Date: 20070426

Docket: T-762-06

Citation: 2007 FC 352

BETWEEN:

BAYER HEALTHCARE AG and
BAYER INC.

Plaintiffs

and

SANDOZ CANADA INCORPORATED

Defendant

PUBLIC REASONS FOR JUDGMENT
(Confidential Reasons for Judgment issued April 2, 2007)

MACTAVISH J.:

[1] Bayer HealthCare AG and Bayer Inc. (referred to collectively in this decision as "Bayer") sought an interim or interlocutory injunction restraining Sandoz Canada Incorporated from manufacturing, constructing, importing, exporting, selling, offering for sale or using Sandoz' ciprofloxacin intravenous formulation, or any other intravenous formulation of ciprofloxacin, on the basis that these activities would allegedly infringe Canadian Patent No. 1,282,006 (the "'006 patent").

[2] Bayer asked that Sandoz be enjoined from dealing in ciprofloxacin intravenous formulations until the earlier of the hearing and disposition of an application for judicial review in a related proceeding, the expiry of the ’006 patent, or the trial of this matter.

[3] Sandoz had previously undertaken not to launch its intravenous ciprofloxacin product until March 6, 2007, that is, the date on which Bayer’s motion for an injunction was heard. Sandoz subsequently agreed to extend that undertaking to Friday, March 9, 2007.

[4] As Sandoz had received a Notice of Compliance for its ciprofloxacin product, as of March 9, it would have been in a position to enter the marketplace with its intravenous ciprofloxacin product, unless enjoined by the Court. Given the urgency of the matter, I dealt with this matter by way of an order on March 9, 2007, whereby I dismissed Bayer’s motion, with reasons to follow.

[5] These are my reasons for that decision.

Background

[6] Bayer originally developed a drug containing ciprofloxacin for use in injection or infusion solutions. Ciprofloxacin is a fluoroquinolone antibiotic. This invention was the subject of Canadian Patent No. 1,228,547 (the “’547 patent”). This patent expired on February 17, 2004.

[7] There were problems with this formulation. Some patients developed phlebitis at their injection sites, and others developed kidney crystalluria, as a result of the solution precipitating out in the kidneys.

[8] Bayer then developed a new drug that avoided these side effects by adding lactic acid to the formulation in specified ratios. This invention is the subject of the ’006 patent.

[9] The ’006 patent is owned by Bayer HealthCare AG. It covers infusion solutions of ciprofloxacin. Ciprofloxacin products are sold by Bayer Inc. in Canada under the brand name Cipro® I.V., under licence from Bayer HealthCare AG.

[10] Amongst other things, the ’006 patent claims:

> 1. An infusion solution of 1-cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-7-(1-piperazinyl)-quinoline-3-carboxylic acid (=ciprofloxacin) which contains 0.015 to 0.5g of the active compound per 100ml of aqueous solution and an amount of a physiologically tolerated acid which suffices to dissolve the active compound and to stabilize the solution, and, where appropriate, one or more formulating auxiliaries.

[11] The ’006 patent also claims other variations of an infusion solution, as well as uses of the infusion solutions. In this regard, Claim 26 claims a concentrate which can be converted into an infusion solution of claims 1, 2 and 3. Claims 36 and 37 relate to the use of an infusion solution for therapeutic treatment in humans and in dosage units having removable contents of 40-600 mL.

[12] The ’006 patent will expire on March 26, 2008.

[13] In 1992, Bayer began selling its ciprofloxacin intravenous formulation in a concentrated form, which was stored in vials. In 1999, Bayer began phasing out its ciprofloxacin vials, and began selling reconstituted ciprofloxacin in ready to administer “mini-bags”.

[14] Given that Bayer’s ciprofloxacin products are intended for parenteral administration, the market for these products is essentially limited to hospitals.

[15] The ’006 patent has been the subject of previous litigation. In September of 2004, a Notice of Compliance was issued to Sabex, a predecessor of Sandoz, for a 10mg/mL ciprofloxacin solution. Bayer then commenced an action for patent infringement against Sabex, as well as an application for judicial review requesting that the Minister of Health quash Sabex’s NOC. Sabex’s Notice of Compliance was then rescinded by the Minister.

