Federal Court  Cour fédérale

Date: 20210112

Docket: T-396-13

Citation: 2021 FC 42

BETWEEN:

HOSPIRA HEALTHCARE CORPORATION

Plaintiff

and

THE KENNEDY TRUST FOR RHEUMATOLOGY RESEARCH

Defendant

AND BETWEEN:

THE KENNEDY TRUST FOR RHEUMATOLOGY RESEARCH, JANSSEN BIOTECH, INC., JANSSEN INC., CILAG GmbH INTERNATIONAL and CILAG AG

Plaintiffs by Counterclaim

and

HOSPIRA HEALTHCARE CORPORATION, CELLTRION HEALTHCARE CO., LTD., CELLTRION, INC., PFIZER CANADA INC. and PFIZER CANADA ULC

Defendants to the Counterclaim

REASONS FOR JUDGMENT
(Reconsideration)

PHELAN J.

I. Introduction

[1] These are the reasons flowing from the Court of Appeal's instruction to reconsider two issues and three specific documents "in light of" the Court of Appeal's reasons in *Hospira Healthcare Corporation v Kennedy Trust for Rheumatology Research*, 2020 FCA 30 [FCA Reasons] at para 116.

[2] More specifically, the Federal Court of Appeal [FCA] directed a Reconsideration of the issues of anticipation and obviousness/obvious to try in light of its comments on the 630 Patent [Patent] – the irrelevancy of the "special advantage" – and in the context of three specific documents which the Federal Court had held were not discoverable by a reasonably diligent search.

[3] The issues relate solely to aspects of the validity of the Patent. The FCA upheld the Court's infringement findings and these are not in issue.

II. Reconsideration

A. *Preliminary*

[4] The facts involving this invention and the Patent are set out in the Federal Court's reasons (*Hospira Healthcare Corporation v Kennedy Trust for Rheumatology Research*, 2018 FC 259). They need not be repeated here. There was no finding that the Federal Court made a "palpable and overriding error of fact".

[5] The scope of the Reconsideration as well as the Reconsideration results were significantly at issue between the parties.

[6] The Plaintiff [Pfizer] continues to take the view that everyone (at least those relevant) knew about the invention. In this Reconsideration the burden remains with Pfizer to establish that the Patent was anticipated and/or obvious/obvious to try despite the common general knowledge that pointed away from what the invention established.

[7] In the Reconsideration, Pfizer says that not only the specific issues and documents identified by the FCA are to be reconsidered but that issues such as credibility of witnesses and the definition of the person of ordinary skill in the art [POSITA] can be reviewed despite no finding of error found by the FCA.

[8] The Defendant [Janssen], on the other hand, takes a more narrow view of this Reconsideration noting that, while the FCA had certain comments on the facts, some of which

were impressionistic, it made no findings of error of fact and that except for the specific issues and documents raised by the FCA, all other matters are *res judicata*.

[9] The Court recognizes the concerns raised by the FCA and bears them in mind. This Court's approach is to take into consideration the letter of the FCA Reasons as well as giving those words a fair and liberal interpretation consistent with the FCA Reasons.

[10] This Reconsideration is tinged with the same problem as at trial – an excessive amount of hindsight wisdom. Things known today are cast as known or knowable in the 1990s despite the fact that, at the time, biologics and the type of invention in the Patent were at the cutting edge of the "art".

[11] The first task of this Court is to consider the scope of the Reconsideration.

B. *Scope of Reconsideration*

[12] As held in *Corlac Inc v Weatherford Canada Ltd*, 2012 FCA 261 at para 19, the first task of this Court is to determine the scope of the Reconsideration. Where the FCA has directed this Court on law – as in the case of what is "publicly available" – this Court is obvious bound by that law. Likewise, where the FCA clearly directs on a matter of fact, this Court must accept the fact. Where the FCA wishes to make such a direction, it does so specifically and clearly – it is not up to the parties or this Court to guess nor would the FCA intend such a result. That principle is well set forth in the "Rainbow Industrial" cases where the "overturning" facts found must be clear and demonstrable (*Rainbow Industrial Caterers Ltd v Canadian National Railway*, [1988]

BCJ No 1710; *Rainbow Industrial Caterers Ltd v Canadian National Railway*, [1990] BCJ No 3044; *Rainbow Industrial Caterers Ltd v Canadian National Railway*, 1991 SCC 27).

[13] Where the FCA found error, it made the point clearly – see FCA Reasons, para 73 dealing with anticipation. On the other hand, the FCA made itself likewise clear in accepting the Federal Court's conclusion on the POSITA but commented on concerns it had if some of the Federal Court's comments were taken too far in future cases (see FCA Reasons, para 77).

[14] The claims at issue in this litigation have been narrowed by the FCA. In respect of independent claims, they are claims 1, 2, 17, 18 and 39-42 and dependent claims 3, 5, 6, 9, 10, 19, 21, 22, 25, 26 and 33. Claims 37 and 38 are not at issue nor were claims 12, 15, 28 and 31 found to have been infringed.

