Date: 20060714

Docket: T-836-04

Citation: 2006 FC 861

BETWEEN:

AVENTIS PHARMA INC. and
SANOFI-AVENTIS DEUTSCHLAND GmbH

Applicants

and

PHARMASCIENCE INC. and
THE MINISTER OF HEALTH

Respondents

AMENDED REASONS FOR ORDER AND ORDER

GAUTHIER J.

[1] Aventis Pharma Inc. and Sanofi-Aventis Deutschland GmbH (collectively "Aventis") seek a declaration that the Pharmascience's letter dated March 11, 2004 (the NOA) is not a notice of allegation and detailed statement as contemplated by the *Patented Medicines (Notice of Compliance Regulations)*, S.O.R. /93-133 (the "Regulations") and, in the alternative, an order prohibiting the Minister of Health from issuing a Notice of Compliance ("NOC") to Pharmascience in respect of ramipril oral capsules of 2.5mg, 5mg and 10mg until after the expiration of Canadian Patent 2,023,089 (the "'089 Patent").

[2] Aventis' brand name product, which is the reference product for Pharmascience's abbreviated new drug submission, is ALTACE.

[3] The drug ramipril is an angiotensin-converting enzyme (ACE) inhibitor that has long been used for the treatment of hypertension (high blood pressure). The patent on the compound itself, Canadian Patent 1,187,087 (the "'087 Patent"), expired on May 14, 2002.

[4] The claims of the '089 Patent are limited to the use of ramipril for the treatment of cardiac and vascular hypertrophy (a general increase in bulk of part of an organ not due to tumor formation) and hyperplasia (an increase in the number of cells in a tissue or organ, for example an increase in the number of cells that line blood vessels). The '089 Patent was added by Aventis to the patent register for ramipril after the expiry of the '087 Patent.

Related patents and proceedings

[5] Although the '089 Patent is the only one in play in the present proceeding, it is worth noting that there are at least three other patents on the patent register for ramipril, they are:

a) Canadian Patent 1,341,206 (the "'206 Patent"), which claims a broad class of compounds that covers ramipril, although this compound is not itself mentioned.
b) Canadian Patent 1,246,457 (the "'457 Patent"), which claims the use of ramipril for the treatment of cardiac insufficiency (heart failure).

c) Canadian Patent 2,055,948 (the "'948 Patent") which claims a further new use for ramipril in combination with a calcium antagonist for the treatment of proteinuria.

[6] Pharmascience has also served a notice of allegation alleging non infringement of the '948 Patent and this resulted in an application in file T-1602-04, which was heard together with this application but will be dealt with in a separate order as different evidence was filed by the parties.

[7] The three patents described in paragraph 5, above, have been the subject of other applications under the Regulations. In *Aventis Pharma Inc. v. Pharmascience Inc*., 2005 FC 340, [2005] F.C.J. No. 511, Justice Judith Snider held that Pharmascience's allegation that the '206 Patent was invalid for obviousness and double patenting was not justified and that Pharmascience's notice of allegation in respect of the '457 Patent was deficient. However, Justice Snider did not comment on the merits of the non-infringement allegations of Pharmascience with respect to the '457 Patent. At the time of the hearing, this order was still under appeal.

[8] In *Aventis Pharma Inc. v. Apotex Inc*., 2005 FC 1381, [2005] F.C.J. No. 1691, Justice Sandra Simpson ruled that Apotex's notice of allegation alleging that it would not infringe the '457 Patent was not justified because it had not been established how it would prevent its product from being used by patients for the treatment of cardiac insufficiency. This order is under appeal.

[9] Justice Anne Mactavish held in *Aventis Pharma Inc. v. Apotex Inc.*, 2005 FC 1283, [2005] F.C.J. No. 1559, that Apotex's notice of allegation, alleging that the '206 Patent was invalid, was

justified. This decision was confirmed by the Federal Court of Appeal in *Aventis Pharma Inc. v. Apotex Inc.*, 2006 FCA 64, [2006] F.C.J. No. 208.

