Date: 20080318

Docket: T-1672-06

Citation: 2008 FC 352

Ottawa, Ontario, March 18, 2008

PRESENT: The Honourable Mr. Justice Barnes

BETWEEN:

ABBOTT LABORATORIES and
ABBOTT LABORATORIES LIMITED

Applicant(s)

and

THE MINISTER OF HEALTH and
SANDOZ CANADA INC.

Respondent(s)

REASONS FOR ORDER AND ORDER

[1] SANDOZ CANADA INC. (Sandoz) brings two matters before the Court which, to some extent, are linked. Sandoz has appealed the decision of Prothonotary Mireille Tabib which dismissed its motion under subsection 6(5)(a) and (b) of the *Patented Medicines (Notice of Compliance) Regulations* S.O.R./1993-133 (the Regulations) seeking the dismissal in part of the underlying prohibition application by ABBOTT LABORATORIES and ABBOTT LABORATORIES LIMITED (collectively referred to as Abbott) with respect to two of Abbott's Patents (2,277.274 and 2,387,361, referred to as the '274 Patent and the '361 Patent.) For the

purposes of the appeal, only the Prothonotary's finding with respect to the '361 Patent is in issue. Sandoz has also moved for the dismissal of Abbott's underlying application under subsections 6(5)(a) and (b) of the Regulations, asserting that:

(a) Abbott's Patents 2,386,527 ('527 patent), 2,387,356 ('356 patent), 2,471,102 ('102 patent) and the '361 (the Abbott Patents) are ineligible for listing on the Patent Register because they are not relevant to the Notices of Compliance (NOC) against which they were listed; and

(b) the underlying application is redundant, scandalous, frivolous or vexatious or is otherwise an abuse of process as an attempt to re-litigate issues that have been determined in other proceedings.

The Appeal from the Prothonotary's Decision

[2] Sandoz' appeal from the Prothonotary's Order is premised on an argument that the Prothonotary erred in her application of the earlier decision by Justice Elizabeth Heneghan in *Abbott Laboratories v. Minister of Health and Apotex, Inc.* 2006 FC 1558, 54 C.P.R. (4th) 356 (upheld on appeal in 2007 FCA 187, 59 C.P.R. (4th) 1) (the Apotex case) which, according to Sandoz, declared the '361 Patent to be ineligible for listing on the Patent Register. Sandoz argued before the Prothonotary that it would be an abuse of process to allow Abbott to re-litigate this issue in this proceeding either because the issue of eligibility had been resolved for all purposes by Justice Heneghan or, alternatively, because Abbott failed to put all of the claims of the '361 Patent into play in that proceeding and thereby failed to "put its best foot forward."

[3] The Prothonotary rejected Sandoz' argument concerning the '361 Patent and determined that the claims in issue in this proceeding (claims 8 to 14) were never in issue in the Apotex litigation and, therefore, abuse of process by re-litigation did not apply.

[4] The Prothonotary dismissed Sandoz' second contention that Abbott had a duty to put into play in the earlier proceeding all of the claims of the challenged patents for the following reasons:

> Sandoz's final argument, to the effect that it is an abuse of process for a first person in an NOC proceeding to litigate an issue against one generic, when it could have, but chose not to litigate it to a final determination in a prior proceeding against another, has no merit whatsoever. The reasons for this are legion, but I will only point out that it is quite possible, and indeed rather common, for a first person, once it has seen the evidence of the Respondent on the allegations of non-infringement, to accept as justified the allegations of non-infringement in relation to certain patents or parts thereof. Once an Applicant chooses not to dispute an allegation of non-infringement of certain claims of a patent, any allegation of invalidity regarding those claims becomes moot, as there can be no point or usefulness in any party litigating the claims in question. The abuse, surely, would then be in insisting that evidence be led and that a determination be made on these issues when they are moot.

[5] I can identify no error in the Prothonotary's approach to these issues. Unlike the process claims under consideration by Justice Heneghan, the claims Abbott asserts on this application appear, on their face, to be claims for the use of a medicine. Both Justice Heneghan and the Federal Court of Appeal examined only Claim 31 of the '361 Patent and whether that claim was eligible for inclusion in the Patent Register. The only discussion of the other 67 claims of the '361 Patent is contained in the following brief passage from the Federal Court of Appeal decision:

> 39 The 68 claims of the '361 Patent vary in scope, <u>but all relate to Form 0 being used to make Form II</u>. None purports to claim Form

> 0 clarithromycin as a medicine. Claims for Form 0 clarithromycin per se and for the use of Form 0 as an antibiotic are made in Patent 2,277,274 which was filed at the same time as the '361 Patent (Appeal Book, Vol. VI, p. 2270).
>
> [Emphasis added]