C. *FCA Decision*

[15] The FCA identified three specific matters to be reconsidered:

- Anticipation: with respect to disclosure, the FCA was not clear from this Court's Reasons how the *1994 Kennedy Report ['94 Kennedy]* and the *Higgins* publication [*Higgins*] did not satisfy the disclosure requirement. Further, the FCA held that it was unclear how the principle of enablement was not satisfied (FCA Reasons, para 73).
- Obviousness: the FCA held that *Higgins* and the *FDA Workshop* were to be considered part of the prior art and should not have been excluded in step 3 of the obvious analysis (FCA Reasons, para 87).

- Obvious to Try: the FCA commented that certain prior art references appear to suggest it was more or less self-evident to try the invention. In its view, it was not clear that the Federal Court properly considered the issue. The FCA accepted the Federal Court's conclusion on the first *Sanofi* factor that it was not self-evident that the combination of anti-TNF and MTX would work to solve the problem identified in the prior art (FCA Reasons, paras 92, 93 and 95).

[16] These conclusions set the scope of the Reconsideration. The context in which these issues arose include the exclusion of the "special advantage, and the finding of a specific result or test as an essential element". They are driven by the finding that certain documents (*'94 Kennedy*, *Higgins*) were wrongly excluded from consideration because the test for prior art is not whether the art was reasonably discoverable, as had been the understanding in multiple Federal Court decisions, but whether the art existed at the relevant time. The FCA also held that the failure to consider the *FDA Workshop* was in error because despite the nature of the attendees (principally highly expert rheumatologists), a POSITA would be in attendance.

D. *Person of Ordinary Skill in the Art (POSITA)*

[17] Pfizer argues that, in effect, the FCA has changed the POSITA from that described by the Federal Court. Pfizer says that the FCA was critical of the Federal Court's description of the POSITA as "neither first nor last in their class". From that, Pfizer says that FCA's reference at its para 87 in respect of the *FDA Workshop* – "Rheumatologists, even the world's top rheumatologists would include the PSA" - means that the POSITA are the highly qualified

extraordinary rheumatologists like Dr. Tugwell. Pfizer further uses Tugwell's expert evidence as being that of a POSITA.

[18] I cannot agree that the FCA altered the definition and composition of the POSITA. Most specifically, the FCA held at para 77:

> I see no reviewable error in the Judge's analysis of the notional "person skilled in the art": see Reasons at paras. 58-80. Though the appellants take issue with many aspects of the Judge's analysis on this issue, I see nothing that rises to the level of an error of law or a palpable and overriding error of fact or of mixed fact and law.

[19] The FCA further elaborated its concurrence with the Trial Reasons at para 79:

> I agree with the Judge's reference to the well-known statement by this Court in *Beloit Canada Ltd. v. Valmet Oy*, [1986] F.C.J. No. 87, 8 C.P.R. (3d) 289 at 294 (F.C.A.) that the classical touchstone for obviousness is the technician skilled in the art but having no scintilla of inventiveness or imagination; a paragon of deduction and dexterity, wholly devoid of intuition; a triumph of the left hemisphere over the right.

[20] Pfizer has taken excessive comfort from the FCA comment on the Trial Reasons' statement as to the POSITA being in the middle of the class. The FCA's comment is at para 80:

> The statement that the PSA is neither first nor last in her class is reasonable to indicate that the PSA has certain qualities of a competent technician (deduction and dexterity), but lacks others (inventiveness and imagination). However, the statement is problematic if it is read to suggest that those at the top of their class are inventive while those at the bottom are not. In fact, the quality of inventiveness is not tied to class rank. Rather, it concerns the ability to look at a problem in a way that would not be obvious to others in their field. An inventive person may be at the bottom of the class, and a person at the top of the class may not be inventive. The same may be said of experts. Highly specialized practitioners may be leaders in their field, but may not be

> inventive. Conversely, inventiveness may manifest in persons with limited expertise.

[21] This comment does not change the composition of a notional POSITA as described in *Whirlpool Corp v Camco Inc*, 2000 SCC 67 at para 69, particularly with respect to "obviousness". Nor should the comment be taken as the FCA resiling its adoption of the Trial Decision's conclusion as to the composition of a POSITA.

[22] The Trial Decision's reference to class placement was an effort to contextualize the theoretical POSITA much as in tort law where courts have used the "man on the Clapham omnibus" to underscore ordinariness.

[23] The FCA's comment on para 80 emphasizes that the POSITA is not only ordinary but also uninventive. The comment underscores that even the highly specialized persons like those at the *FDA Workshop* may be uninventive at the level of a POSITA.

[24] The uninventiveness aspect of a POSITA is germane in this case where the invention was cutting edge, unprecedented and ran contrary to much of the established "wisdom".

[25] Therefore, the FCA's comments do not alter the POSITA nor transform Tugwell into a POSITA. Pfizer's attempt to resurrect Tugwell's credibility is not persuasive.

