Federal Court  Cour fédérale

Date: 20110120

Docket: T-1422-09

Citation: 2011 FC 74

Toronto, Ontario, January 20, 2011

PRESENT: Kevin R. Aalto, Esquire, Case Management Judge

BETWEEN:

PFIZER CANADA INC.,
WARNER-LAMBERT COMPANY AND
WARNER-LAMBERT COMPANY LLC

Applicants

and

RATIOPHARM INC. AND
THE MINISTER OF HEALTH

Respondents

REASONS FOR ORDER AND ORDER

[1] It is well settled law that a generic drug manufacturer cannot have two Notices of Allegation (NOA) for the same drug which are substantially identical. This case raises a novel question concerning the *Patented Medicines (Notice of Compliance) Regulations* (the Regulations). Two different generic drug manufacturers served NOAs regarding the same drug. Subsequently, both of the generic drug companies amalgamated with a third drug company under the name of which they all now carry on business. Is it an abuse of process and contrary to the Regulations to permit the

new amalgamated corporation to maintain both NOAs? That is the question for determination in this motion.

Facts

[2] On May 1, 2009, ratiopharm filed an Abbreviated New Drug Submission (ANDS) with Health Canada seeking the issuance of a Notice of Compliance (NOC) for its pregabalin drug product. On September 18, 2009 Novopharm Inc. (Novopharm) filed an ANDS with Health Canada seeking the issuance of an NOC for its pregabalin drug product.

[3] At the time ratiopharm`s NOA and Novopharm`s NOA were served, both ratiopharm and Novopharm were separate and distinct companies. Both companies retained separate counsel to assist in preparation of their NOA`s. ratiopharm and Novopharm acted independently. They rely upon different experts in support of their allegations in their respective NOAs.

[4] In response to the NOA from ratiopharm, the Applicants (Pfizer) commenced this proceeding on August 26, 2009. Subsequently, on November 13, 2009 Pfizer commenced a Notice of Application being Court File No. T-1868-09 in respect of the Novopharm NOA in which an order was sought prohibiting the Minister of Health from issuing an NOC for the Novopharm pregabalin product (the Novopharm Proceeding). Both this proceeding and the Novopharm Proceeding continue to be litigated in the ordinary course including the service of their respective experts' evidence. ratiopharm served its evidence utilizing experts that are different from the experts relied upon by Novopharm in the Novopharm Proceeding. Further, the ratiopharm pregabalin product and the Novopharm pregabalin product are apparently different pharmaceutical

formulations. Certain of the excipients in the two formulations are different and apparently where the same excipients are present, the amounts used are different. This applies not only to the compositions of the powder blends, but also the compositions of the hard gelatine capsule into which the powder blends are filled. The manufacturer for each of the ratiopharm pregabalin product and the Novopharm pregabalin product are different. Because ratiopharm and Novopharm were independently seeking approval of different formulations, they were required by the Regulations to submit separate ANDS and to serve separate NOAs.

[5] On March 18, 2010 counsel for Novopharm in the Novopharm Proceeding advised Pfizer that Novopharm Limited had changed its name to Teva Canada Limited. Counsel to Novopharm provided an affidavit to Pfizer attaching the Certificate and Articles of Amendment and advised that "[T]he certificate confirmed that only the name of the corporation has changed. The legal entity remains the same. There has been no assignment, transmission, or devolution of interest or liability".

[6] Further, counsel to Novopharm advised that the Novopharm drug submission would be updated over a period of time to reflect the name change and that Novopharm "will be seeking to amend the title of proceedings on consent to reflect the name change at the appropriate time. The amended title of proceedings will substitute 'Teva Canada Limited' in place of 'Novopharm Limited'".

[7] Thereafter, ratiopharm amalgamated with Teva Canada Limited (Teva). In August, 2010, counsel to ratiopharm in this proceeding advised Pfizer of the amalgamation of ratiopharm and Teva. ratiopharm's counsel advised Pfizer that "[A]s a result of the amalgamation, ratiopharm Inc. will henceforth conduct business under the name 'Teva Canada Limited'". ratiopharm's counsel sought Pfizer's consent to amend the title of proceedings herein to "*Pfizer Canada Inc.* v. *Teva Canada Limited*" and also sought Pfizer's consent to add Novopharm's counsel to the Protective Order in this proceeding on the basis that Novopharm's counsel is also counsel to Teva Canada.

