Date: 20060330

Docket: T-114-05

Citation: 2006 FC 411

OTTAWA, ONTARIO, MARCH 30, 2006

PRESENT: DEPUTY JUDGE STRAYER

BETWEEN:

PROCTOR & GAMBLE PHARMACEUTICALS CANADA INC.

Applicant

and

THE MINISTER OF HEALTH and THE ATTORNEY GENERAL OF CANADA

Respondents

REASONS FOR JUDGMENT AND JUDGMENT

Introduction

[1] This is an application for judicial review seeking the quashing of a decision of the Minister of Health not to list patents number 2,122,479 (‘479) and 2,293,815 (‘815). The applicant is a licensee of both these patents. The decision identified in the notice of application is that of the Minister dated December 23, 2004 in which he refused to list these patents under section 4 of the *Patented Medicines (Notice of Compliance) Regulations* (SOR/93-133). The applicant sought the

listing of these patents in relation to its drug Actonel, a drug marketed by it in Canada consisting of a tablet containing the active ingredient risedronate sodium. It is indicated for the prevention and treatment of osteoporis and treatment of Paget's disease of the bone. Notices of Compliance for different dosages of Actonel were issued in the years 1999-2002.

[2] In patent '815, issued on June 29, 2004, the first paragraph of the "Summary of the Invention" states as follows:

> The present invention is directed to a pharmaceutical formulation in an oral generally oval shaped, including but not limited to oval, modified oval and caplet shaped form. The dosage form is film coated and comprised of a safe and effective amount of an active ingredient and pharmaceutically-acceptable excipients. Said dosage forms facilitate rapid esophageal transit time thereby avoiding the release of active ingredient in the buccal cavity, pharynx, and esophagus and protecting the epithelial and mucosal tissues thereof from erosion, ulceration or other like irritation.

In the detailed description of the invention there appears the following paragraph:

> A. The Active Ingredient
>
> *The active ingredient herein may be any ingredient that yields a therapeutic benefit and is required to be delivered to the stomach of said human or other mammal. The benefits of the present invention are particularly realized when the active ingredient if released prior to entering the stomach may cause patient complaints such as heartburn, esophageal burning, pain and/or difficulty upon swallowing and/or pain existing behind and/or mid-sternum.* Such active ingredients are those which when dissolved have a pH below 2-3, drugs with cytotoxic activity (caustic) and/or the local development of a hyperosmolar solution which causes mucosal desiccation. Preferred actives are selected from the group consisting of emperonium bormide, doxycycline, and other tetracyclines/antibiotics, iron preparations, potassium chloride, quinidine, nonsteroidal anti-inflammatory drugs, alprenolol, ascorbic acid, captopril, thophylline, zidovoudine (AZT) and

> bisphosphonates. More preferred actives are risedronate, alendronate and pamidronate, most preferred is risedronate. (emphasis added)

Claim 1 of patent ‘815 is as follows:

> 1. An oral dosage form comprising a safe and effective amount of a bisphosphonate wherein said oral dosage form is oval shaped, about 0.23 to about 0.85 inches in length, about 0.11 to about 0.4 inches in width, and about 0.075 to about 0.3 inches in thickness and said oral dosage form is film coated to facilitate rapid esophageal transit and avoid irritation in the mouth, buccal cavity, pharynx, and esophagus wherein said film coating allows for delivery of said bisphosphonate to the stomach.

Among the claims it is only in claim 5 that risedronate is identified as one possible active ingredient. Claim 6 specifically claims such a dosage form where the active ingredient is risedronate.

[3] Thus it will be noted that the essence of the ‘815 invention is a film coated tablet dosage which avoids irritation to the oesophagus and other upper passages, delivering the active ingredient to the stomach where it is dissipated. Risedronate is identified as one of the possible active ingredients to be carried to the stomach in this fashion.

