Date: 20080408

Docket: T-1836-06

Citation: 2008 FC 454

Vancouver, British Columbia, April 8, 2008

PRESENT: Roger R. Lafrenière, Esquire
Prothonotary

BETWEEN:

NYCOMED CANADA INC. and
NYCOMED GMBH

Applicants

and

NOVOPHARM LIMITED and
THE MINISTER OF HEALTH

Respondents

REASONS FOR ORDER AND ORDER

Introduction

[1] This is a motion by the Respondent, Novopharm Limited (Novopharm), pursuant to section 6(5)(b) of the *Patented Medicines Notice of Compliance Regulations* (*Regulations*), seeking dismissal of the application instituted by the Applicants, Nycomed Canada Inc. and Nycomed GmbH (collectively referred to as Nycomed), on the grounds that the proceeding is redundant, frivolous or vexatious and otherwise an abuse of process.

[2] Nycomed's application was brought under section 6(1) of the *Regulations* to obtain an order prohibiting the Respondent, Minister of Health (Minister), from issuing a Notice of Compliance (NOC) under the *Food and Drug Regulations* to Novopharm for the production and marketing of enteric coated tablets of pantoprazole sodium in 20 mg and 40 mg strengths (Novopharm's Tablets) until after the expiration of Canadian Letters Patent 2,092,694 ('694 Patent) and 2,089,748 ('748 Patent). An earlier patent covering pantoprazole has expired and the use of pantoprazole to treat excess gastric acid secretion is known. The '694 and '748 Patents generally relate to the new use of pantoprazole for the treatment of *H. pylori* bacterial infections.

[3] Novopharm submits that Nycomed's prohibition application constitutes an abuse of process because Nycomed is attempting to relitigate issues that have been decided in *Solvay Pharma Inc. et al v. Apotex Inc. et al*., 2008 FC 308[1], a recent decision by Madam Justice Johanne Gauthier that also involved Nycomed[2], a generic company, Apotex Inc. (Apotex), the same two patents, and the same allegations of non-infringement (Apotex Decision).

[4] Nycomed opposes the motion on the grounds that that the current proceeding is the first and only proceeding in which this Court is called upon to determine questions of infringement and inducing infringement of the '748 and '694 Patents by Novopharm's Tablets and product monograph.

---

[1] Court File No. T-427-06

[2] The Applicants in the Apotex Decision were Solvay Pharma Inc. and Altana Pharma AG. Altana was the owner of the '694 and '748 Patents when the application was instituted, but changed names before the issuance of the Apotex Decision and now operates as Nycomed Pharma Gmbh.

Issue to be Determined

[5] Novopharm does not dispute the validity the ‘748 and ‘694 Patents and their eligibility for listing for the purpose of this motion. The only issue to be determined is whether, in light of the Apotex Decision, this application should be dismissed pursuant to section 6(5)(b) of the *Regulations* on the basis that it is clearly futile on its merits.

Background Facts

[6] By letter dated September 5, 2006, Novopharm served Nycomed with a Notice of Allegation and Detailed Statement (Novopharm NOA) pursuant to section 5 of the *Regulations*. The NOA alleges that the ‘748 and ‘694 Patents, which are owned by Nycomed GmbH, and are listed against the Nycomed’s 20 and 40 mg strength pantoprazole sodium enteric coated tablets (Nycomed’s Tablets), would not be infringed by the making, constructing, using or selling of Novopharm’s Tablets.

[7] The Novopharm NOA alleges, in particular, that no claim for the medicine itself and no claim for the use of the medicine in either of the ‘748 and ‘694 Patents would be infringed on the basis that:

(a) Novopharm is not seeking approval for the use of the Novopharm Tablets for the suppression or eradication of *Helicobacter pylori* (“*H. pylori*”);

(b) Novopharm is not seeking approval for the use of the Novopharm Tablets in combination with an antibacterial drug (or drugs) for any purpose;

(c) The Novopharm Product Monograph will not include the use of the Novopharm Tablets for the suppression or eradication of *H. pylori*;

(d) Upon approval of Novopharm's Abbreviated New Drug Submission ("ANDS"), Novopharm will only be permitted to market and sell the Novopharm Tablets for the approved indications in their Product Monograph, which does not include the suppression or eradication of *H. pylori*;

(e) Novopharm will not induce or procure the infringement of the '748 and/or '694 Patents, nor will it represent to third parties that the Novopharm Tablets can be used for the treatment of *H. pylori*; and

(f) Novopharm cannot directly infringe the '748 and/or '694 Patents.

