Date: 20080520

Docket: A-27-08

Citation: 2008 FCA 186

CORAM: **LÉTOURNEAU J.A.**
SHARLOW J.A.
TRUDEL J.A.

BETWEEN:

ABBOTT LABORATORIES LIMITED,
TAP PHARMACEUTICALS INC. and
TAP PHARMACEUTICAL PRODUCTS INC.

Appellants

and

ATTORNEY GENERAL OF CANADA and
MINISTER OF HEALTH

Respondents

Heard at Toronto, Ontario, on April 17, 2008.

Judgment delivered at Ottawa, Ontario, on May 20, 2008.

REASONS FOR JUDGMENT BY: SHARLOW J.A.

CONCURRED IN BY: LÉTOURNEAU J.A.
TRUDEL J.A.

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REASONS FOR JUDGMENT

SHARLOW J.A.

[1] This is an appeal of a decision of Justice Hughes (2007 FC 1318) rejecting the application of the appellants (collectively, "Abbott") made under section 18 of the *Federal Courts Act*, R.S.C. 1985, c. F-7. Abbott seeks an order prohibiting the Minister of Health (the "Minister") from issuing a notice of compliance ("NOC") to any person for a generic version of Prevacid 15 mg or 30 mg delayed release capsules without requiring that person to address, under section 5 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (the "*PM (NOC) Regulations*"),

Canadian patent number 1,327,010 (the "010 patent") and Canadian patent number 1,338,377 (the "377 patent").

Statutory framework

[2] Most cases under the *PM (NOC) Regulations* involve a dispute between an "innovator" (the manufacturer of a drug that embodies a patent claim) and a generic drug manufacturer who wishes to market a generic version of the innovator drug. This case involves a dispute between an innovator and the Minister.

[3] The *PM (NOC) Regulations* were enacted to discourage potential abuses of the early working exception in section 55.2(1) of the *Patent Act*, R.S.C.1985, c. P-4, in relation to certain pharmaceutical patents. Pursuant to the early working exception, a generic drug manufacturer does not infringe a patent embodied in an innovator drug merely by making use of the patented invention, before the patent expires, for the purpose of seeking regulatory approval for a generic version of the innovator drug.

[4] No drug may be marketed in Canada without a NOC issued by the Minister under the *Food and Drug Regulations*, C.R.C. c. 870. The *PM (NOC) Regulations* operate through that drug approval process. Generally, a NOC is issued when the Minister is satisfied that the applicable conditions in the *Food and Drug Regulations* are met. Once the Minister is so satisfied, he must issue the NOC (*Apotex Inc. v. Canada (Attorney General (C.A.)*, [1994] 1 F.C. 742), unless he is precluded from doing so by section 7 of the *PM (NOC) Regulations*.

[5] The *PM (NOC) Regulations* require the Minister to maintain a "patent register". When the Minister issues a NOC to an innovator for a drug that embodies a patent claim, the innovator may apply to have the patent listed on the patent register in respect of that drug. If the patent is listed in respect of the drug, and a generic drug manufacturer files an abbreviated new drug submission ("ANDS") seeking a NOC for a generic version of the drug based on certain comparisons establishing bioequivalence, then section 7 of the *PM (NOC) Regulations* precludes the Minister from issuing a NOC for the generic drug until the later of certain dates. One of those dates is the day on which the generic drug manufacturer "complies with section 5" of the *PM (NOC) Regulations*. A generic drug manufacturer's application for a NOC is said to be on "patent hold" if the Minister completes his regulatory review of the proposed generic drug, but cannot issue a NOC immediately because of the constraints imposed by section 7 of the *PM (NOC) Regulations*.

[6] A generic drug manufacturer complies with section 5 of the *PM (NOC) Regulations* by "addressing" the patents listed on the patent register in respect of the drug to which the generic drug is compared. A generic drug manufacturer may address a patent by accepting that it will not receive a NOC for its generic drug until the patent expires. Or the generic drug manufacturer may address a patent by making one or more "allegations" that, if true, would entitle the generic drug manufacturer to disregard the listed patent. For example, a patent may be addressed by an allegation that the patent has expired, the patent is not valid, or that no claim of the patent for the medicinal ingredient, the formulation, the dosage form or the use of the innovator drug would be infringed by the generic drug. If such an allegation is made, the generic drug manufacturer must serve the innovator with a detailed statement containing prescribed information about the basis for the allegation.

