**Date: 20081222**

**Docket: A-77-08**

**Citation: 2008 FCA 416**

**CORAM:** **RICHARD C.J.**
**BLAIS J.A.**
**SHARLOW J.A.**

**BETWEEN:**

**APOTEX INC.**

**Appellant**

**and**

**AB HASSLE, ASTRAZENECA AB and ASTRAZENECA CANADA INC.**

**Respondents**

**and**

**THE MINISTER OF HEALTH**

**Respondent**

Heard at Ottawa, Ontario, on October 21, 2008.

Judgment delivered at Ottawa, Ontario, on December 22, 2008.

REASONS FOR JUDGMENT BY: SHARLOW J.A.

CONCURRED IN BY: RICHARD C.J.
BLAIS J.A.

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## REASONS FOR JUDGMENT

**SHARLOW J.A.**

[1] Apotex Inc. appeals the order of Justice Hughes (2008 FC 184) dismissing two motions in which Apotex sought to set aside the order of Justice Kelen in Federal Court File T-1747-00 (*AB Hassle et al.* v. *Apotex*, 2002 FCT 931) ("Case 1") and the order of Justice Layden-Stevenson in Federal Court File T-1878-02 (*AB Hassle et al* v. *Apotex*, 2005 FC 234) ("Case 2"). Both of the

orders sought to be set aside were upheld on appeal (2003 FCA 409 and 2006 FCA 51, respectively). Apotex argues that the two orders should be set aside because they cannot stand with certain conclusions reached by Justice Layden-Stevenson in a more recent case, Federal Court File T-766-03 (*Astrazeneca et al.* v. *Apotex*, 2006 FC 7, appeal dismissed, 2007 FCA 327) ("Case 3").

Facts

[2] Case 1, Case 2 and Case 3 are similar in a number of respects. The applicant in each of the three cases was one (or more) of the respondents in this case. The interests of those parties are so similar that I will refer to them collectively as "Astrazeneca".

[3] Each of the three cases involved an application for an order under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (the *NOC Regulations*) prohibiting the Minister from issuing a notice of compliance to Apotex for its omeprazole drug until after the expiry of one or more patents listed against Losec, the omeprazole drug marketed in Canada by Astrazeneca. Justice Hughes has provided, in paragraphs 3 and 4 of his reasons, a useful factual introduction to all three cases, which I reproduce here:

> [3] […] Omeprazole is a medicine said to be useful in treating certain conditions relating to the stomach. When swallowed, however, the stomach acid affects the medicine detrimentally. As a result, forms of this medicine such as a capsule or tablet containing granules which comprise a core of a blend of omeprazole and other materials include a coating over those cores with a substance that protects the core from the acidic environment of the stomach and which dissolves once the granules reach the alkaline environment of the gut. This coating is called an enteric coat. It was determined, however, that the enteric coat itself would attack the omeprazole and compromise its effectiveness. Thus an intermediate coat,

> called a subcoat, was placed between the omeprazole-containing core and the enteric coat. This is the subject of certain patents owned or controlled by [Astrazeneca] and asserted in the two earlier NOC proceedings at issue in these motions [Case 1 and Case 2]. It was also determined that, in some situations, a coating would form by itself between the omeprazole-containing core and the enteric coat. This is referred to as an *in situ* coating or subcoating. This is the subject [of] another patent owned or controlled by [Astrazeneca] and asserted in a third NOC proceeding [Case 3].
>
> [4] Apotex wanted to market a generic version of omeprazole and asserted, in general (because the specifics were disputed in some of the proceedings) that it simply applied an enteric coating directly to the core. Thus the *NOC Regulations* were engaged in three proceedings that are of interest here.