[10] Finally, in *Aventis Pharma Inc. v. Apotex Inc*, 2005 FC 1461, [2005] F.C.J. No. 1793, Justice Konrad von Finckenstein held that Apotex's notice of allegation was sufficient and justified with respect to its allegation that it would not infringe the '089 Patent since it would be selling ramipril specifically for the treatment of hypertension rather than for treating hypertrophy or hyperplasia. This order is under appeal.

[11] Some of these decisions are relevant because Aventis argued that the Court should, on the basis of judicial comity, follow the decision of Justice Judith Snider with respect to the inadequacy of Pharmascience's notice of allegation, whereas Pharmascience said that the Court should be guided by the decision of Justice Konrad von Finckenstein with respect to the effect of a certain reference in Pharmascience's product monograph (the Benetos reference) upon the latter's allegation of non-infringement.

[12] Also, it is worth noting that the twenty four (24) months stay in the present file and in T-1602-04 will expire on September 1, 2006 (it was extended by consent).

[13] Although, in its NOA, Pharmascience initially alleged that the '089 Patent was invalid for various reasons including anticipation and double patenting, the parties are agreed that this proceeding now only involves the allegation of non-infringement and, more particularly, the non-infringement of the use claims such as Claim 11, which reads as follows:

> 11. A use of a compound of the formula I as claimed in any one of claims 1 to 8 or of an agent as claimed in claim 10 for the treatment of cardiac and of vascular hypertrophy and hyperplasia.

[14] Considering the issues to be decided in this case, the most relevant portions of Pharmascience's NOA are the following:

> 089 Patent Claim 11
>
> (…)
>
> This claim would not be infringed by the making, constructing, using or selling by Pharmascience of the drug for which the submission for the Notice of Compliance has been filed. In particular, the Pharmascience products containing ramipril for which a Notice of Compliance is sought will only be made, constructed, used, promoted for use and sold by Pharmascience for the treatment of hypertension …
>
> (…)
>
> The Pharmascience Product and Its Use
>
> 15. The Pharmascience products for which a Notice of Compliance is sought are capsules containing Ramipril for the treatment of hypertension. These products will not be made or sold for the treatment of cardiac and of vascular hypertrophy and hyperplasia.
>
> 16. In particular, the product monograph will not list such uses, the Notice of Compliance is not being sought for such uses, and the marketing of the product by Pharmascience will not include any references to such use
>
> (…)
>
> Non-Infringement of New Use Claim
>
> (…)

> 39. The grant of an NOC for an old product cannot be restrained unless it is proved that infringement will occur and that the second person has implicated itself in the infringements by, for example, inducing or encouraging them. *AB Hassle v. Canada (Minister of National Health and Welfare)* (2002) 22 C.P.R. (4th) 1 (F.C.A.); *Lundbeck v. Gerpharm* [sic], (supra); *Lundbeck v. Apotex* (supra).

[15] Aventis filed three affidavits. Their affiants are:

i) Franca Macino, the Director of Regulatory Affairs at Aventis Pharma Inc. Her affidavit essentially serves to put into evidence the text of the '089 Patent and Pharmascience's NOA.

ii) John David Parker, a doctor qualified to practice in Ontario and Massachusetts who teaches medicine and pharmacology at the University of Toronto and practices cardiology at the University Health Network and at Mt. Sinai Hospital. Among other things, he describes the practice of physicians that prescribe ramipril and explains how he and others would use the generic version of ramipril in the same way Altace is used.

iii) Barbara Marie Berry, who worked as a licensed pharmacist in Manitoba from 1974 to 2004 and was called to the Bar in that province in 1993. She also worked as a health care consultant and is the author of a textbook entitled *Canadian Pharmacy Law*. Ms. Berry was asked to provide an opinion as to whether Pharmascience's ramipril product, once available on the market, will be used by patients for the treatment of cardiac and of vascular hypertrophy and hyperplasia, even though Pharmascience has not sought federal regulatory approval for such uses.