[4] With respect to patent ‘479, in its disclosures the invention is summarized in part as follows:

> SUMMARY OF THE INVENTION
>
> The present invention is directed to a novel enteric-coated oral dosage form of a risedronate active ingredient comprised of a safe and effective amount of pharmaceutical composition which is comprised of a risedronate active ingredient and pharmaceutically-acceptable excipients. Said dosage forms prohibit the release of the risedronate active ingredient in the buccal cavity, pharynx, esophagus, and

> stomach thereby [sic] protects the epithelial and mucosal tissues thereof from erosion, ulceration or other like irritation.
>
> Accordingly, the novel dosage forms described herein effect the delivery to the lower intestinal tract of said human or other mammal of a safe and effective amount of the risedronate active ingredient, and substantially alleviate esophagitis or esophageal irritation which sometimes accompanies the oral administration of risedronate active ingredients.
>
> DETAILED DESCRIPTION OF THE PRESENT INVENTION
>
> The present invention is directed to a novel enteric-coated oral dosage form of a risedronate active ingredient comprised of a safe and effective amount of a pharmaceutical composition which is comprised of a risedronate active ingredient and pharmaceutically-acceptable excipients. *Said dosage forms prohibit the release of the risedronate active ingredient in the mouth, pharynx, and esophagus and thereby protects the epithelial and mucosal tissues thereof from erosion, ulceration or other like irritation.* In addition, said dosage forms inhibit the release of the risedronate active ingredient to the stomach and anterior duodenum.
>
> Accordingly, the said dosage forms effect *the delivery to the lower intestinal tract* of said human or other mammal of a safe and effective amount of the risedronate active ingredient, *and substantially alleviate esophagitis or esophageal irritation which sometimes accompanies the oral administration of risedronate active ingredients.* (emphasis added)

Claim 1 of the patent is as follows:

> 1. An enteric-coated oral dosage form of a risedronate active ingredient comprised of a safe and effective amount of a pharmaceutical composition comprising a risedronate active ingredient and pharmaceutically-acceptable excipients, *wherein the risedronate active ingredient or the dosage form is enteric-coated or both the risedronate active ingredient and the dosage form are enteric-coated.* (emphasis added)

[5] Thus it may be seen that while patent ‘479 mentions an unspecified risedronate active ingredient, it essentially involves an enteric-coated tablet. The film-coated tablet of patent ‘815 was designed to carry the active ingredient as far as the stomach; the enteric-coated tablet of ‘479 was

designed to carry the active ingredient farther into the lower intestinal tract. If Claim 1 of ‘479 is ambiguous as to whether the delivery system or the payload is the invention, the Specifications in the Summary and Description of the Invention makes clear that its purpose is to secure the delayed-release of the active ingredients.

[6] The Minister’s representative in the letter of decision of December 23, 2004 which is the decision to which the applicant specifically refers in its notice of application for judicial review, concluded that neither the ‘815 patent nor the ‘479 patent was eligible for listing under section 4 of the Regulations because “neither patent contains a claim to the medicine risedronate sodium, or its use . . . .”. Counsel for the applicant alternatively argued that this decision does not apply to patent ‘479 or, if it does, the Minister had not given the applicant any warning in previous correspondence that he was contemplating refusing to list patent ‘479 on this basis. In its notice of application, however, and in written and oral submissions the applicant did not specifically attack the decision on patent ‘479 on the grounds of procedure or denial of fairness, and I must therefore address the validity of the decision as it is written: it is apparently based on paragraph 4(2)(b) of the *Patented Medicines (Notice of Compliance) Regulations* that neither patent could be listed because neither contains a claim to the medicine risedronate sodium or its use. The alternative to doing that would be simply to assume the validity of this decision in respect of patent ‘479 as the applicant has declined to attack it on its merits, taking the position that the decision does not mean what it clearly says.

[7] The decision of December 23, 2004 also refused to list the ‘479 patent on the basis of paragraph 4(7)(b) of the Regulations which requires that for a patent to be eligible for inclusion in the patent list it must be relevant *inter alia* to the dosage form of the drug (in this case Actonel) in association with which the patent is to be listed. The Minister concluded that the ‘479 patent contemplated as its dosage from an enteric-coated risedronate composition whereas Actonel is a film-coated tablet.

[8] I must take it from the applicant’s notice of application that it challenges all these elements in the decision.

Issues

(1) What is the standard of review?

(2) Was the Minister correct in refusing inclusion in the list because neither patent claims a medicine or the use of a medicine?

(3) Was the Minister correct in concluding that the dosage form claimed in patent ‘479 is not relevant to the dosage form of Actonel?

