dictate that less stable forms transform to more stable forms, if the kinetics so permit. Therefore, in a crystallization process to make azithromycin, it is not likely to get at least some aziththromycin dihydrate even if your goal is to get a different form.

[4] However, Dr.Byrn provided no basis for his conclusions and there was no testing by Dr. Byrn or anyone else of the samples provided on July 23, 2003 by Rhoxal of its bulk azithromycin and azithromycin tablets.

[5] Rhoxal filed an affidavit by its own expert a, Dr. Petrov, who refutes Dr. Byrn's findings. He attests to the fact that he subjected the Rhoxal tables to an x-ray powder defraction analysis (XRPD) and that he found no trace of dihydrate. He also disputes the finding of Dr. Byrn by stating in paragraph 24: In fact, the monohydrate structure is more stable than the dihydrate form. The monohydrate does not convert to the dihydrate even in contact with moisture. There is no reason to believe that the monohydrate has a tendency to convert to the dihydrate form. (...) Following the laws of thermodynamics, the monohydrate structure should possess a smaller form. He also conducted empirical tests by immersing Rhoxal dihydrate tablets in water in ambient conditions and found no traces of dihydrate. Consequently, he made the following conclusions in paragraphs 32 and 36: My experiments confirm that the more stable azithromycin structure is the monohydrate, not the dihydrate. (...) This evidence confirms that it is not correct to say, as Dr. Byrn does, that azithromycin dihydrate is the "thermodynamically more stable form". It is not correct that azithromycin monohydrate tends to convert to the dihydrate from on contact with moisture. Therefore, there is no basis for Dr. Byrn's statement that as Rhoxal's production of the bulk azithromycin is scaled up "the formation of dihrydrate would become more prevalent.

[6] Dr. Petrov was vigorously cross-examined on his affidavit and several inconsistencies came to light; inter alia, that:

a) he did not immerse the actual tablet into the water, but removed the outer shell of the tablet, placed it in a container in a petri dish containing water and then covered petri dish;

b) he introduced the concept of strong and weak bonds in his testimony while there was no reference to strength of bonds in his affidavit; and

c) he advanced the view that monohydrate is more polar than water and contradicted himself when answering questions on the polarity of water and monohydrate.

[7] Pfizer therefore moved before Prothonotary Aronovitch under Rule 312 to:

a) file a further affidavit of Dr. Byrne rebutting the theoretical basis of Dr. Petrov's opinion, and

b) file an affidavit of a Dr. Munson who replicated the test conducted by Dr. Petrov and also conducted an allegedly more reliable test using a cross polarization magic angle spinning ("CMAS") test.

[8] Prothonotary Aronovitch provided the following grounds in allowing Pfizer leave to file its new testing and affidavit evidence after completion of cross-examinations:

i) the evidence responds to completely new information raised By Dr. Petrov during cross-examination; ii) the evidence does not amount to Pfizer splitting its evidence; iii) the evidence does not contain evidence that could have been submitted previously; iv) the evidence does not amount to Pfizer remedying its evidence post hoc; and

v) the evidence is required to safeguard the Court's interest in having the best and most conclusive evidence before it in determining the issues.

[9] Rhoxal now appeals the order of Prothonotary Aronovich arguing that Pfizer should not be allowed to introduce further evidence and that, accordingly, the Order should be set aside .

ISSUES

1. Did Prothonotary Aronovitch use the incorrect test in allowing the applicant to file further evidence?

2. Was there an error in principle or a misapprehension of the facts by Prothonotary Aronovitch? STANDARD OF REVIEW

[10] The relevant test is set out in Merck & Co. v. Apotex Inc., [2003] F.C.J. No. 1925 at para. 19 (F.C.A.), where Décary, stated: Discretionary orders of Prothonotaries ought not be disturbed on appeal to a judge unless:

a) the questions raised in the motion are vital to the final issue of the case, or

b) the orders are clearly wrong, in the sense that the exercise of discretion by the Prothonotary was based upon a wrong principle or upon a misapprehension of the facts. If the order meets one of the above criteria, the discretion of the reviewing judge must be exercised de novo.

