Date: 20071214

Docket: T-252-07

Citation: 2007 FC 1318

Ottawa, Ontario, December 14, 2007

PRESENT: The Honourable Mr. Justice Hughes

BETWEEN:

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

Applicants

and

ATTORNEY GENERAL OF CANADA and
MINISTER OF HEALTH

Respondents

REASONS FOR JUDGMENT AND JUDGMENT

[1] This is an application dealing with provisions of the *Patented Medicines (Notice of Compliance) Regulations* SOR/93-133 as amended (NOC Regulations). The Applicants originally asked the Court to prohibit the Minister of Health from issuing a Notice of Compliance (NOC) to any person seeking an NOC in respect of a drug known as PREVACID in 15 mg or 30 mg delayed release capsule form unless such person complies with sections 5(1) or 5(2) of the NOC Regulations as so far as two patents are listed by the Applicants under those Regulations, Canadian Patent No. 1,327,010 ('010 patent) and No. 1,338,377 ('377 patent). The application also seeks a declaration

that any such person seeking such NOC must address those patents in accordance with sections 5(1) or 5(2) of those Regulations. It is important to note that this application was filed February 7, 2007.

[2] During the course of argument and in particular in reply, Applicants' counsel varied the wording of the relief sought to read as follows:

> ***THE APPLICANTS MAKE APPLICATION FOR:***
>
> *1. An order prohibiting the Minister of Health (the "Minister") from issuing a Notice of Compliance ("NOC") to any person who has filed a submission for a NOC comparing that person's drug to PREVACID® 15 mg or 30 mg delayed-release capsules (hereinafter referred to as "PREVACID®") or made reference to PREVACID® in the factual circumstances set out in the Minister's letter dated February 28,2007, unless such person has complied with subsections 5(1) or (2) of the Patented Medicines (Notice of Compliance) Regulations (the "PM(NOC) Regulations"), in relation to the Canadian Patents Nos. 1,327,010 (the '010 Patent) and 1,338,377 (the '377 Patent).*
>
> *2. A declaration that the Minister may not issue a Notice of Compliance in the circumstance of paragraph 1.*
>
> *3. Costs of this application; and*
>
> *4. Such further and other relief as is just.*

[3] For the reasons that follow, I decline to give the relief originally sought or as amended.

FACTUAL BACKGROUND

[4] The Applicants are "first persons" as described under the NOC Regulations. They are involved in the marketing in Canada of a drug sold under the name PREVACID which drug acts as a proton pump inhibitor in the treatment of gastric conditions.

[5] The active ingredient in PREVACID is a medicine known as lansoprazole however, it is sensitive to acid such as that found in the stomach. As a result, in practice, lansoprazole is formulated together with a stabilizing material and shaped into granules that are enterically coated to permit passage through the stomach. The granules are assembled into a capsule. This formulation has remained unchanged since PREVACID was first approved for sale in Canada in 1995.

[6] The Applicants have received a number of NOCs from the Minister in respect of PREVACID. The first NOC was issued on May 12, 1995 for PREVACID Delayed Release Capsules incorporating lansoprazole as the medicinal ingredient in 15 mg and 30 mg dosages. The PREVACID formulation for which approval was given on May 12, 1995 is the same today as it was in 1995. There have been no changes made to that formulation between 1995 and today. The relevant Product Monograph indicates that PREVACID was to be taken orally.

[7] On November 30, 2005, the Applicants filed a Supplementary New Drug Submission (SNDS) seeking what they described as New Administrative Options. On August 7, 2006 an NOC was issued as a result bearing the caption:

"Revised – Correction to dosage forms"

[8] The Reason for the Supplement was stated in the NOC as:

> *New Administration options:*
>
> > *Prevacid FasTab: Dispersed in water and administered via syringe orally or into a nasogastric tube.*
> >
> > *Prevacid: Dispersed in apple juice or water and administered via syringe into a nasogastric tube.*

[9] The resulting new Product Monograph indicates that it is intended that the capsules be opened and granules (which are the enterically coated granules containing lansoprazole and a stabilizer) are to be mixed with apple juice or water for administration by injection or through a nasogastric tube.

[10] Turning to the two patents of interest here, the ’010 patent and the ’377 patent both have a common origin being an application filed in the Canadian Patent Office on February 12, 1987 claiming priority from two Japanese patent applications filed in February 1986. The single original Canadian patent application was divided into two applications resulting in the two patents now of interest. The ’010 patent issued on February 15, 1994 and the ’377 patent issued on June 11, 1996.

