Federal Court of Appeal  Cour d'appel fédérale

Date: 20171207

Docket: A-51-17

Citation: 2017 FCA 241

CORAM: **STRATAS J.A.**
WOODS J.A.
LASKIN J.A.

BETWEEN:

ALEXION PHARMACEUTICALS INC.

Appellant

and

ATTORNEY GENERAL OF CANADA

Respondent

Heard at Toronto, Ontario, on November 1, 2017.

Judgment delivered at Ottawa, Ontario, on December 7, 2017.

REASONS FOR JUDGMENT BY: LASKIN J.A.

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

Federal Court of Appeal  Cour d'appel fédérale

Date: 20171207

Docket: A-51-17

Citation: 2017 FCA 241

CORAM: **STRATAS J.A.**
WOODS J.A.
LASKIN J.A.

BETWEEN:

ALEXION PHARMACEUTICALS INC.

Appellant

and

ATTORNEY GENERAL OF CANADA

Respondent

REASONS FOR JUDGMENT

LASKIN J.A.

I. Overview

[1] The appellant, Alexion Pharmaceuticals Inc., is a party to a proceeding before the Patented Medicine Prices Review Board relating to the pricing of its drug Soliris. Alexion wishes to challenge the constitutional validity of the provisions of the *Patent Act*, R.S.C. 1985, c. P-4, that give the Board the authority to make remedial orders where it finds that a patentee of an invention pertaining to a medicine is selling or has sold the medicine at a price the Board

determines is excessive. These include orders directing the patentee to reduce the price at which the medicine is sold in Canada, and to pay to Her Majesty in right of Canada an amount specified in the order. Alexion says that these provisions amount to a price control scheme that goes beyond the authority of Parliament under subsection 91(22) of the *Constitution Act, 1867* ("Patents of Invention and Discovery") and impermissibly intrudes on provincial authority under subsection 92(13) ("Property and Civil Rights in the Province").

[2] Rather than raising this issue before the Board, Alexion commenced an application for judicial review in the Federal Court, seeking a declaration of unconstitutionality and an order prohibiting the Board from proceeding.

[3] The Attorney General of Canada moved for an order summarily dismissing the application on the ground that it was bereft of any possibility of success. Prothonotary Aalto granted the motion, based on *stare decisis* (2016 FC 716). He recognized the high threshold for granting a motion to dismiss, but determined that this Court had decided the constitutional issue in *Canada (Attorney General) v. Sandoz Canada Inc.*, 2015 FCA 249, 390 D.L.R. (4th) 691, and that the *Sandoz* decision was binding authority against Alexion's constitutional argument in the application. Alexion's appeal to the Federal Court was dismissed (2017 FC 22): Justice Simpson agreed that *Sandoz* decided the constitutional issue and was binding authority, and there was no basis to revisit it. Neither on the motion nor on the appeal did either the Attorney General or the Federal Court raise the propriety of Alexion bringing the constitutional issue directly to the Federal Court without first raising it before the Board.

[4] Alexion now appeals to this Court. It argues that this Court did not decide in *Sandoz* the constitutional issue that it raises, and that any comments this Court made on the issue in that case were merely non-binding *obiter*. It also asserts that its application, in contrast to the proceedings that culminated in the *Sandoz* decision, is supported by a fully developed factual record, and that the Federal Court would and should have the benefit of that record in deciding the constitutional issue.

[5] I would dismiss the appeal. In my view it was incumbent on Alexion to raise the constitutional issue first before the Board. Having failed to do so it was not entitled to bring the issue before the Federal Court. In any event, the Federal Court was correct in concluding that this Court's decision in *Sandoz* represents a binding determination of the issue.

II. The proceeding before the Board

[6] Alexion sells in Canada the breakthrough drug Soliris, which is indicated for the treatment of two life-threatening disorders.

[7] In January 2015, staff of the Board filed a statement of allegations alleging that the price of Soliris was excessive between 2012 and 2014, and seeking an order from the Board requiring Alexion, among other things, to reduce the price of Soliris and pay some $5.6 million to offset cumulative excess revenues.

[8] Following the Board's issuance of a notice of hearing and a lengthy series of interlocutory motions, a 20-day hearing was held from January to April 2017 to determine

whether Alexion is selling or has sold Soliris at an excessive price and, if so, what orders should be made.

[9] In September 2015, after the notice of hearing was issued but before the hearing began before the Board, Alexion commenced in the Federal Court the application for judicial review that is the subject of this appeal.

[10] The Board released its decision on the merits in September 2017, after the decisions of the Federal Court and not long before this appeal was argued. The Board found that the price of Soliris was and is excessive. It ordered Alexion to reduce the price and to pay to Her Majesty in right of Canada an amount approved by the Board, to be calculated by Board staff and Alexion in accordance with parameters set by the Board. The Board's decision is now the subject of a separate application for judicial review in the Federal Court.

