Date: 20090911

Docket: T-1636-08

Citation: 2009 FC 902

Toronto, Ontario, September 11, 2009

PRESENT: Kevin R. Aalto, Esquire, Prothonotary

BETWEEN:

ASTRAZENECA CANADA INC., ASTRAZENECA AB and SHIONOGI SEIYAKU KABUSHIKI KAISHA

Applicants

and

NOVOPHARM LIMITED and THE MINISTER OF HEALTH

Respondents

REASONS FOR ORDER AND ORDER

[1] This proceeding commenced by the Applicants ("AstraZeneca") pursuant to the *Patented Medicines (Notice of Compliance) Regulations* (the "Regulations") seeks an order, *inter alia*, prohibiting the Minister of Health from issuing a Notice of Compliance to the Respondent ("Novopharm") in respect of 5, 10, 20 and 40 mg rosuvastatin calcium tablets until the expiration of Canadian Patents Nos. 2,072,945 (the '945 Patent) and 2,313,783 (the '783 Patent).

[2] This lengthy and intensely argued motion is the second chapter in an exchange of motions regarding the conduct of this proceeding. It is a direct result of a prior order granting a reversal of evidence regarding invalidity on the motion brought by AstraZeneca. On that motion Novopharm strenuously resisted reversing the evidence and argued that if such an order was made that Novopharm be given a right of reply.

[3] Although this motion sought other relief including an order striking the Notice of Application on the ground that it is vague and bereft of any particulars or grounds in support of the bald assertions made, or alternatively an order striking certain paragraphs of the affidavits of AstraZeneca's witnesses, the matter proceeded almost entirely on the basis of Novopharm's right to file reply evidence.

[4] Before dealing with the merits of the motion as it relates to the filing of reply evidence it is helpful to put this motion in context. In its submissions on the motion for reversal of evidence AstraZeneca made the following submissions:

> 2. Novopharm bears the evidential burden on the allegation of invalidity. The proposed reversal of the order of evidence on the allegation of invalidity will ensure that Novopharm adduces evidence on an issue before AstraZeneca does. **This will streamline the proceeding by requiring Novopharm to define more specifically what it is alleging as its grounds of invalidity first. This will avoid the Applicants speculating and filing evidence in a vacuum and specifically, providing evidence on every portion of prior art reference and possible point of alleged invalidity before Novopharm has discharged its evidential burden on every such issue.**

> 39. Requiring Novopharm to serve its evidence on alleged invalidity first will streamline the proceeding. It will focus the dispute. **It will reduce the likelihood of interlocutory motions, including that the Applicants will have to seek to file reply evidence should Novopharm rely, for example, on an unanticipated portion of one of the cited references.** It will also reduce the number of experts, the volume of evidence, and minimize the proliferation of secondary issues. Accordingly reversal of the order of evidence will result in the just, most expeditious and least expensive determination of the merits without affecting Novopharm's substantive rights and maintaining the fairness of Novopharm's procedural rights. [emphasis added]

[5] In response, Novopharm made this argument:

> 49. Having regard to the insufficiency of the Applicants' Notice of Application and evidence on this motion, and the likelihood that the Applicants' will file factual evidence with respect to the validity of the 945 Patent, the Court should not order a reversal of evidence in this proceeding. **Novopharm should not be put in a position where it is forced to speculate regarding the evidence that the Applicants will file on the issues of invalid selection and obviousness. If required to do so, Novopharm will undoubtedly be forced to seek leave to file reply evidence.** Clearly, this will not result in the just, most expeditious and least expensive determination of the issues. [emphasis added]

[6] In granting the motion to reverse the evidence on invalidity, the Court noted as follows:

> In my view, it is not axiomatic that the right to file reply evidence be granted where there is a reversal of evidence on invalidity. However, there will be cases where it is entirely likely that reply evidence will be required once the innovator has responded to the evidence of the generic where the filing of evidence is reversed. **Based on my review of the record and on the submissions of the parties, it is my view that this is likely such a case.** (T-1636-08, January 30, 2009) [emphasis added]

[7] Notwithstanding the vigorous argument of AstraZeneca that the reversal would result in avoiding interlocutory motions dealing with reply evidence and lead to the just, most expeditious and least expensive determination of this proceeding, such is clearly not the case. Indeed, the reversal of evidence has resulted in delaying this proceeding, adding another layer of expense (i.e. the cross-examination of a witness on her affidavit conducted in the United States) in addition to the costs and time expended on this motion.

