Federal Court of Appeal | Cour d'appel fédérale

**Date: 20111117**

**Docket: A-344-11**

**Citation: 2011 FCA 312**

**Present:** **STRATAS J.A.**

**BETWEEN:**

**MYLAN PHARMACEUTICALS ULC**

**Appellant**

**and**

**ASTRAZENECA CANADA, INC.**
**ASTRAZENECA UK LIMITED, and**
**THE MINISTER OF HEALTH**

**Respondents**

Dealt with in writing without appearance of parties.

Order delivered at Ottawa, Ontario, on November 17, 2011.

REASONS FOR ORDER BY: STRATAS J.A.

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**REASONS FOR ORDER**

**STRATAS J.A.**

[1] Mylan Pharmaceuticals ULC appeals from a decision of the Federal Court: 2011 FC 1023. The appeal is yet to be heard.

[2] Two motions have been brought in this Court, one telling us to go slow and the other telling us to go fast:

- AstraZeneca Canada, Inc. and AstraZeneca UK Limited move for an order staying the appeal until after the Supreme Court of Canada has rendered its decision in *Teva Canada Limited v. Pfizer Canada Inc., et al.* (S.C.C. file no. 33951).

- Mylan moves for an order expediting the appeal.

## A. Astra Zeneca's motion for an order staying the appeal

### (1) The applicable legal test

[3] AstraZeneca submits that the legal test is whether, in all the circumstances, it is in the interests of justice to order the stay. It submits that this test emanates from section 50 of the *Federal Courts Act*, R.S.C. 1985, c. F-7. That section empowers this Court to stay proceedings where "it is in the interests of justice that the proceeding be stayed."

[4] On the other hand, Mylan submits that AstraZeneca must satisfy the tripartite test set out in *RJR-MacDonald Inc. v. Canada (Attorney General)*, [1994] 1 S.C.R. 311.

[5] In considering this issue, the relief AstraZeneca seeks must be characterized. AstraZeneca is not asking this Court to enjoin another body from exercising its jurisdiction. Rather, it is asking this Court not to hear this appeal until some time later. There is a material difference between these two things and different considerations apply:

- *This Court enjoining another body from exercising its jurisdiction.* When we do this, we are forbidding another body from going ahead and exercising the powers granted by Parliament that it normally exercises. In short, we are forbidding that body from doing what Parliament says it can do. As the Supreme Court recognized in *RJR-MacDonald Inc.*, this is unusual relief that requires satisfaction of a demanding test. Two parts of that test are particularly demanding. First, there must be persuasive, detailed and concrete evidence of irreparable harm: *Stoney First Nation v. Shotclose*, 2011 FCA 232 at paragraphs 47-49; *Laperrière v. D. & A. MacLeod Company Ltd.*, 2010 FCA 84 at paragraphs 14-22. Second, there must be a demonstration, through evidence, of inconvenience that outweighs public interest considerations, such as the right of the other body to discharge the mandate given to it by Parliament: *RJR-MacDonald Inc.*, *supra* at pages 343-347.

- *This Court deciding not to exercise its jurisdiction until some time later.* When we do this, we are exercising a jurisdiction that is not unlike scheduling or adjourning a matter. Broad discretionary considerations come to bear in decisions such as these. There is a public interest consideration – the need for proceedings to move fairly and with due dispatch – but this is qualitatively different from the public interest considerations that apply when we forbid another body from doing what Parliament says it can do. As a result, the demanding tests prescribed in *RJR-MacDonald* do not apply here. This is not to say that this Court will lightly delay a matter. It all depends

> on the factual circumstances presented to the Court. In some cases, it will take much to convince the Court, for example where a long period of delay is requested or where the requested delay will cause harsh effects upon a party or the public. In other cases, it may take less.

[6] The conclusion that the *RJR-MacDonald* test does not apply in cases where the Court is deciding not to exercise its jurisdiction until some time later is supported by other cases in this Court: *Boston Scientific Ltd. v. Johnson & Johnson Inc.*, 2004 FCA 354; *Epicept Corporation v. Minister of Health*, 2011 FCA 209.

[7] Mylan cites another authority of this Court and says that it is to the contrary: *D & B Companies of Canada Ltd. v. Canada (Director of Investigation and Research)* (1994), 58 C.P.R. (3d) 342 (F.C.A.).

