Federal Court of Appeal | Cour d'appel fédérale

Date: 20240201

Docket: A-205-22

Citation: 2024 FCA 23

CORAM: **DE MONTIGNY C.J.**
LOCKE J.A.
GOYETTE J.A.

BETWEEN:

PHARMASCIENCE INC.

Appellant

and

JANSSEN INC. and JANSSEN PHARMACEUTICA N.V.

Respondents

Heard at Toronto, Ontario, on December 5-6, 2023.

Judgment delivered at Ottawa, Ontario, on February 1, 2024.

PUBLIC REASONS FOR JUDGMENT BY: LOCKE J.A.

CONCURRED IN BY: DE MONTIGNY C.J.
GOYETTE J.A.

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PUBLIC REASONS FOR JUDGMENT

This is a public version of confidential reasons for judgment issued to the parties. The two are identical, there being no confidential information disclosed in the confidential reasons.

LOCKE J.A.

I. Background

[1] This is an appeal of a decision of the Federal Court (2022 FC 1218, *per* Justice Michael D. Manson) in the context of an action brought pursuant to subsection 6(1) of the *Patented*

Medicines (Notice of Compliance) Regulations, S.O.R./93-133. In that action, the respondents, Janssen Inc. and Janssen Pharmaceutica N.V. (collectively, Janssen), sought a declaration that the appellant, Pharmascience Inc. (Pharmascience), would infringe Canadian Patent No. 2,655,335 (the 335 Patent) if it were to make, use or sell its generic version of Janssen's patented medicine called INVEGA SUSTENNA.

[2] INVEGA SUSTENNA involves a suspension of paliperidone palmitate for the treatment of schizophrenia and related disorders. The 335 Patent teaches a regimen to achieve an optimum plasma concentration-time profile. It teaches a first loading dose administered in the deltoid muscle on day 1, a second loading dose administered in the deltoid muscle on day 8, and then monthly maintenance doses thereafter administered either in the deltoid or gluteal muscle. For non-renally impaired patients, the first and second loading doses are 150 and 100 mg equivalent (mg-eq.), respectively, and the monthly maintenance doses are 75 mg-eq. each. For renally impaired patients, the first and second loading doses are 100 and 75 mg-eq., respectively, and the monthly maintenance doses are 50 mg-eq. each.

[3] Pharmascience defended against Janssen's action on a number of grounds. The only ground that remains relevant for the purposes of this appeal is that the claims of the 335 Patent are invalid because they comprise unpatentable subject matter, namely methods of medical treatment. The Federal Court rejected this allegation and found the claims of the 335 Patent valid.

[4] It will be necessary in this decision to explore somewhat the history and nature of the prohibition against patenting methods of medical treatment. For the reasons set out below, I would dismiss the present appeal.

II. The Federal Court's Decision

[5] The Federal Court addressed the question of methods of medical treatment at paragraphs 160 to 172 of its reasons.

[6] After noting that the prohibition against patenting methods of medical treatment has its origin in the Supreme Court of Canada's decision in *Tennessee Eastman Co. v. Commissioner of Patents*, [1974] S.C.R. 111, 33 D.L.R. (3d) 459 (*Tennessee Eastman*), and then observing that the jurisprudence in this area is inconsistent, the Federal Court stated that the starting point is to ask, "what do the claims say?" (see paragraph 161 of the Federal Court's reasons, citing *Bayer Inc. v. Cobalt Pharmaceuticals Company*, 2013 FC 1061, 121 C.P.R. (4th) 14 at para. 162 (*Bayer*)).

[7] The Federal Court then considered Pharmascience's argument that the dosage range for the maintenance dose (from 25 to 150 mg-eq., according to the product monograph for INVEGA SUSTENNA) indicates that no particular dose will work for every patient, and that selection of the appropriate dose for a specific patient will require skill and judgment from the prescriber.

