Federal Court of Appeal | Cour d'appel fédérale

Date: 20090622

Docket: A-373-08

Citation: 2009 FCA 212

CORAM: **NADON J.A.**
LAYDEN-STEVENSON J.A.
TRUDEL J.A.

BETWEEN:

APOTEX INC.

Appellant

and

JANSSEN-ORTHO INC. and
DAIICHI SANKYO COMPANY, LIMITED

Respondents

and

THE MINISTER OF HEALTH

Respondent

Heard at Ottawa, Ontario, on April 28, 2009.

Judgment delivered at Ottawa, Ontario, on June 22, 2009.

REASONS FOR JUDGMENT BY: NADON J.A.

CONCURRED IN BY: TRUDEL J.A.

DISSENTING REASONS BY: LAYDEN-STEVENSON J.A.

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REASONS FOR JUDGMENT

NADON J.A.

[1] This is an appeal from a decision of Shore J. dated June 17, 2008, 2008 FC 744, prohibiting the Minister of Health (the "Minister") from issuing a Notice of Compliance (a "NOC") to the appellant Apotex Inc. ("Apotex") in respect of its levofloxacin hemihydrate tablets until the expiry of Canadian Patent No. 1,304,080 (the " '080 patent").

[2] The proceedings which led to the issuance of the learned Judge's order of prohibition were commenced by the respondents pursuant to subsection 6(1) of the *Patented Medicines (Notice of Compliance) Regulations*, S.O.R./93-133 (the "Regulations").

[3] I conclude that the appeal must be allowed.

THE FACTS

The patent at issue:

[4] The '080 patent which issued to the respondent Daiichi-Sankyo Company, Limited ("Daiichi"), on June 23, 1992, discloses and claims levofloxacin, an antibiotic that treats the most severe forms of pneumonia. The patent expires on June 22, 2009.

[5] Daiichi is also the owner of Canadian Patent 1,157,840 (the " '840 patent") which expired on May 22, 2001. This patent disclosed and claimed the antibiotic ofloxacin, which Daiichi licensed to the respondent Janssen-Ortho Inc. ("Janssen") for marketing in Canada.

[6] The only claim of the '080 patent which is at issue in these proceedings is claim 4, which reads:

> S(-)-9-fluoro-3-methyl-10-1-piperazinyl)-7-oso-2,3-dihydro-7H-pyrido[1,2,3-de][1,4]benzoxaine-6-carboxylic acid.

The parties are in agreement that another name for the compound described in claim 4 is levofloxacin.

[7] Levofloxacin is a chiral compound. Chiral compounds can exist in two different three-dimensional configurations, known as enantiomers. Enantiomers have the same two-dimensional structures, but are non-superimposable mirror images of each other. When the two enantiomers are present in a 50-50 mixture, the mixture is known as a racemate. In the case of levofloxacin, the racemate is given the name “ofloxacin”. Levofloxacin’s mirror enantiomer is called “dextrofloxacin”.

[8] While similar in many respects, enantiomers have different chemical properties and may have different biological effects when administered. The disclosure of the ‘080 patent reveals that levofloxacin has reduced toxicity, increased solubility and twice the antimicrobial activity as compared to racemic ofloxacin. The ‘080 patent also discloses processes to make levofloxacin substantially free of the dextrofloxacin enantiomer.

[9] As disclosed in the ‘080 patent, levofloxacin can exist in both hydrous and anhydrous forms. The anhydrous form (the anhydrate), consists of levofloxacin free from any associated water molecules. Hydrous levofloxacin (the hydrate) is formed of levofloxacin closely associated with water molecules. Levofloxacin hemihydrate is a type of hydrate.

[10] Janssen manufactures levofloxacin for sale in Canada. Apotex, a “generic” company or “second person” under the Regulations, seeks to obtain regulatory approval for its levofloxacin hemihydrate tablets. In accordance with section 5 of the Regulations, Apotex sent a Notice of

Allegation ("NOA") to Janssen, alleging, *inter alia*, that the '080 patent was invalid and that even if valid, its tablet would not infringe it.

[11] On September 2, 2005, Janssen and Daiichi responded to Apotex's NOA by commencing proceedings under the Regulations for an order prohibiting the Minister from issuing a NOC to Apotex for its levofloxacin hemihydrate tablets until after the expiry of the '080 patent.

Previous litigation of the '080 patent:

[12] The '080 patent has already been the subject of legal proceedings in Canada. First, in *Janssen-Ortho v. Novopharm Limited*, 2004 FC 1631, 264 F.T.R. 202 (the "Novopharm proceedings"), Mosley J. of the Federal Court considered the '080 patent in the context of an application for prohibition under the Regulations brought by Janssen in response to a NOA filed by Novopharm Limited. Mosley J. held that Novopharm's levofloxacin hemihydrate tablets infringed claim 4 of the '080 patent, but that claim 4 was invalid for obviousness. An appeal was launched to this Court by Janssen, but it was held to be moot because the NOC had already been issued to Novopharm by the Minister by the time the appeal was heard (see: 2005 FCA 6, 337 N.R. 259); motion for extension of time for leave to appeal to the Supreme Court refused, 2005 SCC 33, [2005] 1 S.C.R. 776.

[13] Second, as a result of Mosley J.'s decision and the dismissal of its appeal by this Court, Janssen commenced an action against Novopharm for infringement of the '080 patent. In *Janssen-Ortho v. Novopharm Limited*, 2006 FC 1234, 300 F.T.R. 166 (the "Novopharm trial"), Hughes J.

found the ‘080 patent to be valid and allowed Janssen’s action. I should point out that because Novopharm had conceded that its product infringed claim 4 of the ‘080 patent, Hughes J. was not called upon to make specific findings in that regard.

[14] While coming to a conclusion different from that reached by Mosley J. on obviousness, Hughes J. noted that his colleague had not had the benefit of the extensive evidence before him and that he had not had the opportunity of seeing and hearing the witnesses who had appeared before him during the course of the trial.

[15] In *Novopharm Limited v. Janssen-Ortho*, 2007 FCA 217 (the “Novopharm appeal”), this Court upheld Hughes J.’s decision and found the ‘080 patent to be valid. Leave to appeal this Court’s decision was denied by the Supreme Court of Canada, 2007 S.C.C.A. No. 442 (Q.L.).

THE DECISION OF THE FEDERAL COURT

[16] Because he was of the view that “no demonstration has been made as to invalidity nor infringement” (see: para. 203 of his Reasons), Shore J. concluded that the respondents were entitled to an order of prohibition. In reaching that conclusion, he made the following findings.

[17] Shore J. held that claim 4 of the ‘080 patent, when properly construed, must include the hemihydrate form of levofloxacin because the patent specifically teaches, in example 7, how to produce levofloxacin hemihydrate. Shore J. also noted that claim 17 of the ‘080 patent includes the hemihydrate of all the compounds of claim 2, which includes levofloxacin.

[18] On the issue of infringement, Shore J. concluded that Apotex's tablets would infringe Janssen's '080 patent and, as a result, he rejected Apotex's allegation that its product would not infringe because the '080 patent did not cover the hemihydrate form of levofloxacin. Shore J. noted that Apotex admitted that the active ingredient in its tablets was levofloxacin hemihydrate and that consequently, if claim 4 of the patent covered the hemihydrate, its allegation of non-infringement could not be justified.

[19] With respect to anticipation, Shore J. rejected Apotex's argument that each claim of the '080 patent was anticipated by the prior disclosure of ofloxacin in the '840 patent. Shore J. relied on the findings made by Hughes J. in the Novopharm trial and concluded that Apotex had not provided any evidence that would justify a deviation from Hughes J.'s determination on this issue.

