Federal Court of Appeal | Cour d'appel fédérale

Date: 20140630

Docket: A-270-14

Citation: 2014 FCA 176

Present: STRATAS J.A.

BETWEEN:

JANSSEN INC.

Appellant

and

ABBVIE CORPORATION, ABBVIE DEUTSCHLAND GMBH & CO. KG and ABBVIE BIOTECHNOLOGY LTD.

Respondents

Heard at Toronto, Ontario, on June 26, 2014.

Order delivered at Ottawa, Ontario, on June 30, 2014.

REASONS FOR ORDER BY: STRATAS J.A.

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REASONS FOR ORDER

STRATAS J.A.

[1] Janssen moves for a stay of an injunction the Federal Court issued on May 22, 2014 (*per* Justice Hughes) (2014 FC 489) until this Court determines three appeals. Janssen also moves for an order consolidating and expediting the appeals.

A. The appeals

[2] The three appeals arise from AbbVie's action against Janssen in the Federal Court. In the action, AbbVie claimed that Janssen's drug product, Stelara, infringes claims 143 and 222 of Canadian patent 2,365,281.

[3] The Federal Court divided the action into a liability phase and a remedial phase: Order of Prothonotary Aalto dated September 26, 2011.

[4] During the liability phase of the action, the Federal Court refused Janssen's motion to amend its pleadings: 2013 FC 1148. Janssen has appealed that refusal (file A-380-13).

[5] Following a trial on the liability phase, the Federal Court found infringement: 2014 FC 55. Janssen has appealed that finding (file A-95-14).

[6] After the Federal Court's finding of liability, it embarked upon the remedial phase. First, it considered AbbVie's request that Janssen be enjoined from certain infringing conduct. It granted the injunction: 2014 FC 489. Janssen has appealed the injunction (file A-270-14). The next part of the remedial phase concerns the issues relating to damages. These issues will not be tried until autumn 2015.

B. Consolidating and expediting the appeals

[7] Janssen requests consolidation of the appeals. Consolidation achieves two purposes: reducing the amount of paper that needs to be filed and allowing all appeals to be heard together. The alternative remedy of hearing the appeals together achieves only the second purpose. Either remedy is appropriate where, as here, the appeals are factually and legally related.

[8] In these circumstances, where the appeals are related but most of the paper for the appeals has already been filed, the appropriate remedy is to order that the appeals be heard together.

[9] Janssen also requests that the appeals be expedited. The pleadings appeal (file A-380-13) and the liability appeal (file A-95-14) are ready for hearing but no date has been set. In the ordinary course, without an expedition order, the injunction appeal (file A-270-14) will be ready for hearing in October 2014.

[10] The parties have advised the Court of their availability at that time. An order will issue setting down the appeals to be heard together on October 8 and 9, 2014.

C. Staying the injunction until the appeals are determined

(1) Janssen's earlier request for a stay in this Court

[11] Following the Federal Court's finding of infringement, Janssen moved in this Court for a stay of the remedial phase of the action. Applying the settled principles in *RJR-MacDonald v. Canada (Attorney General)*, [1994] 1 S.C.R. 311, this Court dismissed the motion: *Janssen Inc. v. AbbVie Corporation*, 2014 FCA 112.

[12] Among other things, this Court found that Janssen had suffered no irreparable harm because the Federal Court had not yet granted AbbVie any remedy. This Court recognized that if the Federal Court were to issue an injunction, the circumstances might be different and so Janssen could reapply to this Court for a stay: 2014 FCA 112 at paragraph 2.

[13] The injunction has now issued and Janssen has moved to stay it.

(2) Janssen's request for a stay from the Federal Court

[14] In this Court, AbbVie submits that Janssen is barred by the doctrine of abuse of process from so moving. Janssen unsuccessfully requested a "stay" of the injunction in the Federal Court. In its appeal from the injunction, Janssen does not impugn this aspect of the Federal Court's decision. AbbVie submits that Janssen, having failed to appeal the denial of the "stay," cannot now ask this Court for one.

[15] I reject this submission. To show why, some further background is needed.

