Federal Court  Cour fédérale

**Date: 20140527**

**Docket: T-1616-12**

**Citation: 2014 FC 501**

**Ottawa, Ontario, May 27, 2014**

**PRESENT: The Honourable Mr. Justice O'Reilly**

**BETWEEN:**

**SANDOZ CANADA INC.**

**Applicant**

**and**

**ATTORNEY GENERAL OF CANADA**

**Respondent**

## JUDGMENT AND REASONS

## I. Overview

[1] Sandoz Canada Inc manufactures generic pharmaceuticals. In 2012, the Patented Medicines Prices Review Board concluded that Sandoz came within the definition of a "patentee" under the *Patent Act*, RSC 1985, c P-4 (see Annex) and, therefore, was subject to the Board's oversight in respect of patented medicines. Accordingly, the Board found that Sandoz was obliged to comply with the obligations under the Act and Regulations to file

information that would enable the Board to conclude whether Sandoz was charging excessive prices for its medicines. The Board was established in 1987, but it was not until 2008 that it sought to extend its jurisdiction to generic companies.

[2] Sandoz argues that the Board has no jurisdiction over it because it is not a "patentee". In addition, Sandoz submits that if it falls under the jurisdiction of the Board pursuant to the *Patent Act*, then the relevant provisions of that Act are unconstitutional as they encroach on provincial jurisdiction over Property and Civil Rights under s 92(13) of the *Constitution Act, 1867*, and are beyond federal jurisdiction over patents.

[3] In my view, taking into account the federal/provincial division of powers, and interpreting the scope of the Act accordingly, Sandoz is not a "patentee". Therefore, the Board has no power to order Sandoz to comply with the Act and Regulations, and I must allow this application for judicial review of the Board's decision.

[4] There are three issues:

1. What is the standard of review applicable to the Board?

2. Was the Board's conclusion that Sandoz is a "patentee" unreasonable?

3. Is the legislation unconstitutional?

[5] Before the Board, there was an additional issue about whether the patents in question pertain to medicines sold by Sandoz in Canada. Given my conclusion that Sandoz is not a patentee, and that the Board has no jurisdiction in this case, it is unnecessary to address that question.

## II. The Board's Decision

[6] The Board characterized the case as being primarily about statutory interpretation. It referred to s 2 of the *Patent Act*, which states that a "patentee" is a person who "for the time being [is] entitled to the benefit of a patent". It also cited s 79(1), included in the part of the Act dealing with patented medicines, which expand on the definition in s 2, providing that a patentee "includes, where any other person is entitled to exercise any rights in relation to that patent . . . that other person in respect of those rights".

[7] The Board described its purpose – to ensure that monopoly rights granted to patent holders do not result in excessive prices for medicines sold to Canadian consumers. In this sense, the Board has a consumer protection mandate (citing *ICN Pharmaceuticals Inc v Canada (PMPRB)*, [1997] 1 FC 32 (FCA), and *Celgene Corp v Canada (Attorney General)*, 2011 SCC 1 at para 25).

[8] The Board was aware of Sandoz's corporate relationships. Sandoz is a wholly-owned subsidiary of Novartis Canada Inc, which is itself a subsidiary of Novartis AG. Novartis AG owns patents relating to some of the medicines that sparked the Board's concerns. Others were owned by unrelated companies. The Board was also aware that Novartis AG authorizes Sandoz

to sell generic versions of those medicines. Without that authorization, Sandoz would be infringing on Novartis AG's patents.

[9] The Board acknowledged that Sandoz holds no patents, and that Sandoz only enters the market once other generics are already there. Still, it found that Sandoz's position as a subsidiary gave it the benefit of Novartis AG's patents, and the power to exercise rights in relation to those patents, bringing it within the definition of "patentee". The fact that Sandoz is a "generic" company did not, in itself, mean that it was beyond the Board's jurisdiction.

[10] The Board rejected Sandoz's argument that it actually competes with its parent. Rather, it found that Novartis AG tells Sandoz when it can enter the market with a generic product. At that point, because it receives permission to sell patented medicines without risk of infringement, Sandoz gains the benefit of the corresponding patents and exercises rights under them. In effect, Sandoz becomes an implied licensee of its parent.