I do not read the above statement as an attempt by the Court to construe the claims which are in issue in this proceeding (Claims 8 to 14). The statement that all of the Patent Claims relate to Form 0 being used to make Form II is accurate but it does not preclude the possibility that Claims 8 to 14 are claims for the use of Form II as an antibiotic and, therefore, are arguably eligible for listing on the Register. The reason that the eligibility for listing of Claims 8 to 14 of the '361 Patent was not in issue in the *Apotex* case becomes obvious when the Apotex Notice of Allegation (NOA) is considered. In that NOA at para. 18, Apotex conceded that those claims "are claims for the use of the medicine [clarithromycin Form II]" and "therefore, in view of the above, the only claims of the '361 Patent to which the [NOC] *Regulations* apply are Claims 8 to 14." In the face of this acknowledgement by Apotex, it is disingenuous for Sandoz to contend that Abbott should have put these claims in play in that earlier proceeding. If Apotex chose not to put claims 8 to 14 in issue in the earlier proceeding, Abbott cannot be faulted for not asserting those claims on that application. There are many reasons why the parties to NOC litigation may not put every potential issue in play not the least of which is the fact that it is the generic challenger which frames the issues through its Notice of Allegation .

[6] In this proceeding Abbott has tendered evidence to attempt to prove the point that was conceded by Apotex. The affidavit of Dr. Stephen Byrn contains the following relevant passage:

> 61. Claims 8 to 14 of the '361 Patent are materially different from claims 31 and 62 which claim the use of one crystal form to make another crystal form. As noted, claims 8 to 14 explicitly claim the use of Form II as an antibiotic. In my opinion, a person of ordinary skill reading these claims would understand that these are claims to the use of Form II as a medicine. Moreover, a person skilled in the art would understand that the use of Form II as medicine is an essential element of these claims.
>
> 62. Claims 8 to 14 are, therefore, claims to the use of the medicine (clarithromycin crystal Form II) "for the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or the symptoms thereof."
>
> 63. The processes for preparing Form II from Form 0 identified in claims 8 to 14 are claimed in claims 1 to 7. Claims 8 to 14 are not process claims or claims to the use of Form 0 to make Form II. Rather, claims 8 to 14 are claims to the use of Form II as an antibiotic, and depend on claims 1 to 7 insofar as the Form II must be made by a process claimed in claims 1 to 7.

[7] The above evidence, which stands unchallenged by Sandoz, is interestingly consistent with Sandoz' acknowledgement in para. 124 of its NOA that Claims 8 to 14 claim the use of clarithromycin Form II, as made by the processes described in Claims 1 to 7, as an antibiotic. In the face of this concession, it is perhaps not surprising that Dr. Bryn's evidence has not been countered by Sandoz.

[8] Accordingly, the issue of whether Claims 8 to 14 of the '361 Patent are claims to the use of the medicine was not judicially determined in the *Apotex* case and, in these circumstances, it is not an abuse of process for Abbott to assert those issues in this proceeding. I therefore uphold the decision of Prothonotary Tabib with costs of the appeal payable to Abbott.

The Listing Eligibility of the Abbott Patents - General Principles

[9] *Wyeth Canada v. Ratiopharm Inc.*, 2007 FCA 264, 60 C.P.R. (4th) 375 leave to appeal to S.C.C. refused, 32287 (February 7, 2008) is the leading authority on the proper test for the listing of patents on the Patent Register under the NOC Regulations in force prior to October 5, 2006 and for describing the process by which a listing can be challenged by a "second person".

[10] It is clear that a motion such as this is to be determined on a balance of probabilities with the burden resting on the moving party. In deciding whether the subject claims of a listed patent are sufficiently linked to a particular NOC, the Court must construe those claims as a question of law, informed, as required, by expert opinion. The failure by one party or the other to put expert opinion evidence forward with respect to a contentious issue of construction is a factor that may be taken into account by the Court.

[11] In the *Wyeth* case, above, a Notice of Compliance (NOC) was issued by the Minister for an anti-depressant medication called Effexor. In 1998, Wyeth obtained a new NOC which authorized a dosage change for Effexor in the form of extended release capsules. Subsequently, Wyeth successfully listed its '778 Patent against six NOCs which had been issued by the Minister in connection with revised indications for Effexor and for product monograph amendments. By the time the matter came before the Court of Appeal, the listing of the '778 Patent was only in issue against two NOCs.

[12] Wyeth's '778 Patent contained claims for the use of the extended release formulations of Effexor in the treatment of major depressive disorder. One of the NOCs it was listed against involved a revised indication for Effexor in the "maintenance treatment" of major depressive disorder. Wyeth contended that maintenance treatment was a clinical subset of treatment and, therefore, the Patent claims should be read to include claims for maintenance treatment. Wyeth put no expert evidence forward to support its construction theory and the Court was left only with the opinion of Ratiopharm's expert that the patent claims did not cover maintenance treatment. The Court resolved the issue before it as follows:

> [61] It seems to me that in theory, if Dr. Schneider's construction of the patent claims is correct, there is no relevant connection between the 778 patent and the NOC issued April 25, 2003. The question, then, is whether to prefer Dr. Schneider's opinion to the argument of Wyeth, which asserts without the support of expert opinion that the word "treatment" in the use claims should be interpreted to include "maintenance treatment". I note that Wyeth, in responding to the motion of Ratiopharm, would have been served with the affidavit of Dr. Schneider and was aware of his opinion. Counsel for Wyeth cross-examined Dr. Schneider, but presented no evidence to contradict his interpretation of the patent claims. In these circumstances, I prefer the opinion of Dr. Schneider. I conclude that the 778 patent is not eligible for listing against the NOC issued April 25, 2003.

