Date: 20080306

Docket: T-1799-06

Citation: 2008 FC 313

Toronto, Ontario, March 6, 2008

PRESENT: Madam Prothonotary Milczynski

BETWEEN:

NYCOMED CANADA INC. and
NYCOMED GMBH

Applicants

and

NOVOPHARM LIMITED and
THE MINISTER OF HEALTH

Respondents

REASONS FOR ORDER AND ORDER

[1] This is a motion by the Respondent Novopharm Limited ("Novopharm") for an order dismissing the application for prohibition with respect to Novopharm's 20 and 40 mg pantoprazole sodium enteric coated tablets ("Novopharm tablets"), pursuant to s.6(5) of the *Patented Medicines (Notice of Compliance) Regulations*, ("*Regulations*").

[2] The issue on the motion is whether or not the only patent at issue in the application, Canadian Patent No. 2,109,697 ("'697 Patent") is eligible for listing on the Canadian Patent

Register ("Register") with respect to the Applicants' (collectively "Nycomed's") 20 and 40 mg pantoprazole sodium enteric coated tablets ("Nycomed tablets"). Presently, the Nycomed tablets are marketed in Canada under the brand name PANTOLOC.

[3] The determination of this issue for the purposes of s.6(5)(a) of the *Regulations* requires:

(i) an identification of the "patented invention" disclosed by the '697 Patent; and

(ii) an analysis, for each Supplemental New Drug Submission ("SNDS") or New Drug Submission ("NDS") upon which a listing was obtained, as to whether there is a sufficiently relevant link between the SNDS or NDS, the Notice of Compliance ("NOC") that resulted from the submission, and the patented invention disclosed by the '697 Patent. (*Wyeth Canada v. ratiopharm Inc.* (2007), 60 C.P.R. (4th) 375 (F.C.A.)

[4] The standard and burden of proof under s.6(5) of the *Regulations* are also set out in *Wyeth:*

> The factual elements of the motion must be decided on the basis of the normal standard of proof in civil matters, the balance of probabilities. As to the burden of proof, it lies where it normally does, on the party filing the motion (the generic drug manufacturer). However, to the extent that the respondent (the innovator) fails to produce relevant evidence that is under its sole control, there may be a basis for drawing an adverse inference.

[5] The '697 Patent is entitled "Oral-Administration Forms of a Medicament Containing Pantoprazole" and is owned by Nycomed. It was filed on June 13, 1992, claiming priority to an application filed in Switzerland on June 17, 1991. The '697 Patent issued on November 22, 2005 and will expire on June 13, 2012.

[6] The ‘697 Patent was submitted for listing on the Register on the basis of five SNDSs and one NDS made by Nycomed in respect of PANTOLOC. Schedule A to these reasons, sets out a chart indicating each SNDS or NDS number, date and the reason for filing.

[7] For the reasons set out below, I find that on a balance of probabilities, none of these submissions can be said to relate to the invention of the ‘697 Patent.

Patented Invention Disclosed by the ‘697 Patent

[8] Nycomed submits that the ‘697 Patent has two aspects. First, that it claims new oral formulations of the medicine pantoprazole. Second, that it claims the use of these new formulations of the medicine pantoprazole to inhibit a particular enzyme. Inhibiting the enzyme causes a reduction in a patient’s stomach acid, which is necessary for the treatment of various gastrointestinal disorders.

[9] As set out in Nycomed’s evidence: the affidavits of Drs. McGinity and Wolman, Nycomed submits that the ‘697 Patent is directed towards new oral formulations of the medicine pantoprazole and the use of these formulations as an inhibitor of the enzyme H+K+-ATPase in the treatment of gastrointestinal disorders. Such inhibitors are also known as “proton pump inhibitors” or PPIs. With respect to formulation, claims 1 and 32 are important claims directed towards the new formulations of the medicine, and claims 31, 96 and 97 are claims for the use of the new formulations as a PPI, which, Nycomed submits, a clinician of ordinary skill would understand to mean as use of the new formulations in the treatment of various gastrointestinal disorders that require the reduction of gastric juice in the stomach.

[10] For Novopharm's part, there does not seem to be significant disagreement with the above interpretation in respect of what is taught or disclosed by the '697 Patent regarding formulation. More specifically, that the new formulation is as a result of the "new knowledge" contributed by the '697 Patent identified in claims 1, 32 and 64, disclosing a formulation for pantoprazole comprising: (i) a core containing pantoprazole and its physiologically tolerated salts, (ii) at least one water-soluble intermediate layer surrounding the core, and (iii) an outer layer which is resistant to gastric juice.

