

**Date: 20090202**

**Docket: T-818-08**

**Citation: 2009 FC 113**

**Toronto, Ontario, February 2, 2009**

**PRESENT: Kevin R. Aalto, Esquire, Prothonotary**

**BETWEEN:**

**PROCTER & GAMBLE PHARMACEUTICALS CANADA INC.  
and THE PROCTER & GAMBLE COMPANY**

**Applicants**

**and**

**THE MINISTER OF HEALTH and RATIOPHARM INC.**

**Respondents**

**REASONS FOR ORDER AND ORDER**

[1] This proceeding is an Application commenced pursuant to the *Patented Medicines (Notice of Compliance) Regulations* (the “Regulations”) seeking an order prohibiting the Minister of Health (the “Minister”) from the issuing a Notice of Compliance to the Respondent, ratiopharm inc. (“ratiopharm”) for its proposed risedronate product.

[2] The Applicants have brought this motion to strike 18 separate items of evidence, including prior art, that references, quotes and includes prior art in the affidavit of Dr. George Lenz (the “Lenz

Affidavit”) that is alleged to exceed the Notice of Allegation (“NOA”). The evidence sought to be struck is described by the Applicants as “precisely the kind of affidavit evidence to be struck.” The main argument of the Applicants is that as none of the fifteen prior art references and three factual references that are sought to be struck are referred to specifically in the NOA they ought to be struck at this early stage of the proceeding. Specifically, the Applicants seek an order striking the following portions of the Lenz Affidavit:

- (a) Paragraph 36, including footnote 4;
- (b) Paragraph 51, including footnote 9;
- (c) Table 1 of paragraph 73;
- (d) The second sentence and quotation of paragraph 76, including footnote 14;
- (e) The second sentence and quotation of paragraph 80;
- (f) The second sentence and diagram of paragraph 89, including footnote 18;
- (g) The second sentence and diagram of paragraph 90;
- (h) Paragraph 131, including footnote 23;
- (i) The first four sentences of paragraph 132, including footnote 24;
- (j) References to the pamidronate patent in paragraphs 133 and 134, including footnote 26;
- (k) Paragraph 144-146, including footnotes 35 and 36;
- (l) Reference to Dr. Benedict in paragraph 149;
- (m) Table 1 of paragraph 159;
- (n) Paragraphs 206-208, including footnotes 42 and 43; and
- (o) Exhibits B, C, D, E, F, G, I, J, K, L, M, P, Q and R.

[3] In turn, ratiopharm argues that the issue of admissibility of the impugned portions of the affidavit is best left to the hearings judge and, in any event, they are merely confirmatory of the opinion expressed in the affidavit. Further, they argue that on the basis of a shift in Canadian Patent Law in *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.* 2008 SCC 61 the impugned portions of the affidavit should be permitted to stand.

[4] In this case, there was a reversal of evidence on invalidity to which ratiopharm consented. ratiopharm served its affidavit evidence on September 30, 2008 which includes the affidavit that is the subject of this motion. Approximately one month after receiving ratiopharm's evidence, the Applicants served this motion to strike out the impugned phrases in issue on this motion.

[5] This motion engages two decisions of the Federal Court of Appeal: *AB Hassle v. Canada (Minister of National Health & Welfare)* 38 C.P.R. (4<sup>th</sup>) 216 (F.C.) affirmed 47 C.P.R. (4<sup>th</sup>) 329 (F.C.A.) ("*Hassle*") and *Mayne Pharma (Canada) Inc. v. Aventis Pharma Inc.*, 38 C.P.R. (4<sup>th</sup>) 1 (F.C.A.) ("*Mayne*"). The *Hassle* case stands for the proposition that "the entire factual basis is to be set forth in the detailed statement rather than revealed piecemeal when some need happens to arise in a section 6 proceeding" (per Justice Layden-Stevenson, as she then was, in the trial decision at paragraph 51 page 236). *Mayne*, on the other hand, while endorsing this proposition, also sends a very clear message that this type of motion should be deferred to the hearings judge.