[26] The FCA made no adverse finding with respect to this Court's credibility findings or the weight attributed to the witnesses, including the experts.

[27] The Trial Decision made it clear that Tugwell's evidence was not overly persuasive, particularly with respect to the POSITA but also in many other areas. It is evident from this Court's Reasons that other expert witnesses were more persuasive and their evidence was more readily accepted than Tugwell's.

[28] A court, when indicating that it has reservations about a witness' evidence, does not have to savage the witness' standing, reputation or expertise. The Court has indicated, both in comments and in non-acceptance of his opinions, that the Court had reservations about Tugwell's evidence and the weight to be given it. Nothing in this Reconsideration varied the weight and credibility given to that trial evidence.

E. *Anticipation*

(1) General

[29] Anticipation is one of the two validity issues referred back to this Court in the following terms:

> [75] In my view, the Judge's apparent errors discussed in this section would best be addressed by having the Federal Court reconsider the 1994 Kennedy Report and Higgins as allegedly anticipating prior art references.

[30] It is important to recognize the areas of concern to the FCA. These are:

- the rejection of *'94 Kennedy* and *Higgins* on grounds of speculation particularly where the basis for distinguishing from the prior art was not based on essential elements (paras 70-72).

- the analysis of *'94 Kennedy* and *Higgins* does not address the two requirements (disclosure and enablement) distinctly – particularly in respect of enablement (paras. 73-74).

[31] While Pfizer says that the FCA reopened all aspects of the anticipation issue, that position is inconsistent with the specific direction at para 75 and the general direction at para 116 to conduct the Reconsideration "in light of these reasons".

(2) Principles

[32] The basic principles of anticipation are described in *Apotex Inc v Sanofi-Synthelabo Canada Inc*, 2008 SCC 61 [*Sanofi*]:

- the prior art reference must disclose the claimed invention such that, if performed, it would result in infringement; and
- the prior art reference must be sufficiently detailed to enable a POSITA to perform the claimed invention without the exercise of inventive ingenuity or undue experimentation.

[33] In *Free World Trust v Électro Santé Inc*, 2000 SCC 66 [*Free World Trust*], the Supreme Court held that the publication must clearly and unmistakeably direct the reader to use the information to produce what the patentee claims to have invented – a signpost will not suffice.

[34] *Sanofi* builds on this so as to require the information to practise the patent be contained in a single publication. In respect of enablement, as referred to in para 33 of that decision, the

POSITA must be able to work the invention based on this level of disclosure. While some routine testing is allowed at the enablement stage, there can be no undue burden.

[35] The analysis requires the disclosure of all the essential elements (*Beloit Canada Ltd v Valmet OY* (1986), 8 CPR (3d) 289 (FCA) [*Beloit*]). As held in *Bell Helicopter Textron Canada Limitée v Eurocopter*, 2013 FCA 219, if one element is missing, anticipation is not made out.

[36] As to the disclosure, as held by the Supreme Court of Canada in *Hoechst v Halocarbon (Ontario) Ltd et al*, [1979] 2 SCR 929, the publication must provide the same knowledge as the patent or "clear and unmistakeable directions".

[37] With these governing principles, the Court must turn to each of the publications separately.

(3) Disclosure

[38] As indicated, the anticipation analysis is addressed on a claim-by-claim basis as held by the FCA in reference to s 28.2(1) of the *Patent Act*, RSC 1985, c. P-4. The FCA accepted this Court's claim construction and noted that there was no serious dispute by the parties as to the essential elements of each claim as set out in Appendix B of the Trial Decision.

[39] One of the essential elements germane to this analysis and common to the independent claims 12 and 17/18 and their dependent claims as well as claims 39-42 is the patient group to receive the drug. They are described in both the independent and dependent claims as "on a

patient with active RA whose disease is incompletely controlled despite already receiving MTX". In claims 39-42 the group is described as "… an adult patient with moderately to severe RA whose active disease is incompletely controlled despite already receiving MTX".

These patients have been called "MTX incomplete responders" or "MTX IR". No party has made an issue of the slight difference in description.

[40] Another essential element of the independent and dependant claims is the purpose provision - "to reduce or eliminate the signs and symptoms of RA" and in claims 39-42 - "for the reduction in signs and symptoms, inhibition of the progression of structural damage or improving physical function".

[41] As held in *Bauer Hockey Ltd v Sport Maska Inc (CCM Hockey)*, 2020 FC 624, for disclosure the prior art reference must contain all of the essential elements of the allegedly anticipated patent claim.

> [117] First, "the requirement of prior disclosure means that the prior patent must disclose subject matter which, if performed, would necessarily result in infringement of that patent:" *Sanofi*, at paragraph 25. In other words, the prior patent or other form of prior art must contain all the essential elements of the patent claim that is anticipated.