[13] The second issue before the Court in *Wyeth* concerned a NOC issued to Wyeth in 2004 authorizing references to nausea reduction in the product monograph for Effexor. This new NOC did not involve any changes to dosages or for the use of Effexor. The Court determined that this NOC could not support the listing of the '778 Patent for the following reasons:

> [70] I do not find Wyeth's argument persuasive because it is premised on a particular construction of the patent claims that has no

> foundation in the evidentiary record except the patent itself. I am not prepared to conclude, on the basis of my own reading of the patent, that nausea reduction is intended to be an element of the claimed use of venlafaxine hydrochloride extended release capsules. A literal reading of the patent claims (which is all the record permits) suggests that the reference to nausea reduction is merely descriptive of the effect of the extended release of venlafaxine hydrochloride in the body. For that reason, I am unable to accept the argument of Wyeth that the SNDS dated February 25, 2003 supports the listing of the 778 patent. I conclude that the 778 patent is not eligible for listing against the NOC dated September 13, 2004.

[14] Beyond the specific dispositions made in *Wyeth*, the decision also provides some helpful general guidance for determining whether there is a sufficient linkage between the claims of a patent and its related NOC to support the listing. Those statements include the following:

> [14] The patent register is the linchpin of the NOC Regulations. It is essentially a list of patents relating to any drug for which a NOC has been issued to an innovator. The listed patents are those that contain a claim for which the innovator seeks the advantages of the NOC Regulations in addition to the rights of a patent owner or licensee under the Patent Act.
>
> […]
>
> [24] It was determined in *Apotex Inc. v. Canada (Minister of Health)* (1999), 87 C.P.R. (3d) 271 (Fed T.D.), affirmed (2001), 11 C.P.R. (4th) 538 (Fed. C.A.), that the reference in section 4 of the *NOC Regulations* to a NDS includes a SNDS. Later cases refined that interpretation. It is now established that a SNDS may support a patent listing application only if the change reflected in the SNDS may be relevant to the potential infringement of a patent claim that is within the scope of the *NOC Regulations* (the jurisprudence is summarized at paragraphs 14 to 22 of *Hoffmann-La Roche Ltd. v. Canada (Minister of Health)*, 2006 FCA 335 (F.C.A.)). Because of the time limits for patent listing applications, the question of whether a particular SNDS may support a patent listing is determined on the basis of the changes reflected in that SNDS, independently of any prior NOCs.

[…]

> [29] This appeal deals with the propriety of a patent listing. The part of *AstraZeneca Canada Inc.* that is most relevant to that issue is the part explaining that the listing of a patent on the basis of a SNDS requires a certain link between the change reflected in the SNDS, the NOC issued in response to that SNDS, and the patent sought to be listed. On this point I agree with the Judge (see paragraph 22 of his reasons).
>
> [Emphasis added]

Abbott's 1998 NOC

[15] The 1998 NOC issued to Abbott allowed for a monograph revision for Biaxin pertaining to a new indication for the medicine clarithromycin in a triple therapy regimen to treat *H. pylori*. This was clearly a substantive change which could support the listing of relevant patents: see *Abbott v. Pharmascience*, 2004 FCA 154, 31 C.P.R. (4th) 321 at para. 28.

[16] Abbott's experts gave detailed evidence that, notwithstanding the fact that the Abbott Patents did not refer to combination therapies, the medicinal use claims in those patents did not exclude, and therefore included, such uses. What is important, they opined, is the claimed use of clarithromycin in Forms I, II and 0 as antibiotics to treat bacterial infections such as *H. pylori* and not precisely how those medicines might be therapeutically administered.

[17] By way of example, Dr. Jerry Atwood's affidavit offers the following construction opinion with respect to the scope of the Abbott Patents:

> 51. I was asked to give my opinion on whether the claims of the Abbott Patents cover the use of clarithromycin when used two other

medicines to eradicate *H. pylori*. In my opinion, the Abbott Patents clearly cover this use.

52. First, as described above, where a claim in the Abbott Patents covers Form I, Form II or mixtures of Form I and Form II, it is a claim that covers any use, including the use to eradicate *H. pylori*. The same applies to claims to compositions of Form I, Form II or mixtures of Form I and Form II.

53. Second, where a claim covers the antibiotic use of Form I, Form II or mixtures of Form I and Form II, it explicitly covers the use of these crystals as an antibiotic. When clarithromycin is used to eradicate of *H. pylori* it is clearly being used as an antibiotic.

