Federal Court  Cour fédérale

Date: 20150626

Docket: T-1440-14

Citation: 2015 FC 797

Ottawa, Ontario, June 26, 2015

PRESENT: The Honourable Madam Justice Strickland

BETWEEN:

BAYER INC AND BAYER INTELLECTUAL PROPERTY GMBH

Applicants

and

PHARMACEUTICAL PARTNERS OF CANADA INC AND THE MINISTER OF HEALTH

Respondents

ORDER AND REASONS

[1] This is an appeal brought by the Applicants, Bayer Inc and Bayer Intellectual Property GmbH (collectively, Bayer), pursuant to Rule 51 of the *Federal Courts Rules*, SOR/98-106, of a decision of Prothonotary Lafrenière, dated March 26, 2015. The Prothonotary granted a motion of the Respondent herein, Pharmaceutical Partners of Canada Inc ("PPC"), seeking an order, pursuant to s 6(5)(b) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-

133 (the "*NOC Regulations*"), striking all portions of the underlying application by Bayer seeking an order prohibiting the Minister of Health from issuing a Notice of Compliance (the "NOC").

[2] For the reasons stated below, the appeal is dismissed.

Background

[3] In March 2014, PPC filed an Abbreviated New Drug Submission to obtain a NOC for its moxifloxacin hydrochloride solution for injection ("PPC-Moxifloxacin"). The reference drug for PPC-Moxifloxacin is AVELOX® I.V., sold in Canada by Bayer. In May 2014, PPC served Bayer with a Notice of Allegation addressing two of three patents listed on the Patent Register, Bayer's Canadian Patent No 2,378,424 (the "424 Patent") and its Canadian Patent No 2,192,418 (the "418 Patent").

[4] The 424 Patent is titled "Moxifloxacin Formulation Containing Common Salt". In applying for its NOC, PPC alleged that PPC-Moxifloxacin will not infringe the claims of the 424 Patent. On June 18, 2014, Bayer commenced an application pursuant to s 55.2(4) of the *Patent Act*, RSC 1985, c P-4 and s 6 of the *NOC Regulations* relating to the 424 Patent alleging, amongst other things, that PPC will infringe, or induce infringement of, the 424 Patent, and seeking an order prohibiting the Minister of Health from issuing a NOC to PPC (the "Prohibition Application"). On January 19, 2015, PPC brought a motion seeking an order, pursuant to s 6(5)(b) of the *NOC Regulations*, striking out all portions of Bayer's Prohibition Application which pertain to the 424 Patent on the grounds that it is scandalous, frivolous and vexatious or

was otherwise an abuse of process. The motion before the Prothonotary, and this appeal, pertain only to the 424 Patent.

[5] PPC did not file any evidence in support of its motion to strike. It relied solely on the affidavit evidence filed by Bayer in support of its infringement allegation in the Prohibition Application. Bayer did not file any additional evidence in response to the motion to strike and no cross-examination was conducted of Bayer's two deponents. Thus, the uncontested evidence before the Prothonotary was comprised of two affidavits: the affidavit, sworn on December 19, 2014, of Dr. Linda Dresser (Dresser Affidavit) who holds a Doctor of Pharmacy (Pharm. D.), is an Assistant Professor of Pharmacy at the University of Toronto, and is a hospital pharmacist with over 25 years of experience; and, the affidavit of Dr. Roland Grossman, sworn on December 18, 2014 (Grossman Affidavit). Dr. Grossman is a staff physician at Credit Valley Hospital and a Professor of Medicine at the University of Toronto. He is an expert on the use of antibiotics, including moxifloxacin, and in the treatment of respiratory infections such as community-acquired pneumonia, which is treated with moxifloxacin.

[6] The 424 Patent covers aqueous formulations containing moxifloxacin and sodium chloride in various specified concentrations. All 49 claims of the 424 Patent require the inclusion of moxifloxacin and sodium chloride. Independent Claim 1 of the 424 Patent claims: "an aqueous formulation comprising: from 0.04% to 0.4% (w/v) of moxifloxacin hydrochloride, based on the amount of moxifloxacin, and from 0.4% to 0.9% (w/v) of sodium chloride". [...].

[7] Neither of Bayer's experts suggested that PPC will directly infringe the 424 Patent and Bayer conceded when appearing before the Prothonotary that there was no evidence of direct infringement. The issue that was before the Prothonotary was whether PPC-Moxifloxacin will be co-administered with sodium chloride in a way that infringes the 424 Patent and, if so, whether the PPC Product Monograph would induce that infringement. The motion was heard on March 5, 2015 and was granted by Order dated March 26, 2015.

Issue

[8] This matter raises only one issue, whether the Prothonotary erred in granting PPC's motion to strike by finding that it was plain and obvious that Bayer's Prohibition Application, in regards to the 424 Patent, should be dismissed as being clearly futile.

Decision of the Prothonotary

[9] In his decision (*Bayer Inc and Bayer Intellectual Property GmbH v Pharmaceutical Partners of Canada Inc and The Minister of Health*, 2015 FC 388, at para 18 [*Bayer*]), the Prothonotary noted that the purpose of s 6(5) of the *NOC Regulations* is to allow the Court to expeditiously dispose of unmeritorious applications brought by first persons, here Bayer, which have no chance of succeeding. This is an extraordinary remedy that will only be granted when an application is "clearly futile" or it is "plain and obvious" that it has no chance of success (*Sanofi-Aventis Canada Inc v Novopharm Ltd*, 2007 FCA 163, at paras 28, 36). A second person, here PPC, can move under s 6(5)(b) to dismiss a first person's application on the basis that the first person's affidavit evidence is insufficient to prove that the second person's

allegations of infringement are not justified (*Novopharm Limited v Sanofi-Aventis Canada Inc*, 2007 FCA 167). The moving party bears the burden of proof in such instances (*Pfizer Canada Inc v Apotex Inc*, 2009 FC 671 at para 33). To make such a determination, the motions judge must be able to make the necessary findings of fact, viewed in the light most favourable to the first person, and then apply the law to the facts. Further, a motion to dismiss will only be granted where it is apparent that there is no arguable case on the merits of the application.

[10] The Prothonotary found that Bayer did not adduce any evidence that PPC would directly infringe the 424 Patent. Rather, Bayer alleged that PPC will induce or procure others to infringe the 424 Patent. Specifically, Bayer alleged that PPC's Product Monograph for PPC-Moxifloxacin directed the infringement and that the sale of PPC-Moxifloxacin would result in infringement. The Prothonotary stated that it is well established that there is no infringement of a patent in selling an article which does not itself infringe the patent, even when the vendor knows that the purchaser buys the article for the purpose of using it in the infringement of a patent (*Slater Steel Industries Ltd v R Payer Co*, (1968), 38 Fox Pat C 139 [*Slater Steel*]; citing *Hatton v Copeland-Chatterson Co*, 1906 CarswellNat 10).