[16] In another case involving the same drug and patent, the Minister of Health required Novopharm Limited to address the ’006 patent in relation to its submission for a 2 mg/mL ciprofloxacin intravenous formulation. This ultimately cumulated in an application for prohibition being brought in this Court. In *Bayer AG v. Novopharm Limited* (2006), 48 C.P.R. (4th) 46, 2006 FC 379, Justice Phelan granted a prohibition order against the issuance of an NOC to Novopharm.

[17] Subsequent to Justice Phelan's decision being handed down, a prohibition order was granted by this Court, on the consent of the parties, against Pharmaceutical Partners of Canada with respect to its 10 mg/mL ciprofloxacin intravenous formulation until the expiry of the '006 patent.

[18] On April 18, 2006, Sandoz received a Notice of Compliance for its ciprofloxacin formulation. Bayer contends that this is the identical formulation to Sabex's ciprofloxacin intravenous formulation.

[19] On May 4, 2006, Bayer commenced this action in the Federal Court alleging, amongst other things, that Sandoz had infringed the '006 patent.

[20] Bayer also commenced an application for judicial review in which it seeks to quash the decision of the Minister to issue a Notice of Compliance to Sandoz for its ciprofloxacin formulation. A hearing in that matter is scheduled for April 12, 2007.

[21] On May 26, 2006, Bayer brought its motion for an injunction. It appears that the parties have been in discussions, and that Sandoz had undertaken to stay off of the market for the past year. Although Bayer's motion was not brought on for hearing until March of 2007, there is no issue between the parties as to any delay in bringing this matter on for hearing.

[22] As Sandoz had not yet actually entered the market with its ciprofloxacin product at the time that the motion was heard, the motion was brought *quia timet*: that is, it is based on the harm that Bayer anticipated that it would suffer if Sandoz was not enjoined from proceeding by the Court.

Issue

[23] In determining whether Bayer is entitled to an interlocutory injunction, the test is that established by the Supreme Court of Canada in *RJR-MacDonald Inc. v. Canada (Attorney General)* [1994] 1 S.C.R. 311. That is, Bayer must establish that:

1. There is a serious issue to be tried;
2. It will suffer irreparable harm if the injunction is not granted; and
3. The balance of convenience favours the granting of an injunction.

[24] Given that the test is conjunctive, Bayer had to satisfy all three elements of the test before it would be entitled to relief.

Preliminary Issue

[25] Sandoz objects to Bayer filing and relying upon two affidavits filed by Bayer in reply, namely those of Lida Steduto and Graham Downie. Being satisfied that the affidavits contain proper reply evidence, and in the absence of any demonstrated prejudice to Sandoz, I am prepared to consider the contents of those affidavits in my deliberations.

Serious Issue

[26] In *RJR-MacDonald*, the Supreme Court of Canada observed that the threshold for establishing the existence of a serious issue:

> [I]s a low one ... Once satisfied that the application is neither vexatious nor frivolous, the motions judge should proceed to consider the second and third tests, even if of the opinion that the plaintiff is unlikely to succeed at trial. A prolonged examination of the merits is generally neither necessary nor desirable. (at pp. 337-338)

[27] In this case, Sandoz concedes that there is a serious issue to be tried, and that Bayer has satisfied the first element of the *RJR-MacDonald* test. However, Sandoz says that the granting of an injunction would have the effect of finally disposing of the action, and that, as a result, it is necessary to take a "hard look" at the merits of Bayer's claim, in weighing where the balance of convenience lies. However, given my conclusion on the issue of irreparable harm, it is unnecessary to consider the balance of convenience.

Irreparable Harm

[28] The vast majority of the hearing was taken up with a consideration of the issue of irreparable harm, and indeed, the result turned on this question. Before addressing the parties' submissions in this regard, it is helpful to start by considering what the Courts have said on the question of irreparable harm.