Analysis

Standard of Review

[9] The parties are in agreement that the standard of review in this case is correctness. I am satisfied that this conclusion would be justified by the usual pragmatic functional analysis. While I

recognize that the mere agreement of the parties does not absolve a judge from making the necessary pragmatic and functional analysis (See *Novartis Pharmaceuticals Canada Inc. v. Minister of Health* (2003), 28 C.P.R. (4th) 1 (F.C.A.). However in this agreement as to the standard of review the parties are in accord with several judicial determinations that in such matters correctness is the proper standard. (See e.g. *Eli Lilly Canada Inc. v. Minister of Health*, [2003] 3 F.C. 140 at para. 5 (F.C.A.)) The decisions involved here concern the interpretation of the patents and the interpretation of the Regulations, matters which a judge is in as good a position as the Minister to decide. It may also be noted that such decisions can have precedential value. There is, of course, no privative clause applicable.

Do Patents '815 and '479 Claim a "Medicine"?

[10] Jurisprudence in this field is roughly divided between the line of reasoning adopted by this Court in *Hoffmann-LaRoche Ltd. v. Minister of National Health and Welfare* (1995), 62 C.P.R. (3rd) 58 and approved by the Federal Court of Appeal (1995), 67 C.P.R. (3rd)25; as compared to the line of "device cases" recently reviewed by the Federal Court of Appeal in *GlaxoSmithKline Inc. v. Canada*, 2005 FCA 197. In *Hoffmann LaRoche* Justice Marc Noël was faced with the argument that where paragraph 4(1)(b) of the Regulations requires that a patent, to be listed, contain "a claim for the medicine itself or a claim for the use of the medicine" a formulation consisting of a medicine as the active ingredient and other substances could not itself be a "medicine". He concluded instead as follows:

> Pharmaceutical compositions with therapeutic value are a medicine in common parlance. Indeed most active ingredients must be combined with stabilized agents or absorption vehicles in one form or another to allow a patient to effectively ingest the medicine and achieve the intended therapeutic effect. As such, a medicine, like a drug, is generally understood to be a preparation or composition including active and non-active ingredients. (62 C.P.R. (3rd) at 72.)

[11] On the other hand, the "devices" cases have involved for the most part mechanical or physical arrangements for administering medicines, and the patents that claimed them have been found not to involve a claim for the medicine itself. Examples of these are inhalers, transdermal patches, implants or even tablets which are ingested but which involve physical devices such as osmotic pumps to distribute active ingredients after the tablet is inside the human or animal.

[12] A means for rationalizing the distinction between a "formulation" approach and the "device" cases was suggested recently by Justice Denis Pelletier in separate concurring reasons in *GlaxoSmithKline Inc. v. Canada* (above). That case involved patents related to tablets with a controlled rate release of active substances or a system for a similar purpose. The entire panel was in agreement that the patents in question did not specifically claim a particular medicine because it made reference to the use of the tablets or the system for the release of "active substances". Justice Pelletier however preferred to decide the matter on the basis that in reality the patents in question claimed in respect of the "delivery system" and not in respect of the "payload". He analyzed the claims in the patents in question and rationalized the jurisprudence as follows:

> 42. It is clear that these patents are designed to protect the system by which a great number of compounds, be they pesticide, herbicide, medicament, or room

> deodorizer, can be released into an aqueous fluid in a controlled manner. The "active substances" referred to in the patents are nothing more than the payload carried by the delivery system protected by the patents.
>
> 43. If one reviews the "medical devices" cases referred to above, one notes that the theme which runs through them all is the dichotomy between the delivery system and its payload. The attempts to define "claim for the use of the medicine itself" on the basis of whether the ingredients are mixed, or the presence of physical devices, all point to a more fundamental distinction between a delivery system and that which is delivered by that system. The distinction articulated in Glaxo Group Ltd. (C.A.) between devices for the administration of medicaments and the medicaments which are themselves administered is another way of expressing the difference between delivery system and payload. But, as this case shows, the distinction is more difficult to make when a tablet is both the thing administered and that which administers the drug. The distinction between delivery system and payload bridges both types of tests by focussing on the substance of the patent. Does the patent protect the delivery system or does it protect the payload?

[13] That case has subsequently been followed by this Court in *Biovail Corp. v. Canada*, [2005] F.C.J. No. 1402. In that case the patent described a kind of control-release tablet made up of an active ingredient and two "intelligent polymers". Only one of the 32 claims in the patent mentioned the drug in issue. Justice James O'Reilly. concluded that the patent was for a formulation for a delivery system that can be used for many different medicines:

> Biovail's tablet involves mixing an active ingredient with other substances, not inserting an active ingredient into a mechanical capsule or shielding it within inactive layers and walls. Still, the patent's paramount purpose clearly is to protect the delivery system, not the payload. (at para. 20).

