Date: 20080729

Docket: T-724-06

Citation: 2008 FC 919

BETWEEN:

ABBOTT LABORATORIES LTD. and TAP PHARMACEUTICALS INC.

Applicants

and

THE MINISTER OF HEALTH, APOTEX INC. and TAKEDA PHARMACEUTICAL COMPANY LTD.

Respondents

REASONS FOR THE ORDER OF APRIL 10, 2008

SIMPSON J.

[1] Abbott Laboratories Ltd. (Abbott) is an innovator pharmaceutical company. TAP Pharmaceuticals Inc. (TAP) is a joint venture between Abbott and Takeda Pharmaceutical Company Ltd. (Takeda). Takeda is the owner of the Canadian Patent No. 1,312,548 (the 548 Patent) and, as such, has been made a party to these proceedings pursuant to subsection 6(4) of the *Patented Medicines (Notice of Compliance Regulations)* S.O.R./193-133 (the *NOC Regulations*). TAP is the licensee under the 548 Patent.

[2] Apotex Inc. (Apotex) is a Canadian generic pharmaceutical manufacturer. It is seeking approval from Health Canada to market and sell a generic drug containing lansoprazole. The Applicants applied for an Order of Prohibition (the Application) preventing the Minister of Health

from issuing a Notice of Compliance (an NOC) to Apotex until the expiry of the 548 Patent. By way of a motion filed on October 3, 2007, Apotex sought to dismiss the Application pursuant to paragraph 6(5)(*a*) of the *NOC Regulations* on the basis that the 548 Patent was not eligible to be listed on the Patent Register. On April 10, 2008, I granted the motion. These are the reasons for that decision.

Lansoprazole

[3] Abbott and TAP (the Applicants) have been marketing lansoprazole delayed release capsules in Canada under the brand name PREVACID® since they received their first NOC from Health Canada in 1995.

[4] Lansoprazole is a proton pump inhibitor which reduces gastric acid secretions in the stomach. After ingestion it is absorbed in the small intestine. Lansoprazole's effectiveness is reduced or destroyed by the presence of acid. It is therefore protected from acid while it moves through the stomach to its point of absorption. The usual way to accomplish this protection is to coat the lansoprazole with an enteric coating.

The 548 Patent and PREVACID®

[5] The 548 Patent has the title "Spherical Granules Having Core and their Production". The abstract of the disclosure reads:

> The spherical granules having a core coated with spraying powder containing a drug and low substituted hydroxypropylcellulose, because of their excellent hardness, can be coated further evenly, (e.g., sustained release coating, gastric coating, enteric coating), and at the same time the granules are excellent in disintegration.

[6] The patent includes 41 claims. Independent claim 1 and dependent claims 8, 9 and 11 are significant and are set out below.

> 1. Spherical granules having a core coated with spraying powder containing a drug and low substituted hydroxypropylcellulose having a hydroxypropyl group content of from about 4 to about 20% by weight
>
> 8. The spherical granules having a core according to claim 1 where the drug is a drug for the digestive system.
>
> 9. The spherical granule having a core according to claim 8, wherein the drug for the digestive system is a benzimidazole compound having antiulcer activity, cimetidine, raniditine, pancreatin or 5-aminosalicyclic acid.
>
> 11. The spherical granule having a core according to claim 9, wherein the benzimidazole compound is [lansoprazole] or [omeprazole].

[7] Many of the other claims limit the drug mentioned in Claim 1 to drugs affecting other systems of the body. For example: Claims 2 and 3 limit the drug to drugs for the central nervous system, Claims 4 and 5 limit the drug to drugs for the circulatory system, Claims 6 and 7 limit the drug to drugs for the respiratory system, Claims 12 and 13 limit the drug to antibiotic or

chemotherapeutic agents, Claims 14 and 15 limit the drug to drugs for the metabolic system and Claims 16 and 17 limit the drug to vitamins. It is unclear from the evidence just how many drugs are covered by the 548 Patent. Counsel for Apotex suggested thousands of drugs. Counsel for Abbott disputed this but conceded that the 548 Patent applies to a "great many" medicines.

