**Date: 20070611**

**Docket: T-773-06**

**Citation: 2007 FC 622**

**Vancouver, British Columbia, June 11, 2007**

**PRESENT: Roger R. Lafrenière, Esquire**
**Prothonotary**

**BETWEEN:**

**ABBOTT LABORATORIES LIMITED**
**and TAP PHARMACEUTICALS INC.**

**Applicants**

**and**

**THE MINISTER OF HEALTH, NOVOPHARM LIMITED**
**and TAKEDA PHARMACEUTICAL COMPANY LIMITED**

**Respondents**

## REASONS FOR ORDER AND ORDER

[1] The Respondent, Novopharm Limited ("Novopharm"), is a Canadian corporation engaged in the business of manufacturing off-patent pharmaceutical preparations, commonly called generic drugs. On August 10, 2006, Novopharm moved for an order pursuant to subsection 6(5) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, as amended (the *Regulations*), dismissing the prohibition application brought against it by the Applicants, Abbott

Laboratories Limited ("Abbott") and Tap Pharmaceuticals Inc. ("TAP"), based on three distinct grounds.

[2] The first ground advanced by Novopharm is that the patent in issue in the application, Canadian Patent No. 2,286,753 (the "'753 Patent"), is irrelevant to the dosage form of its capsules ("Novopharm Capsules") and the reference product (the "relevance" argument). The second ground is that the '753 Patent is not eligible for inclusion on the Register because it does not contain a claim for the medicine itself or a claim for the use of the medicine (the "eligibility" argument). The third ground is that the application is redundant, scandalous, frivolous, vexatious and otherwise an abuse of process (the "abuse of process" argument).

[3] Before addressing the issues raised by the parties at the hearing of the motion, including recent developments in the law and the appropriate standard to apply on this motion, a brief review of the facts and a summary of the claims of the '753 Patent is in order.

**Facts**

[4] The Respondent, Takeda Pharmaceutical Company Limited ("Takeda"), is a Japanese corporation that distributes its drug products around the world directly and through arrangements with other drug companies. It is the patentee of both the '753 Patent and the now expired Canadian patent for the compound lansoprazole, Canadian Patent No. 1,255,314 (the "'314 Patent"), which was issued on June 6, 1989. During the 17 years that the '314 Patent was effective, Takeda and those claiming under it enjoyed a monopoly over lansoprazole as a compound.

[5] TAP is a joint venture between Takeda and Abbott through which lansoprazole is sold in Canada. Abbott and TAP are "first persons" under the *Food and Drug Regulations* in relation to the medicine lansoprazole.

[6] Lansoprazole is a proton pump inhibitor or "PPI" which reduces gastric acid secretion. After ingestion it is absorbed in the small intestine and enters the blood stream. Once absorbed in this way, lansoprazole has the effect of inactivating or inhibiting the hydrogen pumps in parietal cells. These are the cells in the stomach lining that secrete hydrochloric acid into the stomach. However, lansoprazole's effectiveness is reduced or destroyed by the presence of acid. Therefore, lansoprazole must be protected from acid while it moves through the stomach to its point of absorption in the intestine. The usual way to do this is to coat the lansoprazole in an enteric coating.

[7] Abbott and TAP (the "Applicants") have been selling lansoprazole delayed release capsules (the "Applicants' Capsules") in Canada under the brand name PREVACID® since they received their first Notice of Compliance ("NOC") from Health Canada in 1995. These capsules are comprised of a gelatine capsule shell filled with enterically coated granules. The sale of the Applicants' Capsules predates the Relevant Date by approximately 3 years.

[8] Novopharm sought approval from Health Canada through an Abbreviated New Drug Submission ("ANDS") in which it compared the Novopharm Capsules to the Applicants' Capsules as they existed in 2004. This ANDS referred to the three patents then registered against the reference product, being the '314 Patent, Canadian Patent no. 1,312,548 (the "'548 Patent") and Canadian Patent no. 2,009,741 (the '741 Patent).

[9] On December 21, 2004, Novopharm served Abbott with a Notice of Allegation (the "First NOA") in which Novopharm alleged that its Novopharm Capsules would not infringe the '548 Patent or the '741 Patent. The First NOA did not address the '314 Patent, since Novopharm was waiting for the expiry of the '314 Patent before bringing the Novopharm Capsules to market.

