Date: 20081103

Docket: T-703-08

Citation: 2008 FC 1221

Montréal, Quebec, November 3, 2008

PRESENT: The Honourable Mr. Justice Martineau

BETWEEN:

ELI LILLY CANADA INC.

Applicant

and

NOVOPHARM LIMITED and THE MINISTER OF HEALTH

Respondents

and

ELI LILLY and COMPANY LIMITED

Respondent/Patentee

REASONS FOR ORDER AND ORDER

[1] Eli Lilly Canada Inc. (Lilly) has applied to this Court for an order under section 6 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, as amended (the *NOC Regulations*), prohibiting the Minister of Health (the Minister) from issuing a notice of compliance (NOC) to Novopharm Limited (Novopharm) for orally disintegrating olanzapine tablets until the expiry of Canadian Patent 2,214,005 (the '005 Patent).

[2] By the present motion, Novopharm seeks an order:

a. declaring sections 2, 3 and 4 of the *Regulations Amending the Patenting Medicines (Notice of Compliance)Regulations*, SOR /2008-211, enacted on June 12, 2008 (the *2008 Amending Regulations*) *ultra vires* and of no force and effect (the declaratory relief); and,

b. dismissing the herein application pursuant to paragraph 6(5)(a) of the *NOC Regulations* (the regulatory relief).

[3] The ‘005 Patent claims polymorph Form II olanzapine, pharmaceutical formulations that contain polymorph Form II olanzapine, and uses for Form II olanzapine, including the acute and maintenance treatment of schizophrenia and related psychotic disorders and the acute and maintenance treatment of manic or mixed episodes associated with bipolar I disorder.

[4] The ‘005 Patent issued on July 3, 2001 and will expire on March 22, 2016. It is owned by Eli Lilly and Company Limited. At issue, is the inclusion of the ‘005 Patent on the register maintained by the Minister in accordance with subsection 3(2) of the *NOC Regulations* (the Register).

[5] Lilly presently markets orally disintegrating olanzapine tablets in Canada under the brand name ZYPREXA ZYDIS (the Lilly tablets). Novopharm served a notice of allegation (NOA) in respect to the ‘005 Patent and its own olanzapine orally disintegrating tablets on March 18, 2008. The NOA raises a number of preliminary matters, including an allegation of improper listing on the

Register, together with Novopharm's allegations of non-infringement and/or invalidity with respect to a substantial number of claims in the '005 Patent.

[6] Lilly responded to Novopharm's NOA by commencing this application on May 2, 2008. Novopharm originally brought this motion a few days before the coming into force of the *2008 Amending Regulations.* Novopharm's whole case for asking for the dismissal of the herein application rests on the proposition that the '005 Patent is not eligible to be listed on the Register with respect to the Lilly tablets.

[7] Novopharm relies on case law which, in their submission, establishes that there must be a linkage between the invention of the patent and the relevant new drug submission (NDS) or supplemental new drug submission (SNDS) which has been approved by the issuance of a NOC, notably *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, 2006 SCC 49, [2006] 2 S.C.R. 560 (*AstraZeneca Canada Inc.)* and *Wyeth Canada* v. *Ratiopharm*, [2007] F.C.J. No. 1062, 2007 FCA 264 (*Wyeth)*.

[8] The '005 Patent is listed on the Register for the Lilly tablets against three submissions and their corresponding NOCs namely, SNDS No. 062065 (NOC issued December 1, 2000), SNDS No. 070917 (NOC issued March 17, 2003) and SNDS No. 082444 (NOC issued October 20, 2004). In the case at bar, Novopharm submits that there is no link between the subject matter of the three SNDs made by Lilly, their NOCs and the patented invention of the '005 Patent.

[9] Both Lilly and the Minister filed motion records and participated at the hearing. Lilly opposes both aspects of the motion, while the Minister's submissions in opposition are restricted to the first part of the motion (the declaratory relief sought by Novopharm).

[10] The present motion can be decided on limited grounds.