[11] The Prothonotary found that it was not sufficient to claim that pharmacists or physicians would prescribe PPC-Moxifloxacin in an infringing manner and that, therefore, the inducement is made out. It is the second person's actions which are at issue, and not the infringing conduct of others (*Lundbeck Canada Inc v Ratiopharm Inc*, 2009 FC 1102, at paras 367-369 [*Lundbeck*]). However, a second person may be implicated in the infringement by others of a patent if the second person induces that infringement.

[12] The Prothonotary identified the test for inducing infringement as articulated in *Weatherford Canada Ltd v Corlac Inc*, 2011 FCA 228, at para 162 [*Weatherford*] which he described as conjunctive and as follows (para 25):

> First, the act of infringement must have been completed by the direct infringer. Second, the completion of the acts of infringement must be influenced by the acts of the alleged inducer to the point that, without the influence, direct infringement would not take place. Third, the influence must knowingly be exercised by the inducer, that is, the inducer knows that this influence will result in the completion of the act of infringement.

[13] The Prothonotary concluded that Bayer had no reasonable chance of success on the second prong of the inducement test set out above, based on the evidence that was before the Court. He found that there was nothing in PPC's Product Monograph that was capable of establishing that PPC will infringe the 424 Patent by inducing infringement by others. Although infringement by inducement may be established by inferences reasonably drawn from a product monograph, or evidence on the dosage form, or the labelling or marketing of the generic product (*Lundbeck* at paras 356, 399), in this case, there were no facts, other than Dr. Dresser's opinion, to support the claim that PPC is "instructing" others to infringe the 424 Patent. Whether such instructions are actually found in the Product Monograph for PPC-Moxifloxacin is a question of fact, not a matter of opinion. The Prothonotary stated that it is one thing for an expert to provide assistance to the Court in interpreting technical terms and quite another for the expert to proffer an opinion on the very issue to be decided by the Court. There was no evidence, other than speculation, that PPC will be seeking to sell its product in combination with sodium chloride, nor was there evidence of any overt attempt by PPC to influence or encourage others to infringe the 424 Patent.

[14] The Prothonotary went on to find that in the matter before him, there were no explicit instructions or directions to complete an act of infringement (*Windsurfing International Inc v Trilantic Corp* (1986), 8 CPR (3d) 241 (FCA)). Additionally, although "subtle references" in a product monograph may be enough to leave the reader with the impression that a drug can be used in a manner that would infringe a patent (*AB Hassle v Genpharm Inc*, 2003 FC 1443, at para 155), in this case the general and generic references to sodium chloride in PPC's Product Monograph for PPC-Moxifloxacin did not amount to inducement. Merely stating that PPC-Moxifloxacin is safe for dilution with one of the six listed intravenous solutions, including sodium chloride, or that it can be used in sequence with solutions containing sodium chloride, without more, was not sufficient to conclude that PPC is knowingly inducing healthcare practitioners to co-administer PPC-Moxifloxacin with sodium chloride.

[15] Further, Dr. Dresser's assertion that once PPC-Moxifloxacin enters the market in Canada, PPC will have to approach hospitals or wholesalers to convince them to dispense PPC-Moxifloxacin instead of AVELOX® I.V. was nothing more than conjecture and speculation.

[16] The Prothonotary concluded that, on the record before him, PPC had established that it was plain and obvious that Bayer had no reasonable chance of success in showing that PPC is or will be inducing infringement of the 424 Patent. As the test for inducement is conjunctive and Bayer had not adduced any evidence that can arguably satisfy all three prongs of the test, the Prohibition Application as it related to the 424 Patent would inevitably fail.

[17] Accordingly, PPC's motion was granted and the sections of the Prohibition Application which related to the 424 Patent were ordered struck out.

Relevant Legislative Provisions

Patented Medicines (Notice of Compliance) Regulations, SOR/93-133

6. (5) Subject to subsection (5.1), in a proceeding in respect of an application under subsection (1), the court may, on the motion of a second person, dismiss the application in whole or in part…	6. (5) Sous réserve du paragraphe (5.1), lors de l'instance relative à la demande visée au paragraphe (1), le tribunal peut, sur requête de la seconde personne, rejeter tout ou partie de la demande si, selon le cas :
[…]	[…]
(b) on the ground that it is redundant, scandalous, frivolous or vexatious or is otherwise an abuse of process in respect of one or more patents.	b) il conclut qu'elle est inutile, scandaleuse, frivole ou vexatoire ou constitue autrement, à l'égard d'un ou plusieurs brevets, un abus de procédure.

Submissions of the Parties

The Applicants' Position

[18] Bayer submits that it is not plain and obvious that the Prohibition Application has no chance of success. The evidence from the PPC-Moxifloxacin Product Monograph and Bayer's two experts establishes that PPC will be instructing physicians to prescribe and use the drug in an infringing way. Bayer submits that the Prothonotary had no basis on which to discredit the expert opinions adduced by them. It argues that the Prothonotary erred by taking on the role of

the applications judge and assessing the sufficiency of Bayer's evidence and yet failed to follow the law and view the evidence in the best light and in Bayer's favour. Further, and contrary to what is stated by the Prothonotary, counsel for Bayer did not agree that the evidence boils down to a single paragraph in Dr. Dresser's affidavit.

[19] Bayer submits that the PPC Product Monograph instructs pharmacists and physicians that PPC-Moxifloxacin can be co-administered with sodium chloride solutions and that Bayer's expert opinions confirmed that this directs co-administration of PPC-Moxifloxacin in a manner that will result in infringement of the 424 Patent. The Prothonotary could not ignore the experts' evidence, given that they are skilled experts in their fields, and instead adopt his own interpretation of how the PPC Product Monograph would be read. Product monographs are technical documents and it was necessary for experts to provide the Court with evidence of how it would be understood by pharmacists and physicians (*Abbott Laboratories et al v The Minister of Health et al*, 2006 FC 1411 at para 38 [*Abbott Laboratories*]).

[20] Although PPC has not yet marketed its product, the same circumstance would be present in every prohibition application under the *NOC Regulations*. In applications involving an infringement application, the Court and parties are always dealing with hypothetical situations, and therefore the Dresser and Grossman opinions cannot be dismissed as speculative. According to Bayer, the Prothonotary advised it that when PPC enters the market and in fact induces another to infringe the 424 Patent, Bayer will then be able to bring an action for infringement. Bayer submits that its right to bring an infringement action should have no bearing on the analysis under s 6(5)(b) and this statement undermines the purpose of the *NOC Regulations*.

[21] Bayer submits that the Prothonotary also erred in stating that there is no suggestion that PPC-Moxifloxacin will be substituted for AVELOX® I.V. First, the basis for the generic pharmaceutical industry is to market generic products to compete with the brand reference products, as PPC does in this case. Additionally, Dr. Dresser's views on what will happen once PPC-Moxifloxacin enters the market are based on years of experience as a hospital pharmacist. She is familiar with the process a generic pharmaceutical company must take in order to have a hospital stock a generic drug, and her evidence is not conjecture or speculative. Further, there need not be an overt attempt or explicit directions by PPC in order to find inducement to infringe and, in any case, the PPC Product Monograph states that PPC-Moxifloxacin can be co-administered with sodium chloride, resulting in an infringement of the 424 Patent.

