Federal Court of Appeal | Cour d'appel fédérale

Date: 20240416

Docket: A-244-22

Citation: 2024 FCA 72

CORAM: **WEBB J.A.**
RENNIE J.A.
LOCKE J.A.

BETWEEN:

ELI LILLY CANADA INC., ELI LILLY AND COMPANY, LILLY DEL CARIBE, INC., LILLY, S.A. and ICOS CORPORATION INC.

Appellants

and

APOTEX INC., MYLAN PHARMACEUTICALS ULC, TEVA CANADA LIMITED, PHARMASCIENCE INC. and LABORATOIRE RIVA INC.

Respondents

Heard at Toronto, Ontario, on January 17, 2024.

Judgment delivered at Ottawa, Ontario, on April 16, 2024.

REASONS FOR JUDGMENT BY: LOCKE J.A.

CONCURRED IN BY: WEBB J.A.
RENNIE J.A.

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REASONS FOR JUDGMENT

LOCKE J.A.

I. Background

[1] This is an appeal of a decision by the Federal Court (2022 FC 1398, *per* Justice Martine St-Louis) that found various claims of Canadian Patent No. 2,226,784 (the 784 Patent) to be

invalid for overbreadth and insufficiency. As a result, the Federal Court dismissed actions by the appellants against the respondents alleging infringement of the 784 Patent. The respondents had also argued that the claims in issue were invalid for inutility, but the Federal Court elected not to decide that issue.

[2] The present appeal turns principally on the Federal Court's interpretation of the term "physiologically acceptable" in reference to a physiologically acceptable salt of tadalafil, which is an element of all of the claims in issue. Stated briefly, the appellants argue that "physiologically acceptable" simply means non-toxic, such that any salt of tadalafil that is not toxic when administered is physiologically acceptable. For their part, the respondents argue that the Federal Court's interpretation was correct – that a salt that is "physiologically acceptable" must be more than merely non-toxic, it must also be "stable and pure, not degraded" (see paragraph 92 of the Federal Court's reasons (the Reasons)).

[3] The appellants argue that if the Federal Court had not erred in its interpretation of "physiologically acceptable", it would not have concluded that the claims in issue are invalid for overbreadth and insufficiency.

[4] The respondents argue that, even on the appellants' interpretation of "physiologically acceptable", the claims in issue would be invalid for overbreadth and insufficiency. They also argue that, based on its factual findings, the Federal Court should also have found the claims in issue to be invalid for inutility.

[5] For the reasons discussed below, I would dismiss the appeal.

II. The 784 Patent

[6] The 784 Patent concerns the use of tadalafil (among other compounds) and its physiologically acceptable salts in the treatment of erectile dysfunction. The appellants market the alleged invention of the 784 Patent with their drug CIALIS.

[7] The 784 Patent expired in 2016 and the respondents did not enter the market with their generic versions of CIALIS until after that. However, the appellants allege that the respondents engaged in activities prior to expiration, including manufacturing, importing and stockpiling, that constituted infringement of the claims in issue.

[8] The key term "physiologically acceptable" is not defined in the 784 Patent. It is notable that the term "pharmaceutically acceptable" [emphasis added] is used many times in the disclosure and claims of the 784 Patent. In many such instances, this term is used to describe a salt as contemplated by the invention. As explained below, the parallel use of "physiologically acceptable" and "pharmaceutically acceptable" to describe the salts contemplated by the invention led the Federal Court to conclude that these terms are synonymous in the context of the 784 Patent.

[9] Page 4 of the 784 Patent specification provides examples of the salts contemplated therein specific to tadalafil:

> The pharmaceutically acceptable salts of the compounds of formula (I), and in particular compounds A [tadalafil] and B which contain a basic centre are acid addition salts formed with pharmaceutically acceptable acids. Examples include the hydrochloride, hydrobromide, sulphate or bisulphate, phosphate or hydrogen phosphate, acetate, benzoate, succinate, fumarate, maleate, lactate, citrate, tartrate, gluconate, methanesulphonate, benzenesulphonate and p-toluenesulphonate salts. Compounds of formula (I), and in particular compounds A and B can also provide pharmaceutically acceptable metal salts, in particular alkali metal salts, with bases. Examples include the sodium and potassium salts.