[16] During the Federal Court's hearing into whether Janssen should be enjoined from certain conduct, Janssen submitted that if the Federal Court were minded to issue such an order, it should "stay" it until the determination of the appeals. The Federal Court rejected the submission. Its injunction took immediate effect.

[17] Although Janssen phrased its request to the Federal Court as a "stay," in reality it was just a request that the Federal Court delay when its own order should take effect.

[18] There is a difference between that sort of request – one made to the court making its own order – and a request that a court stay the order of another body. The former attracts a broad "interests of justice" test while the latter attracts the tougher *RJR-MacDonald test: Mylan Pharmaceuticals ULC v. AstraZeneca Canada, Inc.*, 2011 FCA 312, 426 N.R. 167; *Epicept Corporation v. Canada (Health)*, 2011 FCA 209, 425 N.R. 353 at paragraph 14; *Korea Data Systems (USA), Inc. v. Aamazing Technologies Inc.*, 2012 ONCA 756 at paragraphs 17-19. In this case, the Federal Court decided that its own order should take effect immediately.

[19] The stay motion presently before this Court is in no way an appeal from the Federal Court's decision concerning when its order should take effect. Rather, it seeks to invoke this Court's own jurisdiction to stay an order on appeal. That jurisdiction arises from this Court's power to make an order addressing its own inability to determine the appeal in time to prevent an appellant from suffering irreparable harm. It is just one example of this Court's broad original

jurisdiction to make orders necessary for its own process: *Canada (Human Rights Commission) v. Canadian Liberty Net*, [1998] 1 S.C.R. 626; *Canada (National Revenue) v. RBC Life Insurance Company*, 2013 FCA 50. Section 50 of the *Federal Courts Act*, R.S.C. 1985, c. F-7 and Rule 398(1)(*b*) of the *Federal Courts Rules*, SOR/98-106 are further sources of this original jurisdiction. Orders made by the Federal Court in related matters cannot oust this Court's original jurisdiction to make orders necessary for its own process.

[20] While this Court is not barred from considering Janssen's stay motion, it must acknowledge that the Federal Court has found in this case that Janssen will not suffer undue harm if the injunction takes immediate effect. As mentioned, Janssen has not appealed that finding.

[21] It seems to me that in an appropriate case this Court might give weight to a finding made by the Federal Court on a related issue that has not been appealed to this Court, especially in the absence of satisfactory submissions to the contrary. This might be such a case, as the record before this Court on this motion does overlap somewhat with the record that was before the Federal Court when it made its finding.

[22] That hypothesis, however, need not be explored further or definitively answered here. For the reasons below, Janssen has failed to establish unavoidable irreparable harm and, thus, is not entitled to a stay of the injunction: *RJR-McDonald*, *supra*.

[23] Janssen proffers evidence of irreparable harm in several categories: legal and other expenses, non-monetary burdens associated with complying with the injunction, injury to its reputation, damage to its market share, and damage arising from the ambiguity of the terms of the injunction. Janssen must show that this harm is likely to arise over the next few months until this Court determines its appeals.

[24] Legal and other expenses without "abnormal, harsh consequences beyond the norm" do not qualify as irreparable harm, as these can be quantified in damages: *Laperrière v. D. & A. MacLeod Company Ltd.*, 2010 FCA 84 at paragraph 21.

[25] In this case, the non-monetary burdens associated with complying with the injunction – training personnel, changing communications, *etc.* – are the sorts of administrative inconvenience that, without more, cannot support suspending the injunction: *Laperrière*, *supra* at paragraph 20; *Janssen*, *supra*, at paragraphs 20-26 (on the importance of the binding effect of orders). Further, although non-monetary on the surface, the burdens identified here may well be quantifiable in monetary terms.

