Federal Court of Appeal  Cour d'appel fédérale

Date: 20121123

Docket: A-312-12

Citation: 2012 FCA 308

CORAM: **NOËL J.A.**
STRATAS J.A.
WEBB J.A.

BETWEEN:

APOTEX INC.

Appellant

and

ALLERGAN INC., ALLERGAN SALES INC. and ALLERGAN, INC.

Respondents

and

THE MINISTER OF HEALTH

Respondent

Heard at Ottawa, Ontario, on October 30, 2012.

Judgment delivered at Ottawa, Ontario, on November 23, 2012.

REASONS FOR JUDGMENT BY: NOËL J.A.

CONCURRED IN BY: STRATAS J.A.
WEBB J.A.

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REASONS FOR JUDGMENT

NOËL J.A.

[1] This is an appeal from a decision of Hughes J. of the Federal Court (the Federal Court judge) who granted the order sought by Allergan Inc., Allergan Sales Inc. and Allergan, Inc. (Allergan) prohibiting the Minister of Health from issuing a Notice of Compliance (NOC) to the appellant (Apotex) pursuant to Section 6 of the *Patented Medicines (Notice of Compliance)*

Regulations, SOR/93-133 (PM(NOC) Regulations) with respect to its ophthalmic drug APO-BRIMONIDINE-TIMOP until the expiry of Patent No. 2,440,764 (the '764 patent).

[2] The appeal comes to this Court in an unusual way. Although the Federal Court judge held that Apotex's allegation of invalidity on grounds of obviousness was justified and that the prerequisite for the issuance of the prohibition order sought by Allergan had therefore not been established, he nevertheless issued it. In so doing, he adhered to the judgment given by his colleague Crampton J. (as he then was) in another NOC proceeding involving the same patent (*Allergan Inc. v. Canada (Health) and Sandoz Canada Inc.*, 2011 FC 1316 (*Sandoz*)), even though he expressly disagreed with the reasons and the conclusion reached in that case. He explained that he adopted this unusual course because he wanted to make sure that his concerns about the application of the doctrine of comity in the context of NOC proceedings could be addressed on appeal (reasons, paras. 192 to 194).

[3] Both Apotex and Allergan take issue with the course of action which the Federal Court judge adopted. They point to the fact that we now have two different constructions of the same patent and invite us to resolve the dispute.

[4] According to Apotex, the Federal Court judge's finding of obviousness is supported by the evidence. It asks this Court to confirm the reasoning of the Federal Court judge in this regard and give the judgment which he ought to have given by dismissing Allergan's application for the issuance of a prohibition order.

[5] Allergan for its part asks that the issuance of the prohibition order be upheld, but does so for reasons that go to the merits of its application. It submits that the Federal Court judge's finding of obviousness cannot stand because it is based on an improper construction of the inventive concept which underlies the '764 patent. In making this submission, Allergan relies on the approach set out by the Supreme Court in *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61, [2008] 3 S.C.R. 265 at paragraph 67 (*Sanofi*) according to which a finding of obviousness can only be made by reference to the inventive concept properly construed.

[6] For the reasons which follow, I have concluded that it was not open to the Federal Court judge to grant the prohibition in order to further his desire to clarify the jurisprudence. As to the merits, I agree with Allergan that the Federal Court judge failed to have regard to the inventive concept properly construed and that had he done so, he could not have found that the invention was obvious. I would therefore dismiss the appeal and confirm that the prohibition order was properly issued, but would do so on the ground that the alleged invalidity of the '764 patent asserted by Apotex in its Notice of Allegation has not been established.

BACKGROUND

[7] Glaucoma is a chronic disease of the optic nerve that leads to progressive, irreversible loss of vision and can lead to blindness. The precise cause of damage to the optic nerve is not entirely understood. However, it is often associated with increased pressure of the aqueous humor located at the front of the eye. This is usually referred to as increased intraocular pressure (IOP), or ocular hypertension. If left untreated, IOP can lead to the development of glaucoma. It

is for this reason, and the fact that IOP-lowering drugs seem to prevent further progression of the disease, that IOP is widely considered to be a major risk factor for glaucoma.

[8] Although there is no cure for glaucoma, several different IOP-lowering drugs have been developed for its treatment. However, these have been associated with significant side effects which prompt afflicted patients not to comply or to discontinue the treatment altogether.

[9] It is useful to describe the '764 patent in some detail. The '764 patent discloses and claims a new combination drug useful for the treatment of glaucoma. This combination drug, known commercially as COMBIGAN®, contains the medicinal ingredients brimonidine and timolol in solution (in a single bottle). Because the bottle contains each medicinal ingredient at a single, fixed concentration, the combination drug is sometimes referred to as a "fixed combination".

[10] The inventors explain that brimonidine and timolol were not new drugs as of the filing date of the '764 patent ('764 patent, pp. 1 to 3, appeal book, vol. 1, pp. 236 to 238). Each had been used to treat glaucoma as each could reduce IOP. In the first paragraph of the patent under the heading "Background of the Invention", the inventors explain, among other things, that there were "concerns … about patient compliance" and a "long felt need" for a "safe" and "effective" fixed combination. The paragraph ends with the following phrase "Unexpectedly it has been discovered that brimonidine in combination with timolol meets these criteria" ('764 patent, p. 1, appeal book, vol. 1, p. 236).

[11] The inventors offer two examples and describe them in the ’764 patent. In Example I, the inventors disclose a fixed combination formulation that contains the specific concentrations of brimonidine and timolol claimed in the ’764 patent (’764 patent, pp. 5 and 6, appeal book, vol. 1, pp. 240 and 241). The pH figure specified in Example I is within the range set out in the formulation claimed in the ’764 patent and all of the excipients used are described in the patent.

[12] Example II goes on to disclose a large human clinical trial (586 individuals) designed to test the safety and efficacy of the formulation disclosed in Example I (’764 patent, pp. 6 to 16, appeal book, vol. 1, pp. 241 to 251). The trial compared the formulation disclosed in Example I administered twice a day (BID) to brimonidine administered alone three times a day (TID). The Example I formulation with the same dosage was also compared to timolol administered alone BID. About 200 patients received each drug.