[10] The 784 Patent also describes pharmaceutically acceptable salts and how to make them at page 9:

> The pharmaceutically acceptable acid addition salts of a compound of formula (I), and in particular compound A [tadalafil] or B which contain a basic centre may be prepared in a conventional manner. For example, a solution of the free base may be treated with a suitable acid, either neat or in a suitable solution, and the resulting salt isolated either by filtration or by evaporation under vacuum of the reaction solvent. Pharmaceutically acceptable base addition salts may be obtained in an analogous manner by treating a solution of compound A or B with a suitable base. Both types of salt may be formed or interconverted using ion-exchange resin techniques.

[11] The term “non-toxic” is used only once in the 784 Patent (at page 5, line 28) to describe the type of salt that is contemplated by the invention. Interestingly, the relevant passage in the disclosure is specific to veterinary use: “For veterinary use, a compound of formula (I), and in particular compound A [tadalafil] or B or a non-toxic salt thereof is administered as a suitably acceptable formulation in accordance with normal veterinary practice …”. A corresponding paragraph describing use of the invention in humans does not mention salts and does not use the term “non-toxic”.

[12] The dispute over the validity of the 784 Patent relates to evidence that any salts of tadalafil that could be made at the filing date of the 784 Patent were unstable and would quickly

degrade. The respondents argue that any such salts were not “stable and pure, not degraded”, and hence not physiologically acceptable. It follows from this, the respondents argue, that the claims in issue are invalid for overbreadth (because they encompass something that the inventor did not invent) and insufficiency (because they do not explain to a person of skill in the art (POSITA) how to make physiologically acceptable salts of tadalafil).

[13] The appellants counter that the disclosure of the 784 Patent clearly identifies salts that it contemplates, and though it calls for them to be “non-toxic”, it does not require that they have any particular degree of stability or purity. The appellants continue their argument by noting that, if the “stable and pure, not degraded” requirement is excluded from the definition of “physiologically acceptable”, and only non-toxicity is required, then there is no basis to find that the claims in issue are either overbroad or insufficiently described.

III. The Federal Court’s Decision

[14] After describing the 784 Patent, the Federal Court outlined the evidence before it. This included the expert evidence of Dr. André Beauchemin on behalf of the respondents (there, the defendants), and Drs. Philip G. Jessop and Stephen Byrn on behalf of the appellants (there, the plaintiffs). All experts addressed the meaning of “physiologically acceptable”. The Federal Court was impressed with the evidence of Dr. Beauchemin and gave his opinion “great weight” (see paragraph 41 of the Reasons). The Federal Court found that Dr. Jessop was a reliable witness, but did not accept his interpretation of “physiologically acceptable” because some of his testimony went outside his area of expertise.

[15] As for Dr. Byrn, the Federal Court expressed "very strong reservations" relying on his testimony because of his manner of responding to questions, contradictions in his testimony and his characterization of evidence he had provided previously (see paragraph 66 of the Reasons). The Federal Court was unwilling to accept Dr. Byrn's testimony as fair, non-partisan and objective, and gave it "very little weight" (see paragraph 68 of the Reasons).

[16] The Federal Court then turned to defining the POSITA from whose point of view the 784 Patent should be read (about which there is no dispute) and construing terms used in the claims in issue. It cited this Court's decision in *Tearlab Corporation v. I-MED Pharma Inc.*, 2019 FCA 179, 166 C.P.R. (4th) 367, paragraphs 30 to 34 of which provide a useful summary of principles of claim construction:

