Federal Court  Cour fédérale

Date: 20110725

Docket: T-2072-10

Citation: 2011 FC 919

Ottawa, Ontario, July 25, 2011

PRESENT: The Honourable Madam Justice Mactavish

BETWEEN:

BRISTOL-MYERS SQUIBB CANADA CO. and MERCK SHARP & DOHME CORP.

Applicants

and

MYLAN PHARMACEUTICALS ULC and THE MINISTER OF HEALTH

Respondents

PUBLIC REASONS FOR ORDER AND ORDER
(Confidential Reasons for Order and Order released July 21, 2011)

[1] Bristol-Myers Squibb Canada Co. and Merck Sharp & Dohme Corp. (the applicants) appeal from an order of Prothonotary Aalto refusing the applicants' request for the production of certain documents for use in a proceeding under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133. In so doing, Prothonotary Aalto concluded that the applicants had not established that the documents in issue were either important or required.

[2] The applicants submit that the Prothonotary imposed an unduly high and improper burden of proof on them to justify compelling the production of information in the possession of Mylan Pharmaceuticals ULC (Mylan). The Prothonotary further erred, the applicants say, in misapprehending the expert evidence of Dr. Allan Myerson. This led the Prothonotary to erroneously conclude that the applicants' theory that the [*] efavirenz used as a starting material in Mylan's product would convert to the Form I crystal form of efavirenz claimed by the patent in issue during the manufacturing process was speculative.

[3] The applicants also submit that the facts of this case are very similar to those in *Glaxosmithkline Inc. v. Pharmascience Inc.*, 2002 FCT 683, [2002] F.C.J. No. 925, and that Prothonotary Aalto erred in failing to follow that decision.

[4] Finally, the applicants say that the Prothonotary erred in having regard to the fact that Mylan had already produced a significant amount of documentary material in this matter, given that none of that material related to the manufacturing process used by Mylan or to the crystal structure of the efavirenz in Mylan's tablets.

[5] For the reasons that follow, I am not persuaded that Prothonotary Aalto erred as alleged. Consequently, the applicants' appeal will be dismissed.

Standard of Review

[6] The first issue for the Court is to identify the standard of review to be applied to the Prothonotary's decision. The order made by the Prothonotary in this case was discretionary in

nature. As the Federal Court of Appeal observed in *Merck & Co. v. Apotex Inc.*, 2003 FCA 488, [2004] 2 F.C.R. 459, at paras. 17-19, discretionary orders of Prothonotaries ought not to be disturbed on appeal unless the questions raised in the motion are vital to the final issue of the case, or the orders are clearly wrong in the sense that the exercise of discretion was based upon a wrong principle or a misapprehension of the facts.

[7] I do not agree with the applicants that the questions raised in the motion are vital to the final issue of the case with the result that the Court should embark on a *de novo* hearing of this matter. The issue raised by the motion before the Prothonotary was simply whether the production of certain documents should be ordered. That question is not vital to the final issue of the case: see, for example, *Pfizer Canada Inc. v. Apotex Inc.*, 2009 FC 226, [2009] F.C.J. No. 296 at para. 27.

[8] Consequently, the question for the Court is whether the order made by Prothonotary Aalto dismissing the applicants' motion for production was based upon a wrong principle or a misapprehension of the facts. In order to answer this question, it is necessary to first have regard to the law governing documentary production under the *PMNOC Regulations*.

Documentary Production under the PMNOC Regulations

[9] Proceedings under the *PMNOC Regulations* are intended to be summary in nature, and the parties do not have the same rights of discovery as they would have in an infringement or impeachment action: *Novartis Pharmaceuticals Canada Inc. v. Abbott Laboratories, Ltd.* (2000), 7 C.P.R. (4th) 264 at 270, [2000] F.C.J. No. 941 at paras.11 and 12 (F.C.A.).

[10] Subsection 6(7) of the *PMNOC Regulations* provides that:

6. (7) On the motion of a first person, the court may, at any time during a proceeding,	6. (7) Sur requête de la première personne, le tribunal peut, au cours de l'instance :
(a) order a second person to produce any portion of the submission or supplement filed by the second person for a notice of compliance that is relevant to the disposition of the issues in the proceeding and may order that any change made to the portion during the proceeding be produced by the second person as it is made; and	a) ordonner à la seconde personne de produire les extraits pertinents de la présentation ou du supplément qu'elle a déposé pour obtenir un avis de conformité et lui enjoindre de produire sans délai tout changement apporté à ces extraits au cours de l'instance;
(b) order the Minister to verify that any portion produced corresponds fully to the information in the submission or supplement.	b) enjoindre au ministre de vérifier si les extraits produits correspondent fidèlement aux renseignements figurant dans la présentation ou le supplément déposé.

[11] As the Federal Court of Appeal observed in *Novartis*, a condition precedent to the exercise of discretion pursuant to subsection 6(7) of the *Regulations* is that the information sought must be relevant. In exercising the discretion conferred by subsection 6(7), it must also be determined on a balance of probabilities that the requested information is "important" or "required".

Did the Prothonotary Impose an Unduly High Burden of Proof?

[12] Prothonotary Aalto accepted that the information sought by the applicants was relevant to the issues in the application, but found that it was neither important nor required. The applicants submit that Prothonotary Aalto erred in finding that the applicants had not met their evidentiary burden in light of the uncontradicted evidence of their expert, Dr. Myerson.

[13] In support of their contention that Prothonotary Aalto applied a wrong principle by imposing an unduly high burden of proof, the applicants point to Prothonotary Aalto's statement that Dr. Myerson had "not *unequivocally* stated in the materials, on this theory of conversion as it applies to [*] efavirenz, that it does in fact convert" [emphasis added]: see page 3 of the transcript of the oral reasons of Prothonotary Aalto.