[4] The application in Case 1 was commenced in response to a notice of allegation from Apotex dated August 1, 2000. The notice of allegation consisted of a non-infringement allegation relating to three patents then listed against Losec: Canadian Patent Nos. 1,292,693, 1,302,891, and 2,166,483. The non-infringement allegation in Case 1 was based on the premise that the relevant patent claims covered a composition consisting of a medicinal core, an inert subcoat and an outer enteric coat. It was the position of Apotex that its omeprazole drug would not infringe any of those claims because its tablets would consist of a medicinal core and an enteric coat applied directly to the core, and that if a subcoat came into existence, it would not constitute a "subcoat" within the meaning of the patent claims.

[5] Astrazeneca's principal position in Case 1 was that it was entitled to a declaration that the notice of allegation was deficient. In the alternative, Astrazeneca sought a prohibition order on the basis that the non-infringement allegation made by Apotex was not justified. Justice Kelen

accepted Astrazeneca's principal position and, on September 4, 2002, made an order prohibiting the Minister from issuing a notice of compliance to Apotex "with respect to this purported Notice of Allegation" (2002 FCT 931 at paragraph 67). In effect, that order precludes the Minister from issuing a notice of compliance to Apotex for its omeprazole drug until July 8, 2014, the expiry date of the newest of the three patents in issue in Case 1, the 483 patent.

[6] On November 3, 2003, the decision of Justice Kelen in Case 1 was confirmed by this Court, although for different reasons (2003 FCA 409). Justice Rothstein, writing for the Court, doubted that the notice of allegation served by Apotex was deficient. However, he noted that the non-infringement allegation was based on a particular construction of the relevant claims, namely, that the claims did not include a tablet in which the medicinal core was covered by a subcoat formed *in situ* by a chemical reaction occurring when the enteric coat is placed on the medicinal core. Apotex had conceded that its appeal could not succeed if the claims were broad enough to cover a tablet with a subcoat between the core and the enteric coat formed *in situ*. After reviewing the evidence on patent construction, Justice Rothstein concluded that the claims were broad enough to cover a tablet that, in its finished product form, contains a subcoat between the medicinal core and the enteric coat, however the subcoat is formed. Given the concession by Apotex, it followed that the non-infringement allegation could not be justified.

[7] Apotex did not give up on its plans for an omeprazole drug to compete with Losec. On September 26, 2002 (shortly after the decision of Justice Kelen in Case 1 but before that decision was confirmed on appeal), Apotex served another notice of allegation relating to the same three

patents that were in issue in Case 1, this time alleging both non-infringement and invalidity. Apotex alleged, among other things, that its drug would not contain a subcoat, whether separately applied or formed *in situ*.

[8] Astrazeneca then commenced Case 2 by filing an application for a prohibition order under the *NOC Regulations* based on three alternative positions. Its first position was that the notice of compliance was deficient. Its second position was that Apotex was precluded by either the doctrine of issue estoppel or the doctrine of abuse of process from alleging non-infringement and invalidity. Its third position was that the allegations of non-infringement and invalidity were not justified. That application was heard by Justice Layden-Stevenson. By the time of the hearing, the issues had been narrowed so that the only patent in issue was the 693 patent.

[9] On February 14, 2005, Justice Layden-Stevenson granted the prohibition order sought by Astrazeneca in Case 2 in relation to the 693 patent, but she did so without considering the merits of the allegations of non-infringement and invalidity in the notice of allegation dated September 26, 2002. Rather, she concluded that the notice of allegation was deficient in so far as it was based on an incorrect construction of the patent claims. She also agreed with Astrazeneca that the doctrine of issue estoppel applied to preclude Apotex from raising the same issue that was determined against Apotex in Case 1, or any other issue that was not raised but that could have been raised in Case 1, including the allegations of invalidity. She indicated that she would have reached the same conclusion in relation to the doctrine of abuse of process. On February 10, 2006, the decision of Justice Layden-Stevenson in Case 2 was confirmed on appeal (2006 FCA 51).

