

Federal Court



Cour fédérale

Date: 20110711

Docket: T-1409-04

Citation: 2011 FC 862

Toronto, Ontario, July 11, 2011

PRESENT: The Honourable Mr. Justice Hughes

BETWEEN:

**ASTRAZENECA CANADA INC., AND
AKTIEBOLAGET HÄSSLE**

Plaintiffs

and

APOTEX INC.

Defendant

AND BETWEEN:

APOTEX INC.

**Plaintiff by
Counterclaim**

and

**ASTRAZENECA CANADA INC.,
AKTIEBOLAGET HÄSSLE and
ASTRAZENECA AB**

**Defendants by
Counterclaim**

REASONS FOR ORDER AND ORDER

[1] The present Order arises from an earlier Order that I made in this action on June 20, 2011.

At that time, I had before me a motion brought by the Plaintiffs to strike certain paragraphs from the Amended Statement of Defence and Counterclaim filed May 11, 2011; or in the alternative, for

particulars. I ordered that paragraph 157S of that pleading be struck out with leave to amend and that a draft should be submitted for consideration by the Plaintiffs, and that a further hearing in respect of any objections to the draft was to be scheduled so as to expedite matters.

[2] Paragraph 157S, as was struck out, read:

157S In addition, courts in other jurisdictions have made findings in certain cases that are contrary to or inconsistent with some or all of the findings relied upon by the Plaintiffs at paragraph 45 of the Statement of Claim. The Plaintiffs, and/or one or more of their proxies, were parties to these cases. Accordingly, neither issue estoppel nor abuse of process can apply to such findings. To the contrary, it is the Plaintiffs who should be estopped from advancing allegations contrary to the findings made by courts in other jurisdictions.

[3] The revised draft pleadings re-numbered the paragraphs, and the proposed revisions are now numbered as paragraphs 176 through to and including 192. Because of their length, I append them to these reasons.

[4] Plaintiffs' Counsel took objection to each of paragraphs 176 to 192 and grouped the objections into four categories as follows:

Category 1 Paragraphs 191 and 192

Category 2 Paragraphs 186 to 190

Category 3 Paragraphs 183 to 185

Category 4 Paragraphs 176 to 182

[5] Plaintiffs' Counsel also objected to the open-ended nature of paragraph 176. Defendant's Counsel undertook to amend that paragraph to add words such as "as particularized in the following

paragraphs” so as to limit what is said in paragraph 176 to the subsequent paragraphs in that pleading.

[6] I will consider each of the paragraphs as categorized:

Category 1: Paragraphs 191 and 192

1. These paragraphs recite that the Defendant Apotex is aware of litigation in certain foreign countries, England, etc., where the Plaintiffs or related parties were litigants and asserted “certain patents...for omeprazole”. The Defendant asks that it be allowed to discover the Plaintiffs to find out more about this litigation, presumably for the purpose of sifting through what might be discovered as to whether it might be useful to support a plea of estoppel or abuse of process.

2. This is a classic fishing expedition. Discovery is not, in and of itself, a separate right to which a party may be entitled; it is part of a process initiated by proper pleading. The pleadings set out in paragraphs 191 and 192 are clearly improper and cannot be included in the Amended Defence and Counterclaim.

Category 2: Paragraphs 186 to 190

1. These paragraphs relate to the United States proceedings as set out in paragraphs 43 to 46 of the Third Amended Statement of Claim, which the Plaintiffs were permitted to file by the Order of Prothonotary Lafreniere dated 8 April 2011 and affirmed by Justice Mosley

dated 20 May 2011. I understand that the Defendant has filed an appeal from the latter Order.

2. In the Plaintiffs' Amended Statement of Claim, they assert that there was an action in the United States Court between the same parties () as are before this Canadian Court and that certain factual determinations as to capsules identical to those of the Defendant as are at issue here were made. The Plaintiffs plead estoppel and abuse of process as a result.