[14] Similarly I have concluded that patent '815 does not contain a claim for a medicine or "payload" but for a "delivery system". Claim 1 is only in respect of a delivery system. Claim 5

identifies risedronate as one possible active ingredient and Claim 6 specifically claimed a dosage form where the active ingredient is risedronate.

[15] It is perhaps appropriate at this point to consider when recourse may be had to the disclosures to clarify the meaning of a claim. (That this Court should even be trying to interpret patent claims in a summary proceeding for judicial review, rather than in a trial for infringement, bespeaks the weakness of the system created by these Regulations.) It is now well settled that in interpreting claims the Court should take a purposive approach to the patent. If the claim is clear and unambiguous then this Court should give it its literal sense. If it is not then this Court may have recourse to the disclosures which are supposed to set out the purpose of the invention in relation to the problem to be solved by it. See e.g. *Whirlpool Corp. v. Camco Inc.*, [2000] 2 S.C.R. 1067 paras. 42-45, 49.

[16] In the case of patent ‘815 I think the claims are adequately clear to indicate that it claims only a delivery system. However, if there is any uncertainty that the invention which is claimed is with respect to the dosage form, I think resort may be had to the disclosures to see that the paragraph quoted above (para. 2) from the “Summary of the Invention” describes only the form of the dose and its purpose which is to avoid the release of the (unspecified) active ingredient in the esophagus, etc. The opening words of the Detailed Description states that “The active ingredient herein may be *any ingredient* that yields a therapeutic benefit and is required to be delivered to the stomach of said human or other mammal. . . .” (emphasis added)

[17] I have similarly concluded that patent ‘479 in reality claims a delivery system and not a payload. It is true that in Claim 1 reference is made to “An enteric-coated oral dosage form of a risedronate active ingredient . . .”. First it may be noted that the claim is specific as to the form of the dosage attached to its coating, and is unspecific as to what risedronate active ingredient would be involved. If there is any ambiguity as to whether the claim is for the form and coating of the dosage or as to the active ingredient, one may again have resort to the disclosures, excerpts from which are quoted above. The Summary of the Invention and its Detailed Description both make clear that the purpose and function of the invention is to avoid the irritations that would flow from the release of risedronate in the upper cavities including the esophagus, the function of the enteric coating be to “effect the delivery to the lower intestinal tract . . . of a safe and effective amount of risedronate active ingredient, and substantially alleviate esophagitis or esophageal irritation which some times accompanies the oral administration of risedronate active ingredients”. I cannot interpret that to mean that the purpose of the patent is to protect a monopoly on risedronate as a payload but rather to protect a system of delivery of that payload to the “lower intestinal tract”.

[18] Adopting, with respect, the reasoning of Justice Pelletier in *GlaxoSmithKline Inc.* (above) at paras. 42, 43, I do not believe that the scope of the claims should depend on whether the payload is formulated with the delivery system or whether the delivery system is a mechanical or physical device separate from the active ingredient.

[19] I therefore will dismiss the application to have the Minister's decision set aside to the effect that neither patent '815 nor '479 contains a claim to a medicine.

[20] After the hearing of this matter was concluded on February 14, 2006 counsel for the Minister brought to my attention a decision of Justice Douglas Campbell, issued on February 16, 2006 in *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2006 FC 210. I gave counsel for the applicant the opportunity to comment in writing on this decision. I have concluded that this decision does not bear on the present case. It appears to concern matters of evidence as to how generic company applications for notices of compliance are or would be dealt with by the Minister, to enable this Court to determine how paragraph 4(2)(b) of the Regulations should be interpreted. While there was some conflicting evidence on this subject referred to by the parties in the present case, I am satisfied that determination of the meaning of paragraph 4(2)(b) is quite possible here without resort to evidence as to how the Regulations may or may not be administered.

Is Patent '479 Relevant to Actonel?

[21] Paragraph 4(7)(b) of the Regulations requires that a person seeking to have his patent included in a patent list in association with a drug approved for sale by a Notice of Compliance

> must certify that . . .
>
> > (b) the patents set out on the patent list . . . 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.

[22] The Minister has determined that patent ‘479 is not relevant to Actonel for the following reason:

> The ‘479 patent contains claims directed to an *enteric-coated* risedronate composition. The dosage form of ACTONEL, on the other hand, is that of a *film-coated* tablet. For this reason . . . the dosage form described in the ‘479 patent [is] not relevant to that of ACTONEL and . . .the ‘479 patent [is] thus ineligible for listing on the Patent Register as a result.