[8] PREVACID® is composed of cores made of a sucrose which are then coated with the spraying powder described in the 548 Patent. The drug in the spraying powder is lansoprazole (the First Coat). The resulting granules (the Granules) are then coated with an enteric coating (the Second Coat) and put into gelatine capsules. Note that the 548 Patent does not claim the Second Coat; it is applied after the process described in the 548 Patent creates the Granules.

Issue

[9] The parties agree that the 548 Patent does not claim a use for lansoprasole. Therefore, the sole question before me is whether the 548 Patent includes a claim for the medicine lansoprazole itself (i.e., the payload) or whether it claims a delivery system. As Justice Karen Sharlow of the Federal Court of Appeal wrote for a unanimous panel in *Wyeth Canada v. Ratiopharm Inc.*, 2007 FCA 264, 60 C.P.R. (4th) 375 at para. 56, leave to appeal to S.C.C. refused, [2007] S.C.C.A. No. 572, if Apotex can show, on a balance of probabilities, that the patent is for a delivery system, then the patent is not eligible to be listed on the Patent Register.

[10] Under the *NOC Regulations*, the Minister of Health maintains the Patent Register. The Register consists of patent lists submitted in respect of drugs for which a NOC has been issued. Paragraph 4(2)(b) of the *NOC Regulations* provides that only a patent "that contains a claim for the medicine itself or a claim for the use of the medicine" may be eligible to be listed on the Register.

Recent Developments in the Law

[11] Recent decisions have held that patents which claim a composition or a formulation may be a claim for the medicine itself or may be a claim for a delivery system. Justice John Evans, writing for a unanimous panel of the Federal Court of Appeal in *Biovail Corp. v. Canada (Minister of Health and National Welfare)*, 2006 FCA 105, 46 C.P.R. (4th) 321 at para. 7 held that it depended on how the patent is construed.

> Whether a patent claims a composition, which can be "the medicine itself", or a delivery system for medicine, is a question of construing the patent. While each claim of the patent must be considered individually, they must not be considered in isolation from the other claims and the rest of the patent.

[12] The decision in *Biovail* builds on the decision of Justice Denis Pelletier in *GlaxoSmithKline Inc. v. Canada (Attorney General)*, 2005 FCA 197, 40 C.P.R. (4th) 193 in which he discussed the prior case law. He said:

> **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] Deputy Justice Barry Strayer followed this reasoning in *Proctor & Gamble Pharmaceuticals Canada Inc. v. Canada (Minister of Health)*, 2006 FC 411, 289 F.T.R. 288 noting at paragraph 18 "that the scope of the claims should [not] 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." To the extent that the claims were ambiguous, Strayer D.J. looked to the disclosures to determine the purpose and function of the invention.

Construction of the 548 Patent

[14] Counsel for Abbott conceded that the fact that the 548 Patent refers to a great many drugs is relevant but argued that it is not determinative. However, for the reasons discussed below, I have concluded that the 548 Patent is claiming a delivery system for a great many drugs and is not claiming lansoprazole or any other drug as a payload.

[15] Dr. Harold Hopfenberg, an expert witness for Apotex, noted that the 548 Patent does not teach anything about lansoprazole itself. Rather, he notes at paragraph 21 of his affidavit that lansoprazole is just one example of the many drugs that can be used in the spraying powder.

> As such, the notional skilled person would understand that no significance is attached to the identification of lansoprazole and omeprazole as two members of the class of benzimidazole drugs for the digestive system other than that these compounds were specifically described in the prior art patents and that the very large number of exemplar drugs disclosed was not meant to be limiting.