[11] The *NOC Regulations* provide for specific conditions under which a patent can be listed on the Register. Their application has stimulated much litigation. In turn, the regulatory provisions with respect to listing have been amended from time to time. The current "relevancy" requirements were introduced in 2006 by the *Regulations Amending the Patented Medicines (Notice of Compliance) Regulations*, SOR/2006-242, enacted on October 5, 2006 (the *2006 Amending Regulations*).

[12] Since the listing of the '005 Patent occurred prior to June 17, 2006, counsel agree that the old listing requirements apply. The old listing requirements were enacted by the *Regulations Amending the Patent Medicines (Notice of Compliance) Regulations*, SOR/1998-166 (the *1998 Amending Regulations*). However, same need only to be considered if I decide that this Court has power to grant the particular relief sought today by Novopharm, but this is not the case here.

[13] Paragraph 6(5)(a) of the *NOC Regulations* was enacted in 1998 (see subsection 6(2) of the *1998 Amending Regulations*). It is apparent that at that time, the Governor in Council was aware of, and allowed for the possibility that ineligible patents may find their way onto the Register and may not be readily capable of being deleted under subsection 3(1) of the *NOC Regulations*. Paragraph

6(5)(a) provided generic drug manufacturers with the opportunity, if and when prohibition proceedings are commenced by a patent holder in respect of a NOA served by the generic, to apply to the Court to dismiss the prohibition application because it is based on an ineligible patent on the Register (see *Apotex Inc. v. Canada (Minister of National Health and Welfare)*, [1999] F.C.J. No. 1978 at para. 23, 181 D.L.R. 4th 404 (*Apotex 1999*)).

[14] However, the *NOC Regulations* currently provide no legal authority to grant the requested regulatory relief under paragraph 6(5)(a). The '005 Patent was submitted by way of patent lists which were all filed prior to June 17, 2006. Subsections 6(5) and (5.1) of the *NOC Regulations*, as enacted by section 3 of the *2008 Amending Regulations*, prevent the Court from dismissing an application in whole or in part "solely on the basis that a patent list that was submitted before June 17, 2006 [such as the '005 Patent] is not eligible for inclusion on the register". This would be the case if I were to accept Novopharm's submissions that there is no subject matter connection between the patented invention in the '005 Patent and any of the three SNDSs mentioned above.

[15] Conversely, subsection 3.1(1) of the *NOC Regulations*, as enacted by section 2 of the *2008 Amending Regulations*, prohibits the Minister from deleting from the Register a patent on a patent list that was submitted before June 17, 2006 ("a grandfathered patent"), subject to certain "common sense exceptions". In this regard, the Minister retains discretion to delete a grandfathered patent from the Register where it has expired, lapsed or been declared invalid in an action under the *Patent Act*, R.S.C. 1985, c. P-4 (*Patent Act*), has been found ineligible for inclusion on the Register under paragraph 6(5)(a) of the *NOC Regulations* or where the identification number assigned to the drug

in respect of which the patent is listed is cancelled under the *Food and Drug Regulations*, C.R.C., c. 870.

[16] Moreover, subsection 3.1(2) of the *NOC Regulations*, as enacted by section 2 of the *2008 Amending Regulations*, prohibits the Minister from refusing to add to the Register a grandfathered patent "solely on the basis that the patent is not relevant to the submission for a notice of compliance to which the patent list relates".

[17] Transitional provisions governing the deletion from, or the refusal to add to the Register, by the Minister a grandfathered patent "solely on the basis that the patent was not relevant" are also enacted by subsections 4(2) to 4(5) of the *2008 Amending Regulations.* That said, subsection 4(8) of the *2008 Amending Regulations* provides that subsection 6(5.1) of the *NOC Regulations* "does not apply to a motion of the second person brought under subsection 6(5) of those Regulations before the date of the publication of these Regulations in Part I of the *Canada Gazette*".

