Federal Court of Appeal | Cour d'appel fédérale

Date: 20220106

Dockets: A-315-20 (lead file)
A-316-20, A-4-21

Citation: 2022 FCA 2

CORAM: **STRATAS J.A.**
LOCKE J.A.
MONAGHAN J.A.

BETWEEN:

PHARMASCIENCE INC.

Appellant

and

TEVA CANADA INNOVATION, TEVA CANADA LIMITED
and
YEDA RESEARCH AND DEVELOPMENT CO., LTD.

Respondents

Heard by online video conference hosted by the registry on November 24, 2021.

Judgment delivered at Ottawa, Ontario, on January 6, 2022.

REASONS FOR JUDGMENT BY: LOCKE J.A.

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

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REASONS FOR JUDGMENT

LOCKE J.A.

I. Overview

[1] Over several weeks during the fall of 2020, Federal Court Justice Catherine M. Kane heard the trial of two patent infringement actions commenced pursuant to the *Patent Medicines (Notice of Compliance) Regulations*, S.O.R./93-133. The actions alleged that the appellant, Pharmascience Inc. (Pharmascience), would infringe Canadian Patents Nos. 2,702,437 (the 437 Patent) and 2,760,802 (the 802 Patent) if it were to enter the market with its product called Glatect 40 mg, which is a generic version of the respondents' product called Copaxone 40 mg for the treatment of multiple sclerosis (MS). The actions were brought by two of the respondents here, Teva Canada Innovation and Teva Canada Limited. The third respondent, Yeda Research and Development Co., Ltd., was added to the actions as the owner of the 437 and 802 Patents. The three respondents are referred to hereinafter collectively as Teva.

[2] In her decision running over 900 paragraphs (2020 FC 1158), Justice Kane (the Trial Judge) carefully reviewed the evidence and the issues and concluded that the 437 Patent would not be infringed (because it is invalid for obviousness—or lack of inventiveness) but that the 802 Patent would be infringed. She dismissed Pharmascience's allegations that the 802 Patent was invalid for obviousness or, alternatively, for lack of utility. Accordingly, she enjoined Pharmascience from, among other things, making, using or selling Glatect 40 mg in Canada.

[3] Pharmascience now appeals the Trial Judge's conclusions concerning the validity of the 802 Patent. The validity of the 437 Patent is not in issue in the present appeal, and therefore I make no comment concerning the Trial Judge's analysis in that regard.

[4] On the issue of utility, Pharmascience notes the requirement that, as of the filing date of the patent in issue, the inventor (or patent applicant) must either have demonstrated the utility of the invention, or have been capable of soundly predicting its utility. The parties agree that, as of the filing date, the utility of the invention had not been demonstrated. Accordingly, Teva had to meet the requirements for a sound prediction of utility. The Supreme Court of Canada listed these requirements in *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77, [2002] 4 S.C.R. 153 at para. 70 (*Wellcome*): (i) a factual basis for the prediction, (ii) an articulable and "sound" line of reasoning from which the desired result can be inferred from the factual basis, and (iii) proper disclosure.

[5] Pharmascience argues that the Trial Judge erred with regard to the requirement for a proper disclosure by applying the disclosure requirement that is applicable to patents in general, and failing to recognize a heightened disclosure requirement applicable to inventions based on sound prediction. The doctrine of sound prediction calls for disclosure of the factual basis and line of reasoning (*Eli Lilly Canada Inc. v. Apotex Inc.*, 2009 FCA 97, 78 C.P.R. (4th) 388 at paras. 14-15; *Eli Lilly and Company v. Teva Canada Limited*, 2011 FCA 220, 94 C.P.R. (4th) 95 at paras. 47 and 51; *Apotex Inc. v. Pfizer Canada Inc.*, 2011 FCA 236, 95 C.P.R. (4th) 193 at para. 52; *Cobalt Pharmaceuticals Company v. Bayer Inc.*, 2015 FCA 116, 131 C.P.R. (4th) 99 at para. 58), unless such factual basis and line of reasoning would be self-evident to a person skilled in the art (*Bell Helicopter Textron Canada Limitée v. Eurocopter, société par actions simplifiée*, 2013 FCA 219, 120 C.P.R. (4th) 394 at paras. 151-155 (*Eurocopter*)). This disclosure requirement exists because "the sound prediction is to some extent the *quid pro quo* the applicant offers in exchange for the patent monopoly": *Wellcome* at para. 70.