[6] In upholding the decision of Justice Leyden-Stevenson in *Hassle*, Justice Sharlow of the Federal Court of Appeal observed as follows:

It has been recognized by this Court that a notice of allegation, together with the detailed statement of the factual and legal basis of the allegations stated in the notice, plays a critical role in defining the issues to be determined in proceedings under the *NOC Regulations*. The notice of allegation and detailed statement must address all relevant patent claims, and must contain enough information to allow the “first person” (as defined in the *NOC Regulations*) to make an informed decision as to whether to respond to the notice of allegation by commencing an application for a prohibition order. A notice of allegation that meets these tests is said to be “sufficient”. The corollary is that a “second person” (as defined in the *NOC Regulations*) cannot, in response to a first person’s application for prohibition, present evidence and argument relating to an issue that is outside the scope of the notice of allegation and detailed statement. (Para. 4, pages 332-33).

[7] The Applicant argues on the basis of the *Hassle* case that the entire factual basis for an allegation must be set out in the NOA. Thus, they argue that as the references in the Lenz Affidavit are not referred to in the NOA they should be struck. As further support for this proposition, the Applicant cites the *Mayne* case in support of the proposition that prior art that is not included in the NOA should be struck out. In *Mayne*, at paragraph 16, Justice Nadon made the following statement:

**Although this Court has stated in unequivocal terms that this type of motion should preferably be deferred to the hearing judge, it has not held, as a matter of principle, that Motions Judges must defer such motions to the hearing judge.** Thus, a Motions Judge will not be found to have erred in law if he or she decides to deal with the motion. Whether or not, in a given case, the Motions Judge has made a reviewable error will be dealt with on the basis of the applicable standard of review. I should add that this Court has also made it clear that it will rarely interfere with a Motions Judge’s decision to defer the matter to the hearing judge. [emphasis added]

[8] This point has been recently emphasized in the decision of *Lundbeck Canada Inc. v.*

*Canada (Minister of Health)*, 2008 FCA 265 at par. 6 as follows:

The fact that the *Federal Courts Act*, R.S.C. 1985, c. F-7, provides for appeals as of right in interlocutory matters from a Prothonotary to a Judge of the Federal Court, and then to the Federal Court of Appeal, is not an open invitation to subject discretionary decisions at first instance to close scrutiny. The interests of justice are normally best served in summary and, indeed, in other proceedings, by minimising delays in the determination of the substantive matter. **Whenever possible, the resolution of ongoing evidential wrangles (and some procedural issues) should be left to be decided by the judge hearing the application, or conducting the trial.** [emphasis added]

[9] Procedural motions such as this seeking to strike all or parts of affidavits in NOC proceedings must be the exception not the norm. The very clear message in *Mayne* is that such motions are better left to the hearings judge. However, the Federal Court of Appeal did not go so far as to make it a firm principle that such motions as this must be deferred to the hearing judge. This is so as it allows the Court to control its own process and to deal with those clear cut cases where new facts are being improperly put forward in some form of a guise when they should have formed part of the NOA.

[10] In *Mayne*, the central argument put forward on the appeal from the motions judge was that the impugned paragraphs which the motion judge struck did not constitute new facts. The Federal Court of Appeal reiterated that the detailed statement must be such as to make a patentee fully aware of the grounds that are relied upon for claiming that the issuance of an NOC would not lead to infringement of a listed patent because it is because upon those grounds that a patentee decides

whether or not to initiate a section 6 proceeding. Permitting other grounds to be raised after the fact would prejudice the patentee. The detailed statement is therefore the key document in the determination of whether or not a section 6 proceeding will be commenced. As noted by Justice Nadon at paragraphs 21-22:

If the Applicant patent holder must plead to the grounds raised in the detailed statement, even though other grounds of infringement may exist, it is patently unfair to allow the Respondent to raise different grounds of infringement in its evidence in reply to the application for prohibition. The Respondent, the second person, sets the parameters of the dispute in its detailed statement it cannot then change those parameters after the Applicant for prohibition, the first person, has framed its application to address the issues raised by the detailed statement.

Whether, in a given case, the detailed statement of the legal and factual basis of a second person's NOA is "sufficiently complete ... as to enable the patentee to assess its course of action in response to the allegation ..." falls to be decided by the motion's judge or the hearing judge, as the case may be. Unless the decision made in regard thereto is made on a wrong principle of law or by reason of a misapprehension of the evidence, it will not be interfered with.