[8] Novopharm is seeking to file the reply affidavits of three expert witnesses who each filed affidavits in chief pursuant to the order reversing the evidence on invalidity. The proposed reply affidavit of Dr. Romero is 24 pages in length and comprises 66 paragraphs and many diagrams of chemical compounds. The proposed reply affidavit of Dr. Scallen is 18 pages in length and comprises 36 paragraphs with several charts. Dr. Scallen's affidavit also attaches as exhibits five decisions of this Court and the Federal Court of Australia, which deal with the drug atorvastatin calcium. The proposed reply affidavit of Dr. Grieco is 15 pages in length and comprises 50 paragraphs.

[9] Each of these affidavits is required, so it is argued, because the Notice of Application is bereft of any relevant facts to permit Novopharm to know the case it has to meet. There is no information in the Notice of Application as to why the '945 Patent is not a selection patent and no information regarding rosuvastatin's special advantage over other statins disclosed in an earlier genus patent. Further, it is argued that the evidence of two of AstraZeneca's experts, Drs. Roush and Bartlett, provide lengthy discussions as to why the '945 Patent is not obvious. That evidence

was not known to Novopharm when it served its evidence. Thus, as none of this evidence was apparent from the Notice of Application and could not reasonably have been anticipated, the issues on the application are not "fairly joined" and will not be "fairly joined" unless Novopharm has a right of reply. Novopharm argues that it was required to file its evidence, essentially in a vacuum, without knowledge of AstraZeneca's position as to:

(a) why the '945 Patent is not a selection patent (or, if is one, why it is a valid selection);

(b) the nature of any alleged special advantage;

(c) why the alleged patent is special;

(d) why the '945 Patent is not anticipated by the Fey Application (the Australian patent); and,

(e) why the '945 Patent is not obvious.

[10] As Novopharm served its evidence without knowledge of AstraZeneca's position on any of these points, should it now have a right of reply?

[11] AstraZeneca argues that no reply is warranted. Essentially, it argues that Novopharm has not demonstrated, based on the affidavit filed in support of this motion, of any need to serve reply evidence; that such evidence in any event is an attempt by Novopharm to split its case; that the evidence is repetitive and duplicative of evidence already given; that "much" of it should have been known to Novopharm and therefore should have been part of its evidence-in-chief; that such reply evidence should be dealt with on cross-examination of AstraZeneca's experts; and, that it was available at an earlier date.

[12] AstraZeneca has filed a responding motion record which includes three charts attached to the written representations. The charts total some 54 pages in length and represent an analysis on a virtual paragraph by paragraph and line by line basis why the reply evidence in each of the affidavits is improper and should not be allowed.

[13] Having reviewed the affidavits in reply and the issues as formulated by Novopharm, it is my view that the Court on the hearing of the Application will benefit from reply evidence and the issues between the parties will be properly joined. In large part this is because it is essential for the Court to have before it a record from a party that responds to new evidence or facts or issues raised for the first time by a party in its materials.

[14] While there is no automatic right of reply in proceedings under the Regulations, where a party raises an issue or puts forward evidence that is new or unanticipated to the other party, then that party ought to have the right of reply. This is particularly so where a notice of application, as here, is bereft of any substantive information or grounds in support and amounts to nothing more than an empty collection of boilerplate denials. Reply evidence in such cases becomes more than likely.

[15] Here, AstraZeneca has obtained a procedural advantage by obtaining an order reversing the order of evidence on invalidity. It now seeks to enhance that advantage by denying any right of reply to Novopharm in the face of evidence from Novopharm's witness that there are aspects of the responding evidence of AstraZeneca that are new or were unanticipated. It is not for a

generic/respondent to speculate in its evidence as to every piece of evidence that an applicant may choose to argue or put forward to support its application. This is especially so, as noted, where the notice of application contains mere bald denials. For example, in this Notice of Application, AstraZeneca simply states in respect of invalidity:

> 20. AstraZeneca disputes that the '945 patent is invalid on any of the legal and/or factual bases asserted by Novopharm, for at least the following reasons.
>
> 21. If the '945 patent properly construed, is a selection patent, AstraZeneca disputes that it is an invalid selection patent on any of the bases asserted by Novopharm.
>
> 22. AstraZeneca also disputes that the claims of the '945 patent are anticipated, obvious, lack utility, and claim more broadly than any invention made or disclosed, and that the patent is insufficient on any of the bases asserted by Novopharm.

