Federal Court of Appeal | Cour d'appel fédérale

Date: 20240112

Docket: A-69-22

Citation: 2024 FCA 10

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

BETWEEN:

PHARMASCIENCE INC.

Appellant

and

JANSSEN INC. and JANSSEN PHARMACEUTICAL N.V.

Respondents

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

Judgment delivered at Ottawa, Ontario, on January 12, 2024.

PUBLIC REASONS FOR JUDGMENT BY: LOCKE J.A.

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

Federal Court of Appeal | Cour d'appel fédérale

Date: 20240112

Docket: A-69-22

Citation: 2024 FCA 10

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

BETWEEN:

PHARMASCIENCE INC.

Appellant

and

JANSSEN INC. and JANSSEN PHARMACEUTICAL N.V.

Respondents

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 62, *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 (the *Regulations*). 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 brought a motion for summary trial or, alternatively, for dismissal of Janssen's action pursuant to section 6.08 of the *Regulations*, on the basis that its product would not infringe the 335 Patent since it would not provide the 75 mg-eq. dose, which is an essential element of all of the claims thereof. The Federal Court dismissed Pharmascience's motion. In the context of the summary trial, the Federal Court decided the infringement issue in favour of Janssen, finding that Pharmascience would induce infringement of the 335 Patent with its generic version of INVEGA SUSTENNA. The action was allowed to proceed on the patent validity issues that had been raised by Pharmascience. That trial resulted in a decision (2022 FC 1218,

198 C.P.R. (4th) 329), which is the subject of an appeal before this Court (File No. A-205-22). That appeal has been heard and remains under reserve at the time these reasons for judgment have been released.

[4] The legal test for a finding of inducing patent infringement was correctly stated by the Federal Court at paragraph 93 of its reasons:

> There is a three "prong" test for inducement: (1) direct infringement by a third party; (2) the inducer influenced the third party to the point that the infringing act would not have occurred without the influence; and (3) the defendant knew that its influence would bring about the infringing act [*Corlac Inc. v. Weatherford Canada Ltd*., 2011 FCA 228 [*Corlac*]].

[5] The Federal Court found that each of the prongs of the test was satisfied. In the present appeal, Pharmascience takes issue only with the first prong. Specifically, Pharmascience argues that the Federal Court erred in finding that direct infringement would result from use of its generic version of INVEGA SUSTENNA, if the 75 mg-eq. dose were sourced from Janssen.

[6] For the reasons set out below, I would dismiss this appeal.

II. The Federal Court's Decision

[7] The Federal Court addressed the first prong of the test for inducing infringement at paragraphs 95 to 120 of its reasons.

[8] It first addressed Pharmascience's argument that any activities falling within the scope of the claims of the 335 Patent would be licensed for prescribing physicians and therefore not infringing (see paragraphs 96-102 of the Federal Court's reasons). According to Pharmascience, this is because whenever a physician would prescribe or otherwise use Pharmascience's generic version of INVEGA SUSTENNA, any such activities would require use of a 75 mg-eq. dose, which would be available only from Janssen. Pharmascience argued that, in the absence of limitations imposed by Janssen at the time of sale, a 75 mg-eq. dose that Janssen sells would include an implied license to use the 75 mg-eq. dose in any way the purchaser or prescribing physician chooses, including in the claimed dosing regimens with other doses obtained from an unlicensed source like Pharmascience.

[9] The Federal Court considered some of the jurisprudence on the issue of the implied license and concluded that it did not apply to the 75 mg-eq. dose. It reasoned that the implied license relates to a patented article itself, and the 75 mg-eq. dose alone is not a patented article. It is merely one component thereof.

[10] It is this portion of the Federal Court's analysis on the first prong of the test for inducing infringement that is the focus of Pharmascience's argument in this appeal.

[11] The remainder of the Federal Court's analysis on the first prong concerned issues that are no longer in dispute. These included whether Pharmascience's product monograph contained instructions concerning the use of the 75 mg-eq. dose, and whether said product monograph would cause prescribers to change their practices regarding prescribing the 75 mg-eq. dose.

III. Standard of Review

[12] 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).

IV. Analysis

[13] Central to Pharmascience's argument that the Federal Court erred in failing to recognize the extent of the implied license in this case is the decision of the Supreme Court of Canada in *Eli Lilly & Co. v. Novopharm Ltd.*, [1998] 2 S.C.R. 129, 161 DLR (4th) 1 (*Eli Lilly*). That case involved a compulsory licence that was granted to Novopharm to manufacture and import bulk nizatidine. Novopharm entered into a supply agreement with Apotex whereby the former would provide the latter with nizatidine to be formulated into capsules. The dispute concerned whether the licensed nizatidine that Apotex acquired from Novopharm included an implied licence to manufacture capsules from the bulk nizatidine.