54. The fact that clarithromycin is being used at the same time as one or two other medicines is no less a use of clarithromycin than if it was being used by itself. It is still being used as an antibiotic.

55. It is also being used "in the treatment of bacterial infections in a host mammal" when used in triple therapy to eradicate *H. pylori*. The term "bacterial infections" includes *H. pylori* which is a gram negative bacteria. The disclosure of the Abbott Patents indicate that clarithromycin is effective against certain gram negative bacteria. *H. pylori* is a gram negative bacteria. The Abbott Patents specifically state that clarithromycin exhibits excellent antibacterial activity against some gram negative bacteria. The term host mammal obviously includes human beings.

56. There is absolutely nothing in the claims or disclosure of the Abbott Patents that would suggest or lead a skilled person to conclude that the antibiotic use claims, or use claims for the treatment of bacterial infections in a host mammal, would require clarithromycin to be used in the absence of other drugs.

57. When clarithromycin is used in triple therapy for the eradication of *H. pylori*, it is being used as an antibiotic or used in the treatment of bacterial infection in a host mammal, irrespective of the fact that two other medications are being administered at the same time. The two other therapeutic agents do not take away from the antibiotic role of clarithromycin.

58. If clarithromycin Form I were to be used as a part of triple therapy for the eradication of *H. pylori*, then it would be claimed an covered by the antibiotic use claims of the '527, '102 and '356

> Patents. If clarithromycin Form II were to be used as part of triple therapy for the eradication of *H. pylori*, then it would be claimed an covered by the antibiotic use claims of the '361 Patent.

[18] Dr. Byrn also gave detailed affidavit evidence on this issue including the following:

> 1. The '527 Patent
>
> […]
>
> 79. I understand from counsel for Abbott that the 1998 NOC was for a new use of BIAXIN; namely the use of BIAXIN in combination with amoxicillin and lansoprazole to treat an *H. pylori* infection.
>
> 80. The '527 Patent is related to the 1998 NOC because it explicitly claims the use of clarithromycin to treat bacterial infections (see claim 5 above). *H. pylori* is a bacterial infection as that term is used in the '527 patent and would be so understood by the skilled person.
>
> […]
>
> 84. Moreover, by June 1997, the United States Food and Drug Administration had approved triple therapy treatment of *H. pylori* using BIAXIN, amoxicillin and lansoprazole. There is nothing in the '527 Patent that would exclude *H. pylori* and, in my opinion, a person skilled in the art would have understood the term "bacterial infection" to specifically include *H. pylori*.
>
> […]
>
> 2. The '361 Patent
>
> 91. The disclosure of the '361 Patent is similar to the '527 Patent. In addition, among other things, the '361 Patent discloses that clarithromycin can exist in a third crystal form called Form 0 (page 2, line 7).
>
> 92. Claim 8: A skilled person would understand that claim 8 of the '361 Patent is to the use of Form II as an antibiotic where the Form II is made by the process of claim 1. A skilled person would

understand that the process claimed in claim 1 is making Form II by heating Form 0 under vacuum at a temperature of between about 70°C and 110°C.

93. A skilled person would further understand that the essential elements of claim 8 are:

(a) The use of Form II
(b) as an antibiotic
(c) wherein the Form II is made by heating Form 0 under vacuum at a temperature of between about 70°C and 110°C.

94. It would be clear to a skilled person that the use of Form II as an antibiotic is essential because that is the very use for which the crystal in this claim is being made. By contrast, a skilled person reading the disclosure of this patent would understand that Form II, as well as (Form 0 and I) could also be used as intermediates in the production of Form 0. Page 9 (lines 1-12) of the patent describes how to make Form 0 by crystallizing 6-*O*-methylerythromycin-A in a desired solvent, preferably ethanol. "6-*O*-methylerythromycin-A" is defined in the patent (p. 6, line 4-7) to mean any crystalline form of clarithromycin, including Form II. Thus, the patent discloses that Form II is useful as an intermediate to make other crystal forms of clarithromycin. This intermediate use is the type of use that is claimed in claim 31, which contains as an essential element the intermediate use of Form 0.

95. In addition, the patent describes (at page 2, line 17) another use of Form II, being the use of Form II to make carbomer complexes.

96. A person skilled in the art would give the same meaning to the word "use" in this patent as described above. A skilled person would understand the term "antibiotic" to mean a molecule that kills bacteria.

97. For the reasons give above, a skilled person would understand that claim 8 covers the use of clarithromycin as an antibiotic. This includes the use of clarithromycin as an antibiotic when it is given in combination with amoxicillin and lansoprazole to treat *H. pylori*.

[…]

3. The '102 Patent

[…]

100. Claims 8 and 18: A skilled person would understand that claims 8 and 18 are to an antibacterial composition of either Form II with impurities or Form I with impurities together with a pharmaceutically acceptable carrier. These terms would have the same meaning as described above with respect to the '527 Patent.

101. Claims 9 and 19: A skilled person would understand that claims 9 and 19 are claims to the antibiotic use of the same products. These terms would have the same meaning as described above with respect to the '527 Patent.

