Date: 20071106

Docket: A-274-07

Citation: 2007 FCA 359

PRESENT: **SEXTON J.A.**
PELLETIER J.A.
RYER J.A.

BETWEEN:

ELI LILLY CANADA INC.

Appellant

and

NOVOPHARM LIMITED

Respondent

and

THE MINISTER OF HEALTH

Respondent

and

ELI LILLY AND COMPANY LIMITED

Respondent/Patentee

Heard at Toronto, Ontario, on November 5, 2007.

Order delivered at Toronto, Ontario, on November 6, 2007.

REASONS FOR ORDER BY: SEXTON J.A.

CONCURRED IN BY: RYER J.A.

DISSENTING REASONS BY: PELLETIER J.A.

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REASONS FOR ORDER

SEXTON J.A.

Introduction

[1] This is a motion by the Respondent, Novopharm Limited ("Novopharm") to dismiss the appeal of the Order of Mr. Justice Hughes dated June 5, 2007 (the "June 5 Order") on the ground that the appeal is moot.

[2] The June 5 Order dismissed Eli Lilly Canada's ("Eli Lilly") application for an order prohibiting the Minister of Health (the "Minister") from issuing a Notice of Compliance ("NOC") to Novopharm for its 2.5 mg, 5 mg , 7.5 mg, 10 mg and 15 mg olanzapine tablets. After the June 5 Order, the Minister granted an NOC to Novopharm.

[3] This Court has consistently held that, once an NOC has been issued, a patent holder's appeal from an application to prohibit the issuance of an NOC will be dismissed due to mootness. Nevertheless, Eli Lilly argues, that, *inter alia*, the recent decision in *Sanofi-Aventis Canada Inc. v. Novopharm Limited et al.* 2007 FCA 163, 282 D.L.R. (4th) 476, 59 C.P.R. (4th) 416, (leave to appeal to the S.C.C. dismissed, [2007] S.C.C.A. No. 311) ("*Sanofi-Aventis*") demands that this Court revisit the law with respect to a patent holder's right to appeal an otherwise moot NOC proceeding.

[4] For the reasons that follow, I disagree with this submission and would allow Novopharm's motion and dismiss this appeal on the ground of mootness.

Background

[5] This motion arises from an appeal from prohibition proceedings pursuant to the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (the "*NOC Regulations*"). The patents that are discussed in these NOC proceedings are for drugs that are used to treat schizophrenia.

[6] The persistent theme in the development of these drugs was that while innovators could discover drugs that were effective in treating schizophrenia, the drugs all had dangerous side-effects. Eli Lilly had identified a number of potential drug candidates that would have reduced side-effects, which led to the development of a class of compounds in Canadian Patent 1,075, 687 (the "'687 Patent").

[7] The '687 Patent claimed a genus of approximately 15 trillion compounds. The only compounds that were individually claimed in the '687 Patents were flumezapine and ethylflumezapine. Testing on these two drugs revealed that they possessed either unacceptable side effects or a lack of effectiveness in treating schizophrenia. Further research, however, was conducted on compounds that were within the class outlined in the '687 Patent; this resulted in favourable results for one particular drug called olanzapine. As a result, Eli Lilly decided to file Canadian Patent 2,041,113 (the "'113 Patent") which characterizes olanzapine as a selection from the class of the '687 Patent. The '113 Patent discloses that Lilly "discovered a compound which possesses surprising and unexpected properties by comparison with flumezapine and other related compounds."

[8] The '113 Patent is what is known as a "selection patent," which is, within the context of pharmaceutical patents, a compound selected from an existing patented class when it is discovered that the selected compounds possess unexpected characteristics which could not be predicted before the discovery was made: see *In re I.G. Farbenindustrie A.G.'s Patents* (1930) 47 R.P.C. 283 (Ch. Div.) at pp. 322-3 ("*I.G. Farbenindustrie*"); Harold G. Fox, *Canadian Patent Law and Practice*, 4th

ed. (Toronto: The Carswell Company Limited, 1969) at 89. Selection patents exist to encourage researchers to discover new advantages for compounds within the known class. This constitutes an inventive skill (*Pfizer Canada Inc. et al. v. Minister of Health et al.* 2006 FCA 214, 272 D.L.R. (4th) 756, 52 C.P.R. (4th) 241 at para. 5).

[9] On June 20, 2005, Novopharm filed the Notice of Application ("NOA") which was the basis for Eli Lilly's application for prohibition to the Federal Court. The NOA alleged that the '113 Patent was invalid for the reasons of anticipation, obviousness, double patenting, an intention to mislead in violation of section 53 of the *Patent Act* R.S.C. 1985, c. P-4 (the "*Act*"), insufficient disclosure and inutility. On Sept. 8, 2005, Eli Lilly applied for a prohibition order to the Federal Court, arguing that the grounds listed in the NOA were not justified. The NOC proceeding before Justice Hughes did not occur until May 25, 2007.