3. Paragraphs 186 to 190 of the proposed Amended Defence relate to this United States litigation and assert that the Plaintiffs in that litigation (the same as or privies of the Plaintiffs here) elected *not* to assert certain claims of the United States patent at issue there and, as a result, cannot assert equivalent claims in the Canadian litigation.

4. This is a novel pleading for which neither Counsel nor I could find a precedent. To the extent that anything comes close, the remarks of Layden-Stevenson J. (as she then was) in *Johnson & Johnson Inc. v Boston Scientific Ltd.*, 2008 FC 552, 71 CPR (4th) 123 at paragraphs 260 to 268 may be of assistance:

260 In support of its arguments, Boston Scientific refers to the comments of Madam Justice Sharlow, then of the Federal Court Trial Division, in Connaught Laboratories Ltd. v. Medeva Pharma Ltd. (1999), 4 C.P.R. (4th) 508 (F.C.T.D.) (Connaught) aff'd. (2000), 4 C.P.R. (4th) 521 (F.C.A.), specifically those at paragraphs 15, 16 and 31 as follows:

In the final analysis, the validity of a patent granted by the laws of Canada cannot be determined by the legal regime in another country.

...

However, I do not understand why inconsistencies in findings of fact made by different tribunals should be tolerated if they can be avoided without offending the substantive law of procedural norms. Connaught is simply attempting to argue in this case that it is wrong in principle for Medeva to be permitted to take inconsistent positions on specific questions of fact that are in issue in this case and that have already been litigated elsewhere.

...

...Any plea of res judicata or a related principle adds complexity, because they compel the Court to consider difficult issues as to the nature of the prior proceedings and the precise significance of particular conclusions reached in the course of those proceedings.

...

It is also worth noting that the problem of complexity may be viewed in different ways. Patent litigation is already complex, in this Court and in every court that deals with patents. Ultimately, patent litigation may be simplified by principles that permit or require, in appropriate cases, the adoption of findings of fact in foreign proceedings. But this will never happen unless, in this case or another one, the Court undertakes an examination of the arguments that would open the door for establishing such a principle. (my emphasis)

261 *No further authority is cited by Boston Scientific, although the following excerpt from Kirin-Amgen Inc. & Another v. Boehringer Mannheim GmbH & Another v. Janssen-Cilag Limited, [1997] F.S.R. 289 (Eng. C.A)(Kirin-Amgen) is cited in Justice Sharlow's reasons:*

...I envisage cases where issue estoppel will arise in patent actions. For instance, the same issue can arise in different countries of the world, for example whether a particular scientific effect occurs when the invention or a manufacturing process is carried out or how an infringing product is made, or the properties of a product or its composition. Thus this judgment should not be taken as concluding that issue estoppel has no place in patent actions. To the contrary, I believe that it does in appropriate cases. (my emphasis)

262 Justice Sharlow's comments in *Connaught* occur in relation to an appeal from a prothonotary's decision to strike portions of a pleading purporting to rely on the findings of foreign jurisdictions to support a finding of *res judicata*. Justice Sharlow allowed the appeal on the basis that, "in principle, there is no reason to conclude that a plea of issue estoppel cannot be based on a foreign judgment, although inevitable difficulties will arise in establishing the conditions for its application." I regard it as settled law that pleadings that are worthy of the Court's attention should not be struck. In *Kirin-Amgen*, although noting that there may be circumstances in which issue estoppel can arise with respect to the findings of a foreign jurisdiction court, the Court declined to apply the doctrine.

263 In the end, whether to apply issue estoppel, even in circumstances where all the conditions are met, is a matter of discretion. Because I do not consider that this is an appropriate case to apply issue estoppel, I see little merit in reciting a lengthy and detailed description of the various proceedings (with their attendant discrepancies) from the foreign jurisdictions.

