Federal Court of Appeal | Cour d'appel fédérale

Date: 20210330

Dockets: A-338-18 (lead file);
A-326-16; A-328-16; A-329-18

Citation: 2020 FCA 30

CORAM: **NADON J.A.**
RIVOALEN J.A.
LOCKE J.A.

BETWEEN:

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

Appellants

and

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

Respondents

Heard at Toronto, Ontario, on October 28, 2019.

Judgment delivered at Ottawa, Ontario, on January 30, 2020.

REASONS FOR JUDGMENT BY: LOCKE J.A.

CONCURRED IN BY: NADON J.A.
RIVOALEN, J.A.

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AMENDED REASONS FOR JUDGMENT

LOCKE J.A.

I. Overview

[1] This decision concerns four appeals of decisions by Justice Michael L. Phelan of the Federal Court (the Judge) in the context of an action by Hospira Healthcare Corporation

(Hospira) to impeach Canadian Patent No. 2,261,630 (the 630 Patent) and a counterclaim for infringement of that patent. The initial plaintiffs in the counterclaim were the patent owner, The Kennedy Trust for Rheumatology Research, and alleged licensees Janssen Biotech, Inc., Janssen Inc. and Cilag GmbH International. The initial defendants to the counterclaim were Hospira and suppliers Celltrion Healthcare Co., Ltd. and Celltrion, Inc. (collectively, Celltrion).

[2] The principal decision under appeal (2018 FC 259 dated March 7, 2018) addressed the merits of the action and the counterclaim, and concluded that the 630 Patent was valid and infringed. Another decision under appeal (2018 FC 960 dated September 28, 2018) granted a motion after trial by the plaintiffs by counterclaim to add a new plaintiff by counterclaim (another alleged licensee, Cilag AG) and a new defendant to the counterclaim (Pfizer Canada Inc., which imports and distributes the allegedly infringing product in Canada). The last two decisions under appeal, both dated September 8, 2016, dismissed motions before trial by Hospira:

1) for a commission and letter of request to the U.K. High Court to compel the giving of evidence by Dr. Ravinder Maini (one of the named inventors of the 630 Patent) for purposes of discovery; and

2) to adjourn the trial (or part thereof) to permit continued examination for discovery of Dr. Marc Feldmann (the other of the named inventors of the 630 Patent).

[3] For all four appeals, the defendants to the counterclaim are the appellants.

[4] For the reasons set out below, I would allow the appeal on the merits, and remit the matter to the Federal Court for reconsideration of certain issues. I would dismiss the other appeals.

[5] Each of the four appeals is dealt with in turn in the sections below after a brief discussion of the 630 Patent and its factual background.

II. The 630 Patent and its Context

[6] As indicated by the Judge, the 630 Patent "essentially details the adjunctive use of methotrexate (MTX) and the anti-tumour necrosis factor-α (anti-TNF-α) antibody "infliximab" for the treatment of rheumatoid arthritis (RA) and other autoimmune diseases." The Judge elaborated as follows:

> RA is an autoimmune disorder that characteristically impacts the joints causing pain and disfigurement, even death.
>
> MTX is a drug that impedes the growth of certain cells.
>
> Infliximab is a chimeric monoclonal antibody biologic drug that prevents TNF-α from binding to TNF-α cell surface receptors. TNF-α is a cytokine (chemical messenger) that plays an important role in the autoimmune reaction.

[7] The application for the 630 Patent was filed on August 1, 1997 naming Drs. Feldmann and Maini as inventors, and claiming priority from a U.S. application (No. 08/690,775) that was filed on August 1, 1996. The 630 Patent was published on February 12, 1998; it issued on December 4, 2012; and it expired on August 1, 2017.

[8] Prior to the 630 Patent, MTX was well known as a treatment for serious cases of RA. Though it was not considered to be a traditional immunosuppressive drug, and its mechanism of action was not well understood, it was understood to have immunosuppressive properties. MTX is an example of a disease modifying anti-rheumatic drug (DMARD). Treatment of RA with drugs other than DMARDs was also known at the time. These included non-steroidal anti-inflammatory drugs (NSAIDs) and steroids.

[9] Unfortunately, many patients with RA do not respond completely to treatment with MTX. These patients are known as MTX Incomplete Responders or MTX IRs. For many years prior to the 630 Patent, there had been no significant advances to assist such patients despite a pressing need for a new and improved treatment. The inventors theorized that an anti-TNF-α antibody like infliximab could be helpful in the treatment of RA. At the time, no biologics had yet been approved. Initial trial results were encouraging, but all patients eventually relapsed, likely because of patients' immune systems responding to the treatment through human anti-chimeric antibodies (HACA). The inventors then tried combining infliximab and MTX. The positive results of these efforts formed the basis for the 630 Patent.

[10] The 630 Patent includes 42 claims of which 23 are in issue. Claims 1, 2, 17, 18, 39, 40, 41 and 42 are independent. The remainder of the claims in issue are dependent on one of these independent claims. Claim 1 is exemplary:

> Use of an anti-human tumor necrosis factor-α monoclonal antibody or a human tumor necrosis factor-α binding Fab fragment thereof for the manufacture of a medicament for performing adjunctive therapy with a medicament comprising methotrexate on an individual suffering from rheumatoid arthritis whose active disease is incompletely controlled despite already receiving methotrexate, to reduce or eliminate signs and symptoms associated with the rheumatoid arthritis,

> wherein the anti-human tumor necrosis factor-α antibody or human tumor necrosis factor-α binding Fab fragment (a) binds to an epitope on human tumor necrosis factor-α, and (b) inhibits binding of human tumor necrosis factor-α to human tumor necrosis factor-α cell surface receptors.

[11] Except as discussed below, the parties do not take issue with the list of essential elements as identified and adopted by the Judge in Appendix B to his reasons on the merits (Reasons). The essential elements of claim 1 are identified as follows:

> (a) use of TNFα inhibiting monoclonal antibody (or Fab fragment thereof) for making a medicine;
>
> (b) for performing adjunctive therapy with MTX;
>
> (c) on a patient with active RA whose disease is incompletely controlled despite already receiving MTX;
>
> (d) to reduce or eliminate the signs and symptoms of RA;
>
> (e) wherein the TNFα-inhibiting monoclonal antibody (or Fab fragment) (a) binds to an epitope on human TNFα, and (b) inhibits binding of human TNFα to human TNFα cell surface receptors.

III. The Appeal on the Merits (A-338-18)

[12] The appellants raised many issues at trial, including many sub-issues within each issue. They were unsuccessful in virtually every case. Most of the issues that the appellants raised before the Judge they raise once again before this Court.

[13] The issues before this Court can be identified as follows:

1) Claim construction issues:

i. Whether the Judge erred in failing to construe the claims in issue as use claims.

ii. Whether the Judge erred in construing the phrase "whose active disease is incompletely controlled despite already receiving [MTX]" to contemplate individuals receiving MTX and other DMARDs.