[10] In his decision, *Eli Lilly Canada Inc. v. Novopharm Limited* 2007 FC 596, which is the subject of the appeal concerned in this motion, Justice Hughes held that Eli Lilly was unable to establish that the allegation by Novopharm that the '113 Patent was invalid by reason of insufficient disclosure was not justified. His findings on this ground can be summarized in paragraph 162 of his decision:

> I find that the '113 patent fails to provide sufficient disclosure in its specification as to the invention, if any, in selecting olanzapine from a previously disclosed group of compounds. The prior art British Patents [*inter alia*, Patent '687] says that the whole class of compounds [is] useful in treating central nervous system disorders. The invention in selecting olanzapine is the so called "surprising and unexpected" properties of olanzapine in "comparison with flumezapine and other related compounds". No such comparison is made anywhere in the '113 patent. No data was given. We are left only with rhetoric such as "high level of efficiency" and "mild and transient" and "lower" side effects.

[11] The main challenge by Eli Lilly to the decision of Hughes J. is stated to be that he found the law of Canada requires that the specification of a selection patent must contain comparative data which demonstrates the advantages of the selected class over the class disclosed in a previous patent. Not only does Eli Lilly argue that this was not raised in Novopharm's NOA, but that such a finding is in contravention of the requirements of the *Act*, and of Canada's obligations under the *Patent Cooperation Treaty* and the Agreement on Trade-Related Aspects of Intellectual Property Rights.

[12] The day following the issuance of the decision of Hughes J., Novopharm received an NOC from the Minister for Novo-Olanzapine tablets, which are Novopharm's 2.5, 5, 7.5, 10 and 15 mg strength olanzapine tablets.

Issues

[13] There are two issues in this motion:

i. Is the appeal moot?

ii. If the appeal is moot, should the Court exercise its discretion to hear the appeal?

Analysis

1) Is the Appeal Moot?

[14] As Novopharm correctly points out, this Court has consistently dismissed, on the grounds of mootness, appeals from orders refusing prohibition applications under the *NOC Regulations* in circumstances where an NOC has issued. See, for instance, *Pfizer Canada Inc. v. Apotex Inc. et al.* (2001) 11 C.P.R. (4th) 245 (F.C.A.) (leave to appeal to the S.C.C. dismissed, [2001] S.C.C.A. No. 111) ("*Pfizer*"); *AstraZeneca AB v. Apotex Inc.* 2004 FCA 224 (leave to appeal to the S.C.C. dismissed, [2004] S.C.C.A. No. 391). The reason for this is that once the prohibition application is dismissed, the Minister is acting entirely lawfully in issuing an NOC to the generic, as per subsection 7(1) of the *NOC Regulations*: *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)* [1999] F.C.J. No. 555 (F.C.A.) (leave to appeal to the S.C.C. dismissed, [1999] S.C.C.A. 313). Moreover, once the NOC has been issued, there is no provision under the *NOC Regulations* that would permit this Court to retroactively prohibit its issuance.

[15] Subsections 7(1) and (2) of the *NOC Regulations* read as follows:

7. (1) The Minister shall not issue a notice of compliance to a second person before the latest of	7. (1) Le ministre ne peut délivrer un avis de conformité à la seconde personne avant la plus tardive des dates suivantes :
(a) [Repealed, SOR/98-166, s. 6]	a) [Abrogé, DORS/98-166, art. 6]
(b) the day on which the second person complies with section 5,	b) la date à laquelle la seconde personne se conforme à l'article 5;
(c) subject to subsection (3), the expiration of any patent on the register that is not the subject of an allegation,	c) sous réserve du paragraphe (3), la date d'expiration de tout brevet inscrit au registre qui ne fait pas l'objet d'une allégation;
(d) subject to subsection (3), the expiration of 45 days after the receipt of proof of	d) sous réserve du paragraphe (3), la date

service of a notice of any allegation pursuant to paragraph 5(3)(b) or (c) in respect of any patent on the register,	qui suit de 45 jours la date de réception de la preuve de signification de l'avis d'allégation visé aux alinéas 5(3)b) ou c) à l'égard de tout brevet inscrit au registre;
(e) subject to subsections (2), (3) and (4), the expiration of 24 months after the receipt of proof of the making of any application under subsection 6(1), and	e) sous réserve des paragraphes (2), (3) et (4), la date qui suit de 24 mois la date de réception de la preuve de présentation de la demande visée au paragraphe 6(1);
(f) the expiration of any patent that is the subject of an order pursuant to subsection 6(1).	f) la date d'expiration de tout brevet faisant l'objet d'une ordonnance rendue aux termes du paragraphe 6(1).
(2) Paragraph (1)(e) does not apply if at any time, in respect of each patent that is the subject of an application pursuant to subsection 6(1),	(2) L'alinéa (1)e) ne s'applique pas si, à l'égard de chaque brevet visé par une demande au tribunal aux termes du paragraphe 6(1) :
(a) the patent has expired; or	a) soit le brevet est expiré;
(b) the court has declared that the patent is not valid or that no claim for the medicine itself and no claim for the use of the medicine would be infringed.	b) soit le tribunal a déclaré que le brevet n'est pas valide ou qu'aucune revendication pour le médicament en soi ni aucune revendication pour l'utilisation du médicament ne seraient contrefaites.