[6] Pharmascience also argues in the alternative that, if the 802 Patent does not fail for lack of utility, it must fail for obviousness. It notes that the 802 Patent does not provide any results of experiments that could form the factual basis for a sound prediction of utility, and therefore the required factual basis and line of reasoning to support of a sound prediction must come from the common general knowledge of the person skilled in the art (PSA). Pharmascience argues that, if the common general knowledge was sufficient to support a sound prediction of utility of the invention of the 802 Patent, then the same common general knowledge would make the invention obvious to try, and therefore invalid for obviousness.

[7] For the reasons set out below, I would dismiss the present appeal. I find no reviewable error in the Trial Judge's conclusions regarding either the utility or the inventiveness of the 802 Patent.

II. Standard of Review

[8] Though there is no dispute regarding the standard of review, it is important to set it out because it is relevant in this appeal.

[9] The standard of review applicable in the present appeal is that set out in *Housen v. Nikolaisen*, 2002 SCC 33, [2002] 2 S.C.R. 235, whereby issues of law are reviewed on a standard of correctness and issues of fact or of mixed fact and law from which no legal error is extricable are reviewed on a standard of palpable and overriding error. A palpable and overriding error is one that is obvious and goes to the very core of the outcome of the case.

[10] Utility is a question of mixed fact and law (*Apotex Inc. v. Janssen Inc*., 2021 FCA 45, 182 C.P.R. (4th) 233 at para. 44) and the soundness of a prediction is a question of fact (*Wellcome* at para. 71). Equally, obviousness is a question of mixed fact and law (*Halford v. Seed Hawk Inc*., 2006 FCA 275, 175 D.L.R. (4th) 556 at para. 39). Therefore, except when a question of law can be extracted, findings of utility and obviousness will be reviewed for palpable and overriding error.

III. The 802 Patent

[11] The 802 Patent, entitled "Low Frequency Glatiramer Acetate Therapy", describes and claims a medicine and use thereof for the treatment of a form of MS called relapsing-remitting multiple sclerosis (RRMS). Specifically, the 802 Patent claims the use of 40 mg of glatiramer acetate (GA) injected three times weekly with at least one day between each injection.

[12] The disclosure portion of the 802 Patent describes a previously known RRMS treatment employing daily injections of 20 mg of GA. The claimed thrice-weekly dose of 40 mg of GA is described as "an effective low frequency dosage regimen" (relative to daily 20 mg injections), which "increas[es] the tolerability of GA treatment" (see pages 4 and 5 of the 802 Patent). Tolerability is described as being "associated with the frequency and severity of post injection reactions and injection site reactions," and as "influenc[ing] the period that a patient can follow GA treatment" (see page 16). The disclosure expands on the issue of tolerability under the heading "Discussion" at page 36:

> A significant drawback to GA therapy is the requirement of daily injections, which can be inconvenient. Moreover, in all clinical trials, injection-site reactions were seen to be the most frequent adverse reactions and were reported by the majority of patients receiving GA. In controlled studies, the proportion of patients reporting these reactions, at least once, was higher following treatment with GA (70%) than placebo injections (37%). The most commonly reported injection-site reactions, which were frequently reported in GA vs. placebo-treated patients, were erythema, pain, mass, puritus, edema, inflammation and hypersensitivity.

[13] The disclosure goes on to describe several obstacles and limitations with potential approaches for addressing the drawbacks, including that "due to the complex pharmacokinetic behavior of a drug, variation in the frequency of administration is unpredictable and requires empirical testing" (see page 36).

[14] From pages 20 to 36, the disclosure provides a detailed description of a multinational, multicenter, randomized, phase III parallel-group study that would assess the efficacy, safety and tolerability of the proposed thrice-weekly dose of 40 mg of GA. This description, which is described as the "GALA trial" at paragraph 883 of the Trial Judge's reasons, sets out the design of the study and the expected results. Importantly, the results actually obtained are not included because the study had not yet concluded when the application for the 802 Patent was filed.

IV. Lack of Utility (Sound Prediction)

A. *Disclosure Requirement*

[15] As indicated above, Pharmascience argues that the Trial Judge erred with regard to the disclosure requirement applicable to an invention that is based on the doctrine of sound

prediction. Pharmascience points to several places in the Trial Judge's reasons (paragraphs 872 and 875) where she described the obligation to provide "a full, clear and exact description of the nature of the invention and the manner in which it can be practised", without acknowledging the requirement to describe the factual basis and line of reasoning supporting the prediction of utility.

[16] I preface my comments on this issue by noting that the parties do not disagree on the question of whether there is indeed a heightened disclosure requirement applicable to inventions based on sound prediction. Accordingly, it is not necessary to comment on that question here.

