

Federal Court



Cour fédérale

**Date: 20101213**

**Docket: T-368-08**

**Toronto, Ontario, December 13, 2010**

**PRESENT: Madam Prothonotary Milczynski**

**BETWEEN:**

**NOVOPHARM LIMITED**

**Plaintiff**

**and**

**NYCOMED CANADA INC., NYCOMED  
GMBH AND NYCOMED INTERNATIONAL  
MANAGEMENT GMBH**

**Defendants**

**ORDER**

**UPON MOTION**, dated the 17<sup>th</sup> day of November 2010, on behalf of the Defendants,  
Nycomed Canada Inc., Nycomed GmbH, and Nycomed International Management GmbH  
(collectively “Nycomed”), for:

1. An order pursuant to rules 75(1) and 201 of the *Federal Courts Rules* granting leave to Nycomed to serve and file an amended statement of defence and counterclaim, in the form attached as Schedule “A” to the notice of motion;

2. The costs of this motion; and
3. Such further and other relief as Nycomed may advise and this Honourable Court may permit;

**AND UPON** reviewing the motion records filed on behalf of the parties, and hearing submissions of counsel at the hearing of the motion on December 2, 2010;

This action was commenced on March 7, 2008 by Novopharm Limited (“Novopharm”) pursuant to section 8 of the *Patented Medicines (Notice of Compliance) Regulations* for damages. Novopharm alleges it suffered from the delay caused by Nycomed in Novopharm obtaining its Notice of Compliance (“NOC”) under the *Regulations* for its Novo-pantoprazole tablets.

At this stage of the proceeding, the parties have exchanged affidavits of documents, but have not commenced oral examinations for discovery. Nycomed has brought this motion to amend its Statement of Defence, stating the amendments narrow the allegations, provide particulars and add a new defence and claim. These amendments, which include deletions, are described more fully at paragraph 15 (a through g) of Nycomed’s written representations, a number with which Novopharm does not take issue. What remains in dispute on this motion are the amendments relating to:

- Nycomed’s allegations of theoretical infringement – that had Novopharm received an NOC and been on the market with its pantoprazole product during the

damage period, there would have been infringement of Canadian Patent Nos. 2,109,697 and 2,089,748 (the “697 Patent” and “748 Patent” respectively), thereby diminishing or negating Novopharm’s right to claim damages under the *Regulations*;

- Nycomed’s allegations of direct infringement of the 697 and 748 Patents, post section 8 damage period;
- Nycomed’s allegations that Novopharm has induced infringement by others;
- Nycomed’s allegations that Novopharm has contributed to the infringement (but is not the sole cause of the infringement) by others; and
- Nycomed’s allegations that Novopharm misrepresented its intentions and breached undertakings given in its Notice of Allegations that upon its receipt of its NOC, Novopharm would not market or sell its Novo-pantoprazole tablets for the (non-approved) use for the *Helicobacter pylori* indication.

Whether leave should be granted for the amendments to be made is governed by Rule 75 of the *Federal Courts Rules* and well settled jurisprudence. Rule 75(1) provides that the Court may, at any time, allow a party to amend a document, on such terms as will protect the rights of all parties. In *Canderel Ltd. V. Canada* [1994] 1 FCA 211, the Federal Court of Appeal stated that:

[T]he general rule is that an amendment should be allowed at any stage of an action for the purpose of determining the real questions in controversy between the parties, provided, notably, that the allowance would not result in an injustice to the other party not capable of being compensated by an award of costs and that it would serve the interests of justice.

In *Varco Canada Limited v. Pason Systems Corp.* 2009 FC 555, the Federal Court stated:

The test to amend a pleading must be applied consistently with the test to strike a pleading. Amendments will be denied, and pleadings will be struck only when it is plain and obvious that the claim discloses no reasonable cause of action. In *Enoch Band of Stony Plain Indians v. Canada* [1993] F.C.J. No.1254, the Federal Court of Appeal made it very clear that the Court should only “deny amendments in plain and obvious cases” where the matter is “beyond doubt”.

In the present case, (and reference should also be made to the decision in Court File T-1786-08, *Apotex Inc. v. Nycomed Canada Inc.*) I am satisfied that leave should be granted for the addition of amendments relating to misrepresentation and breach of undertakings. This type of allegation has previously been found by the Court to give rise to a triable issue, and as pleaded in the defence and counterclaim (subject to my direction regarding particulars below), can be asserted. It is not plain and obvious at this juncture that the pleading would fail, (see *Apotex v. Shire Canada*, 2010 FC 828), or if pleaded from the outset, would not survive a motion to strike.

Similarly, and with the same proviso regarding particulars, leave ought also be granted in respect of amendments relating to the allegations of direct infringement and inducement.

Paragraph 31 of Nycomed’s original statement of defence already made the allegation as follows:

31. Further, at all times, Novopharm’s making, selling and use of its Novo-pantoprazole tablets in Canada would have infringed the Nycomed Patents. At all times, including any during any relevant period under s.8 of the *Regulations*, it would have been contrary to law for Novopharm to make, sell or use its Novo-panteprazole tablets.

Novopharm has already pleaded over this rather bald infringement allegation, denying in equally spare terms:

...Novopharm denies that its making, selling and use of the Novo-pantoprazole tablets in Canada would have infringed the Nycomed Patents at all material times and puts the Defendants to the strict proof of demonstrating the alleged infringement.