[11] In general, the ’010 patent contains claims directed to a pharmaceutical composition containing an effective amount of a class of medicines of which lanzoprazole is one, together with a stabilizer and a pharmaceutically acceptable carrier. The patent also claims a method for producing the composition.

[12] The ’377 patent goes further than the ’010 patent in claiming an enteric coating for the composition.

[13] The evidence, which the Minister has not contested in the present application, is that PREVACID as sold in Canada since 1995 is a composition as described in at least some of the claims of each of the ’377 and ’010 patents.

[14] The ’010 patent and ’377 patents were listed on August 3, 2006 by the Applicants under the provisions of the NOC Regulations but only in respect of the NOC granted to them dated August 2, 2006. These patents could have been listed much earlier. Abbott has provided no evidence or explanation as to why these two patents were not listed earlier. Whether the failure to list was for reasons of inadvertence, oversight, negligence or some form of strategic thinking we simply do not know. It seems the Applicants have now chosen this application as the vehicle by which they hope for some rectification of the situation.

[15] Subsequent to August 2, 2006, no generic drug company has delivered to the Applicants any Notice of Allegation respecting PREVACID referencing either the ’010 or ’377 patents. Prior to that time, at least two generic drug companies had delivered Notices of Allegation making reference to PREVACID and other patents, but not to the ’010 or ’377 patents. They did not make reference to the ’010 or ’377 patents since those two patents were not yet listed against any NOC.

[16] Once the ’010 and ’377 patents were listed at least one of the generic drug companies (Novopharm) communicated with the Minister (Therapeutic Products Directorate (TPD) responsible for administration of the NOC Regulations) inquiring whether it needed to address those patents. TPD responded by letter dated February 28, 2007 stating, *inter alia*:

> *As a starting point in adopting the patent-specific analysis set forth by Binnie J., it appears that a determination of the comparator drug is required. As such, a “comparator drug”, in respect of the PM(NOC) Regulations, will be considered to be the drug relied upon by a second person in order to make a comparison for the purpose of demonstrating bioequivalence under section C.08.002.1(1)(b) of the Food and Drug Regulations [C.R.C., c. 870].*
>
> *The identification of the NOCs issued in respect of the comparator drug, and the subsequent identification of the submissions that gave rise to those NOCs, appears to require a stepwise determination.*
>
> *First, the date on which the second person purchases the comparator drug will be used to determine the NOCs that have been issued in respect of that comparator drug. All patents added to the Patent Register in respect of submissions which have received an NOC as of the date of purchase of the comparator drug must be addressed under subsections 5(1) and 5(2) of the PM(NOC) Regulations.*
>
> *The Office of Patented Medicines and Liaison (“OPML”) will also consider any NOCs that have been issued to the first person after the date of purchase of the comparator drug by the second person. A determination will be made as to whether or not the second person has made use of the changes to the comparator drug as outlined in the relevant submissions. If the second person has made use of the changes to the comparator drugs, all patents added to the Patent Register in respect of those*

> *submissions must be addressed pursuant to subsections 5(1) and 5(2) of the PM(NOC) Regulations.*
>
> *Once all the relevant requirements have been met, the Minister shall issue an NOC to the second person according to section C.08.004 of the Food and Drug Regulations.*
>
> …
>
> *As shown in the table above, on August 2, 2006, after the date of purchase of the comparator drug by Novopharm, one NOC was issued to TAP in respect of submission 103051 for the addition of new administrative options for PREVACID. Both the '010 and '377 patents were added to the Patent Register in respect of that submission. Since Novopharm's ANDS was on patent hold, it has not made use of the new administrative options for PREVACID as approved in submission 103051.*
>
> *Therefore, Novopharm is not considered to be a "second person" in respect of the '010 and '377 patents pursuant to the PM(NOC) Regulations. Furthermore, Novopharm is not required to address these patents under subsections 5(1) and 5(2) of the PM (NOC) Regulations.*

[17] A copy of this letter was sent to the Applicants by TPD. Counsel for the Applicants wrote a letter to Counsel for the Minister dated February 20, 2007 requesting:

> *Will you confirm, on behalf of your client, that the Minister of Health will not issue a Notice of Compliance to any generic drug manufacturer for a generic version of lansoprazole until this application has been heard and determined?*

[18] No response has been made by the Minister. It must be noted that the letters of February 20 and 28 post date the filing of this application. This application was filed on February 7, 2007.