2) Patent infringement issues

i. Whether the Judge erred in finding that MTX IRs were treated.

ii. Whether the Judge erred in finding that certain elements of certain dependent claims of the 630 Patent were present.

iii. Whether the Judge erred in concluding that the activities of Celltrion outside Canada could infringe the 630 Patent.

iv. Whether the Judge erred in finding inducement to infringe.

Claims 37 and 38

The appellants argue that claims 37 and 38 were not asserted by the respondents at trial. The respondents do not oppose this argument. In view of the Federal Courts' explicit statements at paragraph 268 and Appendix B in the

reasons at trial listing the claims in dispute (and not including claims 37 and 38), I conclude that the Federal Court erred in finding infringement of these claims.

3) Patent validity issues:

i. Whether the Judge erred in failing to find the 630 Patent invalid for claiming a method of medical treatment.

ii. Whether the Judge erred in failing to find the 630 Patent invalid for anticipation (lack of novelty).

iii. Whether the Judge erred in failing to find the 630 Patent invalid for obviousness (lack of inventiveness).

iv. Whether the Judge erred in failing to find the 630 Patent invalid for double patenting.

v. Whether the Judge erred in failing to find the 630 Patent invalid for insufficiency of disclosure.

[14] There is no dispute on the principles applicable to the standard of review in this case. As indicated in *Housen v. Nikolaisen*, 2002 SCC 33, [2002] 2 S.C.R. 235, the standard of

correctness applies to questions of law (see para. 8), but findings of fact or of mixed fact and law are reviewable only where the court of first instance has made a palpable and overriding error (see paras. 10 and 36).

[15] Because of the number of sub-issues raised by the appellants, it will not be practical to address each one specifically. The reader should understand that I have considered all of the appellants' arguments, and my silence on any of them does not indicate otherwise. I find no merit in the arguments that I have not addressed.

A. *Claim construction issues*

(1) Construction of claims in issue as use claims

[16] The appellants argue that the Judge erred in not looking behind the plain language of the claims, which are written as Swiss-type claims, i.e. claims to the use of composition X for the preparation of a medicament to be used for Y. The appellants argue that patent claims should be construed purposively, and they cite jurisprudence in which Swiss-type claims have been purposively construed as use claims.

[17] While I accept that patent claims are to be construed purposively, I note that the parties do not disagree on this point, and the Judge was clearly guided by this principle (see para. 118 of the Reasons). Accordingly, it appears that the parties disagree not on the applicable legal principle, but on how that principle was applied to the facts in this case. In light of that, this Court should not interfere in the absence of a palpable and overriding error.

[18] I see no such error in the Judge's decision to interpret the words of the claims to have their plain meaning (see para. 153 of the Reasons): *Lundbeck Canada Inc. v. Ratiopharm Inc.*, 2009 FC 1102 at para. 41; *Zero Spill Systems, (Int'l) Inc. v. Heide*, 2015 FCA 115 at paras. 74-78.

(2) Construction of the claims to include individuals receiving MTX and other DMARDs

[19] The appellants argue that the phrase "whose active disease is incompletely controlled despite already receiving [MTX]" refers to patients receiving MTX only, and that construing the phrase to encompass patients receiving MTX and other DMARDs impermissibly broadens it beyond what would have been understood by a person skilled in the art (PSA) at the relevant time.

[20] The Judge noted that nothing in the 630 Patent indicates that it contemplates treatment only of patients receiving MTX alone. He also pointed to the following passage from the 630 Patent to indicate the contrary:

> Other therapeutic regimens and agents can be used in combination with the therapeutic co-administration of TNF antagonists and methotrexate or other drugs that suppress the immune system.

[21] The appellants argue that the Judge should not have had reference to this passage in the 630 Patent to construe a term in a claim without some ambiguity concerning the meaning of that term. In support of this argument, the appellants cite *Mylan Pharmaceuticals ULC v. Eli Lilly Canada Inc.*, 2016 FCA 119, [2016] F.C.J. No. 406, at para. 39 (*Mylan*), which adopted the following statement:

> In construing the claims, recourse to the rest of the specifications is (1) permissible to assist in understanding the terms used in the claims; (2) unnecessary where the words and [*sic*] plain and unambiguous and (3) improper to vary the scope or ambit of the claims.

[22] However, the appellants' argument that there is no ambiguity in the meaning of the phrase in question is substantially weakened by the fact that the claims are not explicit as to whether MTX IRs are limited to those taking MTX only. Certainly, the parties disagree. In my view, it was entirely open to the Judge, when construing this phrase, to have resort to the above-quoted passage from the disclosure of the 630 Patent.

[23] The appellants also point to evidence that DMARD combinations were known to be risky and uncertain. Despite this evidence, which was disputed, it was open to the Judge to be persuaded by other evidence of the use of combination therapy with other medications for the treatment of patients with RA, and the absence of any indication in the patent itself that an MTX IR could not be receiving some other DMARD in combination with MTX.

[24] I see no error by the Judge on this issue.

B. *Patent infringement issues*

(1) Were MTX IRs treated?

[25] It is not disputed that treatment of an MTX IR is an essential element of all of the claims in issue. This means that it would not be an infringement of any of the claims in issue to administer the adjunctive therapy contemplated therein to someone other than an MTX IR.

Accordingly, in order to establish infringement, there must be evidence that the claimed treatment is for administration to an MTX IR.

[26] That said, it should be noted that the infringement action that has given rise to the present appeals has been bifurcated such that questions of liability (e.g. whether the 630 Patent was valid and infringed) were dealt with in the first phase, and questions of the quantum of damages/profits will be dealt with in the second phase. Therefore, it was not for the Judge in his Reasons to address how much infringement occurred. It was enough that he was convinced that there was some infringement.

[27] The appellants argue that their allegedly infringing product, called Inflectra, has seven indications, only one of which is for RA, and that though its product monograph contemplates use in combination with MTX, it does not specify that it is for MTX IRs. The appellants also argue that the Judge improperly considered IMS evidence that Inflectra is used in combination with MTX in MTX IRs. The appellants say this evidence should have been excluded as hearsay.

[28] Even without the IMS evidence in dispute, there was ample support for the Judge's conclusion that Inflectra was used in MTX IRs. Firstly, it would seem fair to assume that an advanced treatment for RA, such as infliximab in combination with MTX, would be used principally in patients who have not responded completely to standard treatments, such as MTX. This assumption is supported by the Reasons where the Judge noted that (i) the clinical trial relied upon to obtain regulatory approval for Inflectra included MTX IRs; and (ii) only MTX IRs are reimbursed for treatment with Inflectra. This assumption is also consistent with the

appellants' argument on the issue of obviousness that prior art suggested that patients receiving infliximab in clinical studies should be MTX IRs, and should continue receiving MTX during such studies.

[29] I see no error in the Judge's conclusion that Inflectra is to be used for treatment of MTX IRs.

(2) Elements of dependent claims

[30] The appellants argue that there was no evidence, and the Judge made no finding, of the presence of the following essential elements of claims 12, 15, 28 and/or 31, and therefore these claims should have been found not infringed:

1) the TNFα-inhibiting medicine is formulated for administration by infusion at weeks 0, 2, 6, 10 and 14; and

2) the MTX-containing medicine contains 7.5 mg (or 10 mg) of MTX.