[18] Novopharm's motion does not come within the ambit of the regulatory exception enacted by subsection 4(8) of the *2008 Amending Regulations*. Thus, Novopharm is asking this Court to apply paragraph 6(5)(a) of the *NOC Regulations* as if the *2008 Amending Regulations* had not been made, so as to avoid the application of section 6(5.1) of the *NOC Regulations*. Novopharm is further asking the Court to declare that sections 2, 3 and 4 the *2008 Amending Regulations* are *ultra vires* and of no force and effect.

[19] The Constitution is not invoked here. This is not a case where the Court would be called, pursuant to subsection 52(1) of the *Constitution Act, 1982,* to declare some legislative or regulatory enactment invalid, inapplicable or inoperable on the grounds that it "is inconsistent with the provisions of the Constitution", and that same is to that extent "of no force and effect".

[20] Essentially, Novopharm is questioning the administrative exercise of the regulatory powers vested by Parliament to the Governor in Council. In the case at bar, Novopharm submits that the *2008 Amending Regulations* are retroactive and/or are not authorized by subsection 55.2(4) of the *Patent Act*.

[21] That said, I entirely accept the submissions made by Lilly and the Minister that the requested declaratory relief is not summarily available in this proceeding and that, in any event, I have discretion to decline ruling upon the validity of the impugned regulatory provisions. I also accept their submissions that the jurisdiction of this Court to hear and decide an application for prohibition under the *NOC Regulations* is limited to the specific matters governed by same.

[22] The jurisdiction of the Federal Court with respect to industrial property derives from section 20 of the *Federal Courts Act*, R.S.C. 1985, c. F-7 (*Federal Courts Act*), and in this case, from the *NOC Regulations* adopted under the authority of subsection 55.2(4) of the *Patent Act*. Since the Federal Court is a "court" within the meaning of section 2 of the *NOC Regulations*, it has jurisdiction to hear and decide an application made under section 6 of the *NOC Regulations*, including a motion to dismiss same presented pursuant to paragraph 6(5). However, there is nothing

in either the *NOC Regulations* or the *Patent Act* that confers to the Federal Court some general supervisory jurisdiction over the legality of regulatory instruments (except patents). Moreover, it is clear that this Court is not empowered to grant the requested declaratory relief under the *Patent Act* or the *NOC Regulations*.

[23] Accordingly, for this Court to make some general and binding judicial declaration that the *2008 Amending Regulations* are *ultra vires* and of no force and effect would go well beyond the limited scope of the herein summary proceeding under the *NOC Regulations*. See *Eli Lilly & Co. v. Novopharm Ltd.; Eli Lilly & Co. v. Apotex Inc.*, [1998] 2 S.C.R. 129 at paras. 93, 95 and 97.

[24] I also note that the *2008 Amending Regulations* have been made by the Governor in Council, on the recommendation of the Minister of Industry, under the purported authority of subsection 55.2(4) of the *Patent Act*, which enables the Governor in Council to "make such regulations as the Governor in Council considers necessary for preventing the infringement of a patent by any person …", including regulations "respecting the remedies that may be sought by the court, the procedure of the court in the matter and the decisions and orders it may make".

[25] As such, the *2008 Amending Regulations* are to be presumed valid in this proceeding commenced under section 6 of the *NOC Regulations* (*Ontario Hydro v. Canada (C.A.)*, [1997] 3 F.C. 565). Therefore, the Court cannot ignore or discard the *2008 Amending Regulations* unless they are declared *ultra vires* and of no force and effect.

[26] A declaration of invalidity can only be granted by a final judgment of the Court, not by an order made in the course of a summary motion to dismiss an application, especially if the issues of statutory interpretation are complex or there is a triable issue as to the purpose of the regulatory provision. See on these points or by analogy: *Shubenacadie Indian Band v. Canada (Minister of Fisheries and Oceans)*, [2000] F.C.J. No. 1445 at paras. 40 and 49; *Attorney General of Canada v. Gould*, [1984] 1 F.C. 1133 (F.C.A.); *Apotex v. Syntex Pharmaceuticals International Ltd.*, (2001), 16 C.P.R. (4th) 473 (F.C.T.D.) at para. 13, [2001] F.C.J. No. 1880, aff'd (2002), 20 C.P.R. (4th) 190 (F.C.A.); 1515545 *Ontario Ltd. v. Niagara Falls (City)*, (2006) 78 O.R. (3d) 783 at para 40; rev'g (2005) 75 O.R. (3d) 151.

