Date: 20070709

Docket: T-59-06

Citation: 2007 FC 729

Vancouver, British Columbia, July 9, 2007

PRESENT: The Honourable Mr. Justice O'Reilly

BETWEEN:

JANSSEN-ORTHO INC.

Applicant

and

ATTORNEY GENERAL OF CANADA
and THE MINISTER OF HEALTH

Respondents

REASONS FOR JUDGMENT AND JUDGMENT

[1] Janssen-Ortho Inc. asks me to overturn a decision of the Minister of Health refusing to list its drug patent (Canadian Patent No. 2,265,668) on the register. The Minister concluded that the '668 patent was not eligible to be listed because it did not include a "claim for the medicine itself or a claim for the use of the medicine" as required by the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, ss. 3(1), 4(2)(*b*) (relevant enactments are set out in an Annex).

[2] Janssen-Ortho argues that the Minister decision was incorrect. However, I can find no error and must, therefore, dismiss this application for judicial review.

I. Issue

[3] Did the Minister err in refusing to list the ’668 patent?

II. Analysis

(a) Scope of the Regulations

[4] A person who wishes to have a drug patent protected under the Regulations must show that the patent contains a claim for “the medicine itself or a claim for the use of the medicine” (s. 4(2)(*b*)). This requirement is met by patents that claim formulations of active and inactive ingredients: *Eli Lilly Inc.* v. *Canada (Minister of Health)*, 2003 FCA 24, [2003] F.C.J. No. 75 (C.A.) (QL); *Hoffman-La Roche Ltd.* v. *Canada (Minister of National Health and Welfare)*, [1995] F.C.J. 985 (T.D.) (QL). However, it is not met by patents for devices whose purpose is to administer an active ingredient to a patient (such as inhalers or patches): *Glaxo Group Ltd.* v. *Novopharm Ltd.*, [1998] F.C.J. No. 155 (T.D.) (QL); *Novartis Pharmaceuticals Canada Inc.* v. *Canada (Minister of Health)*, 2003 FCA 299, [2003] F.C.J. No. 1065 (C.A.) (QL). Nor is it met by patents for combinations of active and inactive ingredients which protect a “delivery system” for a medicine rather than the “payload” itself: *GlaxoSmithKline Inc.* v. *Canada (Attorney General)*, 2005 FCA 197, [2005] F.C.J. No. 915 (C.A.) (QL) at para. 43-4; *Biovail* v. *Canada (Minister of Health)*, 2005 FC 1135, [2005] F.C.J. No. 1402 (T.D.) (QL), aff’d 2006 FCA 10, [2006] F.C.J. No. 475 (C.A.) (QL).

(b) The Minister's decision

[5] By way of a letter dated December 13, 2005, the Director of the Office of Patented Medicines and Liaison, on behalf of the Minister, informed Janssen-Ortho that the '668 patent was ineligible for listing on the register. After summarizing the decisions of this Court and of the Federal Court of Appeal, the Director concluded that the '668 patent protects "tablets and dosage forms which could be used in the administration of methylphenidate hydrochloride" but does not include a claim for that medicine itself or for the use of that medicine.

[6] The question, then, is whether the '668 patent protects a delivery system or a payload. If it claims the former, the Minister's decision was correct. If it claims the latter, the Minister was wrong.

(c) The '668 patent's claims

[7] Claims 1 to 7 of the patent relate to tablets containing methylphenidate or a pharmaceutically acceptable salt of methylphenidate. Claims 8 to 25 cover particular dosage forms for the various layers of the tablet. Claims 26 and 27 claim the use of the tablets and the dosage forms for the treatment of attention deficit disorder (ADD).

[8] Janssen-Ortho argues that the patent includes claims for the medicine methylphenidate itself and for the use of that medicine in the treatment of ADD. In my view, however, the patent claims

the *design* for a particular tablet containing methylphenidate and the use of that tablet for the treatment of ADD.

[9] Claim 1 of the ‘688 patent refers to a tablet containing methylphenidate with the following characteristics:

- the tablet’s length exceeds its width;
- there is a drug composition containing methylphenidate in the tablet’s first layer;
- there is a second layer containing a polymer;
- a semipermeable layer surrounds the first and second layers;
- the semipermeable layer contains a passageway at one end of the tablet which allows for release of the methylphenidate contained in the first layer;
- the methylphenidate is released over the course of two to 8 hours; and
- the tablet is coated with a composition of methylphenidate.

[10] As I read them, the remaining claims (2 to 25) cover variations in the amounts of the various constituent elements of the tablets and in the kinds of non-medicinal ingredients. As mentioned, claims 26 and 27 relate to the use of these various forms of the tablet in the treatment of ADD.

[11] In my view, these claims are not for the medicine methylphenidate or for its use. They relate to a particular form of tablet that permits a desired release profile for the tablet’s active ingredient,

methylphenidate. This is borne out not just by the drafting of the claims, but by the narrative portions of the ‘668 patent and by Janssen-Ortho’s own expert evidence.