III. The constitutional issue

[11] In its application for judicial review that has led to this appeal, Alexion sought a declaration against the Attorney General and a writ of prohibition prohibiting the Board from proceeding with the hearing or making any order concerning the price at which Alexion is selling or has sold Soliris in any market in Canada.

[12] The declaratory judgment Alexion sought related to sections 83 to 86 of the *Patent Act*, and the words "in any proceeding under section 83" in subsection 87(1) of the Act. Alexion's

notice of application asked for a declaration that these provisions are *ultra vires* the Parliament of Canada

> in that the price regulation scheme created by the impugned provisions exceeds the powers granted to Parliament under s. 91(22), or other federal power, of the *Constitution Act, 1867* and improperly intrudes into provincial jurisdiction over property and civil rights in the province under s. 92(1) of the *Constitution Act, 1867*.

[13] Alexion did not raise this constitutional issue before the Board.

[14] In support of its application Alexion filed two affidavits and an "Applicant's Legislative History Brief." One of the affidavits was sworn by Lionel Bently, the Herchel Smith Professor of Intellectual Property Law at the Faculty of Law of the University of Cambridge in England. As he described it, the subject of his affidavit was "the purpose and effect of patent schemes and the relationships, if any, between patent regulation and price controls on patented products, particularly in the area of pharmaceutical products." The other affidavit was sworn by Dr. Jonathan D. Putnam, an expert in international economics as applied to intellectual property. He provided what counsel for Alexion described as an "economic analysis […] directed to the purpose and effect of the impugned provisions within the administrative framework of the Patent Act."

[15] The Legislative History Brief included an opinion prepared for the Canadian Drug Manufacturers Association in 1992 by the Honourable James C. MacPherson, then Dean of Osgoode Hall Law School and now a Justice of the Court of Appeal for Ontario. The opinion

concluded that if the provisions now challenged were enacted, their constitutionality would be "a serious question."

IV. The challenged provisions

[16] The provisions whose constitutionality Alexion challenged in its application for judicial review were added to the Act in 1993 (*Patent Act Amendment Act, 1992*, S.C. 1993, c. 2, s. 7) and appear under the heading "Excessive Prices." They follow provisions of the Act that empower the Board to require a patentee of a medicine to provide it with information so that it can investigate the price at which the medicine is being or has been sold.

[17] Section 83 authorizes the Board, where it finds that the patentee is selling the medicine in any market in Canada at a price that in the Board's opinion is excessive, to make an order directing the patentee to cause the price to be reduced. Where the Board finds that the patentee has sold the medicine at a price the Board considers was excessive, the Board may make an order directing the patentee to take one or more measures that will offset the amount of the excess revenue that the patentee derived – to reduce the price of the medicine, to reduce the price of another medicine to which a patented invention of the patentee pertains, or to pay to her Majesty in right of Canada an amount specified in the order. The Board may also require a former patentee to take one or both of the latter two measures. Where the Board is of the opinion that the patentee or former patentee has engaged in a policy of selling the medicine at an excessive price, the Board may order that the patentee or former patentee take one or more measures that will offset up to twice the excess revenues. No order may be made under section 83 without first providing the patentee or former patentee a hearing.

[18] Sections 84 to 86 of the Act set a time limit for compliance with any order, specify factors that the Board is to consider in determining whether a price is excessive, and regulate certain aspects of the hearing. Subsection 87(1) includes the words "in any proceeding under section 83" in providing that certain information and documents provided to the Board are privileged and shall not be disclosed.

V. The predecessor legislation

[19] From 1923 until the coming into force of the 1993 amendments, the Act contained provisions authorizing compulsory licensing of drug patents. Beginning in 1987, the Act also included provisions empowering the Board to monitor drug prices and grant remedies if it concluded that prices were excessive. A helpful summary of these provisions and their evolution can be found in this Court's decision in *ICN Pharmaceuticals, Inc. v. Canada (Staff of the Patented Medicine Prices Review Board)*, [1997] 1 F.C. 32 at paras. 3-12, 68 C.P.R. (3d) 417 at pp. 423-425; see also *Manitoba Society of Seniors Inc. v. Canada (Attorney General)* (1991), 77 D.L.R. (4th) 485 at pp. 487-489, 35 C.P.R. (3d) 66 (Man. Q.B.), affirmed (1992), 96 D.L.R. (4th) 606, 45 C.P.R. (3d) 194 (Man. C.A.).