[11] The Court then reviewed the various paragraphs of the affidavits in dispute. The Court determined that certain paragraphs did amount to new grounds and therefore the motions judge was correct in striking them. In so doing the Court observed as follows at paragraph 25:

I cannot conclude that Noël J. erred in concluding that the appellant could not rely on paragraphs 71 to 75 of Professor Durst's affidavit. U.S. Patent '813 is a fact which should have been disclosed in the appellant's NOA, if the intention was to use it as a basis on which to argue non-infringement. This is not a question of replying to a new fact raised by the first person; it is, rather, an attempt to by the appellant to provide an additional basis of non-infringement in the section 6 proceeding. In my view, this is precisely the kind of affidavit evidence to be struck pursuant to our decision in *AB Hassle*, *supra*: the existence of U.S. Patent '813 could or should have been known to the appellant earlier and included in its NOA. To permit a

**new factual basis** for the allegation of non-infringement at this stage would be to allow the appellant second person to improve its case in a “piecemeal fashion”, an unfair result for the respondent first person. If the Appellant intended to rely on U.S. Patent ‘813 to argue that the protective group used by its process could not have been contemplated by the inventors of the ‘682 Patent as an obvious equivalent, it was obligated, as per *AB Hassle, supra*, to disclose its position in the detailed statement. Consequently, I cannot find any error in the conclusion reached by Noël J. [emphasis added]

[12] What is key in this part of the *Mayne* decision is the determination that a new factual basis for the allegation of non-infringement was being raised by the generic and thus the evidence was struck. With respect to other evidence which was also struck by Justice Noel, the Court of Appeal allowed the appeal on the basis that those facts were not “new” facts and were found in the detailed statement.

[13] In this case, the motion is brought at a very early stage of the proceeding before the Applicants have filed their evidence. They are therefore not prejudiced by not having the opportunity to respond to the evidence. It can also be argued that it is easier at this stage of the proceeding to sort out this kind of procedural issue before all the evidence is served. However, this does not address the real issue in dispute. That is, whether on an interlocutory procedural motion such as this, the evidence sought to be struck is so obvious that it is “new” evidence or a new ground being relied upon such that it ought to be struck and not left to the hearings judge. In my view, this evidence is not so clearly outside the ambit of the NOA that it ought to be struck.

[14] Counsel for the respective parties very helpfully provided charts outlining the impugned evidence and providing a summary of their positions as to its propriety. As is apparent from a

review of the impugned evidence in the Lenz Affidavit, it ranges from the seemingly picayune (a single name), to more substantial bits and pieces (a single sentence, footnotes, chemical formulae, portions of paragraphs, and whole lengthy paragraphs and quotations from texts or monographs). The impugned portions are also littered throughout the 223 paragraphs of the 69 page affidavit. The Applicants are seeking to take a fine-toothed comb to each and every sentence and reference in the Lenz Affidavit to determine if it is referred to or somehow referenced in the NOA. At any stage of the proceeding it is difficult to engage in this comparative exercise.

[15] A review of few examples puts the issues in perspective. One of the impugned items in the Lenz Affidavit is a portion of paragraph 51 which reads:

The bioavailability of clodronate, like other bisphosphonates, is very poor. Dr. Benedict, who is named as an inventor of the 727 Patent, reported that the absolute bioavailability of clodronate is 1-2% in man.

[16] The last sentence of this paragraph has a footnoted reference to a monograph which is authored by a number of individuals including Dr. Benedict, one of the inventors of the patent in issue. The monograph is entitled “Clodronate kinetics and bioavailability” and is attached as Exhibit C to the Lenz Affidavit. Clodronate is a prior art compound. Its structure, investigation and use, is extensively discussed in the Lenz Affidavit in paragraphs 41 – 52. Only a portion of paragraph 51 and the cited reference are argued to be improperly included in the Lenz Affidavit as they are not specifically referenced in the NOA.



[17] However, clodronate is specifically discussed in the NOA at p. 11 and in the 727 patent at page 2 and at page 10 of the 376 Patent. It can hardly be said that the impugned paragraph of the Lenz Affidavit does not in some fashion refer back to the NOA.

