Federal Court of Appeal  Cour d'appel fédérale

Date: 20060210

Docket: A-124-05

Citation: 2006 FCA 51

CORAM: **DÉCARY J.A.**
EVANS J.A.
SHARLOW J.A.

BETWEEN:

APOTEX INC.

Appellant
(Respondent)

and

AB HASSLE, ASTRAZENECA AB and ASTRAZENECA CANADA INC.

Respondents
(Applicants)

and

THE MINISTER OF HEALTH

Respondent
(Respondent)

REASONS FOR JUDGMENT

SHARLOW J.A.

[1] Apotex Inc. is appealing the order of the Federal Court dated February 24, 2005, made on the application of AB Hassle, AstraZeneca A.B. and AstraZeneca Canada Inc. (collectively,

"AstraZeneca") under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (the "NOC Regulations"). That order prohibits the Minister of Health from issuing a notice of compliance to Apotex Inc. in respect of 10 mg and 20 mg omeprazole magnesium tablets until after the expiration of Canadian Patent No. 1,292,693 (the "693 patent") in 2008. The reasons for that order are reported as *AB Hassle v. Apotex Inc.* (2005), 38 C.P.R. (4th) 216 (F.C.).

[2] This appeal raises a number of questions about the scope of the doctrine of abuse of process in proceedings under the *NOC Regulations*. These are summary proceedings, intended to facilitate a relatively quick determination by the Federal Court of certain issues of patent construction, infringement and validity, but only for the limited purpose of making (or declining to make) an order prohibiting the Minister of Health from approving the sale in Canada of a new generic drug for which approval is sought on the basis of a comparison to an existing product whose producer has certain patent rights. If the generic drug producer wishes its product to be marketed before the expiry of a particular patent, the *NOC Regulations* require a "notice of allegation" and a "detailed statement" explaining why the product will not infringe the patent, or why the patent is invalid. To obtain a prohibition order, the patent holder must satisfy the Federal Court, on a balance of probabilities, that the generic manufacturer's allegations are not justified.

[3] In this case, the judge granted the prohibition order because (1) the non-infringement allegation made by Apotex was identical to a non-infringement allegation it had raised in a prior proceeding that resulted in a prohibition order, and (2) the allegations of invalidity made by

Apotex were not made in the prior proceeding, but those allegations are not to be considered in this case because of the doctrine of issue estoppel, or alternatively the doctrine of abuse of process.

[4] It has been recognized by this Court that a notice of allegation, together with the detailed statement of the factual and legal basis of the allegations stated in the notice, plays a critical role in defining the issues to be determined in proceedings under the *NOC Regulations*. The notice of allegation and detailed statement must address all relevant patent claims, and must contain enough information to allow the "first person" (as defined in the *NOC Regulations*) to make an informed decision as to whether to respond to the notice of allegation by commencing an application for a prohibition order. A notice of allegation that meets these tests is said to be "sufficient". The corollary is that a "second person" (as defined in the *NOC Regulations*) cannot, in response to a first person's application for prohibition, present evidence and argument relating to an issue that is outside the scope of the notice of allegation and detailed statement. The jurisprudence on sufficiency arises from a line of cases that includes *Bayer AG v. Canada (Minister of National Health and Welfare)* (1993), 163 N.R. 183, 51 C.P.R. (3d) 329 (F.C.A.) at paragraph 15, *AB Hassle v. Canada (Minister of National Health and Welfare)* (2000), 7 C.P.R. (4th) 272, 256 N.R. 172 (F.C.A.) at paragraph 21, *SmithKline Beecham Inc. v. Apotex Inc.* (2001) 10 C.P.R. (4th) 338, 267 N.R. 101 (F.C.A.) at paragraph 27, and *AstraZeneca AB v. Apotex Inc.* (2005), 335 N.R. 1 (F.C.A.) at paragraph 12.