[20] The Act as it stood in the period from 1987 until the enactment of the 1993 amendments continued to provide for compulsory licensing of patents applicable to medicines, but gave patentees a period of exclusivity by prohibiting licensees from exercising rights obtained under a compulsory licence for periods varying from seven to ten years. To address concerns that prices during the exclusivity period might be unacceptably high from the consumer's perspective, the legislation provided for the establishment of the Board to monitor and review patented drug

prices. If the Board concluded that a medicine was being sold at an excessive price, it could put an end to the exclusivity by lifting the prohibition on licensees. It could also lift the prohibition on licensees of one other patent, or direct the patentee to reduce the price of the medicine. The 1993 amendments abolished compulsory licensing and gave the Board its current suite of powers.

VI. Challenge to the predecessor legislation

[21] The 1987 amendments were the target of constitutional attack in *Manitoba Society of Seniors*, above. The attack was based on grounds very similar to those that Alexion now seeks to advance – that the amendments established what was in pith and substance a scheme of price regulation, and therefore exceeded federal authority in relation to patents and intruded on provincial jurisdiction in relation to property and civil rights.

[22] The Manitoba Court of Queen's Bench rejected this argument. It noted (at p. 489) that the regulatory scheme administered by the Board had been put in place because of "legitimate concerns […] that, from the consumer's standpoint, prices might escalate to unacceptable levels during the exclusivity period." It concluded (at p. 492) that the amendments were in pith and substance patent legislation:

> As the legislation reestablishes exclusivity for patented medicines to an extent not enjoyed since 1931, Parliament also provided for a mechanism to deal with price abuse that may incidentally occur as a result of these monopolies it created.

[23] The Manitoba Court of Appeal affirmed the decision of the Queen's Bench. In concise reasons, it agreed that the amendments were in pith and substance patent legislation.

VII. This Court's decision in *Sandoz*

[24] This Court's decision in *Sandoz* arose from proceedings before the Board involving two drug companies, Sandoz and ratiopharm. Both were selling generic versions of patented medicines under arrangements that gave them no ownership rights in the patents. The Board had made an order directing ratiopharm to pay some $65.9 million to offset excess revenues. The proceeding against Sandoz was at an earlier stage: the Board had ordered Sandoz to provide it with pricing information.

[25] The companies argued before the Board that they were not "patentees" within the meaning of subsection 79(1) of the Act, and were therefore not subject to the Board's jurisdiction. Subsection 79(1) defines a "patentee" for the purposes of sections 79 to 103; the definition includes, in addition to the person for the time being "entitled to the benefit of the patent" for an invention pertaining to a medicine, any other person who "is entitled to exercise any rights in relation to that patent other than under a licence continued by subsection 11(1) of the *Patent Act Amendment Act, 1992*."

[26] The companies also argued before the Board that sections 79 to 103 of the Act exceeded federal constitutional authority in relation to patents. Sandoz qualified this position with the proviso that the legislation was unconstitutional "at least insofar as generic pharmaceutical products are concerned" (*Sandoz*, above, at para. 110 [emphasis in original]). When the Board rejected these arguments, the companies sought judicial review in the Federal Court.

[27] The Federal Court allowed the companies' applications, concluding that the companies were not "patentees" within the meaning of subsection 79(1) (*Sandoz Canada Inc v. Canada (Attorney General)*, 2014 FC 501; *Ratiopharm Inc. v. Canada (Attorney General)*, 2014 FC 502). It went on nevertheless to consider the constitutional issue. It saw the 1993 amendments as enhancing the Board's remedial powers, rather than altering the purpose of the legislation. It did not accept the argument that the 1993 amendments provided a basis for departing from the conclusion reached in *Manitoba Society of Seniors*, and held the provisions to be a constitutional exercise of Parliament's authority in relation to patents.

[28] The Attorney General appealed both judgments to this Court; the two appeals were heard together.

[29] At the outset of the hearing of the current appeal, counsel for Alexion sought to file a "Brief of Materials from Sandoz/ratiopharm (now Teva Canada Limited) Appeal," comprising copies of the notices of constitutional question filed in this Court in *Sandoz*, together with the responses of the Attorney General and the replies to those responses. Counsel for the Attorney General objected to its filing on the basis that it did not represent a complete picture of what was before the Court in *Sandoz* and would be of little if any assistance to the Court. The Court ruled that the material could be filed for whatever assistance it might provide; it is open to the Court to take judicial notice of the contents of its own records (*Canada v. Olumide*, 2017 FCA 42 at para. 11; *Craven v. Smith* (1869), L.R. 4 Ex. 146). I will return later in these reasons to the question of what was before the Court in *Sandoz*.

[30] As this Court noted in *Sandoz* (at para. 110), and as the "Brief" confirms, the notices of constitutional question filed by Sandoz and ratiopharm in this Court encompassed sections 79 to 103 of the Act, and reiterated the position that these provisions amounted to "an unconstitutional extension of Parliament's authority over patents, at least insofar as generic pharmaceutical products are concerned." The notices also recognized that the constitutional issue would become a live one if this Court concluded that Sandoz and ratiopharm were "patentees." Sandoz and ratiopharm took the position that the constitutional issue should in that event be remitted to the Federal Court for determination, but both they and the Attorney General put forward considerable argument on the merits of the issue.

