

Date: 20090820

Docket: A-312-09

Citation: 2009 FCA 250

Present: SHARLOW J.A.

BETWEEN:

**JANSSEN-ORTHO INC. and
ORTHO-McNEIL PHARMACEUTICAL, INC.**

Appellants

and

**APOTEX INC. and
THE MINISTER OF HEALTH**

Respondents

Heard at Ottawa, Ontario, on August 19, 2009.

Order delivered at Ottawa, Ontario, on August 20, 2009.

REASONS FOR ORDER BY:

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REASONS FOR ORDER

SHARLOW J.A.

[1] The appellants Janssen-Ortho Inc. and Ortho-McNeil Pharmaceutical, Inc. have appealed the order of Justice Hughes issued on July 29, 2009 (2009 FC 783). That order confirmed the order of Prothonotary Aalto (2009 FC 650), which was issued on June 12, 2009. The order of Prothonotary Aalto granted the motion of Apotex Inc. to dismiss an application by Janssen under section 6 of the *Patented Medicines (Notice of Compliance) Regulations, S.O.R./93-133 (the NOC Regulations)*. That application sought an order prohibiting the Minister of Health from issuing a notice of compliance to Apotex for its generic version of Tramacet until after the expiry of Canadian Patent No. 2,095,523 (which will occur on September 3, 2012). Before me is a motion by Janssen to stay

the order of Prothonotary Aalto pending the disposition of the appeal of Justice Hughes' order. The motion is opposed by Apotex. The Minister of Health did not appear.

[2] Janssen has not sought a stay of the order of Justice Hughes, which is the order under appeal. However, Apotex has not suggested that Janssen's motion is fatally flawed by that omission, and I will say no more about it.

[3] The facts are not in dispute. Janssen manufactures Tramacet pursuant to a notice of compliance issued by the Minister of Health, and has done so since 2005. The active medicinal ingredient in Tramacet is a combination of tramadol and acetaminophen. The 523 patent, which claims certain combinations of tramadol and acetaminophen, is listed against Tramacet on the patent register maintained by the Minister under the *NOC Regulations*.

[4] On February 1, 2008, Apotex filed an abbreviated new drug submission for a generic version of Tramacet. It appears that the Minister is expected to issue a notice of compliance to Apotex for its generic version of Tramacet on August 21, 2009 unless she is prohibited from doing so by an order of this Court. (This motion is being heard on August 19, 2009.)

[5] On or about March 12, 2008, Apotex served Janssen with a notice of allegation pursuant to subsection 5(1) of the *NOC Regulations*. That notice of allegation addresses the claims of the 523 patent as they read on that date, and alleges non-infringement and invalidity. The allegations

of invalidity are based on several alternative grounds, one being that the claims of the 523 patent are broader than the invention.

[6] On April 18, 2008, after Janssen was served with the Apotex notice of allegation and obviously in response to it, Janssen filed a disclaimer of the claims of the 523 patent. The disclaimer was recorded by the patent office on April 22, 2008.

[7] I am not in a position to construe the patent claims, but it seems safe to say that the disclaimer, as its name implies, is intended to reduce the scope of the claims of the 523 patent.

For example, claim 1 reads as follows before and after the disclaimer:

Before 1. A pharmaceutical composition comprising a tramadol material and acetaminophen.

After 1. A pharmaceutical composition comprising a tramadol material and acetaminophen as its sole active ingredients, wherein the ratio of the tramadol material to acetaminophen is a weight ratio from about 1:1 to about 1:1600.

[8] Disclaimers are the subject of section 48 of the *Patent Act*, R.S.C. 1985, c. P-4, which reads in relevant part as follows:

48. (1) Whenever, by any mistake, accident or inadvertence, and without any wilful intent to defraud or mislead the public, a patentee has

(a) made a specification too broad,

48. (1) Le breveté peut, en acquittant la taxe réglementaire, renoncer à tel des éléments qu'il ne prétend pas retenir au titre du brevet, ou d'une cession de celui-ci, si, par erreur, accident ou inadvertence, et sans intention de frauder ou tromper le

claiming more than that of which the patentee or the person through whom the patentee claims was the inventor, or

(b) in the specification, claimed that the patentee or the person through whom the patentee claims was the inventor of any material or substantial part of the invention patented of which the patentee was not the inventor, and to which the patentee had no lawful right,

the patentee may, on payment of a prescribed fee, make a disclaimer of such parts as the patentee does not claim to hold by virtue of the patent or the assignment thereof.

