Date: 20080611

Docket: T-2011-06

Citation: 2008 FC 730

Ottawa, Ontario, June 11, 2008

PRESENT: The Honourable Mr. Justice Blanchard

BETWEEN:

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

Applicants

and

ATTORNEY GENERAL OF CANADA
and THE MINISTER OF HEALTH

Respondents

REASONS FOR JUDGMENT AND JUDGMENT

[1] The Applicants seek judicial review of the October 17, 2006, decision of the Minister of Health (the Minister) not to list Canadian Letters Patent No. 2,338,792 (the '792 Patent) on the Patent Register pursuant to the *Patented Medicines (Notice of Compliance Regulations)* SOR/93-133, as amended SOR/98-166 and SOR /99-379 (the Regulations), in respect of PREVACID 15 and 30 mg delayed-release capsules.

[2] Only patents listed on the Register will be afforded the protection of the Regulations. If a person has both a Notice of Compliance for a drug and a patent with claims to the medicine contained in that drug, that person may apply to the Minister to have the patent included on the Register against the medicine and in respect of the drug.

[3] In respect to listing, the Regulations, in force prior to October 5, 2006, required that the patent list identify the drug submission to which it relates and provide, amongst other information, the dosage form, strength and route of administration of the drug. Subsections 4(1) and 4(7) of the Regulations provide:

4.(1) A person who files or has filed a submission for, or has been issued, a notice of compliance in respect of a drug that contains a medicine may submit to the Minister a patent list certified in accordance with subsection (7) in respect of the drug.	4(1) La personne qui dépose ou a déposé une demande d'avis de conformité pour une drogue contenant un médicament ou qui a obtenu un tel avis peut soumettre au ministre une liste de brevets à l'égard de la drogue, accompagnée de l'attestation visée au paragraphe (7).
4.(7) A person who submits a patent list or an amendment to an existing patent list under subsection (1) or (4) must certify that (*a*) the information submitted is accurate; and (*b*) the patents set out on the patent list or in the amendment are eligible for inclusion on the register and are relevant to the dosage form, strength and route of administration of the drug in respect of which the submission for a notice of compliance has been filed.	4.(7) La personne qui soumet une liste de brevets ou une modification apportée à une liste de brevets aux termes des paragraphes (1) ou (4) doit remettre une attestation portant que : *a*) les renseignement fournis sont exacts; *b*) les brevets mentionnés dans la liste ou dans la modification sont admissibles à l'inscription au registre et sont pertinents quant à la forme posologique, la concentration et la voie d'administration de la drogue visée par la demande d'avis de conformité.

[4] Since the filing of the Applicants' patent list in respect to lansoprazole on January 25, 2006, the requirements for the contents of a patent list have changed by amendments to section 4

of the Regulations. Those amendments apply only to listing applications filed after October 5, 2006, and are consequently not relevant to the within application.

[5] In this instance, the Minister concluded that the ‘792 Patent, in respect of PREVACID 15 and 30 mg delayed-release capsules, was ineligible for listing. The Minister decided that the ‘792 Patent is not relevant to the dosage form of the PREVACID products in question as required by paragraph 4(7)(*b*) of the Regulations. I summarize below the Minister’s findings.

(i) The ‘792 Patent contains claims to an orally rapidly disintegrating solid preparation. However, the PREVACID products at issue are delayed-release capsules and granules for delayed-release oral suspension. For the PREVACID products at issue to be eligible for listing, they must not only be solid preparations, but must also be rapidly disintegrable in the oral cavity;

(ii) The Office of Patented Medicines & Liaison (OPML) agrees with the Applicant’s position that the term “solid preparation” is broad enough to encompass many dosage forms such as capsules and granules. However, the limitation “orally rapidly disintegrable” renders the ‘792 Patent not relevant to the delayed-release capsules and granules for delayed-release oral suspension. Specifically, the OPML does not agree with the Applicants’ claim that that the capsules and granules are rapidly disintegrable in the oral cavity; and

(iii) The OPML notes that ‘792 Patent has been found eligible for listing against PREVACID FasTab which is a rapidly disintegrating tablet product.