[8] The indications in the Novopharm Product Monograph are the use of enteric coated pantoprazole sodium tablets for the treatment of conditions where a reduction of gastric acid secretion is required, listed as follows:

- Duodenal ulcer
- Gastric ulcer
- Reflux esophagitis
- Symptomatic gastro-esophageal reflux disease (such as, acid regurgitation and heartburn).
- Prevention of gastrointestinal lesions induced by non-steroidal anti-inflammatory drugs (NSAIDs) in patients with a need for continuous NSAID

treatment, who have increased risk to develop NSAID-associated upper gastrointestinal lesions.

- Maintenance treatment of patients with reflux espohagitis

[9] In response to the Novopharm NOA, Nycomed commenced this application on October 19, 2006, seeking an order prohibiting the Minister from issuing an NOC to Novopharm for the Novopharm Tablets until after the expiry of the '748 and '694 Patents.

[10] Both parties filed their affidavit evidence in the application and cross-examinations have begun. Eight of the sixteen deponents have been cross-examined to date. Cross-examinations of four of Novopharm's deponents (Dr. Fred Saibil, Dr. David Y. Graham, Dr. Charles Signorino, and Anthony Axon) have yet to be conducted or completed. Four of Nycomed's witnesses have not been cross-examined to date: Mr. Jean-Yves Julien and Dr. Barry Marshall, Dr. Ruth Corbin, and Dr. Peter Malfertheiner.

Apotex Decision

[11] By Reasons for Judgment and Judgment dated March 3, 2008, Justice Gauthier dismissed the Nycomed's prohibition application against Apotex.

[12] Justice Gauthier first decided the legal issue of claim construction of the relevant claims. In respect of the '748 Patent, she construed claims 1 – 14 to all include pantoprazole or a pharmaceutically acceptable salt thereof and a Helicobacter-inhibiting antimicrobial agent ("HIAMA") as essential elements.

[13] With respect to claim 15 of the ‘748 Patent, Justice Gauthier found that the only other essential element was that the composition be used for the “regulation of a gastrointestinal disorder”. “Gastrointestinal disorder” was found to refer to those disorders caused or exacerbated by *H. pylori* and the secretion of gastric acid and “regulation” was found to mean the treatment of gastrointestinal disorder through the combined action of pantoprazole, acting as an anti-secretory proton-pump inhibitor and a HIAMA defined by its ability to eradicate *H. pylori*. She also found that the definition of “eradication” was generally understood to mean elimination of *H. pylori* at some period of time after therapy in some percentage of patients.

[14] Claim 16 of the ‘748 Patent was found to include, as an essential element, the use of pantoprazole and a HIAMA for the treatment of gastric or duodenal ulcer relapse. “Treatment” was held to necessarily involve the eradication of *H. pylori* and the prevention of relapse.

[15] In construing the relevant claims of the ‘694 Patent, Justice Gauthier found that claim 3 has three essential elements: (1) a formulation containing pantoprazole; (2) the formulation being designated to be partially not resistant to gastric juice; and (3) the formulation also being partially resistant to gastric juice. She found that there was no limitation as to a specific use of those compositions. She also found that the essential elements of claims 6 and 13 are: (1) a formulation of pantoprazole; (2) for use as an antimicrobial; and (3) to treat *H. pylori* infections and diseases arising therefrom.

[16] Justice Gauthier then evaluated the allegations of non-infringement in the following context:

(a) An application under the *Regulations* is not an action for infringement so the Court only needs to determine whether the facts, assumed or proved, and the legal assertions made by the second person in its NOA justify its specific allegation of non-infringement.

(b) The *Regulations* are intended to prevent only infringement by (or infringement induced or procured by) generic drug producers who make abbreviated new drug submissions containing one of the stipulated comparisons to an existing drug product.

