Federal Court of Appeal | Cour d'appel fédérale

Date: 20101020

Docket: A-6-10

Citation: 2010 FCA 275

CORAM: **EVANS J.A.**
DAWSON J.A.
STRATAS J.A.

BETWEEN:

BAYER SCHERING PHARMA AKTIENGESELLSCHAFT

Appellant

and

THE ATTORNEY GENERAL OF CANADA

Respondent

Heard at Toronto, Ontario, on October 14, 2010.

Judgment delivered at Ottawa, Ontario, on October 20, 2010.

REASONS FOR JUDGMENT BY: EVANS J.A.

CONCURRED IN BY: DAWSON J.A.
STRATAS J.A.

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REASONS FOR JUDGMENT

EVANS J.A.

A. INTRODUCTION

[1] This is an appeal by Bayer Schering Pharma Aktiengesellschaft (Bayer) pursuant to section 41 of the *Patent Act*, R.S. 1985, c. P-4 (Act), from a decision of the Federal Court (2009 FC 1249), in which Justice Boivin dismissed its appeal from a decision of the Commissioner of Patents, dated May 21, 2008. In that decision, made pursuant to section 40 of the Act, the Commissioner refused to grant a patent for a compound, because a patent had already been issued for the same compound made by a particular process.

[2] Bayer says that the Commissioner erred in law in refusing to issue a patent. Counsel argues that the jurisprudence establishes that a patent may be issued for a product when a patent has been issued for the same product made by a particular process. The general prohibition on issuing patents for inventions which, when compared to an already patented invention, involve no ingenuity does not apply to this situation.

[3] In my view, this cannot be correct because it is inconsistent with a fundamental premise of Canadian patent legislation: a patent is a bargain in which an inventor is granted a time-limited monopoly in the exploitation of an invention, in exchange for fully disclosing it so that the public can use it after the patent has expired. However, if a claimed "invention" is obvious, the public derives no benefit from its disclosure and there is no justification for granting the monopoly. If cases have decided that a patent may issue for a medicinal compound when a product-by-process patent for the same compound has already been issued, they are inconsistent with this principle and, in my opinion, should not be followed.

B. FACTUAL BACKGROUND

[4] The facts of this case must be considered in light of provisions of the *Patent Act* concerning medicines. At the relevant time, subsection 41(1) provided that a patent could not be issued for "inventions relating to substances … produced by chemical processes, and intended for … medicine". However, the subsection also permitted the grant of patents for medicinal compounds when made by a process that was "particularly described and claimed" in the patent; these are

known as process-dependent patents or product-by-process patents. I attach as an Appendix the full text of the statutory provisions referred to in these reasons.

[5] Subsection 41(1) was subsequently renumbered as subsection 39(1) and repealed by an amendment to the Act (subsection 39 (1.1)) enacted on November 19, 1987, with effect from four years later. Thus, regardless of when an application for a patent was filed, a patent could be granted for a medicinal compound itself after November 1991.

[6] The facts in this case are not in dispute. The patent Application under consideration has a substantial history which, for present purposes, can be summarized briefly. The Application was filed in May 1986, but claims divisional status from another application (the parent application) which had been filed in August 1982. The parent application was amended so as to limit it to one invention in accordance with section 36(1) of the *Patent Act*, and to remove claims for compounds in order to comply with subsection 41(1). What remained in the parent application was a process-dependent claim for a compound. The parent application was allowed and a patent (the parent patent) was issued in February 1987.

[7] When filed in May 1986, the Application contained process-dependent claims for compounds which were originally included in the parent application, but were later removed from it for the reasons explained above. Since no patent had been issued as of November 19, 1991, when the repeal of subsection 41(1) became effective, Bayer was able to amend the Application so as to

claim a medicinal compound, which was materially identical to the compound claimed in process-dependent form in the parent patent.

[8] By virtue of the transitional provision in section 78.1 of the *Patent Act*, the Application is governed by the Act as it was immediately prior to October 1, 1989, the date when the Act was significantly overhauled.

