Federal Court of Appeal | Cour d'appel fédérale

Date: 20221101

Dockets: A-38-21 (lead file)
A-36-21
A-37-21

Citation: 2022 FCA 184

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

BETWEEN:

JANSSEN INC., JANSSEN ONCOLOGY, INC. and BTG INTERNATIONAL LTD.

Appellants

and

APOTEX INC., PHARMASCIENCE INC., DR. REDDY'S LABORATORIES LTD, and DR. REDDY'S LABORATORIES, INC.

Respondents

Heard at Ottawa, Ontario, on September 14, 2022.

Judgment delivered at Ottawa, Ontario, on November 1, 2022.

REASONS FOR JUDGMENT BY: LOCKE J.A.

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

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REASONS FOR JUDGMENT

LOCKE J.A.

I. Background

[1] In three separate proceedings (Court File Nos. A-38-21 (the lead file), A-36-21 and A-37-21) against, respectively, the respondents Apotex Inc. (Apotex), Pharmascience Inc. and, collectively, Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories, Inc., the appellants (Janssen Inc., Janssen Oncology, Inc. and BTG International Ltd.) appeal a decision of the Federal Court (2021 FC 7, *per* Justice Michael L. Phelan, the Decision) that declared Canadian Patent No. 2,661,422 (the 422 Patent), owned by the appellants Janssen Oncology, Inc. and BTG International Ltd., invalid for obviousness. The Decision, made following a trial in several actions pursuant to the *Patented Medicines (Notice of Compliance) Regulations*, S.O.R./93-133 (the Regulations), also ordered that the 422 Patent be removed from the Patent Register defined in the Regulations.

[2] In a separate appeal (Court File No. A-267-20), the appellants take issue with a pair of Orders made by Justice Phelan just before trial, which permitted (i) the late addition by Apotex of an addendum to the report of its expert Robert Nam, and (ii) a corresponding amendment to its counterclaim. That appeal was heard on the same day as the others and is addressed in a separate decision (2022 FCA 185).

[3] As a matter of context, it may be interesting to note that a similar dispute between the appellants and Apotex concerning the obviousness of the 422 Patent was heard and decided previously by Justice Phelan (see 2019 FC 1355, the 2019 NOC proceeding). That decision was made in the context of an application under the Regulations as they read prior to amendments made in 2017, and found that allegations by Apotex that the 422 Patent is invalid (on several grounds, including obviousness) were not justified. Finding itself on the losing side in that case,

Apotex appealed to this Court, which dismissed the appeal (2021 FCA 45), leaving the validity of the 422 Patent untainted. Even though the appellants in the present appeals prevailed in the 2019 NOC proceeding, there is no dispute that, for the purposes of the Decision, the Federal Court's prior findings were not binding on the parties or on the courts. The 2019 NOC proceeding involved a different evidentiary record, and the witnesses' testimony in that case was adduced by transcript rather than live in court.

II. The 422 Patent

[4] The 422 Patent is entitled "Methods and Compositions for Treating Cancer", and its claims concern the treatment of prostate cancer in humans. Specifically, the claims concern the co-administration of abiraterone acetate (AA) and prednisone (PN).

[5] The following overview by the Federal Court of the technology leading to the 422 Patent is helpful:

> [20] Prostate cancer, the uncontrolled growth of cells in the prostate gland, is the most commonly diagnosed cancer in men and the second leading cause of cancer-related deaths in men. While early prostate cancer may be treated or not and monitored, at some point the cancer may spread to other parts of the body – becoming metastatic cancer.
>
> [21] Most men with metastatic prostate cancer are treated with androgen deprivation therapy [ADT] because the male sex hormones (androgens) specifically testosterone promote prostate cancer.
>
> Since the 1940s the primary treatment for metastatic prostate cancer by ADT was through medical or surgical castration to suppress androgen production in the testes. Patients treated with ADT still had some residual androgens in their system because the adrenal gland produces 10% of circulating androgens in men.