(c) To establish infringement of a use claim, the inducer must have done something that leads the direct infringer to infringe. Normally, the following elements must be established:

(i) An act of infringement was completed by the direct infringer;

(ii) The act of infringement was influenced by the inducing party to the point that, without said influence, infringement would not take place;

(iii) The inducing party must know that its influence would result in the completion of the act of infringement.

(d) To establish inducement or procurement under the *Regulations*, mere sale by a second person is not sufficient: something more is required. Something active must be done; mere passivity or even knowledge that

> one's product will likely be used in direct infringement of a patent is not sufficient.

[17] Justice Gauthier concluded that Apotex's allegation of non-infringement was justified, namely, that the '748 and '694 Patents were not infringed because the Apotex Tablets would not be marketed or promoted to doctors, pharmacists or others to be used in combination with another antibiotic as part of a regimen for combating, treating or eradicating *Heliobacter* or *H. pyroli* bacteria.

[18] Apotex began marketing its generic version of pantoprazole sodium enteric coated tablets after received a NOC on March 5, 2006,

Evidence Adduced on this Motion

[19] On March 10, 2008, Novopharm brought the present motion, supported by the affidavit of a law clerk, Alisha Meredith. Attached to Ms. Meredith's affidavit are copies of Novopharm's NOA, the '748 and '694 Patents, Nycomed's Notice of Application, the parties' affidavits in the main proceeding (without exhibits), and the Court Index and Docket for Court File No. T-427-06. In cross-examination, Ms. Meredith confirmed that she had no personal knowledge about the documents attached to her affidavit.

[20] Nycomed filed responding affidavits of Dr. James McGinity, Dr. Chuck Chakprani, Mr. Julien, Dr. Krishna Menon and Ms. Carole Morris. Due to time constraints and the fact he was abroad in Thailand, the evidence of Dr. Stephen Wolman was adduced through an affidavit of a solicitor, Daniel McKay. Novopharm did not object to the manner in which Dr. Wolman's evidence was presented.

[21] Dr. McGinity, a pharmaceutical scientist, deposes that the Novopharm productions provide insufficient information to conclude that Novopharm's assertion is justified. He opines, based on Novopharm's data concerning its proposed tablets, that many of the Novopharm Tablets "likely" contain pantoprazole simultaneously in one form that is resistant to gastric juice and in another form that is not resistant to gastric juice. According to Nycomed, this would fall within the scope of claim 3 of the '694 patent.

[22] Mr. Chakrapani, a survey expert, confirms the materiality of Ruth Corbin surveys in the main Application, and states that it is "reasonable to infer" that that Novopharm's Product Monograph will induce doctors and pharmacists to prescribe and dispense Novopharm's proposed pantoprazole tablets to treat *H. pylori* related ulcers.

[23] Drs. Wolman and Menon, both gastroenterologists, maintain that the Novopharm Tablets will inevitably be prescribed and used by physicians to treat duodenal and gastric ulcers, including those associated with *H.pylori*, if Novopharm receives a NOC. Irrespective of the recommended dose and dosage adjustment in Novopharm's Product Monograph, the Novopharm product will benefit from established physician use of and experience with PANTOLOC since the generic is considered to be therapeutically equivalent with the branded version. Absent a specific direction or warning, there would be no reason for a physician to deviate from standard practice and not prescribe the generic product.

[24] Mr. Julien, a pharmacist, states that, absent a warning to health care professionals not to use pantoprazole for the treatment of *H.pylori*, Novopharm's Product Monograph

"directs pharmacists to fill doctor's script for 'pantoprozale' and two antibiotics with [Novopharm's Tablets] for use in triple therapy to treat *H.pylori*.

[25] Ms. Morris, a legal assistant, provides a chronology of events, and attaches as exhibits to her affidavit additional copies of Nycomed's affidavits served in the main proceeding, with selected exhibits, and transcripts of certain cross-examinations that have taken place to date.

[26] Nycomed's evidence on this motion is uncontradicted as Novopharm elected not to cross-examine any of Nycomed's deponents.

Analysis

[27] Novopharm submits that Nycomed's application constitutes an abuse of process because the pivotal matters at issue in this application have already been decided by Justice Gauthier, both in relation to use patents generally and in relation to the two patents generally.