[17] In my view, the Trial Judge did not misunderstand the disclosure requirement under the sound prediction doctrine. At paragraph 870 of her reasons, she recognized the distinction between the requirements of the *Patent Act*, R.S.C. 1985, c. P-4, regarding disclosure generally (subsection 27(3)) and regarding utility (section 2). In addition, at paragraph 874, she discussed the disclosure requirement specific to the context of the doctrine of sound prediction. She quoted from this Court's decision in *Eurocopter*, including paragraph 153 thereof:

> Where the factual basis can be found in scientifically accepted laws or principles or in information forming part of the common general knowledge of the skilled person, then no disclosure of such factual basis may be required in the specification. On the other hand, where the factual basis is reliant on data which does not form part of the common general knowledge, then disclosure in the specification may indeed be required to support a sound prediction.

B. *Small Studies*

[18] Pharmascience also argues that the Trial Judge erred in relying on a series of small studies (identified in the reasons as Flechter 2002, Khan 2008 and Caon 2009, hereinafter the Small Studies) to support the soundness of the prediction in this case, despite the fact that those studies were neither described in the 802 Patent nor part of the common general knowledge of the PSA. These studies explored the administration of 20 mg daily doses vs. 20 mg doses every other day. Pharmascience points to the Trial Judge's clear acknowledgement that the Small Studies were not part of the common general knowledge: see paragraphs 819 and 890 of the reasons. Pharmascience argues that the Trial Judge based her finding of a sound prediction on an erroneous belief that these studies were referred to in the 802 Patent.

[19] Indeed, the Trial Judge does seem to have believed, incorrectly, that the Small Studies were referred to in the 802 Patent: see paragraphs 879 and 890. She noted that these studies are referred to in the "GALA protocol", and seems to have considered this protocol to be synonymous with the "GALA trial" described in the 802 Patent. In fact, the GALA Protocol that refers to the studies in question is a separate, more detailed document that is not available to the public. The 802 Patent does not itself refer to the Small Studies.

[20] Despite this apparent error by the Trial Judge, I am not convinced that it amounts to a reviewable error. The applicability of the Small Studies to the finding of sound prediction is an issue of mixed fact and law to which the standard of review of palpable and overriding error

applies. Even if I accept that the error is palpable (obvious), I am not convinced that it is overriding (going to the very core of the outcome of the case).

[21] I reach this conclusion because the Trial Judge appears to have stated the basis for her finding of a sound prediction of utility at paragraph 885 of her reasons:

> The POSITA would review the '802 Patent and the details of the GALA trial, including its expected results, with the common general knowledge (as noted above to include that 20 mg daily was effective, that 40 mg daily was equally effective (Comi 2008) and that several factors, including injection site reactions, contributed to patient non-adherence), and would accept the logic presented – that 40 mg three times weekly would alleviate symptoms of RRMS (*Eurocopter* at 154-155). A scintilla of utility is all that is required and the POSITA would expect at least a scintilla of utility to treat RRMS based on the logic presented.

[22] This paragraph makes no mention of the Small Studies. It highlights three aspects of the common general knowledge (known 20 mg daily dosing, equally effective 40 mg daily dosing, and the problem of patient non-adherence caused by injection site reactions) as being sufficient to support a sound prediction of utility of the proposed thrice-weekly 40 mg dosing regimen. I see no error in this reasoning, and it is not at all clear to me that the Trial Judge relied on the Small Studies, either in paragraph 885 or elsewhere in the reasons, to support the sound prediction. It is similarly not clear to me that the Trial Judge relied on the other information internal to Teva that was mentioned in the Trial Judge's reasons to support the sound prediction (see paragraphs 877, 898 and 899).

[23] Pharmascience argues that the Trial Judge also erred in the quotation at paragraph 885 in referring to the "logic" presented in the 802 Patent that the proposed lower frequency dosing would alleviate symptoms of RRMS. Pharmascience argues that the 802 Patent includes no such

logic. I disagree. In my view, the concerns expressed therein regarding tolerability, patient adherence and injection reactions with daily dosing (see paragraph 12 above), together with the proposal to study the efficacy and safety of lower frequency dosing, imply a theory that thrice-weekly doses of 40 mg of GA would be successful in alleviating symptoms of RRMS.

C. *Unpredictability of GA Administration*

[24] Pharmascience also points to the statement in the 802 Patent that the complex pharmacokinetic behaviour of GA makes the effect of variation in the frequency of administration unpredictable. Pharmascience argues that this is an acknowledgement that the common general knowledge could not provide a sound prediction of utility in varying the frequency of administration of GA.