> [22] When the prostate cancer begins to progress after ADT, it is referred to as "castration-resistant prostate cancer" [CRPC] and if the cancer has metastasized, it is referred to as mCRPC.
>
> …
>
> [26] Before 2007, aminoglutethimide and ketoconazole were used in prostate cancer therapy but neither improved survival. They were understood to be non-specific inhibitors of adrenal steroid synthesis and had serious side effects, including glucocorticoid deficiency which sometimes required concomitant glucocorticoid use. …
>
> [27] PN, a glucocorticoid, was used to palliate prostate cancer patients and alleviate side effects of treatment. It was an old drug – available since the 1950s. It was known to have some anti-cancer effects but how and how much was not known. PN did offer palliation, relief from side effects and some anti-cancer effects (sometimes called anti-tumour activity) but not an established survival benefit. PN had not been approved as an anti-cancer drug.
>
> [28] As disclosed in the 422 Patient [sic], CYP17 inhibitors, of which AA is one, had been shown to be useful in treating prostate cancer. AA was a newer drug than PN.
>
> [29] The CYP17 enzyme (17α-hydroxylase/C17,20–lyase) has two activities in adrenal steroid synthesis: 17α hydroxylase activity is necessary for the production of cortisol and androgens while 17,20-lyase activity only affects the production of androgens.

[6] It is the inhibition of cortisol production by 17α hydroxylase activity of the CYP17 enzyme that could lead to the side effect of glucocorticoid deficiency.

[7] An important aspect of the 422 Patent is its specific definition of the terms "treat", "treating" and "treatment". Paragraph 22 of the 422 Patent describes these terms as including "the eradication, removal, modification, management or control of a tumor or primary, regional, or metastatic cancer cells or tissue and the minimization or delay of the spread of cancer." Notably, this definition does not mention palliation of symptoms or treatment of side effects; neither does it mention survival benefits.

III. Decision under Appeal

[8] The Decision dealt with a number of grounds of invalidity, but the only ground requiring discussion here is obviousness. On that issue, the Federal Court cited section 28.3 of the *Patent Act*, R.S.C. 1985, c. P-4, which provides the statutory basis for invalidity due to obviousness (see paragraph 125 of the Decision). At paragraph 129, the Federal Court also cited the four-step framework for the assessment of obviousness as set out by the Supreme Court of Canada in *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61, [2008] 3 S.C.R. 61 (*Sanofi*) at paragraph 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?

[9] The Federal Court also noted that, where advances are often won by experimentation, an "obvious to try" test might be appropriate to address at the fourth step.

[10] The Federal Court then went through the steps. At paragraph 138 of the Decision, it noted that there was little disagreement on the first step. The following points should be noted concerning the state of the art:

A. The appellants' expert Matthew Rettig accepted the following facts that he had denied in his testimony in the 2019 NOC proceeding:

   i. Aminoglutethimide, ketoconazole and AA were all known CYP17 androgen inhibitors, part of a class of drugs known for treating mCRPC (paragraph 141 of the Decision);

   ii. Aminoglutethimide was known to have anti-cancer treatment effects in prostate cancer patients (paragraph 142 of the Decision); and

   iii. Ketoconazole was known to have anti-cancer treatment effects (paragraph 143 of the Decision);

B. Androgen inhibitors were known to affect multiple steroid production pathways and compromise cortisol production, thus requiring glucocorticoid replacement (paragraph 144 of the Decision);

C. Glucocorticoid replacement with PN was a common clinical practice (paragraph 144 of the Decision);

D. PN was known to treat prostate cancers (paragraph 156 of the Decision);

E. AA, a CYP17 inhibitor, had been shown to be useful in the treatment of prostate cancer, and the role of CYP17 inhibitors in treating prostate cancer is acknowledged in the 422 Patent (paragraph 145 of the Decision);

F. A paper called O'Donnell 2004 (A. O'Donnell et al., "Hormonal impact of the 17α-hydroxylase/$C_{17,20}$-lyase inhibitor abiraterone acetate (CB7630) in patients with prostate cancer" (2004) 90:12 British J. Cancer 2317) noted that AA resulted in the suppression of testosterone below castration levels (paragraph 146 of the Decision);

G. The need for glucocorticoid replacement when administering AA was recognized (paragraphs 147 and 151 of the Decision);

H. AA was more selective than the other two known CYP17 inhibitors (paragraph 148 of the Decision);

I. AA's more selective quality made it a clear target therapy (paragraph 154 of the Decision); and

J. The use of anti-cancer agents in combination was well accepted; and there was no serious concern that glucocorticoids (and PN in particular) would cancel out or interfere with the anti-cancer activity of CPY17 inhibitors like AA (paragraphs 157 and 158 of the Decision).

