Date: 20080304

Docket: T-127-07

Citation: 2008 FC 291

Ottawa, Ontario, March 4, 2008

PRESENT: The Honourable Mr. Justice Martineau

BETWEEN:

SANOFI-AVENTIS CANADA INC. and
SANOFI-AVENTIS DEUTSCHLAND GmbH

Applicants

and

LABORATOIRE RIVA INC. and
THE MINISTER OF HEALTH

Respondents

REASONS FOR ORDER AND ORDER

[1] This is an application brought under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 as amended (NOC Regulations). The medicine at issue is commonly known as ramipril which is used in the treatment of hypertension, an "old" use for this compound, and in the management of patients at increased risk of cardiovascular events, a "new" use for this drug, among other uses.

[2] The applicants, Sanofi-Aventis Canada Inc. (Sanofi-Aventis) and Sanofi-Aventis Deutschland GmbH, sell drugs in Canada including ramipril which they sell under the name ALTACE. The respondent, Laboratoire Riva Inc. (Riva), wants to sell its generic version of this drug (Riva-Ramipril). In accordance with the NOC Regulations, Riva served a Notice of Allegation on Sanofi-Aventis asserting that the patents listed in respect of the drug, Canadian Patents 2,382,549 (’549 patent) and 2,382,387 (’387 patent) (together, the HOPE Patents), would not be infringed if the Respondent Minister of Health (the Minister) were to issue a Notice of Compliance (NOC) to Riva to permit it to sell its generic Riva-Ramipril in Canada. The Applicants are of the opinion that Riva will induce physicians, pharmacists and patients to infringe the HOPE Patents and have accordingly initiated this proceeding to prohibit the Minister from issuing a NOC.

[3] For the reasons that follow, this application for prohibition is dismissed with costs. Essentially, the applicants have failed to prove, on a balance of probabilities, that Riva will infringe or induce the infringement of the HOPE Patents. There is no issue of construction of the HOPE Patents and Riva is seeking an NOC only for a use that is not within the new use claims of the HOPE Patents. The applicants have put great emphasis in their written and oral submissions on the allegation that Riva’s overall marketing strategy in Canada and in Quebec will induce the infringement of the HOPE Patents. However, having considered the totality of the evidence, the applicants have not established that the allegations of non-infringement are not justified. The evidence before me is inconclusive. The applicants’ numerous legal arguments, which I also dismiss, are analysed in further detail below. However, it is useful to give a bit of background to this application, as well as a general overview of the evidence submitted by the parties. It is not

necessary for the purpose of these reasons for order to state confidential parts of any relevant evidence that is before this Court.

[4] On December 5, 2006, Riva served a Notice of Allegation (NOA) on Sanofi-Aventis asserting that it will not infringe any claim of the HOPE Patents by making, constructing, using or selling its Riva-Ramipril. Riva states it is seeking an NOC for Riva-Ramipril only for the treatment of essential hypertension, the "old" minor use and not for any of the "new" uses claimed by the HOPE Patents.

[5] With respect to the '549 patent, Riva alleges:

> Riva will not infringe any of claims 1 to 36 of the '549 patent because [Riva-Ramipril] will not be made, constructed, used or sold by Riva for any of the claimed uses in the '549 patent.
>
> Riva seeks an NOC for ramipril only with respect to the treatment of hypertension. Ramipril has been approved in Canada for such use since October, 1993, well before any relevant date of the '549 patent. Riva does not seek approval for any other use. […]
>
> Any NOC which arises from Riva's [abbreviated new drug submission (ANDS)] will consequently, by law, restrict Riva's marketing and sale of [Riva-Ramipril] to the therapeutic indication as applied for in its ANDS, namely the treatment of hypertension.
>
> Riva will not market, use, construct, manufacture or sell [Riva-Ramipril] for any other use. Therefore, Riva will not infringe any of the claims of the '549 patent.
>
> Furthermore, Riva will not represent to any other person that [Riva-Ramipril] can or should be used for the uses claimed in the '549 Patent.
>
> In its product monograph, Riva will not include any statement encouraging any of the claimed uses. In its product monograph, Riva

> will include a statement that [Riva-Ramipril] is approved for only the use and indication for which the NOC is issued, that it should be used for such uses and indication and that no statement or reference in the product monograph should be construed or interpreted to be an encouragement, suggestion or recommendation that [Riva-Ramipril] is to be used for anything but the approved use and indication.
>
> In its marketing activities, Riva will not include any reference to any of the claimed uses.