[28] Nycomed counters that it should not be precluded from pursuing its allegations that Novopharm's pantoprazole tablets and Novopharm's own conduct may directly infringe or induce infringement of Nycomed's patent claims merely because Apotex's tablets and conduct were found by Justice Gauthier to not infringe its patents. It points out that the Apotex Decision was only concerned with Apotex's tablets and Apotex's conduct.

[29] Nycomed relies on the recent decision of Prothonotary Milczynski in *Nycomed Gmbh v. Canada (Health)* 2008 FC 330 (Milczynski Decision), rendered after issuance of the Apotex Decision, in which she denied a motion to dismiss brought by the generic Genpharm Inc. (Genpharm) against a Nycomed Notice of Application involving the same patents and substantially the same issues that are the subject of this motion. Prothonotary Milczynski concluded that Genpharm's motion to dismiss based on s. 6(5)(b) of the *Regulations* could not succeed for the following reasons:

> [76] On a motion brought pursuant to s.6(5)(b) of the *Regulations*, the moving party has a very high onus. It must show that the application for prohibition is clearly futile or that it is plain and obvious that it will not succeed (*Sanofi-Aventis Canada Inc. v. Novopharm Limited*, 2007 FCA 163 at para. 36).
>
> [77] This standard is extremely high, and is consistent with the notion that motions brought under s.6(5)(b) of the *Regulations* are intended to be summary in nature. Motions brought under s.6(5)(b) are not intended to provide second persons with the first of two opportunities to argue the merits of their case. Substantive arguments regarding the validity and non-infringement of the patents at issue are properly addressed at a prohibition proceeding; such substantive arguments are not properly raised on a s.6(5)(b) motion, except in the clearest of cases.
>
> [78] The present case is not such a case. Over the course of three days of submissions, counsel for both sides raised and argued many factual and legal points, most of which were highly contentious. Claim construction was heavily disputed. As claim construction must precede any findings with respect to validity and infringement, on this basis alone I would find that Nycomed's position is not clearly futile. I note that many other highly contentious issues were in dispute including the applicability of inherent anticipation to claims for the use of a medicine and the apparently contradictory jurisprudence on inducing infringement. Further, Nycomed's submissions on sound prediction include reference to affidavits filed by experts on the main action that were not experts in the present proceeding. Overall, given the standard of proof that must be met, I am not persuaded that Nycomed's position on validity and infringement is so clearly futile that the inevitable conclusion is that it has no chance of success.

[30] The motion by Genpharm could not have been premised on the Apotex Decision, since it was only issued after the hearing of the motion. In any event, Prothonotary Milczynski did not have the benefit of oral submissions from counsel for the parties on

the question whether the Genpharm NOA was in all material respects the same as the Apotex NOA. In the circumstances, she was in no position to determine whether the same issues would be re-litigated should Nycomed's application be allowed to proceed against Genpharm. The Milczynski Decision is therefore of little assistance in the present case.

[31] I agree with my colleague that substantive arguments regarding non-infringement should, as a general rule, be addressed at the hearing of the application. It remains that the *Regulations* specifically allow for motions to dismiss.

[32] The Court is generally loath to drive an applicant from the judgment seat where the litigation of an issue has not previously been decided between the same parties or their privies. However, if a case is clearly not going to succeed based on findings made in an earlier decision involving the same patents, the same issues, and substantially similar facts, the Court is empowered by the *Regulations* to render judgment in accordance with the inevitable outcome of the litigation.

[33] This interpretation was recently supported by the Federal Court of Appeal in *Sanofi-Aventis Canada Inc. v. Novopharm Ltd.* (2007), 59 C.P.R. (4th) 416 (*Sanofi-Aventis Appeal*). Mr. Justice Sexton, writing for the majority, commented on the purpose of section 6(5)(b), and held that a patentee who unsuccessfully challenges an allegation made by a generic drug manufacturer under the *Regulations* cannot re-litigate the same allegation made by any subsequent generic drug manufacturer. At paras. 36-37, he wrote as follows:

> Proceedings in which the case for the patent holder is clearly futile or plainly has no chance of success because of an earlier, binding authority continue to be impermissible as abuses of process because such proceedings will waste judicial