102. Claim 10 and 20: A skilled person would understand that claim 10 and 20 of the '102 Patent are claims to the use of Forms II and I (as described in claims 1 or 11), respectively, in the manufacture of an antibiotic medicament. "Antibiotic medicament" means, as described above, a medicine in a form capable of being given to a patient, such as a tablet, for use in treating infections.

103. For the reasons given above, a skilled person would understand that the claims of the '102 Patent cover the use of clarithromycin (in crystal Form I and/or II) in combination with amoxicillin and lansoprazole to treat *H. pylori* (claims 9 and 19).

[…]

4. The '356 Patent

105. A skilled person would understand that claim 8 of the '356 Patent is a claim to the use of Form I made by the process of claim 1, as an antibiotic. Also, a skilled person would understand that the process of claim 1 includes making Form I by drying Form 0 at a temperature of from about 0°C to 50°C.

106. For the reasons given above, a skilled person would understand that the claims of the '356 Patent cover the use of clarithromycin in combination with amoxicillin and lansoprazole to treat *H. pylori*.

[19] The only evidence tendered on behalf of Sandoz with respect to the claims in the Abbott Patents is the following brief conclusory statement by Dr. Sohrab Rohani:

> 29. After reviewing the Abbott Patents it is my opinion that none of the patents mention, claim, teach or relate to the use of clarithromycin as a part of a triple therapy in combination with another medicine.

[20] The above statement was somewhat qualified by Dr. Rohani in the following exchange under cross-examination:

> 230. Q. There is nothing in the claims that exclude the use of clarithromycin where there is co-administration with other drugs; right? There is nothing that says you cannot co-administer clarithromycin with other drugs?
>
> A. It is left open; it is general.

[21] Dr. Rohani's evidence, such as it was, was later challenged by Abbott's expert witnesses. Dr. Byrn countered Dr. Rohani's opinion in the following passage from his affidavit:

> 85. Dr. Rohani has expressed the opinion that none of the patents mention, claim, teach or relate to the use of clarithromycin as a part of a triple therapy in combination with another medicine.
>
> 86. In my opinion, Dr. Rohani's opinion that the claims do not claim or cover the use of clarithromycin in combination with other drugs is not correct. Since there are specific claims to the use of clarithromycin to treat bacterial infections, I interpret Dr. Rohani's opinion to be that any claims to the use of clarithromycin must mean use *alone*.
>
> 87. First, the word "use" as it is found in the '527 Patent would be understood by a skilled person to mean given to or taken by a patient. There is nothing whatsoever in the patent to suggest that the clarithromycin must be given or taken alone. A person skilled in the

> art would understand that it is no less a "use" of the clarithromycin if it is given by itself or in combination with other drugs.
>
> 88. Treatment of *H. pylori* bacteria is apparently more effective when clarithromycin is administered with another antibiotic and a proton pump inhibitor (the purpose of the latter is to lower the acidity in the stomach and therefore facilitate the work of the antibiotics). That clarithromycin works better on *H. pylori* when it is given with two other drugs is no less a use of clarithromycin than if clarithromycin were given alone. Either way, the function of clarithromycin is the same; namely it kills the bacteria. In my opinion, this is how the skilled person would understand and interpret the term use as found in the '527 Patent.

[22] The weight of judicial authority favours Abbott's construction of the subject claims in Abbott Patents. In *Abbott Laboratories Ltd. v. Canada (Minister of Health)*, 2006 FC 1411, 304 F.T.R. 104 Justice Konrad von Finckenstein was faced with a very similar construction issue involving the use of lansoprazole as an antibacterial agent in combination with other medicines to treat *H. pylori*. The issue was whether, in the absence of any reference in the patent claims to combination use, the patent should be construed as being limited to single use therapies. Justice von Finckenstein resolved the issue as follows:

> 26 Thus, even if there was a limitation implicit or explicit in the disclosure, it could not be imported into the claims. Drugs often are not administered in a pure state but mixed with an excipient or other drugs and the use of such drugs would be highly restricted if the mention of a use of a drug would be read as implying it has to be used alone. Unless the use claimed specifically employs such words as "alone" or "not in conjunction with other compounds" it would be improper to read such a limitation into the claim….

[23] The Federal Court of Appeal upheld this aspect of Justice von Finckenstein's decision in *Abbott Laboratories Ltd. v. Canada (Minister of Health)* 2007 FCA 251 367 N.R. 120 at paras. 20-

22. I applied this reasoning in *Astrazeneca AB v. Apotex Inc.*, 2007 FC 688, 60 C.P.R. (4th) 199 at paras. 32-33.

[24] In the absence of any meaningful evidence from Sandoz' expert witnesses on this construction issue, I am left with and I accept the essentially unchallenged evidence of Drs. Atwood and Byrn that the Abbott Patents all contain claims for the use of medicinal crystal forms of clarithromycin in the treatment of bacterial infections such as *H. pylori* whether alone or in combination therapies. The question that remains is whether the change made by the 1998 NOC authorizing the use of Biaxin in triple therapy against *H. pylori* may be relevant to the potential infringement of the use claims contained in the Abbott Patents.