(4) *1994 Kennedy Report*

[42] Pfizer's position is that this publication discloses all the essential elements. In essence, Pfizer says that one of the inventors prematurely disclosed the patent. Such things happen sometimes. But it would be unusual for people, as knowledgeable about the importance of the subject matter, to prematurely disclose the invention.

[43] However, the issue is whether a POSITA would read this publication and know he had the invention. *'94 Kennedy* is not a complete endorsement of the discovery. It refers to concerns about the adverse consequences of HACA and it refers to ongoing further tests whose results were expected in 1995. These uncertainties must be considered in the context of the novelty of treatment, the existing art pointing away from the invention and the history of failed DMARDs.

[44] Despite Tugwell's opinion, years later, that all the essential elements were disclosed, *'94 Kennedy* does not disclose the patient group as MTX IR. *'94 Kennedy* also does not disclose that the combination works – that it reduces rheumatoid arthritis [RA] symptoms.

[45] Unlike *Higgins* which refers to MTX IR (though not in the context of infliximab), *'94* Kennedy merely refers to "patients". This essential element cannot just be read in from a reference that, at a trial, patients were being given a low dose of MTX or placebo. There is no compelling evidence that a POSITA would make this type of deduction.

[46] A further difficulty with *'94 Kennedy* is the failure to address the essential element of the reduction or elimination of RA or its symptoms. To refer to the combination being used for the reduction of symptoms, there must be confirmation that it does so.

[47] As held in *Apotex Inc v Wellcome Foundation Ltd,* 2002 SCC 77 at para 52, there must be evidence of some utility. Pfizer takes the position that all that needs to be done is to inject or infuse a patient – something requiring little skill.

[48] Although Janssen's witnesses were erroneously instructed on the need for special advantage, their evidence, particularly that of Schiff, on what a POSITA would know or understand is preferred over Pfizer's witnesses. A POSITA would need to know that it works. Pfizer has not explained how this would be accomplished. It had the burden to do so in making its case on anticipation.

[49] Pfizer says that Janssen's witness Pisetsky admitted that *'94 Kennedy* did disclose the essential elements of the invention. A review of the transcript and the observation of the questioning and answers does not give the Court sufficient confidence that that is what the witness meant. It is unfair to ascribe that meaning to the evidence either specifically or taken as a whole. It is clear that Pisetsky was not resiling from his opinion.

[50] In reviewing *'94 Kennedy* and the monotherapy trials described, Pisetsky found that the descriptions did not disclose or enable the claimed invention:

> 12. In each of the documents, Section 1 relates to experimental therapeutic interventions in arthritis. After discussing the monotherapy trials, the authors note:
>
> > Taken together, these 2 studies clearly demonstrate that TNF blockade is effective in the short-term suppression of inflammation in RA, but that long-term disease suppression, requiring repeated administration of the antibody may present new problems. In order to study this further, a new clinical trial has been set up, once again in collaboration with our European partners. In this trial, patients taking a stable low dose of methotrexate (or placebo tablets) have their treatment supplemented with regular, monthly infusions of cA2 (or placebo) for a period of up to 5 months. The aim is to further investigate the tolerability and efficacy of repeated use of cA2 in a randomised, blinded fashion, both in comparison

> with standard therapy (methotrexate) and in combination with this drug. It is expected that the results will be available by autumn 1995 and should provide an indication of the likely utility of cA2 as a long-term disease suppressing agent in clinical practice.
>
> 13. These references note the fact that a trial is ongoing. The details of the trial are not described, including the dosages of either drug used. The trial hypothesis is not described, other than the possibility of whether it might provide an indication of the use of infliximab as a long term-disease [*sic*] suppressing agent. It cannot even be determined whether this is a two-arm or a three-arm study. There are, of course, no results provided. In my opinion, this reference does not disclose or enable the claimed invention of the 630 Patent.

[51] The Court had found Pisetsky to be a reliable and helpful witness. His opinion is consistent with that of other evidence found by the Court.

[52] While *'94 Kennedy* discloses some of the essential elements of the claims at issue, it does not disclose all of the essential elements. Importantly, a POSITA, with their limitations in the context of a developing area, would not have understood that *'94 Kennedy* disclosed the invention and how to work it.

[53] The uncertainty in *'94 Kennedy* referred to earlier and the matter of awaiting test results gave no assurance to a POSITA.

[54] Pfizer incorrectly contends that the FCA held that no results were necessary – that a simple injection or infusion was sufficient. However, the FCA did not go that far. While it held

that specific results or experiments were not an essential element, it did hold that a POSITA would have to observe results.

> [94] … It would be enough for the PSA to co-administer an anti-TNF-α antibody and MTX as claimed and observe the results. It would not be necessary for any such experiment to pass muster with regulatory authorities.

[55] *'94 Kennedy* fails to address disclosure in the context of knowledge that the combination works, potentially either through tests (which was what was being done at the time) or by way of sound prediction.

[56] In respect of *'94 Kennedy*, the Court cannot conclude that Pfizer has succeeded in making out its case of anticipatory disclosure.