[16] Pharmascience relied on the affidavits of:

i) Leonard Neirinck, Pharmascience's Vice-President of Scientific Affairs, who states that Pharmascience is seeking an NOC only to sell ramipril for the treatment of hypertension. He also says that the application for the listing on provincial formularies by Pharmascience "will be based on approval for use in the treatment of hypertension". He appends a draft product monograph and a draft label. He also explains that, if anyone were to inquire with Pharmascience whether their version of ramipril is "approved for cardiac and vascular hypertrophy and hyperplasia, Pharmascience will respond, 'not at this time'".

ii) Michael Kutryk, who holds a Ph.D. in cardiovascular physiology and is currently an Assistant Professor at the University of Toronto Medical School as well as an interventional cardiologist at St. Michael's Hospital. Dr. Kutryk comments on the prevalence of cardiac and vascular hyperthophy and gives his opinion on the incidence of these conditions as caused by hypertension and as caused by any other factor.

iii) Ronald Henry Kluger, a professor of chemistry at the University of Toronto whose opinion on the meaning of the claims is not particularly relevant to the specific issues to be determined by the Court for reasons that will be explained later.

iv) Ronald Nefsky, a licensed pharmacist in Ontario whose mandate was to describe how a drug product is selected for dispensing when the pharmacist has the choice of more than one brand of the same medication. Mr. Nefsky based his explanation on the premise that Pharmascience would have obtained an NOC for the use of

> ramipril to treat hypertension only and would have sought and obtained a listing under the Ontario Drug Benefit Formulary where its product's interchangeability would be limited to use in the treatment of hypertension.

[17] All these affiants were cross-examined.

Issues

[18] First, Aventis argues as a threshold issue that, as found by Justice Snider in *Aventis Pharma Inc.*, above, the NOA is deficient because it fails to explain how infringement by patients would not occur. In that respect, the NOA contains only a bald assertion of non-infringement.

[19] Second, Aventis says that Pharmascience's allegation of non-infringement is simply not justified because Aventis' expert evidence clearly establishes that infringement by patients will inevitably occur. According to Aventis, this is true regardless of whether one considers the infringement by patients who suffer from hypertension as well as one of the uses covered by the '089 Patent or whether one only looks at the more limited use of patients who suffer from cardiac or vascular hypertrophy or hyperplasia without suffering from hypertension (*Proctor and Gamble Pharmaceutical Canada v. Canada (Minister of Health)*, 2002 FCA 290, commonly known as *Genpharm*).

[20] Moreover, Aventis claims that, even if the Court adopts Pharmascience's interpretation of the law (see *AB Hassle v. Canada (Minister of National Health and Welfare)*, 2002 FCA 421), its allegation of non-infringement would still not be justified. In that respect, it submits, among other

things, that Pharmascience's product monograph contains a reference which clearly teaches that ramipril reverses cardiac hypertrophy (the Benetos reference). Contrary to what is asserted in the NOA, this reference would suggest to an informed person that Pharmascience's ramipril product could be employed for a patented use.

[21] Pharmascience admitted at the hearing that its NOA does not address the issue of infringement by patients. It submits that it did not have to do so. It says that such infringement is only relevant if the use by patients was induced or procured by Pharmascience.

[22] Although Pharmascience does not agree that Aventis has established that infringement by patients would be inevitable, most of its submissions at the hearing focused on the legal test applicable pursuant to sub-paragraph 5.1(b)iv) of the *Regulations* and on whether the Court should follow Justice von Finckenstein's finding that the inclusion of the Benetos reference in the product monograph is not sufficient to justify a finding of infringement by inducement or procurement (*Valmet OY v. Beloit Canada Ltd.* (1988), 20 C.P.R. (3d) 1 at 14 (F.C.A.)).