[20] On the question of obviousness, Shore J. rejected Apotex's argument that the inventors were merely verifying predictable qualities of known compounds. On the contrary, Shore J. held that there could not have been verification because the inventors had found unexpected and unpredictable properties of new compounds.

[21] In order to analyse the question of obviousness, Shore J. determined what could be considered as prior art, and concluded that none of the prior art references alleged by Apotex would have led a skilled person directly and without difficulty to the invention disclosed in the '080 patent, i.e., levofloxacin and its unexpected beneficial properties. In particular, Shore J. did not accept as

prior art the “Gerster papers”, which related to a poster that publicly disclosed the fact that the (-)-enantiomer of flumequine was the more antimicrobially active of the two enantiomers and, thus, more active than its racemate. Shore J. concluded that the Gerster papers did not contain sufficient information to enable a person of ordinary skill and knowledge in the field to understand the nature of the invention and carry it into practical use by purely mechanical skill, without the aid of inventive genius.

[22] Shore J. concluded that Apotex misconstrued the promise of the ‘080 patent and the utility of the invention. Shore J. referred to the findings of Hughes J. in the Novopharm trial, who had found that the utility of claim 4 of the ‘080 patent was that the (S)- or (-)- form of ofloxacin had increased antimicrobial activity, reduced toxicity and markedly high water solubility, giving it an expectation to be a very useful pharmaceutical agent.

[23] Shore J. held that the ‘080 patent was not void pursuant to subsection 30(1) of the *Patent Act*, R.S. 1985, c. P-4 (the “Patent Act”), which stipulates that the application may be deemed abandoned if the applicant fails to answer an examiner’s requirement. Apotex argued that Daiichi had not answered the required questions within the given timeframe, and that it had breached paragraphs 40(1)(a) and (c) of the *Patent Rules*, C.R.C., c. 1250 (the “Patent Rules”), on the basis that Daiichi had not provided the examiner with particulars of interference proceedings or with prior art cited against the application.

[24] With respect to paragraph 40(1)(c) of the Patent Rules, Shore J. concluded that there was no breach of this provision on the ground that Daiichi's patent agent had innocently and inadvertently failed to answer within the time prescribed only one of the examiner's eight questions. Shore J. noted that the patent agent did answer the question at a later stage.

[25] With respect to paragraph 40(1)(a) of the Patent Rules, Shore J. concluded that Daiichi's patent agent had disclosed all of the prior art references cited against the corresponding U.S. and European applications. Shore J. appeared to accept that it was sufficient to provide the examiner with citations to requests for prior art, and that it was unnecessary to provide the documents themselves.

[26] Further, Shore J. rejected Apotex's argument that Daiichi had breached its duty of candour as a result of the alleged breaches of paragraphs 40(1)*(a)* and *(c)* of the Patent Rules. Shore J. held that such a duty of candour did not exist in Canada and that even if such a duty were to be implied, there was nothing in the prosecution of the '080 patent to suggest that the applicant had failed to act with candour and in good faith.

[27] Finally, Shore J. considered whether, in the light of this Court's decision in *Sanofi-Aventis v. Novopharm Ltd.*, 2007 FCA 163, [2008] 1 F.C.R. 174, Apotex had provided "better evidence or a more appropriate legal argument" (this expression is taken from paragraph 50 of *Sanofi-Aventis, supra*, to which I shall shortly return) than that which had been offered in the Novopharm trial so as to entitle it to challenge the prohibition proceedings brought by the respondents.

[28] The learned Judge concluded that Apotex had not met the requirements set out in *Sanofi-Aventis, supra,* according to which either better evidence or better legal arguments had to be put forward in order to justify a relitigation of the same or similar issues. As a result, the Judge concluded that it was an abuse for Apotex to relitigate the issues which had been litigated in the Novopharm proceedings and in the Novopharm trial.

APOTEX'S SUBMISSIONS

[29] First, Apotex argues that Shore J. erred in his construction of claim 4 of the '080 patent. According to Apotex, claim 4 simply provides an unambiguous description of the molecule levofloxacin and resorting to the remainder of the specification to expand or contract the scope of the claim is impermissible. Apotex argues that Shore J. erred by departing from the text of claim 4, by adopting a results-oriented construction of the claim and by failing to distinguish claim 4 from the other claims in the '080 patent.

[30] Second, Apotex contends that Shore J. erred by rejecting its allegation of non-infringement. Apotex argues that there can be no infringement if its construction of claim 4 is correct, i.e. if the claim does not cover the hemihydrate form of levofloxacin.

[31] Third, Apotex says that Shore J. erred by concluding that the '080 patent was not invalid for anticipation. According to Apotex, the properties of levofloxacin and the process to make it are irrelevant in an analysis of anticipation. Furthermore, Apotex submits that since Shore J. held that

the ‘840 patent discloses ofloxacin as a compound that contains levofloxacin, the ‘840 patent also necessarily disclosed levofloxacin to the skilled addressee. In fact, Apotex argues that the evidence clearly established that skilled addressees knew the techniques available to resolve enantiomers from racemic mixtures and that since Shore J. did not refer to this evidence, he must be taken to have ignored it. Apotex also contends that Shore J. appeared to have decided the question of anticipation by adopting the decision of Hughes J. in the Novopharm trial, instead of deciding the question based only on the evidence adduced before him.

[32] Fourth, Apotex submits that Shore J. erred by failing to assess the ‘080 patent as a selection patent. According to Apotex, the ‘080 patent purports to be a selection patent, but it fails to meet the test for one because levofloxacin does not possess special, substantial and unobvious advantages over ofloxacin and because no advantages are properly disclosed. In particular, Apotex argues that Shore J. made palpable and overriding errors in his appreciation of the record with respect to the level of activity, the toxicity, and the solubility of levofloxacin as compared with ofloxacin. Apotex also contends that Shore J. incorrectly stated that Novopharm had unsuccessfully made the same argument in the Novopharm trial when, in fact, Hughes J. had not analysed the ‘080 patent as a selection patent in that decision.

[33] Fifth, Apotex says that Shore J. erred by concluding that the ‘080 patent was not invalid for obviousness. Apotex argues that Shore J. made a number of palpable and overriding errors in his appreciation of the record and, in particular, that he failed to properly appreciate the evidence before him when he concluded that Daiichi’s competitors were not motivated to separate the enantiomers

and that Daiichi had taken four years to accomplish the separation. To the contrary, Apotex submits that the evidence suggests that Daiichi's competitors were indeed motivated to resolve ofloxacin and that during most of the four-year period, Daiichi was doing no work to resolve the enantiomers. Apotex also submits that Shore J. adopted the conclusions of Hughes J. in the Novopharm trial, even though the record before Shore J. could not lead him to the same conclusion. In addition, Apotex argues that Shore J. assessed obviousness on the wrong date, prior to the date of invention, and that this prevented him from considering various pertinent pieces of prior art, including the Gerster 1985 poster.

[34] Sixth, Apotex submits that Shore J. erred in failing to find that the application for the '080 patent was deemed abandoned. According to Apotex, Shore J. erred in concluding that answering 7 out of 8 requirements was sufficient to advance the application and in concluding that an innocent or inadvertent failure excuses an applicant from responding within the required delay. In fact, Apotex contends that such reasons for not responding to a requirement are not stipulated in the Patent Rules. Apotex also argues that Shore J. erred in holding that there was no applicable duty of candour or good faith, when the case law confirms that there is.