[5] There is no doubt that Apotex provided enough information for AstraZeneca to frame an application for a prohibition order. The argument of AstraZeneca as to the sufficiency of the notice of allegation raises a debate about the scope of the notice of allegation and detailed statement. AstraZeneca argues that the notice of allegation and detailed statement raise only one point of patent construction, the very point that was determined against Apotex in *AB Hassle v. Apotex Inc.* (2003), 29 C.P.R. (4th) 23, 312 N.R. 288 (F.C.A., confirming (2002), 223 F.T.R. 43, 21 C.P.R. (4th) 173) (F.C.), leave to appeal to the Supreme Court of Canada dismissed March 25, 2004, S.C.C. Bulletin, 2004, page 471). I will refer to that case as "*AB Hassle 2003*".

[6] Apotex argues that its notice of allegation and detailed statement should be interpreted as raising a point of patent construction that is new (that is, a point that was not raised in *AB Hassle 2003*). In support of that argument, Apotex argues that AstraZeneca discerned that new point of patent construction because it led evidence relevant to that point and addressed that point in its submissions in the Federal Court. AstraZeneca says that its evidence and submissions in the Federal Court are intended to address only the point of patent construction that was considered in *AB Hassle 2003*.

[7] To put this debate into its proper context, it is necessary to consider *AB Hassle 2003* in some detail. This case and *AB Hassle 2003* involve the same parties, the same proposed generic product of Apotex, the same comparison product of AstraZeneca, and the construction of the same words of the same claim of the same patent. The focus of *AB Hassle 2003* is paragraph (b) of claim 1 of the 693 patent. Claim 1 reads as follows:

1. An oral pharmaceutical preparation comprising:

(a) a core region comprising an effective amount of material selected from the group consisting of omeprazole plus an alkaline reacting compound, an alkaline omeprazole salt plus an alkaline reacting compound and an alkaline omeprazole salt alone;

(b) an inert subcoating which is soluble or rapidly disintegrating in water disposed on said core region, said subcoating comprising one or more layers of materials selected from among tablet excipients and polymeric film-forming compounds; and

(c) an outer layer disposed on said subcoating comprising an enteric coating.

[8] In these reasons, I use the terms "medicinal core" to refer to the core described in paragraph (a) of claim 1, "subcoating" to refer to the subcoating described in paragraph (b) of claim 1, and "enteric coating" to refer to the outer layer described in paragraph (c) of claim 1.

[9] In *AB Hassle 2003*, Apotex made only one allegation, which was a non-infringement allegation. That allegation reads as follows (Appeal Book, Volume 1, page 319):

> The claims of these patents cover compositions comprising a core containing a medicine, an inert subcoating, and an outer enteric coating. Our tablets will not fall within the scope of the claims of these patents.
>
> More specifically, our tablets comprise cores containing the drug, and an enteric coating applied directly to the cores without any subcoating between the cores and the enteric coating. Our tablets will not infringe, by reason [sic] there being no subcoating between the cores and the enteric coating.

[10] In the decision of the Federal Court in *AB Hassle 2003*, this allegation was found not to be sufficient, with the result that the Federal Court granted the application for a notice of prohibition. On appeal Rothstein J.A., writing for the Court, doubted that the allegation was

deficient, but confirmed the prohibition order on the basis that the non-infringement allegation could not be justified because it was premised on an incorrect construction of paragraph (b) of claim 1 of the 693 patent.

[11] The non-infringement allegation made by Apotex in *AB Hassle 2003* was based on a particular construction of paragraph (b) of claim 1 of the 693 patent. Apotex construed that part of claim 1 as referring to a layer of material that is applied to the medicinal core and covered with the enteric coating. In other words, Apotex argued in *AB Hassle 2003* that the meaning of "subcoating" in paragraph (b) of claim 1 of the 693 patent must mean a subcoating placed on the core by design and not any material created *in situ* by a chemical reaction that occurs when an enteric coating is applied directly to a medicinal core.

[12] The proposed Apotex product in *AB Hassle 2003* (and in this case) is said to consist of an enteric coating applied directly to the medicinal core. The evidence is that a chemical reaction occurs where the two meet, resulting in a layer of material between the medicinal core and the enteric coating that would fulfil the function of the subcoating referred to in paragraph (b) of claim 1 of the 693 patent but, according to the construction proposed by Apotex, would not meet the description of the subcoating in paragraph (b).