[25] Abbott has claimed a monopoly over the crystal forms of clarithromycin described in the Abbott Patents and over the uses of these forms. As I have found, the Abbott Patents contain claims for the use of those products in combination therapies including therapies to treat *H. pylori*. Abbott says that its 1998 NOC approved the use of Biaxin tablets containing a mixture of Form I and Form II in a triple therapy regimen to treat *H. pylori*. This seems to me to be a sufficient linkage to justify the listing of the Abbott Patents against the 1998 NOC. Whether those claims will be found to be valid remains to be seen.

[26] In conclusion, on the basis of the evidence before me and having regard to the burden resting upon Sandoz, I am unable to conclude that the Abbott Patents are ineligible for listing against the 1998 NOC and that they need not be addressed on their merits in this proceeding. I

therefore dismiss Sandoz' motion with respect to the eligibility of the Abbott Patents for listing against Abbott's 1998 NOC.

Abbott's 2003 NOC

[27] Abbott's 2003 NOC was for a new formulation for its 500 milligram tablet of Biaxin. This NOC authorized the marketing of a 500 milligram tablet that was smaller and contained fewer excipients than its previous 500 milligram Biaxin tablet.

[28] I accept that this NOC also authorized substantive changes to Abbott's clarithromycin product which could support the listing of relevant patents.

[29] Here I accept Sandoz' position that Abbott's 2003 NOC will not support the listing of the Abbott Patents because there is no apparent linkage between the asserted patent claims and the product changes that were authorized by that NOC. The arguments and evidence advanced by Abbott in an attempt to establish such a linkage are strained and unconvincing. I can find nothing in the evidence to establish that the claims for the medicinal use of the crystal forms of clarithromycin described in the Abbott Patents have any relevance whatsoever to the 2003 NOC, which only authorized changes to the inactive excipients in Abbott's Biaxin product. The attempt by Abbott's experts to identify such a linkage by reference to vague or very general formulation information in the Abbott Patents only underscores the weakness of Abbott's arguments. The problems with that evidence are well exemplified by the following evidence from Dr. Byrn and from Dr. Atwood:

<u>Dr. Byrn</u>

113. Q. So my question is perfectly clear, I'm asking you to look at the disclosure and show me a specific formulation of clarithromycin.

A. So it starts - - there's a section called Pharmaceucal Composition on page 9, and that goes through and tells a person skilled in the art how to formulate this product and a whole wide range of formulas, including injectables, topical, depot forms. It talks about all those, and then towards the end, it talks about quantities, amounts of dosage.

114. Q. So do those paragraphs provide you with a specific formulation?

A. Well, for example, if you look on page 11, they define excipients or carriers. In line 6, they say it could be mixed with, at least, one pharmaceutically acceptable excipient or carrier such as… And then it lists a number of other components that could be in there. So that seems pretty specific to me.

115. Q. Could you tell me looking at that paragraph what amounts would be in a specific biaxin tablet and which ingredients?

A. Well, the numbers aren't in there, but a person skilled in the art would need to be able to - - would have capabilities of coming up with a formulation, and then there's the exact numbers, much more specific numbers on page 13, line 6, 7, and so on.

116. Q. So line 6 that relate to excipients?

A. No, now, if you go on to page 13, line 6, now it starts talking about how much clarithromycin, dosages of clarithromycin that should be used.

117. Q. Does it tell you how much of the excipients to use?

A. No, that to some extent would be within one skilled in the art, but there would also be required - - you would also… It's not - - I don't want to make it sound like you could make a formulation of this

without some inventive work, at least, an abbreviated or abridged formulation. But a person skilled in the art with this information would be able to, at least, come up with what I'll call an initial formulation which could be as simple as I already described as a carrier and the antibiotic built into a capsule.

[…]

A. Well, I think the point I'm trying to say is that these patents tell a person skilled in the art how to make an initial formulation but are broad and include numerous types of formulations.

[…]

155. Q. Would you agree that none of these four examples mentions a 500-milligram new formulation or 500 milligram-specific formulation?

A. Well, although those specific words weren't used in those examples, the patent clearly covers those formulations, and it says - - above the examples, it says that the examples are provided to enable one skilled in the art to practice the invention and/or illustrative of the invention. They should not be read as limiting the scope of the invention.

156. Q. Do those examples teach you the amounts of excipients to put in a tablet?

A. Well, as I've said, that's within what one skilled in the art would be able to do. So although it's not in those examples, that's within one skilled in the art to make an initial formulation.

[emphasis added]

Dr. Atwood

102. Q. Okay. Would you agree that the claims in the Abbott patents do not mention a specific 500 milligram formulation?

A. My recollection is that the specific formulation in terms of amount is not mentioned. However, I would note that in the specifications there's considerable information. I'm thinking of the specification of the 527 now. There's considerable information on formulation of the material.

