Federal Court  Cour fédérale

Date: 20100312

Docket: T-411-01

Citation: 2010 FC 287

Ottawa, Ontario, March 12, 2010

PRESENT: The Honourable Mr. Justice O'Reilly

BETWEEN:

APOTEX INC.

Plaintiff

and

MERCK & CO., INC. and
MERCK FROSST CANADA & CO.

Defendant

AND BETWEEN:

MERCK & CO., INC. and
MERCK FROSST CANADA & CO.

Plaintiff by Counterclaim

and

HER MAJESTY THE QUEEN IN RIGHT OF CANADA
as represented by
THE ATTORNEY GENERAL OF CANADA

Defendant to the Counterclaim

REASONS FOR JUDGMENT AND JUDGMENT

I. Overview

[1] The defendant Merck Frosst Canada & Co. holds the rights to a patented drug called norfloxacin. (On consent, the action against the other named defendant Merck & Co., Inc. was dismissed). In the early 1990s, Apotex Inc. tried to enter the market with a generic version of norfloxacin and, to that end, applied to the Minister of Health for a Notice of Compliance (NOC). Apotex alleged that it would not infringe the defendant's patent as it would either use norfloxacin raw material acquired by a third company, Novopharm Ltd., under a license from Merck, or it would produce norfloxacin by a method that would not infringe the patent.

[2] Merck filed two applications to prohibit the Minister from issuing an NOC to Apotex. In respect of the first, relating to the use of a non-infringing method of making norfloxacin, Justice Marshall Rothstein granted the order Merck sought, and the Federal Court of Appeal dismissed Apotex's appeal (*Merck Frosst Canada Inc.* v. *Canada* (*Minister of National Health and Welfare*), [1999] F.C.J. No. 209 (F.C.A.) (QL)).

[3] In respect of the second application, relating to the use of licensed material, Justice Sandra Simpson granted Merck its order in 1995 (*Merck Frosst Canada Inc.* v. *Canada (Minister of National Health and Welfare*) (1995), 65 C.P.R. (3d) 483 (F.C.T.D.)). Apotex appealed her decision unsuccessfully to the Federal Court of Appeal (*Merck Frosst Canada Inc.* v. *Canada (Minister of National Health and Welfare*) (1996), 67 C.P.R. (3d) 455 (F.C.A.)). Apotex appealed again to the Supreme Court of Canada and succeeded in having the prohibition order set aside on July 9, 1998 (*Merck Frosst Canada* v. *Canada*, [1998] 2 S.C.R. 193). A week later, the Minister issued Apotex its NOC.

[4] Apotex now seeks compensation from Merck under s. 8 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, as amended by SOR/98-166 (relevant regulatory provisions are set out in Annexes I and II). Apotex argues that it is entitled to relief for having been kept out of the norfloxacin market for several years while the parties were in litigation.

[5] Two issues arise:

1. Which version of the Regulations applies: the 1993 version, or the version that came into force in March 1998?

2. If Merck had not sought an order prohibiting Apotex from obtaining an NOC, would Apotex have been able to get onto the market and, if so, when?

[6] In short, I find that the 1998 version of the Regulations applies to this action and that Apotex would have entered the market sooner had it not been prohibited by the operation of the Regulations and the order Merck obtained in 1995. Therefore, Apotex is entitled under the Regulations to obtain compensation from Merck. According to a bifurcation order, this phase of the trial is devoted solely to determining whether Apotex has a basis in fact and law for its claim. The quantum of damages will be determined in a subsequent phase.

II. Analysis

1. *Which version of the Regulations applies: the 1993 version, or the version that came into force in March 1998*?

(a) Comparing the 1993 and 1998 versions of the Regulations

[7] The Regulations were amended on March 12, 1998, about four months before the Supreme Court of Canada decided that Merck was not entitled to its prohibition order. The transitional rule in the 1998 Regulations (s. 9(6)) states that the amended remedies section (s. 8) applies to applications that were "pending" at the time the new Regulations came into force.

