A-339-97
(T-1237-95)

CORAM: MARCEAU J.A.
DESJARDINS J.A.
McDONALD J.A.

BETWEEN:

ELI LILLY & COMPANY
and ELI LILLY CANADA, INC.

Appellants
(Respondents)

- and -

APOTEX INC.

Respondent
(Applicant)

- and -

MINISTER OF NATIONAL HEALTH AND WELFARE

Respondent
(Respondent)

REASONS FOR JUDGMENT

MARCEAU J.A.

The Trial Division decision under appeal raises again the difficult problem of defining the nature and scope of the very special set of regulations, in force since 1993, called the Patented Medicines (Notice of Compliance) Regulations (SOR/93-133) (hereinafter "the Regulations"). These Regulations have been analyzed and commented upon in numerous decisions, mostly of the Trial Division but also of this

Court. Nevertheless, another brief overview of their nature and purpose at the outset could greatly facilitate the analysis of the issues raised by this appeal.

Enacted by the Governor in Council under provisions of the Patent Act Amendment Act, 1992 (S.C. 1993, c. 2), which abolished the system of compulsory licensing for patented medicines, and grafted onto the regulatory controlling system established by the Food and Drug Regulations (C.R.C., c. 870), the new set of regulations were aimed at contributing to the protection of private commercial patent rights.

The main features of the new protective scheme may be described in a nutshell as follows: The Minister of National Health and Welfare ("the Minister") is responsible, under the Food and Drug Regulations, for the issuance of "notices of compliance" (hereinafter "NOC") attesting to the health, safety and efficacy of drugs. An NOC is a prerequisite for marketing drugs. The drug manufacturer who holds or is licensed under subsisting patents is invited to file a patent list with the Minister indicating each of the drugs for which it already holds an NOC. From that point on, any other manufacturer who applies for an NOC in respect of the same drug, must support its new drug submission (hereinafter "NDS") by an allegation asserting that the listed drug patent would not be infringed if its application was granted, and explaining the basis for the assertion. A notice of such allegation must be served on the holder of the patent. Within 45 days of service of the allegation, the holder of the patent who wishes to dispute the justification of the allegation must seek an order from the Federal Court prohibiting the Minister from issuing the NOC applied for, and the Court will issue the order unless it finds that the allegation is justified. An NDS for a listed medicine must be left in abeyance until the expiration of the time given to the patent-holder to respond and, if proceedings in prohibition are commenced, until they are dismissed or another 30 months expires. However, in the absence of proceedings, the Minister is directed to process the application and, unless there is any concern for public health and safety, will

issue the NOC requested. The three central provisions of these Regulations read as follows:

> **5.** (1) Where a person files or, before the coming into force of these Regulations, has filed a submission for a notice of compliance in respect of a drug and wishes to compare that drug with, or make a reference to, a drug that has been marketed in Canada pursuant to a notice of compliance issued to a first person in respect of which a patent list has been submitted, the person shall, in the submission, with respect to each patent on the patent list,
> (a) state that the person accepts that the notice of compliance will not issue until the patent expires; or
> (b) allege that
> (i) the statement made by the first person pursuant to paragraph 4(2)(b) is false,
> (ii) the patent has expired,
> (iii) the patent is not valid, or
> (iv) no claim for the medicine itself and no claim for the use of the medicine would be infringed by the making, constructing, using or selling by that person of the drug for which the submission for the notice of compliance is filed.
>
> (2) Where, after a second person files a submission for a notice of compliance, but before the notice of compliance is issued, a patent list is submitted or amended in respect of a patent pursuant to subsection 4(5), the second person shall amend the submission to include, in respect of that patent, the statement or allegation that is required by subsection (1).
>
> (3) Where a person makes an allegation pursuant to paragraph (1)(b) or subsection (2), the person shall
> (a) provide a detailed statement of the legal and factual basis for the allegation; and
> (b) serve notice of the allegation on the first person and proof of such service on the Minister.
>
> **6.** (1) A first person may, within 45 days after being served with a notice of an allegation pursuant to paragraph 5(3)(b), apply to a court for an order prohibiting the Minister from issuing a notice of compliance until after the expiration of one or more of the patents that are the subject of an allegation.
>
> (2) The court shall make an order pursuant to subsection (1) in respect of a patent that is the subject of one or more allegations if it finds that none of those allegations is justified.
>
> ...
>
> **7.** (1) The Minister shall not issue a notice of compliance to a second person before the latest of
> (a) the expiration of 30 days after the coming into force of these Regulations,
> (b) the day on which the second person complies with section 5,
> (c) subject to subsection (3), the expiration of any patent on the patent list that is not the subject of an allegation,
> (d) subject to subsection (3), the expiration of 45 days after the receipt of proof of service of a notice of any allegation pursuant to paragraph 5(3)(b) in respect of any patent on the patent list,
> (e) subject to subsections (2), (3) and (4), the expiration of 30 months after the receipt of proof of the making of any application referred to in subsection 6(1), and
> (f) the expiration of any patent that is the subject of an order pursuant to subsection 6(1).