[10] Abbott responded to the First NOA by commencing an application (Court No. T-214-05), seeking an order prohibiting the Minister of Health from issuing a NOC to Novopharm. This application was heard by Justice Konrad von Finckenstein in Toronto in October 2006. By Order dated November 21, 2006, the application was allowed. This order is currently under appeal (Court No. A-580-06) and is scheduled to be heard by the Federal Court of Appeal on June 27, 2007.

[11] On May 17, 2006, Health Canada responded to Novopharm's ANDS by approving the submission (subject to the outcome of T-214-05 and Novopharm's response to the subsequently listed patents) and issuing a Drug Identification Number ("DIN") for the Novopharm Capsules. In doing so, Health Canada accepted that the Novopharm Capsules are bioequivalent to and have the same dosage form, strength and route of administration as the Reference Product.

[12] On February 13, 2006, after Novopharm had provided Health Canada with its ANDS and after Novopharm had served Abbott with the First NOA, the Applicants caused the '753 Patent to be added to the Register for the Reference Product. Abbott has since caused three other patents to be added to the Register in relation to the Reference Product.

[13] On March 23, 2006, Novopharm responded to the newly listed ‘753 Patent by providing the Applicants with another Notice of Allegation in which it alleged, among other things, that its Novopharm Capsules would not infringe the ‘753 Patent. In response, the Applicants commenced the present application on May 5, 2006.

[14] As indicated as the beginning of these reasons, Novopharm now moves pursuant to ss. 6(5) of the *Regulations* to have this application dismissed.

**Claims of the ‘753 Patent**

[15] The ‘753 Patent contains 29 claims. Claims 1, 10, 11 and 22-26 are independent claims. There are 16 claims which list an active pharmaceutical ingredient, including 11 that relate to lansoprazole (claims 7, 13, 14, 15, 16, 17, 22, 23, 24, 25 and 26).

[16] Claim 1 is the broadest independent claim and describes a solid preparation comprising: i) a pharmaceutically active ingredient; ii) one or more water-soluble sugar alcohols from the group consisting of sorbitol, maltitol, reduced starch saccharide, xylitol, reduced palatinose and erythritol; and iii) low-substituted hydroxypropylcellulose having hydroxypropoxyl group contents of 7.0 to 9.9 percent by weight.

[17] Claims 5, 6, and 7 read as follows:

5. The solid preparation according to any one of the claims 1 to 4, which is capable of buccal disintegration or dissolution.
6. The solid pharmaceutical preparation according to any one of the claims 1 to 5, which is a tablet.
7. The solid preparation according to any one of claims 1 to 6, wherein the pharmaceutically active ingredient is lansoprazole.

[18] Claim 10 relates to the "use of L-HPC" having a hydroxypropoxyl group content of 7.0 to 9.9 percent by weight for the manufacture of a pharmaceutical preparation capable of buccal disintegration or dissolution. Similarly, claim 11 describes a method of improving buccal disintegration or dissolution of a solid pharmaceutical preparation by "using L-HPC" having hydroxypropoxyl group contents of 7.0 to 9.9 percent by weight. These claims require both: i) L-HPC having hydroxypropoxyl group contents of 7.0 to 9.9 percent by weight; and ii) the capability of buccal disintegration or dissolution as that term is used in the '753 Patent.

[19] Claim 12 describes the use of claim 10 where the Active Ingredient is an anti-ulcer agent.

[20] Claims 20 and 21 are dependent claims that refer solely to tablets.

[21] Claims 22 to 26 describe uses of "...preparations containing lansoprazole and low-substituted hydroxypropylcellulose [i.e. L-HPC] having hydroxypropoxyl group content of 7.0 to 9.9 percent by weight, capable of buccal disintegration or dissolution" to treat various conditions.

**Recent developments in the law**

[22] Since the date on which Novopharm's notice of motion was filed, there have been two significant developments in the law. On November 3, 2006, the Supreme Court of Canada released its decision in *AstraZeneca Canada Inc. v. Canada* (Minister of Health), 2006 S.C.C. 49 *("AstraZeneca")*. In addition, effective October 5, 2006, the *Regulations* were amended to, among other things, change the wording of ss. 6(5). The impact of these recent developments on this motion is addressed below.