[11] To support its conclusion, the Board referred to Novartis AG's submission to the US Securities and Exchange Commission (SEC). There, in the section dealing with the "Sandoz Division", the report states that "[w]herever possible, our generic products are protected by our own patents". According to the Board, that statement means that Sandoz's generic products are, wherever possible, protected by Novartis AG patents. Therefore, by the Board's reasoning, Sandoz is sometimes immune from competition from other generic companies and so it falls to the Board to protect Canadian consumers from the excessive prices that Sandoz might be inclined to charge based on its monopoly position.

[12] On the question of the constitutionality of the regulatory scheme, the Board found that there was no reason to distinguish between patentees who actually hold patents and patentees who sell generic products. It stated: "When a generic pharmaceutical company, or its parent or affiliate using the generic company to market the medicine, holds a patent pertaining to medicine such that the purposes of the Act are engaged, the implications are the same as for a brand name company". In other words, in that situation, which the Board found to describe Sandoz's circumstances, the Act does not extend beyond the federal jurisdiction over patents.

[13] Therefore, the Board concluded that Sandoz falls within the definition of a "patentee" and is subject to the Board's jurisdiction. Any different conclusion, it reasoned, would permit patent holders to evade the Board's jurisdiction simply by creating a subsidiary generic company.

## III. Issue One – What is the standard of review applicable to the Board?

[14] Sandoz argues that the Board's decision should be reviewed on a standard of correctness because it relates to the Board's jurisdiction and deals with concepts that transcend the Board's role – for example, the meaning of "patentee", "invention", and "patentee rights". Further, the Board has no special expertise in patent law. Its decision, therefore, does not merit deference.

[15] I disagree. The Board's main conclusion relates to the meaning of "patentee" as defined in the *Patent Act*, which is the principal enactment the Board must interpret. The Board merits deference based on its particular familiarity with that statute (*Celgene*, at para 34; *Alberta (Information and Privacy Commissioner) v Alberta Teachers Association*, 2011 SCC 61, at

para 34). Therefore, on the question of whether Sandoz is a "patentee", I will apply a reasonableness standard.

[16] The same degree of deference does not apply to constitutional questions. There, as the parties agree, the standard of review is correctness.

## IV. Issue Two – Was the Board's conclusion that Sandoz is a "patentee" unreasonable?

[17] The Minister argues that the Board's decision was reasonable because Sandoz is effectively controlled by its parent companies who authorize Sandoz to enter the market. This arrangement provides Sandoz an implied license for the products it puts on the market. Sandoz benefits because it can enter the market without having to challenge any patents, and can readily assert equivalence against the patented products. Therefore, in the Minister's submission, Sandoz enjoys the benefits of, and possesses rights in relation to, patents for medicines and meets the definition of a "patentee."

[18] In addition, the Minister contends that the Board's approach is consistent with the purpose of the Act, which is to protect consumers from excessive prices that patent holders, by virtue of their monopolies, are able to charge for drugs (*ICN Pharmaceuticals Inc v Canada (Patented Medicines Prices Review Board)*, (1996) 108 FTR 190 (FCTD), at para 7; *Celgene*, at para 29). If the Act and the Board's jurisdiction can easily be sidestepped by setting up wholly-owned subsidiaries selling generic versions of patented medicines, that purpose cannot be realized.

[19] For the following reasons, I cannot accept the Minister's position.

[20] First, it is clear that the relevant provisions of the Act were enacted out of concern that patent holders could take undue advantage of their monopolies to the detriment of Canadian consumers. They "address the 'mischief' that the patentee's monopoly over pharmaceuticals during the exclusivity period might cause prices to rise to unacceptable levels" (*Celgene*, at para 28). The Board's paramount responsibility is to ensure "that the monopoly that accompanies the granting of a patent is not abused to the financial detriment of Canadian patients" (*Celgene*, at para 29). In short, the legislation aims to ensure that patent holders cannot take undue advantage of their monopolies and it should be interpreted in keeping with that purpose (*Shire Biochem Inc v Canada (Attorney General)*, 2007 FC 1316, at para 23). Accordingly, the Board should confine its role to reviewing prices charged by patent holders, who benefit from a time-limited monopoly, to determine whether those prices are excessive. As Justice Johanne Gauthier stated, Parliament intended the Board "to control the market power of the monopoly created by the exclusivity of the patent" (*Sanofi Pasteur Limited v Attorney General of Canada*, 2011 FC 859, at para 6).