[11] Step 2 of the obviousness analysis calls for the identification of the inventive concept. At paragraph 171 of the Decision, the Federal Court defined the inventive concept of the claims that were asserted by the appellants as the same as the claims construed: "the use of the combination of therapeutically effective amounts of AA and PN in the treatment of prostate cancer (Claims 3, 6 and 7), refractory cancer (Claim 14) and refractory prostate cancer that is not responding to an anti-cancer agent (Claim 15) in a human."

[12] In step 3 of the obviousness analysis, the Federal Court addressed the differences between the inventive concept and the state of the art. It found that they were not so material that an unimaginative skilled person would not continue down the road to the invention (paragraph 170 of the Decision). It noted that both AA and PN were known to effectively treat prostate cancer, and that the state of the art taught combining drugs like AA and PN (paragraph 172 of the Decision). The Federal Court then stated that "[t]he only part of the puzzle missing in the state of the art/CGK [common general knowledge] is a person actually combining AA and PN to treat prostate cancer including refractory prostate cancer. Given the evidence, to do so was a logical step in the progress of prostate cancer treatment." (paragraph 173 of the Decision).

[13] At step 4, the Federal Court considered obviousness to try, concluding that the claimed combination was obvious to try (paragraph 197 of the Decision).

IV. Issues and Standard of Review

[14] The substantive validity issue that went against the appellants in the Decision was obviousness. They do not challenge all of the Federal Court's reasoning on this issue. They argue only the following as errors by the Federal Court:

A. Finding that AA was known to be a prostate cancer treatment;

B. Identifying and applying the gap between the state of the art and the inventive concept;

C. Declaring that the 422 Patent is invalid; and

D. Ordering the removal of the 422 Patent from the Patent Register.

[15] Within the above-noted issues, the appellants focus on specific points. These are discussed in the analysis below.

[16] There is no dispute that the standard of review on the issues in this case is as set out in *Housen v. Nikolaisen*, 2002 SCC 33, [2002] 2 S.C.R. 235: the standard of correctness applies to extricable questions of law, but absent an error on such a question, this Court will not interfere with the Federal Court's findings on questions of fact or of mixed fact and law absent a palpable (obvious) and overriding (going to the core of the outcome) error.

[17] For the reasons discussed below, I would dismiss the appeals on all issues.

V. Analysis

A. *Finding that AA was known to be a prostate cancer treatment*

[18] The appellants argue that the Federal Court reached its conclusion that AA was known to treat prostate cancer based on two erroneous findings: (i) that an admission in the 422 Patent to this effect was binding on the appellants, and (ii) that the results of a study of AA as a treatment for prostate cancer (the 001 Study) were reported in the prior art O'Donnell 2004 paper. In my view, neither of these arguments can alter the Federal Court's conclusion. I will address each in turn.

(1) Admission in the 422 Patent

[19] Paragraph 35 of the 422 Patent states that CYP17 inhibitors, of which AA is one, have been shown to be useful in the treatment of prostate cancer. The paragraph cites US Patent No. 5,604,213 (the 213 Patent) in support of this statement. The appellants note that the 213 Patent disclosed *in vitro* and rodent studies, but did not disclose any human studies. They argue that it cannot therefore support the statement in the 422 Patent that AA had been shown to be useful in treating prostate cancer. The appellants also argue that the Federal Court erred by treating paragraph 35 of the 422 Patent as a binding admission.

[20] What the Federal Court said on this issue is found at paragraph 115 of the Decision:

> [115] The Patent states that AA was already known as a treatment for prostate cancer. The Defendants contend that this is an "admission binding on Janssen" (see *Bristol-Myers Squibb Canada v Apotex Inc*, 2017 FC 296 at para 183 and cases cited).
>
> There appears to be no dispute from the Plaintiffs on this fact nor given the CGK evidence, could there be.