[16] Once “the court”, which has been held to be the “Federal Court Trial Division” (see *Pfizer*, *supra*, at paragraph 20) has dismissed the prohibition motion, the Minister may issue the NOC. Indeed, the Minister “shall” do so: section C.08.004(1) of the *Food and Drug Regulations*, C.R.C. 1978, c. 870. As Isaac J.A. (as he then was) stated in *Pfizer*, *supra*, at paragraph 21:

> It follows that once the prohibition proceedings brought by the appellants were dismissed by the Trial Division, the Minister was entitled to and did issue the NOCs to Apotex and to Nu Pharm with respect to fluconazole. The issue of these NOCs foreclosed any attempts to continue prohibition proceedings under the Regulations, as the summary procedure therein

> was spent. As Decary J.A. put it in *Merck Frosst Canada*, *supra*, at para. 5, "[t]he appeal is obviously moot, the Minister having done what he is empowered to do under s. 7(1) of the Regulations, i.e., he issued a notice of compliance".

[17] Eli Lilly insists, however, that the reasons in *Sanofi-Aventis* somehow demand that the cases cited above need to be revisited. I do not agree with this proposition. The error in Eli Lilly's logic can be demonstrated through the presentation of their argument on this issue in their Memorandum of Fact and Law:

> As a result of the recent decision of this Court in *Sanofi*, an invalidity finding on any issue in a first prohibition proceeding, once all appeals are final, estops a first person (the patentee or a licensee) from again litigating that same validity issue in subsequent NOC proceedings. Thus, even if this court could not set aside the NOC, the appeal is not moot as other generics can now rely on Justice Hughes' decision.
>
> […]
>
> The result of Justice Sexton's decision in *Sanofi* is that non-party generics can rely on the successful allegation of invalidity that another generic has made once the decision becomes final. Consequently, once an allegation of invalidity succeeds in a NOC proceeding, the innovator is deprived of the opportunity of succeeding against subsequent invalidity allegations.
>
> As a result of *Sanofi*, Justice Hughes' decision affects Lilly's ability to rebut allegations that the '113 patent is invalid for insufficiency by any other generic. If this appeal is not granted, Lilly will be denied both an opportunity to address the basis for Justice Hughes' decision in this case, and an opportunity to address invalidity arguments regarding insufficiency of the '113 patent made by other generics in other NOC proceedings. This is true even though the '113 patent and its foreign counterpart have previously survived attacks on validity.

[18] Nothing in Eli Lilly's reasoning suggests why the law is, or ought to be, any different with respect to mootness after the reasons in *Sanofi-Aventis*. The *Sanofi-Aventis* case simply stands for the proposition that it is an abuse of process for a patent holder, having lost in a prohibition proceeding on an issue relating to invalidity, to relitigate the same issue against another generic. It

does not change the test for mootness as set by the Supreme Court of Canada in *Borowski*, *infra*, nor does it somehow grant this Court the right to quash an NOC that had been issued by the Minister in compliance with the *NOC Regulations*. Rather, Eli Lilly has argued that, due to *Sanofi-Aventis*, Justice Hughes' decision may impact other NOC proceedings. Such considerations, if of merit, would only be relevant in considering a court's discretion to hear a moot appeal.

[19] Notwithstanding the existing jurisprudence on this issue, I will nevertheless address the three arguments Eli Lilly advances for why its appeal is not moot:

a. Justice Hughes decided the case on an issue not raised by the parties, which gives rise to procedural unfairness;
b. There is still a live issue between the parties as Novopharm can rely on the decision of Hughes J. to obtain an NOC for ZYDIS (another Eli Lilly product), as well as a dosage form of olanzapine oral tablets (20mg), both of which are listed under the '113 Patent on the Patent Register; and
c. Due to this Court's recent decision in *Sanofi-Aventis*, *supra*, this appeal would affect the rights of Novopharm *vis à vis* other generics.

[20] With respect to the first argument, I do not find it persuasive. Eli Lilly's lengthy submissions on this point stem from one claim: that Novopharm never raised this issue in their NOA. I fail to see that Novopharm, in its NOA, did not provide sufficient notice of its argument relating to the insufficiency of disclosure in the '113 patent. For instance, the NOA claims:

7. <u>Invalidity – Section 53(1) of the Patent Act and/or Insufficiency of Disclosure</u>

> […]
>
> The person of ordinary skill would not have had sufficient information to put the invention into practice. In fact, they would have had misinformation that olanzapine was "markedly superior" to the other clinical options with an adverse effect profile that was substantially and peculiarly better than those others. If there are circumstances where olanzapine can be used to realize marked superiority, the specification of the '113 patent does not set out the method by which it can be achieved and certainly not in such full, clear, concise and exact terms as to enable a person skilled in the art to achieve it. The patent is therefore invalid because the invention as described would not work to the extent promised without this additional and better information (per s. 27(3)(b) of the *Patent Act*) and because, as shown below, the added or omitted information described was purposively included or withheld (as the case may be) for the purpose of misleading (per s. 53(1) of the *Patent Act*).