> [30] The general principles of claim construction are now well established and were set out by the Supreme Court in three cases (*Whirlpool* [*Corp. v. Camco Inc.*, 2000 SCC 67, [2000] 2 S.C.R. 1067] at paras. 49-55; *Free World Trust v. Électro Santé Inc.*, 2000 SCC 66, [2000] 2 S.C.R. 1024 at paras. 31-67 [*Free World Trust*]; *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.*, [1981] 1 S.C.R. 504 at p. 520 [*Consolboard*]). These principles can be summarized as follows.
>
> [31] The *Patent Act* promotes adherence to the language of the claims, which in turn promotes fairness and predictability (*Free World Trust* at paras. 31(a), (b) and 41). The words of the claims must, however, be read in an informed and purposive way (at para. 31(c)), with a mind willing to understand (at para. 44). On a purposive construction, it will be apparent that some elements of the claimed invention are essential while others are non-essential (at para. 31(e)). The interpretative task of the court, in claim construction, is to separate and distinguish between the essential and the non-essential elements, and to give the legal protection to which the holder of a valid patent is entitled only to the essential elements (at para. 15).
>
> [32] To identify these elements, the claim language must be read through the eyes of a POSITA, in light of the latter's common general knowledge (*Free World Trust* at paras. 44-45; see also [AFD Petroleum Ltd. v.*] Frac Shack* [Inc., 2018 FCA 140, 157 C.P.R. (4th) 195] at para. 60; *Whirlpool* at para. 53). As noted in *Free World Trust*:

> [51] …The words chosen by the inventor will be read in the sense the inventor is presumed to have intended, and in a way that is sympathetic to accomplishment of the inventor's purpose expressed or implicit in the text of the claims. However, if the inventor has misspoken or otherwise created an unnecessary or troublesome limitation in the claims, it is a self-inflicted wound. The public is entitled to rely on the words used *provided* the words used are interpreted fairly and knowledgeably. [Emphasis in the original.]

> [33] Claim construction requires that the disclosure and the claims be looked at as a whole "to ascertain the nature of the invention and methods of its performance, … being neither benevolent nor harsh, but rather seeking a construction which is reasonable and fair to both patentee and public" (*Consolboard* at p. 520; see also *Teva Canada Ltd. v. Pfizer Canada Inc.*, 2012 SCC 60, [2012] 3 S.C.R. 625 at para. 50). Consideration can thus be given to the patent specifications to understand what was meant by the words in the claims. One must be wary, however, not to use these so as "to enlarge or contract the scope of the claim as written and … understood" (*Whirlpool* at para. 52; see also *Free World Trust* at para. 32). The Supreme Court recently emphasized that the focus of the validity analysis will be on the claims; specifications will be relevant where there is ambiguity in the claims (*AstraZeneca Canada Inc. v. Apotex Inc.*, 2017 SCC 36, [2017] 1 S.C.R. 943 at para. 31; see also *Ciba* [Specialty Chemicals Water Treatments Limited's v. SNF Inc., 2017 FCA 225, 152 C.P.R. (4th) 239] at paras. 74-75).
>
> [34] Finally, it is important to stress that claim construction must be the same for the purpose of validity and for the purpose of infringement (*Whirlpool* at para. 49(b)).

[17] The Federal Court also noted that (i) claim construction is a matter of law, (ii) the expert's role is not to interpret the claims, but rather to put the judge in a position to do so, and (iii) claims are to be construed through the eyes of the POSITA armed with the common general knowledge at the date of publication.

[18] Next, the Federal Court construed the term "physiologically acceptable". After noting that it is not defined in the 784 Patent, the Federal Court accepted the experts' view that the terms "physiologically acceptable" and "pharmaceutically acceptable" are synonymous in the context of the 784 Patent (see paragraph 83 of the Reasons). There is no dispute on this point.

