T-1144-97

BETWEEN:

ELI LILLY AND COMPANY and
ELI LILLY CANADA INC.

Applicants,

- and -

APOTEX INC., AND THE
MINISTER OF HEALTH

Respondents.

By originating Notice of Motion filed May 29, 1997, the Applicants ("Lilly") seek the following relief:

a)an Order in the nature of a certiorari quashing the Notice of Compliance issued on April 30, 1997 to Apotex Inc. in respect of 150 mg and 300 mg capsules of nizatidine by the Minister of Health;

b)an Order declaring the Minister of Health is under a duty to comply with section 7(1) of the *Patented Medicines (Notice of Compliance) Regulations ("Regulations")* before issuing a Notice of Compliance to a second person;

(c)an Order declaring that the Minister of Health failed to comply with section 7(1) of the *Regulations* by issuing the Notice of Compliance to Apotex Inc. for 150 mg and 300 mg capsules of nizatidine on April 30, 1997;

(d)an Order declaring that the Notice of Allegation dated February 10, 1995, was not a valid Notice of allegation contemplated by section 5(1) of the *Regulations*;

(e)an Order declaring that the Minister of Health is under a duty to ensure that there is an allegation on file in a second person's New Drug Submission at the time when the second person serves a Notice of that Allegation in accordance with section 5(3)(b) of the *Regulations*;

(f)an Order declaring that the Minister of Health is under a duty to ensure that a detailed statement of the legal and factual basis for the allegation has been provided in accordance with the *Regulations* prior to the issuance of a Notice of Compliance;

(g)an Order declaring that Apotex Inc. failed to comply with section 5(3)(a) of the *Regulations* by not providing a detailed statement of the legal

and factual basis for its allegation; and

(h)an Order declaring that the Minister of Health is under a duty to ensure that any Notice of Compliance which is granted, is granted only with respect to the particular Allegation, Notice of Allegation and detailed statement of the legal and factual basis for its allegation that has been provided to the first person.

By Notice of Motion filed the 27th of June, 1997, Apotex Inc. (the "Apotex motion" and "Apotex" respectively) seeks an Order:

1. Striking paragraphs 20, 23, 24, 25, 27, 28, 29, 30 and 31 of the Originating Notice of Motion and the heading "Torcan Process" on page 8 thereof;

2. Striking paragraphs 9, 10, 11, 12 and 13 of the Affidavit of Peter G. Stringer sworn May 28, 1997;

3. Striking paragraphs 13, 14, 23, 24 and 25 of the Affidavit of Terry McCool sworn May 29, 1997;

4. Extending the time for the delivery of the Respondents' responding evidence so as to be delivered within fourteen days of disposition of the within motion and setting a schedule for the remaining interlocutory steps prior to hearing including the time for cross-examinations upon Affidavit material;

5. Such further and other relief as to this Honourable Court may seem just.

These reasons arise out of the hearing of the Apotex motion on Monday, July 14, 1997 at Toronto.

The grounds stated for the Apotex motion are, first, that paragraphs 13 and 14 of the affidavit of Terry McCool (the "McCool affidavit") and paragraph 13 of the affidavit of Peter G. Stringer (the "Stringer affidavit") are alleged to be on information and belief and therefore contrary to the *Federal Court Rules*, and secondly, in the Originating Notice of Motion and the Stringer affidavit and McCool affidavit, that reference is made to a confidential communication provided to the solicitors for Lilly in the context of other proceedings and the impugned paragraphs, other than paragraphs 13 and 14 in the McCool affidavit and paragraph 13 in the Stringer affidavit improperly utilize such confidential information.

I will deal first with the paragraphs allegedly based on information and belief.

In *Éthier v. Canada (RCMP Commissioner)*,[1] Mr. Justice Hugessen, writing for the Court and by reference to *R. v. Khan*[2] and *R. v. Smith*,[3] wrote:

> As we read them, those two decisions dramatically clarified and simplified the law of hearsay in this country. As Lamer CJ. said in *Smith*, they "signalled an end to the old categorical approach to the admission of hearsay evidence. Hearsay evidence is now admissible on a principled basis, the governing principles being the reliability of the evidence and its necessity."

In *Lecoupe v. Canadian Armed Forces*,[4] Nadon J. held that certain paragraphs of an affidavit were admissible, notwithstanding that the information which appeared therein constituted hearsay evidence. He wrote:

> In another words, in the aftermath of *Khan* and *Smith*, the exception to the hearsay rule have been merged into one broad exception which allows for the admission of proposed evidence that is reliable and necessary, with the appropriate weight to be given to such evidence to be determined by the trial judge. [underlining added by me for emphasis]

I am satisfied that there is merit in leaving the determination of reliability and necessity of proposed evidence on information and belief to the "trial judge", in this matter, the judge hearing the Originating Notice of Motion who, if he or she determines the evidence to be reliable and necessary, is in a position to make the further determination as to the appropriate weight to be given to such evidence, once admitted.

---

[1] [1993] 2 F.C. 659 (F.C.A.)

[2] [1990] 2 S.C.R. 531

[3] [1992] 2 S.C.R. 915

[4] (1994), 81 F.T.R. 91 (F.C.T.D.)

