Federal Court of Appeal

Cour d'appel fédérale

Date: 20100622

Docket: A-369-09

Citation: 2010 FCA 168

CORAM: **NOËL J.A.**
DAWSON J.A.
TRUDEL J.A.

BETWEEN:

SANDOZ CANADA INC.

Appellant

and

ABBOTT LABORATORIES and ABBOTT LABORATORIES LIMITED
and THE MINISTER OF HEALTH

Respondents

Heard at Toronto, Ontario, on May 27, 2010.

Judgment delivered at Ottawa, Ontario, on June 22, 2010.

REASONS FOR JUDGMENT BY: DAWSON J.A.

CONCURRED IN BY: NOËL J.A.
TRUDEL J.A.

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REASONS FOR JUDGMENT

DAWSON J.A.

[1] This is an appeal and cross-appeal from a decision of the Federal Court (2009 FC 648) rendered in an application for prohibition brought pursuant to subsection 6(1) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (Regulations).

[2] The appellant, Sandoz Canada Inc. (Sandoz), served a notice of allegation (NOA) upon the respondent Abbott Laboratories Limited. The NOA advised that Sandoz had filed an Abbreviated

New Drug Submission (ANDS) with respect to clarithromycin extended-release 500 mg tablets. The ANDS compared the Sandoz product with BIAXIN XL 500 mg clarithromycin extended release tablets marketed in Canada by Abbott Laboratories. The NOA addressed four patents, only three of which are relevant to this appeal. The three relevant patents are:

Canadian Patent No. 2,285,266 (‘266 patent)

Canadian Patent No. 2,325,541 (‘541 patent)

Canadian Patent No. 2,358,395 (‘395 patent)

[3] The patents in issue are owned by the respondent Abbott Laboratories Limited. Together, in these reasons Abbott Laboratories Limited and Abbott Laboratories are referred to as Abbott.

[4] The Federal Court found the allegations of invalidity contained in the NOA to be unjustified with respect to the ‘266 patent. Thus, an order issued prohibiting the Minister of Health from issuing a Notice of Compliance to Sandoz until the expiry of the ‘266 patent. This is the subject of the appeal now before the Court.

[5] The Federal Court went on to find that Abbott had failed to adequately respond to Sandoz' allegation of invalidity with respect to the double patenting of claim 22 of the ‘395 patent over the ‘541 patent. Accordingly, Abbott's request for an order of prohibition in relation to the ‘395 patent was dismissed. This is the subject of the cross-appeal now before the Court.

The Issues

[6] The issues raised on the appeal and cross-appeal are narrow.

[7] On the appeal, no legal errors are alleged. Sandoz argues that the Judge erred in holding that its allegation of obviousness in respect of the ‘266 patent was not justified. In so finding, the Judge is said to have erred by:

i) rejecting, without basis, the closest piece of prior art; and

ii) failing to properly assess the common general knowledge of the person skilled in the art.

[8] On the cross-appeal, Abbott argues that the Judge erred in law by assessing the allegations in the NOA as of the wrong date. In the present case, the ‘541 patent, which formed the basis for the allegation that claim 22 of the ‘395 patent was invalid on the ground of double patenting, was dedicated to the public during the course of the litigation. The Judge considered the issue of double patenting as of the date the NOA was served, not as of the date of the hearing. Thus, she did not give effect to the dedication of the ‘541 patent because the dedication was not “executed prior to the service of the NOA.” See: paragraph 200 of the Judge’s reasons.

Standard of Appellate Review

[9] The parties agree that the impugned findings on the appeal with respect to obviousness are findings of fact or mixed fact and law. Thus, this Court may only intervene if a palpable and overriding error is demonstrated. This is correct.

[10] The parties disagree about the nature of the error alleged in the cross-appeal. Abbott characterizes the error as one of law: the Judge is said to have applied the wrong legal principle as to the date on which allegations in a NOA are to be assessed. Sandoz characterizes the issue to be one of mixed fact and law, that is, what is the effect of a purported dedication in litigation commenced under the Regulations.