[13] Rothstein J.A., writing for this Court in *AB Hassle 2003*, did not accept the construction of paragraph (b) of claim 1 of the 693 patent proposed by Apotex. He construed the relevant part of the claim as follows at paragraphs 21 to 24 of his reasons:

> [21] ... Because claim 1 is clearly a product claim and not a process claim, I construe the term "disposed on said core region" as describing the structure of the finished pharmaceutical preparation. The term, in the context of a product claim, describes the location of the subcoating and not the process by which it was formed.
>
> [22] If, as I construe it, claim 1 describes a finished product, nothing in the disclosure detracts from the interpretation that the inert subcoating need not be formed by any particular process or formation. In the finished product, a subcoating applied to the core or a subcoating formed in situ would separate the core from the enteric coating. That the disclosure provides that the core and enteric coating must be separated "during the coating process" might help to construe an ambiguous process claim. But I do not see those words as having any application to a claim that clearly describes a finished product. Similarly, the other references in the disclosure relied upon by Apotex describe one process for making the pharmaceutical preparation -- sequentially applying the subcoating to the core and then the enteric coating to the subcoating. But nothing in claim 1 purports to place a process limitation on the finished pharmaceutical preparation.
>
> [23] Apotex argues that such a construction is inconsistent with the disclosure because the very problem the invention was designed to solve is that direct contact between the omeprazole core and the enteric coating results in discolouration and the eventual degradation of the core. However, the patent goes on to teach that this storage stability problem can be solved by adding sufficient alkaline reacting constituents to the core. A subcoating is only needed to prevent the premature dissolution in the stomach of the enteric coating of tablets with an alkaline core. That problem only occurs when the tablet is ingested and thus claim 1 does not preclude the core and the enteric coating from coming into contact during the manufacturing process so long as a subcoating exists in the final product.
>
> [24] I conclude that patent claim 1 describes a pharmaceutical preparation which, in its finished product form, contains a subcoating or separating layer between the core and enteric coating, however the subcoating or separating layer is formed.

[14] This conclusion is germane to this case because this case involves a similar, if not identical, non-infringement allegation. The key portions of the non-infringement allegation in this case read as follows (Appeal Book, Volume 1, pages 190 to 193):

With respect to ... [claim 1] ..., we allege that no claim for the medicine itself and no claim for the use of the medicine would be infringed by the making, constructing, using or selling by us of the said tablets.

[...]

The '693 Patent, entitled "*Pharmaceutical Preparation Containing Omeprazole*", relates to a pharmaceutical preparation containing omeprazole or its alkaline salts intended for oral use and to the use of these preparations in the treatment of gastrointestinal diseases.

The essence of the alleged invention in the '693 Patent is the development of a formulation which purports to solve the problem of the prior art formulations which consisted of an alkaline core containing omeprazole or an alkaline salt of omeprazole, and an enteric coating disposed on the core that led to degradation. The alleged solution to the problem is asserted in the patent to be the separation from contact of the core and the enteric coating by application of a subcoating within the meaning of the patent.

Each of the claims in issue of the '693 Patent contain among its essential elements, the following essential elements:

(i) within the formulation core region a selection from the group consisting of:

  (a) omeprazole plus an alkaline reacting compound;

  (b) an alkaline omeprazole salt plus an alkaline reacting compound; or

  (c) an alkaline omeprazole salt alone;

(ii) an inert subcoating which is soluble or rapidly disintegrating in water disposed on said core region, said subcoating comprising one or more layers of materials selected from among tablet excipients and polymeric film-forming compounds; and

(iii) an outer layer disposed on said subcoating comprising an enteric coating.

In light of the foregoing, and in light of the very clear discussion within the disclosure, the "subcoating" in part (ii) above cannot mean material comprising a reaction product resulting from a reaction between the core material and the enteric coating when the core is brought into contact with the enteric coating. The reaction product is precisely what the disclosure and the patent are directed not to having formed and hence it is not a subcoating within the meaning of "subcoating" of the patent. It is clearly not what the patent is directed to or what the inventors intended. The patent and the inventors intended the subcoating to be distinct material placed

between the core and the enteric coating so as to avoid their coming into contact.