[21] In any event, even if there had been resulting procedural unfairness, which I conclude there was not, it would not change the fact that an NOC has issued and the Court is unable to change that result. Eli Lilly cites the case of *G.D. Searle & Co. v. Novopharm Limited* 2007 FCA 173, 281 D.L.R. (4th) 207, 58 C.P.R. (4th) 1 (leave to appeal to the S.C.C. dismissed, [2007] S.C.C.A. No. 340) ("*G.D. Searle*") as an example where this Court, in the words of Eli Lilly, "issued the prohibition order that ought to have been imposed." However, in the *G.D. Searle* decision a NOC had not been issued. Thus, the case cannot detract from the general principle already stated that once an NOC has been issued the appeal is moot.

[22] Eli Lilly stressed in oral argument that a finding from this Court that Hughes J. made his decision on a ground not raised in the NOA would render the June 5 Order a "nullity," as he would not have been within his jurisdiction to issue the June 5 Order. As such, so the argument goes, this would lead to the possibility of Eli Lilly applying for judicial review of the Minister's decision

directly. Based on my conclusion that Justice Hughes did decide the case on an issue adequately raised in the NOA, I do not have to address this contention.

[23] With respect to the second and third issues, Eli Lilly's submissions are misplaced. The possibility that generics, or even Novopharm, can rely on Justice Hughes' decision in subsequent proceedings does not make the appeal not moot with respect to the NOC in question *vis à vis* the parties in this proceeding. The Supreme Court of Canada has established the criteria for determining whether a matter is moot in *Borowski v. Canada (Attorney General)* ["*Borowski*"], [1989] 1 S.C.R. 342, 57 D.L.R. (4th) 231 at paragraph 15:

> The doctrine of mootness is an aspect of a general policy or practice that a court may decline to decide a case which raises merely a hypothetical or abstract question. The general principle applies when the decision of the court will not have the effect of resolving some controversy which affects or may affect the rights of the parties. If the decision of the court will have no practical effect on such rights, the court will decline to decide the case. This essential ingredient must be present not only when the action or proceeding is commenced but at the time when the court is called upon to reach a decision. Accordingly if, subsequent to the initiation of the action or proceeding, events occur which affect the relationship of the parties so that no present live controversy exists which affects the rights of the parties, the case is said to be moot. The general policy or practice is enforced in moot cases unless the court exercises its discretion to depart from its policy or practice. [emphasis added]

[24] In this case, the controversy between the parties was whether an NOC should issue to Novopharm in respect of tablets for oral administration of drugs containing olanzapine in strengths of 2.5 mg, 5 mg, 7.5 mg, 10 mg, and 15 mg. Justice Hughes decided that Eli Lilly's application for prohibition against issuing an NOC should be dismissed. The Minister has issued an NOC. This Court cannot alter this decision. Applying the *Borowski* criteria, the appeal is moot. The issue of

whether the decision below could be relevant in other proceedings will be addressed when I consider whether this Court should exercise its discretion in hearing the appeal.

2) If the appeal is moot, should the Court exercise its discretion to hear the appeal?

[25] The Supreme Court of Canada in *Doucet-Boudreau v. Nova Scotia (Minister of Education)* 2003 SCC 62, [2003] 3 S.C.R. 3, 232 D.L.R. (4th) 577 ("*Doucet*") confirmed the three *Borowski* factors to consider when deciding whether to exercise the discretion to hear a moot appeal (at paragraph 18):

> (1) the presence of an adversarial context;
> (2) the concern for judicial economy; and
> (3) the need for the Court to be sensitive to its role as the adjudicative branch in our political framework.

[26] In *Borowski, supra*, the Supreme Court of Canada emphasized that the factors are not to be employed in a mechanical manner (at paragraph 42):

> In exercising its discretion in an appeal which is moot, the Court should consider the extent to which each of the three basic rationalia for enforcement of the mootness doctrine is present. This is not to suggest that it is a mechanical process. The principles identified above may not all support the same conclusion. The presence of one or two of the factors may be overborne by the absence of the third, and vice versa.

[27] There is an adversarial context between Eli Lilly and Novopharm. However, that adversarial context is in fact situated in another proceeding in which Eli Lilly has launched an infringement action with respect to the '113 patent. The main point of controversy between the parties, namely the question of the threshold for sufficient disclosure in selection patents, can be

addressed just as adequately in an infringement proceeding and those proceedings can produce an *in rem* decision as to the validity of the patent which the present proceeding cannot do. Thus, the existence of an adversarial context between the parties does not lend any weight to exercise my discretion in hearing this appeal.

[28] Nor does the prospect of subsequent litigation necessarily affect the discretion to hear a moot appeal. As C.J. Richard stated in *Janssen-Ortho Inc. v. Novopharm Ltd.* 2005 FCA 6, 40 C.P.R. (4th) 1 ("*Janssen-Ortho*"), at paragraph 20:

> With respect to the argument that there will be other challenges for levofloxacin, the Supreme Court of Canada, in *Borowski v. Canada (Attorney General)*, [1989] 1 S.C.R.3 42 at para. 34, rejected the relevance of such considerations as follows:
>
> > [34] The mere fact, however, that a case raising the same point is likely to recur even frequently should not by itself be a reason for hearing an appeal which is moot. It is preferable to wait and determine the point in a genuine adversarial context unless the circumstances suggest that the dispute will have always disappeared before it is ultimately resolved.