**The *AstraZeneca* decision**

[23] In its written and oral submissions, Novopharm advanced additional arguments based on the A*straZeneca* decision. In that case, AstraZeneca, the innovator manufacturer, obtained from the Minister of Health a NOC enabling it to market its drug omeprazole for use in the treatment of acidic stomach conditions. The drug was sold as Losec 20 in Canada from 1989 until 1996, when AstraZeneca decided to remove it from the market and replace it with another formulation. AstraZeneca's patent for omeprazole expired in 1999. In 2002, despite the absence of Losec 20 from the market, AstraZeneca obtained and registered with the Minister of Health two more patents associated with Losec 20, but did not incorporate this new technology into any of its products. In 1993, Apotex filed an abbreviated new drug submission for a NOC for its generic version of omeprazole, comparing its product to AstraZeneca's 1989 version of Losec 20. The Minister determined that Apotex was not required to address the after-issued patents and granted Apotex the NOC in 2004. AstraZeneca applied for judicial review of this decision, and the motions judge upheld the Minister's decision. The Federal Court of Appeal overturned this judgment and quashed Apotex's NOC.

[24] In allowing Apotex's appeal and restoring the motions judge's decision, the Supreme Court of Canada referred to a principled approach to determining which patents must be addressed pursuant to the *Regulations*. Under this approach, the obligations incurred by a generic manufacturer under the *Regulations* are based upon the generic manufacturer's "early working" of a patent listed on the Register. These obligations only arise where the invention of the "early worked" patent is embodied in the specific reference product used by the generic manufacturer as the basis for its ANDS. The *AstraZeneca* decision clarifies that if the invention of the patent is not embodied in the reference product, the patent is irrelevant and need not be addressed.

[25] Novopharm submits that the invention patented by the '753 Patent is not embodied in the specific PREVACID® delayed release capsules to which Novopharm makes reference in its ANDS. According to Novopharm, the '753 Patent is not relevant to TAP's PREVACID® capsules because the Patent refers to a rapidly disintegrating oral form, whereas PREVACID® is a non-disintegrating gelatin capsule containing enterically coated granules, neither of which are designed to disintegrate. Novopharm submits that the '753 Patent is therefore irrelevant and need not be addressed by Novopharm, and that the application ought to be dismissed as frivolous, vexatious and an abuse of the process of this Court.

[26] The arguments based on *AstraZeneca*, although compelling, are beyond the scope of the present motion and the application itself. Novopharm should have sought leave to amend its notice of motion, or brought a separate motion to obtain relief on this additional ground. However, Novopharm gave no notice to the Applicants that it planned to advance an argument based on the *AstraZeneca* decision prior to filing its written representations. Due process requires that a party be

given an opportunity to adduce evidence with respect substantive issues and that the evidence be considered in the adjudication of the issues. The Applicants have been deprived of this opportunity, and have been prejudiced as a result. In the circumstances, it would be inappropriate to entertain Novopharm's argument in a factual vacuum or based on an incomplete evidentiary record.

**Impact of amendments to the Regulations to the relevance argument**

[27] Novopharm's argument on the grounds of relevance has been overtaken by recent amendments to the *Patented Medicines (Notice of Compliance) Regulations*. Where necessary, the previous regulations will be referred to as the "*Old Regulations*", while the amended regulations will be called the "*New Regulations*".

[28] Under the *Old Regulations*, there were two alternative bases for granting a motion to dismiss pursuant to par. 6(5)(a); namely, if the Court was satisfied that (1) the patents were not eligible for inclusion, or (2) the patents were irrelevant to the dosage form, strength and route of administration of the drug for which the second person has filed a submission for a notice of compliance. The old grounds were therefore ineligibility and irrelevance to the generic's product.

[29] The *New Regulations* maintain s. 6(5) as a means by which generic manufacturers can effectively deal with improperly listed patents. However, where the old s. 6(5) provided explicit grounds for attacking the listing of a patent on the basis of irrelevance to the dosage form, strength and route of administration of the product, the *New Regulations* have moved that requirement to section 4.

[30] However, in a strange twist, the transitional provisions of the *New Regulations* provide that s. 4 of the *New Regulations* does not apply to patents on a patent list submitted prior to June 17, 2006. In other words, patents on the register as of the date of the coming into force of the amendments remain subject to the listing requirements as they were interpreted and applied prior to that date. Given that the '753 Patent was included on the Register as of February 2006, Novopharm properly concedes that s. 4 of the *New Regulations* do not apply.