[14] In addressing this point, the Supreme Court of Canada at paragraph 99 adopted the following text from the Federal Court of Appeal decision in that case:

> If a patentee makes a patented article, he has, in addition to his monopoly, the ownership of that article. And the ownership of a thing involves, as everybody knows, "the right to possess and use the thing, the right to its produce and accession, and the right to destroy, encumber or alienate it".... If the patentee sells the patented article that he made, he transfers the ownership of that article to the purchaser. This means that, henceforth, the patentee no longer has any right with respect to the article which now belongs to the purchaser who, as the new owner, has the exclusive right to possess, use, enjoy, destroy or alienate it. It follows that, by selling the patented article that he made, the patentee impliedly renounces, with respect to that article, to [*sic*] his exclusive right under the patent of using and selling the invention. After the sale, therefore, the purchaser may do what he likes with the patented article without fear of infringing his vendor's patent.
>
> The same principles obviously apply when a patented article is sold by a licensee who, under his licence, is authorized to sell without restrictions. It follows that, if Apotex were to purchase bulk Nizatidine manufactured or imported by Novopharm under its licence, Apotex could, without infringing Lilly's patents, make capsules from that substance or use it in any other possible way. [SCC's emphasis.]

[15] The Supreme Court of Canada went on as follows:

> 100 Perhaps the principles underlying this well-founded statement of the law merit some brief elaboration at this stage. As I have already noted in connection with the distinction between a sublicence and an ordinary agreement of purchase and sale of a patented or licensed article, the sale of a patented article is presumed to give the purchaser the right "to use or sell or deal with the goods as the purchaser pleases": see *Badische Anilin und Soda Fabrik v. Isler*, [[1906] 1 Ch. 605], at p. 610. Unless otherwise stipulated in the licence to sell a patented article, the licensee is thus able to pass to purchasers the right to use or resell the article without fear of infringing the patent. Further, any limitation imposed upon a licensee which is intended to affect the rights of subsequent purchasers must be clearly and unambiguously expressed; restrictive conditions imposed by a patentee on a purchaser or licensee do not run with the goods unless they are brought to the attention of the purchaser at the time of their acquisition: see *National Phonograph Co. of Australia, Ltd. v. Menck*, [1911] A.C. 336 (P.C.).
>
> 101 Therefore, it is clear that, in the absence of express conditions to the contrary, a purchaser of a licensed article is entitled to deal with the article as he sees fit, so long as such dealings do not infringe the rights conferred by the patent. On this score, Eli Lilly alleges that the reformulation of nizatidine would in this

> case exceed the scope of the rights obtained by the purchaser because it would constitute not simply the resale of the material purchased, but rather, the creation of a new article in violation of Eli Lilly's patent. However, I can find no basis, either in the evidence or in the case law cited by Eli Lilly, for this submission. In my view, the reformulation of nizatidine into final-dosage form does not have the effect of creating a new article. Rather, it is more akin to repackaging the substance into a commercially usable form, which I do not view as violating any rights under the patents.

[16] So it is clear that the sale of a patented article without restriction includes the right to use that article as the purchaser pleases. This much is not in dispute. This principle is well supported by prior jurisprudence: *Thomas v. Hunt* (1864), 17 C.B.N.S. 183, 144 E.R. 74 at 76; *Betts v. Willmott* (1871), L.R. 6 Ch. App. 239, 19 W.R. 369 at 245; *Badische Anilin und Soda Fabrik v. Isler* (1906), 1 Ch. 605, 75 L.J. Ch. 411 at 610, aff'd [1906] 2 Ch. 443, 23 R.P.C. 633 (C.A.); *Hatton v. Copeland-Chatterson Co.* (1906), 37 S.C.R. 651 at 653; *Gillette v. Rea*, [1910] O.J. No. 587, 15 O.W.R. 345 at para. 2; *National Phonograph Company of Australia Ld. v. Menck*, [1911] A.C. 336, 28 R.P.C. 229 at 234, 238, 246, 248 (U.K.P.C.); *Signalisation de Montréal Inc. v. Services de Béton Universels Ltée*, [1993] 1 F.C. 341, [1992] F.C.J. No. 1151 at paras. 17, 20 (C.A.). The principle is also supported by jurisprudence subsequent to *Eli Lilly*: *Apotex Inc. v. Merck & Co.*, 2002 FCA 210, [2002] F.C.J. No. 811 at para. 39; *Distrimedic Inc. v. Dispill Inc.*, 2013 FC 1043, [2013] F.C.J. No. 1093 at para. 226 (*Distrimedic*); *Angelcare Canada Inc. v. Munchkin, Inc.*, 2022 FC 507, [2022] F.C.J. No. 480 at para. 276 (*Angelcare*).

