

Date: 20080429

Docket: T-1942-07

Citation: 2008FC555

Ottawa, Ontario, Tuesday, this 29th day of April 2008

PRESENT: MADAM PROTHONOTARY MIREILLE TABIB

BETWEEN:

**NYCOMED CANADA INC. and
NYCOMED GmbH**

Applicants

-and-

**THE MINISTER OF HEALTH and
SANDOZ CANADA INC.**

Respondents

REASONS FOR ORDER AND ORDER

[1] The Court is seized of a motion brought by the Respondent, Sandoz Canada Inc., seeking to dismiss the present application on the basis that it is redundant, frivolous or vexatious, or otherwise an abuse of process, pursuant to section 6(5)(b) of the *Patented Medicines (Notice of Compliance) Regulations*, S.O.R./93-133 (the “*Regulations*”).

[2] This application was instituted by the Applicants, Nycomed Canada Inc. and Nycomed GmbH (collectively referred to as “Nycomed”) pursuant to section 6(1) of the *Regulations*, and seeks a prohibition order against the issuance by the Minister of an NOC to Sandoz in relation to its proposed pantoprazole tablets until after the expiration of Canadian Patent 2,092,694 (‘694 Patent). The other relevant patent, 2,089,748 (‘748 Patent), is being separately litigated under the *Regulations* between the same parties in Court file T-1941-07. A similar motion to dismiss was heard concurrently in that matter, and is disposed of in earlier reasons for order, indexed as *Nycomed Canada Inc. v. Sandoz Inc.*, 2008 FC 541 (“*Sandoz I*”). Most of the discussions set out in *Sandoz I* are relevant to and determinative of the present motion, and this order should accordingly be read in conjunction with the reasons in *Sandoz I*.

Preliminary objection as to jurisdiction

[3] As mentioned in *Sandoz I*, Nycomed raised as a preliminary matter an objection to a prothonotary’s jurisdiction to hear and determine a motion to dismiss an application under the *Regulations* in circumstances where an appeal of that order would be expected to become moot as a result of the early issuance of an NOC to the generic. The reasons given in *Sandoz I* for rejecting this argument are equally applicable in this matter, and need not be repeated.

Overview

[4] The drug at issue, pantoprazole sodium, is an old drug, marketed and sold in Canada since the mid-1990s. It is classified as a proton pump inhibitor (“PPI”) or a H⁺K⁺-ATPase Inhibitor, and has long been known to inhibit the secretion of gastric juice or acid in the stomach. Its use as such is no longer protected by patent. For the purpose of this motion, it is fair to say that the relevant claims of the ‘694 Patent appear to be for a composition of pantoprazole both partly resistant and partly non-resistant to gastric juice and its use for the treatment of *H. Pylori*. Thus, unlike the application in *Sandoz 1*, the present application involves issues of direct infringement (whether the formulation of Sandoz’ tablets will be both resistant and non-resistant to gastric juice) and indirect infringement (inducement of infringing use).

[5] Sandoz’ Notice of Allegation alleges that if it is issued an NOC in respect of its proposed pantoprazole product, its making, constructing, using or selling the product will not infringe any of the claims of the ‘694 Patent, since its product will not be in a formulation which is not resistant to gastric juice and that it only seeks approval and will only sell, market and promote its product for the treatment of conditions where a reduction of gastric acid secretion is required and not for combating *H. Pylori*. In addition, Sandoz’ NOA alleges that the ‘694 Patent does not contain claims for the medicine itself or the use of the medicine, and that it was improperly listed as against the relevant Nycomed NOCs. The within application, filed by Nycomed, alleges that all of Sandoz’ allegations are improper, insufficient or unjustified.

Sandoz' motion

[6] As was the case in *Sandoz I*, Sandoz' present motion is exclusively based on sub-section 6(5)(b) of the *Regulations*, which permits the Court, on motion, to dismiss an application, in whole or in part, on the ground that it is redundant, scandalous, frivolous or vexatious or otherwise an abuse of process. This motion does not invoke sub-section 6(5)(a) of the *Regulations*, pursuant to which an application may be dismissed on the ground that a patent is not eligible for inclusion on the register. In fact, Sandoz served and filed, concurrently with the present motion, a separate notice of motion specifically based on sub-section 6(5)(a), which is now scheduled to be heard on May 28, 2008.