[31] This Court saw the "central issue" in the *Sandoz* appeals as whether the Federal Court properly set aside the Board's conclusion that Sandoz and ratiopharm were "patentees" within the meaning of subsection 79(1) even though they were not patent owners (at para. 2), and devoted most of its reasons to this issue. But it also appreciated that if the answer to this question was in the negative, the constitutional validity of subsection 79(1) would require determination (at para. 54).

[32] The Court did indeed answer the interpretive question in the negative: it concluded that the Board's determination that Sandoz and ratiopharm were "patentees" within the meaning of the definition in subsection 79(1) was reasonable, and that there was no basis to interfere with it.

[33] The Court then turned to the constitutional question. The Court's approach to the question was first to consider whether sections 79 to 103 of the Act were constitutionally valid as

they related to patent holders or owners, and then to consider whether the application of the scheme to non-patent holders and owners rendered it unconstitutional.

[34] In addressing the first point, the Court rejected (at para. 115) the contention by Sandoz and ratiopharm that the Board's power under the 1987 amendments to lift the exclusivity provided to the patent owner if it found the price to be excessive was at the heart of the decision in *Manitoba Society of Seniors*, so that the removal of this power in the 1993 amendments rendered the provisions unconstitutional. The Court stated that from a constitutional perspective, the amendment removing the power to lift patent exclusivity was of no consequence; price control remained, as it was when *Manitoba Society of Seniors* was decided, an integral part of the scheme.

[35] The Court went on (at para. 116) to confirm the constitutionality of the scheme as applied to patent holders and owners:

> In my view, the Federal Court judge and the Board before him correctly held that the control of prices charged for patented medicines comes within the jurisdiction conferred on Parliament over patents under subsection 91(22) of the *Constitution Act 1867* when applied to a patent holder or owner.

It noted that Sandoz and ratiopharm had in effect accepted this proposition in submitting that the Federal Court's interpretation of "patentee" (which they had defended on appeal) maintained the necessary connection to the federal head of power.

[36] The Court then turned (at para. 117) to the "remaining question" – "whether this price control scheme [retained] its constitutional validity when applied to non-patent owners or holders." The Court held that it did.

[37] Based on the definition of "patentee" as it stood when *Manitoba Society of Seniors* was decided, the Court saw the decisions in that case as sanctioning the validity of the scheme as it applied to non-patent holders (at para. 119). It also saw no basis for the argument that "the connection with the patent ceases to be sufficient to meet the constitutional imperative when the person targeted holds a licence to sell a patented medicine without holding the patent" (at para. 121). It explained that "the harm which the Act seeks to prevent arises by reason of the existence of the patent pertaining to the medicine being sold […], with the result that nothing turns on the fact that the person exercising the selling rights does not hold the patent itself" (at para. 121).

[38] The Court expressed its conclusion as follows: "I therefore conclude that the Board correctly held that including persons who exercise selling rights under a patent within the ambit of subsection 79(1) does not bring that provision outside the scope of subsection 91(22) of the *Constitution Act* [*1867*]" (at para. 122).

[39] Sandoz and ratiopharm filed a motion for leave to appeal to the Supreme Court of Canada. However, the motion was discontinued as part of a settlement.

VIII. The Attorney General's motion to dismiss Alexion's application for judicial review

[40] The Attorney General moved in the Federal Court for an order summarily dismissing Alexion's application. The basis for the motion was that the application was bereft of any possibility of success because this Court had recently considered and rejected, in *Sandoz*, the same constitutional arguments.

[41] The prothonotary granted the motion. He recognized the high burden on a party who brings a motion to strike, but found this Court's decision in *Sandoz* sufficient to dispose of the motion: "[t]he conclusion of that Court is definitive and […] the doctrine of *stare decisis* applies" (2016 FC 716 at para. 44).

[42] The Federal Court judge dismissed Alexion's appeal. She described the "sole issue [as] whether the Prothonotary was correct when he struck out the [application] as being bereft of any possibility of success because the *Sandoz* decision is binding authority" (2017 FC 22 at para. 18). She concluded that *Sandoz* was binding authority, and that the prothonotary was correct.

[43] As noted above, neither the prothonotary nor the Federal Court judge adverted to the possibility of declining to hear the application on the basis that it was inappropriate for Alexion to bypass the Board and raise its constitutional challenge for the first time in the Federal Court. The Attorney General did not raise this issue either. This is particularly surprising when another application by Alexion for judicial review in relation to the proceeding before the Board, based in part on constitutional grounds, was struck out by the Federal Court as premature (*Alexion Pharmaceuticals Inc. v. Canada (Attorney General)*, 2017 FC 21).