264 The evidence reveals that the decisions from the United Kingdom, the Netherlands, the United States and France are not consistent. In other words, the courts of the foreign jurisdictions did not arrive at the same outcomes. Notably, that was not the situation in *Connaught*.

265 An admission made in a foreign proceeding, which is expressly stated to be for the purpose of that proceeding only, cannot, in my view, be relied upon to establish that very fact in another proceeding, in another jurisdiction.

266 I agree with *Boston Scientific* that the law of the United Kingdom "most closely resembles that of Canada". Notwithstanding, there are distinctions. More specifically, with respect to the patents in issue in the United Kingdom, European Patent 0335341 (EP '341) is an improvement of the invention claimed in European Patent 0221570 (EP '570). However, EP '570 is not the "corresponding" patent for the '505 Patent. Rather, it corresponds to Canadian Patent No.1338303 (the '303 Patent), which is not in issue. The claims of EP '570 and EP '341 are similar to, but not identical to, the claims of the '505 and '186 Patents.

267 Moreover, Mr. John Thomas, a pre-eminently qualified legal expert, cautions that the term "corresponds" is not one of

precision. He states that patents are "among the most complex legal documents that can be produced". He notes that there are language differences that render understanding of foreign laws very complex. Differences in practice and procedure result in "distinctions among these claims".

268 *Further, claim construction is a question of law and is antecedent to issues of infringement and validity. Infringement and validity determinations are made by reference to the claims, as construed. Boston Scientific does not suggest (nor could it) that res judicata applies to claim construction.*

5. Justice Layden-Stevenson properly pointed out that admissions made in foreign litigation expressly for the purpose of that litigation only cannot be relied upon in litigation in Canada. She also correctly pointed out that one cannot readily assume that a foreign patent “corresponds” to a Canadian one and that the Court must be mindful of the differences in claim construction, which is a matter of law.

6. The proposed paragraphs 186 to 190 go a step further than the *Johnson & Johnson* pleadings and assert that what a party *did not* do in foreign litigation somehow precludes them from doing something in respect of a “corresponding” patent in Canada.

7. The Court must be mindful that litigation is costly and that unnecessary irrelevant or distracting matters should not be put in play simply because there is a possibility of relevance. I have in mind the recent decision of the Supreme Court of Canada in *Masterpiece Inc. v Alavida Lifestyles Inc.*, 2011 SCC 27, where Rothstein J. for the Court in dealing with expert evidence wrote at paragraph 76 remarks that are equally pertinent to the pleadings here:

76 In light of the relatively extensive expert evidence in this case, and the difficulties with the evidence that I discuss below, I think it is timely to recall that litigation is costly. Courts must fulfil their gatekeeper role to ensure that unnecessary, irrelevant and potentially distracting expert and survey evidence is not allowed to extend and complicate court proceedings. While this observation applies generally, I focus particularly on trade-mark confusion cases, which is the subject of this appeal.

8. Paragraphs 186 to 190 cannot be included in the Amended Defence.

Category 3: Paragraphs 183 to 185

1. These paragraphs again relate to the United States proceedings recently put into play by the Plaintiffs in their Amended Statement of Claim. The decision of the United States Courts, in part, makes reference to proceedings in Korea and the findings of the Korean Court. The proposed paragraphs 183 to 185 assert that as a result of contradictory positions taken by the Plaintiffs in the United States and Korean proceedings, the Plaintiffs cannot now assert that only the United States proceedings affect and estop Apotex in the Canadian proceedings.

2. Apotex was not a party to the Korean proceedings, nor was it a party to the so-called “first wave” of the United States proceedings. Paragraphs 183 to 185 are directed only to alleged contradiction in the “first wave” United States and Korean litigation; in other words, only to litigation in which Apotex was *not* a party.

3. For reasons as set out earlier respecting Category 2 paragraphs, these paragraphs 183 to 185 do not allege a proper defence and will not be allowed.