[11] In my view, the issue is properly framed as follows. The dedication of the ‘541 patent was made late in the proceeding: ten days before Abbott served its memorandum of fact and law upon Sandoz. The first notice given to Sandoz about the dedication was contained in Abbott’s memorandum of fact and law. The memorandum contained a copy of a document dated January 20, 2009 sent to the Commissioner of Patents by Torys LLP as agent for the patentee. The document was entitled "Dedication to the Public" and stated that the ‘541 patent was dedicated to the public. The terms of the dedication are set out at paragraph 194 of the Judge’s reasons.

[12] Sandoz did not move to strike from the memorandum of fact and law either the document or the submissions made thereon. No request was made for an adjournment to investigate the circumstances surrounding the dedication. At the hearing, a copy of the dedication certified by the

Canadian Intellectual Property Office (CIPO) was filed and Sandoz acknowledged that the ‘541 patent had been dedicated (see: transcript of proceedings of April 1, 2009 at page 694). Sandoz argued that it was prejudiced by the late filing of the document in that it could not explore the circumstances of the dedication. No argument was advanced that prejudice would accrue to it in respect of the impact of the dedication upon its rights under section 8 of the Regulations, or that the dedication allowed Abbott to evergreen the ‘395 patent.

[13] In my view, the Judge may well have possessed discretion either to refuse to allow Abbott to adduce what was in effect new evidence in its memorandum of fact and law, or to adjourn the proceeding to allow Sandoz to conduct an inquiry into the circumstances of the dedication. This Court could only interfere with that exercise of discretion if satisfied that the Judge gave insufficient weight to relevant factors, proceeded on a wrong principle of law, seriously misapprehended the facts, or where an obvious injustice would otherwise result. See: *Apotex Inc. v. Canada (Governor in Council)*, 2007 FCA 374 paragraph 15.

[14] However, once the evidence and submissions were received by the Court, the Judge was required to consider the effect of the dedication. This is a question of law reviewable on the standard of correctness.

The Appeal: Did the Judge err in finding Sandoz' allegation that the '266 patent was obvious was not justified?

[15] The only allegation of invalidity raised by Sandoz against the '266 patent was obviousness. The Judge applied the test for obviousness set out by the Supreme Court of Canada in *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, [2008] 3 S.C.R. 265.

[16] The '266 patent deals with an extended release formulation of clarithromycin. Sandoz argued that before the priority date of the '266 patent, April 11, 1997, a patent application ('422 application) disclosed an extended release formulation of azithromycin, a drug similar to clarithromycin. This formulation is said to be almost identical to the formulation of the '266 patent, but for the different active ingredients.

[17] Sandoz, through its experts, advanced a "substitution" argument that in light of the similarity between clarithromycin and azithromycin, a person skilled in the art would understand, and it would be obvious, that one drug could be substituted for another.

[18] The Judge rejected such argument on the following basis:

> 152 While the Respondent submits that Abbott's '714 Patent shows that substitution can work, this theory is not supported by the evidence. Azithromycin has very particular properties among macrolides, suggesting that it would not be obviously interchangeable with clarithromycin. The '333 patent teaches that wide variations in the physiochemical and p-kinetic properties of different drugs mean that formulations which are suitable for one drug cannot generally be predictably applied to others. This view is supported by at the textbook, *Pharmaceutical Dosage Forms and Drug Delivery Systems*, labeled as Sandoz Document 126.

> 153 The dissimilarities between the two drugs include their distribution in body tissues, half-life, and first pass effect metabolism. I accept the evidence put forth by the Applicants that these differences mean that the performance of these two drugs in the body would be fundamentally different, such that one could not be readily substituted for another.
>
> 154 In my opinion, on the basis of the foregoing, I conclude that the skilled person would not have been led to the composition claimed within the '266 Patent upon the basis of the teachings contained within the '422 patent.

