

Federal Court



Cour fédérale

**Date: 20091231**

**Docket: T-1773-07**

**Citation: 2009 FC 1316**

**Ottawa, Ontario, December 31, 2009**

**PRESENT: The Honourable Mr. Justice Lemieux**

**BETWEEN:**

**ELI LILLY CANADA INC. and  
ELI LILLY AND COMPANY**

Plaintiffs  
(Defendants by Counterclaim)

**and**

**HOSPIRA HEALTHCARE CORPORATION**

Defendant  
(Plaintiff by Counterclaim)

**REASONS FOR JUDGMENT AND JUDGMENT**

Introduction and background

[1] Hospira Healthcare Corporation (Hospira) appeals to this Court the June 19, 2009 Order of Prothonotary Tabib (the prothonotary) who is case managing this patent infringement action launched by Eli Lilly Canada Inc. and Eli Lilly and Company (Lilly) on October 4, 2007 and twice subsequently amended claiming Hospira infringed its Canadian Patent 2,098,881 (the “ ‘881

patent”). The ‘881 patent is a process patent for the preparation, through a S<sub>N</sub>2 chemical reaction known as glycosylation, of a beta anomer enriched nucleoside compound which is the essential component for active pharmaceutical ingredient (API) in the manufacture of the drug gemcitabine hydrochloride which has anti-tumor cancer properties. The prothonotary ordered Hospira to serve upon Lilly a further and better affidavit of documents namely: (1) the open part and the closed part of its Drug Master File (DMF); (2) the relevant parts of its Abbreviated New Drug Submission (ANDS) and amendments to it, filed with the Minister of Health (the Minister), which the Minister based the issuance on August 23, 2007 of an NOC to Hospira authorizing it to sell the drug in Canada; and, (3) the Batch Records relating to the process for manufacturing gemcitabine (the drug or medicinal ingredient) along with the certificates of analysis relating to the medicinal ingredient imported in bulk form and sold in Canada by Hospira (the documents to be produced). She also ordered Hospira to produce to Lilly unredacted and complete copies of the documents.

[2] The documents Hospira had first listed in its initial affidavit of documents on October 6, 2008 were: (1) heavily redacted excerpts of its ANDS; (2) a confidential process description for the manufacture of the drug; and, (3) a batch report for the manufacture of the drug. The last two mentioned documents were obtained by Hospira from Hospira UK in the context of litigation in the UK between the parties in respect of the drug.

[3] Lilly’s claim against Hospira has several unique features:

- i. Hospira is not the manufacturer of the gemcitabine it uses to make appropriate dosages of the drug sold in Canada. Its gemcitabine is manufactured in China by Jiangsu Hansen

- Pharmaceutical Co., Ltd. (Hansen). Hospira imports its gemcitabine in bulk from that supplier.
- ii. Both Lilly and Hospira recognize that the ANDS Hospira filed with the Minister to obtain its NOC was based on a glycosylation chemical reaction known as  $S_N1$  which is not as efficient in producing beta anomers the central element of gemcitabine's API. Rather, the  $S_N1$  reaction is more efficient in producing alpha anomers which do not have anti-tumor properties.
  - iii. Both parties agree, if Hospira's gemcitabine is produced on the basis of a  $S_N1$  reaction, the '881 patent is not infringed because its process is based upon the  $S_N2$  reaction whose effect is to foster the production of the more desirable beta anomers. The  $S_N1$  reaction was disclosed prior to the invention of the  $S_N2$  process step in the manufacture of the API.
  - iv. Both parties also agree that either the  $S_N1$  or the  $S_N2$  reaction is but an intermediary step in the manufacture of the API component of the drug. The '881 patent does not claim a monopoly on the steps leading to the preparation of the  $S_N2$  reaction (the upstream steps), nor does it claim a monopoly on the separation and purification steps that follow the  $S_N2$  reaction (the downstream steps).
  - v. In its statement of claim, Lilly asserted "the processes claimed in the '881 patent are the only processes that can produce commercial quantities of gemcitabine in an efficient and cost effective manner" and that, inter alia, between August 27, 2007 and December 3, 2007,

Hospira imported in Canada commercial quantities of gemcitabine manufactured in China by the S<sub>N</sub>2 reaction.