[8] The Federal Court noted that it is well settled that claims to a vendible product are not prohibited as methods of medical treatment. It went on to conclude that the method of medical treatment analysis was relevant only to use claims, which it identified as claims 17 to 32 of the 335 Patent (use of a dosage form), and not to the product claims, which it identified as claims 1 to 16 (pre-filled syringes), claims 33 to 48 (how a medicament is prepared), and claims 49 to 63 (a dosage form).

[9] At paragraph 164 of its reasons, the Federal Court noted that the focus should be on whether professional skill and judgment are required to practise the claimed invention, and cited jurisprudence to the effect that:

> claims restricted to particular dosages and specific administration schedules have been found to be patentable subject matter, where the amounts and timing are fixed … whereas claims to dosages or schedules with ranges within which the physician must exercise skill and judgment have been found to not be a vendible product and thus not patentable [references omitted].

[10] However, the Federal Court also noted that the dichotomy it described (between fixed and variable dosages and schedules) has a questionable underpinning. On this point, it cited the following passage from this Court's decision in *Hospira Healthcare Corporation v. Kennedy Trust for Rheumatology Research*, 2020 FCA 30, 316 A.C.W.S. (3d) 537 at para. 52 (*Hospira*):

> 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.

[11] The Federal Court found that claims 17 to 32 of the 335 Patent do not require professional skill and judgment because there are no choices to make on dosage amounts, which are all fixed. It found that choices concerning dosing windows and injection sites had no clinical implications, and hence did not interfere with a physician's skill and judgment. The Federal Court noted that a physician could choose whether to prescribe the claimed dosing regimen, but no skill or judgment was involved in implementing it.

[12] The Federal Court concluded that the 335 Patent discloses patentable subject matter.

III. Issues

[13] Pharmascience argues that the Federal Court erred in law in two respects:

A. In excluding claims 1 to 16 and 33 to 63 of the 335 Patent from the method of medical treatment analysis on the basis that they concern a vendible product; and

B. In determining that the claims in issue are patentable on the basis of the dichotomy between fixed and variable dosing regimens.

[14] I will address each of these arguments in turn after first discussing the key jurisprudence on the method of medical treatment exclusion.

IV. Standard of Review

[15] The parties agree that the standard of review applicable in this case is as set out 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. A palpable error is one that is obvious. An overriding error is one that goes to the very core of the outcome of the case. When arguing palpable and overriding error, it is not enough to pull at leaves and branches and leave the tree standing. The entire tree must fall: *Canada v. South Yukon Forest Corporation*, 2012 FCA 165, [2012] F.C.J. No. 669 at para. 46 (cited with approval in *Benhaim v. St-Germain*, 2016 SCC 48, [2016] 2 S.C.R. 352 at para. 38).

[16] Pharmascience describes all of the questions in dispute as being questions of law subject to the standard of correctness. Pharmascience does not argue that the Federal Court made any errors that are subject to the palpable and overriding error standard. I accept Pharmascience's approach.

V. Analysis

A. *Jurisprudence concerning the prohibition on patenting methods of medical treatment*

[17] The *Patent Act*, R.S.C. 1985, c. P-4, contains no explicit prohibition against claims for methods of medical treatment. Moreover, subsection 43(2) of the *Patent Act* provides that a patent is presumed valid. Claims are presumed not to concern methods of medical treatment, and the burden rests on the challenger (Pharmascience, in this case) to prove otherwise.

[18] As indicated above, the origin of this prohibition in Canada is the Supreme Court of Canada's 1974 decision in *Tennessee Eastman*. That case involved an attempt to obtain a patent claiming a surgical method for joining or bonding the surfaces of incisions or wounds in living animal tissue by applying adhesive compounds described in the claims in a liquid state, directly to at least one of the tissue surfaces to be bonded. At the time, subsection 41(1) of the *Patent Act* generally prohibited claims to "substances prepared or produced by chemical processes and intended for food or medicine". Therefore, the bonding compounds of the patent application in question could not be claimed as such.