[13] At pages 12 to 14 of the patent, in the disclosure portion, under the heading “Safety”, the inventors provide a detailed analysis of the results of the human clinical trial. These results are tabulated on page 13 and reveal that the side effect profile and the discontinuance rate of the fixed combination formulation in Example I administered BID was better than the side effect profile of brimonidine administered TID – meaning that patients could be treated for a longer period of time (’764 patent, p. 13, appeal book, vol. 1, p. 248).

[14] At page 16 of the patent under the heading “Conclusions”, the inventors state:

> The Combination administered BID demonstrated a favorable safety profile that was comparable to Timolol BID and better than Brimonidine TID with regard to the

> incidence of adverse events and discontinuations due to adverse events ['764 patent, p. 16, appeal book, vol. 1, p. 251].

[15] Throughout his reasons, Crampton J. refers to "the reduction of incidence of adverse events and discontinuance due to adverse events" as the "improved safety profile" (*Sandoz*, para. 61).

[16] The only claim in issue is claim 22, which narrows the fixed combination claimed. It is common ground that unless Apotex's allegation of invalidity is found to be justified, its proposed ophthalmic drug would infringe claim 22 along with claims 6, 3 and 1 on which it depends:

> **Claim 22** – Topical use of a therapeutically effective amount of a composition according to claim 6 in effected eye for treating glaucoma.
>
> **Claim 6** – A composition according to claim 3 further comprising from 0.001% by weight to less than 0.01% by weight of benzalkonium chloride.
>
> **Claim 3** – A composition according to Claim 1, wherein the amount of brimonidine is 0.2 percent by weight and the amount of the timolol is 0.5 percent by weight.
>
> **Claim 1** – An ophthalmic topical pharmaceutical composition for the treatment of glaucoma or ocular hypertension comprising an effective amount of brimonidine and an effective amount of timolol in a pharmaceutically acceptable carrier therefor.

[17] The Federal Court judge reworded claim 22 to take into account claims 6, 3 and 1 as follows (reasons, para. 111):

> Topical use of a therapeutically effective amount of an ophthalmic pharmaceutical composition for the treatment of glaucoma or ocular hypertension wherein the amount of brimonidine is 0.2 percent by weight and the amount of timolol is, 0.5 percent by weight, and from 0.001% by weight to less than 0.01% by weight of benzalkonium chloride.

[18] No one takes issue with this depiction of claim 22.

[19] The Federal Court judge notes in the course of his reasons that no appeal was taken from the *Sandoz* decision and that, therefore, it is a final decision (reasons, para. 36). He also notes that Allergan was represented by same counsel in both cases and that the evidence of Gary J. Beck – one of the inventors – and the expert evidence of Dr. Robert D. Fechtner was filed in both cases (reasons, paras. 43 and 44). In contrast, Apotex and Sandoz were represented by different counsel and Apotex in this case produced different expert evidence – notably that of Dr. Harry A. Quigley and Dr. Uday B. Kompella (reasons, paras. 43 and 45).

[20] With respect to Dr. Fechtner, Allergan's sole expert whose testimony was accepted by Crampton J. without reservation, the Federal Court judge made the following observation (reasons, para. 29):

> As is usual in these types of applications, the evidence took the form of affidavits and transcripts of cross-examinations. No witness was examined before the Court. Thus, the Court is unable to make a truly proper assessment as to credibility of any witness, nor to weigh properly the competing opinions of the experts. However, having reviewed the transcripts of the cross-examination of Allergan's expert witness Dr. Fechtner, I find him to be evasive and less than forthright on many occasions. I will treat his evidence with great caution.

- *Diverging views as to the inventive concept*

[21] The fundamental difference between the two judgments pertains to the inventive concept underlying the '764 patent. In *Sandoz*, Crampton J. gave lengthy reasons in support of his conclusion that the improved safety profile was part of the inventive concept underlying claim 22

(*Sandoz*, paras. 46 to 62). Specifically, he rejected Sandoz contention that the inventive concept had to be discerned from the claims themselves (*Sandoz*, paras. 50 and 51).

[22] Crampton J. went on to consider the patent as a whole and held that the inventive concept, beyond what is stated in paragraph 1 of the patent, extends to, among other things, (i) the improved safety profile, and (ii) the use of the combination drug BID without afternoon reduction in efficiency (also identified as "the afternoon trough") (*Sandoz*, para. 58).

[23] Crampton J. summed up his conclusion as follows (*Sandoz*, para. 61):

> I accept Dr. Fechtner's opinion that "[t]he [person skilled in the art] would have considered the improved safety profile [of the fixed combination drug], including the reduction of incidences of adverse events and discontinuance due to adverse events, to be part of the invention claimed in the '764 [p]atent". That is to say, I accept his view that improved safety profile is part of the inventive concept of the '764 [p]atent.

[24] The Federal Court judge read the patent differently. He read paragraph 1 of the patent as setting out the results that the combination promises to deliver and held that the inventive concept must be construed by reference to those promises, *i.e.* that the claimed composition (i) improves patient compliance, (ii) contains brimonidine and timolol, (iii) is effective, (iv) is safe, (v) has increased stability, (vi) requires lower effective concentration of preservative than separate doses of each, and (vii) has increased efficacy without increased concentration of brimonidine or timolol (reasons, para. 144).

[25] Giving effect to this approach, he went on to conclude (reasons, para. 145):

> The "inventive concept" is, therefore, that a particular composition of ingredients including brimonidine, timolol and benzalkonium chloride, in particular quantities, achieves the above results as promised.