[8] In *D & B Companies*, a party asked the Competition Tribunal to delay its proceedings. The Competition Tribunal refused. It held that the factors relevant to its discretion to delay its proceedings were the same as those set out in *RJR-Macdonald*. A motion was then brought in this Court to stay the Competition Tribunal's proceedings. As an attempt to have this Court enjoin another body from carrying out its mandate, the test in *RJR-Macdonald* was properly applied and the stay was refused.

[9] In the course of its reasons in *D & B Companies*, this Court observed that the Competition Tribunal was right to apply the test in *RJR-MacDonald* in order to determine whether it should delay the hearing before it. Mylan relies on this observation.

[10] There are three considerations that reduce the authority of this observation. First, in *D & B Companies*, this Court had to apply the test in *RJR-Macdonald* anyway. So its observation must be seen as *obiter*. Second, *D & B Companies* can be seen as one where, in the particular circumstances of that case, the Competition Tribunal saw the factors normally canvassed under the *RJR-MacDonald* test to be relevant to the exercise of discretion before it. Third, *D & B Companies* may be explained as a decision by a specialist administrative tribunal – not this Court – about what factors ought to apply to such matters before it, and, in making its observation, this Court appropriately deferred to the tribunal's decision.

[11] Because of these three considerations, the observation made by this Court in *D & B Companies* should not be seen as a statement of general principle, binding in all future cases.

[12] As a result, I do not agree with the reasoning of certain Federal Court cases cited by Mylan that follow the observation in *D & B Companies*: *Sawridge Band v. Canada*, 2006 FC 1218 and *Re Zündel*, 2004 FC 198.

[13] In any event, the reasoning in *Epicept* and *Boston Scientific* are preferable to that in *D & B Companies*. As explained above, cases such as *Epicept, Boston Scientific* and this case do not

involve forbidding another body from doing what Parliament says it can do. As explained above, in such cases the *RJR-MacDonald* test is inapt.

[14] Therefore, as Astra-Zeneca is asking this Court not to hear this appeal until some time later, the *RJR-Macdonald* test does not apply. Rather, we are to ask ourselves whether, in all the circumstances, the interests of justice support the appeal being delayed.

**(2) Application of the test to the circumstances of this case**

[15] AstraZeneca submits that the decision of the Supreme Court of Canada in *Teva Canada Limited v. Pfizer Canada Inc., et al.* (S.C.C. file no. 33951) has such a bearing on this appeal that this Court should exercise its discretion in favour of waiting until the Supreme Court has released its decision.

[16] Mylan disagrees. It emphasizes that if this Court waits until the Supreme Court has decided the *Teva* appeal, the wait will be a very long one. It also suggests that the decision of the Supreme Court may not have any bearing on the outcome of this appeal.

[17] Mylan is correct about the possible length of the wait. The *Teva* appeal is scheduled to be heard on February 8, 2012. The most recent statistics of the Supreme Court of Canada, filed before me, show that the average time required by that Court to issue a decision after hearing an appeal is 7.7 months. There are recent cases, albeit rare, where it has taken 18 months after a hearing to issue

a decision: *Reference re Assisted Human Reproduction Act*, 2010 SCC 61, [2010] 3 S.C.R. 457; *Ontario (Public Safety and Security) v. Criminal Lawyers' Association*, 2010 SCC 23, [2010] 1 S.C.R. 815. Of course, a number of others are released well below the 7.7 month average.

[18] The parties helpfully filed the memoranda of the parties in the *Teva* appeal. The issues appear to be of considerable complexity. Added to whatever time the Supreme Court takes must be the time for the parties to file their memoranda of fact and law in this Court and to get a hearing. This means that AstraZeneca's request that this Court wait until the Supreme Court has released its decision is really a request that this Court not hold its appeal hearing until, perhaps, the spring of 2013.

[19] This is a request for a long wait. Only a very direct nexus between the issues in the *Teva* appeal and this appeal might warrant an exercise of discretion in favour of that wait.

[20] Upon reviewing the memoranda of the parties in the *Teva* appeal, I am not convinced that such a direct nexus exists.

[21] The *Teva* appeal involves an allegation made by Teva under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 that a patent, which claims the use of sildenafil in the treatment of erectile disfunction, is invalid for insufficient disclosure. Teva's allegation of insufficient disclosure is based on a particular feature of this patent: it is said that this particular patent does not reveal which of 260 quintillion compounds disclosed was observed to induce

erections in men. In this case, the patent at issue, unlike the patent at issue in the *Teva* appeal, only claims a single compound, anastrozole. Mylan is not arguing that the patent in issue in this case is invalid because it conceals the identity of anastozole among numerous other compounds.