[11] Given that the issue of whether the 876 patent contains dihydrate is central to this case, clearly the issues raised in this appeal are vital to the results of this case. However, the key point to be determined is whether the exercise of discretion by the Prothonotary was based upon a wrong principle or upon a misapprehension of the facts. PRELIMINARY ISSUE

[12] Rhoxal as part of its case introduced an affidavit of Ron Bouchard dated November 16, 2004, a partner in the firm of Rhoxal's counsel. That affidavit contains several statements on the evidence and makes a number of legal findings. Pfizer objected to this affidavit given that Mr. Bouchard is not an expert witness and given that legal findings are the domain of the court and not of affiants. On agreement by both parties, I struck the affidavit from the record as being an improper affidavit. I agreed to restrict myself to the affidavit of Mr. Bouchard dated October 19, 2004 as filed before Prothonotary Aronovitch and then only for the purpose of background and giving no weight to any assertions of expertise or law. ISSUE 1: Did the Prothonotary use the incorrect test in allowing Rhoxal to file further evidence?

[13] Rules 84(2) and 312 of the Federal Court Rules, 1998 SOR/98-106 read as follows:

84. (1) A party seeking to cross-examine the deponent of an application shall not do so until the party has served on all other parties every affidavit on which the party intends to rely in the motion or application, except with the consent of affidavit filed in a motion or all other parties or with leave of the Court.

(2) A party who has cross-examined the deponent of an affidavit filed in a motion or application may not subsequently file an affidavit in that motion or application, except with the consent of all other parties or with leave of the Court. 312 With leave of the Court, a party may

(a) file affidavits additional to those provided for in rules 306 and 307;

(b) conduct cross-examinations on affidavits additional to those provided for in rule 308; or

(c) file a supplementary record.

[14] Evidently rules 84(2) and 312 are very similar. They were discussed by Lemieux, J. in Salton Appliances (1985) Corp v. Salton Inc (2000) 4 CPR (4th) 491 where he stated at paragraphs 12 and 13: Rule 84(2) found its place in the former Rules as rule 332.1(6). The former Rules also contained rule 332.1(7) (which is not contained in the current Rules) which provided that "[T]he Court may grant leave to a party to file an affidavit in a motion after the party cross-examines the deponent of an affidavit where the Court is satisfied that the party should be allowed to respond to a matter raised in the cross-examination". Current rule 39.02(2) of the Ontario Rules of Civil Procedure, R.R.O. 1990, Reg. 194, is framed in terms similar to former rule 332.1(7). I also note as background that when the new Rules came into force, Rule 312, in the context of application, now provides for additional affidavits with leave of the Court. The two new Rules 84 and 312 should, in my view, yield similar interpretations. (Underlining added)

[15] Lemieux, J. further observed at paragraphs 16 and 17: I am satisfied Rule 84(2), read in its context and against the history of the former Rules, is designed to deal with matters that arise during cross- examination for which there is a need to address by way of further affidavit with leave of the Court. The cases decided by this Court and by the Ontario Courts recognize that relevancy of the proposed affidavit, absence of prejudice to the opposing party, assistance to the Court, and the overall interest of justice are relevant factors to be taken into account in deciding whether leave to file a further affidavit should be granted.

[16] Thus, when entertaining a Rule 84(2) application, regard must be had to:

a) relevancy of the proposed affidavit

b) absence of prejudice to the opposing party

c) assistance to the Court

d) the overall interest of justice .

[17] The application of Pfizer relied on Rule 312. However, both Rule 312, and Rule 84(2) were argued before the Prothonotary and addressed in Rhoxal's written submissions. Thus, Prothonotary Aronovitch, although not mentioning either Rule 84(2) or Rule 312, was made aware of both rules. Keeping in mind Lemieux, J.'s observation that both rules "should yield similar interpretations", the failure to explicitly mention Rule 84(2) is of no import. Her reasons reveal that she applied the test stated in Salton (supra) and addressed all the four

above mentioned factors. Consequently, she did not apply the wrong test. ISSUE 2: Was there an error in principle or a misapprehension of the facts by the Prothonotary ?

[18] Of the five observations by Prothonotary Aronovitch mentioned in paragraph 8 above, four are not borne out by an examination of the record.

[19] The Prothonotary observed that the evidence responds to completely new information raised by Dr. Petrov during cross-examination. Actually, Dr. Petrov was questioned on his affidavit and tried to defend his findings. In doing so, he had to explain what he meant by immersion, the importance of not only the number, but also the strength of bonds and his views of polarity of dihydrates and water. To the extent that his testimony differs from his affidavit or statements, the weight given to his affidavit will be affected. This may undermine his credibility, but it does not amount to completely new information.