[22] Bayer goes on to submit that the onus on a motion to strike, made pursuant to s 6(5)(b) of the *NOC Regulations* is very high. A Court must find that the case is so clearly futile that it has not the slightest chance of success or that the Prohibition Application discloses no reasonable cause of action (*Pfizer Canada Inc v Apotex Inc*, 2009 FC 671 at paras 33 and 37). It is for the applications judge to weigh the evidence adduced and determine whether it meets the test for infringement (*Pfizer Canada Inv v Apotex Inc*, 2009 FC 250 at para 12; aff'd 2009 FC 671 at para 34). If there is any doubt as to whether Bayer has an arguable case, the appeal must be granted (*Pfizer Canada Inc v Apotex Inc*, 2009 FC 671 at para 34; *Nycomed Canada Inc v Novopharm Limited*, 2008 FC 454 at para 37). Additionally, applications of this type are already meant to be summary proceedings and s 6(5)(b) motions should be rare (*Valeant Canada LP v Canada (Minister of Health)*, 2013 FC 1254 at para 38).

[23] Bayer next submits that PPC will induce infringement of the 424 Patent. A party who induces another to infringe a patent is liable for the infringement and in this case PPC, through its Product Monograph, is directing pharmacists and physicians to co-administer PPC-Moxifloxacin with sodium chloride, resulting in inevitable infringement of the 424 Patent (*Apotex Inc v Nycomed Canada Inc*, 2011 FC 1441 at para 18). Bayer reiterates the test for inducement (*Apotex Inc v Nycomed Canada Inc*, 2011 FC 1441 at para 18; *AB Hassle v Canada*, 2002 FCA 421 at para 17) and submits that infringement can be established through inferences drawn from the contents of the product monograph for the generic drug product (*Lundbeck* at paras 356, 399; *Sanofi-Aventis Canada Inc v Novopharm Ltd*, 2007 FCA 167 at para 11; *AB Hassle v Canada*, 2002 FCA 421 at para 55).

[24] In this regard, Bayer submits, first, that the evidence shows that the 424 Patent will be infringed by PPC-Moxifloxacin. In Dr. Dresser's opinion, when PPC-Moxifloxacin is co-administered with 0.9% sodium chloride injection USP at ratios between […] and […], the resulting formulation will fall within claims of the 424 Patent. Additionally, Dr. Dresser notes that the PPC Product Monograph instructs the pharmacist that AVELOX® I.V. is compatible with six intravenous solutions. Dr. Grossman's evidence was that in his experience physicians often rely upon pharmacists to advise them on drug compatibilities. His opinion was that AVELOX® I.V. is commonly co-administered with 0.9% sodium chloride solution and that a generic version of moxifloxacin would also be so administered. Therefore, the unchallenged evidence of the experts makes it clear that if PPC-Moxifloxacin is on the market, it will be co-administered with sodium chloride and this will result in the infringement of the 424 Patent.

[25] Second, Bayer submits that the PPC-Moxifloxacin Product Monograph directs infringement. Dr. Dresser's evidence was that the determination of whether PPC-Moxifloxacin will be co-administered with sodium chloride, as is done with AVELOX® I.V., depends on the information contained in the PPC Product Monograph. Given that the Product Monograph for PPC-Moxifloxacin instructs that it can be co-administered with sodium chloride, pharmacists would advise that it should be used and co-administered in the same way as AVELOX® I.V.

[26] Third, Bayer makes specific reference to two cases that, it feels, are particularly instructive with respect to the importance of the Product Monograph. In *AB Hassle v Genpharm*, 2003 FC 1443 at para 155(h), the Court found that the product monograph was a "key document". The Federal Court of Appeal held that the product monograph was evidence and the Court could draw adverse inferences from it to find that it would induce infringement. In *Abbott Laboratories* at paras 40-42, the Court found that the subject product monograph could be seen as "an encouragement to infringe" the patent. The Federal Court of Appeal upheld the decision (*Novopharm v Abbott Laboratories*, 2007 FCA 251 at paras 24-27). In that case, the Court indicated that product monographs have to be read through the eyes of physicians and pharmacists (*Abbott Laboratories* at para 38). Bayer submits that in this case the only evidence of how the PPC Product Monograph would be read was found in the Dresser and Grossman Affidavits, which the Prothonotary ignored, and that they have been deprived of the opportunity to have the judge hearing the Prohibition Application consider this evidence.

[27] Finally, Bayer submits that PPC will knowingly induce infringement. PPC chose to include 0.9% sodium chloride in the list of compatible solutions in its PPC Product Monogram

with full knowledge of the existence of the 424 Patent. The Prohibition Application judge should be free to draw the inference that PPC will knowingly induce the infringement. By coming to a different conclusion based on the evidence, the Prothonotary improperly drove Bayer from the judgment seat and deprived it of the opportunity to have the Prohibition Application judge assess the evidence and draw inferences.

The Respondent's Position

[28] PPC submits, in essence, that Bayer has mischaracterized the PPC Product Monograph by claiming that it "instructs" or "directs" the co-administration of PPC-Moxifloxacin with sodium chloride when, in fact, it never refers to co-administration with 0.9% sodium chloride and explicitly states that dilution is not necessary. Further, there is no evidence that PPC would in reality induce any direct infringement, the evidence of Bayer's experts being that practitioners would make treatment decisions based on medical factors and not on any influence by PPC. The Prothonotary properly understood the evidence, accepting Bayer's experts' opinions but not drawing inferences that controverted clear and unmistakable facts in the PPC Product Monograph.

[29] PPC submits that a second person may move under s 6(5)(b) of the *NOC Regulations* to dismiss a first person's prohibition application on the basis that the first person's affidavit evidence is insufficient to prove that the second person's allegations of infringement are not justified. Further, PPC argues that the Prothonotary properly applied the legal standard, being that where the prohibition application is so clearly futile that it does not have the slightest chance of success, or that it is plain and obvious that it will not succeed, then a s 6(5)(b) motion will be

granted, and the moving party bears the entire burden of proof (*Sanofi-Aventis Canada Inc v Novopharm Ltd*, 2007 FCA 163 at paras 28, 36; *Pfizer Canada Inc v Apotex Inc*, 2009 FC 671 at para 33).

[30] PPC submits that inducing infringement is a strict test that is difficult to meet. In this case, Bayer has not adduced any evidence establishing or even suggesting that PPC would directly infringe the 424 Patent. […] and, therefore, there is no direct infringement. The Prothonotary correctly identified and applied the test for inducing infringement (*Slater Steel*, citing *Hatton v Copeland-Chatterson Co* (1906), 10 Ex CR 224 (Ex Ct); aff'sd (1906), 37 SCR 651 (SCC)); *Dableh v Ontario Hydro* (1996), 68 CPR (3d) 129 (FCA) at para 43). The burden is on the plaintiff to adduce conclusive evidence that the direct infringement is the result of the defendant's influence, and this test applies to PPC in these NOC proceedings (*Hershkovitz v Tyco Safety Products Canada Ltd*, 2009 FC 256 at para 160 [*Hershkovitz*]; *Aventis Pharma Inc v Apotex Inc*, 2005 FC 1461 at para 31). The NOC proceeding is focused on the actions of the second person, in this case PPC, and not the actions of other persons, such as physicians and pharmacists (*Sanofi-Aventis Canada Inc v Novopharm Ltd*, 2007 FCA 167 at para 10; *Aventis Pharma Inc v Pharmascience Inc*, 2006 FCA 229*; Lundbeck* at paras 367-371).