[35] Finally, Apotex submits that Shore J. erred in applying the test for abuse of process. According to Apotex, Shore J. applied an extreme form of *estoppel* that prevented it from having a fair hearing, and that, in effect, meant that the Novopharm trial defined its rights for all purposes. In particular, Apotex contends that Shore J. should not have required it to lead better evidence than in the Novopharm trial, given that neither Apotex nor Shore J. had access to the evidentiary record in

that case. In addition, Apotex contends that the burden of proof was different in the Novopharm trial: Novopharm had the burden of proving invalidity, whereas in this case, it is the respondents who had the burden of proving that Apotex's allegations were not justified. Apotex submits that since it is a first time litigant of the '080 patent, it should not have been required to meet a higher burden of proof, and that it is the respondents who should be barred from litigating against Apotex the issues which they have already litigated against Novopharm on two occasions.

THE ISSUES

[36] The appeal raises the following issues:

1. Did Shore J. err in his construction of claim 4 of the '080 patent?
2. Did Shore J. err in holding that Apotex's marketing of its levofloxacin tablets would infringe claim 4 of Janssen's '080 patent?
3. If Shore J. did not err in his conclusions on infringement, did he err in concluding that the '080 patent is not invalid? In particular, did Shore J. err in concluding that the patent is not invalid on the following bases: (a) Anticipation; (b) Obviousness; (c) Should Shore J. have analysed the '080 patent as a selection patent and found that it was an invalid selection patent?
4. Did Shore J. err in concluding that the '080 patent is not void for abandonment?
5. Did Shore J. err in applying the test for abuse of process?

ANALYSIS

[37] For the reasons that follow, I need only address the issue of abuse of process. I have already set out the submissions made by Apotex on this issue. The respondents, not surprisingly, do not

agree with Apotex's position. They say that Shore J. correctly applied the test for abuse of process and that the arguments raised on this issue by Apotex have already been weighed and considered by this Court against the interest in avoiding inconsistent results that threaten the integrity of the administration of justice. The respondents contend that Shore J. was entitled to decide issues of fact with reference to the findings in prior court decisions, such as the decision of Hughes J. in the Novopharm Trial. In addition, the respondents contend that the evidence from the Novopharm Trial was publicly available but Apotex made no effort to introduce it. The respondents also dispute Apotex's argument that only the results of prior proceedings under the Regulations should be considered for abuse of process, and not the results of an action, because the burden on the generic in an action on invalidity is more onerous. The respondents submit that this argument disregards the effect on the administration of justice.

[38] In my view, the learned Judge clearly erred in concluding, as he does at paragraph 205 of his Reasons, that "the Court does agree with the applicants' argument on the abuse of process". Specifically, the Judge agreed with the respondents' submissions that because the validity of the '080 patent had already been determined by the Federal Court in the Novopharm trial and by this Court in the Novopharm appeal, Apotex's attempt in these proceedings to contest the validity of the patent as a selection patent was simply an attempt, under the guise of differently-cloaked arguments, to relitigate the issues which had been litigated in the Novopharm trial and in the Novopharm appeal. Since most, if not all, of the arguments made by Apotex in these proceedings had been considered and dealt with by the Federal Court and this Court, there was simply no basis for

allowing Apotex to contest the validity of the ‘080 patent unless it had either “better evidence or a more appropriate legal argument”.

[39] In determining whether Apotex’s conduct in sending a NOA to the respondents and in contesting their application for prohibition constitutes an abuse of process, Shore J. considered this Court’s decision in *Sanofi-Aventis, supra*. On the basis of that decision, he found that a second person challenging a patent on grounds similar to those put forward in a prior litigation by another generic had to establish, as a condition precedent to the pursuance of its case, that it had either “better evidence or a more appropriate legal argument” to offer than that offered in the previous litigation.

[40] In *Sanofi-Aventis, supra*, Sexton J.A., writing for the majority, made the following remarks at paragraph 50 of his Reasons:

> [50] Finally, Sanofi-Aventis and Schering argue that a finding of abuse of process in this case will lead to unfairness. They say that while first persons will not be permitted to defend against allegations by subsequent generics after the same allegation made by an earlier generic has been found to be justified, subsequent generics will be permitted to repeat allegations already made earlier by other generics even if the earlier allegations were found to be unjustified. However, there is no unfairness in this scenario. All parties are held to the same standard: they must each put forward their entire case, complete with all relevant evidence, at first instance. The innovator is prevented from relitigating an issue already decided in a proceeding to which it was a party with the aid of additional evidence it chose not to adduce in the earlier proceedings. Generics likewise must put forward their full case at the first opportunity. Multiple NOAs issued by the same generic relating to a particular drug and alleging invalidity of a particular patent will generally not be permitted, even if different grounds for establishing invalidity are put forward in each. <u>However, where one generic has made an allegation but has failed to put forward the requisite evidence and argument to illustrate the allegation is justified, it would be unjust to preclude a subsequent generic, who is apprised of better evidence or a more appropriate legal argument, from introducing it. Although this situation may give rise to the possibility of an inconsistent result, this concern</u>

> is overridden by the potential for unfairness to the generic that is barred from bringing forward its case simply because another generic's approach was inadequate. In each situation, it is necessary to balance the effect of a proceeding on the administration of justice against the unfairness to a party from precluding it from bringing forward its case.
>
> [Emphasis added]

[41] This is the paragraph on which the Judge specifically relies for his view on abuse of process in the present matter. It is also the paragraph on which the respondents rely in making their submissions on abuse of process. It is important to note that in *Sanofi-Aventis, supra,* the issue was whether a first person (Sanofi-Aventis), which had failed to establish in a prior NOC proceeding against a different generic company (Apotex) that an allegation of invalidity found in the NOA was not justified, abuses the NOC process by seeking to relitigate the same allegation of invalidity when made by a second generic company (Novopharm).

[42] In *Sanofi-Aventis, supra*, the question of abuse of process arose by reason of paragraph 6(5)*(b)* of the Regulations, which provides that on a motion by a second person, the Federal Court may dismiss an application for prohibition on the ground that it is redundant, scandalous, frivolous or vexatious, or that it is otherwise an abuse of process.

[43] In this appeal, however, the question is not whether the first person's application constitutes an abuse of process, but rather whether the second person's allegations found in its NOA amount to an abuse of process. Paragraph 6(5)*(b)* of the Regulations clearly does not apply in the present matter and this Court is not asked to dismiss an application for prohibition on a motion brought by a second person. There can be no doubt that Sexton J.A.'s comments in *Sanofi-Aventis, supra,* were

made *in obiter* and, thus, are not binding and, in any event, they do not support the position adopted by the Judge.

[44] In my view, a fair reading of paragraph 50 of Sexton J.A.'s Reasons in *Sanofi-Aventis, supra*, does not lead to the conclusion that a second person can only put forward a NOA on grounds similar to those put forward by a different generic in other proceedings when it has better evidence to offer or better legal arguments to make. I believe that at paragraph 50 of his Reasons, Sexton J.A. was simply attempting to explain his view that notwithstanding the possibility that different judgments might be rendered with respect to identical or similar NOAs, fairness required that a generic, such as Apotex in the present case, which had not yet litigated the issues which it raised in its NOA, be allowed to have its day in court. In my view, it cannot be seriously argued that Sexton J.A. was advocating that an assessment of the second generic's evidence and legal arguments had to be made before it could send its NOA and respond to the application for prohibition.