[31] The parties devote little of their arguments to this issue. This may reflect the fact that the issue could be of importance only if these claims were found to be valid while the claims from which they depend were found invalid.

[32] The respondents have not disputed the absence of evidence to support a finding of infringement of claims 12, 15, 28 and 31, and the Court has not been directed to any evidence of

the presence of the essential elements identified in paragraph [30] above. It does indeed appear that there is no such evidence. Therefore, I conclude that the Judge erred in finding infringement of these claims.

(3) Activities of Celltrion

[33] The appellants argue that the Judge made no finding that Celltrion conducted any activities in Canada, and therefore he erred in finding that Celltrion infringed. The respondents acknowledge that there was no direct evidence regarding where Celltrion conducted its activities, but they argue that the Judge did not err when he focussed on whether those activities deprived the patentee of the full enjoyment of the invention defined in the 630 Patent rather than on where those activities took place.

[34] Of importance to this issue is the *Saccharin* doctrine, which gets its name from a decision of the U.K. High Court of Justice – Chancery Division called *Saccharin Corporation, Ld. v. Anglo-Continental Chemical Works, Ld.* (1900), 17 R.P.C. 307. This decision concerned a U.K. patent for a process for manufacturing saccharin, and the issue was whether it was an infringement of that patent to import into the U.K. saccharin made abroad using the patented process. A key passage in the decision appears at page 319: “By the sale of saccharin, in the course of the production of which the patented process is used, the Patentee is deprived of some part of the whole profit and advantage of the invention, and the importer is indirectly making use of the invention.” The *Saccharin* doctrine has been recognized in Canada for many years: see *Monsanto Canada Inc. v. Schmeiser*, 2004 SCC 34, [2004] 1 S.C.R. 902, at para. 44; *Eli Lilly and Company v. Apotex Inc.*, 2010 FCA 240, [2010] F.C.J. No. 1199, at paras.17-20.

[35] On this issue, the appellants challenge not whether the importation and/or sale in Canada of Inflectra is an infringement of the 630 Patent, but rather whether Celltrion's activities conducted entirely outside Canada can be found to infringe the Canadian patent. On this point, a follow-up to the *Saccharin* decision identified above is helpful. Just two months later, the U.K. High Court of Justice – Chancery Division issued another decision involving the same plaintiff but a different defendant: *Saccharin Corporation, Ld. v. Reitmeyer & Co.* (1900), 17 R.P.C. 606. Here, the defendant had used the patented process outside the U.K. and had sold the resulting product for importation into the U.K., but it had done none of this in the U.K. At page 612 of this decision, the Court stated:

> The acts done by the Defendant on the Continent were lawful there, and – being done on the Continent – were not unlawful here. The Plaintiffs have sought to extend the principle laid down in *Elmslie v. Boursier* (L.R. 9 Eq. 217) and *Von Heyden v. Neustadt* (14 Ch. D. 230) that the importation into and sale in England of an article manufactured abroad according to a process protected by an English Patent is an infringement of the English Patent, to a case where the Defendant has neither imported into nor sold in England. … I am not disposed for the first time thus to extend the rights of the Patentee.

[36] Accordingly, the finding of infringement under the *Saccharin* doctrine was limited to those who conduct activities in the territory of the patent, activities such as importing, selling or using the product in question. This limitation to the *Saccharin* doctrine has been recognized in Canada: *Eli Lilly and Company v. Apotex Inc.*, 2009 FC 991, [2009] F.C.J. No. 1229, at paras. 283-284, aff'd 2010 FCA 240, [2010] F.C.J. No. 1199. This limitation also recognizes the general principle that patents are territorial and that Canadian patents cannot be infringed outside Canada: *Beloit Canada Ltd. v. Valmet-Dominion Inc.*, [1997] 3 F.C. 497 at 520, 73 C.P.R. (3d) 321 (F.C.A.); *Varco Canada Limited v. Pason Systems Corp.*, 2013 FC 750, 236 A.C.W.S. (3d)

714, at paras. 265-266; *Canadian National Railway Company v. BNSF Railway Company*, 2018 FC 614, 156 C.P.R. (4th) 1, at para. 46.

[37] Accepting that there is indeed no evidence that Celltrion has conducted any activities in Canada, the facts in the present case appear to be indistinguishable from those in the second *Saccharin* decision. I conclude that there is no evidence to support the conclusion that Celltrion has infringed the 630 Patent, and that the Judge erred in including Celltrion among the companies found to have infringed.

(4) Inducement to infringe

[38] The parties do not take issue with the three-prong legal test for inducing infringement as set out in *Corlac Inc. v. Weatherford Canada Inc.*, 2011 FCA 228, 95 CPR (4th) 101, at para. 162, and adopted by the Judge:

> First, the act of infringement must have been completed by the direct infringer. Second, the completion of the acts of infringement must be influenced by the acts of the alleged inducer to the point that, without the influence, direct infringement would not take place. Third, the influence must knowingly be exercised by the inducer, that is, the inducer knows that this influence will result in the completion of the act of infringement […].

[39] The Judge found that all of the elements of this test were satisfied. The appellants take issue with all three.

[40] The appellants criticize the Judge's reliance on the following passage from *AB Hassle v. Genpharm Inc.*, 2003 FC 1443, 243 F.T.R. 6, at para. 127, aff'd 2004 FCA 413, [2004] F.C.J. No. 2079 (*AB Hassle*): "Infringement of a use patent … is not limited to the act of the generic

producer; it includes infringement by patients." The appellant argues that the Judge read this passage to permit a finding of inducing infringement even without the element of influence by the alleged inducer. In my view, the appellants misread both the passage and the Judge's use of it. By my reading, the Court in *AB Hassle* was simply observing that direct infringement of a use patent may be committed by a patient. It follows from this that use by a patient may satisfy the first prong of the test for inducing infringement. It is clear from a reading of the Reasons that the Judge understood that influence by the alleged inducer was necessary for a conclusion of inducing infringement.

[41] The requirement for an act of infringement completed by the direct infringer was addressed by the Judge's analysis of direct infringement, and is dealt with here in discussion above of the other infringement issues. The Judge made no error in finding that this prong of the test was satisfied.

[42] The appellants' argument against the second prong of the test (influence by the alleged inducer) is similar to that discussed above in the context of the first patent infringement issue (beginning at paragraph [25] above). They argue that the Judge should have recognized that the product monograph for Inflectra does not mention MTX IRs, even though it does instruct use in combination with MTX. In my view, and as alluded to above, it is no great leap to conclude that instructions to use Inflectra in combination with MTX will be followed by patients who have not responded completely to treatment with MTX. The distinction is an attempt at splitting hairs.

[43] In light of the findings that (i) the appellants instructed patients, including MTX IRs, in the infringing use of Inflectra, and (ii) patients, including MTX IRs, followed those instructions, I find no error in the Judge's conclusion that the appellants influenced direct infringement so as to satisfy the second prong of the test for inducing infringement.