[31] On the second prong of the test for inducing infringement, the inducer must exercise sufficient influence over the direct infringer such that, but for the inducing activities, the direct infringement would not have taken place, and being partially responsible is not sufficient (*Apotex Inc v Nycomed Canada Inc*, 2011 FC 1441, aff'd 2012 FCA 195 at para 20; *MacLennan v Products Gilbert Inc*, 2008 FCA 35 at para 38 [*MacLennan*]; *Slater Steel* at para 41). The

inducer must actively do something that leads the direct infringer to infringe. In the context of NOC proceedings, the generic company must do something more than merely selling a product which is used by a third party to complete an act of direct infringement. Additionally, even knowledge that the product will likely be used in direct infringement of a patent is not sufficient to meet the test (*AB Hassle v Canada*, 2002 FCA 421 at para 56; *Aventis Pharma Inc v Apotex Inc*, 2006 FCA 357 at paras 17-18; *Aventis Pharma Inc v Apotex Inc*, 2005 FC 1461 at para 32). Nor is alleging that a generic drug company, through its product monograph, website and marketing strategies, may be partially responsible for direct infringement by physicians, pharmacists and patients (*Apotex Inc v Nycomed Canada Inc*, 2011 FC 1441, aff'd 2012 FCA 195 at paras 2, 19-20).

[32] The Federal Court of Appeal has emphasized the importance of properly applying the test for inducing infringement in the context of NOC proceedings so as not to artificially extend the monopoly held by the patent holder by effectively transforming all pharmaceutical patents into compound patents, meaning that the patent holder would control the compound itself even where it is not protected by the patent (*AB Hassle v Canada*, 2002 FCA 421 at paras 57-58; *Aventis Pharma Inc v Pharmascience Inc*, 2006 FCA 229 at para 58, leave to SCC refused 2007 CarswellNat 859).

[33] PPC submits that Bayer's evidence cannot establish induced infringement. The PPC Product Monograph contains nothing that establishes that PPC will induce others to infringe the 424 Patent. There are no facts that support the conclusion that Bayer asks the Court to draw.

[34] First, the PPC Product Monograph does not influence or instruct co-administration of PPC-Moxifloxacin with a sodium chloride solution. The Prothonotary acknowledged the expert affidavits but noted the distinction between the facts appearing in the PPC Product Monograph and the expert opinion on how the document would be interpreted and used. The facts upon which an expert opinion is based must be found to exist before weight can be given to the opinion. An expert should provide the trier of fact with inferences that the latter cannot make itself because of the technical nature of the facts. If, on the proven facts, the decision-maker can form their own conclusions, the opinion of the expert is not necessary (*R v Abbey*, [1982] 2 SCR 24 at 42 and 46).

[35] PPC submits that Bayer relies on an argument that the PPC Product Monograph "instructs" or "directs" use of PPC-Moxifloxacin with sodium chloride in concentrations that infringe the 424 Patent. Bayer's position is based on the listed six compatible solutions and an alleged infringement by co-administration arising within that compatibility list as identified by Dr. Dresser. However, no witness ever calls the compatibility list an "instruction" or "direction" to co-administer the products. Rather, Dr. Dresser's opinion was that there is an instruction to prescribe and use PPC-Moxifloxacin in the same way as AVELOX® I.V., including co-administering the PPC product with a normal saline solution in circumstances where the treating physician determines it to be advisable, which Bayer's counsel, when appearing before the Prothonotary, described as the "linchpin" of the testimony.

[36] However, the PPC Product Monograph never instructs healthcare providers to co-administer PPC-Moxifloxacin with a sodium chloride solution and, in fact, states that it is

unnecessary to dilute the product. Where the courts have been required to analyze a product monograph in respect of induced infringement, findings of fact pertaining to the product monograph's content have been based on a direct reading of the monograph, not a party's characterization of it (*Sanofi-Aventis Canada Inc v Novopharm Ltd*, 2007 FCA 167 at para 13; *Lundbeck* at paras 383-399). Further, although Bayer argues that PPC did not have to include 0.9% sodium chloride in the list of compatible solutions and that PPC's decision to do so should lead to an adverse inference, Dr. Dresser's evidence was that compatibilities are required to be listed in the product monograph.

[37] PPC submits that its Product Monograph together with Dr. Dresser's evidence cannot support a legal conclusion that PPC will induce a healthcare practitioner to co-administer PPC-Moxifloxacin with a sodium chloride solution, and thereby directly infringe the 424 Patent. The Federal Court of Appeal has held that inducement to infringe cannot be inferred from a passing reference to a patented product embodiment in the monograph of the generic product (*Sanofi-Aventis Canada Inc v Novopharm Ltd*, 2007 FCA 167 at para 11). In this case, the list of six compatible solutions is a passing reference to the context of sequential intravenous therapy. Further, the "H. pylori" cases referred to by Bayer are distinguishable as the patents in those cases involved the uses of a drug and product monographs references to studies in which the drug was shown to be useful for the patented use. PPC submits that it is plain and obvious that, on the available evidence, Bayer cannot establish infringement but for the list of six compatible solutions in its Product Monograph and, accordingly, cannot meet the second prong of the test for inducing infringement.

[38] Second, PPC submits that any co-administration of PPC-Moxifloxacin with sodium chloride would be dictated by physicians based on medical considerations. Dr. Grossman set out decision-making steps that he would take in order to decide whether to co-administer moxifloxacin with anything else. He also admitted that he does not consult product monographs himself to determine the compatibility of products. Dr. Dresser also confirmed that co-administration would only take place where the treating physician determines it to be advisable. PPC cannot be held liable for inducing infringement when all decision-making leading to the infringement is made by the physician treating the patient and is not influenced by PPC. There must be conclusive proof that the direct infringement results from PPC's influence (*Hershkovitz* at para 160). Partial responsibility is not enough and, based on this evidence, Bayer cannot meet the test for inducing infringement (*MacLennan* at para 38; *Apotex Inc v Nycomed Canada Inc*, 2011 FC 1441 at para 20).

[39] Third, PPC submits that Bayer's expert witnesses do not address the inducement test. In an attempt to overcome this omission in the evidence, Bayer has stated that PPC is obviously aware of the 424 Patent and eventual infringement and that *mens rea* can be attributed to PPC as the author of the PPC Product Monograph. However, PPC was required to serve a notice of allegations as per the *NOC Regulations* and Bayer cannot rely on this to establish that PPC knowingly influenced healthcare providers to infringe a patent. It cannot logically be inferred that PPC knew it would infringe the 424 Patent by writing a letter to Bayer alleging that it does not infringe that patent. Further, the PPC Product Monograph expressly states that the product does not have to be diluted (and therefore co-administered). A finding of inducement cannot be made based on an adverse inference (*Weatherford* at paras 155-171).