[7] Sandoz' contention that the present application constitutes an abuse of process is based on the following grounds:

- 1) That the '694 patent has been held to not contain claims for the medicine or the use of the medicine at issue, and that there are therefore no relevant claims against which an allegation may be considered, by judgment issued on March 3, 2008 in *Solvay Pharma Inc. v. Apotex Inc.*, [2008] F.C.J. No. 378, 2008 FC 308 (the "Apotex" case).
- 2) That the '694 patent has been held to be ineligible for listing on the patent register in both the *Apotex* case and in a subsequent case, *Nycomed*

Canada Inc. et al v. Genpharm et al., 2008 FC 313 (the “*Genpharm*” case).

[8] It is to be noted that although it makes fleeting reference to the fact that Apotex’s allegations of non-infringement were held to be justified in *Apotex*, Sandoz’ motion record contains no argument whatsoever that the determination reached in *Apotex* on the non-infringement allegations should equally apply in this case and that Nycomed’s application should therefore be dismissed as an abuse of process. Nycomed, in its responding motion record, notes that omission and specifically states that it would be improper for Sandoz to later attempt to argue that the determination of the non-infringement issues in *Apotex* constitutes grounds for dismissal of this application. Without prejudice to that position, and out of an abundance of caution, Nycomed did include in its evidence some expert evidence going to issues of direct and indirect infringement.

[9] After Nycomed’s record had been filed, a decision was issued by Prothonotary Lafrenière in *Nycomed Canada Inc. v. Novopharm Ltd.*, 2008 FC 454 (“*Novopharm*”) in which he dismissed a similar application in respect of the ‘694 Patent on the basis of the determination made in *Apotex*. It is only then that Sandoz, in supplementary submissions, first raised and attempted to rely on the argument that the allegations of non-infringement had already been determined in *Apotex*.

[10] Despite the fact that Nycomed's forethought has meant that it has not been prejudiced by Sandoz' conduct, Sandoz' attempt to raise an additional ground for dismissal, at the eleventh hour and without properly amending its notice of motion, should not be permitted. All arguments arising out of the *Apotex* case were clearly available to Sandoz at the time its motion was initially filed, and should either have been raised at that time, or added by way of formal amendment. To raise them after Nycomed had filed its record, and apparently solely because they appear to have been successfully argued in a recent case, is inappropriate and abusive of the Court's process; these arguments therefore should not and will not be considered for determination on this motion.

[11] On the grounds that have properly been raised in its notice of motion – abuse of process in relation to ineligibility for listing and irrelevance – Sandoz relies on no expert evidence at all. It relies only on the decisions of the Court in *Apotex* and *Genpharm* and on a comparison between the notices of allegation and notices of application in the *Apotex* case and the present case. Curiously, Sandoz has not introduced the notice of allegation or notice of application in the *Genpharm* case. As in *Sandoz I*, Nycomed has yet to serve its evidence on the merits of the application and still has until May 15 to do so. While Nycomed has filed the evidence of five experts in opposition to this motion, going to issues of claim construction and ineligibility for listing (as well as direct and indirect infringement), the evidence also makes it clear that it is brought solely for the purpose of responding to Sandoz' motion, and that it is not intended to constitute the whole of the evidence to be brought on the merits of the application or on the eventual

6(5)(a) motion. More particularly, Nycomed indicates that more fulsome evidence is intended to be filed in opposition to the 6(5)(a) motion.

Prior litigation involving the ‘694 Patent

[12] It is helpful to review, before considering Sandoz’ argument, the allegations made and conclusions reached in each of the cases relied upon by Sandoz as prior determinations of the issues herein.