Furthermore, the claims in issue of the patent cannot be construed to include within their scope those formulations which are referred to in the disclosure of the '693 Patent as being within the prior art. More particularly, formulations comprising a core with an enteric coating disposed on the core which were prepared by direct application of the enteric coating onto a core containing omeprazole and an alkaline reacting compound, or an alkaline salt of omeprazole optionally including an alkaline reacting compound, cannot be construed as falling within the scope of the claims of the '693 Patent, otherwise, the patent would be invalid as failing to claim something which is new, because it would have within its scope that which is old.

Finally, the claims in issue of the patent cannot be construed to include within their scope those formulations which are disclosed within the disclosure of the '693 Patent as examples of formulations which were used for comparison purposes, and were thus disclaimed from being within the scope of the claimed invention, against those formulations which were described as being examples of the alleged claimed invention of the '693 Patent for the purpose of demonstrating the benefits of the alleged inventive formulations.

Non-Infringement

Each of the claims in issue of the '693 Patent is dependent on claim 1.

We allege that we will not infringe any of the claims in issue of the '693 Patent since we will not infringe claim 1.

Claim 1 will not be infringed since our formulation will not contain a "subcoating", as discussed above, within the meaning of the '693 Patent. Our product will contain a core with an enteric coating disposed on the core. In formulating our product, we will bring into contact the outer enteric coating with the core and will not place a subcoating within the meaning of the patent between the core and the enteric coating, so that our formulation will consist of only components (i) and (iii), not component (ii).

[...]

In addition, given that what we are manufacturing is that which is taught in the prior art, then there clearly cannot be any infringement.

More particularly, our formulation of magnesium omeprazole tablets is taught in European Patent Application No. 124,495, published on November 7, 1984, wherein at pages 5 to 8 and at Example 12 of this Application, formulations containing a base addition salt of omeprazole (including magnesium omeprazole) are disclosed.

> Included within the aforementioned disclosure are references to enteric coated tablet formulations wherein the tablets are coated with an enteric coating which protects the active compound from degradation. Our formulation is in accordance with the aforementioned teachings of European Patent Application No. 124,495.
>
> Should you assert that any of the claims in issue of the '693 Patent are infringed, we allege that the claims are invalid based upon what has become known in Canadian law as the Gillette Defence, as discussed below.

[15] The "Gillette Defence", so named because it was recognized in *Gillette Safety Razor Co. v. Anglo-American Trading Co. Ltd.* (1913), 30 R.P.R. 465 (H.L.), as a defence to a claim of infringement, is made out when it is established that the alleged infringing product is based on the teachings of a prior patent. In this case, the particulars of the Gillette Defence are to be understood on the basis of the following explanation, which appears at the beginning of the allegations of invalidity in the notice of allegation (Appeal Book, Volume 1, page 194):

> As noted above, we assert that the meaning of "subcoating" within the '693 Patent; is a subcoating which consists of material placed there by design and not any material created *in situ*. If you assert that any of the claims of the '693 Patent are infringed by our formulation by reason of the fact that our formulation allegedly contains a "subcoating" which is formed *in situ* between the core and the enteric coating, and said "subcoating" is within the meaning of the claims of the '693 Patent, then we allege that the claims must be invalid in accordance with the principles set out in the decision of the *House of Lords in Gillette Safety Razor Company v. Anglo American Trading Company Ltd.*, (1913) R.P.C. 465, and the decision of *J.K. Smit & Sons, Inc. v. Richard S. McClintock* [1940] S.C.R. 279.
> Our formulation is within the prior art as disclosed by the teachings of European Patent Application No. 124,495, published on November 7, 1984, as discussed above. Further, the use of such a formulation to treat gastrointestinal disease is also in accordance with the teachings disclosed within European Patent Application No. 124,495.
> If our formulation contains a "subcoating" within the meaning of the '693 Patent, then the enteric coated formulations disclosed within European Patent Application No.

> 124,495 would also contain such a "subcoating" and thus any allegedly infringed claims must be invalid.

