

Date: 20080929

Docket: A-114-08

Citation: 2008 FCA 287

**CORAM: NADON J.A.
PELLETIER J.A.
RYER J.A.**

BETWEEN:

NOVOPHARM LIMITED

Appellant

and

**ELI LILLY CANADA INC., ELI LILLY AND COMPANY,
ELI LILLY AND COMPANY LIMITED and ELI LILLY SA**

Respondents

Heard at Toronto, Ontario, on June 18, 2008.

Judgment delivered at Ottawa, Ontario, on September 29, 2008.

REASONS FOR JUDGMENT BY:

NADON J.A.

CONCURRED IN BY:

**PELLETIER J.A.
RYER J.A.**

Date: 20080929

Docket: A-114-08

Citation: 2008 FCA 287

**CORAM: NADON J.A.
PELLETIER J.A.
RYER J.A.**

BETWEEN:

NOVOPHARM LIMITED

Appellant

and

**ELI LILLY CANADA INC., ELI LILLY AND COMPANY,
ELI LILLY AND COMPANY LIMITED and ELI LILLY SA**

Respondents

REASONS FOR JUDGMENT

NADON J.A.

[1] This is an appeal from a judgment of Lemieux J. of the Federal Court, dated March 3, 2008, 2008 FC 281, pursuant to which Novopharm Limited's (the "appellant" or "Novopharm") appeal from an Order of Prothonotary Tabib, dated November 15, 2007, 2007 FC 1195, was dismissed with costs.

[2] At issue in this appeal is the Prothonotary's decision to allow, in part only, Novopharm's motion brought under Rule 227 of the *Federal Courts Rules*, SOR/98-106 (the "Rules"), for an order, *inter alia*, requiring the respondents to serve further and better affidavits of documents.

THE FACTS

[3] On April 24, 1991, the respondents filed an application for Canadian Patent No. 2,041,113 (the "'113 Patent") which issued on July 14, 1998. The claimed compound of the '113 Patent, a selection patent, is olanzapine which is said to be useful in the treatment of disorders of the central nervous system such as schizophrenia, schizophrenic form diseases, acute mania and mild anxiety disorders. The respondents, who market olanzapine under the brand name ZYPREXA, claim that it has atypical anti-psychotic properties and an improved side effect profile over previously used anti-psychotic medicines and that it is a new product within the meaning of section 55.1 of the *Patent Act*, R.S., 1985, c. P-4.

[4] On April 27, 2007, in *Eli Lilly Canada Inc. v. Apotex Inc.*, 2007 FC 455, Gauthier J. of the Federal Court granted the respondents, pursuant to the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (the "NOC Regulations"), an order prohibiting the Minister of Health (the "Minister") from issuing a Notice of Compliance (a "NOC") so as to enable Apotex Inc. to market its olanzapine product in Canada. The Court rejected Apotex's allegations that the '113 Patent was invalid.

[5] On June 5, 2007, in *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2007 FC 596, Hughes J. of the Federal Court dismissed the respondents' application for an order prohibiting the Minister from issuing a NOC to Novopharm for its NOVO-OLANZAPINE product. Hughes J. found the '113 Patent invalid on the ground of the insufficiency of the disclosure found in the Patent. As a result, the Minister issued a NOC to Novopharm, whose olanzapine product is now on the market.

[6] On June 6, 2007, the respondents commenced an action against Novopharm for infringement of the '113 Patent.

[7] On June 20, 2007, Prothonotary Tabib ordered that the action be a specially-managed proceeding and, subject to any direction or order, established a schedule with regard to all further steps to be taken in the action. The schedule fixed dates for the filing and the service of Novopharm's Statement of Defence and Counterclaim, the respondents' Reply and Defence to Counterclaim and, in particular, set September 14, 2007 as the date for serving and filing of the respective affidavits of documents with the possibility for each party to serve on the other party a request for production of documents which they believed exist, are in the possession, power or control of the other party and should have been listed in their opponent's affidavit of documents but were not, with a requirement that the other party respond to such a request within twenty one days following service thereof. Examination for discovery of a representative of Novopharm was ordered to be conducted by the respondents during the week of October 15, 2007 for a duration of one day. Discovery of the representatives of the respondents was contemplated for November or December 2007.

[8] On July 6, 2007, Novopharm filed a Statement of Defence and Counterclaim wherein it alleges that the '113 Patent is invalid on a number of grounds, including the lack of advantages claimed in the '113 Patent, and seeks damages pursuant to section 8 of the NOC Regulations. It should be noted that Novopharm does not dispute that its olanzapine product infringes the '113 Patent.

[9] On July 19, 2007, the respondents filed a Reply and Defence to Novopharm's Counterclaim wherein they deny Novopharm's allegations and allege that olanzapine has "substantial advantages", "possesses the advantages identified in the '113 Patent", and "has a better side effect profile than prior known anti-psychotic agents" (see paragraphs 22 to 30 of the respondents' Reply and Defence to Counterclaim).

[10] The respondents served their affidavit of documents in late August 2007. More particularly, the respondent Eli Lilly Canada Inc. ("Eli Lilly Canada") served its affidavit of documents on August 22, 2007; the respondents Eli Lilly and Company and Eli Lilly Company Ltd. served their affidavits of documents on August 24, 2007; and the respondent Eli Lilly S.A. served its affidavit of documents on August 29, 2007.

[11] Pursuant to the Prothonotary's Order, the parties were obliged to request from one another the correction of deficiencies in the document discovery process. After the respondents served their affidavits of documents, counsel for Novopharm served on the respondents two requests for

additional productions which were, in part, positively responded to by the respondents, resulting in the production of the following documents: Eli Lilly Canada's New Drug Submission ("NDS") to Health Canada; the availability of Eli Lilly Canada's New Drug Application ("NDA") in the United States; communications between Eli Lilly Canada and its Canadian patent agent; and the Statement of Claim filed by the respondents in the product liability litigation conducted in the United States.

[12] Because of its dissatisfaction with the respondents' production and prior to any oral examination for discovery having been held, Novopharm brought a motion, dated October 5, 2007, for an order requiring, amongst other relief, the deponents of the affidavits of documents of each of the respondents to submit to cross-examination on their respective affidavits of documents and requiring the respondents to serve further and better affidavits of documents.

[13] On November 15, 2007, Prothonotary Tabib rendered the Order which Mr. Justice Lemieux upheld by his Order of March 3, 2008, and which is now the subject matter of this appeal.

[14] Before turning to the Prothonotary's Order, I should point out that the validity of the '113 Patent has already been litigated between the parties. More particularly, the validity of the US counterpart to the '113 Patent was litigated in the United States between the respondents and Novopharm's parent company (Teva) and sister company (Zenith). Also, as I indicated earlier, the validity of the '113 Patent was litigated in a proceeding commenced under the NOC Regulations.