[8] The 1998 version of s. 8 makes clear that a company that succeeded in obtaining a prohibition order that was later reversed on appeal must compensate the company that was prevented from getting onto the market for "any loss" suffered from the date a notice of compliance would otherwise have been granted to that company (or some other appropriate date) up until the date of the reversal.

[9] Apotex argues that Merck's application was "pending" at the time the 1998 Regulations came into force because its merits had not been finally determined. That did not happen until the Supreme Court of Canada ruled on it in July 1998. Therefore, Apotex argues, the 1998 Regulations, particularly the amended remedies clause, apply to Merck. Accordingly, Merck must compensate Apotex for its losses from the date Apotex would otherwise have obtained its NOC up until the date of the Supreme Court's ruling. Apotex says the former date is June 10, 1993 and the latter, obviously, is July 9, 1998.

[10] Merck argues that the 1998 Regulations do not apply because its application for a prohibition order was no longer "pending" at the time the new Regulations came into force. Its application, it submits, was decided by Justice Simpson in 1995. The *order* she granted was

appealed and its merits were not finally decided until the Supreme Court handed down its judgment, but the *application* itself was no longer pending.

[11] This is an important question for the parties because the meaning of the remedies provision of the 1993 Regulations is, by all accounts, murky. The 1993 version of s. 8 says that a patent holder is liable for all damage suffered by a second company seeking an NOC where the Minister delays issuing the NOC beyond the expiration of all patents that are the subject of a prohibition order. The Regulatory Impact Analysis Statement (RIAS) that accompanied the 1993 Regulations stated that the Governor-in-Council intended to create liability for a patent holder, like Merck, when a generic competitor, like Apotex, has wrongly been kept out of the market:

> In addition, some generic products that turn out [not] to have infringed an original applicant's product or use patents could be delayed under these Regulations where patents listed in a patentee NOC application turn out either not to be valid or not to be infringed by the sale of a later applicant's drug. However, the frequency and costs associated with any such delays arising from these Regulations will be minimized by the fact that such a patentee will be liable for all damage suffered from the delay.

[12] I must point out that the word "not" in the first sentence was not included in the original RIAS. However, this was an obvious oversight taking into account both the context, as well as the French version of the RIAS, which states that "certains produits génériques qui . . . *ne sont pas* des contrefaçons d'un brevet original pourrait avoir été retardée indûment . . .".

[13] Both parties presented plausible interpretations of what this section might mean. Apotex suggests that the 1993 and 1998 provisions, while differently worded, are identical in their effect. Merck maintains that the 1993 version creates no liability for it while the 1998 version creates

absolute liability. Frankly, the meaning of the 1993 version eludes me. As Justice James Hugessen said of it:

> Section 8 is particularly obscure in its meaning. It appears to create a liability in the first person in the event that the Minister should comply with the 30 month prohibition in circumstances where subsection 7(2) specifically provides that that prohibition shall have ceased to apply. Fortunately, we are not required to interpret it on this appeal. (*Merck Frosst Canada Inc*. v. *Canada (Minister of National Health and Welfare*) (1994), 55 C.P.R. (3d) 302 (F.C.A.) at 316)

[14] It seems reasonably clear from the RIAS that the Governor-in-Council's original intention was to create liability along the lines of what was promulgated in the 1998 Regulations. The 1998 RIAS states that the purpose of the amendment was to provide a "clearer indication" "as to the circumstances in which damages could be awarded to a generic manufacturer to compensate for loss suffered by reason of delayed market entry of its drug". From this, it seems the original intention was to create liability for patent holders where generic companies were denied early entry to the market, and that the purpose of the 1998 amendment was simply to make this clearer. However, in 1993, the Governor-in-Council apparently did not find words to express its intention. In 1998, it did.

[15] In any case, I do not have to determine definitively what the 1993 Regulations mean because, in my view, the 1998 version applies here. In other words, I conclude that Merck's application was, indeed, "pending" in March 1998 and, therefore, according to the transitional rule, the 1998 Regulations apply to this action.