I am further satisfied that, in the context of this matter, Apotex' motion to strike paragraphs 13 and 14 of the McCool affidavit and paragraph 13 of the Stringer affidavit is premature. The Apotex motion, to the extent that it seeks to strike those paragraphs, will be dismissed with leave to Apotex to reapply before the judge hearing the Originating Notice of Motion.

I turn then to the portion of the motion that relates to alleged improper utilization of confidential information.

In November of 1995, in the course of another proceeding before this Court, Apotex delivered to counsel for Lilly, on a confidential basis, information apparently related to a "synthetic process". Paragraph 23 of the Originating Notice of Motion herein reads as follows:

> 23. While the synthetic process which was represented to be the subject matter of the second Notice of Allegation was provided by a letter dated November 29, 1995 to counsel for Lilly, the Minister was not copied with this letter and does not have a copy of it. Therefore the Minister could not and did not determine whether a Detailed Statement had been provided before issuing a NOC to Apotex, and did not determine whether the process in Apotex' NDS was the same process that was disclosed to Lilly.

Counsel for Apotex argued before me that the quoted paragraph of the Originating Notice of Motion is the "seminal paragraph" of the Motion and that all that follows it, presumably with the exception of paragraph 26 since it is not sought to be struck, up to and including paragraph 31, looses all relevance if paragraph 23 is struck. Counsel urges that paragraph 23 amounts to a disclosure of information provided in confidence in the context of other litigation. He argues that the doctrine of implied undertaking applies with respect to the confidential information and that Lilly has simply failed to follow the appropriate course by seeking leave from this Court for relief from the implied undertaking. The same argument is made with respect to paragraphs 9 to 12 of the Stringer affidavit and paragraphs 23 to 25 of the

McCool affidavit, although the paragraphs in the McCool affidavit relate to a different form of disclosure of "confidential information".

Counsel for Lilly argues that the allegedly confidential information, to the extent that it is disclosed in the Originating Notice of Motion and the Stringer and McCool affidavits, has already been publicly disclosed by the President of Apotex in an affidavit filed in the open registry of this Court in another Court proceeding. A copy of that affidavit was before me as an exhibit to the McCool affidavit. Further, counsel argues, the doctrine of implied undertaking only applies to material disclosed on examination for discovery. For this proposition he cites *Eli Lilly and Co. v. Interfarm Inc.*[5] where, at page 213, Macdonald J.A., writing for the majority, adopted the reasons of Reed J. in *Canada v. Ichi Canada Ltd.*[6] to the following effect:

> The defendant will know from the text of these reasons that an implied undertaking automatically arises so that information obtained on discovery is to be used only for the purposes of the litigation for which it is obtained. This does not, of course, restrict the use of any information which subsequently is made part of the public record. Nor does it affect the use of information which while obtained on discovery may also have been obtained from some other source. An implied undertaking cannot operate to pull under its umbrella documents and information obtained from sources outside the discovery process merely because they were also obtained on discovery. In addition, the implied undertaking does not prevent a party from applying, in the context of collateral litigation, for release from the implied undertaking, so that information obtained on discovery might be used in that litigation.
>
> [underlining added by me for emphasis]

As indicated earlier, Lilly has made no application from release from any implied undertaking with respect to the allegedly confidential information here at issue.

Finally, counsel for Lilly referred me to *Pharmacia Inc.*

---

[5](1993), 50 C.P.R. (3d) 208 (F.C.A.)

[6](1991), 40 C.P.R. (3d) 119 (F.C.T.D.)

v. Canada (Minister of National Health and Welfare)[7] where, at pages 213 to 215, Mr. Justice Strayer analyzes the *Federal Court Rules* in the context of whether they provide authority to strike out an originating notice of motion. He concludes:

> Thus, the direct and proper way to contest an Originating Notice of Motion which the respondent thinks to be without merit is to appear and argue at the hearing of the motion itself. This case well illustrates the waste of resources and time in adding on to what is supposed to be a summary judicial review proceeding the process of an interlocutory motion to strike. This motion to strike has involved a hearing before a trial judge and over one-half day before the Court of Appeal, the latter involving the filing of several hundred pages of material, all to no avail.

While the motion before me is not a motion to strike the Originating Notice of Motion herein, I conclude that in substance it is of the same nature. If the paragraphs sought to be struck are struck, it seems to me that what is left of the Originating Notice of Motion herein is without substance.

I am satisfied that the reasoning of Mr. Justice Strayer in the *Pharmacia* decision should apply to the portion of the Motion before me to strike paragraphs of the Originating Notice of Motion herein and, by extension, to strike related paragraphs of the Stringer and McCool affidavits. In light of my conclusion, I make no determination regarding the question of whether the paragraphs in question in fact disclose information in confidence and, if they do, whether the doctrine of implied undertaking applies.

By agreement among counsel, the time for delivery of the evidence of Apotex and the Minister of Health will be extended for fourteen days from the date of my order herein and the time for filing the Lilly record will be extended for thirty days from the day on which the time fixed for delivery of the evidence of Apotex and the Minister of Health expires. These

---

[7] (1994), 58 C.P.R. (3d) 209 (F.C.A.)

extensions and any further variations of time limits that were not addressed before me may have been overtaken or made unrealistic by further steps taken in this matter since the hearing before me. If so, they can, of course, be modified by further Order of the Court.

_____

Judge

Ottawa, Ontario
July 30, 1997