[6] The Applicants contend that PREVACID capsules are an orally rapidly disintegrable solid preparation, the claims of the ‘792 Patent are relevant to PREVACID capsules at issue and the Minister’s decision not to add the ‘792 Patent to the Patent Register was manifestly incorrect. The Respondents say the Minister did not err in deciding as he did.

I. The Issue

[7] Did the Minister commit a reviewable error in not listing the ‘792 Patent, in respect of PREVACID 15 and 30 mg delayed-release capsules, because the patent was not relevant to the dosage form?

[8] In addressing the above issue, the following matters must be considered:

1. What is the applicable standard of review of the Minister’s decision?
2. Having regard to the applicable standard of review:
   - What is the proper interpretation of the dosage forms approved in the NOC particularly in respect to the PREVACID 15 and 30 mg delayed-release capsule?
   - What is the proper construction of the applicable claims of the ‘792 Patent?
   - Is the ‘792 Patent relevant to the PREVACID 15 and 30 mg delayed-release capsules?

II. Standard of Review

[9] The Supreme Court of Canada in *Dunsmuir v. New Brunswick*, 2008 SCC 9, recently decided that there are now only two standards of review; reasonableness and correctness. The Court indicated that correctness must be maintained in respect of jurisdictional and some other questions of law (see *Dunsmuir* at paragraph 50). When applying the correctness standard, a reviewing court will not show deference to the decision maker’s reasoning process and must ask whether the tribunal’s decision was correct.

[10] The Supreme Court also teaches that reasonableness in judicial review is concerned mostly with the existence of justification, transparency and intelligibility within the decision-making process. But it is also concerned with whether the decision falls within a range of possible, acceptable outcomes which are defensible in respect of the facts and law (see *Dunsmuir* at paragraph 47; *Lake v. Canada (Minister of Justice)*, 2008 SCC 23, [2008] S.C.J. No. 23 (Lexis), at paragraph 41).

[11] Guidance with regard to the application of the reasonableness standard may be found in existing case law (*Dunsmuir* at paragraph 54). The appropriate degree of deference to be afforded a tribunal will be decided upon consideration of the following factors: the existence of a privative clause; whether the decision maker has special expertise in a discrete and special administrative regime; and the nature of the question to be answered. (*Dunsmuir* at paragraph 55).

[12] In the present case, the Minister was called upon to answer those questions as posed previously:

i. What is the proper interpretation of the dosage forms approved in the NOC particularly in respect of the PREVACID 15 and 30 mg delayed-release capsule?

ii. What is the proper construction of the applicable claims of the ‘792 Patent?

iii. Is the ‘792 Patent relevant to the PREVACID 15 and 30 mg delayed-release capsules?

[13] The first question concerns the interpretation of the NOC, in particular whether the dosage form at issue is “orally … disintegrable”. The question here, involves consideration of scientific evidence which is essentially factual in nature. The question also requires special expertise by the decision maker in order to understand and assess the evidence. Given the administrative regime at issue, which is specifically set up to consider the listing of patents on the Patent Register, the Minister has expertise to address such questions. The applicable standard of review for the first question is reasonableness. Given the nature of the question, the expertise of the Minister and the absence of a privative clause, the Minister is entitled to significant deference in making such decisions. (*Ferring Inc. v. Canada (Minister of Health)*, 2007 FC 300, [2007] F.C.J. No. 420 (Lexis), at para. 69.)

[14] The second question involves patent claims construction. It is settled law that construing patent claims is a matter of legal interpretation, which is a question of law reviewable on the correctness standard. See: *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, 2006 SCC 49, [2006] 2 S.C.R. 560 at paragraph 25;*GD Searle & Co. v. Canada (Minister of Health)*, 2008 FC 437, [2008] F.C.J. No. 520 (Lexis), at paragraphs 17-18; and *Abbott Laboratories Ltd. v. Canada (Attorney General)*, 2007 FC 797, [2007] F.C.J. No. 1046 (Lexis), at paragraph 13. On such questions, no deference is owed to the Minister. The applicable standard of review is correctness.