Category 4: Paragraphs 176 to 182

1. The Defendant Apotex has already undertaken to make amendments to the draft paragraphs 176, and no further comment is required here.

2. Paragraphs 177 to 182 are directed to the Korean action, which is recited in the United States decisions that the Plaintiffs have recently put in play. The Defendant Apotex says that the Korean Court found the product at issue there did not infringe the Korean patent. That was a different defendant, but Apotex says that the product is the same.

3. Plaintiffs' Counsel, relying on excerpts from its discovery of the Defendant, asserts Apotex's product is different from the Korean product and that the lynchpin of this proposed plea must fail. This is a matter of evidence to be proved at trial, with the assistance of experts, if appropriate. At a pleading stage, the Court must assume the truth of what is sought to be alleged.

4. Paragraphs 176 to 182 raise a triable issue and may be part of the Amended Defence.

CONCLUSION AND COSTS

[7] As a result, the Defendant may, within ten (10) days from the release of these reasons and order, file an Amended Defence to include, with reference to the draft, paragraph 176 with amendment as undertaken, and paragraphs 177 to 182. It may not include paragraphs 183 to 192 of the draft.

[8] The parties have agreed, and I concur, that costs shall be in the cause.

ORDER

FOR THE REASONS PROVIDED:

THIS COURT ORDERS that:

1. The Defendant may file, within ten (10) days hereof, an Amended Defence so as to include, with reference to the draft provided, paragraph 176 as undertaken to be amended, and paragraphs 177 to 182; paragraphs 183 to 192 of the draft shall not be included.

2. Costs in the cause.

“Roger T. Hughes”

Judge

ANNEX A

176. In addition, courts in other jurisdictions have made findings in certain cases that are contrary to or inconsistent with some or all of the findings relied upon by the Plaintiffs at paragraph 45 of the Statement of Claim. The Plaintiffs, and/or one or more of their proxies, were parties to these cases. Accordingly, neither issue estoppel nor abuse of process can apply to such findings. To the contrary, it is the Plaintiffs who should be estopped from advancing allegations contrary to the findings made by courts in other jurisdictions. Further, the Plaintiffs have taken contradictory positions in these proceedings in an attempt to advance their own interests. The Plaintiffs should not be permitted to approbate and reprobate.

177. In or about 1998, Chongkeundang Co., Ltd. (“CKD”) commenced an action in the Republic of Korea against Astra U.S.A. Inc. and Astra Korea Ltd. (the “Astra Korea Parties”) in the Seoul District Court, Department of Civil Affairs XII, being Case Nos. 95 Ka-Hap 55954 and 97 Ka-Hap 89582 (the “Korean Action”). CKD sought damages related to an injunction obtained by the Astra Korea Parties against CKD. The Astra Korea Parties counterclaimed for, among other things, an order that CKD not manufacture omeprazole pursuant to a certain process on the basis that said process and/or the CKD omeprazole product allegedly infringed a patent held by Astra U.S.A. Inc.

178. The Astra Korea Parties are controlled by the Plaintiffs or affiliates or subsidiaries of or are otherwise related to the Plaintiffs. Further, the Astra U.S.A. Inc. patent in issue in the Korean Action is materially the same as the '693 Patent.

179. In the Korean Action, the Seoul District Court held that:

In the course of the Plaintiff’s forming the core with Omeprazole and excess Larginine and enteric coating the above core with HPMCAS [hydroxypropyl methylcellulose], a continuous but non-uniform, thin layer with a thickness of about 15-20 µm is formed between the core of the OMP Tablet and the enteric coating layer. This polymeric thin layer is formed by the spontaneous surface reaction of L-arginine, the main ingredient of the tablet, with HPMCAS, the main ingredient of the enteric coating layer, at ambient temperatures. No separate step is required to form such a thin layer...

[...]