[23] At the hearing, considerable time was spent by the parties discussing the meaning of the decisions of the Court of Appeal in *Genpharm* and *AB Hassle*, above, as well as twelve other decisions of this Court. Similarly, the Court spent quite some time reviewing these cases. But before these reasons were completed, the Court of Appeal issued its decision in *Pharmascience Inc. v. Sanofi-Aventis Canada Inc*., 2006 FCA 229. This decision essentially settles, in my view, the first two issues raised by Aventis. Thus, it will not be necessary to review in any detail the

arguments put forward by the parties, for these were essentially the same ones as those they presented to the Court of Appeal in *Pharmascience*, above.

Analysis

[24] The nature of the proceedings as well as the history and the scheme of the Regulations have been described and commented upon in several cases (*Fournier Pharma Inc. v. Canada (Minister of Health),* 2004 FC 1718 at para. 6, 8-9), including the recent decision of the Supreme Court of Canada in *Bristol-Myers Squibb Co. v. Canada (Attorney General),* [2005] 1 S.C.R. 533, commonly known as *Biolyse*.

[25] The principles with regard to the burden of proof in such proceedings were summarized by Justice Arthur Stone of the Federal Court of Appeal in *Hoffman Laroche Limited v. Canada (Minister of National Health and Welfare),* [1996] F.C.J. No. 1333 at paragraphs 7 and 8.

a) Is the NOA deficient?

[26] The Court agrees with Aventis that there are no relevant factual or evidentiary distinctions between the situation that was before the Justice Snider in *Aventis Pharma Inc*., above, and the present one. The Court would have been bound on the basis of judicial comity to adopt the same conclusion. Given that the Court of Appeal has now found that the NOA in that case was perfectly adequate, because Pharmascience only had to deal with the factual and legal basis supporting its allegation that it did not itself infringe the ’089 Patent, the Court is bound to adopt the same conclusion.

[27] In that respect, it is worth noting that the Court of Appeal found at paragraph 25 that the NOA in *Pharmascience*, above, was not a bald assertion of non-infringement because there was a clear reference to the fact that its marketing would not be directed toward the treatment of cardiac insufficiency. The passage of the NOA quoted at paragraph 23 of the Court of Appeal's decision contains no more information than what is included in the passages quoted at paragraph 13, above.

[28] I conclude that the NOA is adequate.

b) Is Pharmascience's allegation of non-infringement justified?

[29] Before analyzing the evidence, it is essential to determine the test to be applied, for this was the main point of contention between the parties at the hearing. This essentially depends on the interpretation to be ascribed to sub-paragraph 5.1(b)iv) of the *Regulations*.

[30] As mentioned, the arguments made by the parties before the Court were essentially the same as those they presented to the Court of Appeal in *Pharmascience*, above. In its decision, the Court of Appeal addresses the apparent contradictions between the *Genpharm* and *AB Hassle* decisions, above, and clarifies their meaning. **It reconsiders the ambit of sub-paragraph 5.1(b)iv) in light of the recent decision of the Supreme Court of Canada in *Biolyse*, above. In particular Justice Karen Sharlow said:**

> **55. I turn now to the relevant words of subparagraph 5(1)(b)(iv) of the *NOC Regulations*, which sets out the required**

contents of a non-infringement allegation. It states that in a non-infringement allegation, the generic drug producer must allege that:

> **... no claim for the medicine itself and no claim for the use of the medicine would be infringed by the making, constructing, using or selling by that person of the drug for which the submission for the notice of compliance is filed.**
>
> **... aucune revendication pour le médicament en soi ni aucune revendication pour l'utilisation du médicament ne seraient contrefaites advenant l'utilisation, la fabrication, la construction ou la vente par elle de la drogue faisant l'objet de la demande d'avis de conformité.**

56. Pharmascience argues that the words "by that person" means that this provision refers only to acts of Pharmascience that would constitute infringement of the 457 patent (which I understand would include acts of Pharmascience that induce or procure infringement by others). Aventis argues that subparagraph 5(1)(b)(iv) is capable of being read more broadly, and should be read more broadly, so that it includes any infringement by anyone of the 457 patent that results in any way from the issuance of a notice of compliance to Pharmascience.