[27] Even if I assume, as suggested by Novopharm, that this Court has jurisdiction to hear and decide the first part of the present motion, and ultimately to declare the *2008 Amending Regulations* invalid, such discretion could only be exercised on a "proper basis". See *Kourtessis v. Canada (Minister of National Revenue - M.N.R.)*, [1993] 2 S.C.R. 53 at para. 44. I am not satisfied that such "proper basis" exists here.

[28] One compelling factor not to exercise my discretion, is the fact that it remains fully open to this Court to find, on the merit, that any allegations of non-infringement and/or patent invalidity made by Novopharm in its NOA are justified, and to dismiss the present application for prohibition.

[29] Moreover, while Novopharm is obliged to address the '005 Patent to which the proposed generic version of the Lilly tablets is compared, the Court has a broad discretion with respect to the

allowance of costs, particularly if the present application is unsuccessful. In addition, it will always be possible for Novopharm, as the case may be, to institute an action claiming damages against Lilly for any losses suffered during the period contemplated by section 8 of the *NOC Regulations*, and in the manner provided by same.

[30] Another important factor in the exercise of the Court's discretion to refuse today to decide on the invalidity issues raised by Novopharm in this proceeding, relates to the existence of a better procedural mean to decide finally of the issues of statutory interpretation and policy making raised in the herein interlocutory motion.

[31] Normally, a party seeking a declaration of invalidity of delegated legislation passed by the Governor in Council (the Cabinet) must serve and file an application pursuant to sections 18 and 18.1 of the *Federal Courts Act*. The applicant must also name the Attorney General of Canada as respondent.

[32] Applications for judicial review before this Court seeking declaratory relief against the Attorney General of Canada are permitted by subsection 18(1) of the *Federal Courts Act.* Such applications have been brought by pharmaceutical companies in the past, as in *Fournier Pharma Inc. v. Canada (Attorney General)*, [1999] 1 F.C. 327, [1998] F.C.J. No. 1491, where the applicant sought a declaration that subsections 4(3) and 4(5) of the *NOC Regulations* (as they read at that time) were *ultra vires*, together with an order of *mandamus* directing the Minister to file the applicant's patent list in the Register.

[33] In this regard, I do not share Novopharm's concerns that an application for judicial review seeking declaratory relief under subsection 18(1) of the *Federal Courts Act*, is not opened to challenge the legality of the *2008 Amending Regulations*. The judgment rendered by the Federal Court of Appeal in *Apotex 1999*, is clearly distinguishable. In the latter case, the generic manufacturer had made a judicial review application asking the Court to set aside the Minister's decision to include allegedly irrelevant patents on the Register. There was no argument that the *NOC Regulations* themselves were *ultra vires.* The reasoning of the Federal Court of Appeal to deny the application was largely based on the assumption that paragraph 6(5)(a) of the *NOC Regulations* provided, at that time, "a judicial forum in which the eligibility of the specific patent or patents at issue can be decided by the Court after hearing from the patent holder and the generic competitor" (*Apotex 1999*, at para. 24).

[34] Since as of June 12, 2008, the Court cannot dismiss an application solely on the ground that a grandfathered patent "is not relevant to the submission", Novopharm is certainly directly affected by the *2008 Amending Regulations.* In my opinion, Novopharm would have a legitimate interest to ask, by way of a judicial review application, that the Court pronounce itself on the legality of the *2008 Amending Regulations.* Considering the most recent indications of the Federal Court of Appeal in *Apotex Inc. v. Canada (Governor in Council)*, 2007 FCA 374, [2007] F.C.J. No. 1585 and *Canadian Generic Pharmaceutical Assn. v. Canada (Governor in Council)*, 2007 FCA 375, [2007] F.CJ. No. 1586, it is doubtful that this Court would refuse to hear and decide such an application on the basis that Novopharm would lack standing.