[13] The *Apotex* case was decided by Justice Gauthier on the merits of Nycomed’s application for a prohibition order¹. It covered two patents, the ‘694 and ‘748 Patents. In respect of the ‘694 Patent, Apotex’s NOA had made allegations of invalidity and non-infringement, as well as an allegation that some of the claims were irrelevant as not being claims for the medicine itself or the use of the medicine, and that the patent was improperly listed against the relevant NOCs. No motion had been brought by Apotex for dismissal of the application pursuant to section 6(5)(a) on grounds of ineligibility for listing. Nycomed objected to the determination of the eligibility issue on the merits of the application. It is not clear from the decision whether Nycomed had adduced substantive evidence on the eligibility issue, but in any event, the evidence brought by Nycomed on the present motion is to the effect that it had adduced no specific expert

¹ Although the case is reported under the names Solvay Pharma and Altana Pharma, the identity of the Applicants is in fact the same as in the present case, as the Applicants changed their respective names to Nycomed designations in the course of those proceedings.

evidence before Justice Gauthier in respect to listability and had otherwise limited evidence at its disposal on that issue.

[14] Justice Gauthier, in her decision, did conclude that claim 3 of the '694 Patent was not a claim for pantoprazole or pantoprazole sodium or its use and therefore not a relevant claim. However, her comments at paragraph 69 are to the effect that this conclusion was to be considered *obiter*, as her determinative conclusion was that it had not been established that the allegations of non-infringement were not justified.

[15] On eligibility for listing, the Court held clearly that it had no jurisdiction to consider or determine the eligibility for listing of patents on the merits of an application, as these issues could only be resolved by way of a motion brought pursuant to subsection 6(5)(a) of the *Regulations*. Her subsequent conclusion that the '694 Patent was not eligible for listing was clearly intended to be *obiter*, in the event that her finding of lack of jurisdiction was overturned on appeal.

[16] As mentioned above, the Court's determinative conclusions on the application was that the particular claims for which Nycomed was asserting direct or indirect infringement on the part of Apotex, being claims 3, 6 and 13 of the '694 Patent, would not be infringed by Apotex.

[17] In *Genpharm*, Prothonotary Milczynski was seized of a formal motion to dismiss the application on grounds, *inter alia*, of ineligibility for listing of the '694 Patent

pursuant to sub-section 6(5)(a). For whatever reason, the issue before Prothonotary Milczynski was whether the patents (the '694 and '748 Patents) were eligible to be included on the register against a single NOC, being the 055738 NOC ('738) issued to Nycomed on April 14, 1998 in respect of its 40mg enterically-coated Pantoloc® tablets. She held that the '694 Patent was not relevant to the '738 submission and was therefore improperly listed against that NOC and dismissed the application with respect to the '694 Patent.

[18] Because Prothonotary Milczynski did not dismiss the application in its entirety, having determined that the other patent, the '748 Patent, was properly listed, Genpharm could not receive its NOC. Nycomed has appealed the decision of Prothonotary Milczynski to a judge of the Court and as of the hearing of this motion, the appeal was still pending.

Relevance of the patent claims

[19] The issue of whether the '694 Patent contains relevant claims that are required to be addressed in an NOA turns on a determination of whether it contains a claim for the medicine itself or for the use of the medicine. That determination is one that can be properly made on the merits of an application, if properly alleged in the generic's notice of allegation (see *Apotex*, par. 66). Sandoz' NOA does appear to contain allegations to the effect that the '694 Patent is not relevant as containing no claim for the medicine or the use thereof. However, contrary to Sandoz' assertions, no determination has been

made in *Apotex* to the effect that the '694 Patent contains no claims for the use of the medicine. While Justice Gauthier indeed finds that claim 3 of the patent does not contain a claim for the medicine, she specifically mentions that Apotex's NOA, in respect of allegations of irrelevant claims, deals only with claim 3 of the '694 Patent; accordingly, that is the only claim that she herself addresses and determines on the issue of relevance. Indeed, the Court comments that Apotex's failure to make these allegations regarding claims 6 and 13 are presumably explained by the fact that these claims were obviously intended to cover a particular use of pantoprazole.