C. THE DECISION OF THE COMMISSIONER OF PATENTS

[9] The Commissioner agreed that Bayer was not applying for a second patent for the same invention, because the parent patent, now expired, was, by necessity, a product-by-process patent, while the claims in the new application were for the medicinal compound itself. Accordingly, the Application was not refused on the ground that it infringed the rule against the grant of more than one patent for a single invention, which is often called "same invention" double patenting.

[10] However, the Commissioner rejected claims 1-12 in Bayer's Application, on the ground of "obviousness" double patenting. Each claim was dependent on claim 1. This was a claim for a compound, which was the subject of process-dependent claims 1 and 8 of the parent patent. Thus, claim 1 of the parent patent was for a process to produce the compound, while claim 8 claimed the compound as produced by that process.

[11] The invention claimed in the Application (that is, the compound) was not "patentably distinct" from the claim in the parent patent for the materially identical compound when made by a

particular process, and involved no "inventive ingenuity" or novelty when compared to the claims of the process-dependent patent.

D. DECISION OF THE FEDERAL COURT

[12] Bayer appealed the Commissioner's decision to the Federal Court pursuant to section 41 of the current version of the *Patent Act*.

[13] The Court held that the Commissioner's decision was reviewable on a standard of reasonableness, since the question in issue involved the interpretation of the *Patent Act*, the statute administered by the Commissioner, and was within the scope of her expertise. The Court held that reasonableness was also the standard of review to the extent that determining whether a claimed invention is obvious is a question of mixed fact and law.

[14] The Court then turned to the jurisprudence relied on by Bayer in support of the proposition that the prohibition of "obviousness" double patenting does not apply to claims for a product when an earlier patent has been issued for the same product made by a claimed and described process.

[15] It held that the principal authority, *Aventis Pharma Inc. v. Mayne Pharma (Canada) Inc.*, 2005 FC 1183, 42 C.P.R. (4th) 481, rev'd. on other grounds, 2008 FCA 21, 380 N.R. 35 (*Mayne*), dealt only with "same invention" double patenting, not "obviousness" double patenting. Consequently, the Court held, it was reasonable for the Commissioner to apply to the present facts

the general principle that a patent will not issue in respect of a claim that, on the basis of inventions disclosed in existing patents, is obvious and involves no inventive ingenuity.

E. ISSUES AND ANALYSIS

[16] This appeal raises two issues:

1. What is the standard of review applicable to the Commissioner's refusal to issue a patent for the compound claimed in Bayer's Applicaiotn?

2. Does the rule prohibiting "obviousness" double patenting apply to an application for a patent in respect of a product, when a process-dependent patent has already been issued in respect of the same product?

Issue 1: Standard of review

[17] Relying largely on the presumption established in *Dunsmuir v. New Brunswick*, 2008 SCC 9, [2008] 1 S.C.R. 190 (*Dunsmuir*) and *Canada (Citizenship and Immigration) v. Khosa*, 2009 SCC 12, [2009] 1 S.C.R. 339, that a specialized tribunal's interpretation of its enabling legislation is reviewable on a standard of reasonableness, the Judge concluded that this standard applied in the present case to the Commissioner's interpretation of the *Patent Act*.

[18] With all respect, I cannot agree. *Dunsmuir* teaches (at para. 62) that where previous case law has satisfactorily determined the standard of review to be applied to a tribunal's interpretation of its enabling legislation, courts should normally adopt that standard without indulging in a protracted standard of review analysis.

[19] Cases decided both before and after *Dunsmuir* have held that the Commissioner's interpretation of the *Patent Act* is reviewable on a standard of correctness: see, for example, *CertainTeed Corp. v. Canada (Attorney General)*, 2006 FC 436, 50 C.P.R. (4th) 177 at paras. 26-27; *Aventis Pharma Inc. v. Pharmascience Inc.*, 2006 FCA 229, [2007] 2 F.C.R. 103 at para. 20; *Belzberg v. Canada (Commissioner of Patents)*, 2009 FC 657, 307 D.L.R. (4th) 664 at para. 34; *Amazon.com. v. Canada (Attorney General)*, 2010 FC 1011 at paras. 28-29.