[I]t is quite possible that the above thin layer does not contribute to the prevention of decomposition and degradation, due to its discontinuity and the presence of fine pin-holes. Therefore, the above spontaneous thin layer forming process cannot be considered to be the equivalent with [sic] inner layer forming process of Astra U.S.’s patent.

180. In the Korean Action, the Astra Korea Parties took the position that, as a result of the formation of the “thin layer” referred to by the Seoul District Court in the quote above, CKD had infringed Astra U.S.A. Inc.’s patent. The Seoul District Court found that CKD had not infringed Astra U.S.A. Inc.’s patent. CKD’s omeprazole product did not contain a continuous inert sublayer 2 to 6 microns thick that hugs the surface of the core and separates the core from the enteric coating.

The decision of the Seoul District Court was upheld on appeal in Appellate Trial No. 94 Kang Dang 457, which was a final decision.

181. Apotex's process of manufacture is materially the same as the process of manufacture of CKD that was at issue in the Korean Action, and its omeprazole product is materially the same as CKD's omeprazole product that was at issue in the Korean Action.

182. In view of the foregoing, Apotex pleads that the purported findings of the U.S. Proceeding ought not to be applied against Apotex in the event that the Court concludes that findings in a foreign proceeding can be applied to bind parties in a Canadian proceeding, which is denied. If such findings are to be applied, then Apotex pleads that the factual finding of the Korean Court concerning CKD's omeprazole product, a matter which was fully litigated by the Plaintiffs' privies and was finally decided, is binding on the Plaintiffs herein by reason of issue estoppel and abuse of process, and the Plaintiffs are precluded from contesting or making any allegations inconsistent with these findings of fact.

183. Further, in the "first wave" litigation in the U.S. Proceeding referred to above, the plaintiffs therein, being Hassle and other related parties, took a contradictory position to the one taken by the Astra Korea Parties (who are related parties to the Plaintiffs herein and the plaintiffs in the "first wave" litigation) in the Korean Action. In the "first wave" litigation, the plaintiffs therein asserted that CKD's process and product did *not* result in the formation of what the U.S. court called a "separating layer".

184. In *In re Omeprazole Patent Litigation*, 2004 U.S. Dist. LEXIS 9447, the U.S. Court noted that the expert testimony advanced by the plaintiffs (i.e., Hassle and other related parties) in the "first wave" litigation in this regard was "entitled to little if any weight". This decision was upheld on appeal by the United States Court of Appeals for the Federal Circuit in *In re Omeprazole Patent Litigation*, 483 F.3d 1364.

185. Accordingly, given that the Plaintiffs (or related parties) have taken contradictory positions in the U.S. "first wave" litigation and the Korean Action concerning CKD's process and product, and took a position in the U.S. "first wave" litigation concerning CKD's process and product that was contrary to findings of fact of the Korean Court (including on appeal), Apotex states the Plaintiffs should be precluded from asserting that Apotex is bound by the findings in the U.S. Proceeding.

186. In addition, the plaintiffs in the U.S. Proceeding did not assert that Apotex infringed claims 8 and 9 of U.S. Patent No. 4,786,505 ("the '505 Patent"), which was one of the patents in issue in the U.S. Proceeding. The Plaintiffs assert in subparagraph 44(b) of the Third Amended Statement of Claim that the '505 Patent is the United States equivalent of the '693 Patent. However, the Plaintiffs nevertheless assert in the within action that Apotex infringed the equivalent claims to claims 8 and 9 of the '505 Patent, namely claims 11, 12 and 13 of the '693 Patent.

187. In light of the fact that the Plaintiffs (or their privies) have taken contradictory positions in the U.S. Proceeding and the within proceeding concerning the foregoing claims of the '505 Patent

and the '693 Patent, Apotex states the Plaintiffs should be precluded from asserting that Apotex is bound by the findings in the U.S. Proceeding.