[29] In *Aventis Pharma S.A. v. Novopharm Ltd.* (2005), C.P.R. (4th) 210, 2005 FC 815; aff'd 2005 FCA 390, 44 C.P.R. (4th) 326, Justice Russell provided a useful overview of the law relating to irreparable harm, observing that:

> [59] As Mr. Justice Kelen pointed out in *Pfizer Ireland Pharmaceuticals*, at para. 25, it is well established in the jurisprudence that an interlocutory or interim injunction should only be granted in cases where there is clear evidence of irreparable harm. The Plaintiffs must adduce "clear and not speculative" evidence that irreparable harm will follow the entry of Novopharm's Novo-enoxaparin into the market.
>
> [60] It is also well understood that irreparable harm refers to the nature of the harm suffered rather than its magnitude. As the Supreme Court of Canada pointed out in *RJR-MacDonald*, it is "harm which either cannot be quantified in monetary terms or which cannot be cured, usually because one party cannot collect damages from the other." (p. 341)
>
> [61] Furthermore, difficulty in precisely calculating damages does not constitute irreparable harm, provided there is some reasonably accurate way of measuring those damages. See *Merck & Co. v. Nu-Pharm Inc* (2000), 4 C.P.R. (4th) 464 at 476 para. 32 (F.C.T.D.).

Irreparable Harm and Quia Timet Injunctions

[30] While acknowledging that, in the ordinary case, a party seeking an injunction will be required to adduce clear and convincing evidence that it will suffer irreparable harm if the injunction is not granted, Bayer submits that the evidentiary burden on a moving party is lower where the injunction is sought on a *quia timet* basis.

[31] In this regard, Bayer says that it need only demonstrate that reasonable inferences can be drawn from the evidence that irreparable harm to Bayer will result if Sandoz is not prevented from entering the marketplace with its ciprofloxacin intravenous formulation.

[32] In support of this proposition, Bayer relies on the following extract from the decision of Justice Rothstein, then of this Court, in *Ciba-Geigy Canada Ltd. v. Novopharm Ltd.* (1994) 86 F.T.R. 161, 56 C.P.R. (3d) 289, where he observed that:

> [118] I acknowledge that *I shall draw inferences from the evidence* and therefore, the observation of Heald J.A. in *Centre Ice*, [cited below], that proof of irreparable harm cannot be inferred, must be addressed. I interpret Heald J.A. in *Centre Ice*, (supra), to be saying that there must be an evidentiary basis … [of] irreparable harm not compensable in damages…
>
> [119] I do not understand him to be saying that a motions judge may not make inferences that reasonably flow from the evidence. Indeed, the drawing of inferences is virtually always necessary [in civil actions] … In the context in which he says that inferences are not acceptable, I think Heald J.A. was saying that evidence on one element … could not by inference, prove what was required in respect of another related but distinct element … Proof of each element requires its own evidentiary basis. *But once some evidence of an element is present, inferences that logically and reasonably flow from that evidence may be drawn.*
>
> [120] It will be remembered that these applications are brought *quia timet.* There is no actual evidence of harm because the defendants are not yet in the market-place. *The evidence relating to loss resulting in irreparable harm must, of necessity, be inferred. I do not think that Heald J.A. was precluding the drawing of such inferences or other inferences that*

> *logically follow from the evidence.* [Bayer's emphasis]

[33] In considering this statement, however, it is helpful to also have regard to the paragraph of the decision that preceded the extract relied upon by Bayer. That is, Justice Rothstein commenced his comments by observing that:

> [117] In order to establish irreparable harm the plaintiff's evidence must be clear and not speculative (see *Imperial Chemical Industries PLC v. Apotex Inc.*, (supra), at page 351). Further, proof of irreparable harm cannot be inferred (see *Centre Ice Ltd. v. National Hockey League* (1994), 53 C.P.R. (3d) 34 (F.C.A.) at page 54).

[34] As I read the jurisprudence relied upon by Bayer, including the decisions in *Boston Pizza International Inc. v. Boston Market Corp.* (2003), 231 F.T.R. 161, 26 C.P.R. (4th) 78, 2003 FCT 382, and *826129 Ontario Inc. (c.o.b. CD Plus) v. Sony Kabushiki Kaisha (c.o.b. Sony Corp.)* (1995), 105 F.T.R. 99, 65 C.P.R. (3d) 171, an applicant seeking a *quia timet* injunction may establish that it will suffer irreparable harm through inferences that can reasonably be drawn from the evidence before the Court, but that at the end of the day, the applicant's evidence of irreparable harm must nevertheless be clear and not speculative.