[18] Another example of the type of evidence sought to be struck is found in paragraph 73 of the Lenz Affidavit wherein Dr. Lenz includes a reference as follows:

Table 1

1) *Univalent atoms and groups*

F            OH            NH<sub>2</sub>            Me            Cl

[19] The text of the paragraph which describes bioisosteric replacement is not impugned. Only the Table which illustrates the opinion and is confirmatory of the opinion is impugned. As the Table merely confirms his opinion and flows from the opinion and text of the paragraph, again, it can hardly be said that it is “precisely the kind of affidavit evidence that should be struck”. It does not raise a new ground not raised or alluded to in the NOA.

[20] The remaining portions of the impugned evidence in the Lenz Affidavit can also be found to have some point of reference in the NOA or are confirmatory of the opinions expressed in the Lenz Affidavit. At this juncture of the proceedings they should not be struck although the Applicants may argue on the hearing that these parts of the Lenz Affidavit ought not to be considered.

[21] Before leaving this issue it is worthwhile to consider some of the general jurisprudence of this Court relating to the striking of affidavits. While counsel referred the Court to the leading

decisions in proceedings pursuant to the Regulations dealing with the striking of evidence, this Court has opined many times on principles governing the striking of affidavit evidence generally. For example, one helpful case is that of Justice Hugessen, as a member of the Trial Division, in *Sawridge Band v. Canada*, [2000] F.C.J. No. 192, where he was faced with a motion to strike an affidavit. He observed at paragraphs 5 and 6 of his decision:

5. Dealing first with the motion brought by the interveners that the affidavit of Clara Midbo should be struck out as it is an improper affidavit within the meaning of the Rules, I may say that upon examination of that affidavit, I have no doubt whatever that it is improper. It is replete with conclusory and argumentative allegations, almost all of them being on matters of law as to which the deponent is not apparently qualified. I set out below, simply by way of example, paragraphs 3 and 4 of the affidavit in which the deponent attempts to interpret the pleadings, the Rules and various orders that have been made in this case, something which she is eminently unqualified to do and something which is clearly not a matter for evidence in any event:

6. That said, I have not been persuaded that the affidavit should be struck. **In my view, in a sane modern procedure, irregularities in proceedings should not be made the subject of motions and should not require the Court to give orders striking out or correcting such irregularities unless the party attacking the irregularity can show that it suffer some sort of prejudice as a result thereof.** I put that point squarely to counsel for the interveners and the only prejudice he was able to suggest to me that his clients might suffer was that the Court, when it hears the main motion, might be induced to believe that these highly tendentious allegations in the affidavit were uncontested matters of fact. I think that counsel is ascribing to the Court a degree of gullibility which I hope he is not justified in doing. Accordingly, absent any showing of prejudice and notwithstanding that almost all of the affidavit is irregular and should not be before the Court, I have no grounds that would justify me in striking it out. Counsel for the interveners admits readily that virtually every paragraph of the affidavit is proper argument and can properly be made by counsel for plaintiffs and indeed has been made by counsel for plaintiffs in his written submissions in support of the main motion.

I am therefore going to dismiss the motion to strike the affidavit.  
[emphasis added]

[22] Another case dealing with this issue is by Justice Richard, as he then was, as a member of the Federal Court Trial Division in *Unitel Communications Co. v. MCI Communications Corp.*, [1996] F.C.J. No. 1126, where he refused to strike out an affidavit. In paragraph 6 of his decision he notes:

Counsel for the Canadian defendants relied on a judgment of this court in *Home Juice Company v. Orange Maison Limited* [See Note 1 below], a decision of the then President Jackett. In that case, objection had been taken to the relevancy or admissibility of affidavits filed in trade mark proceedings and Mr. Justice Jackett looked at the timeliness of the application to strike. He said:  
As a practical matter, the most efficient and economical way of deciding such questions is by having them so raised and decided at the hearing and as a practical exercise of judicial discretion the parties should not be permitted to raise them before the hearing. The two exceptions of that general rule that I contemplate at the moment are:

(a) where a party has to obtain leave to admit evidence and it is obvious in the view of the court that it is inadmissible, and;

