Date: 20080428

Docket: T-1941-07

Citation: 2008FC541

Ottawa, Ontario, Monday, this 28th 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 Respondent, Sandoz Canada Inc. ("Sandoz"), brings this motion to dismiss the present application on the basis that it is redundant, frivolous or vexatious or otherwise an abuse of process, pursuant to sub-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 2,089,748 ('748 Patent). Another relevant patent, the 2,092,694 Patent ('694 Patent), is being separately litigated under the *Regulations* between the same parties in Court file T-1942-07. A similar motion to dismiss was heard concurrently in that matter, and is disposed of in a separate order.

Preliminary objection as to jurisdiction

[3] Nycomed raised, as a preliminary matter, the issue of a prothonotary's jurisdiction to hear and determine the present motion. Nycomed recognizes that that very issue was considered and determined in *AB Hassle v. Apotex Inc.*, [2003] F.C.J. No. 1601, followed and applied in *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2007 FC 452, the Court concluding that a prothonotary does have jurisdiction to hear and determine such motions. However, Nycomed submits that the circumstances herein command further consideration of these decisions, particularly with respect to the statutory requirement, found in sub-section 46(1)(h) of the *Federal Courts Act*, that jurisdiction conferred upon prothonotaries pursuant to the Rules be exercised "subject to the supervision of the Court":

"46(1) Subject to the approval of the Governor in Council and subject also to subsection (4), the rules committee may make general rules and orders: (…) (h) empowering a prothonotary to exercise any authority or jurisdiction, subject to supervision by the Federal Court, even though the authority or jurisdiction may be of a judicial nature."	« 46(1) Sous réserve de l'approbation du gouverneur en conseil et, en outre, du paragraphe (4), le comité peut, par règles ou ordonnances générales : (…) (h) donner pouvoir aux protonotaires d'exercer une autorité ou une compétence — même d'ordre judiciaire — sous la surveillance de la Cour fédérale. »

[4] It is understood that the "supervision" mentioned in sub-section 46(1)(h) is exercised by way of appeal to a judge of the Federal Court, and in no other fashion. Bearing that in mind, Nycomed submits that because Sandoz' submission for an NOC is currently on "patent hold", orders dismissing both this and the other pending prohibition applications in respect of Sandoz' proposed pantoprazole sodium tablets would clear the way for Sandoz to obtain its NOC within a matter of days. Nycomed submits that any appeal of these orders it might then bring would be moot and the orders would therefore never be subject to the supervision of the Court. Nycomed stated in argument that a prothonotary's jurisdiction to hear and determine a motion pursuant to section 6(5)(b) would not be questionable so long as an effective right of appeal cannot be curtailed by becoming moot. Following that reasoning, I would have jurisdiction to hear and dismiss the motion, but not to hear and grant it <u>if</u> the pending motion in T-1942-07 is also granted; I would also have jurisdiction to hear and grant the motion if I had dismissed the pending motion in T-1942-07, or, if both motions being granted, I also stayed the effect of one or both of them pending appeal.

[5] Nycomed's argument is ill-founded. Jurisdiction to hear and determine a motion seeking a particular relief is either conferred or it is not. It cannot depend on the outcome of the motion, or on external circumstances such as the status of other litigation or the imminence of the issuance of an NOC. At most, Nycomed's argument might be considered in the context of deciding whether the effect of an order dismissing the application should be stayed, or of deciding whether an appeal of such an order should be heard even if moot. As I have concluded that Nycomed's application herein should not be dismissed, the issue of a stay does not arise.

Overview

[6] The drug at issue, pantoprazole sodium, is an old drug, marketed and sold in Canada since the mid-1990's. 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 portions of the '748 patent claim a composition of pantoprozole and a Helicobacter Inhibiting Anti-Microbial Agent ("HIAMA") for use in the treatment of gastrointestinal diseases caused or exacerbated by *H. Pylori* and secreted gastric acid. In other words, the relevant claims of the patent for the purpose of this motion are for the use of pantoprazole in combination therapy where the disease is caused or exacerbated by an *H. Pylori* infection.