[21] It does not appear that the Federal Court necessarily accepted the respondents' argument that the admission was binding. The Federal Court appears instead to have relied on (i) an absence of dispute on whether AA was already known to treat prostate cancer (though the appellants argue that there <u>was</u> dispute on the point), and (ii) common general knowledge supporting the admission.

[22] It is not necessary to decide here whether, to what extent, and under what circumstances an admission in a patent will be binding on the patentee. The Federal Court did not say that it

was treating the admission as binding. Instead, it stated that it was relying on prior art evidence of AA as a treatment for prostate cancer. There was evidence on which the Federal Court was entitled to rely that supported this conclusion. For example, paragraph 305 of Dr. Nam's expert report discusses prior art references that describe the use of AA to treat prostate cancer. The appellants have not persuaded me that the Federal Court made a palpable and overriding error in reaching this factual conclusion.

[23] On the question of the Federal Court's reliance on the absence of dispute, I understand this to be with regard to the idea, rather than an actual instance, of using AA as a treatment for prostate cancer. The Federal Court did not err in this regard. Though the appellants may be right that AA had not actually been studied in the prior art as a prostate cancer treatment, it had certainly been proposed for that purpose on the expectation that it would be effective.

(2) Results of the 001 Study reported in O'Donnell 2004

[24] Paragraph 100 of the Decision states that the results of the 001 Study were reported in O'Donnell 2004. The parties agree that this statement is incorrect. The 001 Study did not begin until after the publication of O'Donnell 2004, and therefore its results could not have been reported in O'Donnell 2004. Moreover, the 001 Study was not part of the prior art. The appellants argue that this error by the Federal Court is palpable. I agree.

[25] However, I do not agree with the appellants' argument that the error is also overriding in that it "likely had an impact on the [Federal Court's] finding that AA was known as a prostate cancer treatment as it narrowed the gap between the art and the inventive concept."

[26] I am not persuaded that the Federal Court actually believed that the 001 Study was mentioned in the prior art, or otherwise misunderstood the state of the art. The Federal Court's description of the evidence related to the prior art was otherwise detailed and without obvious error. The Federal Court does not appear to have relied on the 001 Study being part of the prior art. I agree with the respondents' argument that the Federal Court's erroneous statement was a slip of the pen, and that it likely intended to say that the results of O'Donnell 2004 were reported in the 001 Study, which is correct.

[27] The appellants argue that this correction should have been the subject of a motion to reconsider under Rule 397(1) of the *Federal Courts Rules*, S.O.R./98-106. In my view, the Federal Court's error here does not fit within Rule 397(1) because it does not concern either a discord between the reasons and the resulting Judgment, or a matter that was overlooked. Moreover, Rule 397(2) provides that clerical errors "may at any time be corrected by the Court."

B. *Identifying and applying the gap between the state of the art and the inventive concept*

[28] The appellants argue two errors under this heading, which I address in turn.

(1) Each of AA and PN must be shown to contribute

[29] The appellants note that the accepted construction of the claims requires not just that the combination of AA and PN treat prostate cancer, but also that each of the two compounds contribute individually to the combination treatment. The appellants argue that a proper finding of obviousness of the 422 Patent would require a conclusion that it was obvious that AA

contributed to the treatment of cancer independent of PN. The appellants note that the Federal Court's obviousness analysis was flawed in that it never explained how a skilled person would have come to understand that AA contributed to anti-cancer effects independent of PN. They cite the evidence of Dr. Nam, speaking to the issue of utility, to the effect that such an understanding would have required a study of AA as a monotherapy for comparison with combination therapy. They argue that there is no evidence that a skilled person would have done such a study.

[30] The respondents note that assessment of obviousness to try is different from assessment of utility whereby the usefulness of the invention must have been demonstrated prior to the filing date, failing which the disclosure must include information that supports a sound prediction of utility. They argue that it is inherent in the concept of obviousness to try that the invention has not been tried, and that there is some uncertainty as to whether it will work. The key is the expectation of success.