[11] In his affidavit filed on behalf of Nycomed, Dr. Wolman states that certain aspects of the '697 Patent concern the use of pantoprazole formulations to inhibit H+K+-ATPase, namely claims 31, 96 and 97. He also states that the use aspect of the '697 Patent is directed to clinicians and that the inhibition of H+K+-ATPase is the basis for using pantoprazole in the treatment of reflux esophagitis, gastro-esophageal reflux disease ("GERD") and gastrointestinal lesions induced by NSAIDs.

[12] On cross-examination, however, Dr. Wolman confirmed that there is nothing in the disclosure of the '697 Patent that relates to the clinical indications of pantoprazole or is directed to a clinician. The only portions of the disclosure that Dr. Wolman thought might be relevant to clinicians were the mention of H+K+-ATPase, which was already known, and that the formulations could be made into tablets. Dr. Wolman also admitted on cross-examination that there is no mention anywhere in the '697 Patent of the use of pantoprazole for the treatment of GERD, reflux esophagitis, gastrointestinal lesions induced by NSAIDs, or in combination with appropropriate antibiotics, the eradication of *Helicobacteror* infection associated with an active duodenal ulcer.

[13] The cross-examination of Dr. McGinity also confirmed that the "new knowledge" contributed by the inventors of the '697 Patent is new formulations of pantoprazole with increased stability. Dr. McGinity specifically identified independed Claims 1, 32 and 64 as describing the "new knowledge" contributed by the '697 Patent. The only use aspects of the '697 Patent identified by Dr. McGinity were reference to H+K+-ATPase in a statement on page 3 of the patent, comparing the water content of prior art formulations with the patented formulations and dependent claims 96 and 97.

[14] As set out in paragraph 47 of Novopharm's written representations, in finding that the invention of the '697 Patent does not relate to any new use of pantoprazole, but relates to formulations of pantoprazole, it is also worth noting:

- there is no claim in the '697 Patent for the medicine pantoprazole or any of its physiologically tolerated salts;
- as of the priority date of the '697 Patent, the existence of pantoprazole and its use as a PPI were known;
- the invention disclosed and claimed in the '697 Patent does not relate to particular strengths of the patented formulations;
- the invention disclosed and claimed does not relate to the adverse effects of pantoprazole on patients or to testing of pantoprazole in humans (clinical trials) - The disclosure of the '697 Patent does not mention the clinical indications for pantoprazole and is not directed to a clinician;

- the invention disclosed and claimed in the '697 Patent does not relate to the use of the patented formulation for the treatment of *H. pylori* infections, reflux esophagitis, GERD, or the prevention of gastrointestinal lesions induced by NSAIDs; and
- if the invention of the '697 Patent was directed to the use of the patented formulation as an antimicrobial for the treatment of *H. pylori* infections, reflux esophagitis, or for the treatment of GERD or the prevention of gastrointestinal lesions induced by NSAIDs, there would have to be at least some information or mention of those uses in the disclosure or in the claims. Neither the disclosure nor the claims contain any actual information about such uses of pantoprazole.

[15] Reviewing the patent as a whole, contrary to Nycomed's submissions, I agree with Novopharm, that the invention of the '697 Patent is in respect of the new formulations, not new uses of pantoprazole. The fact that the words "for the use of inhibiting H+K+ -ATPase or variations thereof are added or tagged onto dependent claims 31, 96 and 97 do not lead to the conclusion that the patented invention in the '697 Patent includes the use of the disclosed formulation. The use of pantoprazole as a PPI was already known as of the priority date of the '697 Patent. Adding the known use onto claims 31, 96 and 97 does not add anything to the invention claimed. As stated by the Federal Court of Appeal in *Abbott Laboratories v. Canada (Minister of Health)*, (2007), 59 C.P.R. (4th) 1 (FCA) at para. 43:

> Although the Court should strive to construe claims which do not bear the same words differently, Heneghan J. was on solid ground in this case, when she held that the words "for use as an antibiotic" at the end of claim 31, do not add anything to the invention claimed. At best, these words describe the utility of Form II once made in accordance with the claimed invention. The fact that clarithromycin in Form II is used as an antibiotic was well known. Saying, in effect,

> that an antibiotic is used as an antibiotic adds nothing to the invention.

[16] Similarly, in the case of the ‘697 Patent, the purported new formulations can still be used to do what pantoprazole was already known to do, namely, inhibit H+K+ -ATPase. This is confirmed by Dr. Signorino during his cross-examination, who goes on to say that the use of the claimed formulations to inhibit H+K+-ATPase simply establishes their utility

Is the Patented Invention Relevant to any SNDS and NOC against which it is listed?

[17] Each of submissions and resulting NOCs: 055738 (“‘738”), 066552 (“‘552”), 087266 (“‘266”) and 101809 (“‘809”) relate only to new uses that are not disclosed or claimed in the ‘697 Patent and do not form part of the patented invention disclosed by the ‘697 Patent. There is no linkage between these submissions and the patented invention.