188. In the event that the Court concludes that findings in a foreign proceeding can be applied to bind parties in a Canadian proceeding, which is denied, then the Plaintiffs ought to be precluded from asserting that Apotex infringed claims 11, 12 and 13 of the 693 Patent, as the Plaintiffs' (or their privies) failure to assert the equivalent claims in the U.S. Proceeding amounts to an acknowledgement that Apotex's product (which the Plaintiffs plead is the same in the U.S. and Canada) does not infringe those claims. Specifically, the Plaintiffs' (or their privies) failure to allege in the U.S. Proceeding that Apotex's formulation has a water content less than 1.5% as claimed in claim 9 of the '505 Patent, ought to estop them from now asserting that Apotex's formulation has such a water content, as claimed in claim 13 of the '693 Patent. Similarly, the Plaintiffs' (or their privies) failure to allege in the U.S. Proceeding that Apotex's formulation did not have any of the enteric coatings, optionally with a plasticizer, set out in claim 8 of the '505 Patent, ought to estop them from now asserting that Apotex's formulation has any of the claimed enteric coatings, or that it has a plasticizer, as claimed in claims 11 and 12 of the '693 Patent.

189. Furthermore, claim 1 of the '693 Patent requires a formulation with an enteric coating. All of the asserted claims of the '693 Patent are dependent upon claim 1, directly or indirectly. Accordingly, because the Plaintiffs ought to be estopped from asserting that Apotex's product has one of the enteric coatings claimed in claims 11 and 12 of the '693 Patent for the reasons set out above, there is no enteric coating Apotex used that could infringe claim 1 of the '693 Patent. Therefore, the Plaintiffs ought to be estopped from asserting that Apotex infringed *any* of the claims of the '693 Patent.

190. Furthermore, to the extent that the Court concludes that findings in a foreign proceeding can be applied to bind parties in a Canadian proceeding, which is denied, the Plaintiffs ought not to be afforded a second opportunity to assert these claims against Apotex, having chosen not to do so in the U.S. Proceeding.

191. In addition to the Korean Action, Apotex is aware of litigation in England and Australia wherein certain patents of the Plaintiffs (or related parties) for omeprazole were in issue. It is unclear from publicly available information whether infringement was in issue in these proceedings. Such information is solely within the knowledge of the Plaintiffs. Apotex seeks the right to explore on discovery of the Plaintiffs whether infringement was in issue in these proceedings and whether the results of these proceedings preclude the Plaintiffs' reliance on issue estoppel and abuse of process.

192. Apotex is also aware of litigation in Denmark, Norway, Israel and Germany relating to certain patents of the Plaintiffs (or related parties) for omeprazole. These decisions are referenced in brief on the website of the Plaintiffs at <http://www.astrazeneca.com>. However, Apotex has been unable to obtain, and thus review and consider, the decisions in these proceedings. The details of these proceedings are solely within the knowledge of the Plaintiffs. Apotex seeks the right to explore on discovery of the Plaintiffs whether infringement was in issue in these proceedings and whether the results of these proceedings preclude the Plaintiffs' reliance on issue estoppel and abuse of process.

FEDERAL COURT
SOLICITORS OF RECORD

DOCKET: T-1409-04

STYLE OF CAUSE: ASTRAZENECA CANADA INC., AND
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PLACE OF HEARING: TORONTO, ONTARIO

DATE OF HEARING: June 29, 2011

**REASONS FOR ORDER
AND ORDER BY:** Hughes J.

DATED: July 11, 2011

APPEARANCES:

Mark G. Biernacki
Urszula A. Wojtyra

FOR THE PLAINTIFFS

Andrew Brodtkin
Daniel Cappe

FOR THE DEFENDANT

SOLICITORS OF RECORD:

SMART & BIGGAR
Barristers & Solicitors
Toronto, Ontario

FOR THE PLAINTIFFS

GOODMANS LLP
Barristers & Solicitors
Toronto, Ontario

FOR THE DEFENDANT