[35] Indeed, it is apparent that the present motion constitutes an attempt to circumvent the obligation to serve and file an application for judicial review in the manner provided by sections 18 and 18.1 of the *Federal Courts Act* and Rules 300 and following of the *Federal Courts Rules*, SOR/98-106. The issue becomes whether, and in what circumstances, this Court should accept in an interlocutory motion asking the dismissal of an application brought under subsection 6(1) of the *NOC Regulations*, to consider grounds of attack that are rooted in administrative law.

[36] Novopharm does not rest its case solely on the interpretation of subsection 55.2(4) of the *Patent Act*. The ins and the outs of policy making in the highly specialized and complex pharmaceutical field also have to be concurrently revisited if this motion for a declaratory relief is entertained by the Court. The arguments raised by the parties are directed to the "purposes" of the *2008 Amending Regulations*, and to this extent, to the motivation and the good faith of the Government of Canada in enacting the impugned regulatory provisions.

[37] In attacking the legality of the *2008 Amending Regulations*, Novopharm directly questions the reasonableness of the Government's decision in 2006 to "grandfather" the Register with respect to patent lists submitted before June 17, 2006 (this corresponds to the date the 2006 amendments were pre-published in Part I of the *Canada Gazette).*

[38] In this regard, Novopharm alleges *inter alia* that the Government acted for an illegal and/or improper purpose. Indeed, Novopharm alleges that the Government exceeded its powers or acted

improperly in prohibiting the Minister and the Court from taking action under the *NOC Regulations* with respect to an improper listed patent, solely on the ground that a grandfathered patent is not "relevant" within the meaning given to that term by the relevant case law, in particular in *AstraZeneca Canada Inc.* and in *Wyeth*. This is said by Novopharm to be a repudiation of what the Supreme Court of Canada or the Federal Court of Appeal have decided in these two cases.

[39] In effect, Novopharm is asking this Court today to consider the '005 Patent pursuant to the pre-October 5, 2006 *NOC Regulations* and relevant case law on the grounds that the *2008 Amending Regulations* introduced a "new play-book".

[40] As evidenced by the *Regulatory Impact Analysis Statement* (RIAS), accompanying the *2006 Amending Regulations* (which is not part of same), Novopharm respectfully submits that the Government has admitted that the effect of the *2008 Amending Regulations* is inconsistent with the general scheme of the *Patent Act* and the fulfilment of the Minister's role under the *NOC Regulations*.

[41] The Minister and Lilly take a complete opposite view. They have a very different reading of the comments contained in the RIAS.

[42] Indeed, as evidenced by the RIAS accompanying the *2008 Amending Regulations* (which is not part of same), the Minister and Lilly submit that the impugned regulatory provisions reinforce the predictability, stability and competitiveness of Canada's intellectual property regime for

pharmaceuticals by reaffirming and clarifying the intended effect of the transitional measures included in the *2006 Amending Regulations* with respect to the protection of the "grandfathered" patents (such as the '005 Patent). In this regard, subsection 6(5.1)of the *NOC Regulations (*enacted by section 2 of the *2008 Amending Regulations)* "effectively foreclose further litigation on the proper interpretation of the old listing requirements".

[43] In this context, both Lilly and the Minister recall to the Court's attention, that between January 2003 and June 2006, the law as it related to "product-specific relevance" was established by the Federal Court of Appeal in *Eli Lilly Canada Inc. v. Canada (Minister of Health),* 2003 FCA 24, [2003] F.C.J. No. 75 (*Eli Lilly 2003*). Patents listed without regard for "patent relevance" during that period were, at law at that time, fully eligible for inclusion on the Register (assuming the other requirements were met).

