Federal Court  Cour fédérale

Date: 20140527

Docket: T-1252-11
T-1058-11
T-1825-11

Citation: 2014 FC 502

Ottawa, Ontario, May 27, 2014

PRESENT: The Honourable Mr. Justice O'Reilly

BETWEEN:

RATIOPHARM INC.
(NOW TEVA CANADA LIMITED)

Applicant

and

ATTORNEY GENERAL OF CANADA

Respondent

JUDGMENT AND REASONS

I. Overview

[1] Ratiopharm Inc sells generic drugs in Canada, including an anti-asthmatic medicine called ratio-salbutamol HFA ("ratio HFA"). Ratio HFA is the generic equivalent of Ventolin HFA, a product manufactured by GlaxoSmithKline Inc (GSK). Ratiopharm sold ratio HFA to pharmacies after having purchased it under contract from GSK. The two products competed

against one another and other similar products in the Canadian market. Under the contract with Ratiopharm, GSK retained all patent rights to its product.

[2] In 2011, the Patented Medicines Prices Review Board found that Ratiopharm, by virtue of its contract with GSK, was a "patentee" under s 79(1) of the *Patent Act*, RSC 1985, c P-4 (see Annex), which put its prices within the jurisdiction of the Board. It went on to find that Ratiopharm was obliged to provide the Board with information and documentation about its prices; that Ratiopharm was selling ratio HFA at an excessive price; and that Ratiopharm must pay damages of $65,898,842.76. Ratiopharm challenges all three decisions (Files T-1252-11, T-1058-11, and T-1825-11, respectively). As this decision relates to the three files, the original of these reasons will be filed in T-1252-11 and copies will be placed in the other two files.

[3] Ratiopharm argues that it is not a "patentee" and, therefore, the Board has no jurisdiction over it. Further, it maintains that its prices were not excessive. In addition, Ratiopharm 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.

[4] In my view, taking into account the federal1provincial division of powers, and interpreting the scope of the Act accordingly, Ratiopharm is not a "patentee". Therefore, the Board had no jurisdiction over its sales of ratio HFA and I must allow all three of Ratiopharm's applications for judicial review. There are three issues:

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

2. Is Ratiopharm a "patentee"?

3. Is the legislation unconstitutional?

II. The Board's Decisions

[5] The Board found (in T-1058-11) that the agreement between Ratiopharm and GSK gave Ratiopharm the right to sell and set the prices for ratio HFA. Without that agreement, Ratiopharm would have violated GSK's patent for Ventolin HFA. In that sense, Ratiopharm was entitled to "exercise … rights in relation to that patent", which brought it within the definition of "patentee" in s 79(1). The Board rejected Ratiopharm's argument that the Board has no jurisdiction over a generic company that sells a product under an agreement with a patent holder in which, as here, the latter retains ownership in its intellectual property. If that were the case, according to the Board, the generic company could sell its product to pharmacies and others at an unregulated price.

[6] The Board went on to consider whether Ratiopharm's price for ratio HFA was excessive. It compared that price with the price of similar medicines, prices in other countries, and changes in the consumer price index.

[7] Given its conclusion that Ratiopharm is a "patentee", the Board found (in T-1252-11) that Ratiopharm had a duty to provide the Board with information and documents relating to sales, prices, expenditures, and revenues relating to patented medicines.

[8] Finally, the Board calculated the excessive revenues that Ratiopharm had realized at $65,898,842.76 (in T-1825-11).

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

[9] Ratiopharm argues that the Board's interpretation of the term "patentee" should be reviewed on a standard of correctness because it relates to the Board's jurisdiction. On the other issues, the proper standard of review is reasonableness.

[10] In my view, all of the Board's conclusions should be reviewed on a reasonableness standard. 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 due to its particular familiarity with that statute (*Celgene Corp v Canada (Attorney General)*, 2011 SCC 1, at para 34; *Alberta (Information and Privacy Commissioner) v Alberta Teachers Association*, 2011 SCC 61, at para 34). Therefore, on the question of whether Ratiopharm is a "patentee", I will apply a reasonableness standard.