(b) What is a "pending" application?

[16] Obviously, the word “pending” must take its meaning from the context in which it is used. Merck argues that one must look to the other words in the 1998 Regulations for guidance. It points out that the transitional rule (s. 9(6)) refers to applications pending at the time the Regulations came into force. The remedies section itself (s. 8) provides relief where an application “is withdrawn or discontinued” or “is dismissed by the court hearing the application” or if “an order preventing the Minister from issuing a notice of compliance . . . is reversed on appeal”. In Merck’s submission, when the transitional rule speaks of an application “pending” it is referring to the time period prior to an application being withdrawn, discontinued or dismissed. It is not referring to the point in time after the application has been granted and a prohibition order has been issued, even if the order is reversed on appeal. Had the provision been intended to apply to orders whose merits were pending before appellate courts, the provision would have used the word “order” not “application”.

[17] Merck further argues that to interpret the 1998 Regulations as applying to these circumstances would be to give them a retrospective effect. There is no specific authority given to the Governor-in-Council in the *Patent Act*, R.S.C. 1985, c. P-4, to enact retrospective regulations. Therefore, if I interpret the transitional rule as purporting to apply to these circumstances, Merck says I must find that it is beyond the regulatory authority of the Governor-in-Council. In support of that argument, Merck asserts that application of the 1998 remedies provision would interfere with its vested rights.

[18] In my view, Merck’s application for a prohibition order remained pending when the 1998 Regulations came into force. Accordingly, it is s. 8 of the 1998 Regulations that defines the

remedies available in the circumstances. As I read it, this provision does not operate retrospectively and, even if it did, it does interfere with any vested rights of Merck.

[19] In general, a pending matter is one in which further steps can be taken in it (*In re Clagett's Estate*; *Fordham* v. *Clagett* (1882), 20 Ch. D. 637 (C.A.), at 653)). A matter may be considered pending until it has been finally decided – "[t]he suit does not expire with the decision given by the trial judge". Rather, a proceeding is "still alive, still pending until all avenues of appeal have been exhausted" (*Hampton Lumber Mills Ltd.* v. *Joy Logging Ltd.*, [1977] 2 W.W.R. 289 (B.C.S.C.) at paras. 13, 20).

[20] Within the context of the 1998 Regulations, Justice Roger Hughes found that proceedings are pending if they are "not yet finished" and "there is no final judgment" (*Apotex Inc.* v. *Syntex Pharmaceuticals, et al.*, 2009 FC 494 at para. 38). By contrast, a final judgment is one that is rendered when "all appeals have disposed of the matter" (para. 39). By that reasoning, Merck's application was still pending when the 1998 Regulations came into force; the Supreme Court of Canada was still seized of the matter and had not rendered a final decision on the merits of Merck's application.

[21] Justice Hughes noted that, in the case before him, the application was not pending at the time the 1998 Regulations came into force. The Court had issued a prohibition order and an appeal from that decision had been dismissed well before the 1998 Regulations came into force on March 12, 1998. The matter was not pending; it was final. Therefore, the 1993 Regulations applied, not the 1998 version. At a later point, in 1999, the order was set aside by Justice Barbara Reed who, at the

same time, dismissed the underlying application. Justice Hughes found that the dismissal of the application would have triggered the remedy provision of the 1998 Regulations, had they applied.

[22] I note that in the matter before me the Supreme Court of Canada specifically dismissed Merck's application for an order of prohibition in its July 9, 1998 decision when it allowed Apotex's appeal. Both the dismissal of the application and the reversal of the decision on which the prohibition order was based trigger liability under the 1998 version of the Regulations. If Merck's application had not then been "pending", there would have been no reason for the Supreme Court to dismiss it.