[19] Sandoz argues that in so concluding the Judge ignored evidence, particularly the evidence of its experts and the body of prior art (especially the ‘422 application). Instead, Sandoz submits that the Judge relied upon the evidence of Abbott's expert Dr. Banker. Sandoz further argues that there was no evidence to support the Judge's finding that there were material differences between clarithromycin and azithromycin, and the prior art referenced by the Judge did not mention either of these drugs.

[20] In my view, no palpable and overriding error has been demonstrated by Sandoz. The Judge’s conclusion that there were specific differences between the properties of clarithromycin and azithromycin which would not make them obvious candidates for substitution in the formulation was supported by general references in the prior art relied upon by the Judge.

[21] With respect to the three specific differences relied upon by the Judge, there was evidence in the affidavit of Abbott's expert that supported the existence of differences between the body tissue distribution and the half-lives of clarithromycin and azithromycin. Sandoz’s expert Dr. Chambliss agreed that the first pass effect could affect the onset, intensity or duration of a drug’s activity in the body and that clarithromycin, unlike azithromycin, had a marked first pass effect.

[22] Dr. Banker provided evidence concerning the prior art relied upon by Sandoz. His evidence distinguished such art and supported the Judge's conclusion.

[23] In short, Sandoz asks this Court to re-weigh the evidence and find in its favor. However, the Judge was entitled to prefer the evidence of Dr. Banker over the evidence of Sandoz' experts. Dr. Banker's evidence supported the Judge's conclusion that on the basis of the '422 application it would not have been self-evident to the skilled person to substitute clarithromycin for azithromycin as asserted by Sandoz.

[24] With respect to the second ground of appeal, Sandoz argues that the Judge erred by failing to assess properly the common general knowledge of the skilled person. Again, I find Sandoz has not demonstrated any palpable and overriding error.

[25] A number of arguments are advanced by Sandoz. Turning to its first argument, Sandoz asserts that several prior art references stated, and its experts confirmed, that skilled persons knew how to use hydroxypropyl methylcellulose (HPMC) with all types of drugs, and knew how to adjust the release rate of the drug so as to make an extended release tablet. However, Dr. Banker provided evidence that contradicted Sandoz' assertion about what the prior art contributed to the common general knowledge. Dr. Banker's evidence was supported by the teachings of a 1987 formulation textbook entitled *Hydrogels in Medicine and Pharmacy* (Volume II at page 146). It was open to the Judge to prefer the evidence of Dr. Banker.

[26] Next, Sandoz asserts that the Judge reviewed each prior art reference in isolation, compared it to the ‘266 patent, and dismissed the prior art as irrelevant when it did not disclose every element of the ‘266 patent. However, this submission is inconsistent with the Judge's exposition, at paragraphs 113-114 of her reasons, of what the common general knowledge was at the relevant time period. The reasons of the Judge do not demonstrate that she reviewed each prior art reference in isolation.

[27] Finally, Sandoz points to the Judge's treatment of two patents and a series of brochures published by Dow Chemical Company, the maker of one brand of HPMC. However, the fact a document forms part of the prior art does not make it part of the common general knowledge. See: *Janssen-Ortho Inc. v. Novopharm Ltd.*, 2007 FCA 217 at paragraph 25 (citing factors developed in *Janssen-Ortho Inc. v. Novopharm Ltd.*, 2006 FC 1234) and *Eli Lilly and Co. v. Apotex Inc.*, 2009 FC 991 and the authorities cited therein at paragraphs 96 to 100). Sandoz acknowledges that Dr. Banker testified that a person of skill would not know how to use HPMC to develop an extended release product at the relevant date. Sandoz has not shown that the Judge was not entitled to prefer his evidence.

[28] Having found no palpable and overriding error, I would dismiss the appeal.

The Cross-Appeal: Did the Judge err in law by applying the wrong date on which allegations in the NOA were assessed?