[35] That is, paraphrasing another decision of Justice Rothstein, this time in *Sports Authority, Inc. v. Vineberg* (1995), 95 F.T.R. 96, 61 C.P.R. (3d) 155 at ¶ 4, mere assertions of harm through loss of personnel or sales are insufficient to prove irreparable harm. In a motion for a *quia timet* injunction, there is no evidence of actual harm because the allegedly infringing party is not yet in

the marketplace. Therefore, logical inferences must be drawn from the evidence. However, to demonstrate irreparable harm, an applicant must lead clear evidence showing how such harm will occur and why it will be irreparable. In the absence of such evidence, there is nothing on which an inference of irreparable harm can reasonably and logically be based.

[36] With this understanding of the applicable standard of proof required in matters such as this, I will now consider Bayer's submissions on this issue of irreparable harm.

Bayer's Assertions of Irreparable Harm

[37] Bayer says that unless Sandoz is enjoined from dealing in its ciprofloxacin intravenous formulations, Bayer will suffer significant, irreparable harm in three different but inter-related ways.

[38] Firstly, by "springboarding" into the market now, a year before the expiry of the '006 patent, Sandoz will deprive Bayer of an unrecoverable market share, and non-compensable revenue for the period between the expiry of the '006 patent in March of 2008, and the trial of this matter.

[39] That is, the advantage gained by Sandoz as a result of its premature entry into the market will continue to result in losses to Bayer in the months immediately following the expiry of the '006 patent, which damages, Bayer says, are not recoverable in law.

[40] Secondly, Bayer risks losing [*], which would ultimately result in its loss of [*], causing irreparable harm to the company.

[41] In this regard, Bayer says that the revenues which it would otherwise receive from the sale of its Cipro® I.V. mini-bags between now and March of 2008 (when generic competition should properly begin) would enable it to retain its [*].

[42] Bayer's [*] two intravenous antibiotic drugs – namely Cipro® I.V. and Avelox® I.V.

[43] Avelox® I.V. is another anti-infective which was introduced by Bayer within the last three years. While there is significant overlap between the market for Cipro® I.V. and that for Avelox® I.V., ciprofloxacin is evidently more effective in the treatment of infections caused by gram negative bacteria, whereas Avelox® I.V. is more effective in the treatment of gram positive bacteria.

[44] Avelox® I.V. currently has approximately [*] in sales, in contrast with the [*] in sales of ciprofloxacin currently enjoyed by Bayer. Both products are sold to hospitals by Bayer [*].

[45] Bayer's plan is to [*].

[46] Bayer's overall plan is thus to [*] to the point where new sales will replace the significant loss of revenues that will be suffered by the company after the expiry of the '006 patent. The continued [*] is allegedly critical to Bayer's plans.

[47] According to Bayer, being able to [*] during the upcoming transition year depends entirely on it retaining market exclusivity for Cipro® I.V.

[48] Bayer says that it is at a particularly vulnerable point because [*]. Moreover, Bayer will immediately begin to lose significant market share and revenue for its Cipro® I.V. once Sandoz launches its intravenous ciprofloxacin product. This will inevitably result in the loss of its [*].

[49] The loss of its [*] will cause Bayer's sales of [*] to suffer, and will further result in Bayer being unable to [*]. The failure of these initiatives will result in incalculable harm to Bayer's [*], and damage to its reputation in that area of its business.

[50] Finally, Bayer says that denying the injunction would result in irreparable loss of the time-limited monopoly right granted to Bayer in exchange for Bayer having disclosed its invention.

Analysis

[51] I will deal first with Bayer's "Springboarding" argument. "Springboarding" refers to a competitor establishing a generic brand in the market in advance of the expiry of the innovator's patent. Early entry into the marketplace allows the competitor to 'ramp up' and achieve a share of market penetration prior to the expiration of the patent in issue.

[52] In this regard, it will be recalled that Bayer asserts that it will suffer irreparable harm in this matter because the advantage gained by Sandoz as a result of its premature entry into the market will continue to result in losses to Bayer in the months immediately following the expiry of the '006

patent. According to Bayer, these damages are not recoverable in law, and thus amount to irreparable harm.