[23] As mentioned, the word "pending" takes its meaning from the context in which it is used. Merck rightly points out that, for purposes of determining rights of appeal under s. 27 of the *Federal Courts Act*, R.S.C. 1985, C. F-7, s. 1; 2002, c. 8, s. 14, an application would not be pending after the Federal Court had ruled on it. It would be considered a final decision and amenable to appeal. In this case, the Federal Court decided Merck's application for prohibition in 1995 and, for purposes of Merck's right of appeal, the Court's decision was a final determination. In that context, one could not say that the application was pending.

[24] However, looking at the broader context, it could not be said, once appealed, that the merits of Merck's application had been finally determined. Its application was "pending" in the sense that its legal foundation was very much a live issue before the Supreme Court of Canada when the 1998 Regulations came into effect.

[25] Merck argues that the reference to an "application" in the transitional rule (s. 9(6)) corresponds only to the scenarios outlined in s. 8 in which an application is withdrawn, discontinued or dismissed. It does not extend to an order being reversed on appeal. By this interpretation, an application would be pending only up to the point when it is withdrawn, discontinued or dismissed. An application that gave rise to a prohibition order could not be said to be pending, even if appealed, Merck says. If the intention had been for the 1998 Regulations to apply to orders under appeal, the transitional rule would have used clearer language, such as "section 8 applies to all ongoing proceedings relating to the issuance of a prohibition order".

[26] I am not persuaded by this argument. First, as mentioned, the meaning of "pending" is reasonably clear and I must assume the drafters of the transitional rule would have been aware of its breadth. Second, as the 1998 RIAS describes, the purpose of the revised remedies provision was to clarify the liability of patent holders and not, as Merck suggests, to create an entirely new basis for it. It would not be unfair in that context to apply the amended provision to all cases that were in the system at that point and no particular reason to treat cases in which a prohibition order was under appeal differently from those at an earlier stage of litigation.

[27] Merck relies on the decision of the Federal Court of Appeal in *Hoffman-LaRoche Ltd., et al.* v. *Canada (Minister of National Health and Welfare), et al.* (1999), 235 N.R. 302 (F.C.A.). There, the Court found that when the Regulations refer to an application being "finally dismissed by the court" they mean dismissed by the Federal Court, not the Federal Court of Appeal or the Supreme Court of Canada. Accordingly, Merck says, an application should be considered pending only when it is before the Federal Court. I note, however, that the word "court" is defined in the Regulations

specifically to mean the Federal Court. The passage in issue in that case clearly related to the initial decision by the applications judge. The Regulations have since been amended to refer to the court "hearing the application" (s. 7(4), s. 8). However, in the transitional rule in s. 9(6) of the 1998 Regulations, the word "court" is not used. The provision merely refers to an "application pending" when the Regulations came into force. It does not refer to an "application pending before the court" or to an "application pending before the court hearing the application". When the Governor-in-Council wished to be specific about the relevant stage of proceedings, it used specific language.

[28] Further, I do not interpret the 1998 Regulations as interfering with Merck's vested rights. At best, before the 1998 Regulations came into effect, Merck had the right to have its liability to Apotex determined according to the 1993 version of s. 8, the meaning of which is wholly uncertain. This does not amount to a vested right. Merck had the right to argue that the 1993 version of s. 8 did not impose liability upon it but the outcome of such an argument is unknowable. No court has been required to interpret the former s. 8 and, it follows, no court has found that companies in Merck's circumstances were not liable to generic manufacturers kept out of the market by virtue of the operation of the Regulations. Merck had the right to urge a favourable interpretation of the Regulations on an attentive court, but no more. As mentioned, Merck submits that it went from having no liability under the 1993 Regulations to having absolute liability under the 1998 Regulations. In other words, it made its application to keep Apotex out of the market knowing that there would be no adverse economic consequences of doing so, even if it failed to obtain its prohibition order or if the order was later overturned. I think Merck overstates its case. In my view, it went from having uncertain liability in 1993 to having potential liability in 1998. It did not give up a vested right, only an untested argument. Merck repeatedly asserted that s. 8 of the 1993

Regulations was equivalent to an undertaking in damages and yet, at the same time, maintained that it not impose any obligations on Merck. I find this position unpersuasive. Accordingly, I cannot find that the 1998 Regulations have an impermissible retrospective effect, beyond the competence of the Governor-in-Council.