[31] The respondents note that the Federal Court made the following findings of fact that are relevant to the obviousness to try analysis:

A. AA was known to be useful to treat prostate cancer (paragraph 145 of the Decision);

B. PN was known to be useful to treat prostate cancer (paragraphs 27 and 156 of the Decision);

C. There was motivation to combine AA and PN in the treatment of prostate cancer for several reasons, including their separate anti-cancer effects (paragraph 185 of the Decision); and

D. The skilled person would expect that AA and PN would work together without interfering with one another (paragraphs 157 and 185 of the Decision).

[32] I agree with the respondents that these findings of fact, which are not palpably wrong, are sufficient to support the Federal Court's conclusion that the invention of the 422 Patent was obvious to try. Whether or not the skilled person trying the invention would immediately know that AA had anti-cancer effects independent of the combination is not critical. For one, making such a determination would provide nothing helpful in the use of the invention. Moreover, there is no suggestion that any inventiveness would be required to confirm that each of AA and PN contributes independently to the treatment of prostate cancer when they are administered in combination. It is enough that a skilled person would have expected that each of AA and PN would contribute.

[33] In my view, the Federal Court did not err in its assessment of the contribution of AA as it concerns obviousness to try.

(2) Refractory prostate cancer

[34] The appellants note that the Federal Court correctly stated at paragraph 126 of the Decision that a critical question in this case is what was inventive about combining AA and PN

to treat prostate cancer including refractory prostate cancer. The appellants argue that the Federal Court then failed to consider treatment of refractory prostate cancer in its obviousness analysis. They point to paragraph 184 of the Decision, which states as follows: "Given the success of other combinations, it was reasonable to expect success in anti-cancer treatment to combine AA and PN to treat CRPC patients excluding those being refractory patients." (emphasis added)

[35] I agree with the respondents that this appears to be another slip of the pen, in which the word "excluding" was intended to be "including". Reading the Decision as a whole, I can see no other explanation for the Federal Court recognizing the importance of addressing refractory cancers, and then appearing to exclude them from consideration with no rationale being offered for doing so. I note that paragraph 173 of the Decision, quoted at paragraph 12 above, includes refractory prostate cancer in the analysis. Although the error in paragraph 184 is palpable and unfortunate, it does indeed appear to be simply a clerical error. I read the word "excluding" in paragraph 184 as "including".

C. *Declaring that the 422 Patent is invalid, and ordering its removal from the Patent Register*

(1) Nam addendum and counterclaim amendment

[36] The appellants' arguments on the issues of declaring the 422 Patent invalid and of ordering its removal from the Patent Register are linked to the separate appeal in Court File A-267-20 mentioned above. That appeal concerns the propriety of permitting (i) a late addendum to an expert report, and (ii) an amendment to the counterclaim to reflect the issues addressed in that addendum. The addendum followed Apotex's late realization that Dr. Nam's original expert

report had failed to address the validity of claims that were not asserted by the appellants. The addendum was short, and essentially concluded that these non-asserted claims were similar to the asserted claims (adding only uninventive limitations), and that Dr. Nam's opinion on obviousness (as well as some other issues) applied equally to them. The Federal Court allowed the addendum on the basis that it was in the interests of justice to do so. The Federal Court also observed that an amendment to the counterclaim might be advisable to clarify that the obviousness of the non-asserted claims was in issue. In a later Order, the Federal Court permitted such an amendment.

[37] The appellants argue that neither the addendum nor the amendment should have been allowed, and that the validity of the non-asserted claims was not properly in dispute. It would follow from this that the non-asserted claims of the 422 Patent would remain valid, and therefore the 422 Patent would not be subject to removal from the Patent Register.

[38] As indicated above, the appeal of the Federal Court's pre-trial orders is addressed in a separate decision. The discussion below proceeds on the basis that the separate appeal is dismissed, and the addendum and amended counterclaim are left in place.

(2) Non-asserted claims and subsection 6(3) of the Regulations

[39] The Federal Court clearly agreed with Dr. Nam's view on the similarity of the asserted and non-asserted claims. At paragraph 118 of the Decision, it stated that "[t]he non-asserted claims are essentially the same" as the asserted claims. The appellants do not take issue with this conclusion.