[40] The Prothonotary was entitled to find that Dr. Dresser's opinion about what may happen in the future does not create facts where none exist, and that while better evidence may become available to support Bayer's allegations after approval, this is all speculation at this juncture. As Bayer's witnesses did not turn their minds to PPC's role in influencing any infringing act, and as there is no evidence capable of establishing knowing influence of a direct infringement, Bayer's Prohibition Application cannot possibly succeed. Upholding Prothonotary Lafrenière's order will therefore preserve the administration of justice.

Standard of Review

[41] The parties agree that where a Prothonotary's order is vital to the final issue in a case, on appeal of that issue, a *de novo* hearing is required. Here the Prothonotary's order is vital to the final issue in the case as, pursuant to s 6(5) of the *NOC Regulations*, it dismisses as vexatious all parts of the Prohibition Application pertaining to the 424 Patent (*Merck & Co Inc v Apotex Inc*, 2003 FCA 488 at paras 17-19; *ZI Pompey Industrie v ECU-Line NV*, 2003 SCC 27 at para 18; *City Centre Aviation Ltd v Jazz Air Lp*, 2007 FCA 304 at para 14; *Sanofi-Aventis Canada Inc v Novopharm Ltd*, 2006 FCA 1125 at paras 16-17, 20, aff'd 2007 FCA 163 at para 8; *Pfizer Canada Inc v Apotex Inc*, 2009 FC 671 at paras 1, 30). Once it is determined that a *de novo* review is required, it is not necessary to attempt to identify any error in the decision under appeal (*City Centre Aviation Ltd. v. Jazz Air Lp*, 2007 FCA 304 at para 13).

Analysis

[42] In my view, the Prothonotary did not err in granting the motion to strike Bayer's Prohibition Application in regard to the 424 Patent because the application has no chance of succeeding at the hearing.

[43] The parties in their submissions have set out the general principles of law applicable to an application under s 6(5) of the *NOC Regulations*. They do not dispute these principles, but rather dispute how they apply to this factual situation. These principles are, in essence, that the purpose of s 6(5) of the *NOC Regulations* is to dispose of prohibition applications that have no chance of succeeding. This is an extraordinary remedy and the onus on the moving party in a motion to strike is very high (*Nycomed GmbH v Canada (Minister of Health)*, 2008 FC 330 at paras 76-77; *Pfizer Canada Inc v Apotex Inc*, 2009 FC 671 at paras 33-34, 37). The application should be so "clearly futile that it has not the slightest chance of success" or it should be "plain and obvious" that the applicant has no chance of success (*Sanofi-Aventis Canada Inc v Novopharm Ltd*, 2007 FCA 163 at para 28; *Pfizer Canada Inc v Apotex Inc*, 2009 FC 671 at para 33). Granting motions to strike should be rare and should not be encouraged (*Valeant Canada LP v Canada (Minister of Health)*, 2013 FC 1254 at para 38). The motions judge must make the necessary findings of fact viewed in the light most favourable to the first person, and apply the law to the facts (*Abbott Laboratories Ltd v Canada (Minister of Health*, 2007 FC 622 at para 37; *Nycomed Canada Inc v Novopharm Ltd*, 2008 FC 454 at para 37).

[44] While keeping this in mind, however, one must also consider that this provision is a part of the *NOC Regulations* and, therefore, the threshold for a motion brought pursuant to s 6(5) should not be impossible to attain. Additionally, possible future evidence of infringement is merely speculative and cannot be given any weight in a s 6(5) motion, such as this one (*Sanofi-Aventis Canada Inc v Novopharm Ltd*, 2007 FCA 167 at para 13; *Nycomed Canada Inc v Novopharm Ltd*, 2008 FC 454 at paras 36, 37).

[45] The starting point for this analysis must be that it is clear, and not in dispute, that there is no evidence of direct infringement by PPC in this case. The 424 Patent covers formulations including moxifloxacin and sodium chloride within certain specified concentrations. It was established by the Dresser Affidavit that […]. Bayer nonetheless asserts that health practitioners will infringe the 424 Patent by co-administration as a direct result of PPC's influence in its Product Monograph and its attempts to have PPC-Moxifloxacin substituted for AVELOX® I.V.

[46] The test for inducement of infringement has been confirmed by the Federal Court of Appeal in *Weatherford Canada Ltd v Corlac Inc*, 2011 FCA 228 at para 162 as follows:

> … A determination of inducement requires the application of a three-prong test. First, the act of infringement must have been completed by the direct infringer. Second, the completion of the acts of infringement must be influenced by the acts of the alleged inducer to the point that, without the influence, direct infringement would not take place. Third, the influence must knowingly be exercised by the inducer, that is, the inducer knows that this influence will result in the completion of the act of infringement: *Dableh v. Ontario Hydro*, [1996] 3 F.C. 751 (Fed. C.A.), paras. 42, 43, leave to appeal refused, (1997), [1996] S.C.C.A. No. 441 (S.C.C.); *AB Hassle v. Canada (Minister of National Health & Welfare)*, 2002 FCA 421, 22 C.P.R. (4th) 1 (Fed. C.A.), para. 17, leave to appeal refused, (2003), [2002] S.C.C.A. No. 531 (S.C.C.);

> *MacLennan c. Gilbert Tech Inc.*, 2008 FCA 35, 67 C.P.R. (4th) 161 (F.C.A.), para. 13.

[47] Subsequent jurisprudence has clarified what must be established in order to meet the three parts of the test for inducing infringement. This includes "that it is not an infringement of a patent to sell an article which in itself does not infringe, although it may be so used as to infringe such patent", and this is so even if the seller knows that the article will be used to infringe a patent (*Slater Steel* at para 27; citing *Hatton v Copeland Chatterson Co* (1906), 10 Ex CR 224 (Can Ex Ct)). It is also not sufficient that pharmacists or physicians would prescribe the product in an infringing manner, but rather the Court has to look at the actions of the second person, in this case PPC. It is the generic producer's actions, and not expectations of what might occur, that are at issue in such an application (*Lundbeck* at paras 367-371). The generic producer has to be implicated in order to find that there was inducement of infringement (*Sanofi-Aventis Canada Inc v Novopharm Ltd*, 2007 FCA 167 at para 10). The *NOC Regulations* are to prevent patent infringements by producers, and not patients, or, in this case, pharmacists or physicians (*Aventis Pharma Inc v Pharmascience Inc*, 2006 FCA 229 at para 57).

[48] Furthermore, "[c]ompletion of the infringement act must result of the influence of the direct infringer" (*Hershkovitz* at para 160). According to the Federal Court of Appeal, "an 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" (*Sanofi-Aventis Canada Inc v Novopharm Ltd*, 2007 FCA 167 at para 11).