Riva relies on similar assertions with respect to the ’387 patent. The NOA also alleged patent invalidity. However, Riva has subsequently abandoned all of its attacks on the validity of the HOPE Patents.

[6] In response to the NOA, Sanofi-Aventis filed a Notice of Application, dated January 19, 2007, stating that Riva’s assertion that it will not infringe the HOPE Patents is not legally or factually justified. More specifically, Sanofi-Aventis argues as follows: a) Riva-Ramipril is bio-equivalent to ALTACE; b) Riva admits it will not seek limited interchangeability for Riva-Ramipril on the provincial formularies; c) once Riva-Ramipril is listed on provincial formularies as fully interchangeable with ALTACE, physicians will prescribe, pharmacists will dispense and patients will use Riva-Ramipril for the patented uses; and, d) the focus of Riva’s marketing efforts will be to provide financial inducements to pharmacists to encourage them to stock only Riva-Ramipril as the exclusive generic ramipril; there is no proof that any such inducements are aimed to encourage pharmacists not to stock ALTACE.

[7] I first note that various generic companies such as Apotex, Novopharm and Pharmascience have attempted to enter the ramipril market and that attempts by Sanofi-Aventis to prevent them

from doing so by way of prohibition applications have been unsuccessful at this point of time. With respect to the 1,341,206 patent, Sanofi-Aventis' application for prohibition against Apotex was dismissed (2005 FC 1283, affirmed 2006 FCA 64, leave to appeal to the Supreme Court of Canada dismissed [2006] S.C.C.A. No. 136 (QL)), as was its application for prohibition against Novopharm (2006 FC 1135, affirmed 2007 FCA 163, leave to appeal to the Supreme Court of Canada dismissed [2007] S.C.C.A. No. 311(QL)). Likewise, with respect to the 2,023,089 patent, Sanofi-Aventis' applications for prohibition against Apotex, Novopharm and Pharmascience were all dismissed: 2005 FC 1461, affirmed 2006 FCA 357, leave to appeal to the Supreme Court of Canada dismissed, [2007] S.C.C.A. No. 5 (QL); 2006 FC 1547, reversed 2007 FCA 167; and, 2006 FC 861. With respect to the 2,055,948 patent, Sanofi-Aventis' application for prohibition against Pharmascience was dismissed: 2006 FC 898. It is also worthwhile to note the following three related patents have expired: the 1,187,087 patent, the 1,246,457 patent and the 2,382,387 patent.

[8] I note that prior to the commencement of this proceeding, Sanofi-Aventis sought similar prohibition orders in files T-1384-04 and T-1888-04 involving these same parties with respect to four other patents, three of which claimed alleged "new" uses of ramipril. These applications were dismissed on May 28, 2007, by Orders of Justice Harrington: *Sanofi-Aventis Inc. v. Laboratoire Riva Inc.*, 2007 FC 532, [2007] F.C.J. No. 757 (QL), (the Harrington Orders). No appeal was taken of the final Order made in T-1888-04 and the two Notices of Appeal filed in T-1384-04 relate only to one of the use patents involved in that matter.

[9] Accordingly, this application constitutes the last hurdle preventing Riva from entering the market with Riva-Ramipril.