[20] Two considerations indicate that the case law has satisfactorily resolved the standard of review applicable in this case to the Commissioner's refusal to issue a patent to Bayer for its chemical compound.

[21] First, although ultimately rooted in a fundamental principle of the *Patent Act*, the rule against double patenting has in large part been made by judges on a case by case basis, and is designed to prevent the "evergreening" of an invention by unduly prolonging the period of the monopoly of its use through multiple patents that contain only obvious or uninventive variations on the invention. Whether the rule against double patenting is applicable here depends principally on the interpretation of judicial decisions. The Commissioner has no more expertise than the Court in deciding this question of law.

[22] Second, suppose that in the instant case the Commissioner had granted Bayer a patent for the compound, and that Bayer subsequently brought an action for infringement against a generic drug company producing it or, as was the case in *Mayne*, sought a prohibition under section 6 of the

Patented Medicines (Notice of Compliance) Regulations, SOR/93 133 (PMNOC Regulations). The generic could have defended the proceeding by alleging that the patent was invalid for "obviousness" double patenting, because of the previous process-dependent patent for the same compound. Bayer could have argued, as it does in the present case, that the rule against double patenting does not apply in this situation.

[23] While there is a statutory presumption that, in the absence of evidence to the contrary, a patent granted is valid (subsection 43(2) of the current *Patent Act*), the judge in this hypothetical would have had to determine for herself whether the patent for the compound was valid as a matter of law, without asking whether the Commissioner's decision to issue it was reasonable. On appeal, this Court would review the judge's decision on questions of law on the correctness standard: *Halford v. Seed Hawk Inc*., 2006 FCA 275, 275 D.L.R. (4th) 556 at para. 39.

[24] If a correctness standard is applied to a question of law when it arises in either a trial or a prohibition proceeding under the PMNOC Regulations, there is no basis for applying a reasonableness standard when the same question arises on an appeal from the Commissioner: compare *SOCAN v. Canadian Assn. of Internet Providers*, 2004 SCC 45, [2004] 2 S.C.R. 427 at paras. 48-50. The applicable standard of review cannot depend on whether a patent was granted or refused, or on the nature of the proceeding in which the question of law arose.

[25] For this reason as well, the Commissioner can claim no more expertise than the courts in determining the legal question at issue here: does the rule against "obviousness" double patenting apply on the present facts.

[26] The question at issue in this appeal has no factual element because the parties agree that the compound claimed in Bayer's Application and the compound in the process-dependant claims of the parent patent are materially identical: see para. 42 of Bayer's memorandum of fact and law. It follows from this that the invention claimed in the Application involves no inventive ingenuity when compared to the process-dependent claims made for the same compound in the earlier patent. Hence, it cannot be argued that reasonableness is the appropriate standard of review because the question decided by the Commissioner was one of mixed fact and law.

[27] Thus, in order to succeed in this appeal, Bayer need only establish that the Commissioner's view of the law was wrong. Hence, it may invite the Court to substitute its view of the legal question at issue for that of the Commissioner.

Issue 2: Does the rule prohibiting "obviousness" double patenting apply to Bayer's Application for a patent for the compound?

[28] The rationale of the rule against double patenting was clearly explained in *Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67, [2000] 2 S.C.R. 1067 (*Whirlpool*) at para. 37, where, writing for a unanimous Court, Justice Binnie said (at paras. 37 and 63):

> A patentee who can "evergreen" a single invention through successive patents by the expedient of obvious or uninventive additions prolongs its monopoly beyond what the public has agreed to pay. …
>
> …
>
> The prohibition against double patenting relates back to the "evergreen" problem mentioned at the outset. The inventor is entitled to "a" patent for each invention: *Patent Act*, s. 36(1). If a subsequent patent issues with identical claims, there is an improper extension of the monopoly.