[7] Sandoz' Notice of Allegation alleges that if it is issued an NOC in respect of its proposed pantoprazole product, its using or selling the product will not infringe the '748 patent since it only seeks approval and will only sell, market and promote its product for use in monotherapy, for the treatment of conditions not caused by *H. Pylori*, where reduction of gastric acid secretion is required.

[8] It is common ground between the parties that in order to succeed in its prohibition application, Nycomed must establish that Sandoz' allegation of non-infringement is not justified, in that Sandoz will, if issued an NOC, induce others (such as physicians, pharmacists, patients or provincial formulary authorities) to make infringing use of the product.

[9] In addition to the above-mentioned allegations of non-infringement, Sandoz' NOA alleges that the '748 patent does not contain claims to the medicine or the use of the medicine, and that it was improperly listed against the relevant Nycomed NOCs. On November 7, 2007, Nycomed filed the within application, contesting all of Sandoz' allegations as improper, insufficient or unjustified.

Sandoz' motion

[10] Sandoz' 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.

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

1) That the '748 patent has been held to contain no claims for 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 6, in *Solvay Pharma Inc. v. Apotex Inc.*, [2008] F.C.J. No. 378, 2008 FC 308 (the "*Apotex*" case).

2) That the '748 patent has been held to be ineligible for listing against the relevant NOCs in the *Apotex* case.

3) That the same or a similar allegation of non-infringement has been found to be justified, again, in the *Apotex* case, and that Nycomed's application for a prohibition order in respect of the same allegation of non-infringement of the '748 Patent, against another generic, has since been

dismissed as an abuse of process in *Nycomed Canada Inc. v. Novopharm Ltd.*, 2008 FC 454 (the "*Novopharm*" case).

[12] Sandoz thus submits that for Nycomed to pursue the present application in the circumstances constitutes an attempt to re-litigate issues that have already been finally determined against it, and is an abuse of process, as per the principles applied by the Court of Appeal in *Sanofi-Aventis Canada Inc. v. Novopharm Ltd.*, 2007 FCA 163.

[13] Sandoz does not rely on any expert evidence at all. It relies on the decision of the Court in the *Apotex* case and on a comparison between the Notices of Allegations, Notices of Application and Product Monographs in the *Apotex* case and the present case. Sandoz has not tendered a copy of the affidavits filed in the *Apotex* case or in the subsequent *Novopharm* case. Nycomed has yet to serve its evidence on the merits of this application. In fact, a scheduling order made on consent of both parties provides that Nycomed has until May 15, 2008 to serve its evidence on the merits of the application. While Nycomed has filed the evidence of four experts in opposition to this motion, going to issues of claims construction, ineligibility for listing and inducing 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 on the merits of the application and in opposition to the 6(5)(a) motion.

Prior ligitation involving the ‘748 Patent

[14] As mentioned above, Sandoz’ motion is entirely premised on its contention that the issues raised in this application have already been finally determined in a manner adverse to Nycomed, such that re-litigation would constitute an abuse of process. While Sandoz principally invokes the *Apotex* case as a prior determination, it also relied at the hearing on the subsequently issued decision of Prothonotary Lafrenière in the *Novopharm* case. The ‘748 Patent was, however, the subject of another motion to dismiss, both under sub-sections 6(5)(a) and 6(5)(b) of the *Regulations*, resulting in the decision of Prothonotary Milczynski in *Nycomed Canada Inc. v. Genpharm Inc.*, 2008 FC 330 (the “*Genpharm*” case).

[15] A brief review of the facts, circumstances and conclusions of each case is useful before considering Sandoz’ arguments.

[16] The *Apotex* case was decided on March 3, 2008 by Justice Gauthier, on the merits of Nycomed’s application for a prohibition order (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). The application covered two patents, the ‘694 and ‘748 Patents. In respect of the ‘748 Patent, Apotex had made in its NOA, in addition to allegations of invalidity, allegations that the patent contains no claims for the medicine itself, that claims 15 and 16 are irrelevant because Apotex’s

ANDS does not involve the early working of the use claims (early working issue), that the patent was improperly listed, and that Apotex would not infringe the use claims of the patents. No motion had been brought by Apotex for dismissal of the application pursuant to sub-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. In any event, Nycomed brought evidence on the motion before me to the effect that it had adduced no specific expert evidence before Justice Gauthier in respect of listability, and had otherwise limited evidence at its disposal on that issue.