[26] Significantly, this reading omits from the inventive concept the improvement in safety which Crampton J. had included. While the Federal Court judge does not comment on why he could not agree with Crampton J. on this point, he does comment on another aspect of the inventive concept identified by Crampton J., with which he also disagreed (reasons, paras. 146 and 147):

> [146] At this stage, I will consider what Counsel for Allergan has argued as being part of the "inventive concept"; something which Allergan's Counsel calls the afternoon trough. Crampton J in paragraph 58 of his Reasons has referred to this as an afternoon reduction in efficiency. Allergan places much stress on an assertion that its combination drug can be used only twice a day (BID) with as much effectiveness as the prior use of timolol or brimonidine alone, three times a day (TID). However, this property is not clearly stated in the patent. At page 3 of the patent it is stated that the precise regimen is left to the discretion of the clinician. At page 4 it is stated that adequate lowering of interocular pressure has been obtained when administering the compositions of the invention twice a day when compared to commercially approved brimonidine and timolol solutions twice or three times a day. In Example II, the combination as used twice a day (BID) is said to be superior to a certain concentration of timolol used twice a day (BID), or a certain concentration of brimonidine, used three times a day (TID). I repeat the conclusions at page 16:
>
> > <u>Conclusions</u>
> >
> > The Combination treatment (brimonidine tartrate 0.2%/timolol 0.5%) administered BID for 3 months was superior to Timolol (timolol 0.5%) BID and Brimonidine (brimonidine tartrate 0.2%) TID in lowering the elevated IOP of patients with glaucoma or ocular hypertension. The Combination administered BID demonstrated a favourable safety profile that was comparable to Timolol BID and better than Brimonidine TID with regard to the incidence of adverse events and discontinuations due to adverse events

> [147] The patent draws no general proposition from these conclusions or the previous comments as to comparative frequency of administration. The evidence shows that while some countries, including, apparently, Canada, approve the combination drug for twice a day use; the United States does not. Therefore, unlike Crampton J, I do not accept the avoidance of an afternoon trough (or ability to dose only twice a day) as part of the inventive concept of the patent. The patent at best describes the possibility of twice daily dosing in the discretion of a clinician as a resulting property of the combination but not as an inventive feature.

-*The views of the Federal Court judge on comity*

[27] The Federal Court judge dismissed Allergan's contention that the determination of the inventive concept gives rise to a question of law to which the doctrine of comity applies (reasons, paras. 148 and 149):

> [148] Allergan's Counsel argues that the interpretation of a patent is a legal matter; thus, Crampton J's finding as to what constitutes the inventive concept is an interpretation of law and must, as a matter of comity, be followed by me. I reject that argument.
>
> [149] Allergan's argument rests on an interpretation as to what Binnie J, for the Supreme Court of Canada, wrote in *Whirlpool Inc v Camco Inc*, [2000] 2 SCR 1067, at paragraph 49 (c) [should read 49(*e*)] where he refers to "letters patent" as being a "regulation" as defined in [paragraph] 2(1)(*a*) of the *Interpretation Act*, RSC 1985, c. I-21. As the late W. K. Hayhurst pointed out in his article written in respect of this comment, *"The Distinction between 'Letters Patent' and 'Patent Specification', How Did We Get Where We Are?"* (2007), 57 CPR (4th) 161, the regulation spoken of is the one-page document attached to the patent specification, which is the page *granting* the patent, not the patent itself. The specification is a document drafted by the patentee, not Parliament or the Governor in Council. Interpretation of the specification is like the interpretation of a contract drafted by one or more parties. The level of comity owed by one judge in the interpretation of the same contract by another judge is not as great as the level of comity owed when a statute or regulation has been interpreted.

- *Diverging views as to obviousness*

[28] He later went on to conduct the obviousness analysis by reference to the inventive concept as he construed it (reasons, paras. 150 to 188). In so doing, he noted a number of findings made by Crampton J. with which he also disagreed (reasons, paras. 165 to 189).

[29] Amongst these differences, the Federal Court judge explained why he could not agree with Crampton J. that more than routine work was required in order to arrive at the inventive concept (reasons, paras. 175 and 176):

> [175] I find, on the evidence, that in order to arrive at the alleged inventive concept, no more than routine laboratory work was required. As Floyd J said in *Teva UK Limited v Merck & Co Inc* [2009] EWHC 2952 (Pat) at paragraph 95, it is a basic proposition of patent law that the doctrine of obviousness exists to prevent a patentee from monopolizing products or activities that a skilled person should feel free to make or perform without worrying about the existence of a patent.
>
> [176] Crampton J, at paragraphs 92 to 113 of his Reasons, found differently. I put this down to two reasons. First is on the evidence. In *Sandoz*, Mr. Beck was intensively cross-examined, and during the course of the questioning apparently put in a great deal of evidence not set out in his affidavit as to the work involved. In the case before me, Mr. Beck was not questioned in this way and had no opportunity to provide additional evidence of this kind. Further, in *Sandoz*, the cross-examination of Dr. Fechtner failed to reveal the serious problems with his testimony that have been revealed in the evidence before me. Second, it does not appear that Crampton J's attention was drawn to the *AZT* case, *supra*, where a distinction between efforts expended in clinical studies for regulatory approval must be made from effort expended in arriving at the alleged invention.

[30] The Federal Court judge also disagreed with Crampton J.'s assessment of the motivation to find a solution (reasons, para. 181):

> [181] Crampton J dealt with motivation at paragraphs 114 to 116 of his Reasons. He relies on uncontradicted evidence of Dr. Fechtner. Here, Fechtner is

> contradicted both by other experts and in his own cross-examination. Crampton J also refers to the clinical trials necessary for government approval. As previously discussed, this is not relevant to the question of inventiveness.

[31] The Federal Court judge concluded that the '764 patent was invalid because the purported invention was obvious (reasons, para. 189).

- *The unusual remedy*

[32] Despite this conclusion, the Federal Court judge issued the order of prohibition. He explained at the end of his reasons (reasons, paras. 191 to 194):

> [191] I must consider the question of comity. Is the evidence and argument before me "different" from or "better" than the evidence and argument before Crampton J in *Sandoz*? There is no real way to measure "different" or "better". The evidence and argument is of the same *kind*. In some cases Crampton J had unrebutted evidence whereas I have rebutted evidence. The difference in the evidence and argument is more one of *quality* to the best that can be discerned from the record that I have, and this Court not having the record as to what was before Crampton J.
>
> [192] If I were to dismiss this application on the basis that Allergan did not discharge its burden of proving that Apotex's allegations as to obviousness were not justified; then, within a matter of hours - if not days - the Minister would give Apotex a [NOC], and the issue as to whether the Court should grant a prohibition order would be moot. The Court of Appeal, in all likelihood, would not hear an appeal.
>
> [193] I believe that there have been serious issues raised as to comity. The somewhat contradictory decisions of the Court of Appeal should be considered by that Court and clear instruction given as to how, in an NOC context, previous decisions of a Court on the same issues respecting the same patent, should be considered.
>
> [194] The only practical way to get the matter before the Court of Appeal is for me to grant the Order for prohibition in the likely expectation that Apotex will appeal.