[45] I am therefore satisfied that nothing said in our decision in *Sanofi-Aventis, supra*, supports the Judge's conclusion that a second person, unless it is in a position to show that it has "better evidence or a more appropriate legal argument", cannot send a NOA to a patentee and, hence, respond to the patentee's application for prohibition on grounds similar to those put forward by a different generic in other proceedings with the same patentee. I therefore conclude that the Judge erred in concluding as he did on the issue of abuse of process.

[46] Consequently, although Shore J. erred in his understanding of this Court's opinion in *Sanofi-Aventis*, *supra*, the question which must now be answered is whether his error warrants our intervention. In other words, was the Judge's assessment of the evidence before him tainted by his mistaken view on abuse of process?

[47] Because there was no abuse of process on the part of Apotex, the Judge was required to assess the evidence put before him by both parties independently of the findings made by Hughes J. in the Novopharm trial. I therefore turn to that question. Before answering it, however, it is worth repeating the arguments which Apotex makes in support of its assertion that the Judge erred in applying the test for abuse of process and that, as a result, this Court must intervene.

[48] Reduced to its essentials, Apotex's position is that this was the first time that it raised the issues which are now before the Court and that, as a result, it was entitled to a fresh determination by the Judge of these issues on the evidence before him, which determination had to be made irrespective of the findings made and conclusions reached by Hughes J. in the Novopharm trial. Thus, it submits that it did not have a fair hearing and that its fate was determined by the Novopharm trial.

[49] Contrary to my colleague Madam Justice Layden-Stevenson, I am unable to conclude, as she does, that the Judge conducted an enquiry with respect to the issues before him, namely, claim construction, anticipation and obviousness, distinct from his analysis on abuse of process. Although the Judge purports to make findings of fact, I am uncertain as to the nature of these findings. Is he

making truly independent findings or is he making findings in accordance with those made by Hughes J. in the Novopharm trial? Is he of the view that Apotex, in order to succeed, was bound to adduce evidence that was better and to muster more appropriate legal arguments than what had been adduced and submitted by Novopharm in its litigation?

[50] I am led to this conclusion in great part by the difficulty which I have had in understanding the Judge's Reasons. I therefore propose to review the Judge's Reasons to highlight that difficulty.

[51] The learned Judge expressly considered abuse of process and whether Apotex had provided "better evidence or a more appropriate legal argument" than had been provided in the Novopharm trial and the Novopharm appeal, both at the beginning of his analysis and subsequently at the end thereof. The Judge also appears to have had in mind the principles of abuse of process throughout the entire course of his Reasons.

[52] Commencing at paragraph 40 of his Reasons, under the heading "*Abuse of Process Consideration*", the Judge sets out the principle established by this Court in *Sanofi-Aventis, supra*. Following that, he sets out, under the sub-heading "**Better evidence**", the parties' respective arguments as to whether Apotex has submitted better evidence than that which was before Hughes J. in the Novopharm trial. And then, under the sub-heading "**More appropriate legal argument**", he sets out the "novel legal arguments" which Apotex submits that it has to offer in the present proceedings. He also sets out the respondents' response thereto.

[53] Then, after having listed the witnesses, both expert and factual, who appeared before him, the Judge turned to the issue of claim construction. He states at paragraph 62 of his Reasons that all court decisions which have considered claim 4 of the '080 patent have construed it "in a way consistent with Justice Hughes' construction [in the Novopharm trial]".

[54] At paragraphs 63 and 64 of his Reasons, the Judge cites extensively the construction of claim 4 arrived at by Hughes J. in the Novopharm trial. He concludes on this issue by saying at paragraph 70 of his Reasons:

> [70] Recognizing the decision of Justice Hughes and the subsequent agreement of that decision voiced in the Federal Court of Appeal judgment, presided by justice Karen Sharlow, claim 4 is construed as not placing any limitations on whether the compound is hydrated and to what degree:
>
> > S(-) Ofloxacin, different from that contained in the racemate, obtained in a reasonably pure state.
>
> [Emphasis added]

[55] I am unable to understand the exact meaning of paragraph 70 of Shore J.'s Reasons. As I have a similar problem in regard to his reasons with respect to the other issues which were before him, I will continue my outline of his Reasons and then, at the end of this exercise, will state the reasons which lead me to conclude as I do that his assessment of the evidence was tainted by his misunderstanding of the concept of abuse of process.

[56] After his analysis of claim construction, the Judge turned to the issue of infringement, under the heading "*Is Apotex' allegation of infringement justified?*". This part of his Reasons runs from paragraph 71 to paragraph 83, which he conducts as follows at paragraphs 82 and 83:

> [82] Justice Hughes concludes in the *Novopharm Trial* that the '840 patent did not contain any direction that the enantiomers of ofloxacin would be more active than the racemate nor does it instruct the reader as to how to effect such separation or to produce an enantiomer. (*Novopharm Trial*, above as described in para. 104).
>
> Conclusion
>
> [83] The Court concludes that Apotex' 250 mg, 500mg and 750 mg tablets would infringe Janssen's '080 patent.

[57] After his analysis of infringement, the Judge turned to the issue of invalidity under the heading "*Are Apotex' allegations of invalidity justified?*". This part of his Reasons commences at paragraph 84 and concludes at paragraph176. Here, the Judge deals with the issues of anticipation and obviousness at paragraphs 87 to 104 and at paragraphs 105 to 176 respectively.

[58] With respect to anticipation, after reviewing the arguments and the evidence, the Judge concludes at paragraphs 103 and 104, in the following terms:

> [103] Justice Hughes determined, in the Novopharm Trial:
>
> > [104] Neither the '840 patent nor the publication contain any direction that the optical isomers of Ofloxacin would be more active than the racemate nor do either instruct the reader as to how to effect such separation or to produce an [enantiomer].
> > …
> > [108] The Supreme Court test requires that the "flag" be planted at the point of the claimed invention and that the direction as to how to arrive at that point must be so clear such that an ordinary person skilled in the art would in every case, without possibility of error, be led to that point. No such flag is planted and no such direction is given in either the '840 patent or the Daiichi publication. There is no anticipation of what is claimed in claim 4 of the Patent.
>
> [104] Apotex has not provided this Court with any evidence that would justify a deviation from Justice Hughes' determination on this issue. Consequently, there is no anticipation of what is claimed in claim 4 of the '080 patent.

[59] There can be no doubt that the judge simply adopted Hughes J.'s findings in the Novopharm trial regarding anticipation.

[60] The Judge then turned to obviousness. In the course of his discussion of that issue, he determined whether claim 4 was inventive and constituted a valid claim. At paragraph 170, he made the following remarks:

> [170] In the *Novopharm Trial*, Justice Hughes held that claim 4 of the '080 patent was inventive and a valid claim. His decision was upheld on appeal. In this application, the same issue is being raised along with the same prior art references and substantially the same evidence.
> (*Novopharm Trial*, above at paras. 109-115; Novophann Appeal, above at paras. 23-45; *Sanofi-Aventis v. Novopharm*, above at para. 50, Eli Lilly, 2007 FC 596, above at 238-239.)