[10] On February 27, 2003, Canadian Patent No. 2,186,037 was listed against Losec. It included a claim for a formulation and process for the manufacture of tablets containing a subcoat formed *in situ* by means of a chemical reaction between the enteric coat and the medicinal core. On March 25, 2003, Apotex served a third notice of allegation on Astrazeneca relating to the same drug as in Case 1 and Case 2, alleging non-infringement and invalidity of the 037 patent. The key factual basis for the notice of allegation was that the Apotex drug would not contain a subcoat as claimed.

[11] On May 13, 2003, Astrazeneca commenced Case 3 by filing an application for a prohibition order under the *NOC Regulations*. The application was heard by Justice Layden-Stevenson. On January 4, 2006, she dismissed the application on the basis that the non-infringement allegation was justified (2006 FC 7). On October 16, 2007, her decision was confirmed on appeal (2007 FCA 327).

[12] Justice Layden-Stevenson's conclusion that the non-infringement allegation was justified was based on the construction of the relevant patent claim that Apotex had proposed, which was that the claim covers a tablet in which the medicinal core contains an alkaline reacting compound and a proton pump inhibitor that are discrete substances. As it was undisputed that the medicinal core of the Apotex tablets would not contain an alkaline reacting compound that is separate and distinct from the proton pump inhibitor, the 037 patent would not be infringed. This conclusion was confirmed on appeal (2007 FCA 327).

[13] Justice Layden-Stevenson also gave an alternative reason for her conclusion that the non-infringement allegation was justified. The alternative reason was based on the construction of the

relevant patent claim proposed by Astrazeneca, which was that the claim covers a tablet in which a water soluble separating layer is formed *in situ* as a water soluble salt between the medicinal core and the enteric coating layer by a reaction between the enteric coating polymer and the alkaline reacting compound in the core. Apotex alleged that its tablets would not have a separating layer meeting that description. According to Apotex, any material formed between the core and the enteric coat in its tablets would not completely coat the core or would not be thick enough to function as a separating layer. The onus was on Astrazeneca to establish that this allegation was not justified. Justice Layden-Stevenson engaged in an extensive analysis of a large body of expert evidence about the composition of the Apotex tablets, and concluded that Astrazeneca had not met that onus. That alternative conclusion was not considered on the appeal but, as will be explained in further detail below, it represents the foundation of the motions of Apotex to set aside the orders in Case 1 and Case 2.

[14] Despite the fact that Apotex succeeded in Case 3, it could not receive its notice of compliance as long as the orders in Case 1 and Case 2 remained in effect. The order in Case 2 remained in effect until December 3, 2008 when the 693 patent expired. As stated above, the order in Case 1 will remain in effect until July 8, 2014.

[15] On November 23, 2007, Apotex filed the motions that are the subject of this appeal, seeking an order to set aside the orders of Justice Kelen in Case 1 and Justice Layden-Stevenson in Case 2. The motions cite Rule 399(2)(*a*) of the *Federal Courts Rules*, SOR/98-106, and the inherent jurisdiction of the Court as described in *Hoffmann-La Roche Ltd. v. Canada (Minister of*

*National Health and Welfare*) (1999), 167 F.T.R. 111 (F.C.T.D, per Justice Reed, appeal discontinued, A-330-99). The motions were dismissed by Justice Hughes on February 13, 2008, hence this appeal.

[16] I note that when the 693 patent expired on December 3, 2008, the order of Justice Layden-Stevenson in Case 2 no longer represented a bar to the issuance of a notice of compliance to Apotex for its omeprazole drug. The potential mootness of the motion to set aside that decision was not addressed in this appeal. However, I have disregarded that issue on the assumption that there may still be a dispute as to a potential claim for damages that may be asserted by Apotex under section 8 of the *NOC Regulations* if this Court were to find that the motion should succeed.