[21] Second, while the federal government can regulate patents of invention, it has no overall jurisdiction to regulate the price of generic versions of patented medicines. That responsibility falls squarely on the provinces (*Katz Group Canada Inc. v Ontario (Health and Long-Term Care)*, 2013 SCC 64, at para 3).The provisions of the Act creating the Board have been upheld as constitutional on the basis that they fall within the federal jurisdiction over patents of invention. In 1991, Justice Dureault of the Manitoba Court of Queen's Bench found that the

1987 amendments to the Act extending the duration of patent protection and creating the Board (SC 1987, c 41) served a dual purpose – to increase patent protection for new medicines, and to address the potential abuse of monopolies through excessive pricing by patent holders (*Manitoba Society of Seniors Inc v Canada (Attorney General)*, (1991), 77 DLR ($4^{th}$) 485, at para 21, aff'd (1992), 96 DLR ($4^{th}$) 606 (Man CA)). Accordingly, the legislation did not constitute a scheme for controlling the price of drugs; it addressed issues relating to patent protection and, therefore, fell within the federal domain over patents of invention.

[22] At that time, the Board's powers were limited to curtailing a patent holder's monopoly. Now, as a result of amendments passed in 1993, the Board has the power to order a patent holder to reduce the price at which it sells a patented medicine and to pay to the Crown a specified amount. Sandoz argues that these amendments introduce a price control system, in place of a patent regulation regime, which renders them unconstitutional. For present purposes, without addressing the constitutional argument directly (see below), if the legislation is capable of more than one interpretation, it should be construed in a manner consistent with the federal jurisdiction over patents. That approach suggests that the definition of "patentee" should take into account the limitations on federal jurisdiction over the pricing of medicines and, therefore, should recognize that a patentee is the holder of the exclusive rights that inure to a patent holder. To expand the definition to include generic companies who neither hold patents nor enjoy monopolies would expose the legislation to an attack on constitutional grounds. In other words, if the legislation were interpreted as applying to, and giving the Board jurisdiction over, products sold by generic pharmaceutical companies, its constitutionality would be in doubt. That approach should be avoided.

[23] Further, federal jurisdiction in this area is generally understood to be confined to regulating the "factory-gate" prices of patented medicines (*Pfizer v Canada (Attorney General)*, 2009 FC 719, at para 61-63). Factory-gate prices are those charged by patent holders to their first purchasers; they do not include the prices charged by distributors or wholesalers, or others down the chain of sales. In this case, then, factory-gate prices would be those Sandoz paid for medicines, not the prices at which it sold them.

[24] With those considerations in mind, I also note the following factors.

[25] In my view, the mere fact that a subsidiary generic company sells a version of a patented medicine is insufficient to bring it within the definition of a patentee. Usually, a generic company is not entitled to the principal benefit of a patent – an exclusive monopoly to make, use, or sell the patented product. Nor can a generic company typically exercise rights in relation to a patent held by another company. Before the patent expires, a generic company can enter the market with a license from the patent holder, or with the patent holder's permission, or by successfully challenging the patent. In none of these scenarios does the generic company receive the exclusive benefits and rights that inure to patent holders. On the other hand, in those cases where a generic company owns a patent and holds a monopoly for a drug, that company could be a "patentee" and come within the Board's jurisdiction.

[26] Generally speaking, generic companies either help create or join a competitive marketplace, which helps keep the costs of patented medicines down. Reviewing the prices

charged by generic companies who hold no patents and no monopolies, on its face, appears to be beyond the Board's mandate.

[27] If the term "patentee" is interpreted too broadly so as to catch a company in the position of Sandoz, there are likely few generic companies who would not be similarly placed. Most generics enter the market by comparing their products against drugs that are the subject of patents held by other companies. To that extent, they indirectly enjoy the benefits of patents and, ultimately, may be regarded as having acquired rights in relation to them. If Sandoz is a patentee, so are many other generic companies and possibly other entities down the line of distribution.

[28] I note that Sandoz cannot bring an action for infringement or seek an order of prohibition keeping another company off the market. Sandoz simply does not enjoy the special patent rights that inure to the benefit of the patent holder.