[...]

(4) No disclaimer affects any action pending at the time when it is made, unless there is unreasonable neglect or delay in making it.

[...]

(6) A patent shall, after disclaimer as provided in this section, be deemed to be valid for such material and substantial part of the invention, definitely distinguished from other parts thereof claimed without right, as is not disclaimed and is truly the invention of the disclaimant, and the disclaimant is entitled to maintain an action or suit in respect of that part accordingly.

public, dans l'un ou l'autre des cas suivants :

a) il a donné trop d'étendue à son mémoire descriptif, en revendiquant plus que la chose dont lui-même, ou son mandataire, est l'inventeur;

b) il s'est représenté dans le mémoire descriptif, ou a représenté son mandataire, comme étant l'inventeur d'un élément matériel ou substantiel de l'invention brevetée, alors qu'il n'en était pas l'inventeur et qu'il n'y avait aucun droit.

[...]

(4) Dans toute action pendante au moment où elle est faite, aucune renonciation n'a d'effet, sauf à l'égard de la négligence ou du retard inexcusable à la faire.

[...]

(6) Après la renonciation, le brevet est considéré comme valide quant à tel élément matériel et substantiel de l'invention, nettement distinct des autres éléments de l'invention qui avaient été indûment revendiqués, auquel il n'a pas été renoncé et qui constitue véritablement l'invention de l'auteur de la renonciation, et celui-ci est admis à soutenir en conséquence une action ou poursuite à l'égard de cet élément.

[9] On April 25, 2008, three days after the disclaimer of the 523 patent claims was recorded, Janssen commenced an application under section 6 of the *NOC Regulations* for an order prohibiting the Minister from issuing a notice of compliance to Apotex for its generic version of Tramacet until after the expiry of the 523 patent.

[10] Janssen's prohibition application did not address the merits of Apotex' allegations of non-infringement and invalidity of the 523 patent (except, as an alternative argument, the allegation of deemed abandonment pursuant to section 73 of the *Patent Act*). The main ground of Janssen's prohibition application is that the Apotex notice of allegation is invalid because Apotex did not address the claims of the 523 patent as reduced by the disclaimer.

[11] Obviously, it would have been impossible for Apotex, on February 1, 2008, to address the reduced claims because the disclaimer had not then been filed, and the jurisprudence of this Court precludes a notice of allegation from being amended. If Janssen's argument is correct, Apotex would be required to serve a new notice of allegation based on the post-disclaimer claims of the 523 patent. Then, assuming Janssen would respond with a new prohibition application, a new 24 month statutory stay would commence pursuant to section 7 of the *NOC Regulations*, to the prejudice of Apotex.

[12] On June 27, 2008, Apotex filed a motion under paragraph 6(5)(b) of the *NOC Regulations* for an order dismissing Janssen's prohibition application. That provision reads as follows:

6. (5) Subject to subsection (5.1), in a proceeding in respect of an application under subsection (1), the court may, on the motion of a second person, dismiss the application in whole or in part [...]

(b) on the ground that it is redundant, scandalous, frivolous or vexatious or is otherwise an abuse of process in respect of one or more patents.

6. (5) Sous réserve du paragraphe (5.1), lors de l'instance relative à la demande visée au paragraphe (1), le tribunal peut, sur requête de la seconde personne, rejeter tout ou partie de la demande si, selon le cas : [...]

b) il conclut qu'elle est inutile, scandaleuse, frivole ou vexatoire ou constitue autrement, à l'égard d'un ou plusieurs brevets, un abus de procédure.

[13] After analyzing the relevant jurisprudence, Prothonotary Aalto concluded that Apotex was obliged to address only the claims of the 523 patent as they read when the notice of allegation was served. He held that Janssen's prohibition application was an abuse of process and bereft of any chance of success. On June 12, 2009, he made an order dismissing the prohibition application. That is the order that Janssen now asks this Court to stay.