[8] Thus, both ratiopharm and Novopharm now carry on business under the name Teva and the litigation strategy in both this proceeding and the Novopharm Proceeding is directed by the Director, Intellectual Property of Teva.

Issues

[9] These novel facts raise a number of issues. First, is it an abuse of process for Teva to effectively have two NOAs outstanding simultaneous relating to the same drug? If it is an abuse of process is the appropriate remedy that this proceeding be stayed and an order be made indefinitely extending the 24-months statutory stay under the Regulations?

Discussion

[10] Pfizer argues that as a generic manufacturer is not permitted to maintain two NOAs for substantially the same drug this application must be stayed in favour of the "first" proceeding involving the drug. The "first" application according to Pfizer's ingenious argument is the one commenced by Novopharm.

[11] Pfizer argues that as the amalgamation between ratiopharm and Teva was subsequent in time to the amalgamation of Novopharm and Teva, this proceeding is therefore the second proceeding of Teva involving pregabalin. From a policy perspective, Pfizer's position is that by allowing this proceeding to continue relating to the same issues and patents the principles of judicial economy, consistency, finality and the integrity of the administration of justice are violated. All of this taken together equals an abuse of process that compels the staying of this proceeding in favour of the Novopharm Proceeding some six months after the ratiopharm hearing is to be held. Thus, in Pfizer's submission there is no prejudice to the amalgamated Teva save and except a further six month wait.

[12] Pfizer also points out that the Novopharm Proceeding raises not only the identical allegations raised by ratiopharm (non-infringement, invalidity, obviousness etc.) but also adds the allegation of insufficient disclosure. On cross-examination, General Counsel for Teva took the position that the Novopharm NOA was better than the ratiopharm NOA. Be that as it may it is not determinative of the matter. While it may be better drafted or more comprehensive, if the two NOAs are for different formulations and different excipients then there is no automatic result in one proceeding being stayed and no reason why the two proceedings cannot continue.

[13] This proceeding is the result of ratiopharm exercising its right to enter the marketplace with its generic version of pregabalin. Novopharm did the same for its own formulation. Their amalgamation with Teva has had the unintended result of Teva being involved in two proceedings involving this drug. As counsel for Pfizer so felicitously phrased it "their common ownership is the happy but unintended consequence of a commercial marriage".

[14] However, that does not necessarily result in this proceeding being an abuse of process. Pfizer argues that the doctrine of abuse of process engages the inherent power of the Court to control its own process and prevent misuse of that process which otherwise would bring the administration of justice into disrepute. There is no doubt that the Court does have such a power. The question is whether the facts of this case and the scheme of the Regulations mandate the Court exercising its discretion to effectively permanently stay this proceeding in favour of the Novopharm proceeding on the basis of abuse of process.

[15] Pfizer points to a number of cases to support its position that this application should be stayed as an abuse of process. First, in *AB Hassle v. Canada (Minister of National Health and Welfare)* (1997), 71 C.P.R. (3d) 129, the Court was asked to declare a second or further NOA delivered by a generic manufacturer to be void and of no effect or alternatively staying the proceedings until after final disposition of prior proceedings involving an NOA by the same generic manufacturer. The motion was dismissed. It was held that a stay of proceedings was warranted only if the usual tests were met and as the NOA was a document filed with the Minister, the Court did not have jurisdiction to declare it void and of no effect. In coming to this conclusion the Court observed at p. 137:

> The *Regulations* are silent about whether more than one notice of allegation may be given by a generic producer seeking to compare its drug with one already approved for sale in Canada under an NOC. . . More than one allegation is contemplated by s-s 6(2) which directs the Court, on application by the first person, holding an NOC, for an order prohibiting issue of a second NOC, "to make an order in respect of a patent that is the subject of one or more allegations if it finds that none of those allegations is justified". Yet that subsection does not specify whether more than one notice of allegation may be swerved or whether, as the applicants here would have it, all allegations, one or more, of the second applicant for an NOC, are to be made at the same time in one notice of allegation.