[29] Section 8 sets out the liability of a patent holder for losses of a generic competitor who was kept out of the market by virtue of the operation of the Regulations. That liability, on the facts of this case, was triggered by the Supreme Court of Canada's dismissal of Merck's application and its reversal of the prohibition order. That event did not take place until after the 1998 Regulations came into effect. Apotex's s. 8 claim could not been initiated until after the Supreme Court of Canada's ruling in July 1998 and the remedies provision of the 1998 Regulations, quite naturally, applied to it. Whether the 1993 Regulations would have given Apotex any relief is unknown, but there is nothing peculiar or unfair about Apotex initiating its action on the basis of the remedies provision then in force.

[30] One could say that, in this case, the 1998 Regulations govern events that straddle the date of its coming into force. Section 8 defines the scope of a patent holder's liability according to two dates – first, the date when the second company would have obtained its NOC but for the operation of the Regulations and, second, the date when the patent holder's prohibition order was overturned on appeal (or when its application was withdrawn or dismissed). In this case, the first date precedes the coming into force of the Regulations; the second date follows it. Justice Lebel described this situation as follows:

> New legislation does not operate retroactively when it is applied to a situation made up of a series of events that occurred before and after it came into force or with

> respect to legal effects straddling the date it came into force. If events are under way when it comes into force, the new legislation will apply in accordance with the principle of immediate application, that is, it governs the future development of the legal situation. If the legal effects of the situation are already occurring when the new legislation comes into force, the principle of retrospective effect applies. According to this principle, the new legislation governs the future consequences of events that happened before it came into force but does not modify effects that occurred before that date. (*Épiciers Unis Métro-Richelieu* v. *Collin*, 2004 SCC 59 at para. 46 (citations omitted)).

[31] Even on this characterization of the Regulations, I cannot see any interference with any vested rights Merck might have held. Therefore, to the extent the Regulations can be described as retrospective, I see no basis for Merck's argument that they run afoul of the general rule that subordinate legislation cannot operate retrospectively unless the enabling legislation clearly authorizes it.

[32] In conclusion, I find that the 1998 Regulations apply in this case. Merck is therefore liable to Apotex for "any loss suffered during the period" from the date Apotex would otherwise have obtained an NOC until the date Merck's application was dismissed. I come now to the second issue:

2. *If Merck had not sought an order prohibiting Apotex from obtaining a NOC, would Apotex have been able to get onto the market and, if so, when?*

(a) Burden of Proof

[33] In essence, I must decide if Apotex did, in fact, suffer a loss by having been kept out of the market by virtue of the prohibition proceedings Merck had initiated. This requires me to

consider what would have happened if Merck had not done so.

[34] Apotex argues that it does not have to prove on a balance of probabilities that, but for the operation of the Regulations, it would have entered the norfloxacin market. Rather, it need only show that it had a reasonable chance of doing so. The cases relied on by Apotex for this proposition deal with the calculation of damages where courts must consider the likelihood of future contingencies that might affect quantum (e.g., *Athey* v. *Leonati*, [1996] 3 S.C.R. 458; *Les Laboratoires Servier, et al.* v. *Apotex Inc., et al.*, [2008] E.W.H.C. (Ch.) 2347). But here we are considering Merck's liability for damages, not the quantification of those damages. At this stage, in my view, Apotex must show on a balance of probabilities that it was prevented from getting into the norfloxacin market because of Merck's prohibition application. As Justice Norris said in *Servier*, Apotex must "establish on the balance of probabilities that the chance of making a profit was real and not fanciful" (para. 5(e)). This is consistent with the approach taken by Justice Johanne Gauthier in *Eli Lilly and Company* v. *Apotex Inc.*, 2009 FC 991 at para. 762. In the circumstances, Apotex must show, at a minimum, that it had access to a supply of norfloxacin. Without that, its assertion that it was kept out of the market by Merck's prohibition application would be fanciful, not real.