[10] Subparagraph 5(1)(*b*)(iv) of the NOC Regulations reads:

5. (1) If a second person files a submission for a notice of compliance in respect of a drug and the submission directly or indirectly compares the drug with, or makes reference to, another drug marketed in Canada under a notice of compliance issued to a first person and in respect of which a patent list has been submitted, the second person shall, in the submission, with respect to each patent on the register in respect of the other drug,	5. (1) Dans le cas où la seconde personne dépose une présentation pour un avis de conformité à l'égard d'une drogue, laquelle présentation, directement ou indirectement, compare celle-ci à une autre drogue commercialisée sur le marché canadien aux termes d'un avis de conformité délivré à la première personne et à l'égard de laquelle une liste de brevets a été présentée — ou y fait renvoi —, cette seconde personne doit, à l'égard de chaque brevet ajouté au registre pour cette autre drogue, inclure dans sa présentation :
[…]	[…]
(*b*) allege that	*b*) soit une allégation portant que, selon le cas :
[…]	[…]
(iv) no claim for the medicinal ingredient, no claim for the formulation, no claim for the dosage form and no claim for the use of the medicinal ingredient would be infringed by the second person making, constructing, using or selling the drug for which the submission is filed.	(iv) elle ne contreferait aucune revendication de l'ingrédient médicinal, revendication de la formulation, revendication de la forme posologique ni revendication de l'utilisation de l'ingrédient médicinal en fabriquant, construisant, utilisant ou vendant la drogue pour laquelle la présentation est déposée.

[11] Given that Riva has abandoned its earlier allegation of patent invalidity, the only remaining live issue at this stage of the proceeding is the non-infringement of the HOPE Patents. Sanofi-Aventis must prove on a balance of probabilities that the allegations of non-infringement contained in Riva's NOA are not justified: *Abbott Laboratories v. Canada (Minister of Health)*, 2007 FCA 140, [2007] F.C.J. No. 506 (QL). Under the NOC Regulations, infringement can be direct or induced: *Pharmascience Inc. v. Sanofi-Aventis Canada Inc. et al*, 2006 FCA 229, [2007] 2 F.C.R. 103 (*Pharmascience*); application for leave denied, [2006] S.C.C.A. No. 362 (QL). Given that the HOPE Patents relate only to the "new" uses of ramipril (for the management of patients at increased risk of cardiovascular events), the parties agree that Riva will not directly infringe the HOPE Patents. As such, the issue in this case is whether Sanofi-Aventis can prove on the balance of probabilities that Riva will induce or procure others to infringe the HOPE Patents.

[12] In support of its application, Sanofi-Aventis filed ten affidavits and corresponding documentary evidence. This is just a short overlook of this evidence:

(a) Malcolm O. Arnold, a Professor of Medicine, Physiology and Pharmacology at the University of Western Ontario, a cardiologist at the London Health Sciences Centre, the Director of Research Affairs for the Division of Cardiology at St. Joseph's Health Care, London, Ontario and a scientist and program leader of the Circulation Group at Lawson Health Research Institute, London, Ontario. Among other things, he describes the practices of physicians who prescribe ramipril and explains how he

and others make prescribing decisions based on medical literature, continuing medical education seminars and discussions with other cardiologists. In prescribing ramipril, he and his colleagues commonly use the generic name “ramipril” and do not write the reason why the patient is taking the medicine. He admits to prescribing drugs, including ALTACE, for unapproved uses.

(b) Peter James Lin, the Director of Primary Care Initiatives at the Canadian Heart Research Centre and a family physician. His affidavit essentially serves to describe the impact of the HOPE study, a clinical trial that concluded that ramipril had the immediate and significant effect of changing the management of high risk vascular patients. The HOPE study created a paradigm shift in the way these patients are treated. He suggests that physicians will generally assume that Riva’s generic ramipril product (once approved) will be therapeutically equivalent to ALTACE. He also describes how physicians routinely make prescribing decisions based on medical literature, continuing education seminars and expert opinions.

(c) B. Marie Berry, a pharmacist who practiced in Manitoba from 1974 to 2004 and was called to the Manitoba Bar in 1993. She is the author of the textbook *Canadian Pharmacy Law*. Ms. Berry was asked to provide her opinion as to whether Riva’s generic ramipril product, once available on the market, will be used by patients for the same uses as ALTACE even if such uses are not federally approved indications for Riva’s ramipril product.

(d) Andrew W. Steele, a physician specializing in nephrology, dialysis and hypertension. He explains that if Riva-Ramipril were to receive approval, physicians

would understand that it is therapeutically equivalent to ALTACE and would assume that it may be used to treat the same indications treated by ALTACE, including the patented uses.