[16] The notice of allegation in this case contains, in substance, the same non-infringement allegation that was the subject of *AB Hassle 2003*, although that allegation is described in greater detail in the notice of allegation in this case. Apotex argues that it also contains a new non-infringement allegation, which I summarize as follows: (1) If paragraph (b) of claim 1 of the 693 patent is properly construed, a product is within the scope of that claim only if it has a subcoating that is inert, continuous and comprised of polymeric film-forming compounds. (2) In the proposed Apotex product, the layer of material between the medicinal core and the outer coating lacks those characteristics. (3) Because those characteristics are not present, the Apotex product cannot be within the scope of paragraph (b) of claim 1 of the 693 patent. AstraZeneca argues that the notice of allegation and detailed statement do not raise this new non-infringement allegation, or at least do not raise it with sufficient clarity to meet the "sufficiency" test.

[17] The determination of the sufficiency of an allegation is a question of mixed law and fact. The standard of appellate review is palpable and overriding error, except to the extent that a question of law can be extricated from the conclusion, on which case that question of law must be determined correctly: *Housen v. Nikolaisen*, [2002] 2 S.C.R. 235; see also paragraph 9 of *AstraZeneca AB v. Apotex Inc.* (2005), cited above.

[18] The judge discussed in detail the competing arguments on the sufficiency debate (see her reasons for judgment at paragraphs 17 to 54). The judge refers in her reasons to all of the relevant material, including the material filed by AstraZeneca that, in the view of Apotex, established that AstraZeneca understood that Apotex was raising a new point of patent construction, and that AstraZeneca addressed or attempted to address that new point in the material filed in support of its application for prohibition. In the end, the judge accepted the submission of AstraZeneca that the notice of allegation was not sufficient to raise the new issue.

[19] In my view, the judge's conclusion on this point was reasonably open to her on the record. Having reviewed the same material that she did, and the arguments of counsel, I can find no error of law or any other error that would justify adopting an interpretation of the notice of allegation that departs from the judge's interpretation. This ground of appeal must fail.

[20] It follows that the only non-infringement allegation properly raised in this case was the same point as that raised in *AB Hassle 2003*. The non-infringement allegation in that case was held not to be justified because it was premised on an incorrect construction of the patent. There is no basis for reaching a different conclusion in this case with respect to the same non-infringement allegation.

[21] I turn now to the invalidity allegations. There are a number of them. Most turn on the point of patent construction that was finally accepted in *AB Hassle 2003*. For example, Apotex

asserts that if paragraph (b) of claim 1 of the 693 patent is construed to include a subcoating formed *in situ* between the medicinal core and the enteric coating (as determined in *AB Hassle 2003*), then the claim is invalid because (a) such a subcoating is disclosed in the prior art (refer to the comments above relating to the Gillette Defence), (b) the claim is invalid for anticipation because of the prior art, (c) the disclosure is insufficient and ambiguous because it does not disclose how to achieve a successful formulation with an *in situ* subcoating, and (d) the claims are obvious, based on the prior art. Other allegations of invalidity do not appear to be related to the patent construction issue that was the subject of *AB Hassle 2003*. For the purposes of this appeal it is not necessary to summarize them.

[22] The principal issue in this case is whether Apotex could and should have raised the invalidity allegations in *AB Hassle 2003* and whether, in the particular circumstances of this case, its attempt to raise these invalidity allegations for the first time in this case should be barred on the basis of the doctrines of issue estoppel, *res judicata* or abuse of process. In my view, this issue is best resolved on the basis of abuse of process alone. For that reason, I do not propose to discuss issue estoppel or *res judicata*.

[23] In certain situations, this Court has permitted a second person to make a series of distinct allegations, so that a first person might be forced to consider commencing a new prohibition proceeding to challenge each one. For example, if a first person's product is the subject of a patent list with more than one patent, a second person may submit a separate notice of allegation with respect to each patent, potentially resulting in a separate prohibition proceeding for each

patent: *Parke-Davis Division v. Canada (Minister of Health) (C.A.)*, [2003] 2 F.C. 514, at paragraph 67.