[16] These are simply bald denials and do not inform Novopharm of what evidence may be ultimately lead by AstraZeneca to support them. There is no roadmap for Novopharm to follow to understand the case which AstraZeneca will put forward. Novopharm cannot know everything that AstraZeneca may lead by way of evidence and is not required to speculate on every possible point. This was the exact argument made by AstraZeneca in its motion seeking the reversal of evidence. To speculate on every possible point that might be raised may lead to already unnecessarily long affidavits that do not focus for the Court the issues to be decided and likely lead to obfuscation of the real issues in dispute. It is sufficient that if they can anticipate an area of evidence that will be lead because it is raised or reasonably alluded to in the Notice of Application they should endeavour to deal with it in their evidence-in-chief.

[17] In my view, AstraZeneca cannot have it both ways: obtain a procedural and strategic advantage by having Novopharm lead its evidence first on invalidity and then argue that Novopharm should anticipate everything that AstraZeneca might say in its evidence and not be allowed to reply. As described in more detail below, much of AstraZeneca's argument is that Novopharm "could" or "should" have anticipated the evidence and dealt with it in chief.

[18] The evidence before the Court, which AstraZeneca endeavoured to undermine in cross-examination, is that the issues noted above were unexpected and thus reply is necessary to join issue with AstraZeneca. It is argued by AstraZeneca that it is a requirement for proper reply evidence that it was not available at an earlier date. Thus, AstraZeneca argues that Novopharm and its experts could and should have anticipated the evidence of AstraZeneca. In my view, that is a bit like putting the cart before the horse. If the objective of reversing the evidence on invalidity in proceedings under the Regulations is to let the applicant know the case it must meet on this issue then that is all that is required of the generic/respondent in leading its evidence-in-chief. It must put all of its evidence forward to support the allegations it is relying upon that are contained in its NOA. Novopharm did just that and endeavoured to anticipate some of the evidence of AstraZeneca. However, it is AstraZeneca that has now raised issues that Novopharm says it did not anticipate and now requires leave of the Court to file reply.

[19] The Court has carefully considered all of the cases relied upon by AstraZeneca in support of its arguments. In particular, *Atlantic Engraving v. Lapointe Rosenstein* (2002), 23 C.P.R. (4th) 5 (F.C.A.) sets out the tests to be met by a party seeking to file reply evidence. These tests are as follows:

> (a) the evidence to be adduced will serve the interests of justice;
>
> (b) the evidence will assist the Court;
>
> (c) the evidence will not cause substantial prejudice to the other side;
>
> (d) the evidence was not available at an earlier date.

[20] Subject to the comments below, having reviewed the proposed affidavits and notwithstanding their undue length, I am satisfied that they will assist the Court, serve the interests of justice, and not cause substantial or serious prejudice to the other side. With respect to the latter point, the affidavits are from the same witnesses who gave affidavits in chief. Thus, there are no additional cross-examinations to arrange.

[21] The fourth factor, whether the evidence was available at an earlier date, is more problematic. AstraZeneca strenuously argues throughout its submissions and charts that there is virtually nothing in the affidavits that was not "known" at the time Novopharm delivered its original affidavits in chief. That may very well be true but the fact that it was "known" or "available" is not the end of the analysis. The knowledge of evidence or the availability of evidence at an earlier date must mean evidence that was known to be relevant and required. It must be remembered that it is Novopharm, as a result of AstraZeneca's motion, which is putting its best foot forward on the issues they have

delineated in their NOA to support their case and must meet their evidential burden on the issue of patent invalidity. They have no roadmap from AstraZeneca as to what evidence it will put forward to respond because the Notice of Application comprises bald denials without any guidance as to AstraZeneca's position. It cannot be an answer that Novopharm could or should know that AstraZeneca's experts will take the positions they took. To do so is to require parties in the position of Novopharm to guess and speculate at what all of the evidence of AstraZeneca will be.