[19] The Federal Court acknowledged at paragraph 84 of the Reasons that Dr. Beauchemin "did not specifically dedicate a section of his affidavit to construe the term physiologically or pharmaceutically, nor [was he] instructed to do so." The Federal Court also accepted at paragraph 88 that the POSITA "would have understood that a physiologically acceptable salt was certainly a non-toxic one." However, the Federal Court did not accept that non-toxicity was all that was required, stating as follows: "This is too low a threshold; surely, pharmaceutically acceptable products are held to a higher standard." At paragraphs 89 and 90 of the Reasons, the Federal Court continued:

> [89] The disclosure of the 784 Patent itself provides an indicia that non-toxic does not correspond to pharmaceutically or physiologically acceptable. The patentee does use the term "non-toxic" at page 5 of the disclosure in the context of veterinary use, but nowhere else. There is here no indication that the patentee considered the word non-toxic to be a synonym of the term physiologically acceptable, as it was the case between physiologically and pharmaceutically. The patentee knows the term non-toxic but has used it only in relation with a salt destined to veterinary use. We can thus infer that the patentee, had he intended to limit the meaning of physiologically or pharmaceutically acceptable to non-toxic, would have signaled so.
>
> [90] In addition, the amalgamated use of the terms physiologically with pharmaceutically acceptable obviously elevates the threshold beyond what is merely not toxic or not harmful for the body. I can easily follow Dr. Beauchemin's guidance and conclude that a physiologically or pharmaceutically acceptable salt also must be stable and pure, not degraded.

[20] The Federal Court's conclusion concerning the meaning of "physiologically acceptable" appears to have been based on at least paragraphs 49 and 79 of Dr. Beauchemin's affidavit sworn September 17, 2020 (Dr. Beauchemin's First Affidavit), as well as paragraph 27 of Dr. Beauchemin's affidavit sworn April 15, 2021.

[21] The foregoing analysis led to the following conclusion at paragraph 92 of the Reasons:

> [92] I thus find that POSITA, armed with the common general knowledge of 1997, would have understood a "physiologically acceptable" salt certainly required the salt be non-toxic and to not cause harm. However, I find the POSITA would also have understood that the salt needed to be stable and pure, not degraded.

[22] The Federal Court went on to construe the term "salt", but nothing turns on that construction.

[23] Having completed its claim construction, the Federal Court then considered the respondents' allegations of invalidity of the claims in issue of the 784 Patent: overbreadth, insufficiency and inutility. As indicated above, it concluded that the claims in issue were invalid for overbreadth and for insufficiency, and it elected not to decide the issue of inutility.

[24] To find that the claims in issue were invalid for overbreadth, the Federal Court relied on (i) its conclusion that a physiologically acceptable salt as contemplated therein would have to be stable and pure, not degraded, and (ii) the testimony of Dr. Beauchemin that any salts made by the POSITA as contemplated in the 784 Patent would not be pure and stable. The Federal Court found it "more probable than not that a physiologically acceptable salt of tadalafil cannot be made" (see paragraph 118 of the Reasons). From this, the Federal Court concluded that no salt as claimed was invented.

[25] To reach its conclusion of invalidity for insufficiency, the Federal Court relied again on its construction of the term "physiologically acceptable salt" and evidence that such a salt could not be made by the POSITA. It found that "the disclosure will be insufficient if the POSITA can only find the invention after they have conducted a minor research project" (see paragraph 144

of the Reasons). The 784 Patent indicates that the physiologically acceptable salts contemplated therein “may be prepared in a conventional manner”, and gives no guidance on making them. The Federal Court concluded that the POSITA would indeed have to complete a research project to make the claimed salt.

IV. Issues

[26] As indicated at paragraphs 3 and 4 above:

A. The appellants argue that the Federal Court erred on its interpretation of the term “physiologically acceptable”, and that this error resulted in erroneous findings of invalidity of the claims in issue for insufficiency and overbreadth; and

B. The respondents argue that the Federal Court did not err in construing the term “physiologically acceptable”, and that even if it did err in doing so, its invalidity conclusions should stand.

C. The respondents also argue that the Federal Court should have found the claims in issue invalid for inutility.

V. Standard of Review

[27] The appellants rely heavily on an argument that the applicable standard of review on the claim construction issue in this appeal is correctness because it is a question of law.

[28] The appellants recognize that the standard of review on an appeal is as indicated in *Housen v. Nikolaisen*, 2002 SCC 33, [2002] 2 S.C.R. 235: questions of law are reviewed on a standard of correctness, and questions of fact or of mixed fact and law from which no question of law is extricable are reviewed on a standard of palpable and overriding error.