[19] The Supreme Court maintained the rejection of the patent application by the Commissioner of Patents. Its analysis surrounded the definition of "invention" in the *Patent Act*. At page 118, the Court wrote:

> It is clear that a new substance that is useful in the medical or surgical treatment of humans or of animals is an "invention". It is equally clear that a process for making such a substance also is an "invention". In fact, the substance can be claimed as an invention only "when prepared or produced by" such a process. But what of the method of medical or surgical treatment using the new substance? Can it too be claimed as an invention? In order to establish the utility of the substance this has to be defined to a certain extent. In the case of a drug, the desirable effects must be ascertained as well as the undesirable side effects. The proper doses have to be found as well as methods of administration and any counter-indications. May these therapeutic data be claimed in themselves as a separate invention consisting in a method of treatment embodying the use of the new drug? I do not think so, and it appears to me that s. 41 definitely indicates that it is not so.

[20] At page 119, the Court added, "[h]aving come to the conclusion that methods of medical treatment are not contemplated in the definition of "invention" as a kind of "process", the same must, on the same basis, be true of a method of surgical treatment."

[21] The Supreme Court of Canada had occasion to comment on *Tennessee Eastman* in its later decision in *Shell Oil Co. v. Commissioner of Patents*, [1982] 2 S.C.R. 536, 142 D.L.R. (3d) 117 at 554 (*Shell Oil*):

> In *Tennessee Eastman Co. v. Commissioner of Patents* (1970), 62 C.P.R. 117 (Ex. Ct.), aff'd [1974] S.C.R. 111, the applicant sought a patent on a method of closing incisions following surgery by the use of an adhesive substance discovered to have a marked affinity for adhering to living tissue. The Commissioner refused the patent on the basis that this was not the kind of discovery (the adhesive itself not being new) which fell within the definition of "invention" in the Act. In particular, he found that it was not an "art" because it was useful only in the process of surgical or medical treatment and produced no result in relation to trade, commerce or industry. The applicant appealed to the Exchequer Court and the issue there was limited to the question whether this use of the adhesive fell within the meaning of new and useful "art" or "process" within the meaning of the *Patent Act.* It was held that it did not for the reasons given by the Commissioner. In effect, it was not patentable because it was essentially non-economic and unrelated to trade, industry or commerce. It was related rather to the area of professional skills.

[22] The explicit prohibition in subsection 41(1) of the *Patent Act* against patent claims to "substances prepared or produced by chemical processes and intended for food or medicine" was later lifted by the repeal of this provision. However, that change did not have the effect of removing the prohibition on patenting methods of medical treatment. The Supreme Court of Canada effectively confirmed this in its comments on *Tennessee Eastman* in *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77, [2002] 4 S.C.R. 153 at para. 49 (*Wellcome*), where it cited the explanation in *Shell Oil* that a claim to a method of medical treatment is unpatentable because it is "essentially non-economic and unrelated to trade, industry, or commerce" and "related rather to the area of professional skills".

[23] *Wellcome* concerned a patent on the use of AZT as a treatment for HIV. The Court found that the patent did not concern a method of medical treatment, stating as follows at paragraph 50:

> The AZT patent does not seek to "fence in" an area of medical treatment. It seeks the exclusive right to provide AZT as a commercial offering. How and when, if at all, AZT is employed is left to the professional skill and judgment of the medical profession.

[24] *Tennessee Eastman*, *Shell Oil*, and *Wellcome* are Supreme Court of Canada decisions by which this Court is clearly bound. It is important to keep in mind what they say, and what they do not say. What they say is that a method of medical treatment is not patentable because it does not fall within the definition of "invention" as contemplated in the *Patent Act*. This is because a method of medical treatment is unrelated to trade, industry or commerce, and concerns professional skills that are non-economic. A patent should not seek to fence in the exercise of such skills (including how and when a drug is administered), but it may cover a commercial offering.

[25] The development of the jurisprudence beyond what is discussed in the foregoing Supreme Court decisions (what they do not say) is not equally binding on this Court, although this Court should follow its own decisions unless they are manifestly wrong: *Miller v. Canada (Attorney General)*, 2002 FCA 370, 220 DLR (4^{th}) 149 at para. 10. I will now explore that jurisprudence and discuss the principles that properly arise therefrom.