[31] Novopharm submits, however, that since s. 4 of the *Old Regulations* continues to apply to the '753 Patent, s. 6(5) of the *Old Regulations* must, by extension, also apply. Novopharm has cited no case law in support of this proposition. In my view, it would also be completely arbitrary to assume that the *Old Regulations* apply simply because Novopharm's notice of motion was brought before the *New Regulations* were proclaimed into force. As a general rule, when a law repeals a previous law, the repealed legislation no longer applies to the situations it once did, even if such situations arose before the law was repealed. In the absence of any grandfathering provisions, and taking into account the plain and obvious effect of the amending legislation, I conclude that section 6 of the *Old Regulations* has ceased to exist, and with it, Novopharm's ground for dismissal based on relevance.

**Standard to apply in paragraph 6(5)(a) motions**

[32] Paragraph (6)(5)(a) provides that "the court may, on the motion of a second person, dismiss the application in whole or in part …in respect of those patents that are not eligible for inclusion on

the register". The parties disagree on the standard or test to be applied in assessing the merits of a motion brought pursuant to par. 6(5)(a). The Applicants submit that the burden of proof is on Novopharm and that the standard in very high. Novopharm responds that the purpose of par. 6(5)(a) is to summarily dismiss groundless notices of application and there is therefore no reason to adopt a restrictive standard.

[33] In *Procter & Gamble Pharmaceuticals Canada, Inc. v. Canada (Minister of Health),* 2003 FCT 583, [2003] 4 F.C. 445, Madam Justice Johanne Gauthier had an opportunity to consider whether or not the restrictive standard enunciated in the Supreme Court of Canada case of *Hunt v. Carey* should apply to motions to dismiss under par. 6(5)(a). However, she declined to decide the question because she would have reached the same conclusion applying even the more restrictive standard.

[34] In *Sanofi-Aventis Canada Inc.* v. *Novopharm Limited*, 2006 FC 1547, Justice Roger Hughes was dealing with a motion to dismiss a prohibition application pursuant to par. 6(5)(b) of the *Old Regulations* on the grounds that the reasons of the Supreme Court of Canada in *AstraZeneca* resulted in the patents at issue being irrelevant. He concluded that such motions are to be determined on the same basis as a motion to strike a pleading, and that an application should not be dismissed pursuant to this provision unless clearly futile. At paragraph 11 of his decision, Justice Hughes wrote:

> Taking section 6(5)(b) on an equal footing with old Rule 419 or present Rule 221 we must start with the well entrenched proposition as stated by the Supreme Court in *Hunt v. Carey Canada Inc.*, [1990] 2 S.C.R. 959 that a party should not be driven from the judgment seat at an early stage before trial unless it is "plain and obvious" that the matter cannot succeed. In dealing with an application not an action, the

> Federal Court of Appeal in *Norton v. Via Rail Canada* (2005), 255 D.L.R. (4th) 311, at paragraph 15, states that striking out an application before hearing is an extraordinary remedy, granted only in narrowly defined circumstances.

[35] The question of whether the same high standard applies equally to motions brought pursuant to paragraph 6(5)(a) was subsequently considered by Justice Hughes in the recent decision in *Pfizer Canada Inc. v. Canada (Health)*, 2007 FC 188. He concluded that the Court has a duty to decide if a determination can be made based on the law and "uncontroverted relevant evidence or admissions or plain and obvious findings on the evidence".

> [15] The balance that a Court must consider in this matter concerning section 6(5)(a) of the NOC Regulations is whether, on the one hand, an application should continue where at least one of the patents should not have been on the register in the first place. It would be a waste of judicial resources and those of the parties to do so. On the other hand, a party should not be deprived of its opportunity to make full argument based on all the evidence that would ultimately be before the Court. This latter point is tempered however in cases such as this where the application is to proceed in a summary fashion based on affidavit evidence and written transcripts of cross-examination alone and, at the end of the day, a decision has no binding effect should the parties proceed to an ordinary infringement and validity action.
>
> [16] Taking these matters into consideration I find that a section 6(5)(a) motion should be considered on the basis that if a determination can be made based on law and the application of uncontroverted relevant evidence or admissions or plain and obvious findings on the evidence, then the Court should proceed to make a determination. Section 6(5)(a) must have a purpose that is not trivial. However, if the Court finds itself determining the matter on disputed relevant evidence or having to weight the merits of competing expert opinion, the matter should be left to the hearing at trial. It is difficult to sum this up as simply "plain and obvious", it goes beyond that, but where the law can be applied to admissions and relevant evidence that is quite reasonably found to be undisputed or "plain and obvious" then the Court has a duty to make a determination.