This brief overview of the main legislative features of the Patented Medicine (Notice of Compliance) Regulations would not be complete without referring, in addition, to two refinements attached to them by decisions of this Court.

It is now settled that the proceedings launched by the patented manufacturer seeking prohibition are proceedings in judicial review. In Bayer AG v. Canada (Minister of National Health and Welfare),[1] Mahoney J.A., speaking for a unanimous Court, commented as follows:

> The legislative scheme does not contemplate a proceeding by way of action. The person claiming patent rights must commence the proceeding within 45 days of being served with a notice of allegation and it is contemplated that the court will have resolved the matter within 30 months after that. Patent infringement actions simply do not proceed at a rate that would meet the legislative time frame. (When an extension of time that might delay final resolution of the application beyond 30 months is sought, the court will have to consider the impact of s. 55.2(4)(e) of the Patent Act and s. 7(5) of the Regulations on the discretion provided by Rule 1614).
>
> By merely commencing the proceeding, the applicant obtains what is tantamount to an interlocutory injunction for up to 30 months without having satisfied any of the criteria a court would require before enjoining issuance of a NOC. In particular, no liability as to damages arises from the application as would be imposed by the undertaking any court would require before making an interlocutory injunction. The liability for damages created by s. 8 of the Regulations pertains only to those incurred as a result of the NOC not issuing until after the patent has expired. That is by no means coextensive with the liability that arises on an undertaking exacted when an injunction is issued.
>
> The court has a clear duty to deal with an application expeditiously. Given that, in the scheme of the Regulations, it is the patentee who has both the carriage of the proceeding and the interest in its dilatory prosecution, departures from the schedule imposed by the Part V.1 Rules ought not be routine.

It has also been established that the section 6 proceedings launched by the patentee should not be likened to actions for determining validity or infringement but are of the nature of proceedings in judicial review, to be held expeditiously, whose aim is to determine whether the Minister is free to issue the notice of compliance requested.

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[1] (1993), 163 N.R. 183, at 189.

Their scope is confined to administrative purposes. Strayer J.A., in Pharmacia Inc. v. Canada (Minister of National Health and Welfare),[2] again speaking for a unanimous Court, was clear to that effect:

> It will be noted that the regulations nowhere create or abolish any rights of action between the parties; instead they confer a right on the patentee to bring an application for prohibition against the Minister of National Health and Welfare. That is, the regulations pertain to public law, not private rights of action. Of course the real adversary in such a prohibition proceeding is the generic company which served the notice of allegation.
>
> If the Governor in Council had intended by these regulations to provide for a final determination of the issues of validity or infringement, a determination which would be binding on all private parties and preclude future litigation of the same issues, it surely would have said so. This court is not prepared to accept that patentees and generic companies alike have been forced to make their sole assertion of their private rights through the summary procedure of a judicial review application. As the regulations direct that such issues as may be adjudicated at this time must be addressed through such a process, this is a fairly clear indication that these issues must be of a limited or preliminary nature. If a full trial of validity or infringement issues is required this can be obtained in the usual way by commencing an action.

* * *

Such are the main features of the Regulations involved in this appeal. I now come to the factual and procedural basis for the appeal.

The appellants (hereinafter "Eli Lilly") market a pharmaceutical preparation of the active chemical nizatidine (used to treat peptic ulcers) pursuant to an NOC issued by the Minister on December 31, 1987. They hold two Canadian patents pertaining to processes for synthesizing nizatidine.

On April 29, 1993, the respondent (hereinafter "Apotex"), a Canadian manufacturer of generic products, submitted an application to the Minister for an NOC

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[2] 58 C.P.R. (3d) 209, at 217.

in respect of its own brand of nizatidine compositions. As Eli Lilly had completed, under the Regulations, a "patent list" containing its two patents for nizatidine, Apotex appended to its application and served on Eli Lilly a notice of allegation to the effect that no claim for the medicine itself, and no claim for the use of the medicine in the Eli Lilly patents, would be infringed by the preparation and sale of nizatidine capsules formulated by Apotex, since these would be formulated from bulk nizatidine supplied by Novopharm Ltd. (hereinafter "Novopharm"), a compulsory licensee of Eli Lilly, pursuant to an agreement between the two generic manufacturers.