**(b) where the court can be convinced that as a practical matter the admissibility of the affidavits filed by one of the parties should be considered some time before the hearing so that the hearing can proceed in an orderly manner.** [emphasis added]

[23] A further case supporting the proposition that the hearing judge is best situated to deal with evidentiary issues is that of *Chopra v. Canada (Treasury Board)*, [1999] F.C.J. No. 835. In that case, Justice Dubé expressed the following view at paragraph 6 of his reasons:

On the other hand, there is also jurisprudence to the effect that the Court has no jurisdiction to strike out affidavits by way of motion in anticipation of a judicial review proceedings. The appropriate

procedure is to leave the affidavit for evaluation by the judge who hears the application on the merits [See Note 5 below]. Judicial review is a summary procedure, the focus of which is advancing the application along to the hearing stage as expeditiously as possible. The ultimate adequacy of the allegations and evidence must be addressed by the judge hearing the application on its merits [See Note 6 below]. **There is an exceptional discretion to strike out affidavits but it ought to be exercised sparingly. To maintain the efficiency of judicial review proceedings, interlocutory contests as to affidavits should be discouraged and be left to be dealt with by the judge hearing the application.** [emphasis added]

[24] Finally, the admonition of Prothonotary Hargrave in *Yazdanian et al. v. MCI*, (IMM-4894-97, June 29, 1998) at paragraph 2 is apposite:

**For the sake of efficiency and, as a practical exercise of judicial discretion, parties ought not to be permitted to strike out each others affidavits. This generality is, of course, subject to special circumstances: for example, where an affidavit is abusive or clearly irrelevant; where a party has obtained leave to admit evidence which turns out to be obviously inadmissible; or where the court is convinced that the matter of admissibility should be resolved at an early date so that a hearing may proceed in an orderly manner.** There is case law to this effect in a number of decisions including in *Home Juice Company v. Orange Maison Ltd.*, [1968] 1 Ex.C.R. 163 at 166 (President Jackett) and in *Unitel Communications Co. v. MCI Communications Corporation* (1997), 119 F.T.R. 142 at 143. In the latter Mr. Justice Richard (as he then was) noted that the trial judge would be better placed to assess the weight and admissibility of such affidavit material (pages 143 and 145). Of course conjecture, speculation and legal opinion have no place in an affidavit. [emphasis added]

[25] Taking these various principles in mind, it seems to me that even if there are some portions of the impugned evidence in the Lenz Affidavit that fall outside the ambit of the NOA, there are no special circumstances or prejudice which will be occasioned to the Applicants by leaving the

impugned parts of the Lenz Affidavit in evidence at this juncture of the proceedings. The Applicants allege special circumstances in that they will be prejudiced because if these impugned sections of the Lenz Affidavit are allowed to remain the Applicants will have to respond to these parts of the evidence at extra expense and time in circumstances where they argue a hearing judge will have to ignore them in any event. However, it can hardly be said that any of the impugned evidence is new to them or a surprise in that much of it relates to the chemical formulations of the drug in issue and some references to writings of the inventor. Further, as noted above there is a connection between the impugned evidence and the NOA or it is confirmatory of an opinion expressed in the Lenz Affidavit.

[26] It is to be noted that Justice Hughes dealt with the issue of whether an issue raised which is not in an NOA should be considered at the hearing in the case of *Pfizer et al. v. Minister of Health et al.*, [2008] F.C.J. No. 630. He noted at paragraphs 88 - 89:

[88] This argument is a construct, made after the evidence has been put in and tested by cross-examination and after Pfizer had filed its written Memorandum of Argument. It is not an argument that was put on the table in the Notice of Allegation. There is no clear evidence from Pharmascience's witnesses as to these matters, the matter is argued from bits and pieces of cross-examination of Pfizer witnesses. This matter closely parallels the situation discussed by the Federal Court of Appeal in the "*celecoxib*" case *G.D. Searle & Co. v. Novopharm Ltd.*, 2007 FCA 173. I had determined at the hearing of the matter at the trial level a substantive issue of validity on the basis of evidence adduced during the cross-examination by the generic's counsel of one of the named inventors offered in evidence by the innovator. The matter had not been raised in the Notice of Allegation. This was wrong the Court of Appeal said at paragraphs 33 and 34 of its Reasons:

[33] The NOA defines the issues to be determined in proceedings under the Regulations. Furthermore,

deciding a case on a basis not raised by parties gives rise to an issue of procedural fairness (see *AB Hassle v. Canada (Minister of National Health and Welfare)* (2000), 7 C.P.R. (4th) 272 (F.C.A.) at paras. 16-21; Regulations, ss. 5(1), 5(3)(a); *Pfizer Canada Inc. v. Canada (Minister of Health)* (2006), 46 C.P.R. (4th) 281 (F.C.A.) at para. 32). Counsel for Searle made the valid point that if it had been raised before the Applications Judge, evidence could have been called and submissions made accordingly.

[34] In my analysis, reviewed on a correctness standard, in proceeding as he did, the Applications Judge did not afford procedural fairness to Searle, thereby committing an error of law (see *McConnell v. Canada (Human Rights Commission)*, 2005 FCA 389 at para.7). Furthermore, the determination that Searle is not the applicant under section 2 of the Act is not supported by the record. It is true that the assignment agreements were only executed in May-July of 1996. However, this does not establish that Searle was not the owner of the invention as of the time of discovery. Obviously, a person who is the owner of the rights of the invention can be an applicant. In my view, the Applications Judge erred when he limited the definition of applicant in this case “to a legal representative of the named inventors Talley et al.” (see the passage of the Reasons for Judgment quoted at para. 27 above).

**[89] I find that it would be equally wrong to consider the anhydrate/hydrate issue here where the matter was not raised in the Notice of Allegation and Pfizer had no real opportunity to put in evidence and argument on the point.** Even if I am incorrect in so finding, I cannot provide any view on the evidence given. The evidence is inconclusive and not clearly directed to the issue raised. If anything, the issue should have been framed as a “*claims broader*” than the invention made and/or disclosed issue, but no such allegation was made. I simply cannot provide a proper view on what I would have found had Pharmascience made an allegation in this respect whether framed as “*claims broader*” or otherwise. I would have found, on the evidence that I do have, that the balance of probabilities has not been satisfied by Pharmascience. [emphasis added]

[27] Here, the Applicants have ample opportunity to respond to the evidence of ratiopharm and will not be prejudiced in any way that cannot be compensated for in costs if the hearings judge ultimately determines that this evidence should not be admitted.

[28] Finally, it must be emphasized again that these types of motions are the exception not the rule. Much time is taken up in Court by parties wrangling over procedural issues that are frequently better dealt with either by the hearings Judge or when a more complete record is available. Proceedings under the Regulations need to be more insulated from procedural niceties given the counter-intuitive nature of proceedings under the Regulations. Conducting an “autopsy”, to apply Justice Hughes’ description of discovery [See *AstraZeneca et al v. Apotex Inc.*, 2008 FC 1301, paragraph 19], on every word and reference in an affidavit to determine if they relate to issues raised in the NOA is not conducive to proceedings under the Regulations moving expeditiously.

**ORDER**

**THIS COURT ORDERS that:**

1. This motion is dismissed but without prejudice of the right of the Applicants to raise at the hearing of the Application that the impugned references in the affidavit of Dr. Lenz are inadmissible.
2. If the parties are unable to agree on the issue of costs, ratiopharm inc. may make written submissions, limited to three pages, to the Court within 15 days of the date of this order and the Applicants may respond within 10 days thereafter also limited to three pages.

\_\_\_\_\_  
"Kevin R. Aalto"  
Prothonotary



**FEDERAL COURT**

**NAMES OF COUNSEL AND SOLICITORS OF RECORD**

**DOCKET:** T-818-08

**STYLE OF CAUSE:** PROCTER & GAMBLE PHARMACEUTICALS  
CANADA INC. and THE PROCTER & GAMBLE  
COMPANY v. THE MINISTER OF HEALTH and  
RATIOPHARM INC.

**PLACE OF HEARING:** TORONTO, ONTARIO

**DATE OF HEARING:** December 15, 2008

**REASONS FOR ORDER  
AND ORDER BY:** AALTO P.

**DATED:** February 2, 2009

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