THE PROTHONOTARY'S ORDER

[15] At paragraphs 4 to 7 of her Reasons, Prothonotary Tabib first set out the context in which she had to determine the issues raised in Novopharm's motion. More particularly, she made it clear that the debate before her pertained to the advantages or disadvantages of olanzapine as claimed in the '113 Patent. After setting out the parties' respective contentions, she concluded that documents relevant to the aforementioned issue were to be disclosed by the respondents and that disclosure was not to be limited to the period preceding the issuance of the patent. She explained her view as follows:

- [4] All of the documents Novopharm alleges exist and have not been produced ultimately relate to the issue of the side effects profile of olanzapine. All of Novopharm's arguments as to the relevance or usefulness of these documents were to the effect that these documents would establish, one way or the other, or would lead to a train of enquiry that would have the effect of establishing, one way or the other:
- (a) whether olanzapine had, as of the priority date, the filing date or the date of issuance of the patent, the advantages claimed in the patent;
 - (b) whether, as an objective fact as of the present date, olanzapine in fact has those advantages; or
 - (c) whether up to and until the issuance of the patent, Lilly knew of facts going to those issues that it failed to disclose to the Patent Examiner.

[5] As a matter of legal relevance – that is, whether the facts give rise to a legally arguable case at trial – Lilly does not contest that the facts set out in (a) and (c) above raise reasonably arguable issues, and it submits that it has indeed disclosed all documents relevant to these issues – as per its understanding of relevance for the purpose of Rule 222 of the Federal Courts Rules.

[6] As regards the facts set out in paragraph (b) above, Lilly takes the position that, whether the argument is obviousness, anticipation, lack of sound prediction, inutility, failure of promise or material omission or addition, the existence of the advantages must be assessed on the basis of the state of knowledge of persons skilled in the art, at the very latest, at the laid open date. It submits that any knowledge gained after that date can simply not be considered by the Court and is therefore not relevant. Despite that position, Lilly submits that it has produced documents relevant to the side effects profile of olanzapine up to and including 2001. Lilly's position is that, whether or not further documents dated after 2001

exist (and whether they do is a matter to be established by Novopharm), it is not obliged to disclose them.

[7] Having carefully considered the pleadings, I am satisfied that Novopharm's pleadings do raise the non-existence of the advantages disclosed or claimed in the patent as an objective fact to be ascertained as of the date of the trial, and that Lilly has not made any admission taking that plea out of issue. While Lilly's arguments are compelling, including its ultimate argument to the effect that a patent cannot be valid at the date of the grant and become invalid over time, I cannot conclude that it is plain and obvious that Novopharm's arguments on the issue are devoid of any chance of success at all. Accordingly, I find that documents relevant to that issue had to be disclosed by Lilly; consequently, when I proceed to consider whether Novopharm has established that relevant documents exist in Lilly's possession, power or control that have not been produced, I will include in my consideration whether relevant documents exist relevant to whether the advantages in fact exist in accordance with the state of the art after the laid open date.

[Emphasis added]

[16] She then addressed the issue of the legal test under Rule 222(2) of the Rules. At paragraph 18 of her Reasons, the Prothonotary explained the concept of "relevance" under Rule 222 in the following terms:

18. I do, however, agree with Prothonotary Hargrave's assessment in *Seaspan* [*Seaspan International Ltd. v. "Ewa" (The)*, [2004] F.C.J. No. 161, 2004 FC 124] that the concept of advancing an opponent's case or defeating one's own is central to relevance, both on the *Peruvian Guano* test [*Compagnie Financière et Commercial du Pacifique v. Peruvian Guano Company*, (1882) 11 Q.B.D. 55 (C.A.)] and on the strict wording of Rule 222(2). Unless the party producing the affidavit intends to rely on a document at trial, it 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 to a train of inquiry, which may have either of these two consequences".

[17] On the basis of the above test, the Prothonotary concluded that Novopharm was not entitled to disclosure of every document in the respondents' possession, power or control that "might" relate

to the issues raised in the pleadings. Hence, she concluded that the respondents' affidavits of documents were not *prima facie* deficient, as argued by Novopharm. At paragraphs 22 and 23 of her Reasons, she wrote:

[22] Thus, I conclude that, whether on the wide "train of inquiry" test, or a narrower reading of Rule 222(2), Novopharm is not entitled to disclosure of every document in Lilly's possession, power or control that relate to the facts pleaded, whether or not they can directly or indirectly assist its case. Novopharm is not entitled to disclosure of every document in Lilly's possession so that it might itself consider whether they might be useful. Unless it can establish that Lilly's vetting process was inadequate, Novopharm must be satisfied by the sworn statements appearing in Lilly's affidavits of documents, to the effect that the affiant has diligently caused the records to be searched and has made appropriate inquiries and disclosed, to the full extent of his or her knowledge, information and belief, the documents that would tend to adversely affect Lilly's case or advance Novopharm's.

[23] Thus, with respect to Novopharm's general complaint that Lilly's affidavits of documents are *prima facie* deficient because they fail to disclose all documents disclosed by Lilly in the context of US proceedings, which documents clearly "relate" to the issues in this case, I find the complaint not founded.

[18] The Prothonotary then turned to the question of whether the approach taken by the respondents to determine which of a wider class of documents should be disclosed was reasonable and sufficient. Although she concluded that the respondents' deponents had not proceeded unreasonably, she nonetheless did not rule out the possibility that the respondent might have omitted to disclose those documents which Novopharm argued were relevant and had not been disclosed. At paragraphs 25 and 26 of her Reasons, she explained her reasoning in the following terms:

[25] ... In any event, I am satisfied that in the circumstances of this case, Lilly's affiants did not proceed unreasonably. I do not accept that the Rules require, as a matter of law, that an affiant in every case review personally each document individually. All that the Rules require is that the affiant cause to be conducted a diligent search and make appropriate inquiries for the purposes of disclosure in the affidavit of documents. Lilly's main affiant, having notably also participated in the documentary discovery exercise in the US, was satisfied that a diligent search had already been conducted for the purpose of the US

litigation and did make inquiries, which appear on their face to be reasonable and appropriate, to determine which of those documents corresponded to the Rule 222(2) definition. I can find no fault with this approach generally.

[26] That being said, it may be that this approach proved in practice unreliable or insufficient in that it failed to “catch” relevant documents. A review of the documents which Novopharm contends are missing would be indicative as to whether, despite an apparently reasonable method of identifying documents, Lilly missed relevant documents and should therefore be required to conduct a reassessment of its documents.