[26] The references to "trade, industry or commerce" and "commercial offering" by the Supreme Court appear to be the basis for the focus of many decisions on whether the invention concerns a "vendible product": see *Hospira* at para. 53 as well as the Federal Court of Appeal's decision in *Wellcome* ([2000] F.C.J. No. 1770, 10 C.P.R. (4^{th}) 65 at para. 74). This focus is also discussed in the following Federal Court decisions: *Merck & Co., Inc. v. Apotex Inc.*,

2005 FC 755, 41 C.P.R. (4th) 35 at paras. 136–37; *Merck & Co., Inc. v. Pharmascience Inc.*, 2010 FC 510, 85 C.P.R. (4th) 179 at paras. 110, 114 (*Merck 2010*); *Janssen Inc. v. Mylan Pharmaceuticals ULC*, 2010 FC 1123, 88 C.P.R. (4th) 359 at para. 53 (*Mylan*); *Novartis Pharmaceuticals Canada Inc. v. Cobalt Pharmaceuticals Company*, 2013 FC 985 at paras. 78, 91, 98, aff'd 2014 FCA 17, 236 A.C.W.S. (3d) 1001 (*Novartis*); *Bayer* at para. 162; *Abbvie Biotechnology Ltd. v. Canada (Attorney General)*, 2014 FC 1251, 248 A.C.W.S. (3d) at paras. 115, 125 (*Abbvie*); and *Biogen Canada Inc. v. Taro Pharmaceuticals Inc.*, 2020 FC 621, [2020] F.C.J. No. 611 at para. 211. The idea, with which I agree, is that a vendible product has economic value and is distinguishable from the skilled work of a physician, and hence outside the realm of methods of medical treatment as contemplated by the Supreme Court of Canada.

[27] With regard to inventions relating to the administration of a drug, the jurisprudence at the Federal Court level has developed an approach whereby a claim may be found to be either patentable subject matter or an unpatentable method of medical treatment based on whether it defines a fixed dosage (or interval of administration) or a range of dosages (or intervals). This approach appears to have its origin in *Axcan Pharma Inc. v. Pharmascience Inc.*, 2006 FC 527, 50 C.P.R. (4th) 321 at paragraphs 45–51 (*Axcan*), and was developed in *Merck 2010* at paragraphs 111–14, and *Novartis* at paragraphs 82–99.

[28] As indicated in the passage from *Hospira* quoted at paragraph 10 above, the distinction between fixed and variable dosages (or schedules) has a questionable underpinning, since such a distinction would seem to make no difference to whether the drug in question is a vendible product. However, the distinction makes more sense if one bears in mind the guidance noted in

paragraph 6 above from *Bayer* that what matters is what the claims say; the product that the patentee puts on the market is incidental. In my view, it is permissible to focus on whether the dosing regimen is fixed or variable provided that the analysis remains tied to the ultimate question of whether professional skill is applied in using the invention. This was reflected in *Mylan*, which noted the concern in *Axcan* and *Merck 2010* about dosage ranges, and then stated as follows at paragraph 26:

> What I take from the above authorities is that a patent claim over a method of medical treatment that, by its nature, covers an area for which a physician's skill or judgment is expected to be exercised is not patentable in Canada. This would include the administration of a drug whereby the physician, while relying upon the dosage advice of the patentee, would still be expected to be alert and responsive to a patient's profile and to the patient's reaction to the compound.

[29] The Federal Court in *Mylan* at paragraph 4 noted that "the inventive concept of the [patent in suit] is limited to Janssen's claimed discovery that the slow titration of galantamine improved patient tolerability for the drug, by reducing side-effects and resulted in the ability to use a lower maintenance dose than had previously been shown to be effective." The Court found that the claims in issue concerned an unpatentable method of medical treatment because they defined a "titration regimen" (see paragraph 50) that required the ongoing exercise of a physician's professional skill and judgment. The monopoly asserted by the claims would thereby interfere with the ability of a physician to exercise that skill and judgment.

[30] Despite this, I think it would go too far to say that any drug regimen that requires a physician to monitor a patient is unpatentable. Such a prohibition would cast too wide a net, potentially encompassing almost any drug.