IX. Alexion's appeal to this Court

[44] Alexion's appeal is narrowly framed. In paragraph 29 of its memorandum it states that "[t]he sole issue before this Court is whether Justice Simpson correctly concluded that the *Sandoz* decision was 'binding authority' disposing of the constitutional issues raised by Alexion in the Application." It reiterated this position in opening its oral argument. In oral argument it also accepted that its appeal would fail if the Court were to conclude that the determination by this Court in *Sandoz* that the price control scheme is valid as it applies to patent owners and holders was essential to the Court's decision.

[45] At no point in its response to the Attorney General's motion did Alexion advance the potential alternative argument that even if the *Sandoz* decision would be dispositive if not overruled, this Court should depart from it based on the criteria set out in *Miller v. Canada (Attorney General)*, 2002 FCA 370 at paras. 8-10, 220 D.L.R. (4th) 149. Nor did it argue in the alternative that since this Court's decision in *Sandoz* would not of course bind the Supreme Court of Canada, Alexion should be permitted in the exercise of the court's discretion to develop a record for possible consideration by the Supreme Court, and to try to persuade this Court to characterize the decision in *Sandoz* as legally problematic (see *Canada (Attorney General) v. Bedford*, 2013 SCC 72 at paras. 41-45, [2013] 3 S.C.R. 1101; *Canada v. Craig*, 2012 SCC 43 at paras. 18-22, [2012] 2 S.C.R. 489; *R. v. Déry*, 2017 CMAC 2 at paras. 31-32 per Cournoyer and Gleason JJ.A.).

[46] I will therefore not comment on the viability of other potentially available arguments, but will address only (1) the issue as Alexion has framed it – whether *Sandoz* is binding authority –

and (2) the question, raised by this Court of its own motion in oral argument, whether Alexion was entitled to bypass the Board and bring its constitutional challenge directly to the Federal Court on judicial review. I will start with the latter issue.

X. Was it appropriate to bypass the Board?

[47] The normal rule is that parties to an administrative proceeding may proceed to the court system only after all adequate remedial recourses in the administrative process have been exhausted. This means that, ordinarily, a party to an administrative proceeding must put to the administrative decision-maker all arguments that it has the jurisdiction to hear, and must obtain its decision, before launching an application for judicial review (*Canada (Border Services Agency) v. C.B. Powell Limited*, 2010 FCA 61 at paras. 30-31, [2011] 2 F.C.R. 332; *Halifax (Regional Municipality) v. Nova Scotia (Human Rights Commission)*, 2012 SCC 10 at paras. 35-37, [2012] 1 S.C.R. 364).

[48] The rule applies to constitutional issues as it does to any other. If the administrative decision-maker has jurisdiction to hear constitutional arguments, those arguments should be made in the first instance to it (*Okwuobi v. Lester B. Pearson School Board; Casimir v. Quebec (Attorney General); Zorrilla v. Quebec (Attorney General)*, 2005 SCC 16 at paras. 38-55, [2005] 1 S.C.R. 257). An administrative decision-maker has jurisdiction to hear constitutional arguments when it has power to decide questions of law (*Nova Scotia (Workers' Compensation Board) v. Martin*, 2003 SCC 54, [2003] 2 S.C.R. 504). As this Court recognized in *Sandoz* (at paras. 57-64), the Board here has the power to decide legal questions. It did so, for example, in determining the statutory interpretation and constitutional issues at first instance in *Sandoz* and in

determining the scope of its authority under the Act in a manner approved by the Supreme Court in *Celgene Corp. v. Canada (Attorney General)*, 2011 SCC 1, [2011] 1 S.C.R. 3.

[49] Many of the good reasons that animate this rule and show it to be in the public interest are summarized in *C.B. Powell*, above at para. 32. Among them is avoidance of multiplicity of proceedings, avoidance of the waste associated with interlocutory judicial review applications when the applicant for judicial review may succeed at the end of the administrative process anyway, ensuring that the court has the benefit of the administrative decision-maker's findings, and judicial respect for the legislative decision to invest administrative agencies with decision-making authority. Where the issue is a constitutional issue, proceeding first to court also risks depriving the court of the views of the administrative decision-maker based on "its factual appreciations, insights gleaned from specializing over many years in the myriad complex cases it has considered, and any relevant policy understandings" (*Forest Ethics Advocacy Association v. Canada (National Energy Board)*, 2014 FCA 245 at paras. 42, 45, [2015] 4 F.C.R. 75). The strength of the rule and its underlying rationales is reflected both in its regular invocation as a basis for a motion to strike (*Wilson v. Atomic Energy of Canada Limited*, 2015 FCA 17 at paras. 32-33, [2015] 4 F.C.R. 467) and the court's entitlement to raise the rule on its own motion (*Forest Ethics*, above at para. 22).