[22] In this case, both Mylan and the Federal Court relied on a particular statement made by this Court in its decision on the *Teva* appeal. AstraZeneca says that the validity of that statement is one of the issues before the Supreme Court in the *Teva* appeal. That is true, but the Supreme Court may never decide that issue: many other arguments against the sufficiency and utility of the patent at issue are before it.

[23] AstraZeneca expresses concern that if this Court does not delay the appeal, this Court may decide the appeal against it on a basis that turns out to be wrong in light of the later decision of the Supreme Court in the *Teva* appeal. It points to the unlikelihood of the Supreme Court granting it leave to appeal in such a circumstance.

[24] AstraZeneca overlooks that in that situation the Supreme Court has the power to remand the case back to this Court and "order any further proceedings that would be just in the circumstances," such as a redetermination of the matter based on its decision in the *Teva* appeal: *Supreme Court Act*, R.S.C. 1985, c. S-26, subsection 43(1.1). This can be done without granting leave to appeal: see the words "notwithstanding subsection [43](1)" at the beginning of subsection 43(1.1). In light of this available avenue of relief, the concern expressed by AstraZeneca is insignificant.

[25] I also point out that it may be possible for the parties to intervene in the *Teva* appeal and make submissions on issues that could conceivably affect them later in any remand proceedings ordered under subsection 43(1.1): see Rules 55-59 of the *Rules of the Supreme Court of Canada*, SOR/2002-156, and see also Rule 6 on extensions of time. This option becomes attractive if, contrary to the view I take of the matter, there is in fact a very direct nexus between the issues in the *Teva* appeal and this appeal. An application for intervention in circumstances such as these is not without precedent: the Mounted Police Members' Legal Fund successfully applied to the Supreme Court to intervene in *Ontario (Attorney General) v. Fraser*, 2011 SCC 20, [2011] 2 S.C.R. 3. The application was partly on the basis that the Supreme Court's decision might affect an appeal from a case in which it was a party (*Mounted Police Association of Ontario v. Canada (Attorney General)* (2009), 96 O.R. (3d) 20 (S.C.J.)): see Supreme Court of Canada, *Bulletin of Proceedings*, November 13, 2009 at page 1589 and the intervention materials filed with the Court.

[26] For the foregoing reasons, I shall dismiss the motion for an order staying the appeal, with costs.

**B. Mylan's motion to expedite the appeal**

[27] Mylan offers two reasons for expediting this appeal.

[28] First, Mylan is concerned that if the appeal is not decided before the expiry of the '420 Patent on October 24, 2012, it may be considered moot. I reject this. AstraZeneca has undertaken

not to argue that the appeal is moot. It is true that, on its own motion, this Court could raise the issue of mootness at the hearing of the appeal and dismiss the appeal on that basis. However, the current state of the hearing list is such that this appeal will be heard long before October 24, 2012, most likely in March-May, 2012.

[29] Second, Mylan suggests that if the appeal is expedited, Mylan may gain a first-to-market advantage over other generics, assuming that the appeal is decided before expiry of the patent and Mylan is successful on the appeal. I reject this as well. In my view the evidence is purely speculative as to whether Mylan would get a first-to-market advantage if this appeal were allowed.

[30] In any event, I would exercise my discretion against expediting the appeal. Those who seek expedition should themselves expedite. That has not happened here. Mylan took 25 days to issue its eight page notice of appeal, another 27 days to file the agreement as to the contents of the appeal book, and another 27 days to file the appeal book. All three of these procedural steps took close to the maximum time permitted under the *Federal Courts Rules*. The uneventful pace at which the appeal is being prosecuted belies any need for an expedition order.

[31] Therefore, for the foregoing reasons, I shall dismiss the motion to expedite, with costs.

"David Stratas"

J.A.

**FEDERAL COURT OF APPEAL**

**NAMES OF COUNSEL AND SOLICITORS OF RECORD**

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| **DOCKET:** | A-344-11 |
| **STYLE OF CAUSE:** | Mylan Pharmaceuticals ULC v. AstraZeneca Canada, Inc. AstraZeneca UK Limited, and The Minister of Health |

**MOTION DEALT WITH IN WRITING WITHOUT APPEARANCE OF PARTIES**

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| **REASONS FOR ORDER BY:** | Stratas J.A. |
| **DATED:** | November 17, 2011 |

**WRITTEN REPRESENTATIONS BY:**

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