On June 14, 1993, Eli Lilly commenced an application for prohibition pursuant to subsection 6(1) of the Regulations. By order dated February 9, 1995, the motions judge in the Trial Division, Madame Justice McGillis, allowed the judicial review application. She found that Apotex's allegation was unjustified since the agreement with Novopharm constituted an impermissible sublicense and, in any event, the processing of licensed bulk nizatidine into capsule form would infringe the patentee's rights. An order of prohibition was therefore issued as required by the Regulations, which order was later on appeal upheld by this Court whose judgment is now pending before the Supreme Court.

Following the issuance of McGillis J.'s order, Apotex, while pursuing its appeal, submitted a second notice of allegation and served a copy thereof on Eli Lilly on February 13, 1995. In this second notice, Apotex stated that, in the formulation of its nizatidine capsules, it will use only nizatidine manufactured by means of a process that would not infringe the processes claimed in the Eli Lilly patents. Eli Lilly did not respond. In May, 1995, as Eli Lilly had not applied, under subsection 6(1) of the Regulations, for an order of prohibition within the 45 day limitation period, Apotex requested confirmation from the Minister that its application for an NOC in respect of its own brand of nizatidine would be processed. Being left without comment from the Minister, Apotex applied to the Trial Division of this Court for declaratory relief and an order in the nature of mandamus compelling the Minister to process Apotex's new drug

submission unconstrained by the Regulations and the prohibition order of Madame Justice McGillis.

The different Trial Division judge seized with the application allowed it. Following, in that respect, what he saw as being the jurisprudence of the Court, he held that it was not an abuse of process for Apotex to have filed a second notice of allegation, insofar as the second notice was based on different grounds than the first, which was the case since the first notice was based on the existence of a license, whereas the second was on a non-infringing process. The learned Trial Division judge rejected Eli Lilly's argument that the principle of res judicata applied. As he saw it, the task of the Court in a prohibition proceeding was to determine whether a particular notice of allegation was justified as the contents of the underlying NDS are not directly before the Court. It would appear to him extraordinary to treat McGillis J.'s order as resolving any dispute other than that which was before her at the hearing. She obviously could not rule prospectively in respect of issues and evidence that were not before her. It followed that the scope of her prohibition order had to be confined to the specific allegations that were advanced in the proceedings then involved. The conclusion was inevitable: Eli Lilly having failed to commence an application for a prohibition order within 45 days of service of the second notice of allegation, the Minister was free to process Apotex's request.

Eli Lilly immediately appealed.

* * *

A preliminary technical point should be addressed at the outset. The formal judgment signed by the motions judge simply allowed Apotex's application and granted the relief applied for, referring in general terms to the wording of the notice of

motion. This was obviously inappropriate as part of the relief sought was, by its generality, not available on a judicial review proceeding, while another part was claimed only in the alternative. It is clear that this was done inadvertently. The reasons for judgment should have given rise to a simple order requiring the Minister to process Apotex's NDS for nizatidine capsules without regard to the Eli Lilly patents. If the findings of the Trial Division judge are to be upheld on this appeal, the order will have to be varied to ensure that its scope does not go beyond what is required to give them their full effect.

That being said, let us consider the findings themselves and verify their validity.

Eli Lilly opposes the findings of the Trial Division judge by resorting to a series of arguments ranging from the nature of a prohibition order to the meaning of judicial review proceedings, the spirit of the Regulations, the rules of stare decisis, the principles against frivolous proceedings and the importance of the rules of procedure in implementing a specific administrative scheme. I do not believe it is necessary to decompose so much the analysis in order to dispose of the contentions of the parties. As I see it, the appeal essentially raises two issues. The one basic substantive issue is whether the motions judge could order the Minister to proceed when McGillis J.'s prohibition order was still in force. There is alternatively a procedural issue, which is whether the requirements of the Regulations for making an allegation were sufficiently satisfied to bring into play the effect attached to a failure to dispute its validity.