POSITION OF THE PARTIES ON APPEAL

[33] Focusing on paragraph 194 of the reasons, both Apotex and Allergan agree that the Federal Court judge could not rely on the doctrine of comity for the purpose of provoking an appeal and having the jurisprudential issues which he believed to be of importance decided by this Court. It is common ground, and I agree, that prohibition could only be granted if the conditions set out in the PM(NOC) Regulations were met. According to reasons of the Federal Court, these conditions were not met.

[34] As to the doctrine of comity, Apotex takes the position that the Federal Court judge was not bound to follow the decision of Crampton J. and was entitled to come to his own conclusion on both the inventive concept and the issue of obviousness (Apotex's memorandum, paras. 56 to 67). Allergan for its part maintains that the doctrine of comity required the Federal Court judge to follow the decision of his colleague insofar as it pertained to the identification of the inventive concept (Allergan's memorandum, paras. 45 to 51).

[35] Turning to the proper construction of the '764 patent, there are, for present purposes, two basic elements of the invention on which Crampton J. and the Federal Court judge disagree. According to Crampton J., the afternoon trough (*i.e.* the use of the drug BID) without afternoon reduction in efficiency and the improved safety profile come within the inventive concept, whereas the Federal Court judge excludes both from the inventive concept.

[36] For purposes of this appeal, Allergan focuses its position entirely on the improved safety profile (Allergan's memorandum, para. 2) and concedes that the claimed invention was obvious if this profile does not form part of the inventive concept (Allergan's memorandum, para. 8).

[37] However, it submits that the improved safety profile is part of the inventive concept and that, if it succeeds in making this demonstration, the Federal Court judge's finding that the '764 patent was obvious cannot stand (Allergan's memorandum, para. 61). It points to the fact that the Federal Court judge did not conduct the obviousness analysis with this aspect of the inventive concept in mind, and submits that if he had, he would have been bound to conclude, as did Crampton J., that the '764 patent was not obvious since the evidence points only in that direction (Allergan's memorandum, paras. 65 to 67).

[38] Apotex for its part takes the position that the Federal Court judge correctly construed the '764 patent when he held that the inventive concept did not extend to the improved safety profile (Apotex's memorandum, paras. 23 to 25). This is all the more so since no such improvement was demonstrated (Apotex's reply memorandum, para. 6). It adds that Allergan has not identified any "overriding error" in the Federal Court judge's appreciation of the evidence in order to identify the inventive concept (Apotex's reply memorandum, para. 7). Finally, Apotex submits that, in any event, the improved safety profile was obvious (Apotex's reply memorandum, paras. 10 to 12).

ANALYSIS AND DECISION

- *The concerns expressed by the Federal Court judge*

[39] The Federal Court judge was confronted with a fairly straightforward application of the doctrine of comity. However, it is apparent that he had a broader concern about re-litigation and the application of the notion of abuse of process in the context of NOC proceedings (reasons, paras. 69 to 80). In his reasons, he lumps the two notions together, and suggests that, rather than following this Court's decisions in *Sanofi-Aventis Canada Inc. v. Novopharm Limited*, 2007 FCA 163 (*Novopharm*) and *Janssen-Ortho Inc. v. Apotex Inc.*, 2009 FCA 212 (*Janssen-Ortho*), decisions that he says are conflicting, the matter should be resolved by an elaborate five point approach, described in some of his earlier decisions relating to abuse of process (reasons, paras. 81 and 82).

[40] With respect, I do not believe that it was opportune or useful to attempt to resolve issues relating to comity by reference to a different concept that is not in issue in the present case. The only thing that can usefully be said about abuse of process, is that, contrary to the Federal Court judge's view, the decisions of this Court on point are not inconsistent (reasons, para. 193).

[41] As noted by Sexton J.A. in *Novopharm*, each party must put forward its entire case, complete with all relevant evidence, at first instance. He emphasized that this applies both ways: "Generics likewise must put forward their full case at the first opportunity" (*Novopharm*, para. 50). That is the context in which questions relating to abuse of process are to be addressed in subsequent proceedings. I see nothing in the decision of this Court in *Janssen-Ortho* – see paragraphs 42 to 45 thereof quoted at paragraph 74 of the reasons – which detracts from this approach.

[42] The comments which follow are therefore limited to the doctrine of comity.

- *The doctrine of comity*

[43] Both Apotex and Allergan have the same understanding of the doctrine of comity (Apotex's memorandum, paras. 57 to 64; Allergan's memorandum, paras. 45 to 48). This doctrine is sometimes described as a modified form of *stare decisis, i.e.* horizontal rather than vertical (*House of Sga'nisim v. Canada (Attorney General)*, 2011 BCSC 1394, para. 74). *Stare decisis* requires judges to follow binding legal precedents from higher courts. Although not binding in the same way, the doctrine of comity seeks to prevent the same legal issue from being decided differently by members of the same Court, thereby promoting certainty in the law (*Glaxo Group Ltd. v. Canada (Minister of Health and Welfare)*, [1995] F.C.J. No. 1430, 64 C.P.R. (3d) 65, pp. 67 and 68 (T.D.)).

[44] As a manifestation of the principle of *stare decisis*, the principle of judicial comity only applies to determinations of law. It has no application to factual findings. As was stated by the Ontario Court of Appeal in *Delta Acceptance Corporation Ltd. v. Redman*, [1966] 2 O.R. 37, paragraph 5 at page 785 (C.A.):

> The only thing in a [j]udge's decision binding as an authority upon a subsequent [j]udge is the principle upon which the case was decided.

[45] In the Federal Court, Mactavish J. in *Almrei (Re)*, 2009 FC 3, acknowledged this limitation as follows (para. 70):

> The principle of judicial comity might arise in the context of a ruling on a point of law but I did not consider myself bound by any factual findings made by my fellow judges in the earlier proceedings.