[15] The third question asks whether the ‘792 Patent is relevant to the PREVACID 15 and 30 mg delayed-release capsules, as required by paragraph 4(7)(*b*) of the NOC Regulations. The question requires that the pertinent claims of the ‘792 Patent be construed, and the NOC which

approved the impugned capsules, be interpreted. The claims, as construed must be assessed against the NOC as interpreted. Clearly, this is a mixed question of fact and law. The Federal Court of Appeal in *Ferring Inc. v. Canada (Minister of Health)*, 2007 FCA 276, [2007] F.C.J. No. 1138 (Lexis), at para. 8, held that "where there is a mixed question of law and fact then the standard of review is patent unreasonableness unless the question of law is extricable from the question of fact in which case the question of law is determined on the basis of correctness." I am satisfied that the question as to whether the '792 Patent is relevant to the PREVACID 15 and 30 mg delayed-release capsules is a mixed question of fact and law and reviewable on the reasonableness standard. Given the prior jurisprudence, the special expertise of the Minister in a discrete administrative regime and absence of a privative clause, I am satisfied that a high degree of deference is owed to the Minister on the question.

III. Preliminary matter

[16] In the normal course of events, on judicial review, the Court only considers the record that was before the decision maker in arriving at the decision under review. At the hearing of the application, I raised with the parties whether the Court should consider the affidavit of Dr. Stephen Byrn, sworn December 15, 2006, in this proceeding. Dr. Byrn's is the Applicants' expert and his affidavit was not before the Minister at the time of the decision. However, the Minister did have before him the submissions of the Applicants contained in a letter dated September 27, 2006, sent to the Therapeutic Products Directorate. These submissions comprehensively summarized Dr. Byrn's expert evidence. The Respondents are of the view that the information at issue was before the Minister and consequently, did not object to the Court

receiving the affidavit nor did they take issue with Dr. Byrn's expertise. The Affidavit was received and considered.

IV. What is the proper interpretation of the dosage forms approved in the NOC particularly in respect to the PREVACID 15 and 30 mg delayed-release capsules?

[17] The Drug PREVACID is marketed in Canada by the Applicant Abbott Laboratories Limited in four separate dosage forms: delayed-release capsules, granules for delayed-release oral suspension, FasTab delayed-release tablets and PREVACID® I.V. lyophilized powder for reconstitution. The decision under review concerns only PREVACID delayed-release capsules.

[18] PREVACID delayed-release capsules are opaque, hard gelatin capsules containing the active ingredient lansoprazole, in enteric-coated granules (paragraph 17. Dr. Byrn affidavit). The purpose of the enteric-coated granule formulation is to ensure that absorption of lansoprazole begins only after the granules leave the stomach and enter the small intestine. This is significant, because otherwise the acid content of the stomach would destroy the effectiveness of the active ingredient, lansoprazole (paragraph 20, Dr. Byrn affidavit).

[19] While the Product Monograph outlines administration options for the capsule, it is clear that the capsules are intended to be swallowed whole. This is obvious from a review of the Product Monograph concerning alternative Administration Options beginning at page 27 of the Monograph, which provides in part:

> *Alternative Administration Options*
>
> For adults and children who have difficulty swallowing capsules, there are three options. [My emphasis.]

> Option 1. PREVACID® (lansoprazole delayed-release capsules)
>
> Lansoprazole delayed-release capsules can be opened, and the intact granules contained within can be sprinkled on one tablespoon of applesauce and swallowed immediately. The granules should not be chewed or crushed**.**

[20] Option 2 of the Product Monograph deals with PREVACID FasTab (lansoprazole delayed-release tablets), which are not designed to be swallowed:

> Option 2. PREVACID® Fas Tab (Lansoprazole delayed-release tablets)
>
> Lansoprazole delayed-release tablets are available in 15 mg and 30 mg strengths. Lansoprazole delayed-release tablets are not designed to be swallowed intact or chewed. The tablet typically disintegrates in less than 1 minute.
>
> Place the tablet on the tongue and allow it to disintegrate with or without water until the particles can be swallowed.
>
> Do not chew the granules.