[18] NOC ‘738 was for a new indication for Nycomed’s 40 mg tablets, the treatment of *H. pylori* infections associated with an active duodenal ulcer when used in combination with appropriate antibiotics. The ‘697 Patent is directed to particular formulations of pantoprazole. The ‘697 Patent makes no mention or claims for the treatment of *H. pylori*.

[19] NOC ‘552 was for a new indication for Nycomed’s tablets for the treatment of symptomatic GERD, such as acid regurgitation and heartburn. The ‘697 Patent does not mention or claim the treatment of symptomatic GERD.

[20] NOC ‘266 issued for a new indication for Nycomed’s 20 mg tablets for the prevention of gastrointestinal lesions induced by NSAIDs in patients requiring continuous NSAID therapy. The ‘697 Patent does not claim or mention this indication.

[21] NOC ‘809 issued in respect of revisions to the product monograph for PANTOLOC. A comparison of the product monograph before and after NOC ‘809 was issued shows that the revisions did not relate to any new formulation. The revisions were limited to updates to the adverse reactions, clinical trials, reference and dosing sections of the product monograph. The new formulations of pantoprazole indicated by the ‘697 Patent are not relevant to these non-formulation, administrative changes.

[22] Submission 057926 (“’926”) was for: (1) a new dosage strength of PANTOLOC – 20 mg, and (2) a new indication, namely the maintenance treatment of reflux esophagitis. There is nothing in the ‘697 Patent, however, regarding the use of pantoprazole for this new indication or for the formulation of pantoprazole into 20 mg tablets. The subject matter of the submission is not part of the patented invention and accordingly, the required linkage between the submission and the ‘697 Patent is also absent. On this point, I would add that while there was some conflicting evidence, there was insufficient reliable evidence to draw any conclusion as to what the 20 mg formulation was at the time SNDS ‘926 was filed and whether it was proportional to the 40 mg formulation.

[23] The NOC issued in respect of NDS 104828 was for a manufacturer name change for Nycomed’s tablets. This type of administrative change cannot and does not support a patent listing – the ‘697 Patent is not relevant to the NDS or NOC.

Other Issues

[24] Nycomed adduced evidence that while the ‘697 Patent was not listed against the original NDS for PANTOLOC, it was listed against the original NDS for PANTO-BYK. This is irrelevant to this proceeding.

[25] The reference product in respect of which the bioequivalence comparison was made for Novopharm pantoprazole sodium enteric coated tablets is PANTOLOC – not PANTO-BYK. PANTOLOC and PANTO-BYK 20 mg and 40 mg strength tablets have different Drug Identification Numbers. Under section 5 of the *Regulations,* it is acceptable for the generic manufacturer to chose which approved drug they wish to reference or use as comparator to establish bioequivalence. Since Novopharm referenced PANTOLOC in its Abbreviated New Drug Submission and Notice of Allegation, they are not a “second person” with respect to PANTO-BYK, a different drug, and need not address the patents listed against it.

ORDER

THIS COURT ORDERS that:

1. The motion is granted.

2. The application for an order of prohibition is dismissed.

3. In the event the parties cannot agree on the costs of this motion, they may file written submissions, no longer than three pages in length, within thirty (30) days of the date of this Order.

"Martha Milczynski"
Prothonotary

Schedule “A”

SNDS No.	**NOC Date**	**Dosage**	**Reason for SNDS**
055738	10-Mar-00	40 mg	New Indication: in combination with appropriate antibiotics, eradication of H. pylori infection associated with an active duodenal ulcer.
057926	10-Mar-00	20 mg	New Strength: 20 mg New Indication: maintenance treatment of patients with reflux esophagitis
066552	2-Mar-01	20 mg and 40 mg	New Indiction: treatment of symptomatic gastro-esophageal reflux disease (GERD), such as, acid regurigitation and heartburn.
087266	15-Oct-03	20 mg	New Indication: prevention of gastrointestinal lesions induced by non-steroidal anti-inflammatory drugs in patients with a need for continuous NSAID therapy.
101809	21-Dec-05	20 and 40 mg	Revisions to Product Monograph
104828 (NDS)	17-May-06	20 and 40 mg	Manufacturer Name Change

FEDERAL COURT

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	T-1799-06
STYLE OF CAUSE:	NYCOMED CANADA INC. and NYCOMED GMBH v. NOVOPHARM LIMITED and THE MINISTER OF HEALTH
PLACE OF HEARING:	Toronto, Ontario
DATES OF HEARING:	February 26, 2008
REASONS FOR ORDER AND ORDER:	MILCZYNSKI P.
DATED:	March 6, 2008

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