[7] The serving of the detailed statement permits the innovator to apply to the Federal Court under section 6 of the *PM (NOC) Regulations* for an order prohibiting the Minister from issuing a NOC for the generic drug until after the listed patent expires. The commencement of that application marks the start of a 24 month statutory stay (which may be shortened or lengthened by the Federal Court in certain circumstances) during which the Minister cannot issue a NOC for the generic drug unless one of a number of possible events occurs. One of those events is the dismissal or discontinuance of the prohibition application.

Facts

[8] Since 1995, Abbott has been authorized to market Prevacid capsules in Canada pursuant to NOCs issued by the Minister. Several patents are listed on the patent register in respect of Prevacid, including the two patents in issue in this case, the 010 patent and the 377 patent. It is undisputed in this case that those patents contain claims for compositions of lansoprazole, the active medicinal ingredient in Prevacid. It is also undisputed in this case that the formulation of Prevacid that Abbott is authorized to market in Canada embodies, and has always embodied, at least one claim of each of those patents.

[9] The 010 patent was issued on February 15, 1994 and the 377 patent was issued on June 11, 1996. It appears that an application could have been made under subsection 4(6) of the *PM (NOC) Regulations* to list the two patents within 30 days of their issuance, but that was not done. The record contains no explanation for that. In any event, Abbott applied to have the two patents listed when it made a supplementary new drug submission ("SNDS") for new administration options for

Prevacid. On August 2, 2006, the Minister issued a new NOC for those new administration options and, on the next day, listed the 010 patent and the 377 patent in respect of Prevacid. For the purposes of this appeal, I assume without deciding that the Minister was correct to list both patents at that time.

[10] Prior to the listing of the 010 patent and the 377 patent in respect of Prevacid, Novopharm and one other generic drug manufacturer had each filed an ANDS to obtain a NOC for a generic version of Prevacid. The Novopharm ANDS had been approved by the Minister and placed on patent hold before August 3, 2006, when the 010 patent and the 377 patent were listed in respect of Prevacid. By letter dated February 28, 2007, the Minister advised Novopharm that it would not be required to address either of those patents.

[11] Abbott commenced the present application in the Federal Court on February 7, 2007, after the filing of the two ANDSs referred to above, but before the Minister had advised Novopharm that it would not be required to address the 010 patent and the 377 patent.

Discussion

[12] What prompted Abbott to commence the present application? The answer begins with the decision of the Supreme Court of Canada in *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, [2006] 2 S.C.R. 560, 2006 SCC 49. That decision was released on November 3, 2006.

[13] AstraZeneca had obtained a NOC for the original formulation of a drug called Losec 20, which was marketed in Canada from 1989 to 1996. The patent for the active medicinal ingredient in Losec 20 expired in 1999. Apotex Inc., a generic drug manufacturer, applied for a NOC for a generic version of the original formulation of Losec 20, for the originally approved use. Meanwhile, AstraZeneca had sought and obtained a NOC for a new formulation of Losec 20 for a new use, but containing the same medicinal ingredient. AstraZeneca then listed two additional patents (referred to as "the 037 patent" and the "470 patent") in respect of Losec 20.

[14] Justice Binnie, writing for the Court, held that Apotex Inc. was not required to address the two newly listed patents pursuant to section 5 of the *PM (NOC) Regulations*, because it was comparing its generic drug to the pre-1996 formulation of Losec 20 for its original use, and had not taken advantage of the early working exception with respect to the inventions disclosed in the two newly listed patents.

[15] In analysing the scheme of the *PM (NOC) Regulations*, Justice Binnie noted that they established a certain linkage between the submission of an innovator for a NDS or SNDS, the issuance of a NOC upon the approval of that NDS or SNDS, and the listing of a patent upon the issuance of that NOC. As he said in paragraph 21 (emphasis in original):

> [21] I emphasize the words in s. 4(5) that in the case of patents added afterwards, "the first person must identify the submission to which the patent list or the amendment relates, including the date on which the submission was filed". In addition, s. 3(3) provides that "[n]o information submitted pursuant to section 4 shall be included on the register until after the issuance of the notice of compliance in respect of which the information was submitted." These provisions, it seems to me, provide an important key to understanding the scheme. Entry of the "Patent list" does not destroy the linkage between the patent and the submission(s) to which it relates, nor to the NOC to which the

> submission(s) are directed. Specific patents are associated with one or more NDS, ANDS or SNDS, which in turn (if approved) give rise to specific NOCs, which in turn approve a specific manufacturer's product, which a generic manufacturer may seek to copy. There is no linkage between the 037 and 470 patents and the submissions that lead to the *Losec 20* product copied by Apotex. Those after-acquired patents were listed in relation to a SNDS dated January 22, 1999 by AstraZeneca for a new medical use for *Losec 20* (treatment of *H. Pylori*), a use for which the Apotex product is *not* approved, and to an administrative SNDS submitted by AstraZeneca dated July 12, 2000, which submission has nothing at all to do with the technology incorporated in *Losec 20*.