(e) Jacinta M. De Abreu, a law clerk employed in the Toronto offices of Smart & Biggar, solicitors for Sanofi-Aventis. She states that counsel for Sanofi-Aventis informed counsel for Riva by email dated May 30, 2007 to withdraw its invalidity allegations regarding the HOPE Patents. This former aspect is no longer relevant in this case.

(f) Monica Wilson, a former Director Marketing Cardio-vascular at Sanofi-Aventis and now a consultant for Sanofi-Aventis. She describes how following the presentation and publication of the HOPE study, the number of prescriptions for ALTACE increased significantly in contrast to the total number of prescriptions for other ACE inhibitors which remained relatively constant.

(g) Martin Howard Strauss, a cardiologist and member of the Department of Internal Medicine at North York General Hospital, North York, Ontario, and a scientist in the Department of Cardiovascular Surgery of Saint Michael's Hospital, Toronto, Ontario. He explains how the benefits of ramipril are both statistically and clinically significant in terms of the management of patients at increased risk of cardiovascular events. He also states that cardiologists will probably assume that Riva-Ramipril can be used for the same indications as for ALTACE because it contains the same active medicinal compound. He explains that physicians generally do not write the indication for the drug on the prescription.

(h) Franca Mancino, the Director of Regulatory Affairs at Aventis Pharma Inc. Her affidavit, in essence, serves to put into evidence the text of Riva's NOA.

(i) Maria Nenadovich, a pharmacist licensed to practice in 1974 who currently works as a pharmacist-manager at a Shopper's Drug Mart in Toronto. She was asked to provide her personal opinion as to whether Riva-Ramipril, once available, would be used for all the same uses as ALTACE.

(j) Benoit Gravel, the Vice-President, ALTACE Franchise, Business Support, Resource Allocation and Execution Excellence and a member of the Executive Committee at Sanofi-Aventis Canada Inc. He explains that Sanofi-Aventis has marketed ALTACE in Canada since 1994 and that prior to December 12, 2006, ALTACE was the only ramipril product marketed in Canada. He states that ALTACE is presently listed on all relevant provincial formularies and describes the process whereby if an interchangeable generic product is listed in the formulary, a pharmacist will be compelled to substitute the lower cost generic for the originator's product.

Five of the affiants, Dr. Strauss, Dr. Steele, Ms. Berry, Ms. Nenadovich and Mr. Gravel, were cross-examined by Riva.

[13] Riva filed one affidavit, that of Dr. Guy Pridham, Vice-President of Scientific Affairs for Riva. Dr. Pridham states that Riva is seeking an NOC only to sell Riva-Ramipril for the treatment of hypertension. He also says that the application for the listing on provincial formularies by Riva "will be based on approval for use in the treatment of hypertension". He appends a draft product

monograph and a draft label. Sanofi-Aventis cross-examined Dr. Pridham on his evidence. By Order dated December 5, 2007, Riva was granted leave to file a supplementary affidavit of Mr. Jean-Paul Lefebvre, Consultant, Regulatory Affairs. This Order was appealed and on December 14, 2007, Justice Shore of this Court ruled that the Prothonotary's Order should be set aside.

[14] The applicants' main contention can be summarized as follows.

[15] First, the applicants examine an important marketplace for generic versions of prescription drugs: provincial formularies. Provincial formularies list both single source drugs (where no generic products are available) and multiple source drugs (where generic products are available). In all provinces (except for Quebec), the provincial governments underwrite in whole or in part the cost of drugs prescribed to large segments of the population and attempt to keep costs down by only indemnifying up to the cost of the least expensive equivalent, typically the generic drug. Once an interchangeable generic product is listed without any limitations in the relevant provincial formulary, a pharmacist will likely substitute the lower cost generic product for the originator's product. Failing that, a pharmacist will only be compensated for the cost of the generic product. ALTACE is currently listed on all relevant provincial formularies and Riva admits it intends to apply to list Riva-Ramipril on these same formularies. If approved, Riva-Ramipril will most likely be listed on the formularies as fully interchangeable with ALTACE in a manner which does not prevent use of Riva-Ramipril for any of the uses for which ALTACE is used, including the patented use. Thus, it is alleged that Riva, by not seeking limited interchangeability with ALTACE, will induce the infringement of the HOPE Patents.