[31] In *Abbvie*, the Federal Court provided a detailed review of the jurisprudence concerning methods of medical treatment. At paragraphs 110 and 121, the Court distinguished, properly in my view, between the exercise of skill and judgment in deciding whether to use a claimed invention (which does not indicate a method of medical treatment), and the exercise of skill and judgment in deciding how to use the invention (which is a prohibited method of medical treatment).

[32] As in *Mylan*, *Abbvie* cautioned against a simple distinction between fixed and variable dosages and schedules. Paragraphs 112 to 114 stated as follows:

> [112] The respondent cautioned against relying on catch phrases rather than principles. In my view, the jurisprudence reflects that approach – the principle has been applied regardless of the Courts' references to "fencing in" or to "fixed dosages". The issue in every case has been whether the patent claims a method of medical treatment. In applying the same principles, claims to fixed dosages and schedules which do not involve any professional decision-making have been accepted as patentable.
>
> [113] However, just because the claims involve a fixed dosage and schedule does not mean that they are automatically patentable, nor does it mean that they constitute unpatentable subject matter. The fixed dosage and schedule may be a good signal or starting point, but the evidence about that claimed dosage regime and schedule may indicate that it is not exactly as it is claimed and that adjustments are needed which requires skill and judgment.
>
> [114] The review of the relevant case law supports the appellants' understanding of the principles from the jurisprudence and demonstrates that the Courts have consistently found that a claim directed to the exercise of professional skill or judgment is not patentable. However, a claim which does not restrict, or interfere with, or otherwise engage professional skill or judgment – including a claim for a fixed dosage and or a fixed dosage schedule or interval – is not impermissible subject matter where there is no evidence to contradict that claimed dosage. Contrary to the Commissioner's decision and the respondent's position, [*Mylan*] has not changed the law.

[33] Pharmascience argues that the concern in *Abbvie* about evidence that could contradict a fixed claimed dosage or schedule is directed to cases in which the dosage or schedule in question may not be effective for all patients such that a physician would have to exercise skill and judgment in some cases in determining an appropriate dosage. Pharmascience argues that a claimed dosage regimen that will not be appropriate for all patients constitutes an unpatentable method of medical treatment. As support for this argument, Pharmascience notes the following passage from *Abbvie* at paragraph 121:

> In the present case, the physician's skill is not expected to be exercised within the claim. The prescribing practices are not restricted. The physician must exercise skill and judgment to determine if the claimed use is appropriate for the patient. The physician decides to prescribe it as is or not at all. If prescribed, there would be no restriction on the exercise of skill or judgment. The evidence is that this dosage with the bi-weekly interval is appropriate for all those to whom it is administered.

[34] I do not understand *Abbvie* to exclude as prohibited methods of medical treatment all patent claims to a dosing regimen that may not work for all patients. Such a rigid approach would be inconsistent with the jurisprudence. In practice, I would expect that few drug regimens could be anticipated to be effective for all patients at a particular dosage. In my view, *Abbvie* was properly focused on whether it was expected that professional skill and judgment would be required in using the patented invention. In that case, the Court found no evidence to that effect (see paragraph 111).

[35] The Federal Court reached the opposite result in *Hoffmann-La Roche Limited v. Sandoz Canada Inc.*, 2021 FC 384, 185 C.P.R. (4th) 167 (*Hoffmann*). There, the Court found at paragraph 204 that "the evidence has established that there is a continued need for a physician's

exercise of skill and judgement". Clearly, this issue is factually suffused; it depends on the evidence and it concerns how the patented invention is intended to be used.