[40] However, even basing the discussion below on the addendum and the amended counterclaim being left in place, it remains necessary to address the appellants' argument that the validity of the non-asserted claims should not have been addressed in the Decision. An important basis for this argument is the appellants' position that the Regulations do not permit a defendant in an action under subsection 6(1) thereof to counterclaim for a declaration of invalidity of claims that are not asserted against it. In support of this argument, it points to paragraph 6(3)(a) of the Regulations, which provides as follows:

6 (3) The second [here, Apotex] person may bring a counterclaim for a declaration	**6 (3)** La seconde [ici, Apotex] personne peut faire une demande reconventionnelle afin d'obtenir une déclaration :
(a) under subsection 60(1) or (2) of the *Patent Act* in respect of any patent claim asserted in the action brought under subsection (1); or [emphasis added]	**a)** soit au titre des paragraphes 60(1) ou (2) de la *Loi sur les brevets* à l'égard de toute revendication se rapportant à un brevet faite dans le cadre de l'action intentée en vertu du paragraphe (1); [je souligne]

[41] The appellants argue that the wording is specific to asserted claims, and there is no basis to counterclaim in respect of non-asserted claims. For their part, the respondents argue that paragraph 6(3)(a) is permissive, and does not limit the claims that can be included in a counterclaim in an action under subsection 6(1).

[42] It is important to bear in mind that the Orders issued before trial concerned, first, whether an extension of time should be granted to Apotex for the submission of expert evidence, and second, whether an amended pleading should be allowed. The legal considerations pertinent to these issues touch only incidentally on the interpretation that should be given to paragraph

6(3)(a) of the Regulations. Before trial, the Federal Court was not tasked with deciding the admissibility of such expert evidence.

[43] In the Decision following trial, the Federal Court dealt with the issue of the scope of the counterclaim as follows:

> [229] The Plaintiffs object to the Defendants bringing a counterclaim in respect to the non-asserted claims on the basis that the right to bring a counterclaim is restricted under s 6(3) to counterclaims in respect of "asserted claims".
>
> [230] In the context of the present case, this counterclaim issue appears to have no particular relevance except for appellate comment.
>
> [231] The Plaintiffs argue that s 6.01 limits an action under s 6(1) to asserted claims although those terms are not used. It says that a counterclaim under s 6(3) is specifically limited to asserted claims.
>
> [232] There are two matters of concern to the Court. The first is that the Plaintiffs consented to the delivery of a counterclaim without reservations at the time. The second is that a defendant may not be able to claim invalidity of a patent on grounds but only as it relates to specific claims asserted in an NOC action.
>
> [233] The NOC Regulations are not a complete code but the purpose of s 6(3) must be to confirm that the right to bring a counterclaim in the NOC action exists; but it is restricted to the claims asserted in the action.
>
> [234] A counterclaim is a separate action. Section 6(3) merely allows a party the convenience of bringing a challenge to a patent in the context of an NOC action in respect of asserted claims. Whether a separate claim of invalidity could be consolidated with a NOC action remains an open question.
>
> [235] Given the consent of the Plaintiffs in this case, the parties found a more expeditious way to deal with non-asserted claims, none of which impact the Judgment in this case.
>
> [236] A more thorough analysis of the overall impact of s 6(3) of the NOC Regulations should await a better record and more fulsome legal argument.

[44] Though these paragraphs are not a model of clarity, it appears that the Federal Court concluded that it did not have to decide on the proper interpretation of subsection 6(3) of the

Regulations because the appellants had already agreed "without reservations" to address the validity of non-asserted claims in the counterclaim.

[45] The appellants argue that the Federal Court is a statutory court having only the jurisdiction that is provided to it by legislation, and that neither parties to litigation nor the Federal Court itself have the power to agree to extend that jurisdiction. This much, I accept. However, the appellants go on to criticize the Federal Court for failing to consider its jurisdiction to rule on the validity of the non-asserted claims of the 422 Patent.

[46] To address the appellants' position, it is necessary to consider whether the Regulations permit, in the context of an action under subsection 6(1) thereof, a counterclaim on claims not asserted in the action, whether by right or with leave of the Court. I will address the question of whether such a counterclaim is permitted with leave. As did the Federal Court, I will leave for another day, the question of whether a defendant in an action under subsection 6(1) may make such a counterclaim by right.