[29] Justice Binnie also noted (at para. 66) that the rule against double patenting is not limited to "same invention" double patenting, where an applicant seeks a patent for the same invention as that claimed in an existing patent.

> There is, however, a second branch of the prohibition which is sometimes called "obviousness" double patenting. This is a more flexible and less literal test that prohibits the issuance of a patent with claims that are not "patentably distinct" from those of the earlier patent.

See also *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2010 FCA 197 at paras. 65 and 73.

[30] This passage would seem apposite in the present case, because there is nothing inventive or "patentably distinct" in a claim for a product that is the subject of a previous process-dependent patent. On the other hand, a process-dependent patent may be granted, even though a patent has already been issued for the product itself, if the process claimed and described for making the product exhibits inventive ingenuity.

[31] Despite *Whirlpool*, Bayer says that decided cases establish that a patent may be issued for a compound, even though a product-by-process patent has already been issued in respect of the materially identical compound. Counsel relies on *Mayne*; *Pfizer Canada Inc. v. Canada (Minister of*

Health), 2008 FCA 108, [2009] 1 F.C.R. 253 (*Pfizer*); and *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61, [2008] 3 S.C.R. 265 (*Sanofi-Synthelabo*). Bayer submits that the law excludes the situation under consideration in the present case from the general prohibition of "obviousness" double patenting.

(i) *Mayne*

[32] The decision of the Federal Court in *Mayne* is the principal authority on which Bayer relies. Its facts are materially indistinguishable from those of the present case. Aventis had been granted a product-by-process patent for a medicinal compound (the '343 patent) when subsection 41(1) was still in force. It was later granted a patent (the '682 patent) for the same compound after the Act was amended to permit patents to be issued for a medicinal compound itself.

[33] Aventis sought a prohibition under section 6 of the PMNOC Regulations to restrain the Minister of Health from issuing a Notice of Compliance to Mayne for an infringing medicine until the expiry of its '682 patent for the compound.

[34] The Federal Court Judge rejected (at para. 76) Mayne's argument that the '682 patent was invalid for double patenting.

> Since it is widely recognized that two patents can exist in parallel, one on the medicine *per se* and one on the process used to produce that medicine, the argument on double patenting cannot stand as patent '343 never provided a monopoly on the substance *per se*.

[35] The Attorney General says that *Mayne* is distinguishable, on the ground that it only considered "same invention" double patenting. Counsel submits that this can be inferred from both the paragraph quoted above and the absence of any discussion in the reasons of whether the claims of the '682 patent involved any ingenuity when compared to those of the process-dependent patent for the same compound. Further, counsel argues, Mayne did not specifically allege "obviousness" double patenting. In the alternative, counsel says that *Mayne* was wrongly decided because it is inconsistent with the bargain theory of patent law and the explanation of "obviousness" double patenting in *Whirlpool*.

[36] On the other hand, Bayer points out that Mayne's Notice of Allegation was not restricted to "same invention" double patenting, but alleged simply that the patent for the compound itself was invalid for double patenting. Moreover, since *Mayne* was decided after, and explicitly refers to, the Supreme Court of Canada's decision in *Whirlpool*, it is inconceivable that the Court was not aware of the "obviousness" branch of the rule against double patenting, even though Justice Beaudry did not mention it expressly in his reasons.

[37] On the basis of the arguments advanced by the Attorney General, I am of the view that the Court in *Mayne* did not intend to decide that, as a matter of law, the rule against "obviousness" double patenting excludes a claim for a compound when a process-dependent patent with respect to the same compound has already been issued. However, if *Mayne* did so decide, it is, in my respectful view, wrong. Bayer provided no principled basis for excluding the facts of both *Mayne* and the present case from the "obviousness" branch of the rule against double patenting.