[16] Following the release of *AstraZeneca*, and in an attempt to apply its teaching, the Minister devised a framework for determining when the requisite linkage existed, which in turn would determine whether there were patents listed in respect of an innovator drug that a generic drug manufacturer would not be required to address under section 5 of the *PM (NOC) Regulations*. That framework was summarized by Justice Hughes in *Ferring Inc. v. Minister of Health*, 2007 FC 300, at paragraph 63. First, the Minister would determine the date upon which the generic drug manufacturer purchased the version of the innovator drug it used for the purpose of testing for the required bioequivalence comparison. The generic drug manufacturer would necessarily be required to address any patents listed prior to that purchase. Second, the Minister would consider each NOC issued for the innovator drug after the date of purchase, with a view to determining whether the generic drug manufacturer had made use of any changes made to the innovator drug since the date of purchase. If so, the generic drug manufacturer would be required to address patents listed after the date of purchase in relation to those changes.

[17] Based on that analytical framework, the Minister reviewed a number of pending cases in which patents had been listed in respect of a particular drug after the filing of an ANDS for a

generic version of the drug. In some cases, the Minister issued notices of compliance for the generic drug without requiring the generic drug manufacturer to address patents listed after the filing of the ANDS. In others, the Minister concluded that the generic drug manufacturer would be required to address the later listed patents. Five separate judicial review applications were made to challenge the Minister's decisions. Those applications were heard by Justice Hughes and dismissed on March 20, 2007 (*Ferring*, cited above). There were five appeals. One was dismissed as moot (*Novopharm Ltd. v. Minister of Health*, 2007 FCA 275). The others were dismissed on the merits (*Ferring Inc. v. Minister of Health*, 2007 FCA 276), released September 6, 2007.

[18] As a result of certain comments made by Justice Hughes in *Ferring*, the first step in the analytical framework adopted by the Minister after *AstraZeneca* was changed slightly. The revision appears in the affidavit of a senior official of Health Canada sworn April 12, 2007, and filed in the present case. The change was to the first step. Instead of using as a starting point the date of acquisition of the innovator drug for testing purposes, the Minister would use the date of the filing of the generic drug manufacturer's ANDS. Thus, the generic drug manufacturer would always be required to address patents listed in respect of the innovator drug before the filing date of the ANDS. If an examination of NOCs issued for the innovator drug after that date indicated that the generic drug manufacturer had made use of changes made to the innovator drug after that date, the generic drug manufacturer would be required to address patents listed after that date in relation to those changes.

[19] The most recent version of the Minister's framework is found in a document entitled "Guidance Document", as amended on December 13, 2007, at pages 27 and 28. The description of the framework is substantially unchanged from the description in the affidavit filed in this case. However, the Guidance Document states that the framework is intended to be applied only in respect of the version of the *PM (NOC) Regulations* considered in *AstraZeneca* or, in other words, only where a generic drug manufacturer's ANDS was filed pursuant to the *PM (NOC) Regulations* as they read before certain amendments came into force on October 5, 2006.

[20] Abbott is of the view that the Minister's interpretation of *AstraZeneca*, and his resulting analytical framework, is incorrect. Abbott argues that, because Prevacid embodies claims of both the 010 patent and the 377 patent, any generic drug manufacturer proposing to market a generic version of Prevacid must necessarily have early worked the patented inventions in developing that generic version. That distinguishes the facts of this case from the facts in *AstraZeneca*. Abbott argues that if the Minister were to apply his framework as the basis for issuing a NOC for a generic version of Prevacid without requiring the 010 patent and the 377 patent to be addressed, Abbott would be deprived wrongfully of the benefit of the *PM (NOC) Regulations*, even if the ANDS for the generic version of Prevacid was filed before the 010 patent and the 377 patent were listed.

[21] Justice Hughes rejected Abbott's application without discussing its criticisms of the Minister's interpretation of *AstraZeneca* or his analytical framework.