[17] Janssen argues that this principle does not apply in this case. It notes that the article it would sell in the scenario before this Court (the 75 mg-eq. dose) is not itself a patented article, but merely a component of a patented invention that includes several different doses. Janssen argues that the jurisprudence concerning implied license is limited to the patented article itself,

and therefore the purchase from Janssen of only the 75 mg-eq. dose would not carry with it an implied license to combine that dose with other doses obtained from Pharmascience to practise the patent invention.

[18] Pharmascience disputes the distinction based on whether the article sold is the whole patented article or merely one component. It refers to *Slater Steel Industries Ltd. v. R. Payer Co. Ltd.*, (1968) 55 C.P.R. 61, 38 Fox Pat. C. 139 (Ex. Ct.) (*Slater Steel*), which concerned a patent on a helically shaped rod wound around an electric power transmission line. The claims concerned the combination of the rod and the transmission line. The Exchequer Court noted that the patentee and its Canadian licensee in that case "make use of the patents, not by manufacturing the combination that is the subject of the patents, but by manufacturing the preformed armour rods and selling them to power companies who use the rods to create such combination by applying them to their transmission lines." The Court went on to observe that, "[n]o licence has been granted under the patents to any person in Canada to create the combination covered by the patents except the implied licence flowing from the sale of the preformed armour rods" (see page 65).

[19] The Exchequer Court concluded that the defendant, who supplied a competing rod, had not infringed because it had not directly infringed by making the patented combination, and had not induced its customer to do so. Nevertheless, Pharmascience urges this Court to conclude from the words at the end of the sentence quoted at the end of the previous paragraph ("except the implied licence flowing from the sale of the preformed armour rods") that the sale of one component of a patented combination includes an implicit license to use the combination.

[20] I am not prepared to draw such a general conclusion from this statement by the Exchequer Court more than 50 years ago in *obiter dicta*. In my view, the context of the transaction is relevant. In the context of *Slater Steel*, it appears to have been implicit that the purchaser from the patentee of a pre-formed rod as described in the patent in suit was entitled to use that rod on the patented combination. It does not appear that the purchaser was expected also to source its transmission lines from the patentee. Any implied license would be restricted to making the combination with rods made or sold by the patentee. In the absence of any pleading or evidence otherwise, the Court declined to find that an implied license existed. The Exchequer Court discussed this issue at page 86 of the decision.

[21] However, the same does not necessarily apply in the present case. There appears to be no reason to conclude that either Janssen or its customers (a prescribing physician or a patient) would have understood that the purchase of paliperidone palmitate in a single dose from Janssen would include an implied licence to use the entire dosing regimen of the product in combination with other doses obtained from unlicensed sources, to practise the invention of the 335 Patent. It is difficult to accept that there could be such an implied licence in circumstances where neither the supposed licensor nor the supposed licensee would have understood such a licence to exist.

[22] Pharmascience also cites the Federal Court's decision in *Distrimedic*. In the relevant portion of that case, Distrimedic was accused of inducing infringement of patent claims to a pill-sorting device and a device for opening a set of pill containers with a knife. There was no evidence that Distrimedic had sold any such device, but Distrimedic had sold pill containers to pharmacists who had obtained such devices from the patentee. It appears that the allegation was

that those pharmacists used the patentee's devices with Distrimedic's pill containers, and were induced to do so by Distrimedic. Among the reasons cited by the Federal Court for dismissing this argument was that the patentee "must be presumed to have acquired an implicit right to use [the devices] without restriction" (see paragraph 226 of its reasons).

[23] In my view, this decision can be of little assistance to Pharmascience because the pill-sorting device and device for opening a set of pill containers were the subject of distinct claims that were not interdependent. Hence, the purchase of these items from the patentee was the purchase of the patented article, and not a mere component thereof. This decision does not support the principle that sale of a mere component of a patented invention includes an implied license to use the patented invention without restriction, as Pharmascience urges.

[24] For its part, Janssen relies on this Court's decision in *MacLennan v. Produits Gilbert Inc.*, 2008 FCA 35, [2008] F.C.J. No. 128 (*MacLennan*). The patent in that case concerned a system for replacing damaged or used saw teeth on tooth holders used in circular saws for feller heads in the forestry industry. The idea was to minimize losses by facilitating tooth replacement. The appellants sold the combination of the teeth and tooth holders. They alleged inducing patent infringement by the respondent, which manufactured and sold replica replacement teeth to be used by the appellants' customers with tooth holders purchased from the appellants.