[36] Another possible wrinkle seems to arise in *Novartis*. In finding the claims of the patent in suit invalid, the Federal Court there noted at paragraph 99 that the claims included "treatment by intermittent dosages with some claims specifying a dosage range and others specifying specific dosages; and some claims claiming more frequent intervals of dosing, and others less". The Federal Court continued that the claims therefore included "that which lies within the skill of the medical practitioner". This reasoning suggests that the Court in *Novartis* may have been concerned that, even though some individual claims provided a fixed dosage and schedule, the claims of the patent taken together covered a range of possible dosages or schedules, such that use of the patented invention as claimed effectively required the exercise of skill and judgment. Though preceding paragraphs of that decision discussed variability in the frequency of the intermittent doses (in the disclosure portion of the patent), such variability within any particular claim is not discussed in paragraph 99.

[37] To summarize, whether or not a patent claim to a dosing regimen relates to a method of medical treatment cannot be based exclusively on whether its dosing and schedule is fixed or not. The proper inquiry remains whether use of the invention (i.e., <u>how</u> to use it, not <u>whether</u> to use it) requires the exercise of skill and judgment, and the burden remains on the party challenging the patent. It is difficult to provide more detailed guidance than this for parties involved in future litigation and courts faced with allegations of invalidity of patent claims due to unpatentable

subject matter, namely methods of medical treatment. Such allegations will generally turn on the particulars of the case and the evidence on the record.

B. *Issue 1: Whether claims 1 to 16 and 33 to 63 should have been subject to method of medical treatment analysis*

[38] At paragraph 34 of its reasons, the Federal Court divided the claims of the 335 Patent into four sets:

> i. Claims 1 to 16 relate to prefilled syringes adapted for administration according to the claimed dosing regimens;
>
> ii. Claims 17 to 32 relate to a use of a "dosage form" according to the claimed dosing regimens;
>
> iii. Claims 33 to 48 relate to use of paliperidone as paliperidone palmitate in the manufacture/preparation of a "medicament" adapted for administration according to the claimed dosing regimen; and
>
> iv. Claims 49 to 63 relate to a "dosage form" adapted for administration according to the claimed dosage regimens.

[39] At paragraph 163, the Federal Court found all of the claims except 17 to 32 (the other claims) to be product claims, and not methods of medical treatment.

[40] Pharmascience argues that the Federal Court erred in concluding on this basis. It argues that the other claims do not concern a mere product (pre-filled syringes or a dosage form), but rather a dosing regimen involving ongoing maintenance dosing. Pharmascience argues that these claims should not have been excluded from the method of medical treatment analysis.

[41] In my view, the Federal Court did not err in law in finding that the other claims did not define methods of medical treatment because they were product claims. It is not in dispute that a vendible product is not a method of medical treatment. Therefore, the issue is really whether the Federal Court erred in finding that the other claims are for a vendible product. In my view, a claim may concern a vendible product even if it includes a dosing regimen as an essential element.

[42] The Federal Court specifically indicated its conclusions that the other claims are product claims at paragraphs 99, 109 and 111 of its reasons. I am not convinced that the Federal Court made any error in this regard. Claims 1 to 16 concern pre-filled syringes, which are clearly vendible products. Claims 33 to 48 concern the use of paliperidone, but in preparation of a medicament, which is also a vendible product. Finally, claims 49 to 63 concern a dosage form, which once again is a vendible product. I see no reason to interfere with the Federal Court's conclusion that these are not claims to methods of medical treatment. I acknowledge Pharmascience's argument that it would be an error to focus on form over substance, but I see nothing in the substance of these claims that is inconsistent with their form as claims to vendible products.

[43] I also do not accept Pharmascience's assertion that these claims were excluded from the method of medical treatment analysis. Even though the Federal Court suggests as much in paragraph 163 of its reasons, I am of the view that it did in fact consider these claims and it found that they related to a vendible product and were therefore patentable subject matter. In any

case, the Federal Court's method of medical treatment analysis in relation to claims 17 to 32 of the 335 Patent would apply equally to the other claims.

C. *Issue 2: Whether the Federal Court erred in finding that the claims in issue are patentable on the basis of the dichotomy between fixed and variable dosing regimens*

[44] There are two aspects to Pharmascience's argument on this issue. First, Pharmascience argues that the Federal Court erred in describing the relevance of fixed or variable dosing regimens to the issue of method of medical treatment. Second, Pharmascience argues that the Federal Court erred in characterizing claims 17 to 32 of the 335 Patent as defining fixed dosages and schedules. I will address these two aspects separately.