[29] The appellants also recognize that, though claim construction is a question of law (*Whirlpool* at paras. 61, 76), the applicable standard of review is complicated by the fact that patent claims are interpreted from the point of view of a POSITA (*Whirlpool* at para. 48), and expert evidence is often considered in determining how such a person would have understood certain terms in a claim at the relevant date. The weighing of expert evidence is a question of mixed fact and law. I recently discussed this point in *Google LLC v. Sonos Inc.*, 2024 FCA 44 at para. 6.

[30] The appellants argue that the complication due to the presence of expert evidence does not arise in this appeal because the Federal Court's conclusions regarding claim construction "were entirely the Trial Judge's own and not based on any of the expert evidence." The appellants argue that this Court therefore owes no deference to the Federal Court on its conclusions regarding claim construction.

[31] I am unable to agree with the appellants' premise that the Federal Court's conclusions regarding claim construction were not based on expert evidence. As I explain below, I find that the Federal Court based its claim construction on expert evidence, and its conclusions in that regard are entitled to deference.

VI. Analysis

A. *Claim Construction*

[32] As indicated above, this appeal turns principally on the Federal Court's interpretation of the term "physiologically acceptable".

[33] The appellants argue that the Federal Court erred in relying on Dr. Beauchemin's "guidance" in construing this term. They note that Dr. Beauchemin was never given instructions on how to construe patent claims, and was never asked for his opinion on the subject. Instead, he provided "a functional definition" of the term. The appellants argue that such a definition does not follow the purposive approach that is called for when construing patent claims, and does not meet the standard set out in the following passage from *Bombardier Recreational Products Inc. v. Arctic Cat, Inc.*, 2018 FCA 172, 159 C.P.R. (4th) 319 at para. 24:

> Thus, apart from the specification itself, the only evidence that should be considered to inform a court's analysis of a claim is proper evidence as to how the POSITA would understand it in light of his or her relevant common general knowledge in the context of the specification as a whole.

[34] The appellants argue that (i) Dr. Beauchemin's "functional definition" of the term "physiologically acceptable" was untethered to the 784 Patent in the sense that the patent refers to the salts in question as non-toxic, and does not even use the term "stable and pure, not degraded", (ii) Dr. Beauchemin made his determination that "physiologically acceptable salts" of tadalafil could not be made by the POSITA before seeing the 784 Patent, thus failing to follow the principle that claim construction is antecedent to consideration of validity issues, and (iii) while Dr. Beauchemin opined as to what a skilled person would understand by the term

"physiologically acceptable", he did not indicate that he took into account the relevant common general knowledge. I find no merit in any of these arguments.

[35] It is perhaps advisable to preface the comments below by noting that this appeal is to consider whether the Federal Court made a reviewable error, and not whether the respondents' expert evidence could have been better. As indicated above, the appellants argue only errors of law; they do not take issue with the Federal Court's weighing of the evidence. Accordingly, this appeal turns on whether it was open to the Federal Court to consider Dr. Beauchemin's expert testimony. In other words, did the Federal Court err by giving any weight at all to that testimony?

[36] I disagree that Dr. Beauchemin's interpretation of "physiologically acceptable" was untethered to the 784 Patent. The appellants rely heavily on the fact that, in his First Affidavit, Dr. Beauchemin provided his interpretation of the term before discussing the 784 Patent. While this is true, the order of presentation of his opinions does not, in my view, necessarily affect their admissibility. It was up to the Federal Court to consider the entirety of Dr. Beauchemin's testimony, including the manner in which he arrived at his opinions, and determine what weight to give to it. The Federal Court recognized that Dr. Beauchemin did not provide a formal interpretation of the term by explicitly applying the principles of claim construction, and instead he provided an opinion as to how a POSITA would understand the term. But even if that opinion was initially formed before reviewing the 784 Patent, it was clearly unchanged once he had read the patent: see paragraphs 15, 16 and 70 and following of Dr. Beauchemin's First Affidavit. It was open to the Federal Court to weigh this evidence. The Federal Court clearly understood that

claim construction must precede consideration of validity issues (see paragraph 71 of the Reasons), and so it did not err in law in this respect.