[16] The present case is similar to *Abbott Laboratories v. Canada (Minister of Health)*, 2007 FC 622, 57 C.P.R. (4th) 450, which was affirmed by Mr. Justice James Hugessen in 2007 FC 865, 62 C.P.R. (4th) 45. It dealt with a patent for a rapidly disintegrating oral dosage form which mentioned 190 different possible active ingredients including lansoprazole. In finding that that patent was not eligible for listing, Prothonotary Roger Lafrenière said:

> **49**. … I prefer the evidence of David Graham who asserts that the '753 Patent does not seek to protect the medicine lansoprazole any more than it protects the other 189 Active Ingredients described in the disclosure. The use of lansoprazole, and indeed any other Active Ingredient in the '753 Patent, is included in the patent simply to show how an Active Ingredient, with its known uses, can be delivered by the patented invention. In fact, the uses of the Active Ingredients appear to be included merely to explain the rather obvious point that the appropriate dosing of even a single Active Ingredient will vary depending on the disease state and the subject being treated. I concur that the claims referring to specific active ingredients are merely narrow expressions of the patented delivery system and do not constitute claims to those medicines or their use.
>
> **51**. Lansoprazole is merely one of several "payloads" which can be used in the delivery system. The claims mentioning lansoprazole are no more than a narrow expression or embodiment of the delivery

> system which is the patented invention, applied to 1 of at least 190 possible Active Ingredients

[17] I note that the title, abstract and other disclosure for the 548 Patent clearly show that it discloses spherical granules which are excellent in hardness and disintegration. The benefit of the patent – the problem that it solves – as described in the patent disclosure is that it creates granules which "because of their excellent hardness, can be further coated evenly (e.g., sustained release coating, gastric coating, enteric coating), and at the same time the granules are excellent in disintegration."

[18] The disintegration benefit of the 548 Patent supports its role as a delivery system. According to Dr. Vemula Kusum Devi, an expert witness for Abbott, in paragraph 19 of her affidavit:

> A disintegrant expands when wet, causing the formulation or dosage form to break apart and disintegrate, thereby releasing the [active pharmaceutical ingredient] to be available for dissolution and subsequent absorption.

[19] At paragraph 25 of his affidavit, Dr. Hopfenberg (for Apotex) concluded that the Granules are a delivery system. He said:

> It would be generally understood by the notional skilled person that [low substituted hydroxypropylcellulose] functions as a disintegrating carrier (disintegrant), and in some instances as a binder for tablets (not capsule granules)

[20] Dr. Stephen Byrn, also Apotex's expert, acknowledged that there can be more than one delivery system. In paragraph 30 of his affidavit, he admits that both the Second Coat and the

capsule are delivery systems. The capsule delivers the drug as far as the stomach and from there the Second Coat delivers the drug to the small intestine.

[21] Hence, the 548 Patent may be viewed as a third delivery system. Once the Second Coat delivers the Granules to the small intestine, the Granules created using the 548 Patent disintegrate quickly and deliver the right amount of medicine in a timely way to the blood stream. The Granules are therefore the last step in the delivery process.

[22] The 548 Patent may also be viewed as a means of enhancing the second delivery system which is the Second Coat. Because the hard Granules created using the 548 Patent allow the Second Coat to be applied more easily and evenly, the enteric coating becomes more effective as a delivery system.

[23] In either case, the 548 Patent claims a delivery system and does not include a claim for lansoprazole, the medicine itself. Accordingly, an Order was made stating that the 548 Patent is not eligible for listing on the Patent Register.

"Sandra J. Simpson"

Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-724-06
STYLE OF CAUSE:	ABBOTT LABORATORIES LIMITED et al . v. THE MINISTER OF HEALTH et al
PLACE OF HEARING:	VANCOUVER, ONTARIO
DATE OF HEARING:	MARCH 18, 2008
REASONS FOR ORDER:	SIMPSON J.
DATED:	JULY 29, 2008

APPEARANCES:

Andrew Reddon Ariel Neuer	FOR THE APPLICANTS
Andrew Brodkin Richard Naiberg Belle Chan	FOR THE RESPONDENT (APOTEX)
Vik Tenekjian	FOR THE RESPONDENT (TAKEDA)

SOLICITORS OF RECORD:

McCarthy Tétrault LLP Toronto, Ontario	FOR THE APPLICANTS
Goodmans LLP Toronto, Ontario	FOR THE RESPONDENTS
Gowlings Lafleur Henderson LLP Ottawa, Ontario	