[29] Sandoz enters the market only with the authorization of Novartis AG, after Novartis AG has already lost its monopoly position – that is, once other generics are already on the market. In this way, once Novartis AG has lost its market exclusivity (and the corresponding profits), it allows its own generic subsidiary to enter the market, presumably in an effort to recoup some of its lost earnings. Obviously, Novartis AG's preference would be to maintain its monopoly as long as possible but, once other companies enter the market, the next best scenario would involve authorizing its generic subsidiary to join it. Accordingly, Sandoz generally operates in a

market where no one holds a monopoly, and no one can take undue advantage of a monopoly position by charging excessive prices.

[30] While the Board placed considerable reliance on it, it is not clear to me what Novartis AG's SEC filing means. It states that "[w]herever possible, our generic products are protected by our own patents". The Board concluded that the statement means that Sandoz's generic products are often protected by Novartis AG patents. I find it difficult to conceive how that could be so. It seems more plausible that it means that Sandoz sometimes tries to obtain patents for its own products. In any case, on the facts here, Sandoz would rarely have an opportunity to exploit a monopoly in respect of any medicinal product.

[31] The Board did not consider the French version of s 79(1) of the *Patent Act* which states that a "patentee" ("breveté" ou "titulaire d'un brevet") is "la personne ayant pour le moment droit à l'avantage d'un brevet pour une invention liée à un médicament, ainsi que quiconque était titulaire d'un brevet pour une telle invention ou exerce ou a exercé les droits d'un titulaire". In short, the French version ties the definition of "patentee" more closely to the rights of the patent holder. It is a narrower definition than in the English version, which includes any person entitled to exercise any rights relating to a patent.

[32] Taking account of all of these factors, I find the Board's conclusion that Sandoz is a "patentee" unreasonable. The objectives the legislation sought to achieve do not include regulating the prices charged by companies who do not hold a monopoly. The constitutionality of the legislation depends on its close connection to patent protection and the potential undue

exploitation of the concomitant monopolies. Generic companies, like Sandoz, do not generally hold monopolies and, in fact, do not normally operate in a market where any monopoly exists.

[33] While the Board began by correctly identifying the purpose of the legislation and the leading cases on the issue (*ICN Pharmaceuticals, Inc* and *Celgene*), in my view, it placed too much emphasis on the "consumer protection purpose" of the legislation. That purpose is served solely by reviewing the prices at which patent holders sell patented medicines to determine whether, by virtue of their monopolies, those prices are too high. The legislation is not aimed at protecting consumers from high drug prices generally, and the Board's role certainly does not extend that far.

[34] In my view, had the Board taken into account the factors and considerations set out above, it could not reasonably have concluded that Sandoz is a "patentee".

## V. Issue Three – Is the legislation constitutional?

[35] Even though the relevant provisions of the Act have already been found to be constitutional (*Manitoba Society of Seniors Inc*), Sandoz argues that subsequent amendments to the Act relating to the Board's powers now place those provisions beyond federal jurisdiction over patents, encroaching on provincial jurisdiction over Property and Civil Rights.

[36] Their purpose was to enable the Board "to influence the pricing of patented medicines to much the same extent that the competition fostered by compulsory licensing used to influence it". Those amendments "strengthened the Board's remedial and punitive powers" to offset the

effect of abolishing the prior scheme of compulsory licensing (*ICN Pharmaceuticals, Inc* at para 12).

[37] As I see it, the amendments giving the Board the power to address the pricing of patented medicines more directly through monetary remedies and penalties did not alter the basic purpose of the legislation or expand the Board's mandate. Therefore, I see no basis for departing from the conclusion reached in *Manitoba Society of Seniors Inc* that the provisions of the *Patent Act* dealing with patented medicines, properly interpreted, fall within federal jurisdiction over patents of invention; they are constitutional.

## VI. Conclusion and Disposition

[38] The Board's conclusion that Sandoz is a "patentee" and that Sandoz was obliged to comply with certain requirements under the Act and Regulations was unreasonable. The Board failed to take adequate account of the purpose of the legislation and its limited role in relation to patented medicines. The relevant provisions of the Act, properly interpreted as being closely connected to the federal jurisdiction over patents of invention, are constitutional.

[39] I must, therefore, allow this application for judicial review, with costs.

[40] Sandoz argued that I should not remit the case to the Board for redetermination on the basis that it would be pointless to do so. I agree.