[22] AstraZeneca argues that there is no support for the proposition that Novopharm is entitled to file reply evidence because it could not anticipate the evidence of AstraZeneca. It is argued that to accept this argument would always lead to the conclusion that reply evidence is proper as a party will never be able to anticipate all of what another party will say. This generalization, while at first blush appealing, fails detailed scrutiny. The fact that a party may baldly state they did not anticipate evidence will not be sufficient to permit reply evidence to be filed. The party will have to demonstrate, as here, that they were caught by surprise and did not anticipate a position that is now argued. In *Solvay Pharma Inc. et al v. Apotex Inc. et al.* (T-427-06, June 15, 2007) Prothonotary Tabib made the following observation regarding reply evidence:

> I would add, as a general comment, that the bald statement by any expert that he or she could not have anticipated a certain approach or argument, or that a certain approach or argument is not in the notice of allegation, should be accorded very little weight, if any. To the extent the matter can be assessed on the plain reading of the notice of allegation and affidavits by a lay person, then a bald statement by an expert to the contrary will not carry weight. To the extent the assessment cannot be made without an expert's assistance, then a bald statement is of no assistance in understanding or justifying the subtle distinctions that apparently need to be made.(page 12)

[23] It is to be noted that Prothonotary Tabib's comments were made in the context of a notice of allegation which is a detailed statement of the position of the generic. The affidavit of Dr. Romero in support of this motion states that the reply is focused on matters which were not anticipated and then provides specific details of that evidence and why it was not anticipated and her opinions in response. That is sufficient to meet the required tests for reply evidence.

[24] Having found reply to be appropriate in this case, the affidavits may be served and filed subject to the following observations. Reply evidence should be brief and focused. Reply evidence should not engage in unnecessary and useless editorializing. Reply evidence should not be repetitive of information that is already contained in the evidence in chief except where necessary to establish the point to be made in reply. In this case, AstraZeneca did not concede a single sentence of any of the affidavits as being appropriate by way of reply.

[25] In the cross-examination of Dr. Romero, AstraZeneca endeavoured to demonstrate that Dr. Romero's evidence should be discounted because she was unsure when she had reviewed the Notice of Application and conceded she had never seen the NOA. AstraZeneca criticizes Dr. Romero because if she had reviewed those documents she would have understood better the case of AstraZeneca and "could and should" have raised all of the matters in her reply affidavit in her original affidavit in chief. This argument also fails scrutiny. Properly retained and instructed experts are not advocates of a party. Experts should be independent and provide their opinion on matters as requested or required by a party. It is not for the expert to advocate a position or review documentation for the purpose of advocating a position for a party. Such an approach could bring

the opinion of the expert into question and be given little weight. Here, Novopharm sought and obtained an opinion based upon specific parameters set out in counsel's request. There is no necessity for the expert to go beyond the parameters of the opinion requested unless it is obvious from the scope of the opinion as requested. Failing to review the NOA or Notice of Application in this case by Dr. Romero does not result in her evidence in support of this motion being discounted nor the necessity of her reply evidence.

[26] The major attacks on the various paragraphs of the reply affidavits are that they are argumentative; or they amount to case-splitting; or they are repetitive and duplicate evidence already given; or, there are statements which simply disagree with statements by AstraZeneca's experts and should be the subject of cross-examination. The Court is in agreement that to the extent reply affidavits engage in case-splitting, argument or are repetitive, they are improper. The difficulty is that the Court is being asked to parse the proposed reply affidavits to determine what parts of the affidavits, if any, offend these principles and should be struck. Experienced counsel ought to know the proper approach to reply evidence and include only that which is proper.

[27] Having determined that based on the evidence on this motion that some reply is warranted on the issues described above, it is necessary to provide directions to the parties as to the scope of the reply affidavits. It is an extraordinarily wasteful exercise for the Court to review and parse purported reply affidavits page by page, paragraph by paragraph, line by line or word by word as argued by AstraZeneca. The volume of material and need to review and understand the original

affidavits as well as the proposed affidavits puts a significant and unwarranted burden on the Court and has led, in this case, to substantial delay, which is further discussed below.

[28] Dealing with the Romero affidavit, AstraZeneca made much of the fact that Dr. Romero knew that her opinions should be "thorough and complete" as she acknowledged on her cross-examination. Because Dr. Romero did not deal with certain issues in her affidavit in chief AstraZeneca says that the reply affidavit, in large part, amounts to case-splitting. For example, AstraZeneca makes this argument on page five of its analysis of Dr. Romero's affidavit:

> In any event, at the time of her first affidavit, Dr. Romero did have the Kathawal '895 "patent" and Beck papers (see para. 105a) and f)), and could have been provided with the Kathawal review as it is referenced in the NOA. She had the opportunity to express all her views on these references at that time.