[53] In support of this proposition, Bayer relies on two decisions of the Federal Court of Appeal, namely *Janssen-Ortho Inc. v. Novopharm Ltd.*, 2006 FCA 406 and *Apotex Inc. v. Merck & Co.* (2006), 53 C.P.R. (4th) 79, 2006 FCA 198.

[54] A review of these decisions reveals that they do not stand for the proposition advanced by Bayer. Both decisions relate to motions brought by unsuccessful defendants in patent infringement actions who were seeking stays of adverse trial judgments pending the defendants' appeals of those decisions. The issue before the Federal Court of Appeal in those cases was whether the damages that *defendants* might suffer as a result of a trial judgment would amount to irreparable harm, in the event that the trial judgments were subsequently reversed on appeal.

[55] As Justice Evans noted in the *Merck* decision, this was a concern, as the defendants would not have a right of action against the plaintiffs for any damages that the defendant might suffer as a consequence of the trial judgment, and thus would not have been able to recover damages for any losses that they may have sustained. In both cases, this concern was addressed by an undertaking in damages given by the plaintiffs pending the appeal.

[56] This is not the situation here. Bayer has a right of action against Sandoz for the alleged infringement of the '006 patent, and it is asserting that right through this action. Damages in patent

cases are intended to put a successful plaintiff in the position that it would have been in, but for the infringement. It is, in my view, entirely speculative for Bayer to say at this point that it will not be able to recover damages for any losses that it may suffer in the post-expiry period, as a matter of law, and indeed there is authority for the proposition that such damages are indeed recoverable: see *Gerber Garment Technology Inc. v. Lectra Systems Ltd. et al.*, [1995] R.P.C. 383, aff'd [1997] R.P.C. 443.

[57] Indeed, in refusing to grant an interlocutory injunction in *Bristol-Myers Squibb Co. et al. v. Apotex Inc.*, (2001) 15 C.P.R. (4th) 190, 2001 FCT 1086 at ¶ 22, Justice MacKay specifically rejected the very argument advanced by Bayer in this case, noting that "damages will be calculated in reasonable fashion, providing a normal remedy for infringement, if the trial finds that to have occurred, *whether those are caused before or after expiry of the plaintiffs' patent*." [My emphasis.]

[58] I am also not persuaded that Bayer's damages in the post-expiry period are not quantifiable. While these losses may be difficult to quantify, it is well-established that the mere fact that it may be difficult to quantify a party's losses does not mean that they amount to irreparable harm, as long as there is some reasonably accurate way of calculating those damages: see *Merck & Co. v. Nu-Pharm Inc.* (2000), 4 C.P.R. (4th) 464, at ¶ 32.

[59] Moreover, Bayer's submission is not supported by the evidence. Bayer's evidence on the question of damages was adduced, in part, through Tom Brogan, an economist with expertise in the pharmaceutical industry. In cross-examination, Mr. Brogan acknowledged that while it may be

difficult to project Bayer's losses on a forward-looking basis, these losses could be quantified on an after-the-fact basis.

[60] That Bayer's losses in the post-expiry period can indeed be quantified was also confirmed by the evidence of Suzanne Loomer, Sandoz' expert. Ms. Loomer is a Chartered Accountant and Chartered Business Valuator, who confirms that any losses that Bayer may sustain as a result of Sandoz entering the marketplace with its ciprofloxacin product are quantifiable, for both the pre- and post-expiry periods.

[61] I am also not persuaded that any permanent loss of market share on the part of Bayer that may result from Sandoz' early entry into the market will amount to irreparable harm, as is alleged by Bayer. In support of this contention, Bayer relies on cases such as this Court's decision in *Proctor & Gamble Inc. v. Colgate Palmolive Canada Inc.* (1995), 61 C.P.R. (3d) 160, at page 177.

[62] The *Proctor & Gamble* case related to fabric softener sheets. In that case, the Court determined that in the event that the defendant was permitted to enter the market in advance of the expiry of the plaintiff's patent, the defendant would be a much stronger competitor of the plaintiff in the post-patent expiry period, resulting in a permanent loss of market share. In the Court's view, based upon the evidence before it in that case, this amounted to irreparable harm.