[29] Turning to the question of judicial economy, Eli Lilly submits that this appeal should be heard because of the prospect of other generics looking to obtain NOC's for olanzapine, following the judgment of Hughes J. Contrary to this submission, the question of judicial economy suggests that this appeal should not be heard.

[30] Eli Lilly argues that this Court should hear the moot appeal so that the law could be made clear as to whether comparative data is required to be disclosed in selection patents. They argue that the reasons of Hughes J. stand for the proposition that selection patents which do not contain

comparative data are invalid. I do not agree that one can take this broad principle from his reasons. He said:

> The invention in selecting olanzapine is the so called "surprising and unexpected" properties of olanzapine in "comparison with flumezapine and other related compounds". No such comparison is made anywhere in the '113 patent. No data was given. We are left only with rhetoric such as "high level of efficiency" and "mild and transient" and "lower" side effects.

It is certainly arguable that all Hughes J. meant was that the disclosure in a selection patent must explain what the "surprising and unexpected" properties of olanzapine in the new selection patent were. Even counsel for Eli Lilly admitted in oral argument that one could not tell what Hughes J. meant when he used the words "No data was given." If one cannot tell what the Motions Judge meant, then one cannot conclude that he meant that "comparative data" must <u>always</u> be provided in a selection patent. This being the case, it would be unwise, in the context of deciding whether to exercise the discretion to hear a moot appeal, to assume that this is what he meant and then go on to define, as a matter of first instance in this Court, what the law requires by way of disclosure in a selection patent.

[31] Even if Eli Lilly were correct in arguing that this appeal raises a pure question of law, then it would be better if this Court had the benefit of a full record to adjudicate such a question. Indeed, as counsel for Eli Lilly states in their Memorandum of Fact and Law:

> Thus, the conclusion enunciated by Justice Hughes indicating that a selection patent must have comparative data present in the patent specification was never raised by Novopharm and, as such, <u>Lilly had no opportunity to address this issue in its evidence or in its argument before the Court</u>. [emphasis added]

[32] This appeal arises out of a proceeding under the *NOC Regulations* and the issue relating to insufficient disclosure may turn out to be a complicated one. This Court has said repeatedly that NOC proceedings should be summary in nature and of short duration. In the words of Sharlow J.A. in *AB Hassle v. Apotex Inc.* 2006 FCA 51, 265 D.L.R. (4th) 363, 47 C.P.R. (4th) 329 ("*AB Hassle*") at paragraph 2:

> These are summary proceedings, intended to facilitate a relatively quick determination by the Federal Court of certain issues of patent construction, infringement and validity, but only for the limited purpose of making (or declining to make) an order prohibiting the Minister of Health from approving the sale in Canada of a new generic drug for which approval is sought on the basis of a comparison to an existing product whose producer has certain patent rights.

[33] Unfortunately, the fact remains that parties in disputes like this one are ignoring the intended summary nature of NOC proceedings. As Noel J.A. stated in *Abbott Laboratories v. Canada (Minister of Health)* 2007 FCA 187 ("*Abbott*") at paragraph 28:

> …[the 24-month statutory stay period provided in paragraph 7(1)(e) of the NOC Regulations] was no doubt intended to focus the minds of the parties and the Court on the summary nature of the proceedings and the need for their expeditious prosecution. It is the absence of focus on this time frame which has given these summary proceedings over time the ponderous character of patent infringement actions commonly known to last numerous days and sometimes weeks. The end result is that judicial resources are increasingly being consumed by these so called summary proceedings at the expense of other jurisdictions which advance more obvious public policy concerns.

[34] The following comments in *Sanofi-Aventis, supra*, although contemplating the issue of abuse of process, are particularly apposite in this regard (at paragraph 37):

> In the context of the NOC Regulations, encouraging the efficient use of scarce judicial resources is also of particular concern. Judicial resources are already taxed considerably by the voluminous proceedings brought under the regulations. An attempt to further strain the

> resources of parties and of the courts through repetitious litigation without any compelling justification strongly favours a finding of abuse of process.

[35] The three excerpts above can be applied to the notion of considering the constraint of judicial resources in hearing a moot appeal. As Noel J.A. held in *Abbott*, *supra*, NOC proceedings are taxing the judiciary's resources, and as such it makes little sense to hear moot appeals in those proceedings, especially when the main issue will be the subject of infringement proceedings already in progress.

[36] In deciding whether to hear a moot case on the question of judicial economy, courts must weigh the expenditure of scarce judicial resources against "the social cost of continued uncertainty in the law" (*Borowski*, *supra*, at p. 361). While I am not entirely confident as to what the phrase "social cost" means, I would think that it refers to costs to society generally as opposed to the potential costs to some participants in one particular industry. In the *Borowski* and *Doucet* cases, Charter remedies were in issue.