[12] The ‘668 summarizes the invention it contains as follows:

> This invention relates to a dosage form for delivering an increasing dose of drug. The invention concerns further a dosage form for delivering an increasing dose of drug per unit time over an extended time for continuous effective therapy.

[13] The patent states that the invention it discloses is intended to address problems of drug tolerance. It notes that there is “a critical and pressing need” for novel dosage forms that deliver drugs at a “sustained-ascending rate”. Therefore, the object of the invention is to provide “a novel and unique dosage form that overcomes the shortcomings known to the prior art and thereby makes an advancement in the drug dispensing art”. The bulk of the patent’s disclosure describes the benefits and mechanics of a tablet possessing the characteristics set out in the claims, and described above. There is very little said about methylphenidate. It is clear that the design is a generic one, which would permit administration of many different medicines. For example, the patent states that the overcoat of the tablet could contain “opioids, barbiturates, hypnotics, psychostimulants, psychodepressants, central nervous system acting drugs, analgesics and catecholamines”.

[14] The patent does mention that one of its aspects is a tablet containing methylphenidate. It also includes detailed descriptions of tablets containing methylphenidate among the various examples set

out in the patent. However, all of the examples emphasize the structure and mechanics of the tablet. The particular active ingredient in each of them appears incidental to the workings of the tablet.

[15] Dr. James W. McGinity, Professor of Pharmacy at the University of Texas, Austin, provided an expert opinion to Janssen-Ortho. In it, he states that prior to the invention in the ‘668 patent there was a need to find a way to deliver methylphenidate in a sustained-ascending rate in order to deal with issues of tolerance and dosage frequency. The solution to this problem lay in the creation of novel dosage forms for methylphenidate. He states: “[I]t is clear that the disclosure in the ‘668 Patent relates to a pharmaceutical formulation in which an active ingredient such as methylphenidate may be released in ascending profile and that this is achieved by combining dimensions of the dosage form with certain non-medicinal elements”.

[16] In my view, Dr. McGinity’s opinion confirms that the main thrust of the ‘668 patent is a tablet that possesses the means of delivering an active ingredient according to a particular release profile, and the use of such a tablet for the treatment of ADD. It does not claim the medicine itself or the use of the medicine.

[17] Janssen-Ortho raised a further argument at the hearing. It suggested that the existence of an outer coating of methylphenidate was really the most important part of the invention described in the ‘668 patent and, therefore, because the outer coating was made up of methylphenidate itself, the patent contained a claim for that medicine, and for the use of that medicine in the treatment of ADD. It submitted that the outer coating is critical for dealing with young people who exhibit

symptoms of ADD in the schoolyard. Because the outer coating contains the active ingredient, it will address symptoms immediately, while the rest of the active ingredient is released gradually over the ensuing hours. Further, the outer coating enhances the effectiveness of the remainder of the active ingredient because there will still be some of the active ingredient in the blood stream when the rest of it "kicks in".

[18] I see no support for this submission. The patent mentions the outer coating, but there is no indication in it that the outer coating is as important as Janssen-Ortho suggests. In fact, the opposite is true. There is far more discussion of the internal operation of the tablet and the need for release of the medicine over a longer period of time. The same is true in Dr. McGinity's opinion. Further, the release profile for the tablet shows that the methylphenidate in the outer coating dissipates in the first hour after ingestion. It does not appear to contribute to an elevation in the amount of active ingredient available over the ensuing hours, as Janssen-Ortho suggested.

[19] Based on the foregoing, I have concluded that the Minister did not err in finding that the '668 was ineligible to be listed on the register. I must, therefore, dismiss this application for judicial review with costs.

JUDGMENT

THIS COURT'S JUDGMENT IS THAT:

1. The application for judicial review is dismissed with costs.

"James W. O'Reilly"
Judge

Annex

Patented Medicines (Notice of Compliance) Regulations, SOR/93-133	*Règlement sur les médicaments brevetés (avis de conformité)*, DORS/93-133
Register	Registre
3. (1) The Minister shall maintain a register of any information submitted under section 4. To maintain it, the Minister may refuse to add or may delete any information that does not meet the requirements of that section.	**3.** (1) Le ministre tient un registre des renseignements fournis aux termes de l'article 4. À cette fin, il peut refuser d'y ajouter ou en supprimer tout renseignement qui n'est pas conforme aux exigences de cet article.
Patent List	Liste de brevet
4.(2) A patent list submitted in respect of a drug must	**4. (**2) La liste de brevets au sujet de la drogue doit contenir les renseignements suivants :
…	[…]
(*b*) set out any Canadian patent that is owned by the person, or in respect of which the person has an exclusive licence or has obtained the consent of the owner of the patent for the inclusion of the patent on the patent list, that contains a claim for the medicine itself or a claim for the use of the medicine and that the person wishes to have included on the register;	*b*) tout brevet canadien dont la personne est propriétaire ou à l'égard duquel elle détient une licence exclusive ou a obtenu le consentement du propriétaire pour l'inclure dans la liste, qui comporte une revendication pour le médicament en soi ou une revendication pour l'utilisation du médicament, et qu'elle souhaite voir inscrit au registre;

FEDERAL COURT

SOLICITORS OF RECORD

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