ISSUES

[19] The issues are whether this Court should:

1. Issue an Order prohibiting the Minister from issuing a Notice of Compliance to a generic drug company seeking to market a drug product compared to PREVACID without requiring that company to address each of the ’010 and ’377 patents;
2. Grant a declaration that a generic drug company should address those patents in seeking such a Notice of Compliance.
3. Issue an Order in the modified form submitted by Counsel during argument (*supra*).

[20] The Applicants originally were seeking relief under sections 18 and 18.1 of the *Federal Court Act*, R.S.C. 1985 c. F-7 as against the Minister and as against third parties, so called generics, not before this Court. Applicants’ counsel agreed in oral submissions to the Court that this Court has no jurisdiction to grant the relief requested as against third parties not presently before the Court and withdrew the request for relief set out in the original paragraph 2 as summarized above.

[21] In respect of relief against the Minister, counsel for all parties agreed that this Court has the discretion to grant relief of the kind requested, or not. Certainly the Court would refuse to give an Order that would simply require or declare that the Minister must do what a statute or regulation requires the Minister to do. It is where the Minister has exceeded his jurisdiction or the duties

established by statute or regulation, or fails to fulfill those duties or that it is clear that the Minister would so exceed or fail, that the Court would consider relief of this kind.

[22] The specific instance given in evidence in this application is that of Novopharm and the letter by the Minister to Novopharm of February 28, 2007 which was written after these proceedings were instituted. Counsel advises that ultimately, in that instance, proceedings were instituted against Novopharm in this Court and an Order of prohibition was granted. Thus, at least until the patents at issue in those proceedings expire or perhaps some other pertinent event occurs, Novopharm will not be receiving an NOC. There is little point in now addressing the specific Novopharm situation and certainly not without giving Novopharm an opportunity to be heard.

[23] The Novopharm situation is only one example of a variety of situations that may arise, all fact specific. Facts such as when a generic has acquired its competitor drug, when did it filed its application, what its drug looks like, how it would be used, which particular NOC is referenced and a variety of other facts may all be pertinent to the particular situation at hand. An example of the factors to be considered are those listed at paragraph 59 of the reasons in *Ferring Inc. v. Canada (Minister of Health)*, 2007 FC 300 (aff'd 2007 FCA 276):

> ***59*** *It is important to note that the Supreme Court was quite specific in paragraph 40 as to the reason for the reference, it was for demonstrating bioequivalence. Section 5(1) of the NOC Regulations are specific in stating that a person is only required to take steps to issue a notice of allegation to the innovator who has listed patents (thus become a "second person") if:*
>
> - *that person has filed for an NOC;*
> - *that person has compared reference or made reference to another drug;*

> - *for the purposes of demonstrating bioequivalence;*
> - *and that other drug has been marketed in Canada pursuant to an NOC; and*
> - *there is a patent list pertinent to that NOC.*

[24] Even as to the issue of listing a patent alone, the Federal Court of Appeal in *Wyeth Canada v. Ratiopharm Inc.* 2007 FCA 264 has stated that the jurisprudence "has not yet dealt with all possible scenarios". Sharlow J.A. said at paragraph 25:

> ***25*** *The jurisprudence has not yet dealt with all possible scenarios for listing a patent on the basis of a SNDS, and I do not propose to attempt a comprehensive summary. Each case must be determined on its own facts. For purposes of illustration, it is enough to note that, for example, a SNDS filed to reflect a change in the indicated use of a drug that contains a particular medicine may support the listing of a patent that contains a claim for that use of the medicine. On the other hand, a SNDS filed to reflect a change in the name of the drug or a change in the name of the drug manufacturer cannot support a patent listing.*

[25] It would be inappropriate for this Court to grant an Order of prohibition or a declaration, to the effect that the Minister must require all persons to address the two patents at issue in respect of any application that they make for an NOC. These matters are fact specific and the jurisprudence is evolving.

[26] It is equally inappropriate to grant such an Order respecting a specific fact situation in the absence of the party engaged in that situation. If there is no such party, then the fact situation is speculative and the Court should decline to grant such an Order based on speculation.

[27] Therefore, I will decline to make either the original or amended Order sought. In so declining, it is without prejudice to the Applicants to seek an appropriate Order when an appropriate real situation arises in which the relevant party is given an opportunity to appear.

[28] Costs at the middle of Column III are awarded to the Respondents.

JUDGMENT

For the Reasons given:

THIS COURT ADJUDGES that:

1. The application is dismissed;

2. The Respondents are entitled to costs to be assessed at the middle of Column III.

"Roger T. Hughes"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-252-07
STYLE OF CAUSE:	ABBOTT LABORATORIES LIMITED ET AL and ATTORNEY GENERAL OF CANADA ET AL
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