> resources and impose hardship on generic drug manufacturers without any corresponding benefit such as a more accurate result. However, applying the principles outlined by Arbour J., it is evident that the types of proceedings that constitute abuses of process go beyond those that are clearly futile to include cases such as the one at present. Many of the concerns raised by Arbour J. are applicable to this appeal. Allowing Sanofi-Aventis to proceed with its application will give rise to the possibility of inconsistent judicial decisions, with one judge holding that the inventors of the '206 patent lacked a sound basis for predicting the utility of their invention and another holding that there was sound prediction. Thus one generic would receive an NOC because of invalidity based on lack of sound prediction while another would be refused an NOC even though its NOA raised the same allegation. As Arbour J. identified, permitting that type of inconsistency would threaten the credibility of the adjudicative process. Likewise, as Arbour J. noted, there is no reason to think that a second proceeding under section 6 of the *NOC Regulations* will lead to a more accurate result than the first. This scenario is in contrast to an action for a declaration of patent invalidity, where because the parties have the benefit of a full trial and all the attendant procedural safeguards, a more accurate result may arise. That is why the courts have on numerous occasions stated the principle that decisions rendered under the *NOC Regulations* are not binding on actions for patent infringement or to declare a patent invalid [citations omitted].

[34] Nycomed submits that the decision in *Sanofi-Aventis Appeal* should be distinguished on the basis the case involved a patent holder that lost in a prohibition proceeding on an issue relating to invalidity, and that there is no basis to extend the reasoning of the Federal Court of Appeal to support an abuse of process argument in relation to questions of infringement. Justice Gauthier also expressly cautioned against future courts relying on her infringement findings in relation to Apotex when dealing with questions of infringement involving the same patents but a different generic company, stating that "variations in the specific evidence led from one case to another may lead the Court to different conclusions (on infringement) even where the patents are the same."

[35] Although allegations of infringement are generally fact-specific, it remains that the concerns expressed by Justice Sexton regarding "the integrity of the adjudicative process, the principle of finality, and the efficiency of the judicial system" resonate just as strongly in prohibition proceedings raising such issues. Judicial resources are already

taxed considerably by the voluminous proceedings brought under the *Regulations*. The Court has a legitimate interest in encouraging the efficient use of scarce judicial resources, while at same time discouraging repetitious litigation brought without any compelling justification. The principles expressed in *Sanofi-Aventis Appeal* are therefore apposite, and offer direction as to the appropriate test to be applied in the present case.

[36] Nycomed submits that Novopharm's motion was brought prematurely, before its cross-examination of Novopharm's experts is complete. It also complains that the same experts have been shielded from cross-examination on this motion.

[37] Nycomed's complaints are without merit. Novopharm does not bear the evidential burden to support the allegations in its NOA and detailed statement in the main proceeding. The legal burden was on Nycomed and it cannot expect to make its case through Novopharm's witnesses. Moreover, Nycomed has not established any serious prejudice since the evidence must be viewed in the light most favourable to Nycomed and all reasonable inferences must be drawn in its favour: *Abbott Laboratories Limited v. Canada (Health)* 2007 FC 622. For the purposes of this motion, no weight can be given to the evidence of Novopharm's experts who have yet to be cross-examined.

[38] A motion to dismiss under the *Regulations* consists of a brief and summary review of the evidentiary record, as it stood at the time the motion was brought, to determine whether there is a clear case which would warrant an immediate judgment. In the absence of such a clear case being demonstrated, the application should be allowed to continue.

[39] In order to determine whether the proceeding should be dismissed summarily, the Court must necessarily assess the merits of the parties' evidence in the main proceeding, bearing in mind the following questions:

(a) whether the case is clearly futile or plainly has no chance of success;

(b) whether allowing the application to proceed will give rise to the possibility of inconsistent judicial decisions; and

(c) whether there is a compelling reason to further strain the resources of the parties and of the courts through repetitive litigation.

[40] Nycomed denies that the specific evidence in this case is the same as, or substantially the same as, the record in the Apotex proceeding. It claims that there are many highly contentious factual and legal points between the parties, any of which is reason alone to deny this motion. Reference is made, in particular, to the affidavit of Dr. Wolman sworn February 22, 2007, the affidavit of Mr. Julien sworn November 27, 2006, and the affidavit of Dr. McGinity sworn February 27, 2007.