Legal principles

[17] The Federal Court has the jurisdiction to set aside its own judgments in the circumstances stated in Rule 399 of the *Federal Courts Rules*. That jurisdiction is rarely exercised because there is a significant public interest in the finality of judgments and the integrity of the judicial process. The part of Rule 399(2)(*a*) that is relevant to this appeal reads as follows:

| | |
|---|---|
| 399. (2) On motion, the Court may set aside or vary an order | 399. (2) La Cour peut, sur requête, annuler ou modifier une ordonnance dans l'un ou l'autre des cas suivants : |
| (*a*) by reason of a matter that arose or was discovered subsequent to the making of the order […]. | *a*) des faits nouveaux sont survenus ou ont été découverts après que l'ordonnance a été rendue […]. |

[18] It has also been said that the Federal Court has the inherent jurisdiction to vacate a prohibition order issued under the *NOC Regulations* if changed circumstances demonstrate that the order should cease to have effect (see *Hoffmann-La Roche*, cited above).

[19] *Hoffmann-La Roche* involved a 1996 order made under the *NOC Regulations* prohibiting the Minister of Health from issuing a notice of compliance to Apotex for a certain drug until after the expiration of Canadian patent number 1,204,671 (*Hoffmann-La Roche Ltd. v. Canada (Minister of National Health and Welfare)* (1996), 109 F.T.R. 216, 67 C.P.R. (3d) 484 (F.C.T.D.), confirmed (1996) 205 N.R. 360, 70 C.P.R. (3d) 1 (F.C.A.), leave to appeal dismissed [1996] S.C.C.A. No. 554 (QL)). After the prohibition order was made, Apotex commenced an action to impeach the 671 patent. That action was successful and resulted in an order dated April 23, 1999 declaring the 671 patent to be invalid (*Apotex Inc. v. Syntex Pharmaceuticals International Ltd.* (1999), 166 F.T.R. 161, 1 C.P.R. (4th) 22 (F.C.T.D.), appeal discontinued, A-318-99). Relying on the declaration of invalidity, Apotex sought and obtained from Justice Reed an order setting aside the 1996 prohibition order.

[20] Justice Reed set aside the prohibition order on the basis of what she referred to as "changed circumstances". In doing so, she applied by analogy the principle that a court has an inherent continuing jurisdiction over its own injunctions. That principle is summarized in I.C.F. Spry, *The Principles of Equitable Remedies*, 5th ed. (Sydney: The Law Book Company, 1997) at page 382:

> … [b]oth perpetual and also interlocutory and interim injunctions may at any time be dissolved by the court by which they were granted, should it subsequently become appropriate to do so.

Justice Reed reasoned that, although a prohibition order made under the *NOC Regulations* is a statutory remedy rather than an equitable one, a prohibition order is similar to an injunction in the sense that it prohibits a person from doing something. She noted also that an order disposing of a prohibition application under the *NOC Regulations* is not and is not intended to be a final determination of the validity or infringement of the patent to which it refers, which means that a prohibition order is always subject to being undermined if the patent is invalidated (see also *AB Hassle* v. *Apotex Inc*., 2006 FCA 51, at paragraph 28).

Standard of Review

[21] Both parties argued that the standard of review in this appeal is governed by *Housen v. Nikolaisen*, [2002] 2 S.C.R. 235. However, that case deals with the standard of review on the appeal of the decision of a trial judge. It does not apply in this case, which involves an appeal of the discretionary decision of a judge on a motion to set aside a prohibition order on the basis of Rule 399 or the Federal Court's inherent continuing jurisdiction over injunctions and similar orders. This Court will not reverse such a discretionary decision in the absence of an error of law or a wrongful exercise of discretion in that no weight, or no sufficient weight, was given to relevant considerations, or consideration was given to irrelevant factors: *Elders Grain Co. v. Ralph Misener (The) (C.A.)*, [2005] 3 F.C.R. 367, at paragraph 13.