[25] The appellants were successful in establishing that the respondent induced patent infringement by its sale of the replica teeth. Janssen notes that the fact that the customers had purchased one component of the patented combination (the tooth holders) from the appellants

did not avoid a finding that they had directly infringed the patent. Clearly, the Court in *MacLennan* found no implied licence for the purchasers of the appellants' tooth holders to use them with other components of the patented combination that had been obtained from unlicensed sources. Janssen argues that the facts in *MacLennan* are on all fours with those in the present appeal.

[26] Pharmascience seeks to distinguish *MacLennan* on the basis that the debate there concerned the extent of the implied right of a purchaser to repair. The respondent there had argued that the teeth required replacement because of ordinary use, and the purchaser had an implied license to repair its tooth holders by replacing the damaged or used teeth. This Court disagreed. It found that the focus of the patented invention in that case was the easy replacement of teeth, and therefore their replacement was not repair but remaking of the invention (see *MacLennan* at paragraph 23). Pharmascience argues that the present appeal is distinguishable from *MacLennan* in that it concerns the right to use an invention rather than the right to remake it.

[27] I do not agree with the distinction that Pharmascience urges. On my reading, this Court in *MacLennan* refused to deal with an implied licence to repair because of the nature of the invention there. Nothing in that conclusion contemplates a broad implied licence to use a patented article. In fact, the finding of inducement there indicates that purchasers of tooth holders from the patentee did not obtain an unlimited right to use them in the patented combination.

[28] Further support for the approach described in *MacLennan* is found in the Federal Court's decision in *Angelcare*. That case involved a patent on a combination of a pail for storing soiled diapers and a cartridge of plastic film for use in the pail. Among other things, the defendants were accused of inducing infringement by selling cartridges for use in the appellants' pail. One of the defences was that purchasers of the plaintiffs' pails had obtained an implied licence to use them as they please, including with cartridges purchased from the defendants. The argument was that, with such an implied licence, there could be no act of direct infringement upon which to base an allegation of inducement. The Federal Court addressed *MacLennan* at paragraphs 278 to 280 of its reasons in *Angelcare*. It found no basis to distinguish *MacLennan* and concluded that there was inducement to infringe.

[29] In both of these cases, the patented invention constituted a combination invention and therefore, the sale of a mere component of it was insufficient to grant the implied right to use the entire combination. To grant an implied licence, the sale of the entire combination had to occur, or at least, as in *Slater Steel*, the parties' intended use of the component at the time of sale contemplated its use in the patented combination.

[30] In summary, I am not convinced that the Federal Court erred in any way in its finding that users of Janssen's 75 mg-eq. dose with Pharmascience's doses in other amounts would directly infringe the 335 Patent and hence that the first prong of the test for inducing patent infringement would be met.

[31] Pharmascience argues, in the alternative, that the Federal Court erred in not limiting its findings of inducing infringement to claims 17 to 32 of the 335 Patent, which concern the use of a dosage form according to the claimed dosing regimens. The other claims of the 335 Patent concern prefilled syringes adapted for administration according to the claimed dosing regimens (claims 1 to 16), the use of paliperidone as paliperidone palmitate in the manufacture/preparation of a medicament adapted for administration according to the claimed dosing regimens (claims 33 to 48), and a dosage form adapted for administration according to the claimed dosage regimens (claims 49 to 63).

[32] I am not convinced that the Federal Court erred in this respect either. Just as with claims 17 to 32, all of the other claims of the 335 Patent would be directly infringed by a physician or a patient using Pharmascience's generic version of INVEGA SUSTENNA with 75 mg-eq. doses sourced from Janssen. Moreover, just as with claims 17 to 32, all such direct infringement would be induced by Pharmascience.

V. Conclusion

[33] 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

DOCKET:	A-69-22
STYLE OF CAUSE:	PHARMASCIENCE INC. v. JANSSEN INC. and JANSSEN PHARMACEUTICAL N.V.
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	DECEMBER 5-6, 2023
PUBLIC REASONS FOR JUDGMENT BY:	LOCKE J.A.
CONCURRED IN BY:	DE MONTIGNY C.J. GOYETTE J.A.
DATED:	JANUARY 12, 2024

APPEARANCES:

Marcus Klee Scott Beeser	FOR THE APPELLANT PHARMASCIENCE INC.
Peter Wilcox Marian Wolanski Megan Pocalyuko Oleyna Strigul	FOR THE RESPONDENTS JANSSEN INC. and JANSSEN PHARMACEUTICAL N.V.

SOLICITORS OF RECORD:

Aitken Klee LLP Ottawa, Ontario	FOR THE APPELLANT PHARMASCIENCE INC.
Belmore Neidrauer LLP Toronto, Ontario	FOR THE RESPONDENTS JANSSEN INC. and JANSSEN PHARMACEUTICAL N.V.