[37] This Court previously held, notably, that "There is no evidence that there is a social cost in leaving the matter of 'selection' patents undecided" (*Janssen-Ortho*, *supra*, at paragraphs 21-2). In this motion, counsel for Eli Lilly made no reference to evidence of social costs resulting from any uncertainty in the law, either in his Memorandum of Fact and Law or in oral argument.

[38] Eli Lilly suggests that the concern for judicial economy favours the Court hearing this appeal as there are four or more other generics looking to produce olanzapine; this will result in four

or more infringement actions as the generics obtain their NOCs. Without dictating how the infringement proceedings should specifically proceed, I am not convinced that this will lead to an inefficient use of judicial resources. Even if there are numerous infringement proceedings, they will all have many common issues, including the main issue of controversy in this appeal: the sufficiency requirement for selection patents. It is quite possible that the infringement proceedings could be consolidated, or that the issues could be decided in one proceeding, with the others being stayed.

[39] Eli Lilly also argues that the decision of Justice Hughes will affect the validity of many other patents and patent applications in Canada by adding a retroactive test for the sufficiency of disclosure for selection patents. Furthermore, they argue that the decision of Justice Hughes impacts the sufficiency requirement of many other Canadian patents and pending applications and is thus at odds with Canada's international obligations relating to patents as well as the *Act* itself.

[40] It is doubtful that these propositions have application with respect to an NOC proceeding. It is settled law that decisions under the *NOC Regulations* cannot be taken as an *in rem* determination of the validity of patents: *Pharmacia Inc. v. Canada (Minister of National Health and Welfare)* (1994), 58 C.P.R. (3d) 209 (F.C.A.); *Sanofi-Aventis*, *supra*, at paragraph 36. As Richard C.J. stated in *Janssen-Ortho*, *supra*, at paragraph 19:

> Similarly, in *Novartis v. Apotex*, 2002 FCA 440, [2002] F.C.J. No. 1551 (C.A.) (QL), this Court stated [per Strayer J.A.]:
>
> > [9] I believe that the fundamental principles applicable are those stated in the reasons of Isaac J.A. in the Pfizer case, as approved and followed by another panel of this Court in

> the Rhoxalpharma case less than one year ago. The basic principle is that the extraordinary procedures provided by the Regulations are for the public law purpose of enabling the Trial Division to prevent a public officer from issuing a Notice of Compliance, designed for the protection of the public's health, if the patentee can show that the patents, as referred to by a generic company in its notice of allegation seeking a Notice of Compliance, are owned by the applicant "first person" and that the relevant claims are not invalid and would be infringed. This is a finding of the Court for the limited purpose of deciding whether or not the Minister can issue a Notice of Compliance: no one could suppose that this is a scheme designed for res judicata determinations of the scope or validity of patents.
>
> [emphasis added]

[41] NOC proceedings were never intended to be substitutes for an infringement action: *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)* (1994), 55 C.P.R. (3d) 302 (F.C.A.) at 319 (leave to appeal to the S.C.C. dismissed [1994] S.C.C.A. 330); *Pfizer*, *supra* at paragraph 17. Similarly, it is inappropriate to rely on NOC proceedings to set binding precedent on controversial and uncertain questions in patent law (see *Sanofi-Aventis*, *supra*, at paragraph 49). NOC proceedings are supposed to be summary in nature and do not lend themselves to such determinations. Rather, Eli Lilly can seek resolution of these questions in the infringement proceedings which it has already commenced. The decision in *Sanofi-Aventis*, *supra*, affirms this point at paragraph 40:

> While it is important in each case to ensure the application of the doctrine of abuse of process does not give rise to unfairness in the circumstances, in my view, no such unfairness would result in the present case. Prohibition proceedings under the NOC Regulations do not prevent patentees from enforcing their patent rights through actions for patent infringement in accordance with the *Patent Act*. Moreover, the findings from any such prohibition proceedings have no bearing on patent infringement actions. [emphasis added]

[42] As discussed above, Eli Lilly argues that the decision in *Sanofi-Aventis* elevates the importance of an innovator's right to appeal since other generics can now rely on a Motions Judge's decision. While it may be likely that other generics will attempt to rely on decisions such as the one by Justice Hughes, this does not alter the fact that the innovator has ample means to defend its rights, namely an infringement proceeding. See *Novartis AGC v. Apotex Inc.* (2002) 22 C.P.R. (4th) 450 (F.C.A.) at paragraph 9; *AB Hassle*, *supra*, at paragraphs 28-9. As was stated in *Pfizer*, *supra*, at paragraph 25:

> It should be noted that a decision by this Court that the appeals are moot does not mean that the appellants are without remedies. They may commence actions for infringement if so advised and the facts warrant. This Court has been very clear on this fact that s. 6 proceedings are not adjudicative of the rights of the patentee. In *Merck Frosst Canada*, *supra*, at 319, Hugessen J.A. rejected the notion that prohibition proceedings could be assimilated to an action of any kind:
>
> > The proceedings are not an action and their object is solely to prohibit the issuance of a notice of compliance under the Food and Drug Regulations. Manifestly, they do not constitute "an action for infringement of a patent" …
>
> In these circumstances, it is idle to suggest that any decision that this Court makes in these appeals could be used to attack collaterally a judgment in an infringement action.