[4] Hospira submits Prothonotary Tabib erred in law and/or proceeded on a wrong principle in making the order she did. It asserts her Order enables Lilly to “embark on a fishing expedition by way of discovery, with respect to irrelevant documents falling outside the scope of the process patent at issue, premised only on Lilly’s unpleaded speculation of regulatory fraud on Health Canada.” Hospira also asserts the foundation for Lilly’s speculation is that Hospira’s process is not commercially viable because it was incompatible with Lilly’s business model 20 years ago. Hospira also says the inventor of the ‘881 patent has admitted Hospira’s process for the manufacture of the drug as described in its ANDS filed with the Minister of Health is prior art to the patented process and cannot infringe it.

[5] The parties did not fundamentally disagree on the standard of review on this appeal, the legal test for relevance and the nature and the scope of the ‘881 patent.

(1) The standard of review

[6] In their written material, the parties had initially disagreed on the standard of review. Notwithstanding the fact the prothonotary’s order was made upon a motion by Lilly for a further and better affidavit of documents from Hospira, Hospira’s counsel submitted the effect of the prothonotary’s order is to prolong and maintain this action, since in the absence of that order, Lilly’s action would be effectively over. Hospira’s counsel did not press this view in oral argument

recognizing, in my view, the recent jurisprudence on the issue did not support her argument of this point.

[7] In my view, Prothonotary Tabib's order is not vital to the resolution of this action and therefore her decision is not to be reviewed by this Court *de novo*. This standard of review on appeal was clearly established recently by the Federal Court of Appeal (the FCA) in *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2008 FCA 287 (Novopharm) in which the FCA upheld a decision of this Court, which in turn, upheld a decision of Prothonotary Tabib to compel a further and better affidavit of documents in a patent infringement case launched by Lilly (see Novopharm, paragraph 53). Consequently, Hospira has the burden of demonstrating on this appeal in making the order Prothonotary Tabib made - compelling a further and better affidavit of documents and the production of those documents in unredacted form - she was clearly wrong, in the sense that the exercise of her discretion to make such an order, was based upon a wrong principle or upon a misapprehension of the facts. (See *Merck & Co., Inc. et al v. Apotex Inc.*, 2003 FCA 488.)

(2) The legal test for relevance

[8] The legal test for relevance for determining what documents a party is entitled to have listed in an affidavit of documents and produced for discovery was also settled by the FCA in the Novopharm case. The test is based on the concept of "a train of inquiry" namely, unless the party producing the affidavit of document intends to rely on a document at trial, that person is not obliged to disclose it "unless it is reasonable to suppose that the document would undermine its own case, advance its opponent's, or would fairly lead him [a reasonable likelihood of leading] to a train of inquiry which may have either of these two consequences. [My emphasis.]

(3) The nature and scope of the '881 patent

[9] The nature and scope of the '881 patent is also recognized by the parties. The '881 patent is entitled "Stereoselective Glycosylation Process." As noted, it relates to the manufacture of the drug gemcitabine which has anti-tumor cancer properties. The '881 patent discloses and claims an intermediate process step used in the overall seven step process to make the API of the drug. Specifically, the '881 patent claims a monopoly on step 5 of these intermediate steps, the S<sub>N</sub>2 reaction at the glycosylation stage in the API's production process for the drug.