[61] The learned Judge's final paragraph on obviousness is paragraph 176 and it reads:

> [176] Based on the foregoing, this Court finds that the Respondent has failed to establish that claim 4 is invalid on the basis of obviousness or lack of inventive ingenuity. Consequently, the '080 patent was not obvious.
>
> [Emphasis added]

[62] At paragraphs 177 to 187, the Judge dealt with a different issue, namely, whether the claims were broader than the invention made and whether they lacked sound prediction. He concludes on that issue as follows, at paragraph 187:

> [187] Apotex misconstrues the promise of the '080 patent and the utility of the invention. Apotex states in its NOA that the "reported *in vitro* antimicrobial testing was but a single test relied upon in an attempt to predict levofloxacin's utility - that it would be a very useful

> pharmaceutical agent as compared with ofloxacin"; however, the ‘080 patent merely states that it is "expected" that levofloxacin will be a very useful pharmaceutical agent as compared to ofloxacin. Justice Hughes eloquently summarized the utility of claim 4 in the *Novopharm Trial*:
>
> > [126] …What the Patent asserts, at the end of the day, is set out at page 2. The S(-) form of Ofloxacin has increased antimicrobial activity, reduced toxicity and markedly high water solubility, giving it an expectation to be a very useful pharmaceutical agent. This statement is correct. To even find this distribution of attributes, namely, more of the beneficial properties and at least no more of the detrimental, was itself remarkable.

[63] Finally, at paragraphs 203 and 204 of his Reasons, the Judge comes to a crucial conclusion with regard to the issues which he has dealt with in the course of his Reasons:

> [203] Subsequent to all considerations, on every issue raised, in this NOC proceeding, no demonstration has been made as to invalidity nor infringement. Recognition is given to the previous Federal Court Trial and Federal Court of Appeal proceedings that had, in effect, exhausted all analysis of the asserted ‘080 patent claims. No better evidence, nor more appropriate legal argument, has been submitted in the present proceeding.
>
> [204] The Applicants are thus granted the prohibition order for which they applied.
>
> [Emphasis added]

[64] It would appear that by reason of this conclusion, all analysis had been exhausted, the respondents having been granted the order sought. Unexpectedly, however, the Judge then moves on a new subject entitled “Abuse of Process Analysis and Conclusion”. I say unexpectedly because by then, as I have just indicated, the Judge has granted the remedy sought by the respondents and has indicated that the principle enunciated in *Sanofi-Aventis*, *supra*, has not been met.

[65] At paragraph 205, the Judge says that he agrees with the respondents’ submissions on abuse of process and then states at paragraph 210:

> [210] Subsequent to the Federal Court of Appeal having disposed of this matter in direct regard, the resulting precedent from the Court of higher instance concludes the matter for this Court.

[66] I have reproduced those paragraphs of the Judge's Reasons which, in my opinion, shed greater light on his reasoning. In other words, these paragraphs bear greater importance in determining whether his reasoning was tainted because of his mistaken view on abuse of process. In fact, in the course of his Reasons, the Judge refers on no less than 43 occasions to the decision and opinion of Hughes J. in the Novopharm trial. I am not saying nor suggesting that the number of references *per se* is the determining factor. However, when I read the Judge's Reasons as a whole, I am left in considerable doubt as to whether he in fact conducted an assessment of the facts independent of that made by Hughes J. in the Novopharm trial.

[67] As I have already indicated, at paragraph 203 of his Reasons, immediately following what could be characterized as his analysis of the merits of the case, the Judge states in unequivocal terms that Apotex has not led better evidence nor has it put forward stronger legal arguments than what had been put before Hughes J. in the Novopharm trial. This conclusion seems to suggest that the Judge, in assessing the evidence before him, was attempting to determine whether the evidence led by Apotex was such so as to allow him to reach a conclusion different from that reached by Hughes J. in the Novopharm trial. The considerable number of references to both Hughes J.'s findings and conclusions provide, in my view, strong support for the argument that the Judge did not make findings independent of those made by Hughes J. If he did so, that is not sufficiently apparent, in my respectful view, from his Reasons.

[68] It is also remarkable that notwithstanding the fact that at paragraph 204 of his Reasons, the Judge grants the prohibition order sought by the respondents, he then continues his analysis by engaging once again in a discussion regarding abuse of process. After his conclusion that the prohibition order was granted, one would have expected the Judge to simply set out his order and deal with the issue of costs. This discussion of abuse of process appears to be, with all due respect, totally irrelevant. As I understand the Judge's Reasons, this discussion does not lead to any conclusion other than the remarks found at paragraph 247:

> [247] Viewed as a whole, the "new evidence" concerning inventive ingenuity is no more than conflicting evidence or a repetition of the evidence before Justice Hughes. As stated above, where the "better evidence" in the second case can be capable of different interpretations, it does not meet the standard set for when a second case can be considered in the face of opposite findings in the first case. The Apotex evidence, at its highest, is capable of different interpretations. In such a case "it would be far preferable to observe the witness at trial". (*Sanofi-Aventis v. Novopharm*, above at para. 39; *Pfizer v. Novopharm*, above at para 55.)

[69] In other words, as the Judge has clearly indicated at paragraph 203 of his Reasons, when he says "No better evidence, nor more appropriate legal argument, has been submitted in the present proceeding", that the requirements set out in *Sanofi-Aventis, supra*, have not been met, it is difficult to understand what the purpose of the further discussion is. In my respectful view, it makes the Reasons that more difficult to understand.

[70] To sum up, I have read the Judge's Reasons on numerous occasions. On each occasion, I have attempted to understand the rationale behind his Reasons so as to determine whether he

conducted an assessment of the evidence independent of that made by Hughes J. in the Novopharm trial. As I am unable to so conclude, I am inevitably led to the view that the Judge's misunderstanding of the principles set out in *Sanofi-Aventis, supra*, has tainted his assessment of the evidence before him. Formulated in another way, it is my view that the Judge did not conduct a parallel enquiry, but an enquiry which co-mingled the evidence before him and the findings made by Hughes J. in the Novopharm trial.

[71] In the circumstances, it is my view that it would be preferable for the matter to be returned to the learned Judge for redetermination of the issues in accordance with these Reasons.

[72] Before concluding, I wish to address one additional matter.

[73] In its written submissions and before us at the hearing of the appeal, counsel for Apotex drew out attention to the fact that a minimum of 90 paragraphs from the Respondents' Memorandum filed at first instance had been reproduced verbatim by the Judge in his Reasons. In fact, upon verification, the Judge reproduced verbatim, without so saying, approximately 100 paragraphs, including many of the headings, the underlining, the footnotes and the references to the evidence.

[74] I am somewhat troubled by this, as the matters in respect of which the Judge reproduced verbatim the Respondents' Memorandum concern all the key issues before him and, in particular,

anticipation and obviousness. These include a substantial portion of the Judge's findings with regard to the evidence given by the expert witnesses.

[75] This state of affairs has led Apotex to say that the Judge did not fully consider the evidence that it put before him.

[76] For example, paragraphs 146 to 175 of the Judge's Reasons, which deal with whether the properties of levofloxacin were beneficial, surprising and unexpected, are a verbatim reproduction of the Respondents' Memorandum at first instance. Another noteworthy example is the abandonment issue, where the Judge, at paragraphs 188 to 202, deals with paragraphs 40(1)*(a)* and *(c)* of the Act. Every single paragraph of the Judge's Reasons is taken verbatim from the Respondents' Memorandum at first instance.

[77] It would, in my respectful view, be advisable for a judge who intends to adopt a substantial part of a party's written submissions to say so explicitly. Where a judge is confronted with a complex factual case such as the one before us, the adoption of a party's written submissions without an acknowledgment may lead to the impression that the judge has not done the work which he is called upon to do, namely, to examine all of the evidence before him and to make the appropriate findings.

[78] One must bear in mind that when parties file written submissions, they do not have to make allowances for the other side's case. Specifically, parties tend to maximize the strong points of their

case and to minimize their weaknesses. It is up to the Judge, after careful consideration of all the evidence and the arguments, to draw the line at the appropriate place.