[50] Exceptions to the rule are rare; they include urgency (*Okwuobi*, above at para. 50) and truly exceptional circumstances (*C.B. Powell*, above at para. 33). Many of these exceptional circumstances reflect those where prohibition lies (*Forner v. Professional Institute of the Public Service of Canada*, 2016 FCA 35 at para. 15).

[51] In this case this Court raised the rule of its own motion. Alexion argued in response that it would have been pointless to raise the constitutional issue before the Board given its decisions in *Sandoz*. It also argued that the Board's inability to grant a declaration of invalidity – in contrast to the ability of a court – was a proper reason to bypass the Board.

[52] In my view neither of these reasons justifies an exception to the rule. The Board panel seized of the current proceeding is differently composed than the panel that dealt with the challenges by Sandoz and ratiopharm. It might well have had further insights to offer. The Supreme Court has confirmed that the power of an administrative decision-maker to disregard a provision it finds inconsistent with the Constitution is an adequate remedy at the administrative level and is not a sufficient reason to bypass its jurisdiction (*Okwuobi*, above at paras. 44-45).

[53] In addition, while Alexion's notice of application included a request for prohibition, it is very doubtful that prohibition would have been granted. The Supreme Court, citing *C.B. Powell* among other authorities, has called on courts to show restraint in granting prohibition that "short-circuits" the decision-making role of a tribunal (*Halifax (Regional Municipality) v. Nova Scotia (Human Rights Commission)*, above at paras. 35-37). This Court's decision in *C.B. Powell* (at para. 33) makes it clear that the assertion of a constitutional argument, without more, does not constitute an urgent or exceptional circumstance warranting immediate recourse to courts, bypassing the administrative decision-maker.

[54] Although the Attorney General could have objected to Alexion proceeding on the constitutional issue directly in the Federal Court, no objection was made. In the hearing before

us, counsel for the Attorney General explained that there was no objection because they considered their position on the merits of the constitutional challenge to be a strong one. The Federal Court did not raise the objection on its own motion. In similar circumstances in the future, it would be desirable if the objection were raised by the respondent or, if need be, by the court on its own motion so that the court can consider at the first opportunity whether the rule and the judicial policies that underlie it are engaged.

[55] In my view, this proceeding fully engages the rule and these policies. Several practical and legal reasons favour the Board hearing and deciding the constitutional issue at first instance. Among other things, this proceeding has resulted in a multiplicity of proceedings – one for the constitutional issue and a separate judicial review application now in the Federal Court challenging the Board's decision on the merits. In bypassing the Board, the application has undermined its position as the first-instance forum for decisions of fact and of law within its mandate, and deprived the reviewing court of the Board's insights on the purpose and operation of the challenged provisions.

[56] It is not too late to give effect to the rule. On my own motion, I would apply it and dismiss the appeal on this ground alone.

[57] Since the appeal was fully argued on its merits, and in the interest of judicial economy, I will nonetheless proceed to consider the issue as framed by Alexion. As it turns out, whatever further insights the Board might have had on the matter, this Court's decision in *Sandoz* is dispositive of the constitutional issue.

XI. Is the *Sandoz* decision binding authority?

A. *Standard of review*

[58] The scope and application of the doctrine of *stare decisis* is a question of law (*Apotex Inc. v. Pfizer Canada Inc*., 2014 FCA 250 at para. 62, 465 N.R. 306, leave to appeal refused, 2015 CanLII 20821). It follows that the prothonotary's determination of this question was, and the Federal Court judge's decision is, subject to review on the correctness standard (*Hospira Healthcare Corporation v. Kennedy Institute of Rheumatology*, 2016 FCA 215 at paras. 66, 69, 72, 79, 83, [2017] 1 F.C.R. 331).

B. *What* Sandoz *decided*

[59] The extent to which a decision of this Court is binding under the doctrine of *stare decisis* depends on what the Court actually decided (*R. v. Henry*, 2005 SCC 76 at paras. 53-57, [2005] 3 S.C.R. 609). At the very least, an appellate judgment will stand as authority for its own *ratio decidendi*, or the "reasoning that was necessary for the court to reach a result on the issues that were presented to it for a decision" (*Apotex Inc. v. Pfizer Canada Inc*., above at para. 114). In my view the Federal Court judge was correct in concluding that the Court actually decided in *Sandoz* that the provisions of the Act Alexion now seeks to challenge were validly enacted by Parliament.

[60] The provisions that this Court considered in *Sandoz* were sections 79 to 103. The provisions that Alexion seeks to attack are a subset of these provisions. Once the Court held in *Sandoz* that as a matter of statutory interpretation the scheme applied to non-patent holders and

owners, it had to address the constitutional issue raised by Sandoz and ratiopharm – whether in its application to non-patent holders and owners the scheme was constitutional. As explained above in my review of the Court's decision, the approach it took to that question was first to consider the constitutionality of the scheme as it applied to patent holders and owners, and then to consider the constitutionality of applying the scheme to non-patent holders and owners.