[29] As noted above, the Judge may well have possessed discretion to either refuse to receive new evidence or to adjourn the proceeding. No complaint is made that the Judge improperly exercised such discretion. In my view, in the absence of demonstrated prejudice, the Judge acted reasonably in proceeding as she did.

[30] Sandoz argues that Abbott provided insufficient evidence to establish that it intended to dedicate the ‘541 patent or that the patent was actually dedicated. In its memorandum of fact and law in reply to the cross-appeal, Sandoz appended copies of documents obtained from the CIPO showing that after the dedication Abbott continued to pay the annual maintenance fee for the ‘541 patent.

[31] The reference to such correspondence led to a motion in writing brought by Abbott in which it sought an order striking those portions of Sandoz' memorandum of fact and law that either sought to challenge the dedication or made reference to maintenance fee payments. In the alternative, Abbott sought leave to present reply evidence. Sandoz opposed such motion and filed its own motion in writing for leave to file an affidavit attaching records from the CIPO with respect to maintenance payments. The motions were dealt with at the outset of the hearing of the appeal and cross-appeal. Leave was given to both parties to file the evidence they requested.

[32] Such evidence satisfies me that the ‘541 patent was dedicated and the subsequent payment of maintenance fees was an error made by a patent annuity service. There is nothing in the evidence to detract from the concession made at the hearing by counsel for Sandoz that the ‘541 patent had been dedicated to the public use by Abbott.

[33] I now turn to consider the Judge's treatment of the dedication. Abbott argued that since the effect of a dedication is to in effect re-write the patent as if the dedicated claims had never issued, there was no basis for Sandoz' argument of double patenting. The Judge found, at paragraph 200 of her reasons, that had the dedication "been executed prior to the service of the NOA, Sandoz would not have had a ground for alleging double patenting in respect of the ‘395 Patent." This conclusion was based upon the earlier decision of the Federal Court in *G. D. Searle & Co. v. Merck & Co.* (2002), 219 F.T.R. 64 where, at paragraph 96, the Court found that the dedication of certain claims to the public terminates a patentee’s right to a monopoly in the subject matter described in the dedicated claims and that the effect of the dedication is that “the patent is to be read as if those claims had never issued.”

[34] I disagree with Sandoz' contention that the Judge, at paragraphs 197 and 205 of her reasons, rejected Abbott’s submission that because of the dedication the patent should be read as if the dedicated claims had never issued. I base my conclusion upon the Judge’s statement that there would have been no ground to allege double patenting if the dedication had been executed prior to the service of the NOA (Reasons at paragraph 200). Her later rejection, at paragraph 205 of her reasons, of the effect of this particular dedication is a consequence of its timing and the Judge’s

reliance, by analogy, upon the prior decision of the Federal Court in *Bristol-Myers Squibb Canada Co. v. Apotex Inc.* (2009), 342 F.T.R. 161. More will be said of this case later.

[35] Sandoz seeks to impugn the correctness of the decision of the Federal Court in *G. D. Searle* on the ground that the Court applied reasoning that was subsequently overturned by this Court in *Parke-Davis Division v. Canada (Minister of Health)*, [2003] 2 F.C. 514 (C.A.).

[36] However, the *G. D. Searle* case was not appealed. To the extent that reference was made in that decision to the prior reasons of the Federal Court in *Parke-Davis*, as the Court noted in *G. D. Searle* at paragraph 92, in *Parke-Davis* "no clear statement was made as to the legal consequences of a Dedication nor how the dedication of certain claims might affect non-Dedicated Claims."

[37] Further, at issue in *Parke-Davis* was whether allegations made under the Regulations were justified. The allegations were found to be unjustified by the Federal Court because the applicants had failed to provide a satisfactory analysis of the legal nature of patent dedication and, particularly, the ability to revoke a dedication. See: [2002] 1 F.C. 517 at paragraph 97. The Federal Court did not consider the effect of dedication upon non-dedicated claims, or whether dedication could be relevant to the issue of double patenting.