[46] The assumption that underlies the doctrine of comity is that in theory there can only be one correct answer to a question of law. As was noted by Jackett P. in *Canada Steamship Lines Ltd. v. M.N.R.*, [1966] Ex. Cr. 972, at page 976, while judges are not bound to apply this doctrine by any strict rule of *stare decisis*, what is avoided by adhering to this doctrine is the uncertainty which diverging answers create. In the words of Lord Goddard, C.J. in *Police Authority for Huddersfield v. Watson*, [1947] 1 K.B. 842, at page 848:

> I can only say for myself that I think the modern practice, and the modern view of the subject, is that a judge of first instance, though he would always follow the decision of another judge of first instance, unless he is convinced the judgment is wrong, would follow it as a matter of judicial comity. He certainly is not bound to follow the decision of a judge of equal jurisdiction. He is only bound to follow the decisions which are binding on him, which, in the case of a judge of first instance, are the decisions of the Court of Appeal, the House of Lords and the Divisional Court.

[47] In the Federal Court, the above passage has been referred to as authority for the proposition that while the decisions rendered by colleagues are persuasive and should be given considerable weight, a departure is authorized where a judge is convinced that the prior decision is wrong and can advance cogent reasons in support of this view (*Dela Fuente v. Canada (Minister of Citizenship and Immigration)*, 2005 FC 992, paras. 29; *Stone v. Canada (Attorney General)*, 2012 FC 81, paras. 12).

[48] It is up to the judges of the Federal Court to determine how this doctrine is to be applied to their decisions. I note in this respect that different considerations may arise depending on the jurisdiction being exercised. I have in mind, for example, immigration where decisions of the Federal Court are final in the absence of a question being certified (see *Ziyadah v. Canada (Minister*

of Citizenship and Immigration), [1999] 4 F.C. 152, paras. 9 and 12 (T.D.)). However, the general view appears to be that the conclusions of law of a Federal Court judge will not be departed from by another judge unless he or she is convinced that the departure is necessary and can articulate cogent reasons for doing so. On this test, departures should be rare.

- *Application of the doctrine to the present case*

[49] It is apparent from the foregoing that it was not open to the Federal Court judge to issue a prohibition order for the purpose of having his concerns about the use of the doctrine of comity and the notion of abuse of process addressed by this Court on appeal. As noted earlier, the parties were entitled to have their dispute settled on the merits and the Federal Court judge by issuing a formal judgment that was contrary to the conclusions that he reached on the merits, failed in his task.

[50] Beyond this, the doctrine of comity has no application with respect to findings of fact. A finding that an invention is obvious because the solution proposed was plain to see is one of fact (*671905 Alberta Inc. v. Q'max Solutions Inc.*, 2003 FCA 241, para. 48; *Laboratoires Servier v. Apotex Inc.*, 2009 FCA 222, para. 67 (*Servier*); *Apotex Inc. v. Wellcome Foundation Ltd.*, [2001] 1 F.C. 495, para. 61 (C.A.), aff'd 2002 SCC 77, [2002] 4 S.C.R. 153). In contrast, construing a patent in order to identify the inventive concept when it is not readily discernable for the claim itself requires looking at the whole of the patent (*Sanofi*, para. 77) and gives rise to a question of law (*Western Electric Co. v. Baldwin International Radio of Canada Ltd.*, [1934] S.C.R. 570, pp. 572-573 (S.C.C.); *Weatherford Canada Ltd. v. Corlac Inc.*, 2011 FCA 228, [2011] F.C.J. No. 1090, para. 24 – and the authorities referred to in these passages). It follows that unless the Federal Court judge could demonstrate that Crampton J.'s construction of the patent in order to determine the

inventive concept was wrong or that distinct evidence adduced before him compelled him to reach a different conclusion, it would have been preferable for him to adhere to it.

[51] The Federal Court judge did not identify any error nor did he rely on distinct evidence to explain his diverging view. He simply chose to construe the patent differently and held that the inventive concept did not extend to the improved safety profile which Crampton J. had included. He expressed the view that the identification of the inventive concept turns on the construction of a document drafted by the patentee rather than by Parliament and that the doctrine of comity ought not to apply to the same extent as would be the case if the document had been drafted by Parliament (reasons, para. 149).

[52] If this was the only reason why the Federal Court judge felt that he could disregard the opinion of his colleague, it does not justify his action. Construing a patent in order to identify the inventive concept is no less an exercise that leads to a determination of law because the document being construed is drafted by the patentee. I do not read the article by the late W.K. Hayhurst on which the Federal Court judge relies (reasons, para. 149) as saying otherwise. The only matter discussed in this article is whether the *Interpretation Act*, R.S.C. 1985, c. I-21, applies to the construction of a patent. The analogy which the Federal Court judge drew with a contract (*ibidem*) is no more helpful since all else being equal a contract should not be subjected to contradictory constructions any more than a patent, or a statute.

[53] In any event, as the Federal Court judge chose to revisit the opinion of his colleague, there are now conflicting and equally authoritative decisions as to how the '764 patent is to be construed and it falls upon this Court to determine which is the correct one.

- *Is the improved safety profile part of the inventive concept?*

[54] The identification of inventive concept is the second step in the *Sanofi* analysis (*Sanofi*, para. 67):

> (1) (a) Identify the notional "person skilled in the art";
> (b) Identify the relevant common general knowledge of that person;
>
> (2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;
>
> (3) Identify what, if any, differences exist between the matter cited as forming part of the "state-of-the-art" and the inventive concept of the claim or the claim as construed;
>
> (4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?

[55] No issue was raised with respect to the Federal Court judge's handling of step one. As to step two, the Federal Court judge observed that in Canada (reasons, para. 135):

> Difficulty in applying the … test in *Sanofi* has arisen … The question is whether the "inventive concept" is something different from the claim at issue, even when that claim has been construed by the Court. Is the Court to embark on two separate missions; one to construe the claim, the other to define the inventive concept?

[56] Underlying this question is the apparent belief that a different approach to claim construction has emerged in applying the *Sanofi* test. Although the Federal Court judge in the discussion which follows (reasons, paras. 138 to 140) refers to a number of cases which have applied this test (*Servier*, paras. 58 and 59; *Novo Nordisk Canada v. Cobalt Pharmaceuticals Inc.*, 2010 FC 746, para. 113; *Eli Lilly Canada Inc. v. Novopharm Limited*, 2010 FCA 197, para. 57), he does not point to any as evidencing his concern and the "difficulty" which he says "has arisen". It is therefore difficult to comment on the question raised by the Federal Court judge other than to say that *Sanofi* was intended to bring better structure – *i.e.* precision – to the obviousness inquiry (*Sanofi*, para. 67); it did not purport to change the approach to claim construction.