[57] Moreover, Pfizer's position on anticipatory disclosure requires that one piece of prior art (*'94 Kennedy*) should be read in conjunction with a second piece of prior art (*Elliott*) which is cited in the first. This is an erroneous approach to anticipation as it conflates anticipation and obviousness.

[58] With respect to anticipation, *Free World Trust* adopted the classic statement from *Beloit* at para 29:

> One must, in effect, be able to look at a single publication and find in it all information, which, for practical purposes, is needed to produce the claimed invention without the exercise of inventive skill. The prior publication must contain so clear a direction that a skilled person reading and following it would in every case and without possibility of error be led to the claimed invention.
>
> (Emphasis added)

[59] Given *Beloit*'s reference to a single publication, the approach to refer to a second or more publications violates this teaching. Taken to its logical limits, mosaicking multiple other publication references within a single piece of art could be anticipatory.

[60] In making the case for anticipatory disclosure, Pfizer relies most particularly on Tugwell and Strand. The Court has already discussed the weight given to Tugwell in these Reasons as well as in the Trial Decision. In the Trial Decision, the Court was clear in its rejection of Strand on credibility grounds.

(5) *Higgins*

[61] The *Higgins* In Pharma Bulletin mentions the mere possibility of combining CPD-571 (another anti-TNF-α antibody) with MTX but does not mention the possibility of combining infliximab with MTX, and this is an essential element of and specific to claims 5, 6, 10,12, 15, 21, 22, 26, 28, 31 and 33.

[62] Pfizer, in its argument, refers specifically to dosing in respect of *Higgins*; however, *Higgins* (nor *'94 Kennedy*) disclose the dose or dosing regimen for the TNF-α inhibiting antibody (or infliximab specifically) which are essential elements of claims 9, 10, 12, 25, 26, 28 and 33.

[63] There is a clear conflict between the experts on the POSITA's understanding of *Higgins* – as there was regarding *'94 Kennedy*. In this Reconsideration, Pfizer relies heavily on Tugwell (Strand's evidence has been rejected on credibility grounds). Pfizer correctly points out that Janssen's experts focused on the "special advantage" of the Patent – a concept that embraced

more than the essential elements but included them. The Court has previously dealt with the so-called “Pisetsky admission”.

[64] However, even with this limitation on Janssen’s experts, the Court prefers the evidence of Janssen’s experts, particularly Schiff, regarding what a POSITA would take from the *Higgins* publication. A POSITA would not conclude that one should combine CA_2 with MTX but that such a combination was merely a possibility. The references to two trials in *Elliott* and a future trial about the possibility of combining CDP-571 and MTX in RA patients does not teach the relevant claims in the Patent, including claims 1, 2, 6, 17, 18, 22 and 39-42 as asserted by Pfizer. Pfizer seems to concede that *Higgins* does not disclose a combination of infliximab and MTX or the dose or dosing schedules and therefore does not anticipate claims 5, 6, 9, 10, 12, 15, 21, 22, 25, 26, 28, 31 and 33.

[65] In summary, the Appeal Decision at paragraph 66 states that one of the requirements for establishing anticipation is that the “prior art references must disclose the claimed invention such that if performed, it would necessarily result in infringement”. The weight of the evidence shows that a POSITA following *'94 Kennedy* or *Higgins* would not necessarily result in infringement. The publications do not disclose that a) the claimed combination should be given to a MTX IR; b) the claimed dose or dosing regimen; c) infliximab could be used; and d) a reduction of signs and symptoms of RA could be observed. These essential elements are not disclosed. A POSITA could not simply follow these publications and thereby infringe the claims in the Patent.

[66] As held in *AstraZeneca Canada Inc v Apotex Inc*, 2017 SCC 36, until all of the essential elements are present, there is no invention. For anticipatory disclosure, the invention – all essential elements – must be disclosed. Partial disclosure, statements of ideas or possibilities are not sufficient.

[67] Lastly, to close the claim 33 debate in *'94 Kennedy*, only the 100 mg dosage form is disclosed in *Elliott* and *Elliott* cannot be read with *'94 Kennedy*, as discussed above.

F. *Enablement*

[68] The FCA also requires this Court to consider enablement, particularly in the context of the two publications. Per *Free World Trust*, the test for enablement, as with sufficiency, is whether the POSITA would be able to perform the relevant claims. In so doing, a limited trial and error experiment is permitted.

[69] The law of enablement is summarized in *Sanofi* at para 37:

> [37] Drawing from this jurisprudence, I am of the opinion that the following factors should normally be considered. The list is not exhaustive. The factors will apply in accordance with the evidence in each case.
>
> 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.
>
> (Emphasis added)

[70] Pfizer's position is that a) dosing is not claimed or required; or b) if it was, Tugwell says a POSITA could do it. More importantly, Pfizer's argument ultimately is that the relevant skill required of the POSITA is the ability to inject or infuse the patient with the combination. There is no doubt from the evidence that the ordinary, unimaginative POSITA could inject or infuse a patient.