[19] As a result of the above conclusion, the Prothonotary then directed her attention to the following categories of documents: (1) clinical trial documents; (2) internal memos and documents relating to clinical trial data; (3) correspondence between the respondents and Health Regulators; (4) documents arising from product liability litigation; (5) expert reports from other litigation; and (6) prior art produced in the United States patent action.

(a) *Clinical Trial Documents:*

[20] With respect to these documents, the Prothonotary took note of the fact that the respondents had produced such documents created until 2001, but had not produced any documents created subsequently. Because she was satisfied that these documents were relevant with respect to Novopharm’s allegations pertaining to the non-existence of the advantages claimed or disclosed in the ‘113 patent, the Prothonotary concluded that the respondents should review their records to determine whether clinical trial documents had been created after 2001 and, if so, to include them in further and better affidavits of documents.

(b) Internal Memos and Other Documents Relating to Clinical Trials:

[21] As in the case of the clinical trial documents, internal memoranda and documents relating to the clinical trials created before 2001 were also produced by the respondents. However, no such documents created after 2001 were produced. The Prothonotary concluded that such documents were not relevant unless the respondents “ha[ve] made on the issues corporate statements amounting to admissions” (paragraph 30 of the Prothonotary’s Reasons). She went on to say that even if such documents could be considered as “relevant” within the meaning of Rule 222(2), she would exercise her discretion to relieve the respondents from their disclosure. The Prothonotary nonetheless concluded that should any of these documents contain statements that could be “damaging to Lilly”, they should be disclosed by the respondents. At paragraph 32 of her Reasons, she wrote:

[32] Novopharm submits that these communications might contain statements damaging to Lilly, as, for example, statements admitting that certain information was known to Lilly at the time of the prosecution of the patent, but not disclosed to the Patent Examiner. Obviously, if any internal documents of Lilly contain such statements, the particular documents are relevant and have to be disclosed. As mentioned above, this still does not entitle Novopharm to have production of an entire class of irrelevant documents just so that it can satisfy itself that Lilly did not overlook those that were relevant. Still, it appears that Lilly would not have included in its consideration for potential relevance documents created after 2001. It should therefore, as part of its continuing obligation of disclosure, make reasonable inquiries or take reasonable steps to ensure that internal documents that might contain such damaging admissions are reviewed and disclosed if they exist.

[Emphasis added]

(c) Correspondence Between the Respondents and Health Regulators:

[22] Based on the reasoning that she applied with respect to internal memoranda and documents relating to clinical trials, the Prothonotary held that correspondence between the respondents and

Health Regulators after 2001 was not “relevant” in that it would not advance Novopharm’s case, undermine the respondents’ case or be susceptible of leading to a train of inquiry having either result.

(d) Documents Arising from Product Liability Litigation:

[23] Relying on *Apotex Inc. v. Merck & Co.* (2004), 33 C.P.R. (4th) 387 (F.C.) at para. 15, affirmed (2005), 38 C.P.R. (4th) 289 (F.C.A.), the Prothonotary held that these documents, as a general proposition, were not relevant. She then went on to opine that specific documents could nonetheless be relevant to the issues “properly raised in the present action” (para. 40 of the Prothonotary’s Reasons). In her view, documents tending to establish that the respondents had intentionally misled the Patent Examiner or omitted to provide relevant information were subject to disclosure. Consequently, she concluded that documents which tended to show what the respondents knew at the time of the prosecution of the patent with regard to the side effects profile of olanzapine were relevant with a cut-off date of July 14, 1998, i.e. the date on which the patent was issued.

[24] As a result, documents “R”, “S”, “T”, “U” and “V”, created before 2001, were relevant, as they tended to establish an awareness on the part of the respondents as to whether certain forms of statements could be considered misleading and of the respondents’ knowledge or awareness as to certain side effects of ZYPREXA in the period prior to the issuance of the patent. She thus ordered the respondents to disclose such documents in their affidavits of documents. However, with respect to documents “O”, “P” and “Q”, created between 2001 and 2003, the Prothonotary concluded that

they were not relevant. In her view, the respondents' subjective knowledge after the date of issuance of the patent was not relevant. She concluded that part of her analysis by saying, at paragraph 46:

[46] I stress here that documents "R" to "V" are relevant because of the specific information they contain. Having specific regard to document "R", other documents that can be described as being in the same class of documents (for example, correspondence between X and Y, in year Z, respecting Zyprexa) cannot reasonably be supposed to necessarily contain that type of information, and may be irrelevant. Novopharm is only entitled to disclosure of the documents from this class of documents that are relevant; it is entitled to know that Lilly has reviewed its documents to identify and disclose any document which may contain similarly relevant information. As mentioned before, Novopharm is not entitled to have disclosure of the entire class of documents to satisfy itself that relevant documents have not been overlooked.

(e) *Expert Reports from Other Litigation:*

[25] Prothonotary Tabib found that expert reports from other litigation, obviously created after the date of issuance of the patent, were irrelevant and that the respondents were under no obligation to disclose such documents in their affidavits of documents. However, to the extent that such reports could lead to relevant factual information, that information was subject to disclosure by the respondents inasmuch as the information was within their power, possession and control.

(f) *Prior Art Produced in the US Patent Action:*

[26] With regard to these documents, the Prothonotary held that documents which addressed the issue of the objective non-existence of the advantages claimed or disclosed in the '113 Patent and the invention's objective failure of utility that may tend to advance Novopharm's case or hurt the respondents' case had to be disclosed.

[27] Finally, the Prothonotary did not grant an extension of time for examinations on discovery schedule of a representative of Novopharm, since she was of the view that Novopharm had not established that it would suffer prejudice resulting from submitting to discovery in advance of the possibility of receiving further documentary disclosure from the respondents. However, she granted a short extension of time so as to allow Novopharm to proceed with its discoveries of the respondents and the inventors. She also rejected Novopharm's request to cross-examine the respondents' affiants and the solicitors who signed the certificates attached to the affidavits of document, to be advised of the identity of the representatives selected by the respondents for discovery and to require that all examination to take place in Toronto and Ottawa.

DECISION OF THE FEDERAL COURT

[28] With respect to the standard of review, Lemieux J. held that he would not review Prothonotary Tabib's Order *de novo*, as it was not vital to the final resolution of the action. He then opined that he would not interfere with the Prothonotary's discretionary order unless she had exercised her discretion based upon a wrong principle or a misapprehension of the facts. The Judge also held that as Prothonotary Tabib was the case manager, she was entitled to an additional level of deference and that, in that context, the Federal Court would interfere only in the clearest case of misuse of judicial discretion.