[49] On the second prong of the test for inducing infringement, the inducer, PPC in this case, must establish sufficient influence such that, but for the influence, the direct infringement would not have taken place. Alleging only partial responsibility is not sufficient (*Apotex Inc v Nycomed Canada Inc*, 2011 FC 1441 at paras 19-20). There must be influence from the alleged inducer and this influence must be exercised knowingly (*MacLennan v Gilbert Tech Inc*, 2008 FCA 35 at para 38). The mere sale of a generic product is not sufficient, but rather, there must be something more (*AB Hassle v Canada (Minister of National Health and Welfare)*, 2002 FCA 421 at para 56; *Aventis Pharma Inc v Apotex Inc*, 2006 FCA 357 at paras 17-18). Additionally, simply knowing that the product will likely be used in an infringing way is not enough (*Aventis Pharma Inc v Apotex Inc*, 2005 FC 1461 at para 32, aff'd 2006 FCA 357).

[50] The case law from the Federal Court of Appeal has also emphasized the need to be prudent in applying the law of inducement in NOC proceedings for policy reasons. If patent holders are successful in prohibition applications brought when there is only a possibility that someone will use a generic drug in a patented manner, this would have the effect of artificially extending the monopoly of the patent holder. Although the facts of the case at bar are somewhat different given that it is not only the use of the compound that it at issue, but its co-administration with another solution, the same policy concerns are applicable. As stated by Justice Sexton in *AB Hassle v Canada (Minister of National Health and Welfare)*, 2002 FCA 421 at para 57:

> Thus Apotex cannot be prevented from obtaining a NOC solely on the basis that it will sell omeprazole. If it were otherwise, then serious policy issues would arise. If there was any likelihood that a patient would consume a generic product for a patented use, then the generic product would not be approved. This would prevent new uses from being approved for existing drugs because there is

> always the possibility that someone somewhere will use the drug for the prohibited, patented purpose. This would result in a real injustice: since a generic company cannot possibly control how everyone in the world uses its product, the prevention of the generic from marketing the product would further fortify and artificially extend the monopoly held by the patent holders. The patent holder would, therefore, effectively control not just the new uses for the old compound, but the compound itself, even though the compound itself is not protected by the patent in the first place. The patent holders, as a result, would obtain a benefit they were not meant to have. In the end, society would be deprived of the benefit of new methods of using existing pharmaceutical medicines at a lower cost.

(see also *Aventis Pharma Inc v Pharmascience Inc*, 2006 FCA 229 at para 58)

[51] Jurisprudence has also established that the product monograph can play a "key role" in establishing intentions of the generic company and likelihood of infringement (*AB Hassle v Canada (Minister of National Health and Welfare)*, 2002 FCA 421 at para 55; *Abbott Laboratories* at para 36). The Court has also stated that the product monograph has to be read through the eyes of pharmacists and physicians (*Abbott Laboratories* at para 38). Additionally, infringement by inducement can be established "through inferences reasonably drawn from the contents of the product monograph for the generic drug product" (*Lundbeck* at para 356; see also *Sanofi-Aventis Canada Inc v Novopharm Ltd*, 2007 FCA 167 at para 11).

[52] How then, do these principles apply given the facts of this case?

[53] The Dresser Affidavit discusses the uses for AVELOX® I.V., primarily in the context of its co-administration. Dr. Dresser then indicates how hospitals purchase and carry drugs, more

specifically intravenous antibiotics. She next addresses whether PPC-Moxifloxacin would be co-administered in the same way as AVELOX® I.V.

[54] With respect to the latter point, Dr. Dresser states that she was "specifically asked whether PPC-Moxifloxacin would be co-administered with normal saline solutions in the same way as AVELOX® I.V.". The PPC Product Monograph was attached as an exhibit to her affidavit, as was that of AVELOX® I.V. She stated that her analysis of this question would depend in large part upon the information in the PPC Product Monograph. She stated that the "co-administration" of PPC-Moxifloxacin with compatible solutions is addressed at page 20 of the PPC Product Monograph which lists the same six compatible intravenous solutions as the AVELOX® I.V. Product Monograph. Based on the PPC Product Monograph, she concluded that she would advise physicians that PPC-Moxifloxacin can be prescribed, used and administered in the same way as AVELOX® I.V. It was therefore her opinion that "as instructed by the PPC Product monograph, physicians would prescribe and use the PPC Product in the same way as AVELOX® I.V.", including co-administering the PPC Product with a normal saline solution in circumstances where the treating physician determines it to be advisable (Dresser Affidavit at para 42).

[55] She also concluded that if PPC-Moxifloxacin is co-administered with a 0.9% sodium chloride solution within certain ratios, the resulting formulation would contain a concentration of moxifloxacin and sodium chloride that would fall within the ranges in the 424 Patent (Dresser Affidavit at paras 76 and 77). It is of note that Dr. Dresser acknowledges earlier in her affidavit that the 0.9% sodium chloride injection, USP, listed as compatible with AVELOX® I.V. and

PPC-Moxifloxacin in their respective product monographs, is commonly referred to as normal saline solution (Dresser Affidavit at para 19). Further, it is also of note that of the six listed solutions, it is one of the two most often used solutions (Dresser Affidavit at para 22).

[56] In his affidavit, Dr. Grossman also testified as to the use of AVELOX® I.V. based on his experience and practice. He stated that the manner in which a patient with community-acquired pneumonia is treated depends on a number of factors and considerations (Grossman Affidavit at para 16). He stated that counsel for Bayer asked him whether in his practice and to his knowledge, AVELOX® I.V. is administered concurrently with a 0.9% sodium chloride solution and, if so, why and how it is administered. Dr. Grossman indicated that he does not often consult product monographs to determine compatibility of products, but usually consults and defers to the hospital's pharmacists to confirm a product's compatibility for co-administration (Grossman Affidavit at para 32). He explained that when patients are admitted to hospital to treat community-acquired pneumonic (CAP) they will generally be in hospital for a number of days and require multiple doses of intravenous antibiotics. In that circumstance, it is generally preferable to have the same intravenous line connected to a patient's vein for the duration of their stay. This requires a continuous flow of solution through the line to keep the vein open. The solution most commonly used for that purpose is a 0.9% sodium chloride solution, typically referred to as saline solution (Grossman Affidavit at paras 34-36).

[57] The saline solution is administered in a primary line and any antibiotic or other drug that is needed is administered in a secondary line. As only one line goes into a patient's vein, the primary and secondary lines are connected with a "Y" connection. He described that the primary

line can sometimes be interrupted when a drug is administered but stated that there are numerous circumstances in which it is preferable to continue administering the saline solution while the drug is being administered (Grossman Affidavit at paras 36-37). He stated that the choice of saline solution depends on its compatibility with the drug(s) being administered. The most commonly used saline solution is a 0.9% sodium chloride solution, which is compatible with AVELOX® I.V. and is the saline solution he usually prescribes to be administered with AVELOX® I.V. (Grossman Affidavit at para 46). He concluded that if the generic moxifloxacin product had the same compatibilities as AVELOX® I.V., he would expect it to be used in the same way (Grossman Affidavit at para 49).