[43] Indeed, Eli Lilly has already commenced an infringement proceeding with respect to their '113 Patent in this case. If Novopharm is actually infringing the '113 Patent due to the issuance of the NOC, Eli Lilly can be adequately compensated through various remedies by way of an injunction, an award of damages and/or an accounting of profits, if applicable. See *Bristol-Myers Squibb Canada Inc. v. Canada (Attorney General)* (2001) 11 C.P.R. (4th) 539 (F.C.A.) at paragraphs 22-3.

[44] It has been argued that it may be unfair for a patent holder to not be allowed an appeal when a generic can appeal an unfavourable decision in an NOC proceeding. However, this Court has already held that the fact that generics can appeal, whereas innovators cannot, does not constitute an unfair interpretation of the *NOC Regulations*. See *Pfizer*, *supra*, at paragraph 22. See also *Sanofi-Aventis*, *supra*, at paragraph 50. When one considers the issue of fairness, it must be kept in mind that innovators still have the benefit of a "near-automatic interlocutory injunction" for a period of 24 months. I would point out that in this case, Eli Lilly had a prohibition order for over 20 months even though it was ultimately held that they were not entitled to one. It should also be pointed out that actions of innovators are not the only ones being scrutinized with respect to the multiplicity of proceedings. Generics have been prevented from bringing more than one NOA relating to the validity of a patent (*Abbott Laboratories v. Canada (Minister of Health)* 2007 FCA 140, 282 D.L.R. (4^{th}) 145, 59 C.P.R. (4^{th}) 131).

[45] Once again, innovators like Eli Lilly are not without remedy. They may still commence an infringement action. Thus, even though Eli Lilly cannot proceed with this appeal, it certainly can seek an injunction, damages, and/or loss of profits via an infringement action, which it has done. It has the same remedy against other generics if it considers infringement is occurring.

[46] As to the factor relating to this Court's adjudicative role, there were no submissions that if this Court were to hear the appeal, it would be trespassing upon the role of Parliament. However, this factor seems relatively unimportant in the present case.

[47] Thus, all considerations militate against exercising the Court's discretion to hear this appeal. Even if the Court heard the appeal:

a. The decision to issue the NOC cannot be changed;

b. Eli Lilly can receive a no less conclusive and principled decision with respect to the necessary disclosure in a selection patent via an infringement action based on a more fulsome record; and

c. Eli Lilly can obtain all of the relief it is entitled to if there is indeed infringement by seeking an injunction, damages, and/or loss of profits and costs in an infringement action against Novopharm and other generics.

Conclusion

[48] I conclude that the appeal is moot and decline to exercise my discretion to hear the appeal. The motion to dismiss the appeal for mootness is granted with costs.

"J. Edgar Sexton"

J.A.

"I agree
C. Michael Ryer"

PELLETIER J.A. (Dissenting)

[49] I have read the carefully prepared reasons of my colleague Sexton J.A. I agree with his conclusion that the appeal before us is moot. With respect, I do not agree that we should decline to exercise our discretion to hear the appeal.

[50] In my view, the conditions for the exercise of our discretion under the three part test set out in *Borowski v. Canada (Attorney General)* [1989] 1 S.C.R. 342 have been met. My colleague agrees that there is an adversarial context between Eli Lilly and Novopharm. The question as to whether the matter is one for judicial determination is not contentious. We disagree as to whether the interests of judicial economy will be served by hearing the appeal. In my view, the decision under appeal will increase, rather than decrease, the incidence of litigation in this litigious area.

[51] The fact that the *Borowski* conditions are met does not require us to exercise our discretion; the decision as to whether to do so remains discretionary. In the circumstances of this case, I believe that we should exercise that discretion and hear the appeal.

[52] I say this for the following reasons. The decision under appeal is an authoritative statement of law. It raises a doubt as to the validity of any selection patent which does not contain comparative data in support of the advantage claimed in the patent. That doubt justifies our intervention.

[53] Even though proceedings under the Patented *Medicines (Notice of Compliance) Regulations* ("NOC") do not result in an *in rem* finding of invalidity, the patent law principles applied in NOC

proceedings are necessarily the same as those applied in an infringement action. There is only one law of patents. Decisions of this Court addressing principles of patent law in the context of NOC proceedings are regularly and consistently cited as authority in other NOC proceedings. They are also cited as authority in patent litigation unrelated to NOC proceedings. See, for example, *Calgon Carbon Corp. v. North Bay (City)*, 2006 FC 1373, [2006] F.C.J. No. 1719 at paragraphs 125 and 126, *Johnson & Johnson Inc. v. Boston Scientific Ltd*., 2004 FC 1672, [2004] F.C.J. No. 2040 at paragraphs 52,75 and 97, *Jay-Lor International Inc. v. Penta Farm Systems Ltd*., 2007 FC 358, [2007] F.C.J. No. 688, at paragraphs 74 and 77, *Wessel v. Energy Rentals Inc.*, 2004 FC 791, [2004] F.C.J. No. 952 at paragraph 21, *Varco Canada Ltd. v. Pason Systems Corp.*, 2006 FCA 100, [2006] F.C.J. No. 375 at paragraph 4.