[63] In my view, the fact that the *Proctor & Gamble* case was not a pharmaceutical case is significant, given the unique dynamic of the pharmaceutical industry. That is, it is predictable that

as soon as a patent expires, the innovator of the drug in question will lose a substantial portion of its market share to generic competitors, without any realistic expectation that the innovator company will be able to recover that market share in the future. As such, I am of the view that cases such as *Proctor & Gamble* are of limited assistance.

[64] The real issue will be Bayer's loss of market share between now and the expiry of the '006 patent in March of 2008, and in the months immediately following the expiry of the patent. As noted above, I am satisfied that these damages are both quantifiable and recoverable, and thus do not amount to irreparable harm.

[65] The next issue, then, is whether Bayer has established that it will face irreparable harm by losing [*] as a result of competition from Sandoz, leading in turn to the loss of Bayer's [*].

[66] Relying upon the evidence of Mr. Brogan, Bayer asserts that as soon as Sandoz enters the market, sales of Bayer's ciprofloxacin mini-bags will immediately begin to drop sharply. Noting that the hospital market for pharmaceuticals is extremely price-sensitive, Bayer points to the fact that the price for a single dose of ciprofloxacin prepared from one of Sandoz' ciprofloxacin vials is expected to be approximately [*] less than the cost of a dose from one of Bayer's ciprofloxacin mini-bags as the cause of its projected loss of sales.

[67] Moreover, Sandoz is clearly ready to enter the market. In this regard, the company has admitted having already manufactured [*] vials of its intravenous ciprofloxacin formulation, which

is evidently an amount sufficient to satisfy the entire Canadian market for intravenous ciprofloxacin products for a period of more than [*].

[68] Bayer currently enjoys approximately [*] in annual sales of its ciprofloxacin mini-bags. Bayer estimates that it will lose [*] of these sales within [*], if Sandoz is allowed to enter the market.

[69] Without these sales, Bayer says that [*]. Without [*], Bayer will be unable to [*], or to grow its [*] business to the point that it can compensate for the loss of its Cipro® I.V. business. The cumulative effect of this will be to prevent Bayer from making an orderly transition to a post-patent expiry reality, with the resultant loss of its [*].

[70] I do not accept Bayer's submissions in this regard, as there are a number of problems with Bayer's evidence on these points. Insofar as Bayer's [*] are concerned, it appears that notwithstanding the value that Bayer allegedly places on [*], Bayer itself has recently [*].

[71] Moreover, despite Bayer's assertion that these [*] are [*] other Bayer products if sales of Cipro® I.V. declined, Bayer has recently [*].

[72] It should also be observed that the [*] discussed in the preceding paragraphs were made for reasons that had nothing to do with Sandoz' pending entry into the intravenous antibiotic marketplace.

[73] There are also significant frailties in Bayer's evidence with respect to the extent to which Bayer will lose sales, if Sandoz is allowed to enter the marketplace.

[74] As was explained by Bayer's witness, Jean-Yves Julien, a consultant pharmacist with Partagec Inc., a purchasing organization buying drugs on behalf of hospitals in the Quebec City region, the hospital pharmaceutical market differs from the retail market in some significant respects.

[75] In many areas of the country, there are buying groups that purchase pharmaceutical products on behalf of a number of member hospitals. These purchases are made pursuant to contracts between the group and the pharmaceutical company.

[76] Mr. Julien acknowledged that a number of these contracts have "partner protection" provisions that protect vendors for periods of up to 12 months. These provisions mean that vendors do not have to renegotiate their prices when cheaper products come on to the market during the life of the contract.

[77] In such cases, the buying group in question would be obliged to continue to purchase their intravenous antibiotic products from the vendor at the original contract price.

[78] Thus it is by no means clear that hospitals would be able to purchase Sandoz' ciprofloxacin product right away, even if the hospitals wanted to do so. Indeed, some hospitals may not be able to switch suppliers at all during the remaining term of the '006 patent.

[79] Moreover, while price is clearly a very important factor for the purchasers of intraveneous antibiotics, there are practical reasons why hospitals may be reluctant to switch over to Sandoz' product, notwithstanding the significant price advantage associated with Sandoz' ciprofloxacin vials.