[14] According to the applicants, this statement shows that Prothonotary Aalto improperly required the applicants to provide "unequivocal proof" or "compelling evidence" that the [*] efavirenz used by Mylan as a starting material will convert to the Form I crystal form of efavirenz claimed by the patent in issue.

[15] I do not agree that the Prothonotary erred in relation to the burden of proof. The comment relied upon by the applicants must be read in the context of the Prothonotary's reasons as a whole. At pages 5 and 6 of the transcript of his oral reasons, the Prothonotary refers to the *Novartis* decision cited above, and correctly identifies the burden of proof as being that of the balance of probabilities. Moreover, it is clear from a review of the reasons as a whole that Prothonotary Aalto's examination of Dr. Myerson's evidence was conducted with this standard in mind.

Did the Prothonotary Misapprehend the Evidence of Dr. Myerson?

[16] The applicants submit that in concluding that Dr. Myerson's evidence was speculative, Prothonotary Aalto erred in misapprehending the uncontradicted expert evidence before him. The applicants say that the Prothonotary ignored several of Dr. Myerson's statements in which he clearly

articulated his expert opinion that the [*] efavirenz used as a starting material in the manufacture of Mylan's product would convert to the Form I crystal form of efavirenz claimed by the patent in issue.

[17] Dr. Myerson stated in both his affidavit and on cross-examination that [*] efavirenz "may" convert to crystalline Form I efavirenz under certain conditions. He hypothesized that this would occur in the case of [*] because other crystalline forms of efavirenz convert to the more stable Form I when energy is applied.

[18] I am not persuaded that Prothonotary Aalto misapprehended Dr. Myerson's evidence or that he erred in characterizing Dr. Myerson's conversion theory as "speculative". Dr. Myerson was "certain" that "some efavirenz form" would convert to Form I if energy was applied through grinding the material with a mortar and pestle. However, as Prothonotary Aalto observed, Dr. Myerson also acknowledged in cross-examination that he really had no information about [*] efavirenz.

[19] Dr. Myerson also did not conduct any studies of [*] efavirenz. He says that there were references in the literature to the behavior of forms of efavirenz other than Form I when energy was applied. However, Dr. Myerson did not know whether this literature specifically considered the behavior of [*] efavirenz: see questions 153-155 of the cross-examination of Dr. Myerson.

[20] In these circumstances, it was open to Prothonotary Aalto to weigh Dr. Myerson's evidence as it related to his conversion theory, and to conclude that the applicants had failed to demonstrate on a balance of probabilities that the evidence sought was important or required.

Did the Prothonotary err in Failing to Follow the *Glaxosmithkline* Decision?

[21] The applicants contend that Prothonotary Aalto further erred in failing to follow the decision of Justice Blanchard in the *Glaxosmithkline* case cited above.

[22] *Glaxosmithkline* also involved a motion for production under subsection 6(7) of the *PMNOC Regulations*. Pharmascience alleged in its Notice of Allegation that the patent in question would not be infringed because its tablets were made using paroxetine hydrochloride anhydrate, and not the paroxetine hydrochloride hemihydrate claimed in the patent. The applicants contended that the Pharmascience tablets could contain the patented drug. The applicants adduced expert evidence indicating that the conversion of Pharmascience's anhydrate material to crystalline paroxetine hydrochloride hemihydrate may occur during processing.

[23] On the basis of the expert evidence before him, Justice Blanchard was satisfied that the information and samples sought from Pharmascience were relevant to the question of non-infringement in that case, and that paroxetine hydrochloride anhydrate is known to and may convert to paroxetine hydrochloride hemihydrate under certain conditions. This was a factual determination, based upon Justice Blanchard's assessment of the expert evidence adduced in that case.

[24] I agree with Mylan that Prothonotary Aalto properly distinguished the present case from *Glaxosmithkline* on the basis that the expert evidence regarding the issue of conversion in this case was more equivocal and speculative in nature. Consequently, I am not persuaded that the Prothonotary erred in failing to follow the result in *Glaxosmithkline*.

The Significance of Mylan's Other Productions

[25] Finally, the applicants say that Prothonotary Aalto erred in having regard to the fact that Mylan had already produced a significant amount of documentary material in relation to this matter and had agreed to produce additional information. This was an error, the applicants say, as none of the documentary evidence produced by Mylan related to Mylan's manufacturing process or the crystal structure of the efavirenz in Mylan's tablets.

[26] I do not understand Prothonotary Aalto's reasons to say that he was dismissing the applicants' motion because the applicants had already, or were going to receive documentary disclosure with respect to Mylan's manufacturing process or the crystal structure of the efavirenz in Mylan's finished product. Rather, he was simply observing that Mylan had already provided extensive disclosure in the course of this proceeding.

[27] Even where it is established that the information sought is relevant, a production order will not automatically follow. As was noted earlier, proceedings under the *PMNOC Regulations* are intended to be dealt with in a summary manner. In exercising his discretion in determining whether a production order should be made in this case, it was open to Prothonotary Aalto to have regard to

the extent of the productions already made, or which Mylan had undertaken to provide: see *Pfizer Canada Inc.*, above, at para. 23.

Conclusion

[28] For these reasons, the appeal is dismissed. The parties have agreed that the winning parties should be entitled to their costs in the amount of $2,500 in any event of the cause.

ORDER

THIS COURT ORDERS that the appeal is dismissed, with costs to the defendants fixed in the amount of $2,500, payable in any event of the cause.

"Anne Mactavish"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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