[17] Justice Gauthier's decision, as it relates to the '748 Patent, was as follows:

[18] As to eligibility for listing, she held that the Court had no jurisdiction to consider or determine the eligibility for listing of patents on the merits of an application for a prohibition order, and that the only process by which this issue could be resolved is by way of a motion brought pursuant to sub-section 6(5)(a) of the *Regulations* (see discussion at paragraphs 53 to 66, *ratio decidendi* at paragraph 66). Although she went on to comment on eligibility issues, it is plain that the discussion is entirely *obiter*, and included solely in the event her finding of lack of jurisdiction was overturned on appeal (see paragraph 69). In any event, as regards to the '748 Patent, it is unclear whether she reached any definitive conclusion on eligibility, or merely raised concerns as to the potential consequences of accepting Nycomed's submissions, for ulterior determination.

[19] As to relevance, she notes that Apotex had not alleged in its NOA that claims 15 and 16 of the ‘748 Patent did not contain claims for the medicine itself or for the use of the medicine, such that the argument could not be considered. As to irrelevance on grounds of early working arguments, which was the argument specifically raised by Apotex in respect of those claims, she held that such arguments were akin to eligibility issues and also fell to be determined exclusively by way of motion pursuant to sub-section 6(5)(a) (paragraphs 65 and 66).

[20] Finally, after discussing at length the evidence submitted by both parties, Justice Gauthier concluded that Nycomed had failed to meet its burden of establishing that Apotex’s allegations of non-infringement were unjustified.

[21] No appeal was taken from the decision in the *Apotex* case, presumably because Apotex was issued an NOC shortly thereafter and that any appeal would likely have been declared moot.

[22] The *Genpharm* case was heard well before the judgment in *Apotex* was issued, but determined on March 10, 2008, merely a week after the decision in *Apotex*. Nycomed filed evidence before me showing that the *Apotex* decision was brought to Prothonotary Milczynski’s attention by the parties, Genpharm urging that the decision in respect of eligibility for listing and non-infringement justified its motion being granted and the dismissal of Nycomed’s application.

[23] As mentioned above, the matter before Prothonotary Milczynski was a motion to dismiss on the grounds of ineligibility for listing of the relevant patents (both the ‘748 and the ‘694 Patents) pursuant to sub-section 6(5)(a), and on grounds that the application was redundant, frivolous, vexatious or an abuse of process, pursuant to sub-section 6(5)(b). The argument on that latter sub-section was that it was obvious on the face of the evidence that both patents were invalid or not infringed. On the 6(5)(a) portion of the motion, Genpharm had filed specific expert evidence. It is unclear from the decision whether the evidence relied upon for the 6(5)(b) portion was that as constituted on the merits of the application or whether either party had filed specific evidence for that purpose.

[24] On the evidence before her, and having been apprised of the Court’s earlier decision in *Apotex*, Prothonotary Milczynski found that Genpharm had not established that the ‘748 Patent was ineligible for listing (paragraph 73).

[25] As regards the 6(5)(b) motion in respect of that patent, she held that on the evidence before her, Genpharm had not established that Nycomed’s position on infringement was so clearly futile that the inevitable conclusion was that it had no chance of success (paragraph 78). She did not discuss the incidence of the decision in Apotex.

[26] The *Novopharm* case came before Prothonotary Lafrenière after the judgments in *Apotex* and *Genpharm* had been issued. In that case, Novopharm brought a motion to dismiss Nycomed’s application in respect of both the ‘694 and ‘748 Patents, on the basis

that in light of Justice Gauthier's decision in *Apotex* on the non-infringement issues, Nycomed's application was clearly futile on its merits and should be dismissed. There was no issue of invalidity or ineligibility for listing in play on that motion.