[44] However, on August 1, 2007, the Federal Court of Appeal released its decision in *Wyeth* which according to Lilly and the Minister: 1) explicitly overruled in part its earlier decision in *Eli Lilly 2003* (on the basis of the Supreme Court decision in *AstraZeneca Canada Inc.*); and 2) essentially undid the intended effect of the transitional provisions in the *2006 Amending Regulations,* by ruling that "product-specific relevance" was a listing requirement even prior to June 2006.

[45] Thus, both the Minister and Lilly now submit that the *2008 Amending Regulations* are remedial legislation in its truest form – to essentially re-establish the intended effect of the

transitional provisions in the *2006 Amending Regulations* that had been undone by the Federal Court in *Wyeth*. In any event, based on the evidence on record, Lilly submits that the '005 Patent has been properly listed at all material times; a point, however, I do not have to decide today.

[46] I agree with the Minister and Lilly that the complexity of the matters raised by the first part of the Novopharm motion command that their final adjudication be deferred by the Court at a later date and in a better suited forum (assuming Novopharm eventually makes a judicial review application). At this point, the Court should not summarily decide, in the course of a motion to dismiss an application for prohibition, highly sensitive and debatable issues of fact and law related to the Government's intention and the purpose and object of the impugned regulations, without being first assured that it has all the relevant material or evidence before it. Such assurance does not presently exist in my humble opinion. This is also a consideration in deciding today not to exercise any discretion to rule on the merit of the *vires* arguments raised by Novopharm.

[47] Moreover, it is also plain and obvious that the declaratory relief sought by Novopharm in this motion would decide rights beyond those of the immediate parties to the proceeding. This also commands that the Court takes a prudent and cautionary approach that would avoid, as much as possible, any market disruption and investment uncertainty that might otherwise result if this Court were to summarily grant the declaratory relief sought by Novopharm in this proceeding (a point again I am not deciding).

[48] Again, I stress that Novopharm is seeking by this motion to invalidate:

1) section 2 of the *2008 Amending Regulations*, which adds section 3.1 of the *NOC Regulations* protecting from delisting all "grandfathered" patents;
2) section 3 of the *2008 Amending Regulations*, which amends section 6 of the *NOC Regulations*; and
3) the totality of the transitional provisions enacted by section 4 of the *2008 Amending Regulations.*

[49] I also reiterate that the Attorney General of Canada is not presently a party to this proceeding. I cannot assume that the Attorney General's position would be the same as the one taken today by the representative of the Minister (notably on the issue of an alternative relief to invalidation, as the case may be).

[50] Moreover, while the rights of other holders of the grandfathered patents may also be directly affected by the declaratory relief sought by Novopharm (this is particularly so if the actions contemplated by section 4 of the *2008 Amending Regulations* have already been taken), the *NOC Regulations* simply provide no means for third parties to intervene and be heard by the Court. On the other hand, the *Federal Courts Rules* are more permissive in this respect.

[51] Thus, considering the Court's limited jurisdiction and powers, the summary nature of this proceeding, the public interest, the complexity of the matters Novopharm wishes to raise preliminary, the balance of convenience and the availability of another and better suited recourse, I am not satisfied that it is in the best interests of justice that a final ruling be made today by the Court

with respect to Novopharm's motion to invalidate section 2, 3 and 4 of the *2008 Amending Regulations.* Accordingly, I decline to rule on their alleged illegality.

[52] For the time being, the impugned regulatory provisions are presumed to be valid. Section 6(5.1) of the *NOC Regulations* does not permit the regulatory relief sought by Novopharm in this NOC proceeding.

[53] On these limited grounds, the present motion must be dismissed. Therefore, it is not necessary to address the other issues raised by the parties. Lilly and the Minister shall be entitled to their costs against Novopharm.

ORDER

THIS COURT ORDERS that the present motion be dismissed with costs awarded to Lilly and the Minister.

"Luc Martineau"
Judge

FEDERAL COURT

NAME OF COUNSEL AND SOLICITORS OF RECORD

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