[44] The third prong of the test (the influence was knowingly exercised) is not difficult in this case. It follows from the fact that the source of the influence (the product monograph) was created and distributed by the appellants themselves that they were aware of the influence being exercised.

[45] The Judge easily found that this prong was satisfied. I see no error in this conclusion, but I do take this opportunity to clarify a point that is not clear in the Reasons: the knowledge at issue in the third prong of the test is knowledge that the influence is being exercised, rather than knowledge that the resulting activity will be an infringement. It is true that there are several decisions in the jurisprudence in which an alleged inducer's knowledge (or lack of knowledge) of the patent in issue has been considered in deciding the issue of inducement. However, these decisions have not discussed the knowledge issue in any depth. This issue was discussed in depth by Justice Johanne Gauthier (then of the Federal Court) in *Bauer Hockey Corp. v. Easton Sports Canada Inc.*, 2010 FC 361, [2010] F.C.J. No. 341, at paras. 193-203, aff'd 2011 FCA 83, [2011] F.C.J. No. 331. Justice Gauthier observed that knowledge that a particular activity is an infringement is not an element of direct infringement and, since inducing infringement is not a tort distinct from direct infringement, it should not be an element of inducing infringement either. I agree.

[46] In summary, the Judge did not err in finding that all three prongs of the test for inducing infringement were satisfied, and concluding that the appellants induced infringement.

C. *Patent validity issues*

(1) Method of medical treatment

[47] I preface this section by noting that the appellants' arguments on the subject of methods of medical treatment rely to a large extent on their argument that the Swiss-type claims in this case should have been construed as use claims. That argument has been dismissed in section III.A.(1) above and will not be revisited here.

[48] I begin this section with a brief history which may be helpful. The authority for the principle that a method of medical treatment is not patentable in Canada has its roots in the decision of the Supreme Court of Canada in *Tennessee Eastman Co. et al. v. Commissioner of Patents* (1972), [1974] S.C.R. 111, 8 C.P.R. (2d) 202 (*Tennessee Eastman*), which concerned a patent application based on the discovery that a known adhesive substance was adaptable for surgical use. Section 41 of the *Patent Act* in force at the time limited the scope of patent claims relating to substances intended for food or medicine; claims had to be limited to such substances prepared or produced by particular chemical processes. In *Tennessee Eastman*, the claims in issue were essentially to a new surgical method of joining tissues by means of a known substance. Based on section 41 of the *Patent Act*, the Court concluded that neither such a surgical method, nor a method of medical treatment, fell within the definition of "invention" therein. The Court concluded that such methods are therefore not patentable.

[49] Though the Supreme Court in *Tennessee Eastman* did not explicitly base its decision on the idea that the invention in question was essentially non-economic and unrelated to trade, industry, or commerce (an idea the Exchequer Court and the patent examiner in that case had previously discussed), subsequent decisions of the Supreme Court have accepted that idea: see *Shell Oil Co. v. Commissioner of Patents*, [1982] 2 S.C.R. 536 at 554, 67 C.P.R. (2d) 1; *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77, [2002] 4 S.C.R. 153, at para. 49 (*AZT*).

[50] The Court in *AZT* also noted that section 41 of the *Patent Act* (which had been the focus of the decision in *Tennessee Eastman*) had since been repealed. Therefore, the reasoning in *AZT* would seem to apply despite this repeal.

[51] Though the method of medical treatment issue has been raised in a number of matters before the Federal Court since *AZT*, there has been limited discussion of this issue at the level of the Federal Court of Appeal. Federal Court jurisprudence has developed the principle that a claim to a vendible product, including a substance intended for the treatment of a medical condition, can be good subject matter for a patent claim, but not if the claim encompasses the skill of a medical professional such as a dosage range rather than a fixed dosage (or presumably also a range of intervals of administration rather than a fixed interval): *Merck & Co. Inc. v. Apotex Inc.*, 2005 FC 755, [2005] F.C.J. No. 937, at para. 137; *Axcan Pharma Inc. v. Pharmascience Inc.*, 2006 FC 527, 50 C.P.R. (4th) 321, at para. 51; *Merck & Co., Inc. v. Pharmascience Inc.*, 2010 FC 510, 85 C.P.R. (4th) 179, at para. 114; *Janssen Inc. v. Mylan Pharmaceuticals ULC*, 2010 FC 1123, 88 C.P.R. (4th) 359, at para. 26; *Novartis*

Pharmaceuticals Canada Inc. v. Cobalt Pharmaceuticals Company, 2013 FC 985, 115 C.P.R. (4th) 399, at paras. 91-92, aff'd 2014 FCA 17, 236 A.C.W.S. (3d) 1001 (*Novartis*).

[52] This state of the jurisprudence has a tempting simplicity. However, it is not clear to me that the decisions of the Supreme Court of Canada that form the basis of the principle that methods of medical treatment are not patentable justify a distinction between a fixed dosage (or interval of administration) and a range of dosages (or intervals). It would seem that a medical professional will be constrained in their exercise of skill in either case. Also, a drug is arguably no less a vendible product simply because its dosage or interval of administration is not fixed.

[53] At paragraph 145 of the Reasons, the Judge noted a suggestion by this Court, and supported by Professor Norman Siebrasse, that the policy and logic surrounding methods of medical treatment be given "full consideration before this Court or the Supreme Court of Canada in a case where the issue is squarely raised on the facts": *Cobalt Pharmaceuticals Company v. Bayer Inc.*, 2015 FCA 116, [2015] F.C.J. No. 555, at para. 101. I agree that this issue deserves deep analysis. Unfortunately, this does not appear to be the case for such an analysis. Most of the claims in issue here are limited to fixed dosages and intervals of administration, or do not specify any dosage or interval of administration. I agree with the Judge that these claims concern a vendible product, and are not invalid as methods of medical treatment.

[54] One of the claims in issue arguably encompasses a dosage range: claim 33 defining "a dosage form containing from about 0.1 milligram to about 500 milligrams of infliximab." Other claims in issue arguably encompass a range of intervals of administration: claims 9, 10, 25 and

26 defining “interval of weeks” or “intervals of weeks.” However, the parties’ arguments do not focus on these claims.

[55] The Reasons likewise do not address the dosage range of claim 33 or the intervals of administration of claims 9, 10, 25 and 26. It may be that neither the Judge nor the parties saw the need to focus on these claims because they are dependent on other claims that do not encompass a range of dosages or a range of intervals of administration. The parties may have seen little practical effect of a finding that these claims were invalid.

[56] Having considered the evidence and the limited argument on this issue, I am not prepared to find that the Judge erred in finding none of the claims in issue invalid as a method of medical treatment. In my view, the record is insufficient to show that the Judge erred in law, or that he made a palpable and overriding error of fact or of mixed fact and law, on this issue.

(2) Anticipation (lack of novelty)

[57] There are two aspects to the appellants’ argument on anticipation that require discussion. The first is that the Judge erred in recognizing the priority date of the 630 Patent, and hence in excluding certain prior art as not citable. The second aspect of the appellants’ argument on anticipation concerns the Judge’s conclusion that two other prior art references were not anticipatory because they did not describe the “special advantage” of the 630 Patent. Each of these aspects will be addressed in turn.