[71] However, this position of Pfizer cannot be sustained on either the facts, the claims or the law.

[72] The relevant claims speak in terms of the combination being used to reduce or eliminate the signs or symptoms of RA. At para 94 of its Reasons, in discussing obviousness and the issue of the design and conduct of experiments, the FCA held that:

> It would be enough for the PSA to co-administer an anti-TNF-α antibody and MTX as claimed and observe the results.
>
> (Emphasis added)

[73] The results to be observed must be the results of the injection/infusion to determine whether the co-administration is working as it should. The FCA held that no specific result had to be obtained, it did not hold that no result would be satisfactory. The result referred to in the claims is the effect on the signs or symptoms of RA. The question of regulatory compliance is irrelevant.

[74] As noted earlier, *'94 Kennedy* and *Higgins* disclose an idea. On the issue of how a POSITA would observe the results of the combination injection/infusion, the publications are silent. The common general knowledge is likewise silent.

[75] From the POSITA's perspective, at the time, the injection/infusion of a biologic was risky. Schiff, whose evidence with respect to what a POSITA knew and would do this Court accepts, stated that outside clinical trials, using biologics was not done. Consequently, combining MTX with a biologic was risky and something not done by a POSITA. Even Tugwell in cross-examination conceded as much.

[76] In the context of the times where there were no biologics approved for RA, numerous failures of treatment, and against a backdrop of a history of risk and uncertainty of DMARDS, there is no evidence to suggest that a POSITA would administer the combination outside a clinical trial or that "observing the results" would be routine. The weight of the evidence suggests that a clinical trial would be necessary and that simply infusing/injecting a patient without some further steps would not occur.

[77] There is nothing to suggest there is anything routine in this enablement. A clinical trial for an unapproved drug is not a simple matter. As the Supreme Court found in *Sanofi*, needing to conduct multiple conventional isomer separation methods was an undue burden.

[78] As this Court found in respect of the *Moreland* and *Bologna* publications, the work necessary for enablement is not routine. The same can be said for *'94 Kennedy* and *Higgins*.

[79] Therefore, upon reconsideration as directed, this Court must conclude that as with disclosure, Pfizer has not met the burden of enablement.

[80] In conclusion on this issue of anticipation, the position of Pfizer cannot be sustained.

G. *Obviousness*

[81] The FCA also referred back for reconsideration part of the obviousness issue, including aspects of the "obvious to try" issue. Most specifically, the FCA held that *Higgins* and the *FDA Workshop* should have been included in Step 3 of the *Sanofi* analysis framework as part of the

"state of the art". It is only these documents that were to be the subject of the obviousness reconsideration.

The FCA also directed a clearer analysis of steps in the "obvious to try" analysis.

[82] The FCA confirmed this Court's legal tests and the analysis it performed so far as it went including Steps 1 and 2 of *Sanofi*. The 4 step *Sanofi* obvious test is:

1. identify the POSITA and the common general knowledge;
2. identify or construe the inventive concept of the claim at issue;
3. identify the differences between the state of the art and the inventive concept; and
4. determine whether, without any knowledge of the alleged invention as claimed, those differences would have been obvious to the POSITA or whether they required any degree of invention.

[83] Within the *Sanofi* framework, "obvious to try" arises at the fourth step and involves three factors:

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 the trials would not be considered routine?
3. Is there a motive provided in the prior art to find the solution the patent addresses?

[84] The FCA made no obviousness finding with respect to *Higgins* or the *FDA Workshop* except that they ought to have been considered as part of the state of the art.

[85] The FCA's direction with respect to the *FDA Workshop* contained a notable assumption as to the content of the *FDA Workshop*, presumably on the basis of submissions made:

> [87] … Though the Judge did not discuss the content of the FDA Workshop, the appellants assert that it disclosed the following: (1) MTX was widely used in the treatment of RA; (2) any new biologic would be taken with MTX; (3) evaluation of a new biologic would have to be done in MTX IRs because it would be unethical to remove patients from MTX; and (4) therapeutic antibodies should be tested with MTX because of MTX's ability to reduce the immunogenic response to the antibodies, i.e. HACA. Though it is more appropriate that the Judge consider issues of obviousness, this information, if true, appears to be significant enough to warrant substantial consideration.

The straightforward answer to this assumption is that the said disclosure is not accurate.

[86] Turning to the Reconsideration of Step 3 of *Sanofi* in respect of *Higgins*, the limits on *Higgins* have been discussed under Anticipation. In summary, *Higgins'* limitations include only the possibility of using a biologic; infliximab is not specifically identified but was known; MTX is not taught, nor MTX IR; nor the reduction of symptoms of RA; nor the combination and dosing. It advances the idea of a trial without an assurance of a result.