[10] The focus of the '881 patent is on the S<sub>N</sub>2 reaction known as glycosylation. Hospira's point is that glycosylation can occur by one of two pathways: one through S<sub>N</sub>1 reaction and the other through the S<sub>N</sub>2 reaction. As mentioned, Hospira recognized the S<sub>N</sub>2 reaction yields better beta results but nevertheless the S<sub>N</sub>1 pathway is acceptable even though it yields more undesirable alpha anomers in the nucleoside compound the result of the glycosylation stage. Hospira also recognizes the drug gemcitabine is a beta anomer and that the alpha anomer is not gemcitabine and does not have the anti cancer properties of that drug.

[11] The crux of this litigation is what chemical reaction actually takes place at the glycosylation stage – the S<sub>N</sub>1 reaction or the S<sub>N</sub>2 reaction. Either reaction takes place in Hansen's plant in China.

Prothonotary Tabib's decision

[12] At the beginning of her considerations for Order, she identified the central issue in the patent action:

The central issue in this action is whether the process used by Hospira's supplier, Jiangsu Hansen Pharmaceutical Co. Ltd. ("Hansen") to manufacture in China the bulk gemcitabine subsequently imported and sold by Hospira in Canada infringes the claims of the patent at issue, the '881 Patent.

[13] She explained: "Hospira alleges that the process used by Hansen is a previously known and disclosed process, known as the S<sub>N</sub>1 reaction. Both parties agree that if Hospira's gemcitabine was and is indeed manufactured by Hansen using the S<sub>N</sub>1 reaction, then there is no infringement, as the patented process is an entirely different process, known as the S<sub>N</sub>2 reaction."

[14] She further noted: "Hospira has listed in its affidavit of documents and disclosed to Lilly those portions of its regulatory filings with Health Canada showing the relevant reaction. Again, Lilly concedes that the reaction disclosed in those parts of the filings corresponds to the S<sub>N</sub>1 reaction, and that if it is indeed the process followed by Hansen, there is no infringement."

[15] Prothonotary Tabib next considered Lilly's additional disclosure request category by category. She indicated the main thrust of Lilly's motion was on the issue of the Batch production records and its related certificates of analysis for the gemcitabine product actually imported by Hospira and offered for sale. She devoted much of her analysis to that issue because: "Both parties concede that those batch records would constitute direct evidence of the process actually used by Hansen in manufacturing the bulk gemcitabine, and assuming that they are accurate, would constitute direct evidence of whether the process used by Hansen is the S<sub>N</sub>1 reaction or the S<sub>N</sub>2 reaction, and therefore, whether or not there is infringement." [My emphasis.]

(a) The Batch Records

[16] She identified the question on the motion before her, as it related to the batch records, as “whether it is reasonable to suppose that these documents would undermine Hospira’s case or advance Lilly’s; in other words, is it reasonable to suppose that the batch records would show that Hansen uses the S<sub>N</sub>2 reaction?” [My emphasis.]

[17] She analysed Hospira’s argument such likelihood was negated by the fact that its regulatory filings unequivocally show that the S<sub>N</sub>1 process is used; that Hospira had an obligation to be accurate and complete, and “dire” consequences would result “if Hospira had represented to Health Canada that it used the S<sub>N</sub>1 process while it was using in fact the S<sub>N</sub>2 process.” Hospira urged upon Prothonotary Tabib what was filed with Health Canada “is tantamount to a declaration under oath and that it carries with it a presumption of veracity which can only be rebutted by cogent evidence.”

[18] For a number of reasons, Prothonotary Tabib did not accept Hospira’s submission on this point:

- a. Hospira never specified the nature of the “dire” consequences would strike it should its supplier use the S<sub>N</sub>2 in its manufacturing process and it did not appear from the record any provisions were made in the regulatory scheme for auditing the accuracy of the process information provided.
- b. Unless it contained an admission against Hospira’s interest, she doubted very much a certificate, addressed to Health Canada for the purpose of obtaining an NOC, as to the process that will be carried out by a third party in the future, could be relied upon



by Hospira as evidence of the process actually used in the context of an infringement action and “as such [she had] very serious reservations as to Hospira’s proposition the certificate delivered to Health Canada, in the circumstances of this action, is equivalent or tantamount to a sworn statement by a representative of Hospira as to the process carried out by Hansen.” She noted Hospira had tendered no evidence what system it had in place to verify the continued accuracy of the statements made to Health Canada or that anyone at Hospira has even reviewed the batch records for the imported gemcitabine to verify that they ostensibly conform with the regulatory filings. She further observed, while there was no evidence before her of any falsehood on Hospira’s part, there was nothing on the record which would lead her to believe Hospira’s faith in the continuing accuracy of its filings rests on anything other than its own faith in its supplier and said she was not aware that Hansen “had ever filed a similar certificate with Health Canada or made any representation in this litigation as to the process it uses. She said no party has indicated what penalty, if any consequences would be suffered by Hansen if it chose to manufacture the bulk gemcitabine in a manner different than that contemplated by Hospira.” She concluded: “I am therefore not satisfied that a presumption even attaches as to the truthfulness or accuracy of Hospira’s certificate to Health Canada, as it relates to its supplier’s actual process.” [My emphasis.]

[19] In any event, she was satisfied Lilly had produced sufficient evidence to demonstrate “the likelihood that the batch records would show that Hansen uses the  $S_N2$  reaction instead of the  $S_N1$  reaction.” She analyzed two affidavits and related cross examinations thereon. Lilly’s deponent was

Dr. Douglas Kjell, an expert in chemical process development in that organization. The thrust of his evidence on using the S<sub>N</sub>1 process to manufacture bulk gemcitabine was “so inefficient as to not be viable to produce commercial quantities of that ingredient.” Its yield was very low and uses a highly reactive and dangerous reagent and, as well, an inefficient and wasteful method of purification.”

[20] She also considered the affidavit and cross examination of Hospira’s expert, Dr. Robert Adlington. She described his evidence in the following terms: “However, rather than contradicting or impugning the scientific basis on which Dr. Kjell reached his conclusion that the S<sub>N</sub>1 process is not commercially viable, he suggests, but without citing specific facts, that it is not impossible that these obstacles could be overcome or offset by other efficiencies in other parts of the process. He goes on to state that he has witnessed personally the S<sub>N</sub>1 process being carried out by Hansen at its premises in China “on a commercial scale”.

[21] Prothonotary Tabib indicated it was common ground between the parties the batch Dr. Adlington witnessed being made by Hansen in China had not been identified as one which was imported into Canada, and the batch in question did not result in more than 10.7 kg of API. She said there was no evidence on record as to what Hospira considers to be commercial quantities of gemcitabine, and Dr. Adlington admitted he was not aware of either Hospira’s or Hansen’s cost of production or other economic information. She found Dr. Adlington, unlike Dr. Kjell, had no experience in the area of managing and evaluating the costs of a process that is run on a large or commercial scale. She gave little weight to Dr. Adlington’s view the process he witnessed at Hansen was on a commercial scale. She did not accept Hospira’s submission Lilly had not proven either it or Hansen’s intentions were to make or sell gemcitabine on a commercial basis. She also

discarded an attack on Dr. Kjell's evidence as being self-serving because he is an employee of Lilly who himself had recommended Lilly not use the S<sub>N</sub>1 process. She ruled she could accept evidence from an employee of a party if it was relevant and the expert properly qualified "especially so where, as here, no evidence has been tendered by the other party to directly contradict the scientific basis for the opinion and where the testimony has not been shaken on cross-examination." She concluded:

I therefore accept Dr. Kjell's evidence to the effect that the S<sub>N</sub>1 process is extremely inefficient and wasteful and that it is more likely than not that it would not be used in a commercial operation. That is sufficient to create a reasonable basis to suppose that Hansen is not carrying out the S<sub>N</sub>1 process for the gemcitabine imported and sold by Hospira in Canada, notwithstanding Hospira's perhaps genuinely held belief and intent to the contrary, as evidenced by Hospira's filings with Health Canada. Accordingly, I am satisfied that Lilly has established a reasonable likelihood that the batch records of Hansen for the gemcitabine imported and sold by Hospira in Canada could show the use of the S<sub>N</sub>2 process and therefore directly advance Lilly's case. These documents are relevant and must be listed in the affidavit of documents, either as documents within the power, possession or control of Hospira, if that is the case, or if not, as documents in the power, possession or control of a third party. [My emphasis.]