[11] 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 Ratiopharm is a "patentee" unreasonable?

[12] The Minister argues that the Board's decision was reasonable because Ratiopharm is authorized under its agreement with GSK to sell and market a patented medicine, ratio HFA. But for that agreement, GSK would have held the exclusive right to make, use and sell that product. Ratiopharm obtained its own Drug Identification Number (DIN) for the product, and obtained regulatory approval to sell it. Therefore, by virtue of its agreement with GSK, Ratiopharm was able to exercise rights under the patent and accordingly, in the Minister's submission, is a "patentee".

[13] In addition, the Minister contends that the Board's approach is consistent with the purpose of the relevant provisions 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 v Canada (Patented Medicines Prices Review Board)*, (1996) 108 FTR 190 (FCTD), at para 24; *Celgene*, at para 29). In pursuit of that purpose, Parliament defined "patentee" broadly to include all entities enjoying any advantage, right or benefit from a patent. Here, Ratiopharm enjoys the right to sell patented medicines which is sufficient to bring it within the Board's jurisdiction. It is not necessary, according to the Minister, to show that Ratiopharm actually held a monopoly.

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

[15] 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's 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).

[16] 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.

[17] 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. Ratiopharm 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 it is capable of more than one interpretation, the legislation 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.

[18] 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 Ratiopharm paid for medicines, not the prices at which it sold them.

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

[20] In my view, the mere fact that a company sells a generic version of a patented medicine under contract 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.

[21] 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.

[22] If the term "patentee" is interpreted too broadly so as to catch a company in the position of Ratiopharm, there are likely very 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 Ratiopharm is a patentee, so are many other generic companies and possibly other entities down the line of distribution.

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

[24] Ratiopharm only enters the market under agreement with GSK. GSK decides when it wishes to relinquish its monopoly. Ratiopharm is never in a monopoly position.

[25] 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.

[26] Taking account of all of these factors, I find the Board's conclusion that Ratiopharm is a "patentee" unreasonable. The objectives the legislation sought to achieve did 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 Ratiopharm, do not generally hold monopolies and, in fact, do not normally operate in a market where any monopoly exists.

[27] In my view, had the Board taken these factors and considerations into account, it could not reasonably have concluded that Ratiopharm was a "patentee".

V. Issue Three – Is the legislation constitutional?

[28] Even though the relevant provisions of the Act have already been found to be constitutional (*Manitoba Society of Seniors Inc*), Ratiopharm 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.

[29] Those amendments "strengthened the Board's remedial and punitive powers" to offset the effect of abolishing the prior scheme of compulsory. 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" licensing (*ICN Pharmaceuticals, Inc v Canada (Patented Medicines Prices Review Board)*, [1997] 1 FC 32 (CA) at para 12).

[30] 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

[31] The Board's conclusion that Ratiopharm is a "patentee" and that Ratiopharm 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. Properly interpreted as being closely connected to the federal jurisdiction over patents of invention the relevant provisions of the Act are constitutional.

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

[33] Ratiopharm 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.

[34] 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 Ratiopharm, 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 Ratiopharm 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 to the Board with a direction that it find that Ratiopharm 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
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 Federal Court	Pouvoirs de la Cour fédérale
18.1(3) On an application for judicial review, the Federal Court may	**18.1**(3) Sur présentation d'une demande de contrôle judiciaire, la Cour fédérale peut :
(*a*) order a federal board, commission or other tribunal to do any act or thing it has unlawfully failed or refused to do or	*a*) ordonner à l'office fédéral en cause d'accomplir tout acte qu'il a illégalement omis ou refusé

has unreasonably delayed in doing; or

d'accomplir ou dont il a retardé l'exécution de manière déraisonnable;

(*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.

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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