[80] Unlike Bayer's Cipro® I.V. mini-bags, which are ready to use, medication from Sandoz ciprofloxacin vials has to be diluted prior to being administered to patients. This requires additional staff time, and creates the potential for human error. In addition, unlike Bayer's Cipro® I.V. mini-bags, which can be stored at room temperature for years, mini-bags prepared in hospitals with Sandoz' ciprofloxacin product must be refrigerated, and must be administered within 14 days of preparation.

[81] Given that generic ciprofloxacin mini-bags will be available in Canada as of March 2008, there is a real question as to the extent to which hospitals will want to switch to Sandoz ciprofloxacin vials between now and next March, assuming that their purchasing contracts would allow them to do so.

[82] Moreover, in cases where both Bayer and Sandoz' ciprofloxacin products were on hospital formularies, there is evidence that Bayer's product would be favoured over that of Sandoz. In this regard, I refer to the evidence of Linda Dresser, a hospital pharmacist and Bayer's own witness, who conceded that in such circumstances, hospital pharmacists would be more likely to use the Bayer mini-bag for the day-to-day filling of prescriptions.

[83] As a consequence, Bayer has not persuaded me that its lost sales will be anywhere near the [*] order of magnitude estimated by the company. This in turn leads me to doubt that Bayer will lose its [*], and with [*], its [*].

[84] I am also not persuaded that Sandoz' entry into the intraveneous ciprofloxacin market will result in Bayer being unable to continue to sponsor programs such as the [*] and [*] programs that Bayer says are essential to the development of long-term relationships with key customers. We do not have clear information on the cost of these programs, but we do know that Bayer evidently funds the programs out of its Cipro® I.V. sales.

[85] Bayer does not say that it could not keep sponsoring these types of programs, if it really felt that it was essential that it do so. According to Graham Downie, Bayer's Market Manager for Anti-infective-Hospitals, the costs of this type of promotional program has to "be contained within justifiable limits". That may be so from a purely business perspective, but if the programs are as essential as Bayer says they are, surely between now and trial they could be funded out of Bayer's substantial annual profits.

[86] Given that I am not persuaded that Bayer will lose its [*], I am similarly not persuaded that Bayer's [*] opportunities will be jeopardized if Sandoz is allowed to enter the market.

[87] Finally, with respect to Bayer's claim that denying the injunction would result in the irreparable loss of the time-limited monopoly right it was granted in exchange for having disclosed its invention, I adopt my earlier comments, and find that this loss is one that can be readily compensated for through an award of damages.

Balance of Convenience

[88] Having concluded that Bayer has failed to satisfy the irreparable harm branch of the test, it is unnecessary for me to consider where the balance of convenience lies in this case.

Sandoz Undertaking

[89] Sandoz has undertaken to keep an accounting of all its sales of vials of its ciprofloxacin intravenous product between now and trial. I am of the view that such an undertaking is appropriate, and the order issued in this matter included the requirement that Sandoz do so.

Costs

[90] In *Cutter Ltd. v. Baxter Travelnol Laboratories Ltd.* (1980), 47 C.P.R. (2d) 53, Chief Justice Thurlow observed that in cases such as this, costs are often awarded "in the cause". While this is by no means a hard and fast rule, I am of the view that such a disposition is appropriate in this case.

Bayer's Request for an Early Trial Date

[91] Although not requested in Bayer's Notice of Motion, at the hearing of the motion for the injunction counsel for Bayer asked that an early trial date be fixed for this case.

[92] It appears that this request was a bit of an afterthought, and that the parties clearly had not given any real consideration as to how long the trial will take, or how much time would realistically be required to prepare for the trial.

[93] This Court will fix early trial dates in appropriate cases. Without opining on whether such an order would be appropriate in this case, it is open to Bayer to seek to have this matter continue as a specially managed proceeding, and to bring a formal request for an expedited trial before the case-management judge or Prothonotary assigned to deal with this case. Such a request would have to be accompanied by a proposed schedule for the completion of the necessary pre-trial steps, as well as proper estimate of the time required for the trial itself.

That said, it should be noted that my analysis of the issues is not premised on the assumption that there would be an early trial in this matter.

"Anne Mactavish"
Judge

Ottawa, Ontario
April 26, 2007

FEDERAL COURT

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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