[41] The Apotex record has not been put forward on this motion for comparative purposes (presumably because the expert evidence filed in that proceeding is subject to a confidentiality order). However, upon reading the comprehensive reasons given by Justice Gauthier in the Apotex Decision, striking similarities emerge between the Apotex Application and the present proceeding, both in terms of facts and issues.

[42] First, the indications in the Novopharm Product Monograph are identical to those in the Apotex Product Monograph. Justice Gauthier found that none of them related to

triple therapy or were sufficient to meet the test for inducing infringement of either the ‘748 or ‘694 Patents.

[43] Second, Apotex alleged in its NOA that it would not be making, using or selling its tablets as part of the triple therapy combination which is claimed in the ‘748 Patent and also alleged that the ‘748 Patent would not be infringed since the Apo-pantoprazole tablets will not be marketed or promoted to doctors, pharmacists or others for use in combination with a HIAMA or as part of a medicament package comprising said agent. Novopharm has made this same allegation that it will not be seeking approval for the use of Novopharm Tablets: (1) for the eradication of *H. pylori*, or (2) in combination with an antibacterial drug or drugs for any purpose.

[44] Third, Apotex alleged that because the indications, clinical uses and dosage regimens set out in Apotex’s draft product monograph are distinct from those indicated with respect to pantoprazole triple therapy, its 20mg and 40mg tablets will not infringe any claims of the ‘748 Patent. Novopharm has alleged that the Novopharm labelling, Product Monograph and any other marketing materials will not suggest the use of the Novopharm Tablets in the regulation of a gastrointestinal disorder or as a gastrointestinal disorder regulant. Nycomed has not pointed to any difference between the Apotex and Novopharm materials that could enable the Court to come to a different conclusion on this issue.

[45] Fourth, the dosage indicated in the Apotex Product Monograph with respect to gastric and duodenal ulcers is 40 mg daily for two weeks. The Court found that this dosage could not in any way be construed as referring to the standard triple therapy

regimen of 40 mg twice daily for one week. Novopharm's Product Monograph also only refers to dosing in respect of gastric and duodenal ulcers of 40 mg daily for two weeks.

[46] Fifth, Justice Gauthier found the only question was whether the Court can infer inducement on the sole basis that Apo-pantoprazole is indicated for the treatment of conditions corresponding to an old use, but for which the preferred treatment is now the patented combination therapy. That issue was decided in Apotex's favour. Based on the evidence in the present proceeding, and in order to avoid inconsistent decisions, the issue would also have to be resolved in Novopharm's favour.

[47] Sixth, Nycomed argued that Apotex would induce physicians and pharmacists to use Apo-pantoprazole to treat *H. pylori*. The Court rejected that evidence. In doing so, the Court noted the difficulty of determining a question of patent law on the basis of the statements in a product monograph, which is a document primarily, if not solely, intended to address health and safety issues. The Court also found that there was no clear indication from Nycomed's experts that their prescribing or dispensing practices are actually influenced in any way by the information found in generic product monographs.

[48] Justice Gauthier was not able to conclude from the evidence before her that Apotex intended to market its tablets for use as part of the triple therapy regimen or otherwise established any causal link between Apotex's actions (and its proposed monograph) and the direct infringement the Court was asked to assume. As a result, the Court concluded that Nycomed had not met its burden of establishing that the allegations of non-infringement in respect of the '748 Patent were unjustified. In particular, she

distinguished a decision by Mr. Justice Von Finckenstein in *Abbott Laboratories Limited v. Minister of Health* (2006), 55 C.P.R. (4th) 48; aff'd [2007] F.C.J. No. 935.

[49] Nycomed was required to put its best foot forward in the Apotex proceeding. Since Nycomed failed to lead that evidence in the case against Apotex, it would constitute an abuse of process for Nycomed to try and argue for a different result in this application against Novopharm.