[58] The second branch of the test for induced infringement requires that the completion of the acts of infringement must be influenced by the acts of the alleged inducers to the point that, without the influence, direct infringement would not take place. The Dresser and Grossman Affidavits do not address the issue of influence. Instead they opine that because the PPC Product Monograph and the AVELOX® I.V. Product Monograph describe the manner in which both drugs can be "co-administered" with intravenous saline solutions in the same way, they would be used in this way. Dr. Dresser goes so far as to say that "as instructed by the PPC Product Monograph, physicians would prescribe and use the PPC product in the same way as AVELOX® I.V., including co-administering the PPC Product with a normal saline solution in circumstances where the treating physician determines it to be advisable" (Dresser Affidavit at para 42).

[59] However, as found by the Prothonotary, in this case the PPC Product Monograph speaks for itself. Nowhere does the document "instruct" or "direct" that the PPC- Moxifloxacin is to be "co-administered". The only reference to the 0.9% sodium chloride injection USP is under "Intravenous Administration". This explains that PPC-Moxifloxacin should be administered over 60 minutes by direct infusion or through a Y-type intravenous infusion set which may already be in place:

> Sequential IV / ~~PO~~ Therapy
>
> …
>
> Since only limited data are available in the compatibility of moxifloxacin intravenous injection with other intravenous substances, additives or other medications should not be added to moxifloxacin injection or infused simultaneously through the same intravenous line. If the same intravenous line is used for sequential infusion of other drugs, the line should be flushed before and after infusion of moxifloxacin injection with an infusion solution compatible with moxifloxacin injection as well as with other drug(s) administered via this common line.
>
> **Moxifloxacin injection is compatible with the following intravenous solutions at ratios from 1:10 to 10:1:**
>
> - 0.9% Sodium Chloride Injection, USP
> - IM Sodium Chloride Injection
> - 5% Dextrose Injection, USP
> - Sterile Water for Injection, USP
> - 10% Dextrose for Injection, USP
> - Lactated Ringer's for Injection
>
> If the Y-type or "piggyback" method of administration is used, it is advisable to discontinue temporarily the administration of any other solutions during the infusion of moxifloxacin hydrochloride.

[60] Additionally, as noted at paragraph 31 of the PPC Product Monograph, "NO FURTHER DILUTION OF THIS PRODUCT IS NECESSARY".

[61] Accordingly, while the expert evidence is useful in explaining how pharmacists and physicians will likely use PPC-Moxifloxacin if it comes on the market, the PPC Product Monograph does not direct nor does it instruct the co-administration of PPC-Moxifloxacin with 0.9% sodium chloride. It merely identifies that it is compatible with that solution. Further, as explained by Dr. Grossman if or how a saline solution will be utilized, depends on the condition of the patient. Dr. Dresser opines that PPC- Moxifloxacin and AVELOX® I.V. will be used in the same way and acknowledges that "[d]epending on the patient's condition, the treating physician may elect to administer AVELOX® I.V. along with a saline solution and/or another drug" (Dresser Affidavit at para 16). Dr. Dresser also states that "The decision as to whether the infusion of normal saline solution will be discontinued while AVELOX® I.V. is administered is taken by the treating physician. Whether the normal saline is discontinued or not will primarily depend on the patient's condition" (Dresser Affidavit at para 21). Further, the physician would co-administer PCC- Moxifloxacin "with a normal saline solution in circumstances where the treating physician deems it to be advisable" (Dresser Affidavit at para 42).

[62] It is also significant that the Dresser Affidavit clearly acknowledges that:

> Important information about a drug product, including its compatibility to be co-administered with other drugs or solutions is required to be set out in the Product Monograph…
>
> (at para 12)

[63] Further, the Dresser Affidavit states that "the Product Monograph will also provide information about potential interactions and the drug's compatibility with other products" (at para 13).

[64] On a plain reading of the PPC Product Monograph, this is clearly what is provided in reference to the six listed compatible solutions. In my view, the Prothonotary correctly found that this general reference to sodium chloride in the PPC Product Monograph did not amount to inducement. Merely stating that PPC-Moxifloxacin can be used with the six listed compatible intravenous solutions, including 0.9% sodium chloride, or that if the same intravenous line is used for sequential infusion of other drugs, that the line should be flushed before and after infusion of PPC-Moxifloxacin with a compatible solution, "without more", is not sufficient to conclude that PPC is knowingly inducing heathcare practitioners to co-administer PPC-Moxifloxacin with sodium chloride (*Sanofi-Aventis Canada Inc v Apotex Inc*, 2006 FCA 357 at para 18).

[65] Bayer has also submitted that PPC should have refrained from including 0.9% sodium chloride in the PPC Product Monograph. However, as seen from the above, Dr. Dresser's Affidavit clearly states that the list of compatibilities with other drugs or solutions "is required to be set out in the Product Monograph" (Dresser Affidavit at para 12). Therefore, omitting this information was not an option open to PPC. Nor do I view the stating of this necessary information as encouraging or directing infringement.

[66] Bayer refers to the cases of *AB Hassle v Genpharm*, 2003 FC 1443 and *Abbott Laboratories*, to argue that the product monograph is a key document and that expert opinion should be considered on how it would be interpreted in practice.

[67] In my view *AB Hassle v Genpharm*, 2003 FC 1443 is of little assistance to Bayer. There, the subject patents concerned the new use of omeprazole, a known and existing compound directed to the treatment of Campylobacter pylori (H. pylori) infections. Genpharm claimed its generic version would be used for the old purposes and, therefore, would not infringe the patent. The trial judge had referred to the product monograph as a key document and found that it contained four passages that arguably could be said to constitute evidence of the generic's intent that its product be used for the new use.

[68] The Federal Court of Appeal upheld the trial judge's decision. It too referred to the subject product monograph passages and noted that there was no explanation as to why Genpharm would include in its product monograph a study relative to H. pylori positive patients if it was not intending to imply that its omeprazole could be used to eradicate gastric acid secretions in the treatment of H. pylori infections, the new use protected by the patent.

[69] Significantly, the Federal Court of Appeal stated:

> [20] Genpharm strongly objects to Layden-Stevenson J.'s finding in respect of the product monograph. It says there was no evidence led by Astra to demonstrate that the product monograph would induce infringement of the '668 or '762 Patents. However, the product monograph was itself in evidence and it was open to Layden-Stevenson J. to draw an adverse inference from it.

[70] In this case the PPC Product Monograph was evidence that spoke for itself. Unlike the omeprazole product monograph, however, on a plain reading, it is apparent that the wording relied upon by Bayer and its experts does not support an inference or a finding that it would induce infringement. The necessary findings of fact in this case can be made by directly reading

the product monograph (*Sanofi-Aventis Canada Inc v Novopharm Ltd*, 2007 FCA 167 at para 13; *Lundbeck Canada Inc v Ratiopharm Inc*, 2009 FC 1102 at paras 383-399).

[71] For similar reasons, I do not find *Abbott Laboratories* to be of assistance to Bayer in these circumstances (see paras 41-42).

[72] As found by the Federal Court of Appeal in *Novopharm Limited v Sanofi-Aventis Canada Inc*, 2007 FCA 167 at para 11 in the context of a new use "…an 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". Here the reference was to compatible intravenous solutions and does not support an adverse inference as to inducement to infringe.