[16] The situation in Quebec, however, is different. Quebec does not enforce generic substitutions for fifteen years after the drug has been listed on the Quebec formulary. The Quebec regulatory scheme was summarized at para. 92 of the Harrington Orders as follows:

> Under the "Regulations respecting the conditions on which manufacturers and wholesales of medications shall be recognized," adopted pursuant to an *Act Respecting Prescription Drug Insurance*, R.S.Q c. A-29.01 s. 80 as well as the Act itself, the responsible Quebec Minister draws up a list of medications, the cost of which is covered by the basic plan. The list indicates generic names, brand names and manufacturers' names for each approved medication, the conditions on which they may be obtained from an accredited manufacturer or wholesaler, and the manner in which the prices are established.

[17] For the first fifteen years after a drug has been listed, pharmacists in Quebec will be reimbursed for the product actually dispensed (whether that is the innovator's brand or the generic) at the actual purchase price listed on the list. In the Quebec formulary, ALTACE, Apo-Ramipril and Ratio-Ramipril are listed under the ACE inhibitor class as being fully interchangeable. Riva expects Riva-Ramipril to be listed on the Quebec formulary as an ACE inhibitor and admits it does not intend to seek limited interchangeability. Accordingly, the applicants submit that Riva may be inducing the infringement of the HOPE Patents. Sanofi-Aventis, nonetheless, acknowledges that as the fifteen year period has not lapsed, pharmacists in Quebec will be reimbursed for the actual purchase price of ALTACE if it is dispensed.

[18] Secondly, the applicants argue that neither the older version of its draft product monograph (PM), attached as Exhibit 'A' to the affidavit of Dr. Pridham, nor the draft PM that was revised on

August 6, 2007 (and is on file with the Minister as the current draft PM), contain the disclaimer that Riva-Ramipril is approved for only the use and indication for which the NOC is issued, that it should be used for such uses and indication and that no statement or reference in the PM should be construed or interpreted to be an encouragement, suggestion or recommendation that it is to be used for anything but the approved use and indication, as asserted in Riva's NOA. According to Sanofi-Aventis, this evidences Riva's intent to induce the infringement of the HOPE Patents.

[19] Thirdly, the applicants state that Riva-Ramipril is bio-equivalent with ALTACE regardless of the use to which the patient will be putting Riva-Ramipril. Accordingly, the applicants' experts are of the opinion that pharmacists will not be aware of or believe that patients may be exposed to threats of patent infringement by their "off label" use of the drug. Moreover, even if pharmacists were aware of patent issues, they would not know what steps to take to avoid exposing patients to such threats. Similarly, patent issues are not a factor in patient treatment by physicians: Physicians make prescribing decision primarily based on medical literature, education seminars, expert opinions and the demonstrated effectiveness of a drug. According to the affidavit evidence, in particular the affidavits of Dr. Steele and Dr. Strauss, physicians who prescribe ramipril tend not to write their diagnosis or proposed use on the prescription. As such, according to Ms. Berry and Ms. Nenadovich, pharmacists typically do not know the specific use a physician has in mind when prescribing ramipril to a particular patient. Further, according to these pharmacist affiants, information given to them by the patient herself/himself about the reason why the drug has been prescribed is often quite vague. Given that pharmacists will suffer a financial loss (except in

Quebec) if ALTACE instead of a generic ramipril is dispensed to an eligible patient, the applicant is of the view that Riva will be indirectly inducing the infringement of the HOPE Patents.