[36] The administrative scheme set out in section 6 provides a specific procedure and a judicial forum for a generic manufacturer to short-circuit the prohibition application: *Apotex v. Canada* (2000), 3 C.P.R. (4th) 1 (F.C.A.) at para. 22-24. A second person may, by discrete and interlocutory application, move to dismiss the application on the grounds that the patent is not eligible for inclusion on the register.

[37] In the case at bar, both the Applicants and Novopharm have been given an opportunity to adduce evidence, to conduct cross-examinations, to make written submissions, and to be fully heard on the issue of non-eligibility of the '753 Patent for inclusion on the Register. Since the issue of eligibility of the patent will not be adjudged in this case otherwise than on the current motion, I see no reason to apply a stricter test than would generally apply to application itself. I conclude therefore that although Novopharm bears the burden of proof of establishing that the patent is not eligible for inclusion on the Patent Register, the balance of probabilities standard applies. It remains that the evidence must be viewed in the light most favorable to the Applicants and all reasonable inferences must be drawn in their favour.

**The eligibility argument**

[38] Under the *Regulations*, the Minister of Health maintains a Patent Register. The Register consists of patent lists submitted in respect of drugs for which a NOC has been issued. Patent lists filed for inclusion on the Patent Register are subject to the eligibility requirements under *Regulations*. Paragraph 6(5)(a) of the *Regulations* has been described as an important mechanism

available to generic drug manufacturers to have applications dismissed at an early stage where ineligible patents are on the Register.

[39] Pursuant to par. 4(2)(b) of the *Regulations*, a patent may only be added to the Register if it contains a claim to the medicine or the use of the medicine.

> 4(2) A patent list submitted in respect of a drug must
>
> (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;

[40] Novopharm submits that neither lansoprazole nor its use form part of the "invention" of the '753 Patent. According to Novopharm, the invention of the '753 Patent is a rapidly disintegrating oral dosage form; in short, a delivery system. The Applicants submit that the '753 Patent relates to a lansoprazole composition or preparation, and that, properly construed, the relevant claims of the Patent cover a lansoprazole composition that can include granules. The eligibility argument comes down to whether the claim in the Patent is a claim to a delivery system or to a payload.

[41] The Federal Court of Appeal has held that a patent is not eligible for listing when it is directed to a delivery system rather than a payload: *GlaxoSmithKline Inc. v. Canada (Attorney General)* (2005), 40 C.P.R. (4th) 193 (FCA) at para. 42-44 ("GlaxoSmithKline"); *Biovail Corp. v. Canada (Minister of National Health and WeIfare)* (2006), 46 C.P.R. (4th) 321 (FCA) at para. 6-7

("Biovail"); *Proctor & Gamble Pharmaceuticals Canada Inc. v. Canada (Minister of Health)*, 2007 FCA 31 at para. 4.

[42] Where the patent involves a combination of an Active Ingredient and a device whose purpose is to administer that ingredient to a patient, the patent is not eligible for protection under the *Regulations,* as such a patent does not contain a claim for a medicine or the use of a medicine. In *Biovail*, the Federal Court of Appeal held that where a patent contains claims that can be either the medicine itself or a delivery system, the question is one of construing the patent and that the claims must not be construed in isolation from one another and the rest of the patent.

[43] In *GlaxoSmithKline* above, the Federal Court of Appeal concluded that a patent for a controlled release capsule was not covered by the *Regulations.* According to Justice Desjardins, the patent did not even refer to a particular medicine contained in the capsule. It simply referred to an "active substance", and therefore, the patent could not be said to claim protection for a medicine. In concluding that the patent was ineligible for listing on the Register, Justice Pelletier, who concurred in the result with Justice Desjardins, applied the following reasoning:

> If one reviews the "medical devices" cases referred to above, one notes that the theme which runs though 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?
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> If the patent protects the delivery system, then it does not contain a claim for the medicine itself, or the use of the medicine, even if it contains a reference to the medicine as payload.