[54] Quite apart from the decisions of this Court, the judges of the Federal Court regularly rely upon that court's jurisprudence in NOC proceedings as authority for propositions of patent law in NOC cases and in non-NOC cases. In that regard, see, for example, *Aventis Pharma Inc. v. Apotex Inc*. 2005 FC 1283, [2005] F.C.J. No. 1259 at para. 364 and *Pfizer Canada Ltd. v. Canada (Minister of Health)* 2007 FC 446, [2007] F.C.J. No 596 at para. 31 where judges of the Federal Court applied patent law principles articulated by judges of that court in NOC proceedings in the name of judicial comity.

[55] In the same way, I would assume that until it is set aside or overtaken, the Patent Office will treat the decision under appeal as the current state of the law on the subject of selection patents and will assess pending applications accordingly.

[56] Because it is an authoritative statement of the law, the decision under appeal puts into question the validity of all selection patents whose disclosure does not contain comparative data in support of the unexpected or surprising advantage claimed in the patent. That is so whether the decision is ultimately confirmed or disapproved. All decisions on a point of law are capable of having an effect which reaches beyond the parties. In that respect, the decision under appeal is not unique. What distinguishes it from others the fact that it creates a doubt with respect to selection patents as a class. Every prudent holder of a selection patent will now re-read that patent to see if it is vulnerable to challenge on the ground of insufficiency of disclosure. It is not necessary to know exactly how many of them will decide they have a problem in order to conclude that the question has broad implications for holders of selection patents.

[57] In my view, the uncertainty surrounding the validity of selection patents which do not contain comparative data is undesirable and should be resolved sooner rather than later. I do not see the state of the record as a reason which would prevent us from hearing the appeal now. Had the NOC not issued, we would have heard the appeal on the very record which is now before us.

[58] As for the question of social cost, I would simply say that I do not see how the uncertainty created by the decision under appeal can do other than act as a drag on efficient decision-making in the pharmaceutical industry, or in any other industry which relies on patent protection. To the extent that there is uncertainty as to the validity of a class of patents, the value of patents of that class will

be discounted to reflect that uncertainty. That is inconsistent with the rationale underlying selection patents, which is to encourage inventors to fully exploit the subject matter of their patents.

[59] I do not take this Court's comments about social cost in *Janssen-Ortho Inc. v. Novopharm Ltd*, 2005 FCA 6, [2005] F.C.J. No. 1196 to have set a standard with respect to the determination of social cost. I can only point to the Supreme Court's own treatment of the issue of social cost in *Doucet-Boudreau v. Nova Scotia (Minister of Education)* 2003 SCC 62, [2003] 3 S.C.R. 3, where the court said at paragraph 21:

> 21 Moreover, in deciding whether to hear a moot case, courts must weigh the expenditure of scarce judicial resources against "the social cost of continued uncertainty in the law" (Borowski, supra, at p. 361). The social cost of uncertainty as to the available Charter remedies is high. The Charter is designed to protect those who are most vulnerable to the dangers of majority rule; this aspect of the Charter's purpose is evident in the provisions protecting official minority language education rights. If the Court leaves this matter undecided and courts are left under a misapprehension as to the tools available to ensure that government behaviour conforms with the Charter, the obvious danger is less than full protection of Charter rights. Thus, the expenditure of judicial resources is warranted in the present case despite the fact that the appeal may be moot. The decision of this Court will provide guidance on the important question of the nature and extent of remedies under s. 24 of the Charter in similar cases.

[60] The reasoning employed by the Supreme Court in deciding that there was a social cost in not hearing that appeal had nothing to do with evidence, and everything to do with its view of the likely consequences of inaction. This case is no different.

[61] For those reasons, I believe that we should exercise our discretion to hear this appeal even though it is moot. I would therefore dismiss the motion with costs.

"J. D. Denis Pelletier"

J.A.

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET: A-274-07

(THE RESPONDENT'S (NOVOPHARM) MOTION TO DISMISS THE APPEAL FOR MOOTNESS, FROM AN ORDER OF HUGHES J., DATED JUNE 5, 2007, FILE NO. T-1532-05).

STYLE OF CAUSE:

ELI LILLY CANADA INC.
Appellant
and
NOVOPHARM LIMITED
Respondent
and
THE MINISTER OF HEALTH
Respondent
and
ELI LILLY AND COMPANY LIMITED
Respondent/Patentee

PLACE OF HEARING: TORONTO, ONTARIO

DATE OF HEARING: NOVEMBER 5, 2007

REASONS FOR ORDER BY: SEXTON J.A.
CONCURRED IN BY: RYER J.A.

DISSENTING REASONS BY: PELLETIER J.A.

DATED: NOVEMBER 6, 2007

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