[25] I do not read this statement in the 802 Patent as being as conclusive as Pharmascience submits. I read it instead as an acknowledgement of the need for the trial described therein to test the theory that lower frequency dosing will be safe and effective. Moreover, the Trial Judge considered this statement in her reasons: see paragraph 881.

[26] It is also worth noting the following guidance from *Wellcome* at paragraph 77, which was referenced by the Trial Judge at paragraph 862:

> The prerequisites of proof for a manufacturer who wishes to market a new drug are directed to a different purpose than patent law. The former deals with safety and effectiveness. The latter looks at utility, but in the context of inventiveness. The doctrine of sound prediction, in its nature, presupposes that further work remains to be done.

D. *Dearth of Evidence of Inutility*

[27] A final reason that I would be hesitant to interfere with the Trial Judge's conclusion on utility is that Pharmascience adduced no evidence from its own experts on this issue, an issue on which it had the burden of proof. Pharmascience relies principally on the evidence of Teva's experts and their testimony during cross-examination. However, the reports submitted by these experts discussed the issue of obviousness, not utility. Teva's experts were not instructed on the law concerning utility and were never asked directly for their opinions on the issue.

[28] On this point, I note the Trial Judge's statement at paragraph 28 of her reasons that "[i]n some instances, the questions and answers [on cross-examination] were confusing and contrived and have required me to very carefully consider the totality of the expert's extensive evidence." She also stated at paragraph 786 that

> …there are several examples of the parties seeking to extract responses from the experts on specific points to support particular arguments. The arguments based on isolated responses have glossed over the thrust of the evidence. As a result of this approach, I have been required to very carefully review the evidence in its totality to determine if the experts were in fact supporting the particular argument.

E. *Conclusion on Utility*

[29] Pharmascience has not convinced me that the Trial Judge made any reviewable error on the issue of sound prediction and utility.

V. Obviousness

[30] As indicated above, Pharmascience's obviousness argument applies in the alternative that it is not successful in disturbing the Trial Judge's conclusion on sound prediction. Pharmascience argues that the conclusion that the common general knowledge was sufficient to permit a sound prediction that the invention would work should also have led to the conclusion that the invention was at least obvious to try.

[31] Specifically, Pharmascience argues that the Trial Judge erred in her formulation of the test for obviousness by discounting (or ignoring) certain prior art that would not have been located by the PSA in a reasonably diligent search. Pharmascience also argues that the Trial Judge erred in finding that the obviousness argument was based on a mosaic of prior art.

[32] I am not convinced that the Trial Judge improperly discounted or ignored any of the prior art cited by Pharmascience. The Trial Judge understood the law concerning the relevance of prior art that would not be found in a diligent search (see paragraphs 499 to 501 of her reasons, and references therein to *Hospira Healthcare Corporation v. Kennedy Trust for Rheumatology Research*, 2020 FCA 30), and was apparently concerned that, given the difficulty in locating certain prior art, the PSA would not have been led directly and without difficulty to combine these references. This reasoning was not erroneous.

[33] Pharmascience also has not convinced me that the Trial Judge erred in characterizing Pharmascience's application of prior art as mosaicking. The Trial Judge saw a gap between the

common general knowledge and the invention of the 802 Patent, and was not satisfied that any one of the prior art references cited by Pharmascience that was not part of the common general knowledge bridged the gap. The Trial Judge understood that it is possible in an obviousness analysis to combine prior art references that are not part of the common general knowledge, but the party alleging obviousness must establish that the PSA would have thought to combine these references (see paragraphs 502 to 504 of the reasons).

[34] The Trial Judge saw the starting point for assessing obviousness as 20 mg daily dosing of GA, and she noted that the PSA would know that 40 mg had been demonstrated to be as effective as 20 mg (see paragraph 824 of here reasons). However, she rejected the argument that the starting point was 40 mg every other day, per the Pinchasi 2007 reference (PCT Application Publication No. WO 2007/081975).

[35] Pharmascience also argues that the Trial Judge reached inconsistent findings with regard to Pinchasi 2007. Pharmascience notes that the Trial Judge found both that (i) the proposal to study thrice weekly 40 mg dosing of GA described in the 802 Patent was sufficient to support a sound prediction, and (ii) the description and claim in Pinchasi 2007 concerning every other day 40 mg dosing of GA was not sufficient to support an obviousness argument. I find that Pharmascience's argument here lacks merit for two reasons.