[27] In evidence before the Court in the *Novopharm* matter were all the affidavits filed on the merits of the application by both parties, and the transcripts of all cross-examinations that had been conducted to that point (some experts on both sides had yet to be cross-examined). Nycomed had, additionally, filed direct evidence on the motion. Prothonotary Lafrenière concluded that Nycomed had not adduced any materially different evidence in the application than that which had been held insufficient in the *Apotex* matter, and accordingly dismissed the application as an abuse of process. At the time of hearing of the present motion, the delays to appeal the order of Prothonotary Lafrenière in *Novopharm* had expired, with no appeal having been taken, although Nycomed has filed a motion to reconsider. It was common ground between the parties that Novopharm had since received its NOC.

Eligibility for listing

[28] Sandoz' argument that this application is an abuse of process on the basis of a prior determination that the '748 Patent is not eligible for listing relies solely on the *Apotex* decision. 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 patent. That case cannot therefore stand as a determination, final or otherwise, as to that

issue. Further, any comment made by the Court as to the arguments raised by the parties on that issue are not only clearly *obiter* and therefore not binding but they are, further, ambiguous as to their effective conclusion.

[29] Not only is there clearly no determination in the *Apotex* decision as to the eligibility for listing of the ‘748 Patent, but the subsequent decision in *Genpharm*, exactly on point, issued after *Apotex* and on a full record, holds that the allegations of ineligibility for listing made in that case were not established.

[30] Sandoz’ argument of abuse of process in respect of eligibility is clearly ill-founded, and must be rejected.

[31] I would add that I would, in any event, have had some difficulty in accepting Sandoz’ argument that an application can be dismissed as an abuse of process on an eligibility issue outside the context of a motion regularly brought pursuant to sub-section 6(5)(a). As held by the Court in *Apotex*, the issue of eligibility for listing cannot be considered and determined on the merits of an application. A generic is required to address all patents listed on the register even though they may be improperly listed, and the innovator then has the right to assert that the allegations are unjustified. Unless the Minister acts to de-list a patent, the only process to determine the issue of whether the patents are properly listed and whether the prohibition application must therefore proceed is by way of a motion pursuant to sub-section 6(5)(a). Such a motion must necessarily be brought by the second person and it is the second person, and not the innovator, who

bears the burden of proof. Thus, unless the generic brings, in a timely manner, a motion pursuant to sub-section 6(5)(a), the issue of eligibility for listing cannot and will not be determined, and the application will proceed and may be granted on its merits. In order, therefore, to hold that an application constitutes an abuse of process because of a prior determination of ineligibility for listing in another application, the Court would have to "deem" the generic to have made a motion under section 6(5)(a), raising the same allegations of ineligibility for listing, and supported by similar evidence. I doubt that a generic could attack an application as an abuse of process on the basis that a motion it has not made, and on grounds it has not properly raised, would be bound to succeed.

Relevance of the patent claims

[32] The issue of whether the '748 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 properly be made on the merits of an application, if properly alleged in the generic's NOA (see *Apotex*, paragraph 66). Sandoz' NOA does contain an allegation to the effect that the '748 Patent is not relevant as containing no claim for the medicine or the use thereof. However, contrary to Sandoz' assertions, it is clear that no determination has been made in *Apotex* as to whether or not the '748 Patent contains a claim for the use of pantoprazole sodium. Indeed, as mentioned above, the Court specifically mentions, at paragraph 67 of the reasons, that the Apotex NOA had not alleged the irrelevance of claims 15 and 16 of the '748 Patent on the basis that they contain no claims for the use of

the medicine. Neither the *Genpharm* nor *Novopharm* decisions address that issue. As there are simply no prior determinations to the effect that the '748 Patent contains no claims for the medicine itself or the use of the medicine, Sandoz's argument to that effect is not supported and must consequently fail.