[61] The Court could not have been more explicit in deciding on the first issue that the scheme was constitutional. As set out above, it expressed its conclusion as follows (at para. 116):

> In my view, the Federal Court judge and the Board before him correctly held that the control of prices charged for patented medicines comes within the jurisdiction conferred on Parliament over patents under subsection 91(22) of the *Constitution Act 1867* when applied to a patent holder or owner.

[62] It then proceeded to the "remaining question" – "whether this price control scheme retains its constitutional validity when applied to non-patent owners or holders" [emphasis added] (at para. 117). This question too it answered in the affirmative, stating among other things that "there is no basis for the argument that the connection with the patent ceases to be sufficient to meet the constitutional imperative when the person targeted holds a licence to sell a patented medicine without holding the patent" [emphasis added] (at para. 121).

[63] It is thus apparent, in my view, that the Court "actually decide[d]" in *Sandoz* that the price control scheme as a whole is constitutional. Its determination of that question was essential to its decision of the appeal. To use the distinction drawn by the Supreme Court in *Henry*, above (at para. 57), its conclusion on the constitutional issue was an element of the "dispositive *ratio decidendi*" rather than merely part of the "wider circle of analysis."

C. *Alexion's further arguments*

[64] In its written and oral submissions, Alexion put forward a series of related arguments that in my view do not detract from this conclusion. I will deal with the principal arguments in turn.

(1) Extent of the constitutional analysis

[65] First, Alexion argued that the Court in *Sandoz* did not conduct a "full" pith and substance or ancillary doctrine analysis. A pith and substance analysis calls on the court to consider both the purpose and the effect of legislation to determine the head of power within which it falls (*Kitkatla Band v. British Columbia (Minister of Small Business, Tourism and Culture)*, 2002 SCC 31 at paras. 52-53, [2002] 2 S.C.R. 146). An ancillary doctrine analysis examines whether legislative provisions that might otherwise be beyond the powers of the enacting legislature are constitutional because they are sufficiently integrated with a valid legislative scheme (*Reference re Assisted Human Reproduction Act*, 2010 SCC 61 at para. 126, [2010] 3 S.C.R. 457).

[66] There is no doubt that this Court addressed pith and substance in the *Sandoz* decision (at paras. 115-121). While it relied on the analysis in *Manitoba Society of Seniors*, its reliance on relevant precedent was hardly unusual. It also specifically dealt with (at paras. 114-115) the arguments made to it based on the ancillary doctrine, and agreed with the Board and the Federal Court that price control is an integral part of the statutory scheme. That the Court considered it unnecessary to address these matters at length does not mean that its analysis was other than "full." The "fullness" of a court's analysis is in any event not a determinant of what it decided.

[67] In the same vein, Alexion also submitted that this Court did not address in *Sandoz* the case law concerning the limits on federal authority to regulate prices absent an emergency, to which Professor Hogg refers in his leading text on constitutional law (Peter Hogg, *Constitutional Law of Canada* (Toronto: Carswell, 2007) (loose-leaf revision 2015-1), at pp. 15-47, 17-22, 17-25, 21-9, 21-10). But whether or not the Court referred specifically to Professor Hogg's text or all of the potentially applicable case law cited there, the Court plainly recognized (at para. 113) that Sandoz and ratiopharm were arguing that "the scheme is no longer directed at patents but at the pricing of medicine and therefore intrudes upon the provinces' jurisdiction over property and civil rights." The Court simply disagreed.

(2) Confiscatory nature of the scheme

[68] Second, Alexion argued that the Court in *Sandoz* did not consider or address the confiscatory nature of the price control scheme, as reflected in the authority section 83 gives the Board to require payment to Her Majesty in right of Canada. But the Court in *Sandoz* specifically referred (at paras. 55 and 123) to the Board's order that ratiopharm pay some $65.9 million to offset excess revenues. The Court was plainly aware of the powers that Parliament gave the Board. It cannot be said that it overlooked any of those powers in deciding the constitutionality of the statutory scheme.

(3) Concession on the constitutional issue

[69] Third, Alexion argued that the constitutionality of the statutory scheme as applied to patent owners and holders was largely conceded before this Court in *Sandoz*, so that the issue

was never truly decided. It relied in particular on the second sentence in paragraph 116 of the Court's reasons (the first sentence of which has been quoted above):

> In my view, the Federal Court judge and the Board before him correctly held that the control of prices charged for patented medicines comes within the jurisdiction conferred on Parliament over patents under subsection 91(22) of the *Constitution Act 1867* when applied to a patent holder or owner. The respondents recognize as much when they state that the Federal Court judge's interpretation of "patentee" maintained the connection to the federal head of power, such that the reasoning in *Manitoba Society* remained intact (respondents' respective replies to the response by the Attorney General of Canada to the Notice of Constitutional Question (respondents' replies) at para. 46).