(a) *The priority date of the 630 Patent*

[58] Pursuant to paragraph 28.2(1)(*b*) of the *Patent Act*, R.S.C. 1985, c. P-4, the subject-matter of a patent claim must not have been disclosed before the claim date by a person other than the applicant for the patent (or a person who obtained knowledge from the applicant) in such a manner that the subject matter became available to the public. The "claim date", which effectively defines a cut-off date for citable prior art, is defined in section 28.1 to be the earlier of the Canadian filing date and the filing date of a previously filed application on which a valid priority claim has been made. One of the requirements for a valid priority claim is that the application claiming priority was filed within twelve months after priority application. In addition, subsection 28.4(4) provides that, where there are two or more previous applications on which priority could be claimed, the twelve months counts from the earliest filing.

[59] As indicated in paragraph [7] above, the application for the 630 Patent was filed on August 1, 1997, and a priority claim was made based on U.S. Patent Application No. 08/690,775 which was filed on August 1, 1996 (the 1996 priority).

[60] The appellants argue that the Judge should not have recognized this priority claim as valid because the 1996 priority itself claims priority from another U.S. application (07/958,248) which was filed on October 8, 1992 (the 1992 priority). The appellants argue that the named inventors themselves argued successfully before the U.S Patent Office that this 1992 priority supported a priority claim by the 1996 priority. If the appellants are right in these arguments, then the priority claim on the 630 Patent would be invalid because it was filed more than twelve months after the 1992 priority. The invalidity of the priority claim in the 630 Patent would move

the claim date for the 630 Patent from August 1, 1996 to August 1, 1997, which would make certain additional prior art relevant.

[61] The appellants also argue that the Judge recognized the 1992 priority as the earliest priority application for the subject matter of the claims in issue of the 630 Patent (in particular, the co-administration of an anti-TNF-α antibody and MTX). This is not so. The paragraphs cited by the appellants from the Reasons summarize, but do not adopt, the appellants' arguments on this point. In fact, there is insufficient evidence on the record to determine whether the subject matter of the claims in issue was described in the 1992 priority so as to make it the earliest priority application, as asserted by the appellants.

[62] The appellants argue that the respondents had the burden to establish the priority claim for the 630 Patent, and that they failed to meet that burden by putting the 1996 priority application into evidence. For their part, the respondents argue that the burden of proof was instead on the appellants in that the 630 Patent benefits from a presumption of validity per subsection 43(2) of the *Patent Act*.

[63] Neither of these arguments has merit. With respect to the appellants' argument, even if the respondents had introduced the 1996 priority into evidence, the Judge would not have been in a position to determine what the 1992 priority discloses. Therefore, there is no reason to draw any negative inference from the respondents' failure to introduce the 1996 priority. Turning to the question of the presumption of validity of the 630 Patent, it is notable that the question of priority is not directly relevant to the validity of the 630 Patent. Rather, it affects which prior art

may be relevant for the purposes of an attack on its validity. The respondents cite no authority that the presumption of patent validity extends to a priority claim.

[64] In my view, the appellants' reliance on the 1992 priority is remote enough from the issue of the priority claim on the 630 Patent that, even if that priority claim does not benefit from a presumption of validity, the appellants had the burden to prove the contents of the 1992 priority. To conclude otherwise would overcomplicate the exercise of establishing a priority claim because a patentee would be obliged to try to anticipate which prior applications an adversary might allege disclose the subject matter of the patent in issue.

[65] With no dispute that the 1996 priority supports the subject matter of the claims in issue of the 630 Patent, and in the absence of evidence of the contents of the 1992 priority, I see no error in the Judge's recognition of the claim date of August 1, 1996 for the 630 Patent.

(b) *Prior art references that do not describe the "special advantage" of the 630 Patent*

[66] Before entering into the details of this issue, it is useful to note that there are two requirements for establishing that a prior art reference anticipates:

1) The prior art reference must disclose the claimed invention such that, if performed, it would necessarily result in infringement; and

2) The prior art reference must be sufficiently detailed to enable a PSA to perform the claimed invention without the exercise of inventive ingenuity or undue experimentation.

(See *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61, [2008] 3 S.C.R. 265 (*Sanofi*))

[67] The two prior art references of relevance to this issue are:

1) The 1994 Scientific Report of the Mathilda and Terence Kennedy Institute of Rheumatology (the 1994 Kennedy Report); and

2) G. Higgins, "Cytokine antagonism: still a main attraction in rheumatology R&D", InPharma, 8 July 1995, p. 10 (Higgins).

[68] The Judge noted that the 1994 Kennedy Report discloses the idea of co-administration of stable low doses of MTX and monthly infusions of infliximab, but that no results were yet available, and therefore the special advantage of such adjunctive therapy was not disclosed. The Judge described this special advantage as "reduced HACA responses and improved pharmacokinetics enabling long-term treatment of infliximab with good efficacy and tolerability." The 1994 Kennedy Report stated as follows:

> The aim is to further investigate the tolerability and efficacy of repeated use of [infliximab] in a randomised, blinded fashion, both in comparison with standard therapy [MTX] 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 [infliximab] as a long-term disease suppressing agent in clinical practice.

[69] The Judge also noted that Higgins discloses the possibility of combining an anti-TNF-α antibody with MTX. The Judge noted that the anti-TNF-α antibody mentioned was not infliximab. He also noted that Higgins disclosed neither the special advantage of the combination nor the doses or administration schedule of either drug.

[70] The Judge found both the 1994 Kennedy Report and Higgins not to anticipate the claims in issue because they were speculative. Regarding the 1994 Kennedy Report, he specifically noted that it was impermissibly speculative to expect benefits from combination treatment of infliximab and MTX based on the efficacy of either drug individually.

[71] In my view, the Judge's analysis in this respect was erroneous. In order for any particular results from the claimed combination treatment to be a basis for distinguishing over the prior art, it would be necessary to conclude that such results constituted an essential element of the claim in question. Each claim should be considered separately. Similarly, in order to draw a distinction from the fact that Higgins discloses an anti-TNF-α antibody other than infliximab for co-administration with MTX, it would be necessary to conclude that infliximab (and not just any anti-TNF-α antibody) was an essential element. Further, in order to draw a distinction from the fact that Higgins fails to disclose the doses or administration schedule of either drug, those elements would have to be essential.