[20] The Prothonotary made two other findings: namely a) that the affidavits to be introduced do not contain evidence that could have been submitted previously and b) that the evidence to be introduced does not amount to allowing Pfizer to split its evidence. This is difficult to support. The first affidavit of Dr. Byrn dealt with the Notice of Allegation, the 876 Patent and Rhoxals's allegation. Dr. Byrn refuted the allegations and made statements on scientific grounds without any laboratory evidence to the effect that azithromycin dihydrate is more stable than azithromycin monohydrate. The affidavit of Dr. Munson would introduce laboratory evidence duplicating the experiments made by Dr. Petrov using an XRCP process and also introducing another set of experiments using a CMAS test. This is completely different evidence. Pfizer could have tested the tablets and bulk azithromycin during the eight months before cross-examinations took place. While Pfizer could not anticipate the way Dr. Petrov would conduct an XRCP test, it certainly could have conducted its own XRCP test (employing a more traditional way of "immersing") and conducting the allegedly superior CMAS test. For whatever strategic reasons, it chose not to do so. Allowing Pfizer to introduce such evidence now has the effect of allowing it to split its case i.e. first rejecting the allegations on the basis of scientific argumentation and then after cross-examination, introducing its own experimental laboratory evidence.

[21] The Prothonotary also held the evidence sought to be introduced by Pfizer does not amount to Pfizer remedying its evidence post hoc. As the foregoing discussion has shown, that is precisely what would occur if Pfizer is allowed to introduce the affidavits of Dr. Byrn and Dr. Munson. The original evidence filed by Pfizer contains no report of testing the samples or bulk samples furnished by Rhoxal. This is a deficiency that Pfizer now seeks to repair. If Pfizer is allowed to introduce the two affidavits now, especially the affidavit of Dr. Munson containing two test results, this will allow it to substantially improve its evidence after cross-examinations have taken place. I should also mention that the second affidavit of Dr. Byrn refers to two texts not previously mentioned Solid State Chemistry of Drugs and Physical Chemistry, 3 ed. Both these texts were in print at the time Dr. Petrov was cross-examined. Accordingly, the observations of Lemieux, J. in Salton (supra) at paragraph 18 apply here: As I view the law on the point in this Court there is the additional requirement as to the non-

availability of the material in the proposed affidavit prior to cross-examination; a supplementary affidavit cannot be a substitute for putting available information to a deponent on cross-examination. A further affidavit is not designed to repair answers which cross-examining counsel wishes he did not get. Moreover, normally, parties are obliged to disclose all available information before cross-examination so as to avoid splitting the evidence.

[22] The Prothonotary also referred to my decision in AstraZeneca v. Apotex [2004] FC 761 noting in paragraph 11 that the interests of Justice comprise the Court's interest in having the fullness of pertinent evidence available to it in determining issues in the underlying proceedings. While that principle should apply in most cases, it cannot be used as a shield to cover failures to put available information before affiants on cross-examination or as a cloak to permit the splitting of evidence.

[23] Accordingly, I find in this case the Prothonotary acted on a misapprehension of facts and consequently, her decision cannot stand. ORDER THIS COURT ORDERS that:

1. The affidavit of Ron Bouchard sworn Nov 16, 2004 forming part of the motion record is struck.

2. The order of Prothonotary Aronovitch dated October 28, 2004 is set aside .

3. The Applicants shall have their costs in this motion and in the motion before Prothonotary Aronovitch. "K. von Finckenstein" Judge FEDERAL COURT NAMES OF COUNSEL AND SOLICITORS OF RECORD DOCKET: T-807-03 STYLE OF CAUSE: Pfizer Canada Inc., et al -v- Rhoxalpharma Inc., et al PLACE OF HEARING: Ottawa Ontario DATE OF HEARING: Monday November 29, 2004 REASONS FOR : The Honourable Mr. Justice von Finckenstein DATED: December 1, 2004 APPEARANCES: Mr. J. Mills Mr. M. Richard APPLICANT Mr. E. Hore Mr. R. Bouchard RESPONDENT SOLICITORS OF RECORD: Gowling Lafleur Henderson APPLICANT Ottawa Ontario Hazzard & Hore Toronto Ontario RESPONDENT

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