[79] I am not prepared to conclude, nor is there any basis to so conclude in this matter, that the Judge did not perform his duty to examine the evidence as he was called upon to do. Although the Judge erred by reason of his misunderstanding of our decision in *Sanofi-Aventis*, *supra*, this error cannot, in any way, support an argument that the Judge did not perform his duty.

DISPOSITION

[80] For these reasons, I would therefore allow the appeal with costs, set aside the Judge's judgment and remit the matter back to him for redetermination on the basis that there was no abuse of process on the part of Apotex in making the allegations found in its NOA and in contesting the application for a prohibition order commenced by the respondents. I would also instruct the Judge to assess the evidence before him independently of any findings made by Hughes J. in the Novopharm trial. With respect to the proceedings in the Federal Court, I would make no order as to costs.

"M. Nadon"

J.A.

"I agree.
Johanne Trudel J.A."

LAYDEN-STEVENSON J.A. (Dissenting Reasons)

[81] I have read the reasons of my colleague and I agree, for the reasons given by him, this Court's decision in *Sanofi-Aventis* does not stand for the proposition that, unless a second person is in a position to show it has "better evidence or a more appropriate legal argument", it cannot send a NOA to a patentee and respond to the patentee's application for prohibition on grounds similar to those put forward by a different generic in other proceedings with the same patentee. It necessarily follows that the applications judge erred in concluding as he did on the issue of abuse of process.

[82] There are additional reasons why the abuse of process conclusion cannot stand. The issue of whether claim 4 of the '080 Patent encompassed both anhydrous and hydrous forms of levofloxacin had not been previously litigated. As well, Apotex's allegation that the '080 Patent was deemed abandoned during prosecution had not been raised before. Although, in the end, both allegations were found to be not justified, advancing them could not and should not have been regarded as an abuse of process.

[83] I also agree with my colleague's observations regarding the inappropriateness of an adoption by the judge of a party's written submissions without a formal acknowledgement to that effect. I endorse and adopt my colleague's comments in this respect. However, Apotex specifically renounced any suggestion of *mala fides* on the part of the judge and it did not advance any ground of appeal or specific allegation of error in this regard. The reasons for judgment comprise 250 paragraphs. As noted by my colleague, there is no basis to conclude that the applications judge "did

not perform his duty to examine the evidence as he was called upon to do." In the circumstances, I am not prepared to attach undue weight to this factor.

[84] Although I agree with my colleague that the applications judge erred in concluding as he did with respect to the issue of abuse of process, with respect, I do not agree that Justice Shore's findings regarding anticipation and obviousness were tainted by the abuse of process issue. As I read his reasons, the applications judge conducted parallel inquiries. That is to say, his analyses regarding anticipation and obviousness were distinct and separate from his analysis on abuse of process.

[85] In relation to both anticipation and obviousness, the applications judge addressed the allegations, analysed the evidence as he saw it, had regard to the legal arguments, and arrived at his conclusions. He did so without reference or regard to whether the Apotex NOA constituted an abuse of process. In each instance, after delineating his conclusions on anticipation and obviousness respectively, he turned to the question of abuse of process in relation to each of them. His comments regarding abuse of process were in addition to his previous conclusions. While the abuse of process issue related to, at least in part, the anticipation and obviousness determinations, the analyses of the anticipation and obviousness issues yielded stand-alone conclusions unrelated to the abuse of process issue. In my view, the applications judge's commentary on abuse of process had no effect on his earlier, independent determinations regarding anticipation and obviousness. Consequently, I do not share my colleague's view that the latter were tainted by the former.

[86] Apotex argues that the applications judge erred in construing the claim in issue and was guilty of factual errors and oversights in relation to anticipation, obviousness and valid selection. Claims construction is a question of law reviewable on a standard of correctness: *Whirlpool Corp. v. Cameo Inc.* (2000), 9 C.P.R. (4th) S.C.C.) (*Whirlpool*). In all other respects, Apotex must transcend the test articulated in *Housen v. Nikolaisen*, [2002] 2 S.C.R. 235. A standard of palpable and overriding error applies to findings and inferences of fact as well as to questions of mixed fact and law unless it is clear the applications judge made an extricable error in principle with respect to the characterization of the law, or its application, in which case the error may amount to an error of law and the standard of correctness would apply.

Claims Construction

[87] I do not find any error on the part of the applications judge regarding his construction of the claim. Apotex submits that the applications judge adopted a "results-oriented" construction and incorrectly construed claim 4 of the '080 Patent in two respects: (1) to only include levofloxacin in a reasonably pure state; and (2) to include levofloxacin hemihydrate.

[88] These allegations can be addressed summarily. First, I reject the notion of a "results oriented" construction. The applications judge did nothing other than identify the issue in relation to an analysis of infringement. Second, although it is not permissible to look to the patent disclosure to expand the monopoly, the disclosure may be examined to construe the patent claims: *Whirlpool*; *Freeworld Trust v. Électro Santé Inc.*, [2000] 2 S.C.R. 1024. The principles set out in these authorities are well-known, often cited and need not be repeated here.

[89] Third, although Apotex contends that claim 4 is not ambiguous, thus resort to the disclosure is unnecessary and should not have occurred, its position ignores the fact that the claim 4 language does not specify whether the claimed compound is hydrous or anhydrous, a matter of significance. The applications judge did not err in having regard to the specification.

[90] Fourth, in my view, it is not an error to refer to the construction of the claim, as construed in previous proceedings by different judges (one of whom has been affirmed by this Court). Such constructions may be persuasive, depending on the evidence, as found by the applications judge in this case.

[91] Further, I do not find that the applications judge erred in agreeing with Hughes J.'s construction of claim 4 as being levofloxacin "different from that contained in the racemate, obtained in a reasonably pure state." The invention of the '080 Patent clearly related to producing reasonably pure levofloxacin, rather than racemic ofloxacin. Moreover, the applications judge did not err in construing claim 4 as including both levofloxacin hemihydrate and levofloxacin anhydrate. As the applications judge observed, the disclosure explicitly provided instructions regarding how to make both of these compounds.

[92] In sum, the applications judge did not err in construing claim 4. It was uncontested that the Apotex product would contain levofloxacin hemihydrate. Therefore, the conclusion that Apotex's allegation of non-infringement was not justified was correct.

Anticipation and Obviousness

[93] In relation to the various alleged factual errors, I am not persuaded that the identified errors, if they exist at all, approach the requisite level to warrant setting aside the decision.

[94] Apotex argues the evidence of commercially-available equipment that could be used to separate the ofloxacin enantiomers was ignored and notes that Daiichi had used such equipment.

[95] The applications judge, at paragraph 102 of his reasons, acknowledged the existence of techniques available to separate enantiomers, generally. However, he found that these techniques offered no assurance that a substantially optically pure enantiomer of a new racemate itself or even a substantially optically pure enantiomer of an intermediate, could be obtained. He noted Dr. Kellogg's admission that Dr. Kellogg did not locate the three processes disclosed in the '080 Patent to produce levofloxacin (Processes A, B and C) in any prior art reference.

[96] Apotex has not demonstrated palpable and overriding error in this regard. Moreover, the fact that commercial equipment could be used to separate ofloxacin would not be sufficient to anticipate claim 4 of the '080 Patent. No prior publication or patent disclosed isolated levofloxacin or its advantages.