[16] In essence, as an NOA is not a document submitted to the Court, the Court should not strike it out (see also, *Pharmacia Inc. v. Canada (Minister of National Health and Welfare)* (1994), 58 C.P.R. (3d) 307 (F.C.A.) per Stone J.A. at p. 209). However, in this case the issue does not relate to an NOA *per se* but to staying as an abuse of process a notice of application for prohibition which was properly brought on the basis of an NOA which was properly served pursuant to the Regulations.

[17] There is clear authority for the proposition that a second NOA **which is in all material respects similar to a prior NOA** served by the same generic in an earlier proceeding may be found to be an abuse of process because it would lead to an inefficient use of judicial resources, undermine the integrity of the justice system and threaten the principle of finality (see *Sanofi-Aventis Canada Inc. v. Novopharm Ltd* (2007), 59 C.P.R. (4th) 416 (F.C.A.)). In that case, the proceeding was dismissed on the ground that the innovator had lost a previous prohibition proceeding against a different generic on the basis of sound prediction being the same allegation made in this proceeding which was dismissed. The second application by the innovator was found to amount to an abuse of process because it would lead to an inefficient use of judicial resources, undermine the integrity of the justice system and threaten the principle of finality. The Federal Court of Appeal held that at p. 444 that:

> All parties are held to the same standard: they must each put forward their entire case, complete with all relevant evidence at first instance. The innovator is prevented from re-litigating an issue already decided in a proceeding to which it was a party with the aid of additional evidence it chose not to adduce in the earlier proceedings. Generics likewise must put forward their full case at the first opportunity. Multiple NOAs issued by the same generic relating to a particular drug and alleging invalidity of a particular patent will generally not be permitted, even if different grounds for establishing invalidity are put forward in each. However, where one generic has

> made an allegation but has failed to put forward the requisite evidence and argument to illustrate the allegation is justified, it would be unjust to preclude a subsequent generic, who is apprised of better evidence or a more appropriate legal argument, from introducing it. Although this situation may give rise to the possibility of an inconsistent result, this concern is overridden by the potential for unfairness to the generic that is barred from bringing forward its case simply because another generic's approach was inadequate. In each situation, it is necessary to balance the effect of a proceeding on the administration of justice against the unfairness to a party from precluding it from forward its case.

[18] While the case indicates that the doctrine of abuse of process can be utilized to dismiss an application, it is only on the basis that a prior application was dismissed on grounds substantially similar to those in issue in the second proceeding. Such is not the case here. The NOA served by ratiopharm is not in chronological time a "second" NOA by the same generic nor is there a case which has been determined on the very allegations raised in the ratiopharm NOA. These arguments by Pfizer regarding abuse of process may very well have greater success in connection with the Novopharm Proceeding once this ratiopharm proceeding has been disposed of. However, in my view the NOA issued by ratiopharm which has resulted in this proceeding does not fall within the abuse of process basket.

[19] There is no disagreement with Pfizer's argument that the regime established by the Regulations mandates and encourages the efficient use of judicial resources and discourages repetitious litigation where substantially similar allegations have been disposed of by the Court in prior proceedings. However, in this case no disposition has yet been made by the Court on any of the allegations in ratiopharm's NOA.

[20] The Federal Court of Appeal gave further consideration to the doctrines of issue estoppel and abuse of process in the context of the Regulations in *Pharmascience Inc. v. The Minister of Health and Abbott Laboratories et al.* 2007 FCA 140. That case was an appeal from an order dismissing an application under the Regulations on the basis of issue estoppel. It was held that Pharmascience could not attempt to litigate additional questions which it failed to raise in prior litigation involving the same parties and same patent. The appeal was dismissed. In the course of its reasons, the Federal Court of Appeal noted as follows:

> What the *NOC Regulations* require the second person to establish is, *inter alia*, that the patent is invalid or that it would not be infringed. In other words, the "issue" to be addressed is invalidity or non-infringement. The specific grounds on which the second person wishes to demonstrate invalidity, whether that be by obviousness, anticipation, overbreadth or lack of sound prediction, do not constitute separate issues for the purpose of issue estoppel but are merely different bases on which the second person may address the issue of invalidity. Consequently, multiple NOAs from the same generic relating to a particular pharmaceutical and alleging invalidity of a particular patent **will generally not** be permitted, even if different grounds for establishing invalidity are put forward in each. As a majority of this Court identified in *P & G* at paragraph 22, an exception to the application of this rule might be made in cases where facts material to the issue could not have been discovered with reasonable diligence at the time of the first litigation. No such exception applies in the present case, however, Pharmascience does not deny that it could have raised additional grounds of invalidity in the first NOA, but merely contends that splitting its claims is permissible within the scheme of the regulations. [emphasis added]

[21] The Federal Court of Appeal disagreed with the position of Pharmascience and concluded that "multiple NOAs alleging invalidity will **generally** not be permitted." The Court concluded that this approach is consistent with the jurisprudence and cited, *inter alia*, Madame Justice Carolyn Layden-Stevenson (as she then was) in *AB Hassle v. Apotex Inc. et al.* (2005), 38 C.P.R. (4th) 216 (F.C.), aff'd 2006 FCA at paras 73 and 76 wherein Justice Layden-Stevenson observed:

> The general rule, stated in *P &G, supra*, is that a party in one proceeding is estopped from raising an issue that it could and should have raised in a previous proceeding between the parties. Although this form of estoppel is of the weaker variety, when the conditions are met, it is a matter of discretion as to whether the party should be estopped . . .
>
> . . .
>
> As I understand it, the jurisprudence holds that a subsequent NOA is permissible when a previous NOA has been withdrawn due to difficulties in meeting regulatory requirements or **where the subsequent NOA is separate and distinct from the previous one (such as a new formulation)** or where a procedural defect with respect to the previous NOA opens the door for the transmission of a subsequent NOA. [emphasis added]

[22] It is therefore not axiomatic that two NOAs for the same drug by the same generic will necessarily result in a finding of abuse of process. Thus, on the unique facts of this case, it is apparent the ratiopharm NOA and the Novopharm NOA are separate and distinct and, as is alleged, they each rely on different formulations and excipients. They also rely on different evidence. Clearly, when they were drafted they were entirely separate and distinct and the fact of amalgamation does not change that fact.

[23] Thus, in my view, based on a consideration of all of these authorities, the very helpful submissions of counsel, and a consideration of the legal effects of an amalgamation, this application is not an abuse of process and should not be stayed (even if it could be stayed, as discussed below).

Amalgamation Issue

[24] The unique facts in this case also raise a further issue concerning the application of the *Canada Business Corporations Act* (CBCA) which, in section 186, sets out the effect of an amalgamation as follows:

> On the date shown in a certificate of amalgamation
>
> (a) the amalgamation of the amalgamating corporations and their continuance as one corporation becomes effective;
>
> (b) the property of each amalgamating corporation continues to be the property of the amalgamated corporations;
>
> (c) the amalgamated corporation continues to be liable for the obligations of each amalgamating corporation;
>
> (d) an existing cause of action, claim or liability to prosecution is unaffected;
>
> (e) a civil, criminal or administrative action or proceeding pending by or against an amalgamating corporation may be continued to be prosecuted by or against the amalgamated corporation;
>
> (f) a conviction against, or ruling, order or judgment in favour of or against, an amalgamating corporation may be enforced by or against the amalgamated corporation; and
>
> (g) the articles of amalgamation are deemed to be the articles of incorporation of the amalgamated corporation and the certificate of amalgamation is deemed to be the certificate of incorporation of the amalgamated corporation.

[25] Notably, sub-section (c) provides that "a civil, criminal or administrative action or proceeding pending" may continue to be prosecuted. Further, in sub-section (d) an "existing cause of action, claim or liability to prosecution" remains "unaffected".