[29] Notwithstanding this conclusion, Lemieux J. held that the disclosure of documents pursuant to an affidavit of documents was a matter of relevance rather than one of discretion. He then stated his view that the exercise of discretion by a Prothonotary under Rule 227 pertained only to the

remedial options when the Prothonotary finds that an affidavit of documents is either inaccurate or deficient. He found, however, that there was discretion remaining to restrict the scope of discovery if it was not at all likely to advance the questioner's legal position, or if the answer to a question would require much time and effort and expense to obtain the answers and that value thereof was minimal, or where the question forms part of a "fishing expedition" of vague and far-reaching scope.

[30] Lemieux J. then dealt with Novopharm's specific arguments. He dismissed its submission that the Prothonotary erred in law by accepting that partial documentary discovery prior to the commencement of oral examinations for discovery was an acceptable practice. In his view, the Prothonotary's reasons were not to that effect and he underlined the fact that the Prothonotary had ordered the production of the documents by December 15, 2007, i.e. well before the start of oral examinations.

[31] With respect to whether the Prothonotary erred in her application of the test for relevance under Rule 222(2), the Judge held that when the Prothonotary's Reasons were read in their entirety, it clearly appeared that she had correctly applied the test for relevance. The Judge then made, at paragraph 77 of his Reasons, the following comments:

77. To the extent the example she gave cited at paragraph 19 of her reasons deviates from the test set out in Rule 222(2), a finding which I am not obliged to make, it was made *in obiter* and did not affect her correct application of the test as she expressed it in the previous paragraph.

[32] The Judge further held that the Prothonotary had not imposed on Novopharm the obligation to show that a document which had not been produced by the respondents met the train of inquiry test. He was satisfied that the Prothonotary had only required Novopharm to show that a reasonable possibility existed that a document could have or could lead to one of the desired effects.

[33] Accordingly, Lemieux J. found that the Prothonotary had not made an error of law or exercised her discretion improperly when she excluded from production technically-relevant documents when such production could be of no benefit to Novopharm.

[34] Finally, the Judge concluded that Novopharm had failed to show that Prothonotary Tabib had made any palpable and overriding error in regard to her findings of fact.

[35] For these reasons, the Judge dismissed Novopharm's appeal with costs.

ISSUES

[36] At paragraph 64 of its Memorandum, Novopharm formulates as follows the issues which, in its view, call for determination in this appeal:

- (a) What is the appropriate standard of review?
- (b) Did the Prothonotary err in principle by endorsing and adopting a piecemeal approach to discovery?
- (c) Did the Prothonotary err in her interpretation and application of the test for relevance under rule 222 by purporting to distinguish binding decisions of this Court and, in particular, by reformulating the test to require a "reasonable likelihood" that a document (unseen by the Court and by the party asking for it) would lead to "useful information"?

- (d) Did the Prothonotary err by effectively striking out portions of Novopharm's defence by denying Novopharm discovery on issues clearly raised in the counterclaim and clearly traversed by Lilly?
- (e) Is it an error to draw conclusions as to what information documents may "reasonably be supposed to contain" when one has seen neither the documents themselves nor any evidence about what they contain?

SUBMISSIONS OF THE PARTIES

(a) Appellant's Submissions:

[37] Novopharm's statement of the standard of review is somewhat confused. Novopharm first submits that this Court may not interfere with the decision of the Judge unless it was arrived at on a wrong basis or was plainly wrong. Novopharm further submits that Lemieux J. correctly stated that relevance was not a matter of discretion and that the standard of review applicable to the Prothonotary's decision in respect of the relevance of classes of documents was correctness. However, Novopharm then suggests that this Court has to examine whether the Judge committed an error of law, or whether findings of fact were made in a perverse or capricious manner or were the result of some palpable and overriding error. In the event that Prothonotary Tabib's Order was discretionary, Novopharm argues that her decision was vital to the final issue or that it was clearly wrong.

[38] Novopharm contends that Prothonotary Tabib erred in principle in accepting that partial documentary discovery prior to examinations for discovery was an acceptable practice. According to the appellant, the Prothonotary was of the view that Novopharm's complaints were to be dealt with through informal requests and on examination for discovery. Such an approach would lead to

multiple rounds of oral discovery, increases the chances of missing critical documents the respondents have not produced and is unfair to the appellant.

[39] On the issue of whether the Prothonotary applied the correct test for relevance, the appellant argues that she erred in law in distinguishing *SmithKline Beecham Animal Health Inc. v. Canada*, [2002] 4 C.T.C. 93 and *Apotex Inc. v. Canada* (2005), 41 C.P.R. (4th) 97 (F.C.A.). The appellant further argues that the Prothonotary erred in her application of the “train inquiry test” when she stated, at paragraph 19 of her Reasons, that:

19. In other words, it is not sufficient for a document to merely relate to the facts at issue. If, for example, a document can only reasonably be construed as supporting the disclosing party's case, and cannot be shown to lead to information that would reasonably be supposed to be helpful to its opponent, then it need not be disclosed in an affidavit of documents. [...]

[40] Novopharm suggests that this conclusion requiring the party seeking disclosure to show that a document that has not been produced would lead to information falling within the “train of inquiry” requirements places the bar impossibly high. The Prothonotary’s conclusion also disregards the principle enunciated by this Court in *Apotex, supra*, that all documents relevant to an issue between the parties must appear in an affidavit of documents, whether or not the party filing the affidavit intends to rely on that document. According to the appellant, the Judge erred in failing to correct these errors.

[41] Novopharm further argues that the effect of Prothonotary Tabib’s decision to limit her order of further production to post-2001 documents and to hold that no internal correspondence or

communications to health authorities respecting the clinical trial data needed to be produced was to strike Novopharm's pleadings with respect to the respondents' state of knowledge regarding olanzapine's side effects. Novopharm also argues that Prothonotary Tabib had no discretion to relieve the respondents from the disclosure of internal memoranda that could technically be considered relevant.

[42] Novopharm finally submits that the Prothonotary made several findings of fact on the basis of no evidence or contrary to the evidence before her.

B. Respondents' Submissions

[43] With respect to the standard of review, the respondents argue that Lemieux J. could not interfere with the Prothonotary's Order unless she was clearly wrong in the sense that she exercised her discretion based on an error or a misapprehension of the facts. Further, they submit that this Court may only interfere with the Judge's decision if it is based on a wrong principle or is plainly wrong.

[44] According to the respondents, Novopharm's submissions with respect to the errors of law allegedly made by the Prothonotary result from a mischaracterization of the Prothonotary's Order and, consequently, there is no basis whatsoever to interfere with the Judge's decision in that regard.

[45] First, the respondents submit that the Judge correctly held that Prothonotary Tabib had not endorsed and adopted a piecemeal and partial approach to discovery.