[23] The Minister in support of this position argues that patent ‘479 is not relevant to the “dosage form” of Actonel because Actonel is a rapid release drug whereas the patent is for an enteric coated or modified-release dosage form for the delivery of risedronate sodium.

[24] The applicant, on the other hand, argues that the relevant dosage form is that of a tablet containing the drug and both Actonel and patent ‘479 involve the administration of a drug by an oral tablet.

[25] The applicant relies principally on the decision of the Federal Court of Appeal in *Eli Lilly Canada Inc. v. Minister of Health*, [2003] 3 F.C. 140. There a majority of two concluded, as best I can understand it, that paragraph 4(7)(b) does not require that the invention disclosed in the patent be included or embodied in the drug named in the Notice of Compliance for it to be relevant to that drug. Instead, as I infer from the facts, it is sufficient that both contain the same active ingredient. Justice Sharlow, writing for herself and Justice Malone, in reference to the words of paragraph 4(7)(b) quoted in paragraph 18 (above) stated that these words do not describe any relationship

between the drug named in the notice of compliance and the patents that may be included on the patent list. “Rather ‘the drug in respect of which the submission for a notice of compliance has been filed’ is, simply, Tazidime” (para. 34). In the context I take this to mean that because the patent was for a formulation including the active ingredient ceftazidime, it could be listed in association with any NOC drug containing ceftazidime as an active ingredient.

[26] Happily I need not consider further the implications of this. Whatever its significance, Justice Sharlow expressly said that the Minister in that case had not taken a position based on paragraph 4(7)(b), that the patent in issue there was not “relevant to the dosage form, strength and route of administration” of the drug named in the NOC. (See *Eli Lilly* above at para. 28). But in the present case the Minister has taken that position precisely: namely that patent ‘479 is not relevant to the dosage forms of Actonel. (see para. 22 above). This is an issue expressly not raised in *Eli Lilly* and the decision has no application.

[27] As discussed above I am satisfied that the invention of patent ‘479 is the delivery system, the enteric coating on the tablet. Actonel embodies no such delivery-system: it is in an immediate-release form.

[28] The applicant argues that the coating on a tablet does not pertain to “dosage form”. It cited a remark made in passing by Justice Iacobucci in *Eli Lilly & Co. v. Novopharm Ltd.*, [1998] 2 S.C.R. 129 at para. 102, to the effect that in that case the “final-dosage form” was distinguished from the

bulk form of the same drug by being coloured and pressed into tablet shape. From this the applicant deduces that "dosage form" as referred to in the *Patented Medicines (Notice of Compliance) Regulations* simply refers to the shape of the tablet. Thus the fact that patent '479 contemplates an enteric-coated tablet (where the coating for delayed-release purposes is the very invention taught by the patent) is, in the applicant's view, irrelevant to dosage form. It should first be observed that Justice Iacobucci's remark in the *Eli Lilly* case (1998) (above) did not involve paragraph 4(7)(b) of the Regulations but rather concerned a question of infringement and the rights of a licensee under a license to change the "final-dosage form". It is clear that he was not purporting to give an exhaustive definition of "final-dosage form". Secondly, patent '479 itself in its detailed description of the invention and in claim 1, consistently refers to "an enteric-coated oral dosage form" clearly associating the coating with the form. I am therefore satisfied that a tablet with an enteric coating for delayed-release is a different dosage form from a tablet with no such coating.

[29] I therefore conclude that patent '479 should not be listed because it is not relevant to the dosage form of Actonel.

Disposition

[30] The application for judicial review will therefore be dismissed with costs.

JUDGMENT

IT IS HEREBY ORDERED AND ADJUDGED THAT:

(1) the application for judicial review be dismissed; and

(2) the respondent be awarded costs of the application.

"Barry L. Strayer"
Deputy Judge

FEDERAL COURT

NAME OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	T-114-05
STYLE OF CAUSE:	PROCTOR & GAMBLE PHARMACEUTICALS CANADA INC. v. THE MINISTER OF HEALTH and THE ATTORNEY GENERAL OF CANADA
PLACE OF HEARING:	Toronto, Ontario
DATE OF HEARING:	February 14, 2006
REASONS FOR JUDGMENT:	STRAYER D.J.
DATED:	March 30, 2006

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