(1) Relevance of fixed or variable dosing

[45] I have discussed the jurisprudence relevant to this aspect of issue 2 at paragraphs 27 to 37 above. In light of that discussion, the Federal Court's description of the law as it relates to fixed dosages and schedules at paragraph 164 of its reasons (see quote at paragraph 9 above) is incomplete. The question of patentable subject matter does not necessarily turn simply on whether the claim in question is limited to a fixed dosage and schedule. Rather, the proper question is whether professional skill and judgment would be required in using the patented invention. Though a fixed dosage and schedule may be a good indication that no such skill and judgment would be required, evidence may indicate otherwise.

[46] Pharmascience also draws the Court's attention to paragraph 167 of the Federal Court's reasons:

> As Pharmascience's expert Dr. Jeffries agreed, claims 17-32 do not prevent physicians from practicing in a manner they had previously "because they weren't doing anything before" the 335 Patent with paliperidone palmitate to treat schizophrenia.

[47] I am inclined to agree with Pharmascience that this observation may be relevant to the issue of obviousness, but it is not relevant to whether the claims in question define patentable subject matter.

[48] Despite this, I do not see either paragraph 164 or 167 as representing a reviewable error. I read paragraph 167 as an aside that was unnecessary to the Federal Court's decision. With regard to paragraph 164 and the Federal Court's failure to acknowledge the potential relevance of evidence that contradicts the fixed nature of the claimed dosing and schedule, I am satisfied that it made no difference to the result. Firstly, the same judge (Justice Manson) was aware of this precise issue, having considered it just the year before in *Hoffmann* at paragraph 202. Secondly, as discussed below in relation to the second aspect of this issue, Pharmascience has not convinced me that any evidence on the record was sufficient to contradict the fixed nature of the dosing and schedule claimed in the 335 Patent. It would have been preferable for the Federal Court to have acknowledged this nuance in the legal test, but I do not see this omission as a reviewable error.

[49] At paragraphs 168 to 171 of its reasons, the Federal Court properly focused on whether use of the claims required the exercise of skill and judgment. At paragraph 171, the Federal Court properly recognized the distinction between the exercise of skill and judgment in deciding

whether to use the invention, and the exercise of skill and judgment in deciding how to use the invention.

(2) Characterization of claims 17 to 32 as defining fixed dosages and schedules

[50] Pharmascience points to paragraph 162 of the Federal Court's reasons as an acknowledgement that different dosages may be required for different patients, and therefore the 335 Patent does not define a fixed dosage regimen. Pharmascience argues that the patented regimen is not "one size fits all", and therefore it constitutes a method of medical treatment. As indicated above in discussion of *Abbvie*, I do not accept the fact that a fixed dosage may not work for some patients as sufficient to conclude that the invention is an unpatentable method of medical treatment. As indicated several times already in these reasons, the proper question is whether skill and judgment is required to use the invention.

[51] Pharmascience also cites various elements of the claims of the 335 Patent as instances of variability in dosing and scheduling that require a conclusion that the invention is not limited to a fixed dosage and schedule. One example is the window provided in claims 17 to 32 for the second loading dose ("one week ± 2 days after the first loading dose") and for the maintenance doses ("monthly ± 7 days dosing interval after the second loading dose"). Pharmascience argues that the claims therefore effectively call for the second dose in a range from day 6 to day 10, and the maintenance dose in a range from 23 to 37 days after the second dose.

[52] The Federal Court acknowledged this argument at paragraph 170 of its reasons, but found that these choices have no clinical implications, and are there to allow flexibility in administering

the drug. The Court concluded based on this that the claims do not interfere with a physician's exercise of skill and judgment. I see no legal error here, and Pharmascience does not assert any palpable and overriding error of fact or of mixed fact and law. In *Wellcome*, claims that defined the intended dosage as "an effective amount" were held to be patentable subject matter despite the fact that they clearly contemplated some variability.