[20] It is also argued that the impact of this infringement by Riva would be particularly significant in this case. As stated by Mr. Gravel in his affidavit, the HOPE study, which was published in August 1999, was a landmark trial which helped propel ALTACE into its position as the leader in the ACE inhibitor market in December 2006. Ramipril was not the first ACE inhibitor; however, following the release of the HOPE study, ALTACE became the ACE inhibitor of choice for physicians. In 2006, ALTACE represented more than 50% of all prescription in Canada written for ACE inhibitors. In that same year, ALTACE was Sanofi-Aventis' most successful product. Sales of ALTACE grew from $38.5 million in 1999 to over $375 million in 2006 (public affidavit of Benoit Gravel at paras. 12 and 13). The main use of ramipril in Canada today is the HOPE indication.

[21] Finally, it is asserted by the applicants that the focus of Riva's marketing strategy in the provinces (including Quebec) will be directed at pharmacists to encourage them by financial inducements and allowances permissible under law to include Riva-Ramipril within their inventories for dispensing to patients. Sanofi-Aventis relies on excerpts from the transcript of Dr. Pridham's cross-examination on his affidavit to conclude that these inducements and allowances will be provided to pharmacists on the condition that other generic ramipril products are removed from their inventories. The ultimate goal of Riva's marketing strategy is to have Riva-Ramipril as the only generic on the inventory shelf in the pharmacies. (Read the statements made by Dr.

Pridham in his cross-examination.) As previously noted, ALTACE, Apo-Ramipril and Ratio-Ramipril are already listed under the ACE inhibitor class as being fully interchangeable.

[22] As was done by the Federal Court of Appeal, in *Pharmascience*, above at para. 34, for the purpose of this application, I am ready to assume, without deciding, that any patient who takes Riva-Ramipril for the management of their increased risk of cardiovascular events will infringe the HOPE Patents. I am also ready to assume, without deciding, that a prescribing physician or a dispensing pharmacist may be found to have induced that infringement if Riva-Ramipril is prescribed or dispensed for use in the management of patients at increased risk of cardiovascular events. However, that does not change the fact that infringement by patients, physicians or pharmacists is not contemplated by subsection 5(1) of the NOC Regulations. It is well within the power of Sanofi-Aventis to educate physicians and pharmacists as to the existence and breadth of Sanofi's patent rights and to demand that these rights be respected. Accordingly, unless Riva participates in inducing infringement, the remedy in such a case is not to prohibit the Minister from allowing the generic to enter into the marketplace.

[23] In *AB Hassle v. Canada (Minister of National Health and Welfare)*, 2001 FCT 1264, [2001] F.C.J. No. 1725 (QL) (*AB Hassle*); affirmed 2002 FCA 421, [2002] F.C.J. No. 1533 (QL), application for leave to appeal to the Supreme Court of Canada dismissed [2002] S.C.C.A. No. 531 (QL), the Federal Court of Canada articulated the test for inducing and procuring infringement at para. 68 as follows:

> A patentee wishing to rely on the doctrine of induced infringement must allege and prove each of the following elements:

> (a) that the act of infringement was completed by the direct infringer;
> (b) the completed act of infringement was influenced by the seller, to the point where without said influence, infringement by the buyer would not otherwise take place; and,
> (c) the influence must knowingly be exercised by the seller, such that the seller knows that his influence will result in the completion of the act of infringement.

[24] In *Sanofi-Aventis Canada Inc. v. Novopharm Ltd.*, 2007 FCA 167, [2007] F.C.J. No. 582 (QL) (*Sanofi-Aventis*), the Federal Court of Appeal found that an allegation of non-infringement of a claim for the use of a medicine is justified if the generic drug manufacturer is seeking an NOC only for a use that is not within the new use claim and the evidence fails to establish that the generic drug producer will infringe the new use claim by inducing others to prescribe or use the generic product for that new use.

[25] In *Sanofi-Aventis*, above at para. 11, Justice Sharlow provided examples of how infringement by inducement may be established:

> A generic drug manufacturer may be implicated in the infringement by others of a claim for a new use of a medicine if the generic drug manufacturer induces that infringement. Infringement by inducement may be established, for example, by inferences reasonably drawn from the contents of the product monograph for the generic drug product, or evidence relating to the dosage form of the generic product, or its labelling or marketing.