103. Q. So if we can go back for a second, so I'm not just talking about the weight, but an actual specific formulation. So it will basically have the active ingredient and excipients.

Is there anything in the Abbott claims or anything in the claims in the Abbott patents that mention a specific formulation?

A. Yes, in fact there is. The Abbott patents, the claims in the Abbott patents cover virtually any formulation that one could envision.

[…]

107. Q. That's fine. My question is, do the claims mention a specific 500 milligram formation?

A. Well, they don't mention 500 milligrams, but they are broad enough to encompass 500 milligrams and other weights of clarithromycin. With regard to particularly the claim 3 that we were talking about, it's Form I clarithromycin. Indeed in the specification of the 527, if I recall correctly, there is a specific mention of 1 to 1,000 milligrams of clarithromycin.

[…]

111. Q. I mean, sorry, in the patent, the 527 patent. You said it provides you ample information, so I just want to know where you're talking to.

A. Let me leaf back through the patent. Let's see. We're on page 9 of roughly line 27. It states pharmaceutical compositions.

112. Q. Okay.

A. And then I'm leafing on through the patent down through page 10, into page 11, and I'm looking here at page 11, line, starting with line 5: "Solid dosage forms for oral administration include capsules, tablets, pills…" Pharmaceutical - - reading further down on to line 7: "…pharmaceutically acceptable excipient or carrier such as sodium citrate or dicalcium phosphate and/or…" Then it goes into a shopping list of fillers, binders, humectants…

113. Q. So, for example - -

A. …retarding agents, absorption accelerators, wetting agents, absordents, lubricants, and examples for each of these classes of excipients are indeed given.

114. Q. You wouldn't put all those excipients in a tablet. That's not what you're saying?

A. No, and that's not the teaching of the 527, nor is it the reading that one of ordinary skill would put on this extensive section on pharmaceutical compositions. One would understand, from the reading of the specification with regard to pharmaceutically acceptable excipients, that there are a wide range of suitable materials, and one would understand then, going into the claims, what is meant by a composition containing a crystal form.

I'm looking again at claim 3: "…in combination with a pharmaceutically acceptable carrier."

One clearly understands what the claim means when it says "pharmaceutically acceptable carrier" because one has read the specification and sees what this term means in the specification, and one then understands that one could easily formulate a 500 milligram tablet with croscarmellose sodium, magnesium stearate, other excipients, and fall within claim 3 if one were using, as claim 3 covers, Form I clarithromycin.

115. Q. So just so I understand then, on page 11, and I'll read four sentences down, it talks about fillers or extenders. So it lists starch - -

A. Just a moment. Let me get back to page 11. All right. And you're under fillers. So that's number A - - that's (a)?

116. Q. Yes. It says, "fillers or extenders". It says, "such as starches, lactose, sucrose, glucose, mannitol, and silicic acid"?

A. Yes, you've read that list correctly.

117. Q. It's not telling you which one to use?

A. No, and it does not specify that the list stops with this grouping.

[Emphasis added]

[30] In conclusion, I can identify nothing in the changes authorized by the 2003 NOC which could be relevant to the potential infringement of the patent claims asserted by Abbott in this application. I therefore find that the Abbott Patents are ineligible for listing against its 2003 NOC and to that extent need not be addressed in this proceeding by Sandoz.

Does Abbott's Prohibition Application Constitute an Abuse of Process by Re-Litigation?

[31] Sandoz also seeks the dismissal of Abbott's prohibition application on the ground that the clarithromycin products claimed in the Abbott Patents have, in proceedings involving other generics, been declared to be old products or their uses well-known. In the result, Sandoz says that the Abbott application is an abuse of process by re-litigation and should be struck out under subsection 6(5)(b) of the Regulations.

[32] This motion is unmeritorious essentially for the same reasons that were given by the Prothonotary in Sandoz' initial motion – that is, that the earlier decisions relied upon by Sandoz did not examine the patent claims that are in issue in this proceeding and it is, therefore, not an abuse of process to now subject those claims to substantive scrutiny.

[33] Abbott says, correctly in my view, that it does not intend to re-litigate any patent claims that have been previously resolved against it. This point is addressed in the following passages from the affidavit of Andrew Reddon:

> 4. The Applicants were served with a letter dated July 31, 2006 from Sandoz purporting to be Sandoz' Notice of Allegation ("NOA") in which Sandoz alleged that certain Abbott patents (nine in total) are not infringed, invalid or ineligible for listing on the Patent Register.
>
> 5. In response to Sandoz' NOA, the Applicants commenced this Application on September 14, 2006 in accordance with s. 6(1) of the *NOC Regulations*, seeking an order prohibiting the Minister from issuing to Sandoz Notices of Compliance for clarithromycin 250 mg and 500 mg tablets until the expiry of the nine patents.
>
> 6. The only patents now in issue are the '527, '102, '361 and '356 Patents. This is based on a number of factors, including decisions of the Federal Court and Federal Court of Appeal related to previous cases involving some of the nine patents. It is also based on our review of Sandoz' disclosure of its clarithromycin manufacturing process, as contained in its submission to Health Canada, which was provided to Abbott after this application was commenced. Abbott has not filed any evidence asserting that any claim of any of the other patents listed against BIAXIN® BID are infringed.
>
> 7. The process used by Sandoz to make its clarithromycin is materially different than the processes used by each of the other generics involved in the other cases referred to in the affidavit of Mr. Niemkiewicz.