[72] As indicated in paragraph [11] above, the parties do not dispute most of the list of essential elements of the claims in issue as identified in Appendix B of the Reasons. Based on Appendix B, all of the claims in issue define adjunctive therapy on MTX IRs to reduce or

eliminate the signs and symptoms of RA. This may or may not suggest some sort of improvement over results obtained from treatment with MTX not in combination, but there is no requirement for any particular results, including the kind of results described by the Judge as the special advantage. Moreover, the paragraph from the 1994 Kennedy Report quoted at paragraph [68] above appears to point the reader to precisely the kind of improvement that would occur from the claimed adjunctive therapy: improved long-term disease suppression. As regards infliximab as an essential element (rather than another anti-TNF-α antibody), this is the case only for claims 5, 15, 21, 31 and 33, when referring to Appendix B of the Reasons. The words of claims 12 and 28 also appear to include infliximab as an element. However, for some reason, Appendix B does not identify infliximab as an essential element of these claims. The other claims in issue do not define infliximab as an essential element. Finally, the doses and administration schedule that the Judge found missing in Higgins are likewise essential elements of only a subset of the claims in issue.

[73] Though the Judge acknowledged that the test for anticipation has the two distinct requirements of disclosure and enablement as identified in paragraph [66] above, his analysis of the 1994 Kennedy Report and Higgins in the Reasons does not address these requirements distinctly. The Judge appears to have dismissed the appellants' anticipation arguments concerning these two references on the basis that they fail to meet the disclosure requirement because they do not disclose results of the proposed experiments. This approach appears to conflate disclosure and enablement. The disclosure requirement is satisfied if performing what is described in the prior art reference would necessarily result in infringement. From a reading of the Reasons, it is not clear how this requirement is not satisfied at least as regards the 1994

Kennedy Report. Even for Higgins, it is not clear how this requirement is not satisfied for those claims that do not include either infliximab or dosing or an administration schedule as an essential element.

[74] The Judge does not appear to have considered enablement in relation to these two prior art references. Two points should be noted here:

1) What must be enabled are the essential elements of claimed invention in issue, not the particular experiments disclosed in the 630 Patent; and

2) When considering whether the PSA would have the skills necessary to enable them to make the claimed invention using the allegedly anticipating prior art reference in issue, care must be taken to avoid any inconsistency with the assessment of whether the information in the specification of the 630 Patent is sufficient to meet the requirement that the PSA be capable of making the invention (see Sufficiency of disclosure issue addressed below) – the PSA has the same skills for the purposes of enablement as they do for the purposes of sufficiency.

[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.

(3) Obviousness (lack of inventiveness)

[76] I agree with, and the parties do not dispute, the Judge's reference to section 28.3 of the *Patent Act* as the statutory basis for a requirement of inventiveness, as well as the four-step approach to obviousness analysis as set out in *Sanofi* at para. 67:

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

(a) *The PSA*

[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.

[78] However, I do have a comment on the statement by the Judge that the PSA is "neither first nor last in her class but somewhere in the middle": see Reasons at paras. 69 and 74, citing *Merck-Frosst-Schering Pharma GP v. Canada (Health)*, 2010 FC 933, 385 F.T.R. 1, at para. 69, and *Amgen Canada Inc. v. Apotex Inc.*, 2015 FC 1261, 138 C.P.R. (4th) 383, at para. 45, aff'd on other grounds 2016 FCA 196, 141 C.P.R. (4th) 245.

[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.

[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.

(b) *Differences between the state of the art and the inventive concept*

[81] An important aspect of the appellants' case on this issue concerns the Judge's exclusion of certain prior art references from the "state of the art" for the obviousness analysis on the basis that they would not have been found by the PSA conducting a reasonably diligent search. Specifically, the following prior art references were excluded for this reason:

1) Higgins; and

2) Proceedings of the Food and Drug Administration Rheumatoid Arthritis Workshop on March 27, 1996 in Washington, D.C. (the FDA Workshop).

[82] Higgins was excluded on the basis that it was written for pharmaceutical industry workers, and would not have been reviewed by the PSA, a rheumatologist. The FDA Workshop was excluded because it was attended by "a small number of the top rheumatologists in the world, far removed from the ordinary skilled worker."

[83] As support for the principle that the state of the art is limited to prior art that would have been uncovered by the PSA conducting a reasonably diligent search, the Judge cited the decision of this Court in *E. Mishan & Sons, Inc. v. Supertek Canada Inc.*, 2015 FCA 163, 134 C.P.R. (4th) 207, at paras. 20-22 (*Supertek*). However, in my view, *Supertek* does not stand for the principle that prior art that was available to the public at the relevant date should be excluded from consideration in an obviousness analysis on the basis that it would not have been found by the PSA conducting a reasonably diligent search.

[84] First, the facts in *Supertek* are distinguishable from those in this case: the prior art in question there had been <u>included</u> by the trial judge as part of the prior art, and the appellants were arguing for its exclusion on the basis that it would not have been found in a search. This Court found no error in that case. Moreover, though *Supertek* at para. 20 cited an earlier decision of the Federal Court (*Apotex Inc. v. Sanofi-Aventis*, 2011 FC 1486, [2011] F.C.J. No. 1813, rev'd 2013 FCA 186, [2013] F.C.J. No. 856) in which the requirement that prior art be locatable in a reasonably diligent search was adopted, the discussion of this issue in that earlier Federal Court

decision concerned not the state of the art generally, but rather common general knowledge. Common general knowledge is merely a subset of the state of the art.

[85] Some jurisprudence of the Federal Court supports the Judge's position on this issue: e.g. *Novartis Pharmaceuticals Canada Inc. v. Teva Canada Limited*, 2015 FC 770, 135 C.P.R. (4th) 211, at para. 53; *Eurocopter v. Bell Helicopter Textron Canada Ltée*, 2012 FC 113, [2012] F.C.J. No. 107, at para. 80; *Pfizer Canada Inc. v. Apotex Inc.*, 2007 FC 971, [2007] F.C.J. No. 1271, at para. 108; *Illinois Tool Works Inc. v. Cobra Fixations Cie / Cobra Anchors Co.*, 2002 FCT 829, [2002] F.C.J. No. 1104, at para 100. The obviousness analysis in each of these decisions was affirmed before this Court, however without comment on the question of excluding prior art that would not have been located in a reasonably diligent search. In fact, some jurisprudence of this Court suggests a broader scope for relevant prior art: *Ciba Specialty Chemicals Water Treatments Limited v. SNF Inc.*, 2017 FCA 225, 152 C.P.R. (4th) 239, at paras. 50 and 60; *Mylan* at para. 23. Moreover, commentaries by authors well-known in the field of patent law have expressed doubt as to whether it is appropriate to limit the scope of relevant prior art to the results of a diligent search since the wording of section 28.3 of the *Patent Act* is not so limited: see D.H. MacOdrum, *Fox on the Canadian Law of Patents*, 5th ed. (Toronto: Carswell, 2013) at 4:11(i); R.H. Barrigar, *Canadian Patent Act Annotated*, 2nd ed. (Toronto: Thomson Reuters, 1994) at 28.3:640. Section 28.3 contemplates "information disclosed … in such a manner that the information became available to the public." This Court in *Supertek* found it unnecessary to address this point.