[38] Sandoz has failed to demonstrate that the decision in *G. D. Searle* was based upon any legal principle that was later reversed by this Court.

[39] That said, for the purpose of this appeal I do not believe it is necessary to consider whether the effect of the dedication of claims of a patent is that the patent is to be read as if those claims had never issued. It is sufficient for the purpose of this appeal to conclude that after claims have been dedicated, the patent is to be construed without reference to the dedicated claims.

[40] There remains to consider the effect of the timing of the dedication of the ‘541 patent.

[41] The Judge held that because it "was upon the content of the NOA that the Applicants decided to commence these proceedings […] it must be upon the date the NOA was issued that the status of the ‘541 Patent is considered" (Reasons at paragraph 201). Her conclusion was based upon the reasoning of the Federal Court in *Bristol-Myers*, cited above.

[42] In *Bristol-Myers*, the innovator disclaimed certain claims in a patent after a NOA had been served, but before it filed its notice of application seeking a prohibition order under the Regulations. The Court concluded that because the generic could not revise its NOA, the disclaimed patent had to be construed on a date prior to the disclaimer. The Court construed the patent as of the date the NOA was served.

[43] In neither the present case nor in *Bristol-Myers* did the Federal Court consider the decision of the Supreme Court of Canada in *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)*, [1998] 2 S.C.R. 193 (*Merck*).

[44] In *Merck*, the innovator argued that a NOA filed by Apotex was premature. The Supreme Court found that the appropriate date for assessing the justification for the NOA was the date of the hearing of the prohibition proceeding.

[45] To reach this conclusion, the Court considered a number of decisions of the Federal Court and this Court in proceedings brought pursuant to the Regulations. Three of those decisions are of assistance in the present case.

[46] The first was the decision of the Federal Court in *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)* (1997), 132 F.T.R. 60 (*Merck #2*). There, the generic alleged that its product would not infringe as a result of the existence of a compulsory license. Non-infringing activity was not possible at the time the NOA was filed. Non-infringing activity was possible at the time of the hearing. Relying upon the language of subsection 6(2) of the Regulations, which required the Court to issue an order of prohibition "if it finds that none of those allegations is justified" the Court found the appropriate date for assessing the allegation was the date of the hearing. [Emphasis added.]

[47] In *Glaxo Wellcome Inc. v. Canada (Minister of National Health and Welfare)* (1997), 75 C.P.R. (3d) 129, the Federal Court considered an application for prohibition in respect of a patent which had expired after a NOA had been served. The Court rejected the submission that the relevant date for assessing the validity of the allegation of non-infringement was the date the NOA issued. The relevant date was held to be the date of the hearing.

[48] Justice Iacobucci, writing for the Supreme Court in *Merck* referred specifically to the decision of Justice Muldoon in *Merck #2* and to the *Glaxo Wellcome* decision. He wrote as follows at paragraph 27:

> Muldoon J. noted at p. 73 that, by s. 6(2) of the Regulations, the court is required to make an order of prohibition "if it finds that none of those allegations [i.e., those contained in the NOA] is justified" (emphasis added). In his words, at p. 73:
>
> > When does or can the court make such a finding? Not earlier than the hearing of the motion for prohibition, is when. It is noteworthy that the regulation does not provide: ". . . it finds that none of those allegations was justified", i.e. "both at the date of the Notice and at the date a NOC could have issued under the Notice". . . . Clearly, if time be the critical consideration, however, the time of the allegations' "prematurity" or "ripeness" is the time at which the court "finds that none of those allegations is justified", which at earliest is the hearing of the prohibition motion and at latest is the date of the court's order and reasons for order, if reasons there be. After all, is that not precisely the time reg. 6(2) provides in so many words, and not some earlier? As above illustrated reg. 6(2) could easily have exacted what the learned judge found about "prematurity", but it does not exact that. [Emphasis in original.]
>
> This approach was adopted in Smithkline Beecham Pharma Inc. v. Canada (Minister of National Health and Welfare) (1997), 138 F.T.R. 310, and in Glaxo Wellcome Inc. v. Canada (Minister of National Health and Welfare) (1997), 75 C.P.R. (3d) 129 (F.C.T.D.). In my view, it is a correct statement of the law.