[87] In terms of obviousness, *Higgins* was not a document that would have been read by a POSITA. The experts did not, on their own, refer to *Higgins* – in fact the document surfaced through a search by a lawyer and was given to Strand. While there is nothing untoward in counsel searching for documents and providing them to an expert, it runs counter to an obviousness argument if virtually no one knew of the document.

(1) *FDA Workshop*

[88] The *FDA Workshop* in March 1996 was attended by expert rheumatologists and the FCA has concluded that these attendees would include POSITAs. There were 75-100 top rheumatologists and trialists present, all closely aligned with the pharmaceutical industry. The question is whether a POSITA attending this Workshop or coming upon the transcript of the Workshop would then conclude that the path to the invention was obvious. Pfizer's experts, some of whom attended, say that it is obvious, but they do so from hindsight. There is no evidence that any attendee, at the time or thereafter until this litigation, claimed that the invention had all been obvious from the Workshop nor is there evidence that anyone went further to try to create the invention on the basis of the Workshop. There is an absence of corroboration that the Workshop made the invention obvious to a POSITA.

[89] A fair reading of the whole of the Workshop transcript and the context of the Workshop is that it was informed high-level discussion and professional "brain storming", much of it speculative. There was no consensus arising from the discussion and no one person put forward the type of detail to show that the invention was obvious.

[90] Pfizer relies upon disparate quotes to create a tapestry of obviousness. There is no evidence that a POSITA would take from these comments laced through the transcript, that the way forward was obvious. It bears repeating that the POSITA is uninventive – not a person who can look at a problem differently from others. What is being asked of the POSITA by Pfizer is to

look at a new risky area and stitch together from comments in the *FDA Workshop*, a new solution.

[91] As argued by Janssen, the type of information with which the FCA was concerned might have been present but was not. Janssen accurately points out the problems that this mosaicking raises and provides examples.

> 85. For example, the FCA was led to believe that the *FDA Workshop* disclosed "(4) therapeutic antibodies should be tested with MTX because of MTX's ability to reduce the immunogenic response to the antibodies, i.e. HACA." However, as stated in the *FDA Workshop* transcript, it was unknown whether immunogenetic responses would be a problem and, if so, what the impact of any concomitant medications, MTX or others, would be: "In addition, if, in fact, this turns out to be a problem in a fraction of patients … it would be appropriate to have some information about … whether or not the administration of concomitant meds., such as methotrexate or other immunosuppressive agents, have any impact on the formation of bioactivity neutralizing antibodies".
>
> 86. The statement that this information should be collected in the future shows the opposite of the supposed disclosure noted by the FCA – the world's top rheumatologists did not know the answer; they were still asking questions. As Dr. Tugwell fairly conceded, whether MTX would have any effect on immunoglobulin response for a new biologic was "not known" at that time.
>
> 87. Similarly, contrary to supposed disclosures (2) and (3) noted by the FCA, even Dr. Strand at the *FDA Workshop* meeting was uncertain as to whether new agents would be compared with MTX or superimposed on MTX:
>
> > I think the two important points that have come up in the recent discussion are, one, the business about combination therapy and the fact that very likely we are going to take a new agent and compare it to the current agent, methotrexate, or are we going to superimpose the new agent on the background

> therapy, which would now include methotrexate as well as plus/minus steroids and nonsteroidals?
>
> (Memorandum of Fact and Law of the Defendant/Plaintiffs by Counterclaim; footnotes omitted)

[92] It was incumbent on Pfizer to show that it was obvious to connect the so-called dots of information. It has not done so except in hindsight. The weight of the evidence is that an ordinary/uninventive POSITA would not likely connect the dots when so much evidence pointed away from the path to the invention.

> Two fusion proteins against different TNFα receptors, lenercept (against the p55 receptor) and etanercept (against the p75 receptor), were in clinical trials, with differing results. I was personally involved in the development of etanercept, which successfully made it through clinical trials and eventually obtained approval as a monotherapy for RA in 1998. It was the first approved biologic therapy for RA and is still widely used and well-known under the trade name Enbrel.

[93] The concept of combining new biologics with MTX ran contrary to the prevailing goal of monotherapy. The *FDA Workshop* did not disclose the concept of combination and any discussion of the subject is speculative and not obvious.

[94] The difference between the invention and the prior art was not clear. All of the publications in evidence, even with the inclusion of *Higgins* and the *FDA Workshop*, did not point to a clear path. There were a myriad of drugs being tested, such as TNC, as a cytokine. The number of potential combinations was significantly large. The history of failures meant the benefits of combining biologics and DMARDs was not predictable without trials – a role this Court found a POSITA would not engage in.

[95] The gaps in the state of the art and the invention have been filled in by impermissible hindsight. Knowledge and actions must be assessed against the relevant timeframe (1996 largely).

[96] Therefore, taking into account *Higgins* and the *FDA Workshop*, the prior art does not render the invention obvious. The assumed conditions which the FCA referenced to be examined by this Court did not exist.