[29] Much of the case-splitting argument of AstraZeneca when one reviews their chart in detail is that Dr. Romero "could" have given all of the evidence in chief. However, Dr. Romero is not required to provide opinions she is not asked to provide if AstraZeneca has not put the position in play. Thus, this argument falls flat and the proposed reply affidavit should be accepted.

[30] AstraZeneca also points to a number of sentences which are repetitive of evidence given in her first affidavit. One example of this is found in paragraph 24 of the proposed reply affidavit (page 10 of the chart). A sentence fragment is alleged to be repetitive of the first Romero affidavit. There is a lengthy analysis by AstraZeneca of why this sentence fragment is repetitive. Frankly, having carefully read the submissions it is virtually impossible, unless one were a chemist, to understand how it is repetitive and, in the scheme of the affidavit and the evidence as a whole, why

it is improper reply. Even responding to new unanticipated positions requires some modest amount of repetition.

[31] AstraZeneca also argues that a number of paragraphs of the proposed reply affidavit are improper because they are not expert opinions but are essentially editorializing. Paragraphs 42 and 67 are examples. They are improper and should be struck. The remainder of the affidavit is acceptable even though some portions are repetitive of positions taken. They are not substantial in the scheme of the affidavit and counsel should in future refrain from permitting experts to engage in repetition of evidence previously given unless absolutely required for context.

[32] With respect to the Grieco reply affidavit, AstraZeneca makes many of the same points. It also argues that any references to the need for reply evidence should be ignored as Dr. Grieco was not made available for cross-examination. Having found on the basis of Dr. Romero's affidavit that reply is appropriate, I need not consider further the comments in either the Grieco or Scallen proposed reply affidavits to the effect that reply is necessary. The most inappropriate paragraph of the proposed Grieco reply affidavit is the final paragraph which is nothing more than editorializing and is struck. It reads:

> 50. Drs. Roush and Bartlett ignore these points and present a biased and misrepresentative view of the art that does not reflect what a person of ordinary skill in the art, in the real world, would have been taught.

[33] AstraZeneca is correct that this kind of argumentative editorializing oversteps the boundary of proper reply. However, having carefully reviewed all of the allegations made by AstraZeneca in its 19 page chart, the bulk of the allegations fall into the same categories as those relating to Dr. Romero's proposed reply affidavit. Thus, having considered them all, even though some are repetitive, they do not detract from the reply evidence and may remain.

[34] Finally, the attack on Dr. Scallen's proposed reply affidavit is the same as that of Drs. Romero and Grieco. Examples of the kind referred to above relating to Dr. Romero's affidavit abound. The attacks are fundamentally focused on what Dr. Scallen could or should have said in his first affidavit. However, as he did not, as with Dr. Romero's and Dr. Grieco's proposed reply affidavits, his reply affidavit may stand subject to the removal of the argumentative editorializing in paragraphs 35 and 36.

[35] The other issues on the motion were argued briefly but not to the extent of the need for reply which was the real focus of the motion. Having considered the submissions of the parties on these matters, those parts of the motion are dismissed. It is my view that the Notice of Application should not be struck as Novopharm now has the entirety of AstraZeneca's positions and evidence on the allegations in the Notice of Application. The fact that leave is granted to Novopharm to file reply evidence permits a response to any of the concerns regarding the bald allegations in the Notice of Application. Finally, although Novopharm sought to strike the affidavit of Dr. Leiter and other portions of AstraZeneca's evidence on the basis that it did not deal with issues raised in the Notice

of Application, again by virtue of filing reply evidence the issues with AstraZeneca are now fairly joined.

[36] As Novopharm has been substantially successful on this motion it is entitled to its costs in any event of the cause.

[37] The hearings coordinator has established hearing dates for this matter in March, 2010. By virtue of the delay that has occurred by this motion, the parties are now required to use their very best efforts to ensure that cross-examinations are completely quickly to ensure the necessary filing dates are met for a March hearing. The fact that this may put pressure on the parties is one of the results of motions such as these which are vigorously contested in circumstances where the need for reply has been met and should have been clear to counsel.

ORDER

THIS COURT ORDERS that:

1. The Respondent, Novopharm Limited, is granted leave to file the proposed reply affidavits of Drs. Romero, Grieco and Scallen in accordance with the reasons given herein.

2. The balance of the motion is dismissed.

3. Costs of the motion to Novopharm Limited, in any event of the cause.

"Kevin R. Aalto"
Prothonotary

FEDERAL COURT

SOLICITORS OF RECORD

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