[44] Novopharm submits that the proper approach in determining eligibility for listing under s. 6(5) of the *Regulations* is to examine the "nature of the invention" (also referred to as the "purpose of the patent", "nature of the patent" and "essence of the invention") in determining whether a patent constitutes a "delivery system" or a "payload". In doing so, the Court examines the claims of the patents, but also looks to the disclosure to identify the "substance of the patent", even where there are specific claims to a particular payload. Thus, the determination of the "nature of the invention" (the land) is critical on this motion while the scope of the monopoly (the fence posts) is merely a component of the larger analysis. *Biovail Corp. (c.o. b. Biovail Pharmaceuticals Canada) v. Canada (Minister of National Health and Welfare),* [2005] F.C.J. No. 1402 ; aff'd (2006), 46 C.P.R. 4th 321 (F.C.A.) *("Biovail"); GlaxoSmithKlineInc. v. Canada (Attorney General),* [2006] F.C.J. No. 1620 (CA) (GSK1), *Proctor & Gamble Pharmaceuticals Canada Inc. v. Canada (Minister of Health),* [2006] F.C.J. No. 515 (P&G1); aff'd (2006) (F.C.A.) 347; *Pfizer Canada Inc. v. Canada (Attorney General)* 7 2004 F.C. 370.

[45] The Applicants disagree that a determination of whether a patent claims the medicine itself involves a determination of the "nature of the invention". According to the Applicants, the issue is one of claims construction and requires a consideration of each claim. They submit that a patent

must be given a purposive construction in accordance with the decision of the Supreme Court of Canada in *Free World Trust v. Électro Santé Inc.* (2000), 9 C.P.R. (4th) 168 at para 30, rather than relying on vague notions like the "essence" or the "spirit" of the invention.

[46] Even applying the purposive construction proposed by the Applicants, the result would be the same. Without having to refer to the abstract, I am satisfied on a plain reading of '753 Patent as a whole that it protects a delivery system in which seemingly any active compound can be packaged and delivered in a rapidly dissolving oral form.

[47] Lansoprazole is not mentioned in claim 1 or dependent claims 2-6, 8 or 9. Therefore, these claims are not claims for lansoprazole itself or the use of lansoprazole. Further, claims 1-6 relate solely to a delivery system that can be used with the 190 or more Active Ingredients described in the disclosure. They are therefore solely directed to a means of administering any medicine. Claims 7-9 relate to lansoprazole, voglibose and candesartan cilexetil respectively. Claims 10 or 11 do not mention lansoprazole or its use. Both claims relate solely to the delivery system applicable to the numerous Active Ingredients mentioned in the disclosure. The only "use" described in these claims is the "use of L-HPC having hydroxypropoxyl group contents of 7.0 to 9.9 percent by weight." This is not a use of lansoprazole.

[48] As lansoprazole is not mentioned in claim 12, this is not a claim for the medicine lansoprazole or its use. Depending from claim 10, it too is related solely to the aspects of a delivery system applicable to the numerous Active Ingredients mentioned in the disclosure. While claims 13-17 mention lansoprazole, they are not claims to the medicine lansoprazole itself. The uses referred

to in claims 13-20, are not uses of lansoprazole but uses of L-HPC. Specifically, they are uses of L-HPC having a hydroxypropoxyl group content of 7.0 to 9.9 percent by weight for the manufacture of a pharmaceutical preparation capable of buccal disintegration or dissolution. Depending from claim 10, these claims are related solely to the patented delivery system which can be used to deliver the numerous Active Ingredients mentioned in the disclosure.

[49] I am not satisfied that the experts put forward by the Applicants took a proper approach to the claims construction of the ‘753 patent. Instead, they incorrectly focused on lansoprazole to the exclusion of all the other medicines covered by this patent. 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.

[50] Lansoprazole, enteric coatings, enterically coated lansoprazole, delayed release enterically coated granules of lansoprazole and the uses for all of these were known for many years prior to May 26, 1997, the earliest relevant date for the ‘753 Patent. Lansoprazole and its uses were known long before the Relevant Date. Therefore, the invention of the ‘753 Patent cannot subsist in

describing this particular Active Ingredient and its known uses. Instead, the ‘753 Patent explains that various medicines can be used with the delivery system invention.