[22] Finally, she remarked that the batch records for the production of gemcitabine made in the presence of Dr. Adlington were eventually produced to Lilly, but in a heavily redacted form. The only rationale she could see for the redactions was on the grounds of relevance i.e. they relate to parts of the process which is not strictly covered by the claims of the patent, and that they are therefore not relevant. She observed Hospira did make an argument relating to confidentiality, but produced no evidence whatsoever showing that the portions it has redacted are "particularly sensitive or confidential", such that the provisions of the confidentiality order already in place would not adequately protect them.

[23] She concluded:

Hospira's sole basis for going through the trouble and expense of redacting portions of such documents (therefore producing an obviously incomplete document) is lack of relevance. In my view, the practice of parties redacting portions of documents on no justification whatsoever other than lack of relevance, thus putting the receiving party to the onus of establishing the relevance of the redacted portions, is one to be avoided. Partial productions and redactions should not be permitted unless on grounds of proportionality, onerousness, or convenience or when genuine issues of confidentiality arise. Documents produced pursuant to this order shall therefore not be redacted. [My emphasis.]

(b) The other documents sought

[24] With respect to the other categories of documents requested by Lilly for listing and production, Prothonotary Tabib ruled "the same reasoning applies to Lilly's request that the entire, unredacted parts of the closed and opened portions of Hospira's DMF and of the ANDS, as they relate to the manufacture of bulk gemcitabine, be disclosed and produced without redaction. To the extent they are self-contained documents, rather than a collection of independent documents, no reason for redaction has been made out."

Analysis

(a) The Standard of Review

[25] I have already held that to succeed Hospira must show the Prothonotary erred by exercising her discretion based upon a wrong principle or upon a misapprehension of the facts.

(b) Hospira's arguments

[26] In her written material, counsel for Hospira prefaced her points stating “the key issue in this appeal is whether Lilly should be permitted to embark on a wide-ranging discovery based on unpleaded speculation Hospira has misrepresented its manufacturing process to Health Canada.” She added that the foundation for Lilly’s speculation is that Hospira’s process is not commercially viable because it is incompatible with Lilly’s business model nearly 20 years ago.”

[27] First, Hospira asserted the prothonotary had misconstrued Lilly’s cause of action when she ordered Lilly should have access to Hospira’s entire process for the manufacture of gemcitabine and not merely the intermediate stage (the glycosylation stage that is relevant to the ‘881 patent). Counsel submits prothonotary Tabib erred when she “concluded that “commercial viability” of a defendant’s action is relevant to a determination of possible infringement” and further erred when “finding the entire synthesis is the relevant process for the purposes of an infringement analysis [and] in doing so she effectively redefined the scope of the ‘881 patent providing protection for the production of gemcitabine per se as opposed to the intermediate.”

[28] Second, she argues the prothonotary’s finding “that an  $S_N1$  reaction is not “commercially viable” because it requires the use of a dangerous chemical known as TMS-triflate” constitutes a collateral attack on the Minister’s decision to issue an NOC to Hospira, because in so doing, he had to consider whether Hospira’s drug based on gemcitabine was safe and effective.