[14] Janssen appealed the order of Prothonotary Aalto. On June 29, 2009, Justice Hughes made an order dismissing that appeal. The order of Justice Hughes is the subject of this appeal.

[15] As indicated above, the Minister is expected to issue a notice of compliance to Apotex for its generic version of Tramacet on August 21, 2009, unless she is prohibited from doing so by an order of this Court. One possibility for such an order would be an order allowing Janssen's appeal, setting aside the order of Justice Hughes and, making the order that he should have made, allowing the appeal of the order of Prothonotary Aalto, setting that order aside, and dismissing Apotex' motion to dismiss Janssen's prohibition application.

[16] Janssen tried to have this appeal heard before August 21, 2009, but without success. The possibility of a successful appeal before that date being out of the question, Janssen is seeking a stay of Prothonotary Aalto's order, based on the assumption that such an order would have the effect of treating Janssen's prohibition application as though it had not been dismissed by the order of Prothonotary Aalto.

Is the order of Prothonotary Aalto subject to being stayed?

[17] Generally, the function of a stay of a court order is to stop a party from taking some step that the order requires to be taken. An order that does nothing but dismiss an unmeritorious claim does not require anybody to do anything. Apotex argues that such an order cannot be stayed.

[18] Apotex points out, correctly, that the order of Prothonotary Aalto is an order dismissing a claim that he found to be unmeritorious. It does not require anybody to do anything. It merely puts an end to Janssen's attempt to stop the Minister from doing something that she is required to do because of her statutory mandate, namely, issuing a notice of compliance to Apotex upon being satisfied that the applicable requirements of the *Food and Drug Regulations*, C.R.C., c. 870, have been met. On that basis, Apotex argues that no stay is possible.

[19] Counsel for Janssen conceded that he had been unable to find any case in which a court had granted a stay of an order that does not require anything to be done, but he argues that such a stay is possible as a matter of law. He points out that the expected exercise by the Minister of her statutory mandate to issue a notice of compliance to Apotex (assuming the applicable regulatory requirements are met) is an inevitable outcome of the order of Prothonotary Aalto. The fact is, however, that the Minister is compelled to act because of the *Food and Drug Regulations*, not because of Prothonotary Aalto's order.

[20] Janssen relies on the following excerpt from *RJR – MacDonald Inc. v. Canada (A.G.)*, [1994] 1 S.C.R. 311 (per Justice Sopinka and Justice Cory, writing for the Court) at page 329:

We are of the view that the Court is empowered, pursuant to both s. 65.1 [of the *Supreme Court Act*] and r. 27 [of the *Rules of the Supreme Court of Canada*], not only to grant a stay of execution and of proceedings in the traditional sense, but also to make any order that preserves matters between the parties in a state that will prevent prejudice as far as possible pending resolution by the Court of the controversy, so as to enable the Court to render a meaningful and effective judgment. The Court must be able to intervene not only against the direct dictates of the judgment but also against its effects. This means that the Court must have jurisdiction to enjoin conduct on the part of a party in reliance on the judgment which, if carried out, would tend to negate or diminish the effect of the judgment of this Court.

[21] The Court would have entered the motion for a stay even without its statutory authority.

The following appears at page 332:

Finally, if jurisdiction under s. 65.1 of the Act and r. 27 were wanting, we would be prepared to find jurisdiction in s. 24(1) of the *Charter*. A *Charter* remedy should not be defeated due to a deficiency in the ancillary procedural powers of the Court to preserve the rights of the parties pending a final resolution of constitutional rights.

[22] I am not persuaded that *RJR – MacDonald* establishes that the order of Prothonotary Aalto in this case may be stayed. What was being sought in *RJR – MacDonald* was a stay of a judgment of the Quebec Court of Appeal declaring that certain provisions of the *Tobacco Products Control Act*, R.S.C. 1985, c. 14 (4th Supp.) were valid. After the judgment, regulations were enacted under *Tobacco Products Control Act* that, if enforced, would impose costly obligations on the parties asserting the constitutional challenge. It was in those circumstances

that the Supreme Court of Canada determined that it had the jurisdiction to stay the judgment of the Quebec Court of Appeal, even though it was in form a declaratory judgment.