[49] By affirming the correctness of the Court's approach in *Glaxo Wellcome*, the Supreme Court endorsed the principle that a court should not issue a prohibition order where a patent has expired at the time of the proceeding.

[50] Justice Iacobucci went on to consider the decision of this Court in *Apotex Inc. v. Canada (Attorney General)*, [1994] 1 F.C. 742; aff'd [1994] 3 S.C.R. 1100. He quoted the following passage from the decision of this Court:

> As a general proposition, it is not difficult to accept a rule which seeks to eliminate premature applications for mandamus. It is certainly open to a respondent to pursue dismissal of an application where the duty to perform has yet to arise. However, unless compelling reasons are offered, an application for an order in the nature of mandamus should not be defeated on the ground that it was initiated prematurely. Provided that the conditions precedent to the exercise of the duty have been satisfied at the time of the hearing, the application should be assessed on its merits.

[51] While Justice Iacobucci noted that this statement did not give "rise to any general rule concerning the date of assessment in all matters of judicial review", he went on to state that:

> 30 However, the logic underlying the holding does provide some guidance. In my view, the matter comes down to a question of common sense. Certainly, it would not be appropriate for this or any court to permit the premature grant of a NOC where the statutory conditions have not been met. On the other hand, I have great difficulty with the notion that where, at the date of hearing, the court is satisfied that the conditions have been met, it should nonetheless prohibit the Minister from granting a NOC. The purpose of the Regulations is simply to prevent patent infringement by delaying the issuance of NOCs until such time as their implementation would not result in such infringement. They are not, in my view, intended to punish generic drug producers for asserting their rights prematurely. If a generic producer can accurately predict the date on which the exercise of rights under a given NOC would not infringe the relevant patents, and times its application for the NOC accordingly, I can see no reason why the application should be rejected solely on the basis that the allegation made in its support was not justified when the NOA was issued, notwithstanding that there was no possibility that the NOC could be granted on that date. [Emphasis added.]

[52] From the decision of the Supreme Court in *Merck*, I conclude it is correct to assess the justification of allegations contained in a NOA as at the date of the hearing, at least where assessment as at the date of the hearing will promote the purpose of the Regulations.

[53] The purpose of the Regulations is to ensure a proper balance between the benefits flowing from effective patent protection of new and innovative drugs and the benefits flowing from timely market entry of lower priced generic products. See: *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, [2005] 1 S.C.R. 533 at paragraphs 14 and 15; *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, [2006] 2 S.C.R. 560 at paragraphs 11 and 50.

[54] Early entry was facilitated by the 1993 enactment of the *Patent Act Amendment Act, 1992*, S.C. 1993, c. 2. Subsection 55.2(1) of the *Patent Act*, as amended, brought into force the "early-working" exception which permits generic companies to work a patented invention embodied in a drug prior to the expiry of the patent to the extent necessary for the generic to obtain a Notice of Compliance effective at the time the patent expires.

[55] The Regulations were brought into force to ensure that no abuse flowed from the "early-working" exception. The Regulations fulfil this function by linking the issuance of a Notice of Compliance in respect of a generic drug to the patent status of the equivalent innovative product the generic seeks to copy.

[56] In my view, the purpose of the Regulations is not served in the present case by considering the allegation of double patenting as at the date the NOA was served. To do so ignores the fact and the effect of the dedication of the '541 patent. The result is that the Minister of Health may issue a Notice of Compliance to Sandoz, yet at the time of such issuance its allegation of double patenting is unjustified.