[36] First, while Pinchasi 2007 does refer briefly to the idea of trying every other day 40 mg dosing of GA, and includes a claim thereto, it is no more than a mere mention (a "bare suggestion" as it is characterized in paragraph 654 of the Trial Judge's reasons), with no

supporting explanation, discussion or data. As found by the Trial Judge, the focus of Pinchasi 2007 is daily administration, and Pinchasi 2007 did not "teach an every other day administration": see paragraphs 654, 749, and 815 to 817. Moreover, it appears to be common ground that Pinchasi 2007 was not part of the common general knowledge. I see no error in the Trial Judge's reading of Pinchasi 2007.

[37] I disagree with Pharmascience's argument that the disclosure in the 802 Patent concerning thrice-weekly administration is "bare" like the disclosure in Pinchasi 2007. As discussed in paragraphs 21 to 23 above, the factual basis and line of reasoning for the sound prediction of utility in the 802 Patent is provided by the common general knowledge available to the PSA supplemented by the logic presented in the disclosure.

[38] My second reason for rejecting Pharmascience's argument that the Trial Judge's findings on sound prediction and on obviousness were inconsistent is that the legal tests on these issues are distinct and different. There is no necessary inconsistency between the finding, on the one hand, that an idea is sufficiently described in the patent disclosure and the common general knowledge to support a sound prediction that it will be useful (a *prima facie* reasonable inference of utility, *per Eli Lilly Canada Inc. v. Novopharm Limited*, 2010 FCA 197, 85 C.P.R. (4th) 413 at para. 85) and, on the other, that the idea is not sufficiently known in the prior art (including but not limited to the common general knowledge) to lead the PSA directly and without difficulty to the solution taught in the patent. The Trial Judge recognized this distinction at paragraphs 884 and 890 of her reasons, and it was open to her to find enough in the common general knowledge

to support a sound prediction of utility of the invention, but not enough to find the invention obvious.

[39] Another wrinkle is that the relevant date for assessing sound prediction is the filing date of the patent, whereas the relevant date for assessing obviousness is the claim date (in this case, one year earlier than the filing date). In certain circumstances, the common general knowledge could change between these two dates. The PSA could have information sufficient to support a sound prediction that was not available at the time for assessing obviousness.

[40] A final point made by Pharmascience on the issue of obviousness was that several foreign courts have found patents corresponding to the 802 Patent to be invalid for obviousness, and further that a re-examination board of the Canadian Intellectual Property Office (CIPO) concluded that all of the claims of the 802 Patent are likewise invalid for obviousness. Firstly, I note that Pharmascience provides no detailed analysis of any of those decisions. Secondly, there are myriad reasons that this Court is not bound by any of them. As regards the foreign decisions, the law is different, the patents are likely different, and the evidence is surely different. With regard to the re-examination by CIPO, our analysis as an appellate court applying standards of review is necessarily different, and the decision under appeal here is that of the Trial Judge, not that of the re-examination board.

[41] Before concluding on the issue of obviousness, I wish to make two comments on the Trial Judge's reasons. First, she observed several times (see paragraphs 625, 813, 815 and 817) that Pinchasi 2007 was an unapproved patent application. At paragraph 813, she even stated, "if

the POSITA did turn up Pinchasi 2007, the POSITA would assess its teachings based on the fact that it was simply an application that was not approved." These references should not be understood to mean that whether a prior art patent has issued is relevant to its citability on the issue of obviousness. Generally speaking, that would be wrong. However, this does not amount to a reviewable error since the Trial Judge accepted expert evidence that, in this case, the PSA would not have looked for unapproved patent applications: see paragraphs 749 and 813 of the reasons. She was entitled to accept such evidence, and to discount the obviousness argument based on Pinchasi 2007 on that basis.

[42] My second concluding comment on the issue of obviousness concerns the Trial Judge's description of the test for obviousness at paragraphs 494 and following of her reasons. She referred to the well-known test as set out by the Supreme Court of Canada in *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61, [2008] 3 S.C.R. 265 at para. 67 (*Sanofi*):

> (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?

[43] The Trial Judge then stated that the fourth step is referred to as the "obvious to try" test.

[44] It is not quite correct to identify the fourth step in the *Sanofi* obviousness test as the "obvious to try" test. This step does not always involve an assessment of whether the invention was obvious to try. As stated in *Sanofi* at paragraph 68, an "obvious to try" test may be appropriate "[i]n areas of endeavour where advances are often won by experimentation" because of "numerous interrelated variables". However, "obviousness to try" is not really a consideration in cases where experimentation is unnecessary. Having said this, an "obvious to try" test does seem to be appropriate in the present case because it concerns biological responses to certain therapeutic approaches.

VI. Conclusion

[45] I would dismiss the appeal with costs.

"George R. Locke"
J.A.

"I agree
David Stratas J.A."

"I agree
K.A. Siobhan Monaghan J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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