T-187-95

IN THE MATTER of an application for an Order pursuant to Section 55.2(4) of the *Patent Act* and Section 6 of the *Patented Medicines (Notice of Compliance) Regulations*.

BETWEEN:

ELI LILLY AND COMPANY and
ELI LILLY CANADA INC.

Applicants

AND:

NOVOPHARM LIMITED and
THE MINISTER OF NATIONAL HEALTH AND WELFARE

Respondents

REASONS FOR ORDER

JOYAL, J.:

This case arose out of a motion brought by Eli Lilly and Company and Eli Lilly Canada Inc. ("the Applicants"), pursuant to section 6(1) of the *Patented Medicines (Notice of Compliance) Regulations* ("the *NOC Regulations*"). The Applicants sought an order prohibiting the Minister of National Health and Welfare from issuing to the respondent manufacturer, Novopharm Ltd. ("the Respondent"), notices of compliance in connection with its 500mg, 1g, and 10g powder form of the drug vancomycin hydrochloride for intravenous administration, until after the expiration of the patent owned by the Applicants. After closely considering the written submissions provided by the parties and upon hearing their oral arguments, I rendered judgment in the matter by order dated July 30th, 1997, wherein the prohibition order was granted with respect to the 1g and 10g dosage forms and the application dismissed with respect to the 500mg dosage form. I now give my reasons for judgement.

I find it unnecessary to dwell on the facts surrounding this case. It is sufficient, in my opinion, to state briefly that as part of the procedure to market the impugned dosage forms of the drug vancomycin hydrochloride in Canada, the Respondent submitted to the Minister an application for a notice of compliance, alleging that the Applicants' patent would not be infringed by the making, constructing, using or selling of the three dosage forms. Notice of these allegations was served on the Applicants, as well as a detailed statement outlining the factual and legal basis of the Respondent's allegations.

The Applicants contested the Respondent's allegations, claiming that they were unjustified. Two arguments were submitted for the Court's consideration.

The first one pertains solely to the 1g and 10g dosage forms. The Applicants contend that the Respondent's allegations of non-infringement relating to these two dosage forms are unjustified and the notices of allegations invalid, given that the allegations are devoid of any factual basis. The Applicants are referring here to the absence of material relating to the 1g and 10g dosage forms in Novopharm's new drug submission, which was filed with the Minister in order to obtain approval for the sale and advertising of the drug in Canada. It is my understanding of the Applicants' position that for every notice of allegation listing a specific dosage form of a given drug, the *NOC Regulations* require that there be a corresponding new drug submission containing information relating to that particular dosage. In other words, the listing of one dosage form in the new drug submission is not sufficient to cover all other forms.

At the hearing of the motion, the Respondent took a different stand. Counsel argued that since all dosage forms are prepared using the same methods and processes, the mention of one dosage form in the new drug submission is sufficient to

comply with the requirements of the *NOC Regulations*. With this proposition, I disagree. It is my interpretation of the regulatory framework which governs the process by which new drugs are approved for sale in Canada - that is the scheme provided for by the *NOC Regulations* and the *Food and Drug Regulations* - that the new drug submission, notice of allegation and notice of compliance are intimately linked. My colleague McGillis J. states that they are "inextricably linked"[1]. What is meant by this is that in order for a generic manufacturer to obtain a notice of compliance for which a notice of allegation can be served on the patentee, it is necessary to submit a new drug submission[2] The Minister cannot issue a notice of

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1 *Janssen Pharmaceutica Inc.* v. *Apotex Inc.* (1996), 68 C.P.R. (3d) 114 (F.C.T.D.) at p. 116.

[2] Section C.08.002 of the *Food and Drug Regulations* provides that no person shall sell a new drug unless the manufacturer has filed with the Minister a new drug submission and the Minister has issued a notice of compliance in respect of the new drug submission. Furthermore, s. C.08.004 requires that the Minister issue a notice of compliance only after having completed an examination of the new drug submission and being satisfied that the new drug submission complies with the relevant provisions of the regulations.

compliance before it is satisfied that the new drug is safe and effective. It is the comprehensive information and materials contained in the new drug submission which allows the Minister to reach such a conclusion. Hence, if there is no new drug submission, there can be no notice of allegation and furthermore, no notice of compliance can be issued.

However, the question remains: can a reference of the medicine in one dosage form on the new drug submission be sufficient to comply with the requirements of the regulations and protect the other dosage forms of the product? I do not think so. In the event that such a proposition were valid, it would be possible for generic companies to have approval for other dosage forms of drugs for which a notice of compliance has already been issued, this despite the fact that they were using different methods. Not only does this pose an obvious problem for patentees mindful of their proprietary rights, but it also potentially creates a larger problem for the public, that is how could the Minister properly ascertain the safety and effectiveness of a drug without the relevant information usually set out in the new drug submission.

Finally, if the Respondent wants to include other dosage forms in its new drug submission, the *Food and Drug Regulations* already provides it with a proper mechanism. In fact, whenever a notice of compliance is issued to the Respondent in connection with its drug, it can avail itself of section C.08.003(1) of the *Regulations* and file with the Minister a supplement to it submissions, detailing such information pertaining to its new dosage forms.

As a result, it appears that in the case at bar, the Minister can only issue a notice of compliance for the 500mg product. This leads us to the second argument raised by the Applicants. In their originating notice of motion, they maintained that contrary to the Respondent's assertions, their patent did indeed have claims to the

medicine itself as well as to the use of the medicine, and that the methods used by Novopharm to make vancomycin hydrochloride infringed their patent. However, it is interesting to note that in their written brief, the Applicants addressed this issue only in passing. Specifically, they asserted that their patent disclosed a formulation claim, which claims have been held in the past to be valid claims to the medicine itself[3]. The Respondent replied in turn by alleging that the claim disclosed in the Applicants'

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[3] See *Hoffman-La Roche Ltd*. v. *Canada (Minister of National Health and Welfare)* (1995), 62 C.P.R. (3d) 58.

patent is a process claim which is clearly outside the ambit of the statutory definition of "claims to the medicine itself"[4].

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[4] See *Deprenyl Research Ltd*. v. *Apotex Inc*. (1995) 60 C.P.R. (3d) 510 (F.C.A.).

Whether or not the Applicants' patent is truly a formulation or a process one, it is my respectful opinion that they have not satisfied their legal burden of proof. In proceedings of this nature, the Court always starts from the premise that the allegations of fact in the generic company's notice of allegation are true, except to the extent that the contrary is shown by the applicant. It is up to the latter to prove that its patent contains a claim to the medicine itself and that it would be infringed if a notice of compliance is issued. In the case at bar, the Applicants have not satisfied this legal burden. Insufficient evidence in their affidavits was adduced. On the preponderance of the evidence, they have not proved that their patent contains a claim to the medicine itself and that it would be infringed if the Minister issued a notice of compliance to the Respondent.

In any event, the case for the 1g and 10g dosage forms is not before the Court and cannot be dealt with at this time. Thus, a prohibition order is granted for the 1g and 10g product forms and is denied for the 500mg dosage form. As for costs, there are no special reasons for awarding them.

L-Marcel Joyal

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J U D G E

O T T A W A, Ontario
August 11, 1997.