H. *Obvious to Try*

[97] The FCA, in confirming this Court's application of the first *Sanofi* factor – namely that it was not self-evident that the combination of anti-TNF-α and MTX would work – held that this factor was not determinative. This Court's consideration of the other factors, particularly the second factor (effort required), as expressed in the FCA's Reasons, was not adequate.

(1) Factor 1 – Self-evident

[98] As directed by the FCA, this Court has considered *Higgins* and the *FDA Workshop* and, as indicated earlier in these Reasons, the prior art references do not disclose that it was more or less self-evident to try to obtain the invention, including co-administration of an anti-TNF-α antibody and MTX to treat RA in MTX IRs.

[99] The addition of *Higgins* and the *FDA Workshop* did not affect the conclusion on Step 1 as they are, in effect, two more references speculating as to what could be done without any

reasonable assurance that the invention would work particularly against a backdrop of multiple failures.

This factor does not favour obvious to try.

(2) Factor 2 – Nature, extent and amount of effort to achieve the invention

[100] As held in *Janssen Inc v Teva Canada* Ltd, 2020 FC 593 at para 205 [*Janssen*], this factor requires an assessment of what would be needed to achieve the invention. As held in *Sanofi* at paras 89 and 91, the Court is to look at what steps are required to achieve the invention, not just the last step.

[101] As held in *Janssen* above, the examination of the 4th Factor – the actual course of conduct – is related to this 2nd Factor. The nature of the inquiry is on what it would take to achieve the Patent not just on how to practice it (injection or infusion).

[102] Relevant to this issue, this Court found, and those findings have not been overturned, that the trials to get to the Patent were not routine; that the common general knowledge did not create an expectation of certainty in using a biologic; and that there was no consensus on combination therapy particularly in respect of a biologic. It found that it was not more or less obvious to co-administer a biologic with MTX.

[103] The experts such as Schiff and Rubin testified that to achieve the invention, a POSITA would need to know that the combination was effective in reducing or eliminating the signs of RA.

[104] This Court found that the design and running of clinical trials to establish the efficacy of the combination would likely have been prolonged and difficult. This is not a case where there is an established, simple test or a surrogate measurement criteria such as a PSA score.

[105] The Court dealt earlier with Pfizer's argument that all a POSITA had to do was inject/infuse the patient with the combination. The result could be either it worked or not – there was no assurance at the time that it would. As Schiff indicated, no POSITA would rely on a one-person result. There is no evidence to suggest a single patient result would be sufficient.

[106] The necessary testing may not have been as much as the T-14 trial but it had to be more than Kavanagh. Pfizer has not shown what it had to be.

[107] On this factor, the evidence is that the nature, extent and effort required to achieve the invention would not be simple and routine but prolonged and difficult as well as uncertain. If the achievement was so simple that a POSITA could do it, none of the attendees at the *FDA Workshop* or anyone else took the path that the inventors did.

This factor does not favour the obvious to try defence.

(3) Factor 3 – Motivation in prior art to find the solution

[108] As found by this Court, undisturbed by the FCA, the motive to find a solution was strong. While there was no motive to necessarily use a combination, for reasons already cited including multiple failures, there was the motive which was pursued on several fronts.

[109] This factor supports an obvious to try conclusion except that only the inventors of the Patent did so.

(4) Factor 4 – Actual course of conduct for the invention

[110] The facts leading to the invention were set out in the Trial Decision. The T-14 Study was a 26-week, double blind dose finding study covering 101 patients with three groups receiving infliximab at 1, 3 and 10 mg/kg. There is nothing in Pfizer's evidence that anyone else had come to this point in the invention development.

[111] Pfizer's argument on obvious to try depends on reading into *Higgins* (and *'94 Kennedy*) and the *FDA Workshop* more than was said or understood by a POSITA.

[112] *Sanofi* not only teaches the principles of the obviousness test but it is factually relevant because it was dealing with a circumstance where monotherapy was the goal and a combination ran contrary to that goal. The combination was not obvious or obvious to try.

[113] This 4th Factor does not favour the obvious to try defence.

[114] As pointed out by the FCA, *Sanofi* sets out factors that must all be considered. Weighing these factors, the Court concludes that the defence of obvious to try has not been made out.

III. Conclusion

[115] For these Reasons, upon reconsideration as directed, the Trial Decision Judgment is upheld and is reinstated with the following exceptions noted at paragraphs 117-118 of the FCA decision as follows:

- Paragraphs 5, 6(a) and 6(b) of that Judgment is amended to remove the claims, being claims 12, 15, 28 and 31 of the 630 Patent, therein referred from the list of claims found to be infringed.
- Paragraph 5 is also amended by deleting references to Celltrion Healthcare Co, Ltd and Celltrion, Inc.

[116] As to costs, this matter is deferred until after the judgment on the quantification of damages scheduled to resume on February 1, 2021.

"Michael L. Phelan"
Judge

Ottawa, Ontario
January 12, 2021

FEDERAL COURT

SOLICITORS OF RECORD

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