Naturally, it is to the substantive issue that the major part of the analysis must be directed. Counsel for Eli Lilly advanced two arguments in order to dispute the validity of the motions judge's conclusion that the prohibition order did not preclude the issuance of his own order. Counsel argued first that by its very nature and on its face, the prohibition order then in force was not open to interpretation as to its scope. It had to be taken as having an absolute effect; it imposed a prohibition without restriction and

qualification which was meant to remain operative until the expiration of the patents, as provided in paragraph 7(1)(f) of the Regulations. Such an order, it was urged, cannot be set aside or varied collaterally on a simple judicial review proceeding where its involvement is raised only indirectly. Furthermore, added counsel, an order with an absolute effect was precisely what was contemplated by the Regulations, which did not provide for the possibility of further proceedings with the result that the second notice of allegation could have no legal meaning, which is why Eli Lilly did not react to it.

I have come to the view that neither of these two arguments has merit. I do not see why a court, in a clear situation, could not proceed to an assessment of the scope and meaning of an order of the type issued by McGillis J., and then attach to it an effect which is not absolute. There is no doubt that this is possible only exceptionally, but when the order was clearly made in a particular context, was rendered to give effect to stated reasons, and its wording in general terms can be explained, I think it can be done. This is precisely the position adopted by the Manitoba Court of Appeal in Allen v. Manitoba (Judicial Council),[3] where Twaddle J.A., writing for a unanimous court, had this to say:

> A court order should ordinarily be construed in the context of the application for it. Reference to the application in this case shows that what Judge Allen sought to have prohibited was the inquiry pursuant to the notice dated December 21, 1989.
>
> The Court is also entitled, when construing an order previously made by it, to look at its reasons for making it. In this case it is quite clear that the inquiry was prohibited only because it had not been properly convened pursuant to either s. 31(1) or s. 31(2) of the relevant legislation. Nothing was said to indicate that a properly convened inquiry was prohibited.
>
> I therefore construe the previous order of this Court as prohibiting the irregularly convened inquiry of which noted was given in December, 1989. The order was not intended as a general prohibition against any subsequent inquiry that might be convened either at the request of the Attorney-General or following an investigation and report. The new inquiry is not prohibited by the old order and a new order, if one is to be made, must be justified on fresh grounds.

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[3] [1993] 3 W.W.R. 749 (Man. C.A.), reversing (1992), 79 Man. R. (2d) 81 (Q.B.), at 752-754.

I do not think that anyone could dispute the very unique nature of the proceeding which led to the order here involved, a proceeding grafted onto the administrative process of issuing an NOC. What comes before the Court is a particular allegation and the order, which is required by the Regulations to be worded in general terms, is made with the sole view of giving effect to the finding that the allegation is unjustified. The conditions for an assessment of the scope and meaning of the order, in my opinion, are clearly there. That such an assessment is not outside the purview of a procedure of the nature of the one here involved raises no difficulty since the question is not of setting aside the order or varying the order, but of interpreting the order.

On the other hand, it does not appear to me that the legislator, in imposing this special set of rules, could have contemplated that the issuance of an order of prohibition on a finding that a particular allegation was unjustified would be absolute and would be deemed to cover any future allegation, however new and distinct it might be. That would give a summary procedure an effect that goes way beyond its meaning and object. As pleaded by counsel for Apotex: "it would be truly perverse to condemn a second person (the second manufacturer) to advance a ‘once and for all’ allegation of non-infringement in a single proceeding when the subject patent may have an unexpired term of 17 years or more, and newly discovered processes which contravene no patent rights are only developed after the initial allegation has been determined." I agree with the views expressed in the numerous Trial Division decisions referred to by the motions judge to the effect that successive allegations are possible and each one must be treated independently provided it is separate and distinct from the others and its bringing before the Court cannot be seen as an abuse of process.

In my judgment, the substantive argument advanced by counsel for Eli Lilly in support of the appeal fails. The motions judge was correct in determining the scope of McGillis J.'s order with regard to the context in which it was rendered and the reasons given for it. He was also correct in believing that a second allegation, if distinct from the first, as was the case here, must be treated independently of the first one.

Which leads me to the second argument relied upon in support of the appeal. It is submitted that the second allegation was not made by Apotex in the manner prescribed by the Regulations, so that it could not attract the effects attached to valid allegations by those Regulations.