[26] ratiopharm argues that in light of the provisions of section 186 this proceeding is statutorily permitted to continue. The delivery of an NOA is a step in an administrative proceeding involving the regulation of drugs and the process whereby generic drug companies obtain a required Notice of Compliance.

[27] This proceeding was commenced prior to amalgamation and therefore s. 186 should apply to permit the proceeding to continue. Pfizer argues that it is not the intention of s. 186 to oust the Court's discretion to dismiss a proceeding for abuse of process where the circumstances require such a remedy. While the Court retains discretion to control its process and stay or dismiss actions that warrant it, the circumstances must compel a finding that the proceeding is an abuse of process. Thus, while s. 186 does not oust the jurisdiction of the Court to control its own process by applying the abuse of process doctrine it provides support for the proposition that the NOA of ratiopharm is not an abuse of process under the regulatory scheme of the Regulations. It is therefore another factor which has been considered in exercising the discretion of the Court not to declare the ratiopharm NOA, now meaning the Teva NOA, which gives rise to this proceeding, an abuse of process.

Staying this Proceeding

[28] Pfizer argues that if it is determined that this proceeding is an abuse of process then the Court should stay this proceeding indefinitely. Even if it were found to be an abuse of process it is doubtful the proceeding could be stayed absent the requirements of the Regulations being met. The Regulations provide in s. 7(5)(b) that the Court may extend the 24-month statutory stay granted under section 7(1). However, the stay may be extended in only two circumstances: 1) where the

parties consent; or, 2) if the Court finds that one party has failed to reasonably co-operate in expediting the proceeding. None of these circumstances apply here. The parties do not consent and there has been no failure by the parties to move the matter forward. Indeed, a hearing date is imminent in March, 2011. Pfizer did not, and in this case managed case, could not put forward evidence to satisfy the second part of the statutory requirement.

[29] Thus, this is not a case where the Court could extend the stay. While the Court has inherent jurisdiction to control its own process which would extend to issuing stays in appropriate cases, in the face of a clear statutory admonition that the stay can be extended on only two specific grounds, it is questionable whether such a remedy could be granted. As noted by Justice Mackay in AB *Hassle v. Canada (Minister of Health), supra*, at p. 134 as follows:

> In the alternative, the applicants seek an order staying these proceedings until final disposition of the appeal proceedings, A-394-96 and A-398-96, initiated following the first round of proceedings, with an extension of the time provided by paragraph 7(1)(e) of the *Regulations* for the Minister to refuse issue of an NOC, for a period equal to the stay. **Even if I were so disposed, I am not sure that s-s 7(5) would here be applicable for there is no evidence before me that a party to this application failed to cooperate reasonably in expediting the application, the statutory ground upon which the Court may extend the time.** [emphasis added]

[30] Thus, on the basis of the provisions of the Regulations the granting of a stay is severely circumscribed. To use Justice Mackay's approach, even if the Court were to conclude that this proceeding was based on an NOA which was a "second" NOA by the same generic and finding it raised substantially similar allegations based on substantially similar formulations and excipients, the Court's ability to extend the stay, without evidence meeting the statutory requirements of the Regulations, is doubtful.

Conclusion

[31] Thus, in considering all of these matters and the unusual sequence of events giving rise to the arguments on this motion, it must be dismissed. The disposition of costs was not reviewed at the hearing. The parties therefore, if they are unable to agree on costs, may make brief written submissions not exceeding three pages. The moving party shall submit their submissions within 15 days and the responding party shall submit theirs within 10 days thereafter.

ORDER

THIS COURT ORDERS that:

1. The motion is dismissed.

2. In the event the parties are unable to agree on costs, they make brief written submission not exceeding three pages in length. The moving party shall serve and file their written submissions within 15 days of the date of this Order. The responding party shall submit their written submissions within 10 days thereafter.

"Kevin Aalto"
Case Management Judge

FEDERAL COURT

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKETS:	T-1422-09
STYLE OF CAUSE:	PFIZER CANADA INC., WARNER-LAMBERT COMPANY AND WARNER-LAMBERT COMPANY LLC v. RATIOPHARM INC. AND THE MINISTER OF HEALTH
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