[46] Second, the respondents submit that Prothonotary Tabib correctly determined the test for relevance as being “[U]nless the party producing the affidavit intends to rely on a document at trial, it 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 to a train of inquiry, which may have either of these two consequences’”.

[47] Third, the respondents argue that there is no basis for Novopharm’s argument that Prothonotary Tabib struck some of its pleadings. To the contrary, she found that it was not plain and obvious that Novopharm’s arguments were devoid of any chance of success. Furthermore, extensive documents have been produced on the issue of the respondents’ state of knowledge with respect to olanzapine’s side effects, such as clinical trial reports, product monographs and correspondent between the Canadian patent agent and the patentee for the prosecution of the ‘113 Patent. With respect to internal memoranda discussing clinical trial data, the Prothonotary also ordered the respondents to produce any internal memoranda and documents that contain damaging admissions. Therefore, Lemieux J. did not err in refusing to interfere with Prothonotary Tabib’s Order, as he was satisfied that she had neither committed any error nor misused her judicial discretion.

[48] Fourth, the respondents argue that Prothonotary Tabib had the discretion not to order technically relevant documents to be disclosed if they were not likely to advance the questioner's legal position, or if the answer to a question would require much time, effort and expense to obtain

and its value appeared minimal, or where the question formed part of a "fishing expedition" of vague and far-reaching scope.

[49] Lastly, the respondents submit that the appellant has failed to show any palpable and overriding error in the Prothonotary's findings of fact and that Lemieux J. did not err by refusing to interfere with such findings.

ANALYSIS

[50] Before turning to the specific issues raised by Novopharm in this appeal, a few words must be said regarding its submission that the Federal Court has apparently adopted "new procedures and principles to govern scheduling, the scope of discovery and other matters in patent actions" (see paragraph 3 of Novopharm's Memorandum). Novopharm also submits that these "new procedures and principles" are part of the Federal Court's unwritten policy to move patent cases to trial as quickly as possible. This leads counsel for Novopharm to state, at paragraph 6 of his Memorandum:

6. In part, therefore, this appeal calls upon this Court in its supervisory capacity to decide whether these "new rules" for patent actions ought to be permitted to be followed to the prejudice of a party litigating in the Federal Court, by altering, among other things, the scope of discovery, in a way that squarely contradicts the pronouncements of this Court. Novopharm requires the assistance of this Court to ensure that its right as a litigant are not further abused, overridden or discarded.

[51] In my view, whether or not the Federal Court has adopted "new procedures and principles" or whether it has a policy designed to ensure that patent cases are moved to trial swiftly is irrelevant to the determination of the issues in this appeal. Novopharm's rights are to be determined on the

basis of the law and the Rules of this Court. Consequently, if the learned Motions Judge erred in his understanding or application of the law and the relevant Rules, this Court will intervene.

1. Standard of Review

[52] I am satisfied that the standard of review applicable to the Prothonotary's Order was correctly determined by the Judge. Indeed, he relied on this Court's decision in *Merck & Co. v. Apotex Inc.*, 2003 FCA 488, where Décary J.A. concluded, relying on the standard previously enunciated by this Court in *Canada v. Aqua-Gem Investment Ltd.*, [1993] 2 F.C. 425 (F.C.A.), that discretionary orders of prothonotaries ought not to be disturbed on appeal to a judge unless they raise questions vital to the final issue of the case, or they are clearly wrong in the sense that the exercise of discretion by the Prothonotary was based upon a wrong principle or upon a misapprehension of the facts.

[53] In my view, for the reasons which he gave, Lemieux J. was correct in finding that he did not have to exercise his discretion *de novo* because the questions determined by the Prothonotary in her Order were not vital to the final issue of the case.

[54] Lemieux J. also opined that Prothonotary Tabib, as the case manager, was entitled to an additional level of deference and, in so concluding, relied on this Court's decision in *Sawridge Band v. Canada*, [2002] 2 F.C. 346, where Rothstein J.A. (as he then was), at paragraph 11 of his Reasons for the Court, held that the judge managing a case was to be given latitude in that regard and that

this Court would only interfere where it was clear that there had been “the clearest case of misuse of judicial discretion”.

[55] I agree, however, with the view put forward by Novopharm that a case manager’s expertise does not insulate him or her from review where an error of principle has been made (see *Merck and Co. Inc. v. Apotex Inc.* (2003), 28 C.P.R. (4th) 491 at 497 (per Strayer J.A.)). In any event, I am satisfied that nothing in this appeal turns on the “additional level of deference” to which the case manager is entitled.

[56] As I indicated earlier, Lemieux J. concluded, correctly in my view, that the disclosure of documents in an affidavit of documents was a matter of relevance and not of discretion. In so concluding, he relied on McNair J.’s Reasons in *Reading and Bates Construction Co. v. Baker Energy Resources Corp. et al* (1988), 24 C.P.R. (3rd) 66, where the learned Judge wrote at page 70, *inter alia*, that:

The test as to what documents are required to produce is simply relevance. The test of relevance is not a matter for the exercise of the discretion. What documents parties are entitled to is a matter of law, not a matter of discretion. The principle for determining what document properly relates to the matters in issue is that it must be one which might reasonably be supposed to contain information which may directly or indirectly enable the party requiring production to advance his own case or to damage the case of his adversary, or which might fairly lead him to a train of inquiry that could have either of these consequences: [authorities omitted].

[57] On appeal, it is clear that this Court may only interfere with Lemieux J.’s decision if he either had no grounds to interfere with the Prothonotary's decision or, where such grounds existed,

that decision was arrived at on a wrong basis or was plainly wrong (see. *Z.I. Pompey Industrie v. Ecu-Line N.V.* (2003), 224 D.L.R. (4th) 577 at 586, para. 18 (S.C.C.)).

2. *Did the Prothonotary Err in Principle by Endorsing and Adopting a Piecemeal*

Approach to Discovery?

[58] Novopharm submits that the Prothonotary erred in adopting a piecemeal approach to discovery in that she accepted that partial documentary discovery, prior to examinations for discovery, was an acceptable practice. Accordingly, Novopharm says that the Lemieux J. ought to have intervened and corrected this error.

[59] I disagree. Like Lemieux J., I conclude that Novopharm's criticism of the Prothonotary is not well-founded. In particular, I agree entirely with Lemieux J. that the Prothonotary's Reasons, more specifically paragraph 11 thereof, cannot be read as either an endorsement or an adoption by her of a piecemeal and partial approach to discovery.

3. *Test for Relevance*

[60] Rule 222(2) reads as follows:

222(2) For the purposes of rules 223 to 232 and 295, a document of a party is relevant if the party intends to rely on it or if the document tends to adversely affect the party's case or to support another party's case.