[26] The legal test for induced infringement is not met on the facts of this case. I have carefully reviewed the transcripts of the various cross-examinations. I have also considered the arguments raised by the parties with respect to the weight that should be given to the evidence. This includes the particular weight that I should give to Ms. Berry's affidavit as well as some of the contradictions

or admissions made by Dr. Pridham. I am of the opinion that the applicants have not met their burden of demonstrating that Riva's allegations of non-infringement are not justified. Despite applicants' counsel's able presentation, the totality of the evidence is not conclusive to establish infringement or infringement by inducement on the part of Riva. I need only to make a few comments with respect to arguments raised by the parties.

[27] The starting point in my analysis has been to carefully examine Riva's NOA. Riva argues that it will not infringe any claim of the HOPE Patents by making, constructing, using or selling its Riva-Ramipril for use in the treatment of essential hypertension. Riva states that it will not include any of the uses claimed by the HOPE Patents in its PM. Indeed, Riva asserts its PM will contain a disclaimer that Riva-Ramipril should only be used for the approved use and indication, the treatment of hypertension. Riva also alleges that if it obtains an NOC, it will restrict its drug marketing and sales of Riva-Ramipril to that treatment. These statements made by Riva in its NOA are presumed to be true in the absence of evidence to the contrary: *Pharmascience*, above at para. 30. Sanofi-Aventis argues the fact that Riva's revised draft PM does not presently contain the disclaimer set out in the NOA, provides such evidence to the contrary. I respectfully disagree. A generic is not required to include a disclaimer in its PM. Further, in *Aventis Pharma Inc. v. Apotex Inc*., 2005 FC 1461, [2005] F.C.J. No. 1793 (QL) (*Aventis Pharma*), Justice von Finkenstein considered this issue and concluded that "[s]uch a warning might be useful factor helping to negate any idea of intention by the alleged infringer. However the absence of a warning cannot not be used by itself to infer an intention to infringe through inducement, procurement, marketing or some other nexus."

[28] Turning to particular statements made by Riva in its NOA, I note again that Riva is seeking approval for Riva-Ramipril only for use in the treatment of hypertension. Secondly, Riva's ANDS also clearly identifies "treatment of essential hypertension" as the only use of Riva-Ramipril for which it is seeking an NOC. Thirdly, Riva's Proposed Canadian Labelling Material evidences that the packaging for Riva-Rampiril capsules will be labelled in a manner that will inform anyone who reads the label that the capsules are approved for use in the treatment of "essential hypertension." Finally, the revised draft PM that would be approved by Health Canada would state that the Riva-Ramipril is for use in the treatment of hypertension. Riva will, thus, be limited in its promotion endeavours to this treatment under the NOC Regulations and Health Canada cannot approve Riva-Ramipril for another use. To emphasize, I find as a fact that the revised draft PM does not say that Riva-Ramipril may or should be used in the management of patients at increased risk of cardiovascular events, the "new" use for this compound covered by the HOPE Patents.

[29] Sanofi-Aventis further emphasizes that the "References" section of Riva's draft revised PM makes mention of Sanofi-Aventis' PM for ALTACE (including for the patented uses) and that it also contains a reference to a bioavailability study that compares ramipril 10 mg capsules to ALTACE capsules. In *Pharmascience*, above at para. 31, the Federal Court of Appeal concluded that references mentioned in a PM in the context of "Contraindications" could not be construed as an attempt to encourage the use of the ramipril capsules for the treatment of one of the patented uses. In *Sanofi-Aventis*, above at para. 11, Madam Justice Sharlow states the following regarding off label prescriptions in the context of a prohibition proceeding for non-infringement: "[A]n

inducement to infringe generally cannot be inferred from a mere reference to the new use in the product monograph, for example, in the course of explaining contraindications or drug interactions, or as part of a list of scientific references." [Emphasis added] A similar conclusion must be reached in this instance. The mere fact that Riva mentions ALTACE in the "References" section of its PM coupled with a reference to a comparative bioavailability study with ALTACE capsules is insufficient "evidence to the contrary" to rebut the presumption of truth afforded to Riva's NOA. Riva remains entitled to the benefit of the presumption that it will market Riva-Ramipril capsules only for use in the treatment of hypertension.