[47] I do not accept that the Federal Court's jurisdiction to address a counterclaim against non-asserted claims in the context of an action under subsection 6(1) of the Regulations must be expressed in the Regulations themselves. The jurisdiction of the Federal Court to address a challenge to the validity of a patent, whether by counterclaim in the context of a patent infringement action or otherwise, is already clear from the *Patent Act* and the *Federal Courts Rules*, S.O.R./98-106. The question for this Court is whether the Regulations limit that

jurisdiction by prohibiting either (i) parties from agreeing to address the validity of non-asserted claims in proceedings thereunder, or (ii) the Federal Court from so ordering.

[48] Focusing first on the text of paragraph 6(3)(a) (reproduced at paragraph 40 above), it is indeed permissive. It provides that asserted claims can be included in a counterclaim, but it does not explicitly prohibit anything. The appellants argue that the prohibition is implicit in the mention of asserted claims, and the corresponding silence on non-asserted claims. That is a reasonable argument. However, in my view, any such implicit limitation would have to be supported by the context and/or the purpose of the Regulations.

[49] Other provisions of the Regulations provide arguments for either side of the debate. The appellants note provisions introduced with 2017 amendments that are designed to simplify proceedings to ensure that they can readily proceed to a decision following trial within the 24-month period contemplated therein. For example, section 6.02 provides that, with limited exceptions, no other action may be joined to an action under subsection 6(1) of the Regulations during the 24-month period. In addition, section 6.09 requires parties to reasonably cooperate in expediting proceedings under subsections 6(1) and 6(3). On the other side of the debate, Apotex notes that many provisions of the Regulations that are intended to be mandatory say so explicitly (with words like “shall” and “must”); no inference is necessary. Apotex suggests that, if the intention had been to prohibit non-asserted claims in a counterclaim, subsection 6(3) could have said so.

[50] Apotex also argues that limiting counterclaims under subsection 6(3) to asserted claims would not necessarily be more expeditious. Requiring a second person (a defendant) in proceedings under the Regulations to pursue another action separately to obtain a declaration of invalidity (or non-infringement) concerning non-asserted claims could result in unnecessary additional proceedings and an increase in the use of court resources, as well as a risk of inconsistent decisions. Moreover, not all provisions of the Regulations are intended to limit the scope of proceedings under section 6. Subsection 6(3) itself is an excellent example: it permits the introduction of a counterclaim. Though a defendant may need to argue as part of its defence against an infringement allegation that the asserted claims in such proceedings are invalid, it is not necessary that such a defence take the form of a counterclaim. Invalidity merely as a defence would be sufficient to decide the action under subsection 6(1). An important reason to permit a counterclaim (for a formal declaration of invalidity) is to avoid the potential need for additional legal proceedings (by the same defendant or another person) to obtain such a declaration. This also avoids the risk of inconsistent decisions. Arguably, these goals apply equally to non-asserted claims. It is also arguable that the objective of the Regulations is overall efficiency rather than expediting each individual proceeding.

[51] A review of the Regulatory Impact Analysis Statement (RIAS) that accompanied the 2017 amendments is interesting. This can be found in the *Canada Gazette*, Part II, Vol. 151, Extra No. 1, dated September 7, 2017. The RIAS explicitly mentions the aim of "overall efficiency" three times: (i) at the end of the "Issues" section on page 32, (ii) at the end of the "Description" section on page 35, and (iii) at the end of the "Rationale" section on page 52. A plaintiff's agreement to address a counterclaim alleging invalidity of non-asserted claims in the

context of its action under subsection 6(1) suggests its acknowledgement of the efficiency of addressing these issues in the same proceeding. This is particularly so in this case in which the non-asserted claims are so similar to the asserted claims. Under the heading “Objectives” on page 34, the RIAS highlights the aim of “provid[ing] impacted parties with some flexibility and choice.” Later on the same page, the RIAS recognizes that the aim of expediting proceedings applies in parallel with the desire of “leaving the Court broad discretion to manage proceedings.” Along the same lines, the RIAS notes, under the heading “Description” on page 35, the decision to limit the introduction of procedural rules, and “to leave such matters to be dealt with by the Court on a case-by-case basis.”