57. In my view, the interpretation proposed by Pharmascience is more consistent with the ordinary grammatical meaning of subparagraph 5(1)(b)(iv) of the *NOC Regulations*, and is also more consistent with the legislative scheme and purpose. Subsection 55.2(4) of the *Patent Act* and by extension the *NOC Regulations* are intended to prevent patent infringement by Pharmascience, not by patients.

58. The narrower interpretation proposed by Pharmascience is also more consistent with the general scheme of the *Patent Act*. The bargain represented by the 087 patent permits anyone to use the patented invention (that is, to make ramipril using one of the claimed processes) once the term of that patent expired in November of 2002. If Pharmascience is now prevented from obtaining a notice of compliance for its ramipril capsules for use in the treatment of hypertension only because the inevitable result is infringement of the 457 patent by patients who use the Pharmascience product for the

> **treatment of cardiac insufficiency, the practical result will be an artificial extension of the monopoly represented by the now expired 087 patent. I do not believe that Parliament intended the *NOC Regulations* to permit such a result. (This point is also made in *AB Hassle*, at paragraph 57.)**
>
> **59. I acknowledge that there are statements in *Genpharm* that could be taken to support the broader interpretation of subparagraph 5(1)(b)(iv) proposed by Aventis (see, for example, paragraphs 45 to 50). I make three observations about those statements. First, they are *obiter dicta*, made in the context of evidence that Genpharm would in fact market its product for a use that came within the claims of one of the listed patents, which was not true in *AB Hassle* and is not true in this case. Second, *Genpharm* was decided before this Court had the benefit of the decision of the Supreme Court of Canada in *Biolyse*. In my view, the statements in paragraphs 45 to 50 of *Genpharm* interpret subparagraph 5(1)(b)(iv) in a manner that is not consistent with *Biolyse*. Third, although I remain of the view that *Genpharm* was correct in result, paragraphs 45 to 50 of *Genpharm*, read in isolation, do not reflect the correct interpretation of subparagraph 5(1)(b)(iv) of the *NOC Regulations*, and to that limited extent should be taken to have been reversed by *AB Hassle*.**
>
> **60. For these reasons, I conclude that the narrower interpretation of subparagraph 5(1)(b)(iv) of the *NOC Regulations*, as proposed by Pharmascience, is correct. As there is no evidence that Pharmascience will infringe the 457 patent, or that it will induce or procure the infringement by others of the 457 patent, the allegation of non-infringement of the 457 patent is justified. It follows that, even before the 457 patent expired on December 13, 2005, there was no basis upon which the Federal Court could have granted the application of Aventis for an order prohibiting the Minister from issuing a notice of compliance to Pharmascience for its ramipril capsules.**

[31] This means that even if Aventis does prove that infringement by patients of the use claims of the ’089 Patent is highly probable, if not inevitable, it would not be sufficient to establish that Pharmascience’s allegation of non-infringement is not justified.

[32] In that context, it would normally only be necessary to make a finding in respect of use by patients if I found that Aventis had established that Pharmascience's product monograph or its other proposed actions can support a finding of infringement by inducement or procurement.

[33] However, given that the delay to seek permission to appeal in *Pharmascience*, above, has not expired, the Court will assess the evidence in respect of potential infringement by patients.

[34] For that purpose, it will not be necessary to determine whether the claims at issue should be construed restrictively or not. I am satisfied that my conclusion on this issue would be the same whether or not the use claims are construed, as suggested by Pharmascience, to cover only the use by patients suffering from cardiac or vascular hypertrophy not caused by hypertension.

[35] As is the case here, Pharmascience had submitted evidence to Justice Snider with respect to limited interchangeability (in particular the affidavit of Mr. Nefsky). The learned judge had considered that this was an impermissible attempt by Pharmascience to expand the factual basis of its non-infringement allegation. The Court of Appeal in *Pharmascience*, above, did not make any finding in that respect (see para. 28) but it noted that the remedy in such a case would be to disregard the evidence, not to find the NOA to be inadequate.