[24] It has also been recognized that, in certain circumstances, a second person may submit more than one notice of allegation in relation to a certain patent in respect of the same proposed generic product: see *Apotex Inc. v. Attorney General (C.A.)*, [2000] 4 F.C. 264, (2000) 188 D.L.R. (4th) 145, 255 N.R. 319, 24 Admin. L.R. (3d) 279, 6 C.P.R. (4th) 165, per Evans J.A., at paragraph 44 (leave to appeal refused, [2001] 1 S.C.R. v); *Apotex Inc. v. Canada (Minister of National Health and Welfare)* (1997) 153 D.L.R. (4th) 68, 219 N.R. 151, 76 C.P.R. (3d) 1 (F.C.A.) (leave to appeal refused, [1998] 1 S.C.R. viii, *sub.nom Eli Lilly and Co. v. Apotex Inc.*). However, if a second person submits a second or subsequent notice of allegation relating to the same proposed product and the same patent, the first person may commence prohibition proceedings and argue that the second or subsequent notice of allegation is an abuse of process. Similarly, the second person may argue (if a prohibition order was previously denied), that a second application for a prohibition order is an abuse of process.

[25] It would be fruitless to attempt an exhaustive list of situations in which a second or subsequent notice of allegation would not be an abuse of process. However, by way of example, it may be that there would be no abuse of process if the second notice of allegation is based on new facts, a newly discovered process, a change in the law, a situation that limits the scope or application of an existing prohibition order, or a new and definitive decision as to the validity or construction of the patent. Even if it is determined that a second or subsequent notice of

allegation is an abuse of process, the Federal Court nevertheless has the discretion to determine the application for a prohibition order on its merits: *Apotex Inc. v. Attorney General (C.A.)*, cited above, per Evans J.A., at paragraphs 46 and 47.

[26] The judge in this case found that Apotex could have raised its invalidity allegations in the previous proceedings, from which she concluded that issue estoppel, or alternatively abuse of process, applies. In my view, the judge made no error of law in reaching that conclusion. The judge went on to consider whether she should nevertheless exercise her discretion to hear the invalidity arguments, and concluded that she should not. In that regard, she considered a number of issues, which are discussed comprehensively in her reasons at paragraphs 82 to 90 (with respect to issue estoppel) and paragraphs 91 to 98 (with respect to abuse of process).

[27] This Court will not interfere with the exercise of a judge's discretion unless there is an error of law or principle, or a failure to exercise the discretion judicially: *Elders Grain Co. v. M/V Ralph Misener*, 2005 FCA 139, at paragraph 13. The record in this case discloses no such error.

[28] It is apparent that Apotex disagrees with the point of patent construction adopted in *AB Hassle 2003*, and remains of the view that the 693 patent is invalid. If so, Apotex is not without a possible remedy. It is well established that proceedings under the *NOC Regulations* cannot result in decisions that are conclusive for all purposes on questions of validity and infringement. It is

open to parties to proceedings under the *NOC Regulations* to obtain a full trial on such issues by commencing an action under the *Patent Act*.

[29] For example, if a patent holder applies unsuccessfully for a prohibition order under the *NOC Regulations* in response to a non-infringement allegation, but still believes that the product will infringe its patent once it is brought to market, the patent holder retains the right to sue for damages for infringement. Similarly, in this case Apotex may bring an action under section 60 of the *Patent Act* to impeach the 693 patent: *Apotex Inc. v. Syntex Pharmaceuticals International Ltd.* (1999), 166 F.T.R. 161, 1 C.P.R. (4th) 22 (F.C.T.D.). If such an action were to result in a declaration that the 693 patent is invalid, then either the prohibition order in *AB Hassle 2003* would cease to have any effect, or the prohibition order could be set aside under Rule 397 of the *Federal Courts Rules*, SOR/98-106: see *Hoffmann-La Roche Ltd. v. Canada (Minister of National Health and Welfare)* (1999), 167 F.T.R. 111 (F.C.T.D.) (paragraphs 14 to 16).

[30] For these reasons, I would dismiss this appeal with costs.

"K. Sharlow"

J.A.

"I agree
Robert Décary J.A."

"I agree
John M. Evans J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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