> 8. None of the patent claims being asserted in this Application were adjudicated or asserted by Abbott in any of the cases contained in the Affidavit of Mr. Niemkiewicz, which was filed by Sandoz in support of this second motion to strike.

[34] It is apparent from Mr. Reddon's evidence that Abbott understands the Sandoz manufacturing process to be different from the processes employed by the other generics involved in its earlier litigation thereby putting in issue different patent claims. Sandoz has tendered no evidence to counter this point.

[35] Abbott also maintains, correctly in my view, that it is not necessarily appropriate to extrapolate the construction of one patent claim from the construction adopted for a claim contained in a different patent even where the same product is involved. That was the clear holding of the Federal Court of Appeal in *Abbott Laboratories v. Canada (Minister of Health),* 2006 FCA 187, 350 N.R. 242 which, coincidentally involved Abbott's clarithromycin Form II. In that case a composition distinction was important because a piece of prior art rendered only one of the claims anticipated. The relevant passage from the Federal Court of Appeal relied upon by Abbott is the following from para. 38:

> [38] Abbott argues that the judge, in finding that Claim 1 of the 606 patent includes a solvate form of Form II, arrived at a conclusion that was the opposite of the conclusion he reached in a case involving Canadian Patent No. 2,261,723 (the 723 patent): *Abbott Laboratories v. Minister of Health*, [2005] F.C.J. No. 1351, 2005 FC 1095. I am not persuaded that the judge's conclusion in the case involving the 723 patent necessarily required him to adopt, in this case, the construction of Claim 1 of the 606 patent that would exclude solvates. The issues and the evidence in the two cases were substantially different. Although the 606 patent and the 723 patent both involve Form II, the 606 patent claims Form II characterized by

> the specified 2θ values (it is a claim for a particular substance), while the 723 patent claims methods of producing clarithromycin "crystal Form II" (it is a claim for a method of producing a particular substance). Claim 1 of the 606 patent (the claim in issue in this case) describes Form II by reference to certain characteristics, while the claims of the 732 patent do not.

[36] I do not agree with Sandoz that the abuse of process holding in *Sanofi-Aventis Canada Inc. v. Novopharm Ltd.*, 2007 FCA 163, [2008] 1 F.C.R. 174 can be applied as broadly as Sandoz contends. I interpret that holding to be limited to situations involving attempts to re-litigate the same allegations of invalidity or the very same issue that was previously determined. While there may also be instances of abuse of process where a first party attempts to assert a claim which could have been resolved in an earlier case, such situations will be fairly rare in NOC proceedings for the reasons I have earlier stated – most notably because it is the generic's NOA followed by the exchange of evidence that will determine the justiciable issues in each case.

[37] Here Abbott is asserting two patents (the '527 Patent and the '356 Patent) that have never been considered in any earlier proceeding. While Abbott's '361 and '102 Patents have been judicially considered, the previously examined claims from those patents are not the claims in issue in this proceeding. It does not necessarily follow that, because a claim to Form II in one patent was found to be invalid, all other patent claims to Form II must be invalid. That is so because each claim in a given patent must be construed within the context of that patent. For instance, the validity of a product use claim that is process-dependant may well be resolved differently than another type of claim related to the same product.

[38] While I agree with Sandoz that many of the issues from the earlier litigation involving Abbott's various clarithromycin patents may overlap with issues raised in this proceeding and, therefore, Abbott will likely be faced with serious validity challenges, I do not accept that it is appropriate to summarily dismiss Abbott's application as an abuse of process. These are questions that should be resolved on the evidence presented and not by extrapolation from earlier decisions involving different patents or different patent claims.

[39] I, therefore, dismiss Sandoz' motion for a dismissal of Abbott's application on the ground of abuse of process.

[40] Because success has been divided with respect to Sandoz' second motion to dismiss, I make no order of costs with respect to that matter.

ORDER

THIS COURT ORDERS that the motion by the Respondent, Sandoz, to appeal the Order of the Prothonotary dated July 26, 2007 is dismissed with costs payable to the Applicants;

THIS COURT FURTHER ORDERS that:

(a) the motion by the Respondent, Sandoz, for the dismissal of the Applicants' prohibition application is allowed with respect only to the listing of the Abbott Patents against Abbott's 2003 Notice of Compliance. In all other respects, the Respondent's motion is dismissed; and

(b) there shall be no order of costs with respect to this motion.

" R. L. Barnes "
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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