[53] Pharmascience makes a similar argument regarding flexibility as to the location for injection of the monthly maintenance dose, which may be in "a deltoid or a gluteal muscle". The Federal Court reached the same conclusion, which was open to it, that this choice has no clinical implications and does not interfere with a physician's exercise of skill and judgment.

[54] Pharmascience also argues that the disclosure portion of the 335 Patent indicates that physicians are intended to exercise skill and judgment in using the invention. It points specifically to the following passage at page 12, lines 23 to 25 thereof:

> Those of ordinary skill in the art will understand that the maintenance dose may be titrated up or down in view of patients condition (response to the medication and renal function).

[55] Titration has been cited in the jurisprudence as a basis for concluding that use of an invention requires skill and judgment: see *Mylan* and *Hoffmann*. But in my view, this sentence is insufficient to find a reviewable error in this case. While the Federal Court was required to consider the implications of this sentence as part of its review of the 335 Patent as a whole, it is not of such a nature as to require the Federal Court to conclude that use of the claimed invention demands the exercise of skill and judgment. Once again, I see no legal error here, and Pharmascience does not assert any palpable and overriding error of fact or of mixed fact and law.

[56] Another potential argument of variability in the 335 Patent is the difference between dosing for patients with renal impairment and dosing for those without. However, it appears that this is an objective distinction that does not involve the exercise of a physician's skill and judgment. Rather, it reflects the fact that a different intended dosage regimen applies for patients with renal impairment.

D. *Scope of injunction*

[57] A final issue that was raised as an alternative argument in Pharmascience's memorandum of fact and law concerns the scope of the injunction that was granted by the Federal Court in its judgment. This issue was not addressed orally at the hearing of this appeal, but it also was not given up.

[58] Pharmascience argues that the injunction is too broad, in that it covers activities that are outside the scope of the exclusive rights for a patent enumerated in section 42 of the *Patent Act*, namely the right to make, construct, use and sell the invention.

[59] The injunction granted by the Federal Court appears in paragraph 4 of its judgment:

> An injunction is granted until the expiry of the 335 Patent on December 17, 2028, restraining Pharmascience, as well as its subsidiary and affiliated companies, officers, directors, employees, agents, licensees, successors, assigns, and any others over whom it exercises lawful authority, from:
>
> a. Making, constructing, using or selling pms-PALIPERIDONE PALMITATE in Canada in accordance with ANDS Nos. 244641 and 251767;
>
> b. Offering for sale, marketing or having pms-PALIPERIDONE PALMITATE marketed in Canada in accordance with ANDS No. 244641 and 251767; and

c. Importing, exporting, distributing or having pms-PALIPERIDONE PALMITATE distributed in Canada in accordance with ANDS Nos. 244641 and 251767.

[60] Pharmascience effectively takes issue with the following activities being included in the injunction: (i) offering for sale, (ii) marketing, (iii) having marketed, (iv) importing, (v) exporting, (vi) distributing, and (vii) having distributed.

[61] Pharmascience has provided little by way of explanation as to how these activities are supposed to fall outside the scope of a patentee's exclusive rights. I note that an injunction of similar scope was recently granted by this Court against Apotex Inc. in a parallel action involving Janssen and the 335 Patent (*Janssen Inc. v. Apotex Inc.*, 2023 FCA 253). Paragraphs 64 to 70 of that decision explain the reasoning for granting an injunction of that scope.

[62] I note also, as does Janssen, that Pharmascience did not raise this issue in its notice of appeal.

[63] I would reject Pharmascience's alternative argument concerning the scope of the injunction both because it was not raised in the notice of appeal, and for the reasons discussed in paragraphs 64 to 70 of the decision mentioned in paragraph 61 above.

VI. Conclusion

[64] It follows from the foregoing that I would dismiss the present appeal. I would award costs to Janssen in the agreed amount of $10,000, all-inclusive.

"George R. Locke"
J.A.

"I agree.
Yves de Montigny C.J."

"I agree.
Nathalie Goyette J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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CONCURRED IN BY:	DE MONTIGNY C.J. GOYETTE J.A.
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