[97] Apotex also argues the applications judge "relied upon Mr. Hayakawa's affidavit to say that it took Daiichi four years to obtain levofloxacin, but overlooked that Mr. Hayakawa had admitted

on cross-examination that no work was being done by Daiichi during most of this period, and that the Daiichi scientists had very little knowledge and experience in performing resolutions when they initiated their work."

[98] Mr. Hayakawa did admit there were no documented attempts by Daiichi to separate the ofloxacin enantiomers between November 1982 and June 16, 1984 and that most members of the research group would not have had actual experience separating enantiomers (Hayakawa Cross-examination, Appeal Book, Vol. XXXI, Tab 50). However, even if the applications judge "overlooked" this evidence, it does not constitute palpable and overriding error. These facts, taken with the other evidence, do not support the proposition that levofloxacin and its advantages were disclosed and enabled by any prior patent or publication.

[99] Apotex asserts the applications judge failed to consider evidence that Daiichi's competitors were motivated to resolve ofloxacin and did so at approximately the same time as Daiichi. Specifically, Apotex states that on December 10, 1985, Bayer AG, a Daiichi competitor, filed a German Patent Application for levofloxacin that disclosed its increased antimicrobial activity over ofloxacin and a method for its synthesis. Although this patent application does not constitute 'prior art', according to Apotex, it contradicts the applications judge's finding that Daiichi's competitors were not motivated to resolve ofloxacin.

[100] At paragraph 232 of his reasons, the applications judge acknowledged Apotex's evidence demonstrated that "in 1985 four competitors came to levofloxacin shortly after Daiichi." Although

this observation is not included in the obviousness analysis, it nonetheless indicates the applications judge did not "ignore" or "overlook" the evidence. In any event, whether competitors were motivated to pursue the invention is but one factor to consider in an obviousness analysis. The applications judge listed a number of factors pointing to a determination that claim 4 of the '080 Patent was not obvious, including:

- at least until June 1985, no researcher other than Gerster had obtained the enantiomers of any racemic fluoroquinolone, despite the competitive nature of this field;
- the only other fluoroquinolone that had been resolved into its enantiomers (flumequin) had a different structure than ofloxacin;
- other similar fluoroquinolones taught away from the importance of the chirality of the methyl group;
- there was no generalized expectation that the bulk of the antibacterial activity of ofloxacin would lie in one enantiomer;
- levofloxacin's lower toxicity was unexpected, as was the fact that the enantiomer having the lower toxicity was also the more active enantiomer; and
- levofloxacin's increased solubility was unexpected.

[101] Apotex also claims the applications judge erred by assessing obviousness as of June 1985 rather than as of the date of invention (December 1985). This failure ostensibly prevented him from considering various pieces of prior art, including the Gerster 1985 Poster. I do not agree. The applications judge clearly considered the Gerster 1985 Poster in his obviousness analysis. He acknowledged that the Gerster 1985 Poster taught that the "S" flumequine enantiomer was more

active that the “R” enantiomer. However, he found, since flumequine and ofloxacin are structurally distinct, the properties of the former could not be used to predict those of the latter.

[102] The remaining allegations of “palpable and overriding errors” constitute mere disagreement with the manner in which the applications judge weighed the evidence. To the extent that any errors were made, they are not palpable or overriding.

Selection Patent

[103] Apotex claims that if the applications judge had considered its selection patent argument, the results in relation to anticipation and obviousness would have been different. I am not persuaded that is so. In *Sanofi*, Justice Rothstein conducted his analysis by reference to the facts as found by the applications judge. In *Apotex Inc. v. Pfizer Canada Inc. et al.* (2009), 74 C.P.R. (4th) 141 (F.C.A.), Justice Noël of this Court did likewise. I propose to do the same.

[104] Upon review of his reasons, I am satisfied the applications judge conducted a proper analysis for anticipation notwithstanding that, at the time of the hearing, he did not have the benefit of the Supreme Court’s reasons in *Sanofi*. As for the issues concerning validity of the selection and obviousness, the applications judge’s factual determinations, when applied to the *Sanofi* analysis, point to a conclusion that the '080 Patent is valid.

(a) Valid Selection

[105] In *Sanofi*, the Supreme Court referred to a line of authority stemming from *I.G. Farbenindustrie A.G.'s Patents* (1930), 47 R.P.C. 289 (Ch. D.) in support of its conclusion that a system of genus and selection patents is acceptable in principle. Three conditions must be satisfied for a selection patent to be valid.

> 1. There must be a substantial advantage to be secured or disadvantage to be avoided by the use of the selected members.
>
> 2. The whole of the selected members (subject to "a few exceptions here and there") possess the advantage in question.
>
> 3. The selection must be in respect of a quality of a special character peculiar to the selected group. If further research revealed a small number of unselected compounds possessing the same advantage, that would not invalidate the selection patent. However, if research showed that a larger number of unselected compounds possessed the same advantage, the quality of the compound claimed in the selection patent would not be of a special character (*Sanofi*, paragraph 10).

[106] The applications judge concluded that the combination of higher activity, low toxicity and increased solubility properties of levofloxacin resulted in an advantage over ofloxacin. There was evidence before him to support this factual finding. Although Apotex claims the applications judge's failure to refer to certain evidence constitutes error, I do not accept its argument. A review of the noted evidence reveals that some of it, when read in context, does not support the position for which it is cited. In other instances, the evidence was contradicted by other evidence. Again, it boils down to the weight assigned to the evidence. Apotex has failed to establish palpable and overriding error in this respect.

[107] The selection in this case was comprised of one enantiomer. Therefore, the second condition is not relevant in this case. The applications judge also found that the unselected R(+)

ofloxacin enantiomer did not have the quality of special character. The factual findings made by the applications judge satisfy the *Sanofi* test for a selection patent.

(b) Anticipation

[108] *Sanofi* refined the test for anticipation. The inquiry now encompasses the requirements of prior disclosure and enablement, considered separately. The *Sanofi* reasoning is synthesized in the paragraphs below.

[109] With respect to disclosure, the skilled person is reading the prior art to understand whether it discloses the second invention. No trial and error or experimentation is permitted. If the disclosure requirement is satisfied, enablement requires the skilled person to have been able to perform the invention.

[110] In the case of a selection patent, the compound made for the selection patent was only soundly predicted at the time of the genus patent. It was not made and its special advantages were not known. Thus, a patent should not be denied to the inventor who made and discovered the special advantages of the selection compound for the first time. If the genus patent discloses the special advantages of the invention covered by the selection patent, there is prior disclosure and the test for anticipation fails. If the special advantages of the invention of the selection patent are not disclosed, the enablement requirement comes into play, that is, the skilled person must be able to perform or make the invention of the patent without undue burden. The Supreme Court, at paragraph 37, set out a non-exhaustive list of factors that should normally be considered.

> 1. Enablement is to be assessed having regard to the prior patent as a whole including the specification and the claims. There is no reason to limit what the skilled person may consider in the prior patent in order to discover how to perform or make the invention of the subsequent patent. The entire prior patent constitutes prior art.
>
> 2. The skilled person may use his or her common general knowledge to supplement information contained in the prior patent. Common general knowledge means knowledge generally known by persons skilled in the relevant art at the relevant time.
>
> 3. The prior patent must provide enough information to allow the subsequently claimed invention to be performed without undue burden. When considering whether there is undue burden, the nature of the invention must be taken into account. For example, if the invention takes place in a field of technology in which trials and experiments are generally carried out, the threshold for undue burden will tend to be higher than in circumstances in which less effort is normal. If inventive steps are required, the prior art will not be considered as enabling. However, routine trials are acceptable and would not be considered undue burden. But experiments or trials and errors are not to be prolonged even in fields of technology in which trials and experiments are generally carried out. No time limits on exercises of energy can be laid down; however, prolonged or arduous trial and error would not be considered routine.
>
> 4. Obvious errors or omissions in the prior patent will not prevent enablement if reasonable skill and knowledge in the art could readily correct the error or find what was omitted.