222(2) Pour l'application des règles 223 à 232 et 295, un document d'une partie adverse est pertinent si la partie entend l'invoquer ou si le document est susceptible d'être préjudiciable à sa cause ou d'appuyer la cause d'une autre partie.

[61] At paragraphs 18 and 19 of her Order, Prothonotary Tabib sets out as follows her understanding of the “train of inquiry test” enunciated in *Peruvian Guano, supra*, which this Court has constantly approved

18. ... Unless the party producing the affidavit intends to rely on a document at trial, it 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 to a train of inquiry, which may have either of these two consequences".

19. In other words, it is not sufficient for a document to merely relate to the facts at issue. If, for example, a document can only reasonably be construed as supporting the disclosing party's case, and cannot be shown to lead to information that would reasonably be supposed to be helpful to its opponent, then it need not be disclosed in an affidavit of documents. A document which is neutral and can only reasonably be supposed to lead to other similarly neutral documents is not relevant for the purpose of an affidavit of documents. And on a motion for a further and better affidavit of documents, the reasonable possibility that a document can have or lead to one of the desired effects must be established by the moving party. To say that a document might conceivably lead to other documents, which, although not in themselves relevant, might then conceivably lead to useable information, is not enough. It is precisely the type of fishing expedition which the jurisprudence of this Court consistently refused to sanction. That is not to say that the moving party must establish that the document sought will necessarily lead to useable information: a reasonable likelihood will suffice; an outside chance will not.

[62] In my view, the Prothonotary correctly stated the test. However, Novopharm takes issue with the use of the word “show” found in para. 19 of the Prothonotary's Reasons:

19 ... If, for example, a document can only reasonably be construed as supporting the disclosing party's case, and cannot be shown to lead to information that would reasonably be supposed to be helpful to its opponent, then it need not be disclosed in an affidavit of documents.

[Emphasis added]

[63] Novopharm argues that the use of the word “show” means that it has to actually prove that a document which has not been produced would lead to information falling within the “train of inquiry” test. I cannot agree with Novopharm’s submission. In my view, the Prothonotary’s Reasons, when read in their entirety, clearly establish that Novopharm’s submission is without merit. It is clear from the Prothonotary’s Reasons that she was of the view that if there was a reasonable likelihood, as opposed to an outside chance, that a document sought for production would lead to information relevant under Rule 222(2), then an order for production should be made.

[64] Furthermore, the Prothonotary’s reference to a fishing expedition in paragraph 19 of her Reasons was one where a party was required to disclose a document that might lead to another document that might then lead to useful information which would tend to adversely affect the party's case or to support the other party's case. In my view, limiting the “train of inquiry” test in this manner is consistent with the test described in *Peruvian Guano, supra*, and applied by this Court in *SmithKline Beecham Animal Health Inc. v. Canada*, [2002] 4 C.T.C. 93 (F.C.A.), where, at para. 24 of her Reasons for the Court, Madam Justice Sharlow wrote:

[24] The scope and application of the rules quoted above depend upon the meaning of the phrases "relating to any matter in question between ... them in the appeal" and "relating to any matter in issue in the proceeding". In *Compagnie Financiere et Commerciale du Pacifique v. Peruvian Guano Company* (1882), 11 Q.B.D. 55 (C.A.), Brett, L.J. said this about the meaning of the phrase "a document relating to any matter in question in the action" (at page 63):

It seems to me that every document relates to the matters in question in the action, which not only would be evidence upon any issue, but also which, it is reasonable to suppose, contains information which may - not which must - either directly or indirectly enable the party requiring the affidavit either to advance his own case or to damage the case of his adversary. I have put in the words

"either directly or indirectly," because, as it seems to me, a document can properly be said to contain information which may enable the party requiring the affidavit either to advance his own case or to damage the case of his adversary, if it is a document which may fairly lead him to a train of inquiry, which may have either of these two consequences.

[Emphasis added]

[65] I therefore conclude that there can be no doubt that the Prothonotary understood the “train of inquiry” test. She found that Novopharm had to establish that it was reasonable to suppose that the documents at issue contained information which could either directly or indirectly enable it to advance its own case or to damage that of the respondents. Not only did she understand the test, she consistently applied it in her assessment of the documents at issue. Therefore, it cannot be said that the Prothonotary’s Order was based upon a wrong principle, and Lemieux J. did not err by refusing to interfere with her Order on that ground.

D. The Striking out of Portions of Novopharm’s Defense and the Denial of Discovery to Novopharm on Issues Raised in the Counterclaim:

[66] The essence of Novopharm’s submissions under this heading is found at paragraphs 85 to 88 of its Memorandum of Fact and Law, which I reproduce:

85. By this Order, the Prothonotary negated Novopharm’s ability to discover any aspect of Lilly’s state of knowledge respecting olanzapine’s side effects around the critical times. She put this misapplied principle into practice by limiting her order of further production to post-2001 documents and by holding that only the clinical trial data, and not internal correspondence discussing that data or communications to health authorities respecting that data, needed to be produced.

86. The Prothonotary effectively struck out Novopharm's pleadings respecting at least the s. 53(1) and para. 73(1)(a) allegations by denying any discovery relating to Lilly's state of knowledge with respect to olanzapine's side effects. No notice was given to Novopharm that such a result was being contemplated by the Prothonotary and no elucidation was given as to why this pleading was "irrelevant". Novopharm was not asked and was precluded from answering this assertion; there was no evidence to support it.

87. The Prothonotary's only task on the motion before her was to determine the classes of documents made relevant by the pleadings that had been categorically overlooked in Lilly's review. Despite this, she held that Lilly need not review whole classes of documents that would be most likely to contain information relating to Lilly's state of knowledge.

88. Also, without notice to Novopharm, the Prothonotary stated that she would exercise her discretion to "relieve Lilly from their disclosure" (paragraph 31), even if the documents being discussed (internal memoranda) could "technically" be considered relevant. The Prothonotary has no such discretion absent a motion under Rule 230. There was no such motion pending before her, no jurisdiction to make a ruling of this kind, no evidence on which to make such a finding and no submissions from counsel on this issue.

[67] I will deal firstly with the submission found at paragraph 88 of Novopharm's Memorandum. In Novopharm's view, absent a motion under Rule 230, the Prothonotary had no discretion to relieve the respondents from their obligation to disclose relevant documents.