[73] As in *Lundbeck*, the question is whether the product monograph will induce infringement. There Justice Mactavish found that the subject product monograph made no reference to combination therapy and nowhere in the document was there any statement that ratiopharm was seeking approval to sell memantine for use in combination with any other drug. In reference to *AB Hassle*, Justice Mactavish noted that in that case there was evidence that the references in the product monograph to a particular study which would be understood to refer to a particular infringing use of the drug in question (*AB Hassle v Genpharm Inc*, 2003 FC 1443). However, in the case before her, the study in question was not mentioned by name or in the bibliography of the product monograph. Nor was there any evidence from a disinterested doctor or pharmacist asserting that ratiopharm's product monograph would induce them to use ratio-memantine as a

part of combination therapy. Justice Mactavish reviewed the remaining relevant references in the product monograph and concluded:

> [399] As Justice Layden-Stevenson observed in Genpharm, "subtle references" in a product monograph may be enough to leave a reader with the impression that a drug can be used in a manner that would infringe a patent: see para. 155. However, in my view, the references to the Tariot study in ratiopharm's draft product monograph are not just subtle; they are both obscure and confusing. They would not, in my view, induce anyone to prescribe memantine for use as part of a combination therapy with an acetylcholinesterase inhibitor.

(Also see *Aventis Pharma Inc v Apotex Inc*, 2005 FC 1461)

[74] In this case, the reference to compatible intravenous solutions similarly cannot be seen as inducing infringement.

[75] Dr. Dresser's opinion, that "as instructed by the PPC Product Monograph, physicians would prescribe and use the PPC Product in the same way as AVELOX® I.V., including co-administering the PPC Product with a normal saline solution in circumstances where the treating physician determines it to be advisable", is not supported by the plain wording of the PPC Product Monograph. Further, it is also subject to the treating physician's assessment of his or her patient. Nowhere in the PPC Product Monograph does it "instruct" or "direct" the "co-administration" of PPC-Moxifloxacin with 0.9% sodium chloride. Those words do not appear in the Product Monograph. The only reference to 0.9% sodium chloride is made in the context of the list of the six compatible intravenous solutions. Although it has been found that a "subtle reference" in a product monograph could leave a reader with the impression that a drug could be used in a way that infringes a patent, in my view the reference to sodium chloride in this case is

not sufficient to constitute inducement (*AB Hassle v Genpharm Inc*, 2003 FC 1443 at para 155). This is reinforced by the fact that the PPC Product Monograph also states clearly in bold letter that "NO FURTHER DILUTION OF THIS PRODUCT IS NECESSARY". The infringement to which Bayer refers constitutes direct infringement by pharmacists and physicians and is not an induced infringement by PPC by way of its Product Monograph. Further, merely stating that the product is compatible with 0.9% sodium chloride is not sufficient to establish that PPC is knowingly inducing healthcare practitioners to breach the 424 Patent by co-administering PPC-Moxifloxacin with 0.9% sodium chloride.

[76] Although not raised by the parties, the fact that Bayer alleges induced infringement based on the use of the proposed generic with what its experts describe as the most commonly utilized, or normal, saline solution, could raise a policy concern. Specifically, the administration of the saline solution may be medically necessary regardless of the prescription of moxifloxacin. Therefore, should patients be denied the use of a generic simply because, when PPC-Moxifloxacin is administered together with normal saline solution, in a certain narrow range of concentration, it would infringe the 424 Patent? However, that question was not raised and, accordingly, I make no finding in that regard.

[77] Although in its appeal Bayer has not argued that the Dresser Affidavit establishes that once PPC-Moxifloxacin enters the market PPC will have to approach hospitals or wholesalers to convince them to dispense PPC-Moxifloxacin instead of AVELOX® I.V., I would agree with the Prothonotary that this evidence amounts to speculation. Further, the Dresser Affidavit states that where generics are available, a hospital's decision to list an antibiotic will generally be made

based on the attributable compound as opposed to a particular brand stating that "Which of the available products the hospital will list on its formulary will generally be determined as a result of tender process" (Dresser Affidavit at paras 29-31) and that:

> Hospitals usually put out requests for tenders and wait for drug manufacturers to submit their bids. It is the drug manufacturer who approaches hospitals to offer their products. Consequently, once the PPC Product enters the market in Canada, PPC will have to approach hospitals or wholesalers to convince them, to switch from AVELOX® I.V to the PPC Product.
>
> (Dresser Affidavit at para 35)

[78] I have some difficulty in understanding how responding to a tender request which is put out by a hospital translates into requiring PPC to approach hospitals seeking to convince them to switch products. I do not see this as evidence that in any way supports the allegations of induced infringement.

[79] At paragraph 30 of his decision, the Prothonotary indicated that there is no evidence that PPC will be seeking to sell its product in combination with sodium chloride. Bayer asserts that this means that applications under the *NOC Regulations* would never be successful because they take place before the actual sale of products. The Prothonotary, however, was referring to the sale of PPC-Moxifloxacin with sodium chloride, of which there is no evidence. The only relevant evidence in this case is the PPC-Moxifloxacin Product Monograph and the evidence from the two experts, which do not indicate the sale of PPC-Moxifloxacin with sodium chloride in a way that would directly infringe the 424 Patent or induce others to do so. The Prothonotary's observation, therefore, does not mean that every application under the *NOC Regulations* would be unsuccessful. He was simply noting that given the particular facts of this

case, being that there is no evidence of direct or induced evidence by selling the product with sodium chloride, it would be more appropriate for Bayer to wait and bring an action for infringement, should this eventually happen.

[80] In summary, to meet the second branch of the inducing infringement test, PPC as the inducer must exercise sufficient influence over the direct infringer, being physicians or pharmacists, such that "but for" the inducing activity the direct infringement would not have taken place. For the reasons set out above, neither the PPC Product Monograph nor the expert evidence meet this requirement. In addition to the second prong of the test not being met, it is likely that the third prong of the inducement infringement test would also not be met in these circumstances. The third prong of the test states that "the influence must knowingly be exercised by the inducer, that is, the inducer knows that this influence will result in the completion of the act of infringement" (*Weatherford* at para 162). As stated in the paragraphs above, the only reference to 0.9% sodium chloride is in the list of compatible solutions, which must be included in the Product Monograph. Additionally, the PPC Product Monograph states that the product does not have to be diluted before being co-administered, which does not support Bayer's allegation that PPC is knowingly inducing infringement by co-administration through its PPC Product Monograph. Given that the second prong of the test is not met, however, it is not necessary to make a definitive finding on the third prong of the test for inducement.

[81] PPC has met its burden of establishing that it is plain and obvious that Bayer has no chance, based on the evidence adduced, of establishing that PPC is or will induce infringement of the 424 Patent. Given that the second prong of the test for inducing infringement will

inevitably fail, those aspects of the Prohibition Application which relate to the 424 Patent should properly be struck and, therefore, the appeal is dismissed. A lump sum cost award of $2,500.00 is appropriate in these circumstances.

JUDGMENT

THIS COURT'S JUDGMENT is that

1. The appeal of the Prothonotary's decision is denied; and

2. PPC shall have its costs in the all-inclusive lump sum of $2,500.00.

"Cecily Y. Strickland"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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