[52] One of the objectives mentioned in the RIAS is the elimination of the “costly and inefficient practice of dual litigation” (see page 34), which existed under the prior Regulations. This objective is restated under the “Claims at issue” heading on page 37 where, in discussion of a former limitation on the types of claims that could be addressed, the RIAS refers to the benefit of eliminating “the need for separate proceedings to address all claims in a single patent.” This same benefit may be gained by addressing the validity of non-asserted claims at the same time as the validity of asserted claims.

[53] A final observation on the purpose of the Regulations is that the passage in the RIAS that appears to address subsection 6(3) directly, under the heading “Focus on infringement and validity” on page 36, states that “a second person may commence a counterclaim seeking to invalidate the patent.” Notably, this passage refers to the invalidity of the patent, and does not focus on the asserted claims thereof.

[54] In my view, the intention of the Regulations is to leave to the Federal Court the discretion to permit a counterclaim under subsection 6(3) that includes non-asserted claims. The Federal Court exercised that discretion, and provided the reasons quoted at paragraph 43 above. I would not interfere with this exercise of discretion. I would also not interfere with the finding of invalidity of all claims of the 422 Patent, and the Order to remove it from the Patent Register.

(3) "Dismissal" of counterclaim

[55] The Federal Court reached a confusing conclusion at the end of the Decision. On the strength of its finding that the claims of the 422 Patent were obvious, the Federal Court concluded as follows at paragraph 261 of the Decision: "For these Reasons, the Plaintiffs' [the appellants'] action will be dismissed. The counterclaim will likewise be dismissed. The invention is obvious/obvious to try. The 422 Patent is and has been invalid." In light of the reasons, it is easy to understand the conclusions that the appellants' action was dismissed, and that the 422 Patent was invalid. On the other hand, it is not clear why the Federal Court stated that the counterclaim would be dismissed. The finding that the 422 Patent is invalid for obviousness would seem to indicate that the counterclaim should be granted because it is the counterclaim that sought that declaration.

[56] The confusion was compounded by the Judgments accompanying the Decision. The Federal Court issued separate Judgments in respect of each of the actions against the respondents. These Judgments declared that the 422 Patent is invalid for obviousness, and ordered that it be removed from the Patent Register. The Judgment concerning the action against Apotex (cited as 2021 FC 3) also adjudged that the action and the counterclaim were dismissed.

Given the finding of invalidity of the 422 Patent, it is difficult to understand the dismissal of the counterclaim. Further, given the dismissal of the counterclaim, it is difficult to understand the basis for ordering that the 422 Patent be removed from the Patent Register.

[57] Remarkably, neither the appellants nor Apotex took any steps before the Federal Court to clarify these confusing statements in the Decision and the accompanying Judgment involving Apotex (for example, a motion to reconsider under Rule 397(2)). Asked about this confusion at the hearing before this Court, both sides appeared prepared to accept that the dismissal of the counterclaim was deliberate, and not a mistake. In view of what I have said above, I do not understand how that could be. Reading the Decision as a whole, I can see no reason that the Federal Court would have dismissed the counterclaim. In my view, the only reasonable conclusion is that the Federal Court intended to find in favour of the respondents on both the main claim and the counterclaim, and grant the counterclaim. Treating the dismissal of the counterclaim as yet another slip of the pen clears up the confusion concerning the Federal Court's conclusion. Accordingly, I would read the second sentence of paragraph 261 of the Decision as "The counterclaim will be granted".

(4) Amendments to Judgment involving Apotex

[58] Reading the Federal Court's conclusion as a grant of the counterclaim, rather than a dismissal, necessitates a change to the Judgment involving Apotex. Making the Judgment that the Federal Court should have made, I would amend paragraph 3 thereof to read as follows:

> The action **is dismissed, and the counterclaim is granted,** with costs to the Defendant **in both proceedings**, the whole of which is to be the subject of a further determination by the Court.

VI. Conclusion

[59] I would dismiss the appeals with costs, and amend the Judgment involving Apotex (cited as 2021 FC 3) as indicated in the preceding paragraph.

"George R. Locke"
J.A.

"I agree
Anne L. Mactavish J.A."

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

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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CONCURRED IN BY:	MACTAVISH J.A. MONAGHAN J.A.
DATED:	NOVEMBER 1, 2022

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