[68] In the context of his discussion regarding the test for relevance, the learned Motions Judge stated his view that the Federal Court could, in proper circumstances, notwithstanding the relevancy of documents, refuse to compel the production thereof. For that proposition, he relied, *inter alia*, on this Court's decision in *Merck & Co. v. Apotex Inc.*, 2003 FCA 438, (2003), 28 C.P.R. (4th) 491 (F.C.A.), where, at paragraph 10, Strayer J.A. stated:

The jurisprudence in this Court on the scope of discovery is well settled. For convenience it is summarized in *Reading & Bates Construction Co. et al v. Baker Energy Resources Corp. et al* (1988) 24 C.P.R. (3rd) 66 at 70-72 (F.C.T.D.). It is clear that the primary consideration is relevance. If a prothonotary or a judge does, however, find a question to be relevant he or she may still decline to order the question to be answered if it is not at all likely to advance

the questioner's legal position, or if the answer to a question would require much time and effort and expense to obtain and its value would appear to be minimal, or where the question forms part of a "fishing expedition" of vague and far-reaching scope.

[69] Lemieux J. then went on, paragraph 79 of his Reasons, to apply that principle to the issues before him. He stated:

79. These reasons have already discussed the scope of the discretionary power residing in the Court to require the filing of a further and better affidavit under Rule 227 as well as its discretionary power to dispense with the production of relevant documents. Novopharm's argument seems to focus on the Prothonotary's finding on the relevance of internal memoranda with respect to clinical trials and her statement at paragraph 31 of her reasons where she would "exercise my discretion to relieve Lilly from their disclosure" such internal documents "even if they would be construed as technically included in the definition of relevance because they lead back to the clinical trial data". As I see it, she exercised her residual discretion not to compel the production of technically relevant documents when such production would have no beneficial benefit to Novopharm. In my view, this is a proper exercise of her discretion (see Strayer J.A., *Merck & Co. v. Apotex Inc.*, above, at paragraph 66 of these reasons.)

[70] I agree entirely with the Judge's statement of the relevant principle. Whether or not the Prothonotary ought to have ordered the respondents to disclose more documents than what she ordered is a question to which I will return shortly. However, I accept, as I must, the proposition that the Prothonotary had discretion to refuse to order the respondents to disclose relevant documents.

[71] I now turn to Novopharm's submissions which appear in paragraphs 85, 86 and 87 of its Memorandum. Although these submissions and those made orally by counsel at the hearing address a number of issues, a common thread is readily apparent from the submissions, i.e. that the Prothonotary was wrong to conclude that the approach taken by Eli Lilly to determine the classes of

documents which ought to be disclosed was reasonable and sufficient. As a corollary to this argument, Novopharm says that the Prothonotary further fell in error when she held that although the clinical trial data had to be disclosed, the internal correspondence discussing that data and the respondents' communications to health authorities regarding the data did not have to be disclosed. The effect of these rulings, in Novopharm's view, was to strike its pleadings concerning Eli Lilly's state of knowledge as to olanzapine's side effects. I cannot subscribe to Novopharm's contention.

[72] As the respondents point out, it is beyond dispute that the Prothonotary did not strike Novopharm's pleadings. To the contrary, she clearly understood those pleadings and she emphasized the fact that the respondents had not "made any admissions taking that plea out of issue" (paragraph 70 of the Prothonotary's Reasons). As a result, she made it clear that her consideration of the issues raised by Novopharm in its motion would be carried out in the light of Novopharm's allegations pertaining to the non existence of the advantages disclosed or claimed in the '113 Patent. This led the Prothonotary to say, at paragraph 7 of her Reasons, which I again reproduce, in part, for ease of reference, that:

7. ... Accordingly, I find that documents relevant to that issue had to be disclosed by Lilly; consequently, when I proceed to consider whether Novopharm has established that relevant documents exist in Lilly's possession, power or control that have not been produced, I will include in my consideration whether relevant documents exist relevant to whether the advantages in fact exist in accordance with the state of the art after the laid open date.

[73] After her discussion of "relevance" under Rule 222(2), the Prothonotary squarely addressed the issue of pre-2001 and post-2001 production. She began by saying that, on the basis of her understanding of the test for relevance, Novopharm was not entitled to disclosure of every

document in the respondents' possession, power and control that related to the facts pleaded, adding that Novopharm was only entitled to those documents that tended to adversely affect Eli Lilly's case or advance its own case.

[74] As I have already indicated, I am satisfied that in so concluding, the Prothonotary made no error. She properly understood the test for relevance and, in my view, she made no error in applying it.

[75] The Prothonotary then turned to the first prong of Novopharm's argument to the effect that the respondents' approach in determining which of a wider class of documents ought to be disclosed did not pass muster. In making that argument, Novopharm says that the effect of the Prothonotary's conclusion was to limit her order of further production to post-2001 documents. It says that that was an error on her part which the Judge ought to have corrected. At paragraphs 34 to 36 of his Reasons, Lemieux J. carefully and thoroughly explained the manner in which the Prothonotary proceeded in rejecting Novopharm's argument on this point:

[34] She then stated the question which arose is whether Lilly's approach in determining which of a wider class of documents should be disclosed was reasonable and sufficient. She described the three levels of disclosure previously discussed in these reasons and noted Lilly's affidavit evidence was that, having considered the issues in the U.S. and in the present proceeding, its affiants were satisfied all documents that might possibly relate to the issues in this action had been part of the initial U.S. disclosure and that it was reasonable to assume any document which might undermine its case or assist an opponent's case on these same issues had been selected by Lilly's opponents and included in the UTL and in the ATL.

[35] She then said Novopharm's position was as a matter of legal principle, Lilly's disclosure had to include all documents relating to the issues pleaded, thus all of the documents in the initial U.S. production. She observed Novopharm did not argue, other than through the specific categories discussed later in her reasons, that the basis upon which Lilly proceeded was unreasonable or that applying that method resulted in relevant documents being omitted. She was satisfied, in the circumstances of this case, Lilly's affiants did not proceed unreasonably and referring to Mr. Stemerick's affidavit in which he stated he was satisfied a diligence search had already been conducted for the purpose of the U.S. litigation and that he made inquiries, which she found appear on their face to be reasonable and appropriate, to determine which of those documents corresponded to Rule 222(2) definition concluding: "I can find no fault with this approach generally."

[36] However, she cautioned it may be this approach proved in practice unreliable or insufficient in that it failed to "catch" relevant documents and stated a review of the documents which Novopharm contends are missing would be indicative of whether, despite an apparently reasonable method of identifying documents, Lilly missed relevant documents and should therefore be required to conduct a reassessment of its documents. She then proceeded to consider the specific categories of documents which Novopharm contends are missing. They were:

- Clinical trial documents;
- Internal memos and documents relating to clinical trials;
- Correspondence between Lilly and Health Regulators in Canada and in the US;
- Certain documents from product liability litigation related to olanzapine where Lilly was a defendant;
- Expert reports from other litigation; and
- Prior art produced in the U.S. action.