[37] The discussion in the previous paragraph applies equally to the appellants' argument that Dr. Beauchemin failed to follow the principles of claim construction. As indicated, the question is not whether Dr. Beauchemin erred in considering validity issues before construing the claims, but rather whether the Federal Court did. In my view, it did not. The real question at the root of this appeal is whether the Federal Court erred in giving any weight at all to Dr. Beauchemin's testimony. This is a question of mixed fact and law from which no question of law is extricable. The appellants do not allege any palpable and overriding error that would permit this Court to interfere with the Federal Court's decision.

[38] The fact that the 784 Patent does not use the term "stable and pure, not degraded" is insufficient to conclude that, as a matter of law, the Federal Court could not accept Dr. Beauchemin's definition of "physiologically acceptable". The Federal Court understood that the proper interpretation of the term depends on the POSITA's understanding. Further, the use of the term "non-toxic" to describe the claimed salts does not necessarily determine the scope of "physiologically acceptable". As indicated at paragraph 19 above, the Federal Court accepted that non-toxicity was one quality of the claimed physiologically acceptable salt, but found that more was required. As indicated at paragraph 11 above, the term "non-toxic" is used only once in the 784 Patent. It is used in a discussion of veterinary use of the invention; a corresponding paragraph discussing human use of the invention does not mention non-toxicity. In my view, it was open to the Federal Court to conclude that non-toxicity was not the only requirement of a

physiologically acceptable salt in the context of the 784 Patent. I do not agree with the appellants' argument that the Federal Court's construction of the term "physiologically acceptable" was purposeless and hence contrary to the principles of claim construction.

[39] The appellants also criticize the Federal Court's reliance on "the amalgamated use of the terms physiologically with pharmaceutically acceptable" as "obviously elevat[ing] the threshold beyond what is merely not toxic or not harmful for the body": see paragraph 19 above and paragraph 90 of the Reasons. The appellants argue that the 784 Patent contains no amalgamated use of these terms. I agree that the use of these terms is not amalgamated in the sense of combining; it is not the combination of these terms that leads to an elevated threshold. However, in the context of the Federal Court's discussion of these terms, in which "physiologically acceptable" and "pharmaceutically acceptable" are synonymous, I understand the Federal Court's use of the word "amalgamated" to be simply a recognition that both contribute to the elevated threshold. I see no reviewable error here.

[40] With respect to the appellants' concern that Dr. Beauchemin did not indicate that he took into account the relevant common general knowledge in determining how a POSITA would understand the term "physiologically acceptable", I see no problem. In fact, I see no issue at all. The POSITA from whose point of view patent claims are to be construed is, by definition, aware of all of the common general knowledge: see *Free World Trust* at para. 44, *Whirlpool* at para. 53. Dr. Beauchemin's consideration of the common general knowledge was implicit in his reference to the POSITA. Any doubt in this regard was for the Federal Court to consider. The appellants' attempt to distinguish the knowledge of the POSITA from the common general knowledge by

reference to jurisprudence of this Court is misguided. That jurisprudence (*Gemak Trust v. Jempak Corporation*, 2022 FCA 141, 196 C.P.R. (4th) 215 at para. 96; *Sandoz Canada Inc. v. Abbott Laboratories*, 2010 FCA 168, 85 C.P.R. (4th) 279 at para 27; and *Novopharm Limited v. Janssen-Ortho Inc.*, 2007 FCA 217, 59 C.P.R. (4th) 116 at para. 25) was concerned with the distinction between prior art (or public knowledge) and common general knowledge. That is a distinction that is very important in some contexts, but I see no reason to conclude that it is relevant here.

B. *Insufficiency*

[41] Since the appellants' argument on insufficiency depends on the success of its argument on claim construction, and since I have concluded that the Federal Court did not err on its claim construction, it is not necessary to review the question of invalidity for insufficiency.