[20] There are no other cases in which the relevance of any other claims of the '694 Patent has been discussed. Accordingly, Sandoz' argument to the effect that it has been determined that the '694 Patent in its entirety contains no relevant claim for the medicine or the use thereof is without foundation and is dismissed.

Eligibility for listing

[21] Insofar as Sandoz' argument that this application is an abuse of process on the basis of a prior determination, made in *Apotex*, that the '694 Patent is not eligible for listing, it is also ill-founded and must be dismissed. As mentioned above, the Court's decision in *Apotex* is to the specific effect that it had no jurisdiction to consider or determine the eligibility for listing of the patents. That case can therefore not stand as a determination, final or otherwise, as to that issue and any comment made by the Court as

to the arguments raised by the parties on that issue are clearly *obiter* and therefore not binding.

[22] The only true prior determination as to the eligibility for listing of the ‘694 Patent was made in the *Genpharm* case. However, Sandoz mischaracterizes that decision when it states that it determined that the ‘694 Patent was ineligible for inclusion “on the register”. The *Genpharm* case stands only for the proposition that there is no linkage between the ‘694 Patent and one of the NOCs against which it is listed, being the ‘738 NOC. Any linkage between the ‘694 Patent and the other NOCs against which it is listed and which are specifically referred to Sandoz’ NOA, being the 066552 NOC and the 087266 NOC was not at issue before Prothonotary Milczynski and was not determined in *Genpharm*. Accordingly, even if *Genpharm* could stand as a binding determination on the issue of eligibility for listing of the ‘694 Patent, from which an argument of abuse of process could be drawn, it would be limited to its eligibility for listing as against the ‘738 NOC and would therefore not justify the dismissal of this application as it relates to the ‘694 Patent, there still being no determination as to whether that patent was properly listed against other relevant NOCs.

[23] The comments I made in *Sandoz I* as to whether it would, in any event, be appropriate to dismiss an application as an abuse of process based on a prior determination of ineligibility for listing outside the context of a formal motion to dismiss pursuant to sub-section 6(5)(a) also remain apposite.

[24] In view of the conclusion I have come to, I need not determine whether the pending appeal of the *Genpharm* decision would prevent the application of the principles of abuse of process in the particular circumstances of this case (see *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2008 FC 513).

Non-infringement

[25] As held above, Sandoz' argument that Nycomed's application is an abuse of process in view of the earlier determination in *Apotex* that similar allegations of non-infringement were justified was not properly raised in this motion and will not be determined.

[26] However, should it have been appropriate for me to exercise my discretion to consider these arguments, I would have rejected them.

[27] As discussed in *Sandoz 1*, the decision in *Apotex* determines only the issue of whether Apotex would likely infringe or induce the infringement of the '694 Patent. The issue in this application is whether Sandoz would infringe or induce the infringement of that patent. The *Apotex* decision therefore cannot stand as a prior determination of the infringement issues in this application.

[28] For Sandoz to have succeeded on this argument, it would have had to establish that it would be impossible for Nycomed to adduce evidence sufficient to show that

Sandoz' non-infringement allegations are unjustified. Merely pointing to similarities between some aspects of the Apotex and Sandoz product monographs is not sufficient. Similarities in some of the factors from which inducement may be inferred does not preclude the possibility that other factors exist and could be adduced in evidence to show an intent on the part of Sandoz to induce infringement. In particular, Sandoz has not shown that Nycomed could not possibly adduce evidence relating to Sandoz' marketing or promotional practices which would support an inference of intention to induce infringement. Indeed, some evidence to that effect has been led by Nycomed on this motion, including evidence from a pharmacist that Sandoz' sales representatives would visit pharmacists and actually promote the complete interchangeability and equivalence "for all purposes" between Sandoz' product and Nycomed's.