[26] Janssen is concerned about its reputation with doctors who prescribe Stelara. I am not persuaded on this record that these doctors will think less of Janssen or Stelara because of this intellectual property dispute. In accordance with the terms of the injunction, Janssen remains free to explain to physicians the dispute. As well, physicians understand the frequency of intellectual property litigation among pharmaceutical companies. If Stelara is helpful to their patients and if the physicians, themselves, are not involved in the dispute – and on this record they are not –

they will continue to prescribe Stelara. Accordingly, Janssen's long term reputation as a reliable supplier of good pharmaceutical products will not be hurt. See the similar observations in *Hoffman-La Roche Ltd. v. Canada (Minister of National Health and Welfare)* (1999), 168 F.T.R. 24 at paragraph 19 (T.D.) (*per* Evans J. as he then was) and *Novopharm Ltd. v. Janssen-Ortho Inc.*, 2006 FCA 406 at paragraph 11 (*per* Sharlow J.A.).

[27] Janssen's related concern that it will lose market share is unpersuasive. On this record, it appears that treating physicians in this area know Stelara well and, as mentioned in the preceding paragraph, they will continue to prescribe it. The injunction allows doctors to prescribe Stelara to new patients and allows Janssen to supply it to them. Evidence shows that doctors learn about the usefulness of Stelara from many sources of readily available information and, thus, are poised to introduce Stelara to new patients. Against this concrete backdrop, the evidence only shows general and speculative assertions about loss of market share, unsupported by particularity. Further, like Justice Rothstein in *Apotex Inc. v. Wellcome Foundation Ltd.*, 2000 CarswellNat 4299 at paragraph 13 (Fed. C.A.), I suspect that, despite the *obiter* statement of the Supreme Court in *RJR-MacDonald* to the contrary, any such loss nevertheless might be quantifiable in monetary terms.

[28] Finally, Janssen submits that it is suffering and will continue to suffer irreparable harm because of ambiguities in certain terms of the injunction. It focuses upon certain wording in the injunction, such as the prohibition in paragraph 2 against "influencing" physicians. It alleges that certain paragraphs of the injunction conflict.

[29] These ambiguities, it says, force it to take very restrictive views of the meaning of the terms of the injunction, resulting in over-compliance. Further, the ambiguities create the spectre of contempt proceedings arising from breaches of the injunction, a most serious matter. Janssen points out that AbbVie has threatened such proceedings arising from a specific, recent incident.

[30] Janssen says that it has attempted in the Federal Court to address the ambiguities but the Federal Court rebuffed it. In particular, soon after the Federal Court issued the injunction, Janssen sought direction and guidance from the Federal Court concerning some of the injunction's terms and whether certain activities would be caught.

[31] The Federal Court refused to give any direction or guidance. It advised that if Janssen wanted specific relief concerning the injunction, it would have to bring a motion.

[32] In response to that invitation, Janssen brought a motion to clarify the terms of the injunction. The Federal Court dismissed that motion.

[33] In these circumstances, Janssen says that further recourse to the Federal Court would not assist it. In its view, only this Court can rescue it from the real harm caused by the ambiguities in the terms of the injunction.

[34] I disagree. If ambiguities in the terms of the injunction cause it real harm, Janssen can seek a variation of the terms of the injunction from the Federal Court. The Federal Court is an adequate, alternative forum for that relief and Janssen has not properly sought that relief to date.

This is demonstrated by an examination of the *Federal Courts Rules*, *supra* and the Federal Court's reasons dismissing Janssen's motion.

[35] The general principle here is *functus officio*: an order, once made, cannot be revisited by the Court that made it. However, limited exceptions to this principle exist. In the Federal Courts, Rules 397-399 of the *Federal Courts Rules* express those exceptions. Two are in play here, Rule 397 and Rule 399.

[36] The scope of Rule 397 is set by its strict text. Under Rule 397, the Federal Court may correct the terms of an order if "the order does not accord with any reasons given," "a matter that should have been dealt with has been overlooked or accidentally omitted," or the order contains "[c]lerical mistakes, errors or omissions." To paraphrase, Rule 397 is available only for slips, errors and oversights in the preparation of the document expressing the Court's order. It is not a means by which the Court can revisit any part of the substance of its decision.