[111] The applications judge's analysis that the '080 Patent was not anticipated by the '840 Patent was in keeping with the *Sanofi* analysis. He correctly stated and applied the requirements of disclosure and enablement. He determined that the '840 Patent disclosed a process to make racemic ofloxacin and not levofloxacin in a reasonably pure state. Although the non-disclosure in the '840 Patent, in and of itself, was sufficient to conclude that it did not anticipate the claim, the applications judge additionally found that the '840 Patent did not enable the skilled person to make the invention of claim 4 because there were no routine techniques in which the skilled person could isolate levofloxacin.

(c) Obviousness

[112] *Sanofi* endorsed the inquiry for obviousness set out in W*indsurfing International Inc. v. Tabur Marine (Great Britain) Ltd.*, [1985] R.P.C. 59 (C.A.) (*Windsurfing*), restated in *Pozzoli SPA v. BDMO SA*, [2007] EWCA Civ 588 (*Pozzoli*).

> 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.

[113] At the fourth stage of the *Windsurfing* approach, the issue of "obvious to try" arises. To find that an invention was "obvious to try", and therefore invalid for obviousness, *Sanofi* teaches "there must be evidence to convince a judge on a balance of probabilities that it was more or less self-evident to try to obtain the invention. Mere possibility that something might turn up is not enough" (paragraph 66). The "obvious to try" test will be appropriate in areas of endeavour where advances are often won by experimentation, such as in the pharmaceutical industry. A non-exhaustive list of factors to be taken into consideration is proposed at paragraph 69.

> 1. Is it more or less self-evident that what is being tried ought to work?
> Are there a finite number of identified predictable solutions known to persons skilled in the art?
>
> 2. What is the extent, nature and amount of effort required to achieve the invention? Are routine trials carried out or is the experimentation prolonged and arduous, such that trials would not be considered routine?
>
> 3. Is there a motive provided in the prior art to find the solution the patent addresses?

[114] The actual course of conduct that culminated in the making of the invention may be an important factor. In this inquiry, it is not enough that there is a possibility of finding the invention. The invention must be self-evident from the prior art and common general knowledge in order to satisfy the "obvious to try" test.

[115] At paragraph 85, Justice Rothstein specifically referred to isolating enantiomers of a racemate as follows:

> Just because there are known methods of separating a racemate into its isomers does not mean that a person skilled in the art would necessarily apply them. The fact that there are such known methods of separation will be of no account if the evidence does not prove that it was more or less self-evident to try them. It is true that at the relevant time there was evidence that a skilled person would know that the properties of a racemate and its isomers might be different. However, a possibility of finding the invention is not enough. The invention must be self-evident from the prior art and common general knowledge in order to satisfy the "obvious to try" test.

[116] It is common ground that the applications judge did not conduct the precise obviousness analysis taught in *Sanofi*. Notwithstanding, his factual determinations, applied to the *Sanofi* analysis, support the conclusion that claim 4 is inventive.

Identify the notional person skilled in the art

[117] No issue was taken in relation to the applications judge's finding that the skilled person would be "a person with at least a first level university education, and at least a few years of experience concerned with chemical compounds and deriving optically active compounds therefrom particularly in the area of compounds having medicinal uses" (paragraph 57).

Identify the relevant common general knowledge of that person

[118] The applications judge concluded that the skilled person would be familiar with the principles of stereochemistry and nomenclature (paragraphs 56, 58) and, although there were general techniques known in the art to separate enatiomers, no specific techniques existed that could be used to separate the ofloxacin enatiomers (paragraphs 100, 102, 144, 173).

Identify the inventive concept of the claim in question or if that cannot readily be done, construe it

[119] The applications judge identified the inventive concept of claim 4 to be isolated levofloxacin with the unexpected advantages of increased solubility and activity and lowered toxicity over ofloxacin (paragraphs 143-168). He further found that the combination of the three beneficial properties was an unexpected advantage (paragraph 169).

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

[120] The applications judge found that levofloxacin was fundamentally different from ofloxacin and that the former was twice as potent, less toxic and ten times more water soluble than the latter (paragraphs 143-169). He additionally concluded that levofloxacin could not be made following prior art references (paragraph 102).

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?

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

[121] The applications judge found that determining the properties of levofloxacin required more than mere verification (paragraph 111). He properly concluded that one cannot "verify" unexpected and unpredictable properties (paragraph 111). The applications judge further found that the improved properties of levofloxacin were unpredictable (paragraphs 143-169) and that there were no standard techniques which could be used to separate the enantiomers (paragraph 102). If there was more than mere verification, the advantage of the selection of levofloxacin would not have been more or less self-evident. The factual determinations clearly indicate that the invention was not self-evident.

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

[122] The applications judge found, as a fact, that the inventors of levofloxacin had to devise new processes to isolate this enantiomer from racemic ofloxacin, since they were unable to obtain it using standard techniques (paragraph 173).

(c) Is there a motive from the prior art to find the solution that the '080 Patent addresses?

[123] The applications judge recognized the competitiveness of the pharmaceutical industry (paragraph 126). However, his factual conclusion, at the end of the day, was that nothing in the '840 Patent or common general knowledge provided a specific motivation for a skilled person to isolate the enantiomers of ofloxacin, including the fact that there was no general expectation that one enantiomer would possess the unexpected properties of levofloxacin (paragraph 127).

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

[124] The applications judge found that Daiichi first began trying to separate the enantiomers of ofloxacin in April, 1981 (paragraph 24) but did not succeed until April, 1985 (paragraph 25) when its improved activity was also discovered. Further, levofloxacin's increased solubility and reduced toxicity were only discovered in September and October 1985, respectively (paragraphs 26 and 27).

[125] Applying the noted factual findings of the applications judge to the *Sanofi* analysis, the inescapable conclusion is that the applications judge did not err in finding that the '080 Patent was not rendered obvious by the '840 Patent. Although the analyses on the issues of selection and obviousness were not performed strictly in accordance with the manner in which they are delineated in *Sanofi*, the *Sanofi* decision was not available at the time the applications judge arrived at his determinations. When the *Sanofi* analysis is conducted, utilizing the factual findings of the applications judge, the conclusion is that the '080 Patent was a valid selection and was not obvious.

Deemed Abandonment

[126] Apotex did not address this issue during oral argument. In its written submissions, it asserted that the applications judge erred in failing to find that the application for the '080 Patent was deemed abandoned during prosecution. The issue is one of mixed fact and law and is reviewable on a standard of overriding and palpable error.

[127] In addressing this argument, the applications judge had to have regard to the *Patent Act* as it stood immediately prior to October 1, 1989. The applications judge made a number of factual

findings, none of which disclose palpable or overriding error. Applying those findings to the applicable law and, in particular, *Bourgault Industries Ltd. v. Flexi-Coil Ltd.* (1999), 86 C.P.R. (3d) 221 (F.C.A.), leave to appeal dismissed, [1999] S.C.C.A. No. 223 (*Flexi-Coil*), he determined that the patent was not deemed abandoned. More specifically, he concluded that the ruling in *Flexi-Coil* was dispositive. That conclusion, in my view, was correct.

[128] For the foregoing reasons, I would dismiss the appeal with costs.

"Carolyn Layden-Stevenson"
J.A.

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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