[29] Further, the infringement issues in this application include direct infringement, in particular, whether Sandoz' tablets are in a form which is partially not resistant to gastric juice. The uncontradicted evidence led on this motion by Nycomed is to the effect that portions of stability data for the tablets showing initial assay potency of pantoprazole and the percentage of pantoprazole found at various phases in the dissolution tests were expected to be provided by Sandoz but had not yet been received. I note that in *Apotex*, that very data (but for Apotex's product) was produced and showed that all of the pantoprazole sodium that was assayed in Apotex's tablets during the manufacture was accounted for in the buffer stage of the dissolution test, supporting Apotex's contention that none of the pantoprazole intended to be in the core of the tablets would have found its way onto the enteric coating, as hypothesized by Nycomed. Sandoz has not shown

that its own data, when produced, would not show the opposite: That not all of the pantoprazole assayed during the manufacture was accounted for in the buffer stage. Suggestion, in Sandoz' data, that some of the pantoprazole used in manufacture may not be contained in the core may support a finding of direct infringement.

[30] The above should not be taken as the only aspects upon which Nycomed's evidence could permissibly and materially differ from that in *Apotex*. That particular evidence is specifically discussed here merely as an example of why Sandoz could not have succeeded on this motion in showing that Nycomed's application is bound to fail.

Costs

[31] Nycomed was successful in opposing this motion and accordingly shall have its costs. In addition, the only two grounds properly raised by Sandoz on this motion, eligibility for listing and irrelevance of the patent, were based on a reading of the Court's decisions in *Apotex* and *Genpharm* which could not reasonably be supported on the clear reasons given by the Court in both cases. This motion was therefore ill-considered, ill-founded and should not have been brought. It has unnecessarily wasted the Court's time and the efforts of Nycomed, at a time where Nycomed should have been concentrating on constituting its evidence on the merits of the application. I have already mentioned that Sandoz' eleventh hour arguments with respect to non-infringement were inappropriate. Even though these allegations were not raised in the notice of motion, Nycomed chose, out of an abundance of caution, to lead some evidence on that aspect. Although the Court

will not generally compensate a party for costs it has incurred unnecessarily and out of excessive caution, Nycomed's caution was eventually proven justified; although the evidence it has led was only discussed in *obiter*, its expert's costs of adducing that evidence, to the extent they are not already compensated by the order of costs already made in *Sandoz 1* (and I suspect that in large part, they are) will be payable by Sandoz.

[32] As mentioned in *Sandoz 1*, Sandoz' repeated and unjustified insistence that this motion be heard on an urgent basis and its shifting scheduling demands also contribute to the Court's determination that Nycomed's costs should be assessed at the high end of Column V of Tariff B. As the costs of the telephone conferences to schedule and reschedule the motion and the costs of counsel's travel to attend the hearing of the motion are already covered in the order of costs in *Sandoz 1*, they will not be assessed as costs on this motion. Nycomed's costs of expertise on the eligibility issue and on whether the patent includes claims for the medicine itself or the use thereof are, however, recoverable on this motion.

ORDER

IT IS ORDERED THAT:

1. The motion of the Respondent, Sandoz Canada Inc., is dismissed, with costs as directed in the reasons for order, payable forthwith and in any event of the cause.

“Mireille Tabib”

Prothonotary

FEDERAL COURT
SOLICITORS OF RECORD

DOCKET: T-1942-07

STYLE OF CAUSE: NYCOMED CANADA INC. ET AL. v. THE
MINISTER OF HEALTH ET AL.

PLACE OF HEARING: OTTAWA

DATE OF HEARING: APRIL 21, 2008

REASONS FOR ORDER: TABIB P.

DATED: APRIL 29, 2008

APPEARANCES:

NEIL BELMORE
KEVIN SATORIO

FOR THE APPLICANTS

EDWARD HORE
KEVIN ZIVE

FOR THE RESPONDENT
SANDOZ CANADA INC.

SOLICITORS OF RECORD:

GOWLING LAFLEUR HENDERSON LLP
TORONTO

FOR THE APPLICANTS

HAZZARD & HORE
TORONTO

FOR THE RESPONDENT
SANDOZ CANADA INC.

JOHN H. SIMS, Q.C.
DEPUTY ATTORNEY GENERAL
OF CANADA

FOR THE RESPONDENT
THE MINISTER OF HEALTH