She went on, in the balance of her reasons, to consider each of those categories. I discuss her findings separately for each.

[76] Although the Judge does not appear to have reached any particular conclusion regarding the Prothonotary's determination that the respondents' approach with respect to the disclosure of documents in their affidavits of documents was not unreasonable, I cannot detect, after careful consideration of the Prothonotary's Reasons, any error of principle in her reasoning, nor can I detect any error in her appreciation of the facts relevant to her determination. It is clear that the Prothonotary properly understood Novopharm's argument and that she carefully considered the

evidence before her prior to making her determination. I see no ground to interfere with that determination.

[77] Notwithstanding her conclusion that Eli Lilly's approach to disclosure was reasonable and sufficient, the Prothonotary nonetheless turned to the specific categories of documents which Novopharm argued were missing and ought to have been disclosed. This led the Prothonotary to address Novopharm's submission that post-2001 documents should have been disclosed.

[78] Before proceeding, I again point out that Eli Lilly's submission, which the Prothonotary rejected, was that although it has disclosed documents created up to and including 2001, it had no obligation to disclose documents created after the laid open date, i.e. 1998, even though it had disclosed documents created up to 2001.

[79] Because, as she made clear in paragraph 7 of her Reasons, the respondents had not taken out of issue Novopharm's allegation which raised the non existence of the advantages disclosed or claimed in the Patent as an objective fact to be ascertained as of the date of the trial, she proceeded to determine whether those documents which Novopharm argued were relevant had to be disclosed by the respondents.

[80] This leads to the second prong of Novopharm's argument, i.e. that internal correspondence discussing the clinical trial data and communications to health authorities concerning that data were relevant and had to be disclosed.

[81] With respect to internal documents, Novopharm challenged the Prothonotary's view that for purposes of relevancy, internal correspondence did not so qualify unless it amounted to "corporate statements amounting to admissions" (paragraph 30 of the Prothonotary's Reasons). The Prothonotary then considered whether internal documents commenting on the clinical trial data could reasonably lead to a train of enquiry that would advance Novopharm's case or hurt the respondents'. On the evidence before her, she held that such documents did not. She went on to opine that even if the respondents' internal correspondence could "technically" be viewed as falling within the definition of Rule 222(2), she would nonetheless exercise her discretion to relieve the respondents from disclosing them. She then, however, made the following comments at paragraph 32 of her Reasons:

[32] Novopharm submits that these communications might contain statements damaging to Lilly, as, for example, statements admitting that certain information was known to Lilly at the time of the prosecution of the patent, but not disclosed to the Patent Examiner. Obviously, if any internal documents of Lilly contain such statements, the particular documents are relevant and have to be disclosed. As mentioned above, this still does not entitle Novopharm to have production of an entire class of irrelevant documents just so that it can satisfy itself that Lilly did not overlook those that were relevant. Still, it appears that Lilly would not have included in its consideration for potential relevance documents created after 2001. It should therefore, as part of its continuing obligation of disclosure, make reasonable inquiries or take reasonable steps to ensure that internal documents that might contain such damaging admissions are reviewed and disclosed if they exist.

[Emphasis added]

[82] Hence, the respondents were ordered to search their documents and disclose those which might contain statements damaging to the respondents' case such as, "for example, statements admitting that certain information was known to Lilly at the time of the prosecution of the patent, but not disclosed to the Patent Examiner".

[83] It is obvious from the above that the Prothonotary clearly understood Novopharm's submission and dealt with it in the light of the evidence and the applicable Rules. She ultimately exercised her discretion not to order the disclosure of documents which might be relevant but, in her view, would likely be of little value to Novopharm. Notwithstanding this conclusion, she nonetheless ordered the respondents to disclose internal documents that might contain statements "damaging to Lilly".

[84] I am satisfied that Prothonotary Tabib did not exercise her discretion based upon a wrong principle or upon a misapprehension of the facts.

[85] I now turn to the other group of documents which Novopharm says ought to have been disclosed, i.e. the respondents' correspondence with health regulators. The Prothonotary's reasoning regarding these documents appears from paragraph 34 of her Reasons:

[34] Again, however, and based on the evidence adduced by Novopharm itself, this correspondence would squarely be based on, and would merely interpret or discuss the clinical data which Lilly has already or will be disclosing. It cannot reasonably be supposed that Lilly has, in this correspondence, admitted to any other negative side effects than those

against which publicly available labels and product monograph warn. Again, the only information to which this correspondence might be supposed to lead is the same clinical data and reports which have or will be produced. I am satisfied that this class of documents would not advance Novopharm's case, undermine Lilly's or be susceptible of leading to a train of inquiry having either result.

[86] In my view, the above statement does not reveal any error on the part of the Prothonotary. She considered the nature of the documents and their potential relevance and concluded that they would not further advance Novopharm's case, hinder Eli Lilly's case or lead to a train of enquiry which might yield either result. Notwithstanding Novopharm's forceful arguments, I have not been persuaded that the Prothonotary erred.

D. Is it an Error to Draw Conclusions as to what Information Documents may Reasonably be Supposed to Contain when one has seen Neither the Documents Themselves nor Evidence About what they Contain?

[87] In its Memorandum, Novopharm has entitled this issue as "errors of fact". As the respondents submit, many of the errors of fact which Novopharm says the Prothonotary made simply constitute a different manner of rearguing its submissions concerning the Prothonotary's errors of law. In any event, I have not been persuaded by Novopharm's arguments that the Prothonotary either misapprehended the facts relevant to her determinations or that she made a palpable or overriding error in reaching her conclusions.

CONCLUSION

[88] For these reasons, I would dismiss Novopharm's appeal with costs.

“M. Nadon”

J.A.

“I agree.

J.D. Denis Pelletier J.A.”

“I agree.

C. Michael Ryer J.A.”

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET: A-114-08

(APPEAL FROM A JUDGMENT OF THE FEDERAL COURT, DATED MARCH 3, 2008, IN COURT FILE T-1048-07)

STYLE OF CAUSE: NOVOPHARM LTD. v. ELI LILLY CANADA INC. et al.

PLACE OF HEARING: Toronto, Ontario

DATE OF HEARING: June 18, 2008

REASONS FOR JUDGMENT BY: NADON J.A.

CONCURRED IN BY: PELLETIER J.A.
RYER J.A.

DATED: September 29, 2008

APPEARANCES:

Jonathan Stainsby FOR THE APPELLANT

Anthony G. Creber FOR THE RESPONDENTS

SOLICITORS OF RECORD:

Heenan Blaikie LLP FOR THE APPELLANT
Toronto, Ontario

Gowling Lafleur Henderson LLP FOR THE RESPONDENTS
Ottawa, Ontario