[21] The Product Monograph indicates that the capsules could be opened and their contents sprinkled on apple sauce, in cases where a patient had difficulty swallowing the capsule. This suggests that the capsules were intended to be swallowed whole. The FasTab dosage form, on the other hand, is specifically designed not to be swallowed intact, but to be placed on the tongue and kept there until the tablet disintegrates and the enteric-coated granules then swallowed. This dosage form was found to be relevant to the ‘792 Patent and consequently listed by the Minister.

[22] The Applicants contend that the apple sauce preparation, noted as an alternative option of administration, would be rapidly disintegrable in the mouth and as such is a solid preparation

relevant to the ‘792 Patent. In support of their contention, the Applicants rely on paragraphs 56 and 57 of Dr. Byrn’s affidavit, which I reproduce below:

> 56. The applesauce sprinkled with granules would itself constitute a solid preparation. That solid preparation would be rapidly disintegrable in the mouth. As saliva acts on the solid preparation in the mouth it disintegrates beginning the process by which the solid preparation is fully digested and the contents of the enteric-coated granules are absorbed in the bloodstream.
>
> 57. The disintegrants contained in the capsule should assist this process, and assist with patient compliance by ensuring that the granules are readily dispersed, thereby avoiding clumping which would make the preparation unpalatable.

[23] I disagree with Dr. Byrn’s characterization of the apple sauce preparation. In my view, it does not constitute an approved dosage form. It constitutes a method of administration of the contents of one of the approved dosage forms, namely the PREVACID delayed-release capsules. The Product Monograph speaks of an orally disintegrable dosage form. I agree with the Respondents, the act of opening and sprinkling the contents of the capsules on apple sauce is an act which in effect assists in the disintegration of the capsules. The capsules cannot then be said to be orally disintegrable. While the non-active incipient, included in the capsule, may assist in preventing clumping once sprinkled on the apple sauce, it cannot be said that the apple sauce so prepared is a solid preparation approved for marketing by the NOC. It is simply one method of administering the contents of the capsules.

[24] Upon consideration of the Product Monograph, on the whole, I do not read the PREVACID 15 or 30 mg delayed-release capsule to constitute a dosage form intended to be orally disintegrable. It is a dosage form intended to be swallowed whole.

[25] The Minister did not err in finding that "…the [delayed-release] capsules are to be swallowed whole." Nor did he err in concluding that "…the ideal preparation embodying the invention of the '792 Patent is a lansoprazole tablet designed to disintegrate rapidly in the mouth in order to facilitate delivery of the medicine to patients who have trouble swallowing tablets whole." These findings were reasonably open to the Minister on the record.

[26] I therefore conclude that the Minister's interpretation of the NOC in relation to the PREVACID 15 and 30 mg delayed-release capsules was reasonable. He committed no reviewable error in interpreting the NOC as he did.

V. What is the proper construction of the applicable claims of the '792 Patent?

[27] The '792 Patent is entitled "Rapidly disintegrable solid preparation" and contains 21 claims. Claims 1 through 12 are directed toward an orally disintegrable solid preparation comprising lansoprazole, a sugar, and a low-substituted hydroxypropylcellulose. Of particular interest to the issue in this application are claims 1 through 9 which I reproduce below:

1. An orally rapidly disintegrable solid preparation which comprises:

   (i) lansoprazole;

   (ii) a sugar in an amount of 5 to 97 parts by weight per 100 parts by weight of the solid preparation; and

(iii) a low-substituted hydroxypropylcellulose having 5% by weight or more to less than 7% by weight of a hydroxypropyl group, in an amount of 3 to 50 parts by weight per 100 parts by weight of the solid preparation.