[57] The purpose of the Regulations is served in the present case by considering the effect of the dedication as of the date of the hearing. This result is consistent with the language of subsection 6(2) of the Regulations which allows the issuance of an order of prohibition if the Court finds that none of the allegations made by a generic "is justified". It is also consistent with decisions such as *Glaxo Wellcome* which was cited with approval by the Supreme Court of Canada in *Merck*. It follows that, in my respectful view, the Judge erred by considering the status of the '541 patent as of the date of the NOA was issued. The status of the '541 and '395 patents should have been considered as of the date of the hearing.

[58] As noted above, the Judge accepted that had the dedication taken place prior to the service of the NOA, the effect of the dedication would have been to remove the evidentiary basis for the allegation of double patenting. Had she taken cognizance of the dedication by considering the '541 patent as of the date of the hearing she would have concluded that the allegation of double patenting was not justified. In my view, that is the correct result.

[59] One final issue requires comment. Sandoz argues that should this Court accept that the Judge erred by finding its allegation of double patenting was justified, this Court should also find that the Judge erred by finding Sandoz' allegation that the '395 patent was invalid for obviousness was not justified.

[60] The Judge construed the '395 patent "as revealing what is essentially the same invention as that claimed in the '266 patent, with the added limitation listed in Claim 22 that the

composition must exhibit an improved taste profile” when compared against the immediate release composition of clarithromycin (Reasons at paragraph 106). No issue is taken with the Judge’s construction of the ‘395 patent.

[61] Sandoz argued that it was obvious that an extended release composition would have an improved taste profile. The Judge found as follows:

> *The Improved Taste Profile*
>
> 155 There is also some dispute between the parties as to whether taste perversion was known to be dose-dependent and whether it was self-evident that extending the release of the formulation would address this adverse effect. The parties provided evidence supporting two diametrically opposing conclusions.
>
> 156 The Respondent provided the Court with a number of references to the prior art in support of its argument. These included US Patent 3,065,143 (the "'143 patent"), being Sandoz Document 1, and the Robert E. Notari article labeled Sandoz Document 24, which each support the conclusion that higher C-max levels can lead to an increase in adverse effects, and that side effects are dose-dependent. Further, the article by Dr. J.K. Aronson and Dr. C.J. Van Boxtel posits that taste perversion as described by patients taking clarithromycin, seems to be dose-related.
>
> 157 The Applicants pointed to the evidence of Dr. Banker, who disputes the Respondent's conclusion, stating that to this day, it is not known what exactly causes the bitter metallic taste associated with clarithromycin following ingestion.
>
> 158 In addition, the Applicants point to the statements made on cross examination by Dr. Thiessen and Dr. Einarson. Dr. Thiessen stated that he believed it would take "a leap of faith" to conclude that an inventor could reasonably have expected the ER formulations to have resulted in a lowering of any adverse effect. Furthermore, Dr. Einarson stated that it is not true to state that there is a correlation between increased exposure to a drug and increases in the adverse effects associated with the drug, and that he does not believe that taste perversion is necessarily dose-related.
>
> 159 Even if I accept that adverse effects may be dose-dependent, that higher C-max levels could lead to an increase in adverse effects and that it was self-evident that reducing a drug's C-max could serve as a method by which to reduce adverse effects, I do not believe that it was self-evident that the C-max could have been reduced simply by extending a drug's release rate.
>
> 160 A reduction in the drug's C-max when compared against the IR formulation was amongst those favourable p-kinetics disclosed within the claimed compositions. I

> concluded above that the favourable p-kinetics disclosed within the compositions were not inherent in any ER formulation. Upon this basis, it could not inherently be the case that extending a drug's release would result in the lowering of the drug's C-max.
>
> 161 If it was not self-evident that one could reduce a drug's C-max simply by extending the drug's release, then it follows that it also could not have been self-evident that any benefit flowing from the reduction in the drug's C-max would result simply by extending a drug's release.
>
> 162 In sum, I find that it would not have been self-evident to the skilled person that extending the drug's release could lead to a reduction in the incidence of taste perversion and an improvement in the drug's taste profile.