[50] Seventh, in considering Apotex's allegation of non-infringement of claim 3 of the '694 Patent, Justice Gauthier found that there was no dispute about whether the Apotex tablets would contain pantoprazole sodium in a form that is at least partially resistant to gastric juice. The dispute was found to center on whether the Apotex tablets were also in a form which is partial not resistant to gastric juice. In contesting Apotex's allegation of non-infringement, Nycomed relied on the evidence of Dr. McGinity. Dr. McGinity also gives evidence on this same subject in the present proceeding. Dr. McGinity explains in his affidavit why Novopharm cannot have established that its tablets fall outside formulation claim 3 of Nycomed's '694 Patent and opines that the most reasonable conclusion from Novopharm's own productions is that Novopharm's tablets directly infringe this claim. Justice Gauthier concluded, on essentially the same facts, that all Nycomed had done is raised a "vague theoretical doubt". Even absent cross-examination of Dr. McGinity, his theories on infringement were found to be "no more than speculation". I conclude that Nycomed's case against Novopharm hangs on the same insufficient speculation.

[51] Eight, with respect to the allegations of non-infringement of claims 6 and 13 of the ‘694 Patent, Justice Gauthier was not satisfied that Nycomed had established that the Apo-pantorprazole tablets would have any antimicrobial effect and therefore could not infringe the ‘694 Patent. Similarly, the Court found that there is nothing in the Apotex Product Monograph that refers to or deals with the treatment of asymptomatic *H. pylori* infections and that Apotex was not seeking an NOC for pantoprazole as an antimicrobial. Apotex’s dosage regime was found to be particularly relevant to this inquiry. There is similarly no evidence that Novopharm, which has the same dosage regime, is seeking approval for use of the Novopharm Tablets to treat *H. pylori*.

Conclusion

[52] By commencing a proceeding under the *Regulations*, a patent holder obtains an automatic stay, shutting out a generic company’s product from the market for up to 24 months, without first having to satisfy any of the criteria required before enjoining issuance of a NOC.

[53] The *Regulations* were enacted for the dual purpose of protecting legitimate patent rights and accelerating the market entry of affordable generic drugs. To ensure that generic competition is not pre-empted by baseless or tactical litigation, section 6(5)(b) of the *Regulations* allows the Court, at an early stage, to “separate the wheat from the chaff”, and to dismiss an application that is redundant, scandalous, frivolous, vexatious, or an abuse of process. A patent holder (first person) who fails to obtain an order of prohibition under the Regulations may nonetheless seek to protect its legal rights by bringing a patent infringement action.

[54] It is not necessary to show that the prior decision would dictate the outcome of the present application or that the first person has no chance of success in order for a 6(5)(b) motion for abuse of process to be granted. The primary concern is to promote fairness and effectiveness, to reduce unnecessary litigation, and to minimize the risk of inconsistent results in respect of the same issues.

[55] On the evidence before me, I am satisfied that Novopharm has made the same allegations of non-infringement in respect of the ‘694 and ‘748 Patents based on the same factual nexus that was considered in the Apotex Decision.

[56] In light of the facts that Nycomed's position with respect to infringement was found to be untenable in the Apotex Decision, and that Nycomed has not adduced any materially different evidence in this proceeding, I conclude that the application should be dismissed as an abuse of process.

ORDER

THIS COURT ORDERS that

1. The motion is granted.

2. The application is dismissed pursuant to s. 6(5)(b) of the *Patented Medicines (Notice of Compliance) Regulations*.

3. The Respondent, Novopharm Limited, shall serve and file a draft bill of costs and its written submissions respecting costs of this motion and the application by April 18, 2008.

4. The Applicants shall serve and file responding submissions on costs by April 28, 2008.

"Roger R. Lafrenière"
Prothonotary

FEDERAL COURT

NAME OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	T-1836-06
STYLE OF CAUSE:	Nycomed Canada Inc. and Nycomed GMBH v. Novopharm Limited and The Minister of Health
PLACE OF HEARING:	Vancouver, British Columbia
DATE OF HEARING:	March 17, 2008
REASONS FOR ORDER AND ORDER:	LAFRENIÈRE P.
DATED:	APRIL 8, 2008

APPEARANCES:

Mr. Neil Belmore	FOR THE APPLICANTS
Ms. Lindsay Naidrauer	
Mr. Andrew Skodyn	FOR THE RESPONDENT,
Mr. Bill Mayo	NOVOPHARM LIMITED

SOLICITORS OF RECORD:

Mr. Neil Belmore	FOR THE APPLICANTS
Gowling Lafleur Henderson LLP	
Mr. Andrew Skodyn	FOR THE RESPONDENT,
Heenan Blaikie	NOVOPHARM LIMITED