2. The preparation of claim 1, which is a tablet.

3. The preparation of claim 1 or 2, wherein the sugar is a sugar alcohol.

4. The preparation of claim 3, wherein the sugar alcohol is mannitol or erythritol.

5. The preparation of claim 2, which disintegrates in buccal saliva of a healthy adult within 5 to 50 seconds and in water within 5 to 40 seconds; and has a hardness of 2 to 20 kg as measured with a tablet hardness tester.

6. The preparation of claim 5, wherein the sugar is a sugar alcohol.

7. The preparation of any one of claims 1 to 6, which further comprises a basic inorganic salt of sodium, potassium, magnesium or calcium, for stabilizing lansoprazole.

8. The preparation of any one of the claims 1 to 7, which comprises fine granules.

9. The preparation of claim 8, where lansoprazole is contained in the fine granules of the solid preparation. [My emphasis.]

[28] Claim 13 is directed toward the use of a low-substituted hydroxypropylcellulose for producing an orally rapidly disintegrable solid preparation comprising lansoprazole and sugar. Claims 14 and 21 are process claims. Claims 15 through 20 are directed toward an orally rapidly disintegrable pharmaceutical tablet consisting of lansoprazole, at least one sugar alcohol, a low-substituted hydroxypropylcellusole and at least one other ingredient selected from a number of excipients. Claim 21 provides for a process for producing tablets defined in any one of claims 15 to 20.

[29] The solid preparations claimed by the ‘792 Patent must be “orally rapidly disintegrable”. The Respondents agree that “solid preparation” is broad enough to include dosage forms such as capsules and granules. The meaning of “rapidly” is not in issue in this application. The capsules are capable of disintegration in the mouth within less than a minute, well within the time set out in the disclosure for rapid disintegration. The dispute between the parties turns on the correct construction of the terms “orally … disintegrable” in Claim 1 of the ‘792 Patent.

[30] Dr. Byrn’s opinion in respect to this aspect of the claim is found at paragraph 45 of his affidavit. He attests that “[u]se of the term “disintegrable” makes clear to a person skilled in the art that the preparation must be capable of such disintegration, not that it actually does so on each administration.”

[31] At paragraph 46 of his opinion, Dr. Byrn attests that the term “orally…disintegrable” read alone in the words of the claim might be considered ambiguous as to whether it actually requires rapid disintegrability in the mouth or merely after being taken orally. He opines that the specification of the ‘792 Patent supports the latter view. At paragraph 47 of his affidavit he states:

> Consideration of the specification of the ‘792 Patent supports the view that “orally disintegrable” as used in the Patent is a broad term that means the preparation is capable of breaking apart after being taken orally. At page 2, line 1-3 of the Disclosure, the Patent states “there has been desired the development of a rapidly disintegrable solid preparation having fast disintegrability in the existence of saliva in the oral cavity, in a little water or in the stomach”.

I do not agree that the terms “orally…disintegrable” in claim 1 to be ambiguous. In my view a solid preparation that is orally disintegrable, is clearly intended to disintegrate in the oral cavity. Turning to the disclosure statement, another passage supports a narrower construction of the terms “orally… disintegrable” than that proposed by the Applicants. Page 2, lines 5 to 11 of the disclosure, speaks to the nature of the dosage form intended to be protected by the invention:

> The present invention relates to:
>
> (1) a rapidly disintegrable solid preparation which comprises (i) a pharmacologically active ingredient, (ii) a sugar and (iii) a low-substituted hydroxypropylcellulose having 5 % by weight or more or less than 7 % by weight of hydroxypropoxyl group;
>
> (2) the preparation of the above (1), which is an orally rapidly disintegrable solid preparation;
>
> [My emphasis.]

[32] This last cited passage from the disclosure reflects the language of Claim 1, namely, “An orally rapidly disintegrable solid preparation…” In my view, “Orally disintegrable” can only mean, in the circumstances, that which disintegrates in the mouth, not, as argued by the Applicants, taken by mouth and subsequently disintegrable in the stomach.