[37] In support of its motion to the Federal Court to clarify the terms of the injunction, Janssen invoked only Rule 397 of the *Federal Courts Rules*. The Federal Court dealt with it strictly on that basis. In its reasons dismissing the motion, the Federal Court noted that "there is no clerical error in [the] Judgment [setting out the injunction]" and the parties made "no comment…as to any amendment to [the] Judgment."

[38] I have no doubt that in bringing its motion to clarify the terms of the injunction, Janssen hoped that the Federal Court might supply more specific wording and direction supplementing,

modifying or replacing the terms of the injunction. However, that goes beyond slips, errors and oversights in the preparation of the document expressing the Court's order – *i.e.*, the subject-matter of the rule Janssen invoked, Rule 397. The Federal Court properly dismissed Janssen's motion.

[39] However, another route was – and still is – available to Janssen to try to gain the clarity it says it needs. Under Rule 399(2)(*a*), the Federal Court may set aside or vary an order "by reason of a matter that arose…subsequent to the making of the order."

[40] Janssen has had experience working under the injunction and today alleges that ambiguity in its terms is causing real difficulties. These real difficulties, if true and if proven satisfactorily, can potentially qualify as "a matter that arose…subsequent to the making of the order." Janssen can ask the Federal Court to supplement, modify or replace what it says are unclear terms with clear terms.

[41] If Janssen brings a motion in the Federal Court under Rule 399(2)(*a*), it will be for that Court to determine whether the real difficulties alleged by Janssen constitute "a matter that arose…subsequent to the making of the order." The Federal Court could take the view that the difficulties were fully canvassed before the injunction was made and the wording of the injunction represents its final solution to them. In oral argument, Janssen appears to be taking the position that many of the difficulties it says are now happening were unforeseen and unaddressed at the time the Court set the terms of the injunction. To the extent that is true, a motion under Rule 399 is open to it. The Federal Court has said nothing foreclosing Janssen's resort to one of

the exceptions to *functus officio* – a Rule 399 motion supported by detailed, concrete and proper evidence.

[42] In argument before me, the spectre of constant, repetitive Rule 399 motions was raised. This is unpersuasive. Only concrete matters of such significance warranting a change to the terms of the injunction can qualify, and that threshold is quite high: *Ayangma v. Canada*, 2003 FCA 382, 313 N.R. 312; *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2007 FCA 407, 371 N.R. 174. An even higher threshold must be met to set aside all of an injunction or a key part of it: *Del Zotto v. Canada (M.N.R.)*, [1996] 2 C.T.C 22, 195 N.R. 74 at paragraph 12 (F.C.A.); *UHA Research Society v. Canada (Attorney General)*, 2014 FCA 134 at paragraph 9. Further, the Federal Court has the power to prevent relitigation, among other things by ordering (following brief written submissions) that an improperly filed notice of motion be removed from the court file under Rule 74: in analogous circumstances, see *Rock-St Laurent v. Canada (Citizenship and Immigration)*, 2012 FCA 192.

[43] In a situation such as this, a party moving for variation of the injunction under Rule 399 would have to present specific, particularized evidence of significant, unforeseen difficulty in following its terms. Absent significantly changed circumstances later, it would likely be limited to only one kick at the can.

[44] Quite aside from Janssen's ability to pursue a motion under Rule 399 to clarify any ambiguities – as yet unpursued – Janssen's stay motion in this Court must fail for another reason. Its evidence of irreparable harm falls short of the mark. It has not presented evidence of

sufficient particularity concerning what actions, activities, plans or communications have been or will be affected by the injunction's ambiguity.

[45] General assertions cannot establish irreparable harm. They essentially prove nothing:

> It is all too easy for those seeking a stay in a case like this to enumerate problems, call them serious, and then, when describing the harm that might result, to use broad, expressive terms that essentially just assert – not demonstrate to the Court's satisfaction – that the harm is irreparable.

(*Stoney First Nation v. Shotclose*, 2011 FCA 232 at paragraph 48.) Accordingly, "[a]ssumptions, speculations, hypotheticals and arguable assertions, unsupported by evidence, carry no weight": *Glooscap Heritage Society v. Minister of National Revenue*, 2012 FCA 255 at paragraph 31.