(ii) *Pfizer*

[38] Counsel for Bayer also relies on statements by Nadon J.A. as authority for the proposition that this Court has already decided that "obviousness" double patenting does not apply to the present fact situation. I do not agree, for two reasons.

[39] First, the patent for a compound in issue in *Pfizer* (the '546 patent) claimed a selection from compounds covered by the '768 patent. Justice Nadon rejected (at para. 69) the allegation that the '546 patent was invalid for anticipation, obviousness and double patenting because the generic had not challenged the validity of the selection. Consequently, he found it unnecessary to examine the generic's allegations under the headings of anticipation, obviousness and double patenting.

[40] Nonetheless, Justice Nadon decided (at para. 69) to "say a few words regarding the issues of double patenting and anticipation." Since he explicitly recognized that his "few words" on double patenting were not necessary for the disposition of the appeal, they are *obiter dicta* and not binding as a matter of precedent.

[41] Second, he examined the generic's argument that the '546 patent was invalid for double patenting because another patent, the '441 patent, claimed processes for making the compound claimed in the '546 patent. Justice Nadon said (at para. 76):

> In my opinion, the double patenting allegations are not justified. The '441 patent covers processes whereas the '546 patent covers compounds. As explained by *Hughes & Woodley* [*on Patents*, 2nd ed. loose leaf (Markham, Ont.: 2005, LexisNexis Canada)], (at §15, page 172), "[a] previous patent for a product by a claimed process does not invalidate a later patent for the product alone for reasons of double patenting" (see: *Aventis Pharma Inc. v. Mayne Pharma (Canada) Inc.*, …at paras. 72-76).

[42] In my opinion, the comparison in this passage of claims for a process in one patent and claims for a compound in another suggests that Justice Nadon had "same invention" double patenting in mind. He does not consider whether the '546 patent was obvious when compared to the '441 patent.

[43] This view of Justice Nadon's reasons is confirmed by his agreement (at para. 78) with the following statement of the relevant law in *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2006 FC 1471, (2007), 54 C.P.R. (4th) 279. After rejecting the argument that the '546 patent for a compound was invalid for "same invention" double patenting because the '768 patent was in process-dependent form, the Judge in that case, Justice von Finkenstein, said (at paras**.** 101-102):

> As far as "obviousness" double patenting is concerned, the claims or disclosure must exhibit novelty or ingenuity in order for the second patent to be valid ….
>
> As the Court found that the [second] patent was a selection patent, by definition it is novel and unexpected. It thus cannot be invalid on the basis of "obviousness" double patenting.

[44] Thus, in my opinion, it cannot be said on the basis of *Pfizer* that this Court has decided that a patent for a compound is not invalid for "obviousness" double patenting on the ground that a patent in process-dependent form has been granted with respect to the same compound.

(iii) *Sanofi-Synthelabo*

[45] Finally, Bayer invokes the decision of the Supreme Court of Canada in *Sanofi-Synthelabo*, where the Court held that a selection patent must exhibit inventive ingenuity. The Court's discussion of the prohibition of double patenting (at paras. 94-110) was principally directed to the

"same invention" branch of the rule. However, the Court also briefly commented on "obviousness" double patenting in the context of selection patents. Thus, delivering the judgment of the Court, Justice Rothstein said (at para. 113):

> A selection patent that claims a compound that is patentably distinct from the genus patent will not be invalid for obviousness double patenting.

[46] Again, I do not see how this assists Bayer in the present case, where it cannot be said that the claims for the compound in the Application are patentably distinct or exhibit any ingenuity when compared to those in the process-dependent patent for the same compound.

[47] Having found that the Commissioner was correct to reject the Application for "obviousness" double patenting, I need not address the other arguments advanced by Bayer to support its appeal.

F. CONCLUSIONS

[48] A claim for a compound that is materially identical to the subject of a process-dependent claim exhibits no inventive ingenuity or novelty. Since the claim for the compound in Bayer's Application is not materially different from that in the process-dependent parent patent, the Application lacks novelty and inventive ingenuity.