[33] Further, page 12 of the disclosure also notes the preferred dosage form of the invention to be an orally disintegrable tablet:

> **4) Dosage Forms**
>
> As the dosage form of the rapidly disintegrable solid preparation of the present invention, for example, tablet, granule, fine granule and the like, preferably tablet is exemplified. Among rapidly disintegrable tablets such as an orally disintegrable tablet

> and a tablet disintegrable in water, the orally disintegrable tablet is preferable. [My emphasis.]

[34] In my view a correct claim construction of the ‘792 Patent is:

(a) the “solid preparation” claimed includes capsules;

(b) the “solid preparation” is intended to disintegrate in the oral cavity and not swallowed for disintegration in the stomach;

(c) the “solid preparation” is rapidly disintegrable within the meaning of the Patent.

[35] The Minister’s interpretation of the Claims is consistent with the above construction of the Claims of the ‘792 Patent. The Minister’s interpretation is therefore correct.

VI. Did the Minister err in deciding that the ‘792 Patent is not relevant to the PREVACID delayed-release capsules?

[36] In the context of this application, paragraph 4(7)(*d*) of the Regulations requires a determination as to whether the ‘792 Patent is relevant to the PREVACID 15 and 30 mg delayed-release capsules, a dosage form claimed in the NOC.

[37] The Minister’s finding is set out in David Lee’s letter of October 17, 2006. The following passage from the letter summarizes the finding:

> The PREVACID products at issue in the present matter are delayed-release capsules and granules for delayed-release oral suspension. Each of these products **are** delayed-release dosage forms comprised of enteric-coated granules (see page 35 of the PREVCID Product Monograph dated November 5, 2004). As indicated in our February 2, 2006 and February 14, 2006 letters informing your client that the ‘792 Patent was ineligible for listing

> on the Patent Register, the '792 Patent contains claims to an **orally rapidly disintegrating** solid preparation. Thus, in order to be eligible for listing on the Patent Register, the above-mentioned PREVACID products must, in the OPML's view, not only be solid preparations, but must also be rapidly disintegrable in the oral cavity. [Emphasis in original.]

[38] As discussed earlier in these reasons, I have determined the Minister's interpretation of the applicable claims of the '792 Patent is correct and his interpretation of the NOC is reasonable. In order to determine the issue of relevancy of the Patent to the dosage form, the Patent must be compared to the NOC. I find no error in the Minister's comparison of the claims of the '792 Patent and the NOC.

[39] In respect to the requirements of paragraph 4(7)(*b*) of the Regulations, the only disagreement is whether PREVACID capsules are "orally … disintegrable". The Applicants submit and contend that the uncontested expert evidence proves the PREVACID capsules are orally rapidly disintegrable for the following reasons:

> (i) Because, when placed in the mouth (whole), they are capable of rapid disintegration and therefore constitute "orally rapidly disintegrable solid preparations"; and
>
> (ii) Because they can also be administered by opening the capsule contents and sprinkling the granules on food (applesauce). When administered in this way, it is a solid preparation that is also capable of rapid disintegration and therefore constitutes an "orally rapidly disintegrable solid preparations".

[40] As stated earlier in these reasons, I have found the Applicants' stated position to be inconsistent with the correct construction of the applicable claims of the '792 Patent. I have also

determined that the Minister did not err in his interpretation of the NOC and the claims of the ‘792 Patent. The impugned capsules are intended to be swallowed and are not, as a consequence, orally disintegrable even though they are capable of rapid oral disintegration. I am left to conclude that the Minister’s decision that the ‘792 Patent is not relevant to the dosage form of the PREVACID delayed-released capsules to be reasonable such that adding the Patent to the register, pursuant to paragraph 4(7)(*b*), cannot be allowed.

VII. Conclusion

[40] For the above reasons, I will dismiss the application with costs to the Respondents, to be assessed in accordance with the middle of Column IV of Tariff B of the *Federal Courts Rules*, SOR/2004-283, s. 2.

JUDGMENT

THIS COURT ORDERS AND ADJUDGES that

1. The application is dismissed;

2. The Respondents are awarded costs to be assessed in accordance with the middle of Column IV of Tariff B of the *Federal Courts Rules*, SOR/2004-283, s. 2.

"Edmond P. Blanchard"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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