According to subsection 5(3) of the Regulations, an allegation with respect to a patented medicine must be attached to a new drug submission, must be completed by a detailed statement as to its legal and factual basis and must be served on the patent holder. The three requirements were met here, albeit in an order different from the one that was used to enumerate them in the provision. Indeed, the allegation was served before the NDS could be updated to refer to it, and prior to the filing with the Minister of a detailed statement as to its factual and legal basis. Apotex explained that, in abstaining from making full disclosure of its non-infringing process in the allegation itself, it was merely acting in accordance with the teachings of the Court in Bayer, supra, where it was said:

> An applicant for a NOC alleging a different process cannot be expected to make full disclosure without a protective order. Confidentiality cannot be assured until there is a proceeding in court.

And in delaying to update its NDS, it was trying to avoid having its submission stripped of its rank among the submissions to be considered under the administrative procedure then applied by the Minister.

The only position taken by the Minister on this appeal was with respect to this procedural argument which incidentally Eli Lilly had not raised as such before the motions judge. In the Minister's submission, the three step sequence as set out in section 5 is merely directory, not mandatory. The Minister argues that the process cannot be vitiated by the sole fact that the requirements of section 5 were complied with in an out-of-sequence manner. I fully agree. The basic purpose of the Regulations is to provide a means by which patents are noted and protected from possible infringement

at the instance of the patent-holder. The Regulations thus ensure that an NOC is not issued without a patent-holder having the opportunity to defend its patent. This opportunity is not diminished by the fact that the notice of allegation is given first, if, as here, it contains sufficient information for the patent-holder to determine whether to seek a prohibition order and the Court can immediately proceed to determine its justification. If the sequence is held to be mandatory, the process would simply have to be commenced anew and this would cause a purposeless delay in the marketing of a drug in cases where the allegation proves to have been justified. The intent of the Regulations shows that compliance with section 5 in a manner inconsistent with the sequence set out should not be considered a defect sufficient to vitiate the process.

It is my opinion, therefore, that the motions judge did not err in his reasoning and that this Court should uphold his conclusion. For those who would feel uncomfortable with the idea that the mere failure to react properly to a somewhat unclear legal requirement could have such a drastic result, I will repeat that the Regulations are not aimed at opening the way to proceedings directly adjudicating on issues of infringement or validity of patents. They simply provide a certain protection to a patent-holder by allowing a court to determine summarily, on the basis of the evidence adduced, whether the allegation of non-infringement is justified. The appellant is, in no way, deprived of all the recourses normally available to a patent-holder to enable it to enforce its rights.

I would therefore suggest that, subject to a variation of the impugned order so as to limit its scope to what the motions judge obviously had in mind, that is to the first two paragraphs of the notice of motion, the appeal be dismissed with costs.

"Louis Marceau"
J.A.

"I agree.
Alice Desjardins, J.A."

"I agree.
F.J. McDonald, J.A."

A-339-97
(T-1237-95)

CORAM: MARCEAU J.A.
DESJARDINS J.A.
McDONALD J.A.

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- and -

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- and -

MINISTER OF NATIONAL HEALTH AND WELFARE

Respondent
(Respondent)

Heard at Ottawa, Ontario, on Thursday, September 4 and Monday, September 8, 1997.

Judgment rendered at Ottawa, Ontario, on Monday, September 29, 1997.

REASONS FOR JUDGMENT BY: **MARCEAU J.A.**

A-339-97
(T-1237-95)

OTTAWA, Ontario, Monday, September 29, 1997.

CORAM: MARCEAU J.A.
DESJARDINS J.A.
McDONALD J.A.

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MINISTER OF NATIONAL HEALTH AND WELFARE

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(Respondent)

J U D G M E N T

The order of the Trial Division here under appeal, dated April 25, 1997, is varied so as to be understood as being restricted to the first two items of the relief sought in the notice of application which was then before the Court and was being granted, namely:

> 1.An Order declaring that, in relation to the Notice of Allegation dated February 10, 1995 filed with the Minister of National Health and Welfare ("Minister") and served upon the Respondents on or about February 13, 1995, there is

no restriction upon the Minister under the *Patented Medicines (Notice of Compliance) Regulations* ("Regulations") restricting the Minister from issuing Apotex a Notice of Compliance in respect of its 150 mg and 300 mg nizatidine capsules;

2. An Order directing the Minister to process Apotex' New Drug Submission for 150 mg and 300 mg capsules of nizatidine without regard to any patent lists filed by the Respondents, Eli Lilly & Company and Eli Lilly Canada Inc. ("Lilly"), pursuant to section 4 of the *Regulations*.

In all other respects, the order is upheld and the appeal is dismissed with costs.

"Louis Marceau"
J.A.

IN THE FEDERAL COURT OF APPEAL

A-339-97
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REASONS FOR JUDGMENT