[49] Consequently, the Commissioner correctly denied the Application on the ground of "obviousness" double patenting because the patent would have disclosed no new invention.

For her to have granted a patent for the compound would have improperly "evergreened" the parent patent, now expired, by creating a second monopoly in the use of the compound running from the date when the Application was approved.

[50] If *Mayne* decided otherwise, it is, in my respectful view, incorrect and should not be regarded as authority for the proposition that the prohibition of "obviousness" double patenting excludes claims for a compound that has also been the subject of a process-dependent patent.

[51] For all these reasons, I would dismiss Bayer's appeal with costs.

"John M. Evans"
J.A.

"I agree
Eleanor R. Dawson J.A."

"I agree
David Stratas J.A."

APPENDIX A

Patent Act, R.S., 1985, c. P-4 (as amended).

36.(1) A patent shall be granted for one invention only but in an action or other proceeding a patent shall not be deemed to be invalid by reason only that it has been granted for more than one invention.	36.(1) Un brevet ne peut être accordé que pour une seule invention, mais dans une instance ou autre procédure, un brevet ne peut être tenu pour invalide du seul fait qu'il a été accordé pour plus d'une invention.
40. Whenever the Commissioner is satisfied that an applicant is not by law entitled to be granted a patent, he shall refuse the application and, by registered letter addressed to the applicant or his registered agent, notify the applicant of the refusal and of the ground or reason therefore.	40. Chaque fois que le commissaire s'est assuré que le demandeur n'est pas fondé en droit à obtenir la concession d'un brevet, il rejette la demande et, par courrier recommandé adressé au demandeur ou à son agent enregistré, notifie à ce demandeur le rejet de la demande, ainsi que les motifs ou raisons du rejet.
41. Every person who has failed to obtain a patent by reason of a refusal of the Commissioner to grant it may, at any time within six months after notice as provided for in section 40 has been mailed, appeal from the decision of the commissioner to the Federal Court and that Court has exclusive jurisdiction to hear and determine the appeal.	41. Dans les six mois suivant la mise à la poste de l'avis, celui qui n'a pas réussi à obtenir un brevet en raison du refus ou de l'opposition du commissaire peut interjeter appel de la décision du commissaire à la Cour fédérale qui, à l'exclusion de toute autre juridiction, peut s'en saisir et en décider.
78.1 Applications for patents in Canada filed before October 1, 1989 shall be dealt with and disposed of in accordance with section 38.1 and with the provisions of this Act as they read immediately before October 1, 1989.	78.1 La présente loi dans sa version du 30 septembre 1989 s'applique aux demandes de brevet déposées jusqu'à cette date. Ces demandes sont également régies par l'article 38.1.

Patent Act (before October 1, 1989).

39.(1) In the case of inventions relating to naturally occurring substances prepared or produced by, or significantly derived from, microbiological processes and intended for food or medicine, the specification shall not include claims for the resulting food or medicine itself, except when prepared or produced by or significantly derived from the methods or processes of manufacture particularly described and claimed.	39.(1) Lorsqu'il s'agit d'inventions portant sur des substances que l'on trouve dans la nature, préparées ou produites, totalement ou pour une part notable, selon des procédés microbiologiques et destinées à l'alimentation ou à la médication, aucune revendication pour l'aliment ou le médicament ne peut être faite dans le mémoire descriptif, sauf pour celui ainsi préparé ou produit selon les modes du procédé de fabrication décrits en détail et revendiqués.
(1.1) Subsection (1) ceases to have effect four years after the coming into force of that subsection.	(1.1) Le paragraphe (1) cesse d'avoir effet quatre ans après son entrée en vigueur.

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-6-10

AN APPEAL FROM THE JUDGMENT OF THE HONOURABLE MR. JUSTICE BOIVIN, DATED DECEMBER 8, 2009, IN FEDERAL COURT, FILE NO.: T-1761-08

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