[22] It is common ground that Justice Hughes was entitled in his discretion to grant or to refuse Abbott's application. A discretionary decision will not be reversed on appeal unless there is an error of law, or a failure to exercise the discretion judicially: see *Sanofi-Aventis Canada Inc. v. Novopharm Ltd.*, 2007 FCA 163, at paragraph 13. In my view, Justice Hughes did not err in law or fail to exercise his discretion judicially.

[23] Justice Hughes said, and I agree, that the Federal Court will not grant an order that simply requires the Minister to do what the *PM (NOC) Regulations* require. In this case, it has not been suggested that the Minister has failed to do what the *PM (NOC) Regulations* require. Rather, Abbott is concerned that the Minister may make a decision in the future that will contravene the *PM (NOC) Regulations*.

[24] Justice Hughes also said, and I agree, that the Federal Court should be reluctant to prohibit the Minister from making any decision under the *PM (NOC) Regulations* in the future unless it is certain that the Minister will make that decision, and that the decision necessarily is or would result in a contravention of the *PM (NOC) Regulations*. The requisite certainty is lacking in this case because it is not clear when the Minister will be required to decide whether to issue a NOC for a generic version of Prevacid, what the relevant facts will be at that time, or whether at that time the Minister will still be following the analytical framework described above. Also, the jurisprudence relating to the *PM (NOC) Regulations* is continually evolving, and it is not clear what the law will be when the Minister must make that decision.

[25] In that regard, it is relevant to note that there has already been considerable litigation involving the application of the *PM (NOC) Regulations* to Prevacid. Canadian patent number 2,269,053 (the "053 patent") was listed on the patent register in respect of Prevacid on July 25, 2006. On March 1, 2007, the Minister removed that patent from the register. Abbott was successful in having the listing restored: *Abbott Laboratories Ltd.* v. *Canada*, 2007 FC 797. An appeal from that decision is scheduled to be heard on June 11, 2008 (A-383-07).

[26] In addition, Abbott has commenced at least three prohibition applications under section 6 of the *PM (NOC) Regulations* in relation to Prevacid. One of those applications (T-2052-06, *Abbott Laboratories Ltd. v. Novopharm Limited*) involves the 053 patent referred to above. I assume that application will continue if the Federal Court decision requiring the 053 patent to be listed stands. Another prohibition application, relating to Canadian patent number 2,286,753, was dismissed: *Abbott Laboratories Ltd. v. Novopharm Limited*, 2007 FC 622, affirmed 2007 FC 865. A third application, relating to Canadian patent 2,009,741 (the "741 patent"), was successful: *Abbott Laboratories Limited v. Novopharm Limited*, 2006 FC 1411, affirmed 2007 FCA 251. Therefore, regardless of the outcome of the litigation involving the 053 patent, the Minister cannot issue a NOC for Novopharm's generic version of Prevacid until the 741 patent expires on February 9, 2010.

[27] I also agree with Justice Hughes that granting Abbott the order it seeks would not be fair to Novopharm or the other generic drug manufacturer who filed an ANDS for a generic version of Prevacid prior to the listing of the 010 patent and the 377 patent, unless they are given an opportunity to be heard.

[28] As indicated above, Justice Hughes did not address the substance of Abbott's argument, and I will not do so either. However, I note that it remains an open question whether the Minister would be correct to apply his analytical framework in every case where a question arises as to whether a generic drug manufacturer must address a patent listed after the date of the filing of the generic drug manufacturer's ANDS. Chief Justice Richard, speaking for the Court in the *Ferring* appeals (cited above), said this at paragraph 6 of his reasons:

> [6] We have concluded that the analytical approach adopted by the Minister in these four appeals was adequate for the factual circumstances of these cases. Whether it is adequate for all possible circumstances [. . .] is a question upon which we express no opinion.

[29] It would appear from the preface to the Guidance Document that the Minister is aware of the need for a case by case determination. The preface reads in part as follows:

> Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document ***may be*** acceptable provided they are supported by adequate justification.

[30] I note also that if the Minister issues a NOC for a generic version of Prevacid without requiring the 010 patent and the 377 patent to be addressed because the ANDS for the generic drug was filed before those patents were listed, the dismissal of Abbott's application in this case will not preclude Abbott from challenging the Minister's decision to issue the NOC. In addition, Abbott retains all of its rights under the *Patent Act* to sue for infringement if it has a basis for claiming that anyone marketing a generic version of Prevacid would infringe the 010 patent or the 377 patent.

Conclusion

[31] I would dismiss this appeal with costs.

"K. Sharlow"

J.A.

"I agree
Gilles Létourneau J.A."

"I agree
Johanne Trudel J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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