[46] Instead, "there must be evidence at a convincing level of particularity that demonstrates a real probability that unavoidable irreparable harm will result unless a stay is granted": *Glooscap*, *supra* at paragraph 31. See also *Dywidag Systems International, Canada, Ltd. v. Garford Pty Ltd.*, 2010 FCA 232 at paragraph 14; *Canada (Attorney General) v. Canada (Information Commissioner)*, 2001 FCA 25, 268 N.R. 328 at paragraph 12; *Laperrière*, *supra* at paragraph 17.

[47] The main affidavit offered by Janssen on irreparable harm says that "extremely complicated questions" are arising about the scope of the injunction and these questions are "difficult to answer" as they have "many grey areas of uncertainty": Motion Record at page 9. But the Court is told neither the questions nor the areas of uncertainty.

[48] The affidavit says that "[c]omplications in drawing the line between permitted and non-permitted activities" are arising with "potential risk": Motion Record at page 16. But specifics regarding the complications are missing.

[49] A communication plan is being developed in the face of "difficulties" but has not been implemented: Motion Record at pages 11-13. But even if Janssen had settled on its communication plan and disclosed it to the Court – in other words, even if the matter were not premature – it is unclear what the "difficulties" are.

[50] "Practical problems" are said to arise when Janssen's representatives discuss another drug with clients (Motion Record at page 13), but it is unclear what those problems are and no specific examples are offered.

[51] Disseminating medical information might run afoul of the prohibition in paragraph 2 of the injunction against Janssen "influencing" physicians (Motion Record at page 16), but exactly what information might be disseminated is unclear.

[52] In oral argument, Janssen emphasized this last-mentioned point, stressing the breadth and vagueness of the word "influencing" in paragraph 2 of the injunction. Arising from that one fuzzy word, Janssen hypothesized all sorts of potential harm that might arise.

[53] But the word "influencing" must be seen in its context. Paragraph 1 of the injunction prohibits "making, using, selling, offering for sale or promoting" any infringing product, such as

Stelara. Paragraph 2 operates as an exception. It allows Janssen to continue to provide Stelara to patients already using it under a physician's prescription or to provide Stelara to new patients whose physician "has determined that [it] is necessary for that purpose." But that is subject to one condition: Janssen "shall not communicate directly or indirectly with any such physician for the purpose of influencing the decision to initiate or continue such treatment." Seen in its actual context, "influencing" does not sit in isolation with a sprawling meaning poised to trap Janssen. It is qualified. And practical steps available to Janssen qualify it further: Janssen can protect itself against harm by documenting all its contacts with physicians and memorializing the purpose and content of any communications. Nothing in Janssen's evidence proves that irreparable harm will arise in the face of these qualifications.

[54] Moving from the terms of the injunction to the nature of the harm that Janssen says it will suffer, Janssen's motion is again flawed. Much of the harm identified by Janssen is the sort of inconvenience suffered by any party when it must comply with an injunction – issues of interpretation, judgment calls and practical implementation. Undoubtedly these can create burdens, uncertainties and risks.

[55] But an injunction cannot be suspended just because it creates usual or normal burdens, uncertainties or risks. Otherwise, injunctions that, as here, are intended to take immediate effect would almost always be suspended as a matter of course. That would conflict with the consistent thread running through the *RJR-MacDonald* test for a stay – the need to engage in a careful, case-by-case, fact-specific balance between fairness and the principle of legality: see *Janssen*, *supra*, at paragraphs 19-26. A moving party seeking to suspend an injunction pending appeal

must adduce evidence showing unusual or abnormal burdens, uncertainties and risks. Here, that evidence is missing.

[56] Overall, for the reasons set out above, despite the very able submissions of Janssen's counsel, irreparable harm has not been established.

[57] Therefore, for the foregoing reasons, I shall dismiss Janssen's stay motion with costs. As mentioned, the appeals shall be heard together and set down for hearing in October, 2014.

[58] I thank all parties' counsel, including junior counsel, for their excellent submissions and high-quality written materials.

"David Stratas"

J.A.

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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