[70] The arguments put before the Court in *Sandoz* appear to have been nuanced in a number of respects. Among other things, the position of Sandoz and ratiopharm (referred to at para. 110) that the scheme was unconstitutional "at least insofar as generic pharmaceutical products are concerned" posed some challenges both for them and for the Court: as the Court pointed out (at para. 111), Sandoz and ratiopharm seemed to appreciate that "their argument, if accepted, could result in the entire scheme devised by Parliament being struck down."

[71] But these nuances did not determine the scope of this Court's decision. As already mentioned, the Court considered that to address the arguments of Sandoz and ratiopharm that the scheme was invalid as applied to non-patent owners and holders, it first had to address its validity as applied to patent owners and holders. It proceeded to do so. It decided that the scheme was constitutional as it applied to both patent owners and holders and non-patent owners and holders. There is no basis, in my view, to conclude that the validity of the scheme was not decided.

(4) Differences in the record

[72] Finally, Alexion argued that differences between the record before the Court in *Sandoz* and the record that it marshalled in this case required the conclusion that the *Sandoz* decision was not binding. It relied for this proposition on the decision of this Court in *LJP Sales Agency Inc. v. Canada (National Revenue)*, 2007 FCA 114, [2007] 3 C.T.C. 123. There, the Court dismissed an appeal from the decision of a Federal Court judge upholding the striking out of an application for judicial review as bereft of any possibility of success in light of a binding decision on point. In doing so it stated (at para. 8):

> First, the Minister's motion to strike was not inappropriate, even though, as this Court held in *David Bull Laboratories (Canada) Inc. v. Pharmacia Inc.* […], motions to strike applications for judicial review should only be brought in exceptional circumstances because of the summary nature of the proceedings. However, the presence of an authority which is directly contrary to the position on which an application is based can be such an exceptional circumstance, when no further development of the factual record is required.

[73] Alexion submitted that this is a case in which "further development of the factual record is required." In paragraph 35 of its memorandum of fact and law, Alexion went so far as to submit that in *Sandoz* "[t]here was no factual record underlying the constitutional challenge" [emphasis added]. In oral argument it acknowledged that there was a factual record in *Sandoz*, but when pressed on the differences between that record and the record here it could not specify them. However, it emphasized the particular importance in the current case of the evidence of Professor Bently, Dr. Putnam and then-Dean MacPherson. But as oral argument proceeded, it became common ground that the record before this Court in *Sandoz* included both an affidavit of Dr. Putnam and the opinion of then-Dean MacPherson. A cursory review of the affidavit of Dr. Putnam filed in *Sandoz* indicates strong similarities to his affidavit filed in this case.

[74] Even if a comparison between the record in this case and the record in *Sandoz* was relevant in determining whether *Sandoz* is binding, it would in my view be necessary before the Court could consider this factor for the parties to provide a much more definitive comparison than that with which we were provided here. It is not for the Court to sift through the record in past cases to assess the relative completeness of the evidence underlying a decision that on its face is binding. In any event, it appears to me that the availability of new or never-before-considered evidence has greater relevance in considering a request by a party to develop a record of the kind referred to in *Bedford*, above. No request of that nature was made here.

Disposition

[75] For these reasons, I would dismiss the appeal. In accordance with the parties' agreement, I would order that Alexion pay costs to the Attorney General in the amount of $5,000.00, all-inclusive.

"J.B. Laskin"
J.A.

"I agree.
David Stratas J.A."

"I agree.
J. Woods J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-51-17
APPEAL FROM AN ORDER OF THE HONOURABLE MADAM JUSTICE SIMPSON OF THE FEDERAL COURT DATED DECEMBER 28, 2016 IN DOCKET NO. T-1537-15.	
STYLE OF CAUSE:	ALEXION PHARMACEUTICALS INC. v. ATTORNEY GENERAL OF CANADA
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	NOVEMBER 1, 2017
REASONS FOR JUDGMENT BY:	LASKIN J.A.
CONCURRED IN BY:	STRATAS J.A. WOODS J.A.
DATED:	DECEMBER 7, 2017

APPEARANCES:

Malcolm N. Ruby David T. Woodfield Adam Bazak	FOR THE APPELLANT
Joseph Cheng Jon Bricker	FOR THE RESPONDENT

SOLICITORS OF RECORD:

Gowling WLG (Canada) LLP Barristers and Solicitors Toronto, Ontario	FOR THE APPELLANT
Nathalie G. Drouin Deputy Attorney General of Canada	FOR THE RESPONDENT