[23] I do not read *RJR – Macdonald* as support for the argument that the order dismissing Janssen’s prohibition application under the *NOC Regulations* is subject to being stayed because it removes an obstacle that would stop the Minister from issuing a notice of compliance to Apotex pursuant to the *Food and Drug Regulations*. I agree with Apotex that Janssen’s motion should fail because there is nothing to stay.

Scheme of the *NOC Regulations*

[24] I also agree with Apotex that Janssen’s motion for a stay is an attempt to extend the statutory stay beyond the term stipulated in the *NOC Regulations*. This Court has rejected such attempts in other contexts: see *Merck Frosst Canada Inc. v. Apotex Inc. (C.A.)*, [1997] 2 F.C. 561 and *Janssen-Ortho Inc. v. Novopharm Ltd*, 2005 FCA 2.

[25] The statutory stay begins, according to paragraph 7(1)(d) of the *NOC Regulations*, when the Minister receives proof that a prohibition application has been commenced. The statutory stay ends, according to subsection 7(4) of the *NOC Regulations*, when the prohibition application is dismissed by the court hearing the application.

[26] In this case, the statutory stay ended when Prothonotary Aalto made his order. In seeking to stay the order of Prothonotary Aalto, Janssen is seeking a remedy that is not contemplated by the statutory scheme. In my view, that remedy should not be granted.

The *RJR – MacDonald* test

[27] Even if I had not concluded that the motion for a stay should be rejected for the reasons stated above, I would have rejected it on the basis of *RJR-MacDonald Inc.*(cited above).

[28] I am prepared to assume without deciding that there is an arguable case. However, I have not been persuaded that Janssen has established that it would suffer irreparable harm if the stay is not granted and its appeal of Justice Hughes' order succeeds, or that the balance of convenience favours granting the stay.

[29] All of the elements of harm alleged by Janssen flow directly or indirectly from the competition represented by Apotex entering the marketplace with its generic version of Tramacet. However, the fact that its prohibition application has been dismissed does not impair any of Janssen's rights as a holder of the 523 patent. Janssen retains the right to seek all possible remedies against Apotex for infringement, including an injunction and damages.

[30] Janssen argues that it will suffer some harm that is not compensable in damages because of negative effects on its marketing and promotional programs, and various hindrances to the company's plan to become a leader in the field of pain management. However, the evidence

submitted by Janssen on these points falls short of establishing that such negative effects, assuming they occur, cannot be quantified in monetary terms.

[31] Janssen argues also that if the stay is not granted, its right of appeal will be rendered moot and be permanently extinguished, which constitutes irreparable harm. I agree that if the Minister issues the notice of compliance to Apotex, Janssen's appeal is likely to be rendered moot. However, Janssen's right of appeal will not be extinguished because the Court may agree in its discretion to hear the appeal despite its mootness.

[32] Janssen's real complaint is that, because its appeal will be moot, it will be deprived of the chance to preserve the benefit of the statutory stay provided by the *NOC Regulations*. However, it is now well established that the loss of the statutory stay cannot constitute irreparable harm (*Bristol-Myers Squibb Canada Inc. v. Canada (Attorney General)* (2001), 11 C.P.R. (4th) 539 (F.C.A.), *Janssen-Ortho Inc. v. Canada (Minister of Health)*, 2004 FCA 168).

[33] Finally, Janssen has failed to provide a clear and unequivocal undertaking to compensate Apotex if the stay is granted and Janssen's appeal is dismissed. What Janssen has presented as an undertaking is the following statement in the written submissions of counsel for Janssen:

Apotex may be in a position to seek compensation under s. 8 of the *Regulations* if there is any delay in the approval of its product and the Appellants agree to provide an undertaking in damages [...]

[34] It is not clear from this statement exactly what Apotex would be entitled to claim from Janssen, or when, or in what circumstances. For example, it is not clear to me whether Jansen is undertaking to compensate Apotex for damages that fall or may fall outside the scope of section 8 but may nevertheless be causally connected to the prohibition application.

Conclusion

[35] For these reasons, the motion of Janssen for a stay of the order of Prothonotary Aalto will be dismissed with costs.

“K. Sharlow”

J.A.

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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v. APOTEX INC. et al

MOTION DEALT WITH IN WRITING WITH APPEARANCE OF PARTIES

REASONS FOR ORDER BY: SHARLOW J.A.

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