[57] In the present case, the Federal Court judge recognized that the inventive concept was not readily discernable from the claim itself since, like Crampton J., he did not limit his analysis to claim 22. The Federal Court judge read paragraph 1 of the '764 patent as revealing what the patent promises to deliver and held that the inventive concept was limited to those promises (reasons, paras. 144 and 145). As this paragraph only promises a fixed combination that is safe, he held that the inventive concept was limited to a fixed combination that is safe.

[58] Crampton J. on the other hand did not read paragraph 1 as placing a limit on the invention. He accepted Allergan's submission that this paragraph merely outlines the objectives which the inventors set out to achieve in creating the fixed combination, a reading which is consistent with the title "Background of the Invention". However, beyond achieving these goals, the inventors discovered during the course of their work that the combination had an improved safety profile.

[59] Reading the '764 patent further, Crampton J. read Example II as disclosing these improvements (*Sandoz*, para. 66):

> With respect to the superior safety profile of the Composition, the '764 [p]atent disclosed, among other things, that in the clinical trial discussed in Example II of the specification, adverse events leading to the discontinuation of patients occurred in only 3.6% (7/193) of the patients who were administered the Composition, versus in 14.3% (28/196) of the patients who were administered brimonidine alone. In addition, it was disclosed that serious adverse events were reduced by 50% for the combination product, relative to monotherapy treatment of brimonidine or timolol. Moreover, it was disclosed that the composition had what may be described as a statistically significant ($p \leq 0.034$) improved allergy profile, compared with brimonidine monotherapy.

[60] Significantly, the improved safety profile was disclosed as a result of the human clinical trial. Against this background, Crampton J. did not read paragraph 1 of the '764 patent as setting out the whole of the invention underlying claim 22, and held that the improved safety profile was part of the invention disclosed.

[61] The Federal Court judge does not confront Crampton J.'s reasoning. He simply holds that the inventive concept is set out in paragraph 1 and therefore does not include the improvements which Example II reveals and which the inventors assert under the heading "Conclusion" as being "better".

[62] Apotex attempted to justify this seemingly narrow reading of the patent by reference to a number of arguments. It first highlights the fact that claim 22 embraces formulations having pH levels within a range whereas Example I refers to a pH which, while within that range, is a specific

figure. As pH can affect safety, Apotex argues that the person skilled in the art would not read Example II as part of the inventive concept (Apotex's reply memorandum, para. 6).

[63] In the same vein, Apotex argues that the dosage regimens set out in Example II (BID) is not set out in claim 22. Since the dosage regimens may impact on safety and since this is a matter that is left to the discretion of the clinician, Apotex again submits that the person skilled in the art would not read the improved safety profile as part of the inventive concept (*ibidem*).

[64] Both these arguments go to the validity of claim 22. The argument with respect to pH, if established by the evidence, puts into question the validity of claim 22 by reason of its overbreadth, *i.e.* the claim is wider than the invention (see namely *Eli Lilly Canada Inc. v. Apotex Inc.*, 2009 FC 320, 75 C.P.R. (4^{th}) 165, paras. 52 to 59 (F.C.)). The argument with respect to dosage goes to the sufficiency of the disclosure which, according to section 27 of the *Patent Act*, R.S.C. 1985, c. P-4, must reveal the manner in which the invention can be practised.

[65] The suggestion by Apotex that the person skilled in the art would read the '764 patent with these considerations in mind runs directly against the state of the law which requires that, at this stage of the analysis, the patent be construed without regard to issues of validity (see *Whirlpool Corp. v Camco Inc.*, 2000 SCC 67, [2000] 2 S.C.R. 1067, para. 49;. *Dableh v. Ontario Hydro*, [1996] 3 F.C. 751, para. 26 (C.A.); *American Cyamanid Co. v. Berk Pharmaceuticals Ltd.*, [1976] R.P.C. 231, p. 234 (Ch. D.); *Xerox of Canada Ltd. et al. v. IBM Canada Ltd.*, (1977), 33 C.P.R. (2d) 234, p. 43 (F.C.T.D.)). With respect to the attacks *per se*, neither can be considered in the present

proceeding since Apotex's Notice of Allegation does not put into issue the validity of claim 22 on either ground.

[66] Apotex makes the further argument that the differences in the records in *Sandoz* and in the present case justify the Federal Court judge's construction of the patent. In particular, Apotex asserts that in *Sandoz* the Court emphasized that the respondent both conceded that Example II disclosed a surprising result, and failed to adduce evidence of any study showing that the safety profile of brimonidine/timolol combinations from separate bottles was the equal of the safety profile of the fixed combination. In this case, not only has Apotex made no such concession but it also led into evidence two such studies which predate the claim date (Apotex's reply memorandum, para. 9).

[67] I would observe that the concession in *Sandoz* that Example II discloses a surprising result and the fact that no such concession was made in this case goes to the issue of obviousness and begs the question as to whether this concession was warranted. This issue is discussed later under the heading "Obviousness". As to the two studies – the first is more accurately described as an abstract (appeal book, vol. 4, p. 1089); and the second is an article that reports on a study (appeal book, vol. 4, p. 1248) – they seem more relevant to the determination of the state of the art, *i.e.* step three of the *Sanofi* analysis. That said, I do not believe that any weight can be given to these studies regardless of the perspective from which they are considered.

[68] I first note that the Federal Court judge does not rely on either of these studies to explain his reading of the patent. Furthermore, what this evidence appears to show is that the concomitant use of brimonidine and timolol is "well tolerated" (affidavit of Harry A.Quigley, paras. 332 and 334,

appeal book, vol. 4, p. 982); they do not suggest that this concomitant use is safer than brimonidine. Finally, the results on which Apotex relies have little probative value since the studies reported on did not compare Example I to concurrent therapy, and Apotex did not see fit to ask its experts how they correlate with the improved safety profile of the claimed combination.

[69] Given the above shortcomings, I do not accept that these studies can be useful in assessing the state of the art – a matter more fully discussed at paragraphs 76 and 77 below – nor do I accept that they provide support for the Federal Court judge's reading of the patent.