Non-infringement

[33] Sandoz submits that it has made the same allegation of non-infringement in respect of the '748 Patent as was made by Apotex, that the indications and dosage regimen in its product monograph are similar to those in Apotex's product monograph, and that, as with Apotex's product monograph, its own monograph does not refer to triple therapy or use for the treatment of *H. Pylori*. Sandoz then argues that, as the Court in *Apotex* has found that nothing in Apotex's product monograph would lead others to infringe, so it must follow that Nycomed cannot succeed in establishing inducement by another generic when its product monograph is, in those respects, similar to Apotex's. Sandoz argues that Nycomed's application therefore seeks to re-litigate this issue and must be dismissed as an abuse of process.

[34] In my view, Sandoz' argument improperly conflates the doctrine of abuse of process, as applied by the Court of Appeal in *Sanofi-Aventis*, supra, and the determination that, on the evidence led by an applicant on the merits of an application, it is inevitable that the application would fail.

[35] The Court of Appeal in *Sanofi-Aventis* made it quite clear that the abuse of process in that case arose because the same allegation of invalidity of a patent had already been litigated unsuccessfully by Sanofi-Aventis, and that while it could not be said that Sanofi-Aventis could not possibly succeed on the same allegation in a subsequent proceeding, allowing it to do so would create the risk of contradictory judgments on the same issue, which was impermissible in the context of NOC litigation (see paragraph 31 of *Sanofi-Aventis*). That approach assumes that different, better evidence could be tendered in the subsequent proceeding and that the application could thus succeed. The policy ground that then operates to foreclose the applicant from that opportunity is the risk that there will indeed be contradictory judgments, such that "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" (par. 36). For that policy consideration to even come into play, the allegations must be the same, otherwise, they could not give rise to contradictory judgments.

[36] The allegation that was held to be justified in *Apotex* was that Apotex would not sell, promote or market its tablets for use in combination therapy, and would not induce others to do so. The allegation made in the present matter is that Sandoz will not sell, promote or market its tablets for infringing use and would not induce others to do so. A judgment holding that Apotex would not induce infringement would, on its face, not contradict a judgment finding that Sandoz would induce infringement. To the extent the Court has to consider various factors to determine whether inducement would occur, and that the existence or incidence of these factors have already been considered in other

cases, these consideration would not dictate the outcome, but would be taken into account by the Court, as judicial comity requires.

[37] In the end, allowing Nycomed, through different or better evidence, to attempt to establish that Sandoz will induce infringement cannot be an abuse of process, since that issue was not determined in *Apotex* and could therefore not give rise to contradictory judgments.

[38] In contrast, the other cases relied upon by Sandoz as instances where the Court has dismissed applications pursuant to sub-section 6(5)(b) on allegations of non-infringement were cases where the Court was satisfied that the applicant could not possibly succeed in establishing that the allegations were not justified.

[39] The first such cases were *Hoffman-La Roche Ltd. v. Pro Doc Ltée,* (1998), 85 C.P.R. (3d) 50 and *Hoffman-La Roche Ltd. v. Pharmascience Inc.*, (1999), 87 C.P.R. (3d) 251. In the *Pro Doc* case, the Court reviewed the evidence filed by Hoffman on the merits of the application, and found that it "adds nothing new to assist in the construction of the relevant words of the patent". In view of the fact that prior determinations had turned on that construction and that Hoffman could not bring any evidence of the composition of the proposed drug as direct evidence of infringement (the disclosure requirements of section 6(7) of the *Regulations* not yet being in effect), the Court concluded that the application was simply re-litigation on the same evidence and was an abuse of process (see paragraphs 10 and 14). In *Pharmascience*, the Court held that it

was bound by the interpretation of the patent in the earlier decisions; as the Notice of Allegation stated that the medicine would contain none of the acids claimed, with no opportunity for Hoffman to bring evidence to the contrary, the application could not possibly succeed on that ground (see paragraphs 8 and 9).