[62] Sandoz argues that in so finding the Judge erred by:

i) ignoring the fact that taste perversion includes taste in the mouth;

ii) ignoring Dr. Banker's evidence that extended release tablets were known to reduce bad taste in the mouth; and

iii) relying upon the evidence of its experts who were not put forward on issues of obviousness.

[63] These asserted errors are errors of fact. Thus, this Court can only intervene if Sandoz demonstrates the Judge committed a palpable and overriding error. For the following reasons, it has not.

[64] First, the Judge did not ignore the issue of the taste in the mouth left by the extended release formulation. Abbott had tendered the evidence of Daniel Weiner to opine about whether, compared to the immediate release formulation, the extended release formulation exhibited:

(a) an improved taste profile; and

(b) a statistically significant reduction in severity of adverse effects to the digestive system.

[65] It was Dr. Weiner's evidence that in the context of clarithromycin taste perversion is the perception of a bitter metallic taste some time after ingesting the formulation. He found the extended release formulation exhibited a statistically significant lower incidence of taste perversion (i.e. an improved taste profile). The Judge preferred this evidence over the conflicting evidence of Sandoz' expert Dr. Thiessen. She did not ignore the fact that taste perversion includes a taste in the mouth.

[66] Second, with respect to the issue of obviousness, it was Dr. Banker's evidence that:

> 238. As discussed above, there is very little known about the phenomenon of taste perversion and almost nothing was available to the POSA on the topic. To this day it is not known exactly what causes the perception of a bitter metallic taste some time after clarithromycin is ingested. To link the phenomenon with p-kinetics is not something the POSA would be capable of doing. The same can be said about the severity of adverse effects to the digestive system.

[67] Dr. Thiessen's evidence on cross-examination was that:

> 513. Q. Now, let's talk about the pharmacokinetics of the extended-release formulations, which I understand is an area of expertise for you, pharmacokinetics?
>
> A. Yes.
>
> 514. Q. It is a speciality?
>
> A. Yes.
>
> 515. Q. Now, I am going to put it to you that because the extended-release compositions decreased the Cmax of clarithromycin in the blood, the inventors could

> reasonably expect that the ER formulations would result in a lowering of any adverse event, including taste perversion?
>
> A. That is a leap of faith that is not necessarily supported.
>
> 516. Q. I am going to put it to you and say the same is true for a decrease in the severity of adverse effects to the digestive system.
>
> A. Those are not logical extensions. They are perhaps generic extensions that are often used, but in a specific case, until one knows what the cause and effect relationship is, you do not know whether, in fact, such a development with an extended-release product compared to an immediate-release product is a safe one.
>
> 517. Q. So you are saying you have got to do the experimentation?
>
> A. You need some experimental work, yes.
>
> [Emphasis added.]

[68] I have read the relevant portions of the cross-examination of Dr. Banker. In my view, the admissions relied upon by Sandoz were sufficiently qualified that the Judge was entitled to rely on Dr. Banker's evidence with respect to the non-obvious nature of claim 22 of the '395 patent. This is particularly so in light of the above quoted evidence of Dr. Thiessen on cross-examination. This evidence was expressed by him to be squarely within his area of expertise.

[69] For these reasons, the Judge's conclusion that Sandoz failed to justify its allegation that the '395 patent was obvious has not been shown to be tainted by any palpable and overriding error.

Conclusion

[70] For the above reasons, I would dismiss the appeal and allow the cross-appeal with costs. Pronouncing the judgment the Federal Court ought to have pronounced, I would allow the application for an order of prohibition in respect of the ‘395 patent with costs to Abbott.

"Eleanor R. Dawson"
J.A.

“I agree.
Marc Noël J.A.”

“I agree.
Johanne Trudel J.A.”

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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