[86] In light of section 28.3 of the *Patent Act* and the applicable jurisprudence and commentaries, I conclude that it is an error to exclude from consideration prior art that was available to the public at the relevant date simply because it would not have been located in a reasonably diligent search. The likelihood that a prior art reference would not have been located by a PSA may be relevant to consideration of step 4 of the obviousness analysis (whether differences between the state of the art and the inventive concept constitute steps which would have been obvious to the PSA) in that the uninventive PSA might not have thought to combine that prior art reference with other prior art to make the claimed invention. However, excluding prior art simply because it is difficult to find is problematic because it would result in the possibility of a valid patent on an invention that had, but for some non-inventive tweak, already been disclosed to the public. In my view, that is not what Canada's patent regime is intended to permit.

[87] Neither Higgins nor the FDA Workshop should have been excluded in step 3 of the obviousness analysis on the basis that they would not have been located in a reasonably diligent search. The failure to consider the FDA Workshop as prior art seems particularly problematic because of the Judge's acknowledgement that rheumatologists attended the proceedings. Rheumatologists, even the world's top rheumatologists, would include the PSA. 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.

(c) *Obviousness to try*

[88] The Supreme Court of Canada stated in *Sanofi* at para. 68 that "[i]n areas of endeavour where advances are often won by experimentation, an 'obvious to try' test might be appropriate." Also in *Sanofi* at para. 66, the Supreme Court stated:

> For a finding that an invention was "obvious to try", 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.

[89] The Supreme Court also provided the following guidance:

> [69] If an "obvious to try" test is warranted, the following factors should be taken into consideration at the fourth step of the obviousness inquiry. As with anticipation, this list is not exhaustive. The factors will apply in accordance with the evidence in each case.
>
> 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?
>
> [70] Another important factor may arise from considering the actual course of conduct which culminated in the making of the invention. It is true that obviousness is largely concerned with how a skilled worker would have acted in the light of the prior art. But this is no reason to exclude evidence of the history of

> the invention, particularly where the knowledge of those involved in finding the invention is no lower than what would be expected of the skilled person.

[90] It should be noted that, whereas being "more or less self-evident to try to obtain the invention" (per *Sanofi* at para. 66) is a requirement for obviousness to try, being "more or less self-evident that what is being tried ought to work" (per *Sanofi* at para. 69) is not a requirement but merely a factor to be considered.

[91] The Judge considered obviousness to try in this case, and the respondents do not dispute that this was appropriate in this case.

[92] The foundation of the Judge's conclusion that the claimed invention was not obvious to try is found at paragraph 226 of the Reasons:

> Although the [PSA] may have had "good reason" to pursue the combination of anti-TNF-α and MTX, it was not self-evident that this combination would work to solve the problem identified in the prior art (i.e., shortened duration of response).

[93] This is a clear application of the first factor identified in *Sanofi* at para. 69. But this factor is not determinative. The other factors also required consideration. In my view, the Judge's analysis of the second factor (concerning the extent, nature and amount of effort required to achieve the invention) was inadequate.

[94] At paragraph 227 of the Reasons, the Judge noted that the PSA did not have the skills necessary to design and conduct the experiments described in Examples 1-3 of the 630 Patent. There are two problems with this statement as a basis to dismiss obviousness to try. Firstly, it

assumes that the results provided by those experiments were part of the claimed invention. As indicated above, the claimed invention for any given claim in issue is defined by the essential elements thereof, which do not contemplate any particular experiments or results. The second problem is that obtaining the claimed invention does not require the PSA to be capable of designing or conducting the particular experiments described in the 630 Patent. 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.

[95] The determinative test on this issue is whether 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. Given the various prior art references that appear to suggest just that, it is not clear to me from reading the Reasons that the Judge properly considered this issue.

(4) Double patenting

[96] The courts in Canada have developed a principle whereby a patent may be invalid for double patenting if the inventor has received a previous patent either for the same invention (this can be called same invention double patenting) or for an invention that is not patentably distinct from the second (this can be called obviousness double patenting). In either case, the object is to prevent a patentee from effectively extending the life of the previous patent.

[97] The appellants argue that the Judge erred in finding that the 630 Patent was not invalid for double patenting in view of Canadian Patent No. 2,146,647 (the 647 Patent). They focus on

claim 4 of the 647 Patent which claims the use of anti-CD4 antibody and anti-TNF-α antibody in combination with an anti-inflammatory drug for treating autoimmune or inflammatory diseases. The appellants argue that the Judge improperly focused on the disclosure of the 647 Patent rather than its claims. The appellants also argue that the Judge failed to respect the claim construction analysis that he had conducted for the purposes of assessing infringement and the other grounds of invalidity.

[98] With respect to claim construction, the appellants note that the Judge found that the 630 Patent encompassed patients who were receiving drugs other than MTX before beginning adjunctive therapy (see section III.A.(2) beginning at paragraph [19] above). Accordingly, the claims of the 630 Patent encompass patients receiving anti-CD4 antibody as claimed in the 647 Patent. The appellants also note that MTX is an anti-inflammatory drug, thus constituting another similarity between the claims of the two patents.

[99] I do not accept the appellants' argument on this issue. The question is not whether the scope of the claims of the two patents overlap so that they cover the same embodiments. Rather, the issue is whether there is a patentable distinction between the two patents such that the claims of the 630 Patent are not obvious in view of the claims of the 647 Patent. There are several distinctions between the claims of these two patents that form a proper basis for finding that the 630 Patent is not invalid for double patenting. For example, the claims of the 630 Patent are specific to RA, whereas claim 4 of the 647 Patent defines autoimmune or inflammatory diseases more broadly. In addition, the claims of the 630 Patent define MTX specifically, not just any anti-inflammatory drug. Finally, the claims of the 630 Patent fail to specify what appears to be

the most important element of the claims of the 647 Patent: anti-CD4 antibody. In summary, the 630 Patent concerns a different invention from that claimed in the 647 Patent.

[100] With respect to the argument that the Judge improperly focused on the disclosure of the 647 Patent rather than its claims, I recognize that the Reasons do mention the disclosure as the comparator on at least two occasions: paras. 231 and 236. While the disclosure is indeed not the proper comparator, I am satisfied that the Judge properly compared the claims of the two patents. In my view, the Judge committed no reviewable error on this issue.

(5) Sufficiency of disclosure

[101] The Judge correctly noted that, to be valid, a patent must include a description of the invention defined therein sufficient "to enable a [PSA] to produce it using only the instructions contained in the disclosure" (see *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)*, [1989] 1 S.C.R. 1623 at 1638, 25 C.P.R. (3d) 257).

[102] The appellants argue that the Judge made a palpable and overriding error on this issue when he stated at paragraph 245 of the Reasons that "there is nothing unique or inventive in the way infliximab and MTX have at all times been commercially available." The appellants note that infliximab was not approved for use (and hence was not commercially available) until after publication of the 630 Patent. They argue that, as of the publication date of the 630 Patent, the PSA would not have been able to make the invention because they would not have had access to infliximab.

[103] I reject this argument. First, I note that the phrasing of the passage quoted above from paragraph 245 of the Reasons is peculiar and suggests some sort of typographical error. The statement that "there is nothing unique or inventive" does not seem to belong with the observation as to when something was commercially available. It seems possible that the Judge intended the statement about uniqueness and inventiveness to apply to infliximab, and that the observation about commercial availability was intended to apply only to MTX. In that case, there would be no error.