[42] That said, I do wish to make a few comments about the Federal Court's discussion of the fact that putting the invention of the 784 Patent into practice would require completion of a minor research project. The Federal Court suggested that this was the reason for concluding that the claims in issue are invalid for insufficiency. However, the need to conduct a minor research project is not the determinant factor for insufficiency of a patent disclosure in the present context.

[43] A finding of insufficiency is really a finding that the patent in question fails to meet the requirements of subsection 27(3) of the *Patent Act*, R.S.C. 1985, c. P-4. This provision requires that the specification "correctly and fully describe the invention and its operation or use as

contemplated by the inventor" in order that, "when the period of the monopoly has expired the public will be able, having only the specification, to make the same successful use of the invention as the inventor could at the time of his application": *Consolboard v. MacMillan Bloedel (Sask.) Ltd.*, [1981] 1 S.C.R. 504, 122 D.L.R. (3d) 203 at 520.

[44] The reference to a minor research project seems to come from *Teva Canada Ltd. v. Pfizer Canada Inc.*, 2012 SCC 60, [2012] 3 S.C.R. 625 (*Teva*) where the Supreme Court of Canada found a patent invalid for insufficiency because a skilled reader of the patent in issue would be unable, without undertaking a minor research project, to determine which of two compounds was favoured by the inventors. As the Court in *Teva* stated at paragraph 76, "Pfizer had the information needed to disclose the useful compound and chose not to release it." In that sense, the patent specification in that case failed to meet the requirement to teach the public the same successful use of the invention as the inventor could at the time of the application.

[45] The present appeal is not about the patentee's decision to withhold certain information, but rather a more general insufficiency of information in the patent specification. As this Court has stated several times in recent years, it remains the case that a patent specification may be sufficient even if some amount of non-inventive trial and error experimentation is required, so long as it is not undue: *Teva Canada Limited v. Leo Pharma Inc.*, 2017 FCA 50, 145 C.P.R. (4th) 350 at para. 56; *Bombardier Recreational Products Inc. v. Arctic Cat, Inc.*, 2018 FCA 172, 159 C.P.R. (4th) 319 at para. 78; *Western Oilfield Equipment Rentals Ltd. v. M-I LLC*, 2021 FCA 24, 331 A.C.W.S. (3d) 743 at para. 114; *Seedlings Life Science Ventures, LLC v. Pfizer Canada ULC*, 2021 FCA 154, 339 A.C.W.S. (3d) 69 at para. 68. Accordingly, a patent

may be sufficient even if it requires a minor research project, provided no inventiveness or undue experimentation is involved.

[46] The foregoing comments do not impair the Federal Court's finding of invalidity for insufficiency in this case. The Federal Court relied on testimony from the appellants' expert Dr. Byrn to the effect that salt formation is unpredictable, and "the search for salt requires a lot of experimental work and requires a skilled person to exercise some degree of inventiveness" (see paragraph 65 of the Reasons). That is enough to support the conclusion of insufficiency.

C. *Overbreadth and Inutility*

[47] As with insufficiency, it is not necessary to review the question of invalidity for either overbreadth or inutility. However, my silence on the Federal Court's discussion of these issues should not be taken as agreement.

VII. Conclusion

[48] I would dismiss the appeal with costs.

"George R. Locke"
J.A.

"I agree
Wyman W. Webb J.A."

"I agree
Donald J. Rennie J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-244-22
STYLE OF CAUSE:	ELI LILLY CANADA INC., ELI LILLY AND COMPANY, LILLY DEL CARIBE, INC., LILLY, S.A. and ICOS CORPORATION INC. v. APOTEX INC., MYLAN PHARMACEUTICALS ULC, TEVA CANADA LIMITED, PHARMASCIENCE INC. and LABORATOIRE RIVA INC.
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	JANUARY 17, 2024
REASONS FOR JUDGMENT BY:	LOCKE J.A.
CONCURRED IN BY:	WEBB J.A. RENNIE J.A.
DATED:	APRIL 16, 2024

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