[30] I have also specifically considered the fact that physicians may prescribe drugs based on uses supported by medical literature (a practice often referred to as "off label" use). I note that Ms. Berry and Nenadovich's opinions as pharmacists cannot be extended to mean all pharmacists in the marketplace. The same remark applies to Dr. Steele and Dr. Strauss' opinions as physicians specializing in nephrology or cardiology. It is not challenged by Riva that if Riva is given the NOC, certain physicians may prescribe Riva-Ramipril for use in the management of patients at increased risk of cardiovascular events (the patented use), certain pharmacists may dispense Riva-Ramipril for the patented use, and certain patients may take Riva-Ramipril for that use. This is likely to happen regardless of the steps taken by Riva to ensure that its product is labelled and described in its PM as being only for use in the treatment of hypertension. However, I find nothing in the legislative scheme, the related jurisprudence or even the submissions raised by Sanofi-Aventis' counsel which would lead me to conclude that Riva should seek a limited interchangeability in the provincial drug formularies. Like in the Harrington Orders, I find this argument to be "without merit."

[31] However significant the off-label use may be, the jurisprudence is clear: it can no longer be argued by the innovator that the mere presence of the generic drug on the market, coupled with the fact that it could be used for purposes other than those for which the NOC was obtained, constitutes infringement of a patent. “Something more” than simply making the product available is required: *AB Hassle,* above, citing to the Federal Court of Appeal decision at para 18. In *Aventis Pharma,* above, at paras. 27-32, Justice von Finckenstein summarized the case law on off label prescription and clearly held that “off label” prescription by doctors and subsequent use by patients does not satisfy the “something more" requirement established by Sexton J.A. in *AB Hassle*. He further stated that whether the "something more" consists of inducement, procurement, marketing or some other nexus will depend upon the facts of each particular case. In this case, I am of the opinion the “something more” requirement is simply not met based on the evidence on record. Mere passive recognition that "off-label" prescription or consumption will occur does not amount to "something more".

[32] Sanofi-Aventis argues that Riva’s marketing strategy establishes infringement by inducement. In this regard, the facts contained in the Pridham affidavit “clearly confirm that Riva does intend to negotiate exclusive generic supply contracts with pharmacists for its Riva-Ramipril.” In my opinion, Sanofi-Aventis has overstated the issue. Riva will be entering into agreements (permissible at law) with pharmacists. These agreements will be designed to ensure that Riva-Ramipril is stocked on their shelves. However, nothing in the evidence before me suggest that Riva will be providing financial inducements or allowances to these pharmacists to dispense Riva-

Ramipril for a purpose other than the use for which it is intended, namely the treatment of hypertension. Any exclusivity will be in relation to other generics and for the authorized use. For greater emphasis, there is nothing in the evidence to convince me that Riva will be providing financial incentives to pharmacists to compel them to dispense Riva-Ramipril for the management of patients at increased risk of cardiovascular events, the patented use.

[33] For all these reasons, the present application must fail. Costs against the applicants shall be in favour of Riva.

ORDER

THIS COURT ORDERS that this application is dismissed with costs to the respondent Laboratoire Riva Inc.

" Luc Martineau"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-127-07
STYLE OF CAUSE:	**SANOFI-AVENTIS CANADA INC. and SANOFI-AVENTIS DEUTSCHLAND GmbH and LABORATOIRE RIVA INC. and THE MINISTER OF HEALTH**
PLACE OF HEARING:	Toronto, Ontario
DATE OF HEARING:	January 15, 2008
REASONS FOR ORDER AND ORDER:	MARTINEAU J.
DATED:	March 4, 2008

APPEARANCES:

Mr. Gunars A. Gaikis Ms. Junyi Chen	FOR THE APPLICANTS
Mr. Arthur B. Renaud	FOR THE RESPONDENT (LABORATOIRE RIVA INC.)

SOLICITORS OF RECORD:

SMART & BIGGAR Toronto, Ontario	FOR THE APPLICANTS
BENNETT JONES LLP Barristers and Solicitors Toronto, Ontario	FOR THE RESPONDENT (LABORATOIRE RIVA INC.)