[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.

[52] Based on the above, it is clear that the ‘753 Patent does not contain a “claim for the medicine itself” or a “claim for the use of the medicine” and is therefore not eligible for listing on the Register. Pursuant to the first portion of par. 6(5)(a), this application should be dismissed.

**The abuse of process argument**

[53] Inclusion of patents on the Patent Register is significant to an innovator, providing it with an opportunity to delay, for up to 24 months, a generic from entering the market where the patent may be infringed. Novopharm maintains that Abbott’s litigation strategy in this application and two other related applications is intended to delaying the entry of the Novopharm Capsules into the Canadian marketplace through an abuse of the *Regulations,* improperly taking advantage of the availability of successive 24-month stays and listing patents against unrelated products. In light my conclusion that the application should be dismissed pursuant to par. 6(5)(a), I need not determine this issue.

[54] Takeda appeared on this motion to counter certain allegations of abuse of process levelled against them by Novopharm. At paragraphs 15 to 17, and 36 to 40 of his affidavit sworn August 11, 2006, Brian Des Islet, Executive Director of Research and Development at Novopharm, states that Takeda added 18 new claims to the '753 Patent application in August 2005, within 12 days of Novopharm's disclosure of its formulation to the Applicants and Takeda in Court No. T-214-05, and began "vigorously prosecuting" its patent application that had laid dormant in the Patent Office for two years. Takeda views the allegations as serious since they insinuate that Takeda misused confidential information received from a different proceeding during the prosecution of the '753 Patent, and abused the *Regulations* in an attempt to delay Novopharm's entry in the workplace.

[55] Novopharm did not pursue the allegations in its written submissions and abandoned them at the start the hearing of the motion. Although I disagree with Takeda's characterization of Mr. Des Islet's evidence as tantamount to charges of "dishonesty, fraud, breach of a Court Order, and conspiracy", the allegations were serious and needed to be rebutted. In the circumstances, I conclude that Takeda should be entitled to its costs and disbursements associate in defending its reputation.

## ORDER

**THIS COURT ORDERS** that

1. The application is dismissed.

2. The Applicants' motion for disclosure will not be dealt with.

3. Novopharm's costs of the motion and the application are to be paid by the Applicants. Novopharm shall provide written submissions of no more than three pages concerning the appropriate scale and amount of its fees and disbursements, the Applicants shall provide a response on the same issues not exceeding five pages, and Novopharm shall provide a reply not exceeding three pages.

4. Takeda's costs of the motion, with fees assessed based on the middle of Column III of Tariff B, and reasonable disbursements, shall be paid by Novopharm. Takeda is entitled to claim costs for two counsel, including the costs related to attend the motion to dismiss in Toronto, the cross-examination of Mr. Goto in Osaka, and the cross-examination of Mr. Des Islet in Toronto. If the parties cannot agree on quantum, Takeda shall provide written submissions of no more that three pages explaining its claimed fees and disbursements and Novopharm shall provide a response not exceeding three pages.

"Roger R. Lafrenière"
Prothonotary

**FEDERAL COURT**

**SOLICITORS OF RECORD**

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| **DOCKET:** | T-773-06 |
| **STYLE OF CAUSE:** | ABBOTT LABORATORIES LTD ET AL v. THE MINISTER OF HEALTH ET AL |
| **PLACE OF HEARING:** | Toronto |
| **DATE OF HEARING:** | March 28 and 29, 2007 |
| **REASONS FOR ORDER:** | LAFRENIÈRE P. |
| **DATED:** | June 11, 2007 |

**APPEARANCES:**

| | |
|---|---|
| Mr. Reddon<br>Mr. Neuer | FOR THE APPLICANT,<br>Abbott Laboratories |
| Mr. Godfrey<br>Mr. Skoyden | FOR THE RESPONDENT,<br>Novopharm Ltd |
| Mr. Van Barr<br>Mr. Tenejkian | FOR THE RESPONDENT,<br>Takeda |

**SOLICITORS OF RECORD:**

| | |
|---|---|
| McCarthy Tetrault | FOR THE APPLICANT,<br>ABBOTT LABORATORIES |
| Heenan Blaikie | FOR THE RESPONDENT,<br>NOVOPHARM |
| Gowlings | FOR THE RESPONDENT,<br>TAKEDA |