[41] Based on the applicable law and the evidence in this case, there is only one possible conclusion – that the Board does not have jurisdiction to review the prices at which Sandoz, a company holding no patents and no monopolies, sells medicines. In this situation, it would be futile to send the matter back to the Board for reconsideration. The proper recourse, therefore, is to send the matter back to the Board with a direction, pursuant to s 18.1(3) of the *Federal Courts Act*, RSC, 1985, c F-7, that it find that Sandoz is not a "patentee".

## JUDGMENT

**THIS COURT'S JUDGMENT is that** the application for judicial review is allowed, with costs, and the matter is referred back the Board with a direction that it find that Sandoz is not a "patentee".

"James W. O'Reilly"
Judge

Annex

| *Patent Act*, RSC 1985, c P-4 | *Loi sur les brevets*, LRC (1985), ch P-4 |
|---|---|
| Interpretation | Définitions |
| **2.** In this Act except as otherwise provided | **2.** Sauf disposition contraire, les définitions qui suivent s'appliquent à la présente loi. |
| "patentee" means the person for the time being entitled to the benefit of a patent; | « breveté » ou « titulaire d'un brevet ». Le titulaire ayant pour le moment droit à l'avantage d'un brevet. |
| **79(1)** In this section | **79.(1)** Les définitions qui suivent s'appliquent au présent article |
| "patentee" | « breveté » ou « titulaire d'un brevet » |
| "patentee", in respect of an invention pertaining to a medicine, means the person for the time being entitled to the benefit of the patent for that invention and includes, where any other person 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*, that other person in respect of those rights; | « breveté » ou « titulaire d'un brevet », la personne ayant pour le moment droit à l'avantage d'un brevet pour une invention liée à un médicament, ainsi que quiconque était titulaire d'un brevet pour une telle invention ou exerce ou a exercé les droits d'un titulaire dans un cadre autre qu'une licence prorogée en vertu du paragraphe 11(1) de la *Loi de 1992 modifiant la Loi sur les brevets*. |
| *Constitution Act, 1867* | *Lois constitutionnelles de 1867* |
| Subjects of exclusive Provincial Legislation | Sujets soumis au contrôle exclusif de la législation provinciale |
| **92.** In each Province the Legislature may exclusively make Laws in relation to Matters coming within the Classes of Subjects next hereinafter enumerated; that is to say, | **92.** Dans chaque province la législature pourra exclusivement faire des lois relatives aux matières tombant dans les catégories de sujets ci-dessous énumérés, savoir : |
| … | […] |
| 13. Property and Civil Rights in the Province. | 13. La propriété et les droits civils dans la province. |
| *Federal Courts Act*, RSC, 1985, c F-7 | *Loi sur les Cours fédérales*, LRC 1985, ch F-7 |
| Powers of the Federal Court | Pouvoirs de la Cour fédérale |

**18.1**(3) On an application for judicial review, the Federal Court may

(*a*) order a federal board, commission or other tribunal to do any act or thing it has unlawfully failed or refused to do or has unreasonably delayed in doing; or

(*b*) declare invalid or unlawful, or quash, set aside or set aside and refer back for determination in accordance with such directions as it considers to be appropriate, prohibit or restrain, a decision, order, act or proceeding of a federal board, commission or other tribunal.

**18.1**(3) Sur présentation d'une demande de contrôle judiciaire, la Cour fédérale peut :

*a*) ordonner à l'office fédéral en cause d'accomplir tout acte qu'il a illégalement omis ou refusé d'accomplir ou dont il a retardé l'exécution de manière déraisonnable;

*b*) déclarer nul ou illégal, ou annuler, ou infirmer et renvoyer pour jugement conformément aux instructions qu'elle estime appropriées, ou prohiber ou encore restreindre toute décision, ordonnance, procédure ou tout autre acte de l'office fédéral.

**FEDERAL COURT**
**SOLICITORS OF RECORD**

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|---|---|
| **DOCKET:** | T-1616-12 |
| **STYLE OF CAUSE:** | SANDOZ CANADA INC. v ATTORNEY GENERAL OF CANADA |
| **PLACE OF HEARING:** | TORONTO, ONTARIO |
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| **JUDGMENT AND REASONS:** | O'REILLY J. |
| **DATED:** | MAY 27, 2014 |

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