[29] Third, counsel for Hospira urged upon the Court, the prothonotary erred when she failed to recognize Lilly’s allegation of infringement rests solely on its speculation as to the intentions and/or

motive of Hospira/Hansen, i.e. a finding that Hospira was motivated to make and sell gemcitabine on “a commercial basis” under Lilly’s undefined parameters. In other words, the prothonotary erred when she took into account a totally irrelevant factor in assessing infringement – the factor of “commercial viability”.

[30] Fourth, she argues the prothonotary fell into error when she found there was no presumption that the content of Hospira’s ANDS should be presumed true. Counsel for Hospira submits the prothonotary’s conclusion on this point reflects a misinterpretation of the regulatory scheme of the *Food and Drug Regulations*. She refers to a UK decision holding an untrue certification would constitute a fraudulent misrepresentation to a regulatory authority and such a course of action being “commercial suicide”. She couples this argument with a further point the prothonotary erred in finding that no serious consequences could ensue from a misrepresentation to Health Canada. She also asserts prothonotary Tabib further erred Hospira had the burden of proving regulatory fraud which had not been pleaded by Lilly.

[31] Finally, Hospira argued the prothonotary misrepresented the facts when she concluded there was a reasonable likelihood the batch records sought by Lilly would show use by Hansen of the S<sub>N</sub>2 process and therefore infringement.

[32] In oral argument, counsel for Hospira on the following findings said to have been made in error: (1) ordering the disclosure of the entire seven steps to produce the API when the ‘881 patent only claimed a monopoly on the S<sub>N</sub>2 glycosylation stage; (2) a finding of no presumption that what had been filed with the Minister was true; (3) a finding of an un-pleaded regulatory fraud; and, (4)

misapprehension of the facts by giving weight to an old business model of “commercial viability” proffered through the affidavit of Dr. Kjell, a current and longtime employee of Lilly who was neither independent or objective. In reply argument, counsel for Hospira argued the prothonotary made her critical findings when she had insufficient evidence before her to do so. She pointed for example: (1) the yield for the S<sub>N</sub>1 reaction had not been updated; (2) the prothonotary overplayed the risks of producing gemcitabine using TMS-triflate; and, (3) Lilly’s commercial viability model did not appropriately take into account the changes in labour costs in developed countries versus China.

#### Analysis and conclusions

[33] I will quickly dispose of some of the arguments put forward by counsel for Hospira because, with respect, in my view, what is asserted by Hospira as findings made by the prothonotary were in fact not findings at all.

[34] A reading of her decision as a whole clearly tells this Court Prothonotary Tabib was focussed on one issue which is all she decided: whether the evidence presented by the parties assessed in their totality was sufficient to satisfy her the relevancy test and, in particular, the “train of inquiry” test had been met i.e. the evidence was such that it was reasonable to suppose the documents sought in the further and better affidavit of documents would undermine its Hospira’s case, advance by Lilly’s case or would fairly lead to a train of inquiry which may have either of these consequences.

[35] In coming to the conclusion she did that additional disclosure was warranted, the prothonotary carefully weighed the evidence submitted by both sides and the cross-examination on those affidavits.

[36] In this context, in my opinion, the prothonotary made no finding:

- i. That Hospira had made any misrepresentation in its ANDS to the Minister. However, she also found there was no evidence Hansen (as opposed to Hospira in its ANDS) had made any representation whatsoever to the Minister and, in particular, asserting the use of the S<sub>N</sub>1 reaction at the glycosylation stage.
  
- ii. That Hospira's ANDS did not have the benefit of truthfulness, but held, in the particular facts of the case before her, where the supplier of the bulk gemcitabine was an offshore supplier who had made no representations to the Minister, where Hospira had not led evidence of any verification system in place to review and verify what glycosylation process was used in the bulk gemcitabine it imported and Lilly's evidence on the commercial viability of the S<sub>N</sub>1 reaction, Hospira could not rely on the presumption.
  