[40] In *Sanofi-Aventis v. Novopharm*, 2007 FCA 167 (a decision subsequent to the *Sanofi-Aventis* decision earlier cited), the Court of Appeal granted a motion to dismiss pursuant to sub-section 6(5)(b), not on the basis of an earlier decision, but on the basis that the evidence already filed by the applicant in the main application on the non-infringement issue could not possibly succeed. As stated by the Court of Appeal (at paragraph 13):

> "13 There is nothing in the redacted product monograph, or any of the other documents in the record, that is capable of establishing that Novopharm will infringe the 089 patent or the 948 patent, either directly or by inducing infringement by others. Sanofi does not contend that there is such evidence, but argues that something might emerge on cross-examination. In my view, that argument should have been rejected as entirely speculative. Once the speculative possibility of additional evidence is set aside, it is inevitable that the prohibition application in this case would fail because Novopharm's non-infringement allegation is justified."
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> (Emphasis mine)

[41] Likewise, it is clear from the reasons of Prothonotary Lafrenière in the recent *Novopharm* case that he carefully reviewed the evidence that had been tendered by Nycomed on the merits of the application, and, excluding the speculative possibility that

additional evidence might emerge on cross-examinations, proceeded, in light of the decision in *Apotex*, to determine whether there was any additional or materially different evidence from that which had been considered by Justice Gauthier in *Apotex*. Although the Court in *Novopharm* does discuss the impact of the Federal Court of Appeal's decision in the first *Sanofi-Aventis* case, it is clear that the final determination of the Court rested on the conclusion that Nycomed had not adduced any materially different evidence that would justify a different result:

> "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."

[42] Properly understood, then, because Sandoz' allegation that it will not infringe or induce infringement of the '748 Patent has never been determined, Sandoz' burden on this motion is to establish that Nycomed could not possibly succeed in establishing that the allegation is not justified. Unlike the situation in *Novopharm*, however, the evidence to be adduced by Nycomed on the merits of the application is not before the Court – it has in fact yet to be filed. Sandoz' burden is therefore all the heavier because it has to show that Nycomed could not possibly adduce sufficient evidence to be successful.

[43] Sandoz submits, in essence, that because its product monograph is not materially different from Apotex's in the crucial aspects of indications, dosage regimen and lack of

reference to treatment of *H. Pylori* infections by combination therapy, it would be impossible for Nycomed to bring evidence that would show that the product monograph would induce infringement.

[44] Sandoz' argument that Nycomed cannot establish inducement because its product monograph is indistinguishable from Apotex's in its crucial aspects is fundamentality flawed because it is premised on the incorrect assumption that inducement can only be established on the basis of the product monograph. However, the Court of Appeal has clearly held, in the second *Sanofi-Aventis* decision, that infringement by inducement may be established by a variety of factors, either alone or in combination, beyond mere inferences drawn from the content of the product monograph.

> "11 (…) Infringement by inducement may be established, for example, by inferences reasonably drawn from the contents of the product monograph for the generic drug product, or evidence relating to the dosage form of the generic product, or its labelling or marketing. However, an inducement to infringe generally cannot be inferred from a mere reference to the new use in the product monograph, for example, in the course of explaining contraindications or drug interactions, or as part of a list of scientific references."
>
> (Emphasis mine)

[45] The clear implication of this passage is that inducement may indeed be established by a generic's marketing practices, quite independently of the content of the product monograph and that it is open for the Court to consider all these factors.

[46] Sandoz has brought no evidence to suggest – let alone establish – that Nycomed could not possibly bring evidence as to Sandoz' marketing or promotional practices from which an intent to induce infringement could be inferred.

[47] Even as concerns the inferences to be drawn from the product monograph itself, none of the authorities referred to by Sandoz suggest that the indications, dosage regimen and the absence of express reference to the protected uses are the only aspects of a product monograph that can be considered. Indeed, the *Apotex* decision reviews various cases where the following were found to indicate an intent to adduce infringement: Voluntary omissions in a generic's monograph as compared with the innovator's, the choice of reference product for comparison and reference to studies relevant to the protected use. More importantly, this discussion emphasizes that the product monograph must be looked at as a whole. It is not a mechanical exercise involving simply looking at the list of indications, the dosage regimen and whether the words "*H. Pylori*" are used.