[70] Finally, Apotex made the general assertion that "the Federal Court judge's determination of the inventive concept must stand since the record contains extensive evidence of relevance to this issue and Allergan has not identified any overriding error … in his appreciation of the evidence" (Apotex's reply memorandum, para. 7).

[71] The difficulty with this argument is that, as we have seen, the Federal Court judge did not refer to any evidence in order to justify his reading of the patent. It follows that there was nothing to which Allergan could point to other than to show that the Federal Court judge's reading of the patent was not consistent with established principles.

[72] Apotex has not been able to provide any justification for the Federal Court judge's narrow reading of the patent. In holding that the inventive concept is restricted to what is stated in paragraph 1 of the patent, the Federal Court judge read this paragraph in isolation. Claim

construction must be conducted in light of the patent as a whole. This was reiterated by Layden-Stevenson J.A. in *Servier* at paragraph 58:

> *Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67, [2000] 2 S.C.R. 1067 (*Whirlpool*) decides that claims construction is antecedent to issues of both infringement and validity. It also stands for the proposition that purposive construction requires a court to have regard to the whole of the patent (including the claims and the disclosure) when ascertaining the nature of the invention. Indeed, several of the authorities cited in Apotex's memorandum of fact and law illustrate the application of these principles. More recent authority indicates that the inventive concept need not be readily discernable from the claims, even in circumstances where construction of the claims is not in issue. A bare chemical formula may require recourse to the specification to determine the inventive concept of the claims: [*Sanofi*] [See also *Eli Lilly Canada Inc. v. Novopharm Ltd. (2010)*, 85 C.P.R. (4th) 413 (*Lilly*) at paras. 52, 63 and 64 (F.C.A.). See also *Bridgeview Manufacturing Inc. et al. v. 931409 Alberta Ltd. c.o.b. Central Alberta Hay Centre et al. (2010)*, 87 C.P.R. (4th) 195 (F.C.A.)].

[73] The most recent and authoritative statement on point is the decision of the Supreme Court in *Teva Canada Ltd. v. Pfizer Canada Inc.*, 2012 SCC 60 at paragraph 50:

> … the entire specification, including the claims, must be considered in determining the nature of the invention …

[74] In my respectful view, a purposive and complete reading of the ’764 patent leads to the conclusion that the improved safety profile forms part of the claimed invention.

[75] Given this conclusion, it is apparent that the last two steps of the *Sanofi* analysis conducted by the Federal Court judge cannot stand given that he did so without regard to the improved safety profile. One option would be to return the matter to the Federal Court judge so that he may complete the analysis based on a correct understanding of the inventive concept. However, as this is a summary proceeding based entirely on paper evidence, and as the record before us contains all the

evidence that is relevant to the conduct of the two remaining steps, it is more efficient for this Court to complete the analysis.

- *Difference between state of the art and inventive concept*

[76] The next step requires this Court to identify the differences between the improved safety profile and the state of the art. In this respect, it was known as of the claim date that brimonidine and timolol, either alone or in concomitant use were effective as IOP-lowering medications ('764 Patent, p. 3, appeal book, vol. 1, p. 238); that both brimonidine and timolol had adverse side effects (affidavit of Robert D. Fechtner, paras. 29 and 97 as to brimonidine, and para. 24 as to timolol, appeal book, vol. 2, pp. 334 and 335 and p. 318); that COSOPT, another fixed combination drug (combining dorzolamide and timolol) which operates as an IOP-lowering medication, had been commercially available prior to the claim date (affidavit of Robert D. Fechtner, para. 345, appeal book, p. 986); that the safety profile of the COSOPT fixed combination reflected that of the combined active ingredients administered separately (*A Randomized Trial in Patients Inadequately Controlled with Timolol Alone Comparing the Dorzolamide-Timolol Combination to Monotherapy with Timolol or Dorzolanide*, Colleen Clineschmidt et al., 1998, appeal book, vol. 4, p. 436 (the Clineschmidt paper)); and that the efficacy and safety of the COSOPT combination are comparable to those observed with concomitant use of dorzolamide and timolol (*The Efficacy and Safety of the Dorzolamide-Timolol Combination Versus the Concomitant Administration of its Component*, Kim Strohmaier et al., 1998, appeal book, vol. 4, p. 1137 (the Strohmaier paper)).

[77] Measured against the state of the art, the claimed composition combines brimonidine and timolol into a new chemically stable formulation which when administered BID has a superior

safety profile relative to brimonidine administered TID. Specifically, the '764 patent discloses that in the clinical trial discussed in Example II, adverse events leading to the discontinuation of treatment occurred in only 3.6% (7/193) of the patients who were administered the composition, versus in 14.3% (28/196) of the patients who were administered brimonidine alone ('764 patent, p. 13). In addition, it was disclosed that serious adverse events were reduced by 50% for the combination product, relative to monotherapy treatment of brimonidine or timolol. Moreover, it was disclosed that the composition had what may be described as a statistically significant [$p \leq 0.034$] improved allergy profile, compared with brimonidine monotherapy.

- *Obviousness*

[78] The issue at this stage is whether the differences that I have identified would have been obvious to the skilled person, or whether coming upon these differences would have required a degree of inventiveness. The questions which are relevant to this aspect of the analysis are (*Sanofi*, paras. 84 to 92):

(1) Is it more or less self-evident that what is being tried ought to work?

(2) What is the extent, nature and amount of effort required to achieve the invention?

(3) Is there a motive from the prior art to find the solution that [the patent] addresses?

(4) What is the course of conduct which was followed which culminated in the making of the invention?

(5) Was the invention "obvious to try"?

[79] According to Allergan, the answer to these questions is somewhat simplified by reason of the length and extent of the clinical trial which led to the discovery and by the fact that the only

expert evidence that was tendered with respect to the obviousness of the improved safety profile is that of its expert Dr. Fechtner. Dr. Fechtner testified that this result was entirely unexpected (affidavit of Robert D. Fechtner, paras. 35, 69 and 194, appeal book, vol. 2, pp. 322, 334, 335, 377 and 378). The inventor, Mr. Beck also testified to his surprise (affidavit of Gary J. Beck, para. 24, appeal book, vol. 2, p. 261).