- iii. The prothonotary did not make a finding "commercial viability" was a factor in considering whether there was infringement or not. What she decided was there was sufficient evidence before her leading her to be satisfied what she was ordering was relevant to Lilly's action.



iv. The prothonotary did not find that by ordering the production of the entire process followed to make the API for the gemcitabine, Lilly was expanding the limited claims protected under the '881 patent. All she decided was that disclosure of the entire process was relevant to a specific plea in Lilly's statement of claim, namely, of patent infringement by using the  $S_N2$  reaction. Sufficient evidence had been led to convince her the sought after documents by Lilly met the relevancy test in the context of a further affidavit of documents motion.

v. The prothonotary's decision was not a collateral attack on the Minister's finding in terms of the Minister's statutory duty as to the safety and efficiency of the drug Hospira sold to consumers in Canada in dosage form. Lilly has not attacked the Minister's NOC to Hospira and has not alleged the drug Hospira markets in Canada is unsafe or ineffective. What Lilly has alleged is that, in so doing, Hospira has infringed its '881 patent by its supplier's use of the  $S_N2$  reaction.

[37] I have had an opportunity to review the affidavits and the cross-examinations of Drs. Kjell and Adlington. I agree with counsel for Lilly there was in the record before her sufficient evidence to support each of her findings made by the prothonotary which were based, in my view, on the application of the correct test for relevance in the context of a motion for a further and better affidavit of documents.

[38] In particular, for example, Dr. Adlington acknowledged that:

- a. All yields of each step in the process to the making of the gemcitabine is important as they all contribute to the overall yield (Adlington's cross-examination, page 29, question 77).
- b. Knowing the starting material for the process related to an  $S_N2$  reaction is important. Such starting material had to be based on an alpha anomer (Adlington's cross-examination, page 153, question 547).
- c. To determine whether gemcitabine was prepared in a cost effective manner a person with the particular expertise would have to have information on the upstream steps necessary to prepare for the  $S_N2$  reaction (Adlington's cross-examination, pages 86 to 89).
- d. Costs were factors which needed to be considered for a company to be commercially viable i.e. make a profit to support its overall business venture (Adlington's cross-examination, pages 30 and 87).

[39] Clearly, on the basis of this evidence, the prothonotary had ample evidence to find the upstream and downstream steps from step 5 were relevant and should be produced.

[40] It should be noted the question whether the prothonotary had sufficient evidence or misconstrued the evidence is a finding of fact in respect of which the prothonotary is owed a large measure of deference. See by analogy the Supreme Court of Canada's recent decisions in *Dunsmuir*

*v. New Brunswick*, 2008 SCC 9 and *Canada (Citizenship and Immigration) v. Khosa*, 2009 SCC

12.

[41] In terms of Dr. Kjell's affidavit evidence and cross-examination, a review of the record reveals the prothonotary had sufficient un-contradicted evidence to support her finding the use of the S<sub>N</sub>1 process was inefficient in terms of yields, residual waste and dangers related to its production with TMS-triflate.

[42] She was not persuaded by the argument advanced by Hospira a change of material circumstance had occurred since the early 1990's when Dr. Kjell worked on the S<sub>N</sub>1 reaction to determine if commercial quantities of gemcitabine could be made in a viable way. Moreover, I find no error in her appreciation of Dr. Kjell's evidence the weight she gave to that evidence and the preference she gave to that evidence over the evidence of Dr. Adlington which in any event she found largely corroborative of Dr. Kjell's.

[43] In the result, Hospira's appeal must be dismissed as it has not satisfied its heavy onus of demonstrating to the Court the prothonotary clearly erred in making the order under review. On the contrary, I am of the view the order she made was correct and proper.

**JUDGMENT**

**THIS COURT ORDERS AND ADJUDGES** that this appeal is dismissed with costs, fixed at the upper range of the units in Column IV of the Tarriff.

“François Lemieux”

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Judge

**FEDERAL COURT**  
**SOLICITORS OF RECORD**

**DOCKET:** T-1773-07

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