The proposed amendments relating to Novopharm's alleged infringing activities (direct and by inducement) provide some measure of particularization of the allegation as it appeared as Nycomed's defence in the original pleading. To the extent the amendments seek to clarify or narrow existing issues and relate to the quantum of damages payable to Novopharm, it is appropriate they be added now and determined in the defence and counterclaim, not as suggested by Novopharm, to be pursued by Nycomed in a separate and new patent infringement action.

Leave is not granted, however, to the amendments that assert "contributory infringement" as a cause of action or plead what Novopharm "ought to have known". By these proposed amendments, Nycomed alleges that Novopharm, distinct from the "but for" allegation of inducement, has contributed to physicians prescribing, pharmacists dispensing, and patients using Novo-pantoprazole tablets in combination with *Helicobacter*-inhibiting anti-microbial agents for the regulation of gastrointestinal disorders and treatment of *Helicobacter pylori*-associated duodenal and gastric ulcers. Nycomed alleges that Novopharm may not be the sole cause, but has contributed to the infringing activities of these third parties through its product monograph, website and its marketing strategies to physicians and pharmacists.

Nycomed relies upon the Supreme Court of Canada's decision in *Monsanto v. Schmeiser*, 2004 SCC 34 in support of what it admits is a novel cause of action and argues that the law and jurisprudence relating to patent infringement is evolving. At paragraph 43 of *Monsanto*, the Supreme Court did state, "...the main purpose of patent protection is to prevent others from depriving the inventor, even in part and even indirectly, of the monopoly that the law intends to be theirs: only the inventor is entitled, by virtue of the patent and as a matter of law, to the full enjoyment of the monopoly conferred". Thus, Nycomed submits that it is not beyond doubt that contributing to an infringement, by depriving the inventor, even in part and even indirectly, of the monopoly that the law intends to be theirs, is not a triable issue.

The *Monsanto* decision, however, concerned direct infringing activity, and other cases cited by Nycomed deal only with inducement, where (i) there is an act of infringement by a direct infringer; (ii) this act was influenced by the seller to the point where, without this influence, infringement by the buyer would not take place; and (iii) the influence was knowingly exercised by the seller – meaning that the seller knows that this influence will result in the completion of the act of infringement, (*MacLennan v. Gilbert Tech Inc.* (2008), 67 C.P.R. (4<sup>th</sup>) 161 (FCA). There is no evolution of the law that recognizes "contributory infringement" as a cause of action and I am satisfied that if originally plead, such allegations would not survive a motion to strike. If a party has not directly infringed or induced infringement, then it cannot be liable for infringement.

Accordingly, that part of Nycomed's motion must fail, and having regard to Rule 75 and the Court's discretion to attach terms to the granting of leave to allow the other amendments, I

am satisfied on review of the proposed amendments and hearing the arguments of counsel for both Nycomed and Novopharm, that Nycomed should be directed to provide particulars, as set out in Novopharm's written representations.

In its defence to the claim for s.8 damages, Nycomed alleges that Novopharm would have infringed all of the claims of the 697 Patent if it had received its NOC and entered the market on September 1, 2006. In its amended counterclaim, Nycomed alleges that Novopharm infringes all of the claims of the 697 Patent. Nycomed recites claims 1, 32 and 64 of the 697 Patent and then asserts that Novopharm would have and has infringed each claim, restating the elements of each independent claim and asserting that Novopharm's tablets have each element. Nycomed does not plead which elements of Novopharm's formulation infringe which claims of the 697 Patent.

Nycomed also alleges, as a defence and counterclaim, that Novopharm would have and has infringed and/or induced other to infringe claims 1-12, 44, 47 and 48 of the 748 Patent by manufacturing or having manufactured, importing, marketing and promoting, offering for sale and selling its Novo-pantoprazole tablets in Canada. This is a bald allegation of patent infringement and does not provide any material facts linking the alleged acts to the claims of the 748 Patent. The same type of boilerplate allegations are made in respect of inducement including that Novopharm has induced physicians to prescribe, pharmacists to dispense and patients to use Novopharm's pantoprazole tablets for the claimed uses and combinations of the 748 Patent or made representations or submissions to Canadian health-care authorities. Finally, there are also no material facts in support of the plea that Novopharm breached its undertaking,

as made in its NOA. Accordingly, in order to amend the statement of defence and counterclaim as permitted, Nycomed will be required to provide particulars.

**THIS COURT ORDERS that:**

1. Leave is granted to the Defendants Nycomed Canada Inc., Nycomed GmbH and Nycomed International Management GmbH to amend the statement of defence and counterclaim, consistent with the reasons above.
2. The amended statement of defence and counterclaim shall provide the particulars as set out in paragraph 84 (a-i) of Novopharm Limited's written representations filed on this motion.
3. The amended statement of defence and counterclaim shall be served and filed within fifteen (15) days of the date of this Order, unless otherwise agreed to by the parties.
4. In the event the parties cannot agree on the costs of this motion, written submissions no longer than three (3) pages in length may be filed within fifteen days of the date of this Order.
5. The parties shall, within twenty (20) days of the date of this Order submit dates of mutual availability for a case management teleconference to discuss:
  - (i) any issues arising out the amended statement of defence and counterclaim,



- (ii) the reply and defence to counterclaim,
- (iii) the matter of whether the issue of Nycomed's damages should be bifurcated, and
- (iv) the schedule for the remaining steps in this proceeding.

“Martha Milczynski”

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Prothonotary