[80] Allergan emphasizes the fact that neither Dr. Fechtner nor Mr. Beck were cross-examined on their evidence about the unpredictable nature of the safety improvement, and Apotex's experts were not asked to opine on whether the improved safety profile would have been obvious to the person skilled in the art at the claim date. It submits that the only conclusion that can be reached on this record is that the improved safety profile would not have been obvious to the person skilled in the art on the claim date.

[81] In response, Apotex takes the position that the record contains ample evidence which shows that the improved safety profile was obvious. In particular, Apotex submits that the skilled person could achieve the improved safety profile without difficulty or prolonged work in a manner analogous to what had been done with COSOPT (Apotex's reply memorandum, para. 10). It adds that it would have been apparent to the person skilled in the art that "when one gives less brimonidine, one expects fewer brimonidine side effects" (*ibidem*).

[82] Apotex also takes issue with Allergan's reliance on the length and extent of the clinical trial. It relies in this respect on the Federal Court judge's conclusion that this trial was conducted in order

to obtain regulatory approval, and does not evidence any degree of difficulty in coming upon the improved safety profile (Apotex's reply memorandum, para. 12).

[83] Apotex added during the course of the hearing that this Court cannot rely on the evidence of Dr. Fechtner to establish that the improved safety profile was unexpected given that his evidence was rejected by the Federal Court judge.

[84] Dealing with this last contention, the Federal Court judge did not dismiss Dr. Fechtner's evidence outright. As he noted, it is difficult do make a proper assessment of credibility given that the witness did not appear before him. Indeed, I note that Apotex itself relies on the evidence of Dr. Fechtner in order to establish some of its propositions (Apotex's reply memorandum, para. 4, notes 5 and 8). I would add that a key reason why the Federal Court judge had difficulties with Dr. Fechtner's evidence was his answers to cross-examination questions and his lack of expertise on formulations. On the obviousness issue, as I have mentioned, Dr. Fechtner was not cross-examined, and his lack of expertise on formulations is irrelevant. The Federal Court judge expressed the view that one had to be very cautious in assessing the evidence of Dr. Fechtner and that is how I have assessed his evidence.

[85] The testimony of Dr. Fechtner on this point is uncontradicted, well explained and is supported by the scientific literature that was available as of the claim date, notably the Clineschmidt and Strohmaier papers. Approaching the matter with caution, in light of the foregoing, I conclude that Dr. Fechtner's testimony is worthy of consideration on the issue of obviousness.

[86] I now turn to Apotex's argument based on COSOPT. Apotex first asserts that "[as the Federal Court judge] found …, it would be obvious to the skilled person to prepare the single bottle, brimonidine/timolol formulation of claim 22 with the expectation of success and that the skilled person would do so without difficulty or prolonged work in a manner analogous to what had been done with COSOPT" (Apotex's memorandum, para. 10).

[87] I note that the argument so framed does not advance the debate since Allergan has conceded, for purposes of the appeal, that the '764 patent is obvious if the inventive concept does not include the improved safety profile (see para. 36 above). However, to the extent that Apotex relies on COSOPT to show that the improved safety profile was obvious, I note that the COSOPT combination was reviewed in both the Clineschmidt and the Strohmaier papers for the precise purpose of testing its safety profile. Both authors came to the conclusion that the safety profile of the COSOPT combination showed no improvement over the two component active ingredients administered concomitantly (affidavit of Robert D. Fechtner, paras. 156 to 158, appeal book, vol. 2, pp. 364 and 365; cross-examination transcript of Harry A. Quigley, appeal book, vol. 7, pp. 2075 and 2076). I agree with Allergan that, if anything, COSOPT teaches away from the invention.

[88] Apotex's further argument – that it would have been obvious to the person skilled in the art that the decrease in adverse effects results from the reduction in the dosage of brimonidine (*i.e.* from TID to BID) – is based on Dr. Quigley's evidence that [affidavit of Harry A. Quigley, para. 395, appeal book, vol. 4, p. 999]:

> … t]his difference alone could easily account for the reduced adverse events profile of the combination owing to the decreased number of administrations in the eye per day.
>
> [My emphasis]

[89] This assertion falls short of saying that the improved safety profile was obvious to the person skilled in the art as of the claim date. This is particularly so when one considers that the same reduction in dosage in the administration of COSOPT, *i.e.* from TID to BID, did not result in a reduction of adverse side effects (Clineschmidt paper, appeal book, vol. 2, p. 430; Strohmaier paper, appeal book, vol. 4, p. 1137). In any event, the fact that less brimonidine leads to fewer adverse side effects has no bearing on the claimed invention which discloses that the administration of more drug – a fixed combination of timolol and brimonidine administered BID, four doses in total – results in fewer adverse side effects than brimonidine administered TID.

[90] Apotex also relies on the reasoning of the Federal Court judge who dismissed the extensive clinical trial disclosed in the '764 patent (Example II), as a factor in assessing obviousness (Apotex's reply memorandum, para. 12). The Federal Court judge came to this conclusion because in his view (reasons, para. 173):

> A distinction must be made between considering the time and effort expended in clinical studies for purposes of obtaining regulatory approval, and time and effort expended in considering whether there has been an invention. …

[91] In my respectful view, this reasoning is of no relevance in the present case given that the clinical trial was not conducted with the expectation that the fixed combination would reveal the improved safety profile (see the '764 patent, pp 1 and 6, appeal book, vol. 1, pp. 236 and 241,

Example II under the heading "Objectives"). The relevant factor in this context is the 4th, *i.e.* "What is the course of conduct which was followed and which culminated in the making of the invention?".

[92] In answering this question the clinical trial is of importance since the invention is the bi-product of this extensive, multicentered, double masked, randomized trial. There was nothing routine about this exercise and the manner in which the inventors came upon the improvement shows in the clearest possible way that it was not obvious to try.

[93] Therefore, I conclude that the improved safety profile has not been shown to be obvious.

CONCLUSION

[94] The result is that although the prohibition order was issued by the Federal Court for the wrong reason, it was nevertheless properly issued. Therefore, I would dismiss the appeal, with costs.

"Marc Noël"
J.A.

"I agree.
David Stratas J.A."

"I agree.
Wyman W. Webb J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-312-12
(APPEAL FROM A JUDGMENT OF THE HONOURABLE MR. JUSTICE HUGHES DATED JUNE 18, 2012, DOCKET NUMBER T-1560-10.)	
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