[36] Having carefully considered the NOA before me, I am satisfied that Pharmascience cannot support its allegation of non-infringement on the basis of the fact that it would only seek a limited interchangeability listing on the Ontario formulary and that it would send a separate warning to

health professionals with respect to the limited use for which its NOC was granted. This simply goes beyond the factual basis asserted in the NOA.

[37] However, the Court has considered this evidence in assessing the weight to be given to the evidence of Ms. Berry for she asserts at paragraph 14 of her affidavit that it is highly probable that Pharmascience's product would be listed as a generic bio-equivalent of ALTACE in the Manitoba drug benefits and interchangeability formulary, regardless of its federally approved use. Pharmascience is entitled to present evidence to rebut that statement.

[38] I have also reviewed very carefully the transcripts of the various cross-examinations and considered the arguments raised by Pharmascience with respect to the little weight that should be given to Ms. Berry's affidavit as well as some of the contradictions or admissions made by Dr. Parker.

[39] Based on my review of all the evidence, I find that it is highly probable that Pharmascience's ramipril product will be listed without restriction, at least in Manitoba and in Ontario (*Astrazeneca Canada Inc. v. Apotex Inc.*, 2006 MBCA 21). Although it is conceivable that the situation would be the same in the other provinces, there is no evidence to that effect before me, for I agree that Ms. Berry and Mr. Nefsky are not qualified to give an opinion in respect of the situation in those provinces. I also note that these two affiants are not qualified to opine on the knowledge and practices of doctors, even in their respective provinces.

[40] I accept the evidence of Dr. Parker and Dr. Kutryk, who are both well qualified as experts on the matters referred to in their affidavits. I accept Dr. Kutryk's opinion that the rate at which ramipril would be prescribed for the treatment of hypertrophy or hyperplasia, in cases where the cause is something other than hypertension, is very low. Nevertheless, considering the popularity of this drug and the prescribing practices of doctors in Ontario, including the fact that hospitals use mostly, if not only, the generic version of drugs (even for Zoloft, which was the only product listed for a limited use in Ontario), I have concluded that it is probable, if not inevitable, that at one point patients suffering from hypertrophy and hyperplasia that do not also suffer from hypertension (albeit few in number) will use Pharmascience's product for the patented uses.

[41] That said, is there any evidence that Pharmascience's proposed product monograph or the actions it intends to take will induce the infringement by such patients? Aventis alleges that the uses covered by the '089 Patent are discussed in an article of Athanase Benetos *et al.*, "Effects of Ramipril on Arterial Hemodynamics" (1991) 18:2 Journal de Cardiovascular Pharmacology 153 (the Benetos reference). As I mentioned earlier, Aventis made this same argument before Justice von Finckenstein in *Aventis Pharma Inc*., above. In that case, the Court found that the Benetos reference could not be considered to link ramipril with the treatment of cardiac and vascular hypertrophy and hyperplasia. In that respect, Justice von Finckenstein said:

> [35] As for the Benetos Article, on which Aventis "hangs its hat" to quote its counsel, I do not find that it amounts to the requisite "something more" for the following reasons:

a) it does not appear in the body of the product monograph nor is it footnoted anywhere. The Benetos Article is merely cited as the first reference among 18;

b) it does not deal with Hypertrophy but as the introduction states:

the aim of this study was to determine the arterial effects of the ACE inhibitor ramipril in relation to its acute and chronic antihypersentensive action.

c) the word hypertrophy is only mentioned once; the word hyperplasia is not mentioned at all;

d) the sentence containing the word "hypertrophy" is in the introductory background portion of the article and it refers to another article. The sentence reads:

Angiotensin-coverting enzyme (ACE) inhibitors have been reported to lower BP, reverse cardiac hypertrophy (3), and improve large arteries compliance (4) .