[48] Yet Sandoz invites the Court to do just that. It puts before the Court its own proposed product monograph, Apotex's product monograph (it bears noting that there is no evidence that Apotex's official product monograph, now available through Health Canada, is the same as the draft product monograph considered by Justice Gauthier) and invites the Court to note that the indications are essentially similar, that the dosage regimen is similar and that apart from two instances, it does not use the words *H. Pylori*. Sandoz has not filed the evidence of any expert who might have read these 32-page

scientific documents and might have understood whether there might be subtle, yet significant differences between them.

[49] Sandoz has therefore failed to meet its burden of establishing, by evidence or cogent argument, that no evidence whatsoever could be brought on the merits of this application by Nycomed, outside the specific aspects of the product monograph upon which Sandoz relies, from which the likelihood of inducement could be found. Nycomed therefore did not need to prove, on this motion, that it could or would lead such evidence. A motion to dismiss pursuant to sub-section 6(5)(b) is not a motion for summary judgment where an applicant is compelled to show the existence of a triable issue, but a motion upon which the entire burden of persuasion rests on the moving party.

[50] Nevertheless, Nycomed did bring some evidence of its ability to bring different and relevant evidence, as was prudent. Without going over all the aspects of the evidence Nycomed has tendered to show the type of evidence it would propose to lead on the merits of this application, I note that the evidence includes a statement from a pharmacist to the effect that, having had prior dealings with Sandoz' sales representatives, Sandoz' marketing practices include representations by sales representatives promoting and insisting upon the complete interchangeability and equivalence "for all purposes" between Sandoz' product and the innovator's product, and that he believes the same would occur with respect to pantoprazole. Sandoz has the burden of establishing that Nycomed cannot or even should not be permitted to bring better evidence against Sandoz than it has led against Apotex. Yet, Sandoz has not attempted to show that similar

evidence was brought before Justice Gauthier with respect to Apotex's promotional practices, or even that Apotex has similar practices which could have been put in evidence before her. Nor has Sandoz attempted to show that, if believed, that evidence could not support a finding that Sandoz would induce infringement or be encouraging "off label" uses. Certainly, neither Justice Gauthier in *Apotex* nor Prothonotary Lafrenière in *Novopharm* discussed evidence of this type, suggesting that it was not before them.

[51] As mentioned, I refer to this evidence merely because it is a clear example of the kind of potentially significant and different evidence which Nycomed appears to be both capable and justified in bringing on the merits of this application.

[52] If it was needed, that evidence is sufficient to confirm to me that Sandoz has not met the heavy onus upon it to show that Nycomed's application cannot possibly succeed, or that allowing it to proceed would be an abuse of process.

Costs

[53] Nycomed was successful in opposing this motion and accordingly shall have its costs. In addition, I have found that at least two of the grounds relied upon by Sandoz on this motion (eligibility for listing and irrelevance of the patent) were based on a reading of the Court's decision in *Apotex* which could not reasonably be supported on the clear reasons given by the Court. These arguments were ill-considered, ill-founded and should

not have been raised. They have 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. As to Sandoz' arguments with respect to non-infringement, they were, while novel, based on assumptions as to what evidence could be available to Nycomed that were far too sweeping and unjustified. This lack of balance and restraint has again forced Nycomed to disrupt the orderly preparation of its evidence on the merits to package a "preview" of its evidence for use on this motion. The matter was not aided by Sandoz' inappropriate insistence, on several occasions, that this motion should be heard urgently, its repeated requests for case management telephone conferences and modifications to the schedule to meet its shifting views of how quickly or advantageously its motions under 6(5)(a) and 6(5)(b) ought to be heard. Sandoz' precipitation and sense of urgency were driven only by its desire to have an NOC as soon as possible, and then only because its competitors, having filed their own Notices of Allegation years before it, were naturally reaping the benefits of their diligence earlier than Sandoz. In all the circumstances, the Court considers it appropriate that Nycomed be awarded its costs of this motion, including all the case management telephone conferences held to schedule and re-schedule it, at the high end of Column V of Tariff B. Nycomed shall also have its costs of its counsel's travel for the purposes of the hearing and, of course, of its experts, all forthwith and in any event of the cause.

ORDER

IT IS ORDERED THAT:

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

"Mireille Tabib"
Prothonotary

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1941-07
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 28, 2008

APPEARANCES:

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