Analysis

[22] As I understand Justice Hughes' reasons, the most important factual basis of his decision is found in these statements from paragraphs 43 and 44 of his reasons (the emphasis is mine):

> [43] […] [In] the first of the earlier proceedings, Apotex failed to put in a sufficient allegation to put the question of non-infringement into play and in the second proceeding Apotex failed to persuade the Court that its conduct in the first proceeding did not preclude it from making such allegations and leading evidence in the second proceeding.
>
> [44] It is evident that Apotex is endeavouring through the present motions, to do what it did not do in the first proceeding and could not do in the second. […]

[23] In my view, this description of the relevant circumstances is unassailable. The problem faced by Apotex is that, although it must have known from the outset that it had a basis for asserting that its tablets had no subcoat, it chose a litigation strategy in Case 1 that resulted in no determination on the merits of the non-infringement allegation it had made on the basis of the absence of a subcoat.

[24] Apotex says that the notices of allegation considered in Case 1, Case 2 and Case 3 involved the same Apotex tablets, and that the composition of the tablets did not change. Justice Hughes did not accept that. Apotex argues that he was wrong in that regard because the point was not in dispute between the parties. I am not persuaded that this appeal turns on this point. For the purposes of this appeal, I will assume without deciding that the Apotex product in each case was in fact the same.

[25] I will also assume without deciding that, given the decision of Justice Layden-Stevenson in Case 3, Astrazeneca probably could not have disproved the allegation of Apotex that its tablet has no subcoat as contemplated by the relevant claims of the patents in issue in Case 1 (the 693 patent, the 891 patent and the 483 patent) and Case 2 (the 693 patent). I make that assumption knowing that it was a matter of dispute before Justice Hughes.

[26] From the assumptions stated above, it could be inferred that if the evidence in Case 3 had been presented in Case 1, Justice Kelen might have reached the same conclusion as Justice Layden-Stevenson in Case 3, and he might have declined to issue the prohibition order in Case 1. In that event, there would have been no Case 2 and no second prohibition order.

[27] However, the hypothetical situation described in the previous paragraph remains only hypothetical. Apotex chose to proceed in Case 1 without presenting the evidence it later presented in Case 3 and, according to Justice Kelen, without providing sufficient details about its tablets or samples for analysis. In Case 2, Apotex apparently provided the same or nearly the same evidence as it presented in Case 3, but it was then too late to put its best foot forward. Case 2 was not determined on the merits, but on the basis of issue estoppel and abuse of process.

[28] Justice Hughes declined to exercise his discretion to set aside the orders in Case 1 or Case 2 because he understood that Apotex was attempting to reverse the effects of its unsuccessful litigation strategies in Case 1 and Case 2 by arguing that those cases might have been decided differently if Apotex had conducted itself differently. In these circumstances, I find no error of law

or any other basis upon which this Court should intervene in the decision of Justice Hughes to dismiss the motions.

[29] For these reasons, I would dismiss this appeal with costs.

[30] As mentioned above, it has been established that a final determination by the Federal Court that a patent is invalid will prevail over a prohibition order relating to that patent, justifying the setting aside of the prohibition order (*Hoffmann-La Roche*, cited above). By the same reasoning, the prohibition orders in Case 1 or Case 2 may be set aside if it is determined in an action that the Apotex product will not infringe any of the patents in issue in those cases. I understand from the submissions of Astrazeneca in this appeal that the question of infringement is to be determined in an action in the Federal Court (File T-1409-04). Nothing in these reasons will prejudice the right of Apotex to seek to set aside the prohibition orders in Case 1 or Case 2, if it is successful in that case.

"K. Sharlow"

J.A.

"I agree.
J. Richard C.J."

"I agree.
Pierre Blais J.A.

**FEDERAL COURT OF APPEAL**

**NAMES OF COUNSEL AND SOLICITORS OF RECORD**

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|---|---|
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| **CONCURRED IN BY:** | RICHARD J.C.<br>BLAIS J.A. |
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