If one then looks up footnote (3) of the Benetos Article, one finds the following reference:

Asmar R, Journot H, Lacolley P, Santoni JP, Billaud E, Safar M. Treatment for one year with perindopril: effect on cardiac mass and arterial compliance in essential hypertension. *J Hypertens* 1988; 6 (suppl 3): S33-40. (Underlining added)

There is no dispute that perindopril is an ACE inhibitor but there is also no dispute that it is not ramipril;

e) there is no evidence that the reference to the Benetos Article will guide the behaviour of physicians or pharmacists. Aventis' star expert witness, Dr. Dagenais, whose qualifications are not questioned by Apotex merely states in his affidavit:

20. The list of references at page 45 of the draft product monograph includes a paper dealing with the use of ACE inhibitors in the treatment of cardiac hypertrophy. In reference 1, entitled "Effects of Ramipril on Arterial Hemodynamics", published in 1991 the authors note on page S153:

> Angiotensin - converting enzyme (ACE) inhibitors have been reported to lower BP [Blood Pressure], reverse cardiac hypertrophy, and improve large arteries compliance.
>
> A copy of the reference is attached as Exhibit "B".
>
> Neither Dr. Dagenais nor any other expert witness provide any evidence that purports to show how the Benetos article is linked to infringement by doctors, pharmacists or patients.

> [36] In short, Aventis would like to establish a nexus between Apotex and indirect infringers not on the basis of anything contained in the body of the Original PM but on the basis of a mere footnote contained in a reference appended to the Original PM. However, as the foregoing analysis shows, except for the one word " hypertrophy" in the background introductory paragraph of the appended reference (directing one to a study on perindropril), there is no link whatsoever between the Benetos Article and Hypertrophy. I fail to see how the mere use of the word in a referenced article not dealing with Hypertrophy can in any way be interpreted to establish a nexus (i.e. meet the "something more" requirement as that term was used by Sexton J.A. in *AB Hassle v. Minister of Health & Welfare, supra*).
>
> (My emphasis)

[42] Aventis argues that the Court should not follow this decision because it is clearly wrong. It says that Justice von Finckenstein did not properly consider the fact that the sentence underlined in the passage quoted above refers to inhibitors and not simply to the inhibitor referred to in the reference at footnote 3 of the article (perindopril).

[43] Even if this were true (and I do not need to decide this), the Court does not find that it could justify the conclusion sought by Aventis.

[44] Although, there is some evidence that Pharmascience would provide copies of this article on request (Q:136 of the cross-examination of Mr. Neirinck), there is no indication that it is customary for health professionals to make such requests. It is also far from evident that pharmacists and doctors customarily review generic products monographs when they are familiar with the brand name product. In fact, Dr. Kutryk indicated that he infrequently reads the product monograph when a drug is genericized (Q:179 of his cross-examination). Mr. Nefsky also indicated that, in the normal course of things, he would not read a generic product monograph when he receives it because he would have already read the innovator product monograph and there would be no real need to do so. (Q: 76 of his cross-examination).

[45] There is no evidence as to how the Benetos reference would affect other health professionals if they happened to read the product monograph, requested a copy of this reference from Pharmascience and actually reviewed it.

[46] I have no good reason not to adopt the conclusion reached by Justice von Finckenstein in *Aventis Pharma Inc*., above. In fact, I am convinced that I would have reached the same conclusion, even in the absence of this precedent.

[47] Finally, I have considered the other argument put forth by Aventis on the basis of Pharmascience's statement that it would not send letters to health professionals advising them of the possible infringement of the '089 Patent.

[48] The evidence and the arguments presented to the Court cannot support the conclusion that Pharmascience's allegation of non-infringement is not justified. Aventis has not met its burden of proof.

[49] This application is dismissed with costs which should be assessed on the basis of Column III of Tariff B.

ORDER

THE COURT ORDERS that:

1. The application is dismissed with costs to be assessed on the basis of Column III of Tariff B.

"Johanne Gauthier"

Judge

FEDERAL COURT

NAME OF COUNSEL AND SOLICITORS OF RECORD

DOCKET: T-836–04

STYLE OF CAUSE: Aventis Pharma Inc. et al. v. Pharmascience Inc. et al.

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REASONS FOR ORDER: The Honourable Madam Justice Gauthier

DATED: **July 14, 2006**

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