[104] In any case, nothing turns on the timing of infliximab becoming commercially available. Even though the sufficiency of the 630 Patent depends on the PSA's ability to obtain infliximab, and even if the PSA was not imbued with the skills necessary to make infliximab, it is undisputed that infliximab was known, and there is no suggestion that the PSA could not obtain it on a non-commercial basis. In my view, this is sufficient to support the disclosure.

IV. The Appeal on the Addition of New Parties (A-329-18)

[105] As indicated in paragraph [2] above, the Judge granted a motion after trial by the respondents to add Cilag AG as a new plaintiff by counterclaim, and Pfizer Canada Inc. as a new defendant to the counterclaim. The appellants did not object to the addition of Pfizer Canada Inc., but they do take issue with the addition of Cilag AG.

[106] The appellants argue that the Judge erred in several respects in granting the respondents' motion. These alleged errors include:

1) He failed to recognize a contradiction between the appellants' evidence on the motion and his findings at trial concerning Cilag AG as a licensee;

2) He erred in recognizing Cilag AG as a licensee with a cause of action as a person claiming under the patentee as contemplated in subsection 55(1) of the *Patent Act*;

3) He failed to consider the appellants' delay in seeking to add Cilag AG as a party in view of the information that was available to them before trial;

4) He erred in concluding that the addition of Cilag AG did not create a new action; and

5) He failed to recognize the prejudice to the appellants due to the denial of the right of discovery they would have had if Cilag AG had been added as a party before trial.

[107] I find no merit in any of these arguments.

[108] I am not convinced that there is any contradiction in the evidence that might have made a difference to the outcome of the appellants' motion. At paragraph 11 of his reasons on the motion, the Judge cited authorities for the requirements of a person claiming under the patentee, including *Signalisation de Montréal Inc. v. Services de Béton Universels Ltée*, [1993] 1 F.C. 341 at para. 24, 46 C.P.R. (3d) 199 at 210 (F.C.A.) which indicated that "a person 'claiming under'

the patentee is a person who derives his rights to use the patented invention, at whatever degree, from the patentee," and need not be a licensee or assignee. Accordingly, the appellants' arguments that Cilag AG was not a licensee are insufficient. Based on the evidence, Cilag AG was part of the respondents' supply chain, a position derived from the patentee. Hence, Cilag AG was a person claiming under the patentee.

[109] I do not agree that the Judge failed to consider the appellants' delay in seeking to add Cilag AG as a party. This point was adequately addressed in paragraphs 14-17 of the Judge's reasons on the motion.

[110] The appellants do not explain their position that the Judge erred in concluding that the addition of Cilag AG did not create a new action. I see no error here.

[111] Finally, I see no prejudice to the appellants due to a denial of discovery. The addition of Cilag AG as a person claiming under the patentee may affect the quantification of damages/profits in the next phase of the infringement action. However, the appellants will have a right to discovery of Cilag AG in that phase. This would seem to obviate the alleged prejudice.

V. The Appeal Concerning the Commission for Discovery of Dr. Maini (A-326-16)

[112] The decision under appeal in this section dismissed a motion by Hospira for a commission and letter of request to the U.K. High Court to compel the giving of evidence by one of the inventors of the 630 Patent, Dr. Maini, for purposes of discovery. The Judge concluded that the motion was not made in good faith, and that commissions will not normally be issued to

obtain discovery evidence. The appellants challenge both of these conclusions, but I see no error. The appellants have not convinced me that it was an error to find that the motion was not made in good faith. Likewise, I am not convinced that the Judge erred in relying on the general rule that commissions are not available to obtain discovery evidence.

VI. The Appeal Concerning Adjournment of the Trial (A-328-16)

[113] The decision under appeal in this section dismissed a motion by Hospira to adjourn the trial (or part thereof) to permit continued examination for discovery of the other inventor of the 630 Patent, Dr. Feldmann. The Judge noted that Hospira had declined to conduct examinations according to a prothonotary's Order pending an appeal of that Order on the question of the duration of discovery, even though no stay pending appeal was in place. The Judge concluded that Hospira had assumed the risk arising from its choice.

[114] The appellants' arguments on this appeal concern alleged failures by the Judge to adequately consider the interests of justice. I am not convinced that the Judge erred. One of the main assertions by the appellants concerned awards given to the inventors, their significance to the validity of the 630 Patent, and the appellants' inability to question the inventors about them in discovery. In my view, nothing turns on this because the Judge placed little apparent importance on the inventors' awards, and did not link them directly to the validity of the 630 Patent.

VII. Conclusion

[115] I would allow the appeal on the merits with costs.

[116] In my view, the Judge's error in his consideration of the 1994 Kennedy Report and Higgins in analysis of the issue of anticipation merits reconsideration of this issue. Likewise, the Judge's error in excluding Higgins and the FDA Workshop from consideration on the issue of obviousness, and the lack of clarity in the Judge's assessment of the question of obviousness to try, merit reconsideration of the issue of obviousness. I would remit this matter to the Federal Court for reconsideration of the issues of anticipation and obviousness in light of these reasons.

[117] In view of my conclusion that there is no evidence to support a finding of infringement of claims 12, 15, 28 and 31 of the 630 Patent, and my conclusion that claims 37 and 38 were not among the asserted claims, I would, in the event that the claims in issue are found to be valid after reconsideration, amend paragraphs 5, 6(a) and 6(b) of the Judgment on the merits by removing those claims from the list of claims found to be infringed.

[118] In view of my conclusion that there is no evidence that either Celltrion Healthcare Co. Ltd. or Celltrion, Inc. conducted any activities in Canada, I would, in the event that the claims in issue are found to be valid after reconsideration, amend paragraph 5 of the Judgment on the merits by removing reference to those companies.

[119] I would dismiss the other appeals with costs.

"George R. Locke"
J.A.

"I agree.
M. Nadon J.A."

"I agree.
Marianne Rivoalen J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKETS:	A-338-18 (lead file); A-326-16; A-328-16; A-329-18

APPEAL FROM A JUDGMENT OF MR. JUSTICE PHELAN OF THE FEDERAL COURT, DATED SEPTEMBER 28, 2018, NO. T-396-13

STYLE OF CAUSE:	HOSPIRA HEALTHCARE CORPORATION, CELLTRION HEALTHCARE CO., LTD., CELLTRION, INC. and PFIZER CANADA INC. v. THE KENNEDY TRUST FOR RHEUMATOLOGY RESEARCH, JANSSEN BIOTECH, INC., JANSSEN INC., CILAG GmbH INTERNATIONAL and CILAG AG
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	OCTOBER 28, 2019
REASONS FOR JUDGMENT BY:	LOCKE J.A.
CONCURRED IN BY:	NADON J.A. RIVOALEN J.A.
DATED:	JANUARY 30, 2020 Amended March 30, 2021

APPEARANCES:

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Andrew Skodyn Melanie K. Baird	FOR THE RESPONDENTS

SOLICITORS OF RECORD:

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