[35] Section 8 provides relief within a defined period, beginning on the date the Minister would have issued an NOC to the generic manufacturer (unless some other date is more appropriate) and ending on the date the prohibition order was overturned. In this case, the relevant time frame is between June 10, 1993 and July 9, 1998. There is no basis in law for choosing a more appropriate

beginning date, although that is not to say that Apotex, as a matter of fact, started suffering a loss on June 10, 1993.

[36] As mentioned above, this phase of the trial is confined to determining whether Apotex has shown a basis in fact and law for its claim. Above, I found that s. 8 of the 1998 Regulations provides a basis in law for Apotex's claim. Now, I must decide whether Apotex has proved a factual basis for it – that is, whether it would actually have been able to enter the norfloxacin market before 1998 and, if so, when.

[37] In summary, Merck argues that Apotex has failed to meet that burden because Apotex has not proved that it had an available supply of non-infringing material that would have permitted it to get product on the market.

(c) Factors Affecting Market Entry

[38] I need only consider whether Apotex could have entered the market with material obtained from Novopharm under Novopharm's compulsory license with Merck. The other possible route, through use of norfloxacin manufactured by a non-infringing process, was foreclosed by the decisions of Justice Rothstein and the Federal Court of Appeal, where it was found that the process proposed by Apotex actually did infringe the patent. It was also held up, as a matter of fact, by the difficulties that Apotex's supplier, Delmar Chemicals Inc., encountered in producing norfloxacin by an allegedly non-infringing process without impurities.

[39] Apotex's alternative was to use material obtained through Novopharm. Novopharm had a compulsory license from Merck for norfloxacin and had a reciprocal agreement with Apotex to supply licensed material on request. The Federal Court of Appeal concluded that this supply agreement amounted to an improper sublicense but the Supreme Court of Canada found otherwise in its decision of July 9, 1998. Therefore, the supply agreement created a means by which Apotex could, at least in theory, enter the norfloxacin market without infringing Merck's patent rights.

[40] In my view, however, Apotex was not in a position to enter the norfloxacin market in June 1993 even if there had been no prohibition application by Merck. There are two main reasons for this:

1. Apotex did not have a willing supplier.
2. Apotex did not have a willing partner in Novopharm, notwithstanding their mutual supply agreement.

[41] On the other hand, as discussed below, Apotex probably would have been able to enter the market by July 1996, when it could have asked Novopharm to obtain raw material from a foreign source, as it did in 1998, after Apotex received its NOC. The question, then, is whether Apotex could have entered the market prior to July 1996, notwithstanding its difficulties getting cooperation from its intended supplier, Delmar, and putative partner, Novopharm.

(d) Problems with Supply

[42] Apotex submits that in 1993 it had a supplier who was ready and willing to provide Apotex with norfloxacin. Apotex was a minority shareholder in Delmar Chemicals Inc. and, accordingly, Apotex was entitled to request Delmar to provide it with material so long as doing so would not strain Delmar's capacity. However, Delmar was clearly uncomfortable with the arrangements Apotex was proposing.

[43] Apotex purported to order norfloxacin directly from Delmar on Novopharm's behalf. Delmar raised concerns about Apotex's proposal and, in 1995, sought a legal opinion about it. Thereafter, it agreed to supply norfloxacin only if it obtained indemnification from Apotex and Novopharm, and received a direct request from Novopharm. Apotex provided an indemnity, but not until October 27, 1997. Delmar never did receive an order from Novopharm or any indemnity from it.

[44] Clearly, Delmar would not have been ready, in June 1993, to start providing Apotex with norfloxacin by way of Apotex's supply agreement with Novopharm. At a minimum, even if Apotex had its NOC in hand, it would have taken several months to arrive at an arrangement that would have been satisfactory to Delmar.

(e) Problems with Novopharm

[45] Since October 15, 1991, Novopharm had a compulsory license from Merck in respect of norfloxacin. The licence entitled Novopharm to make, use or sell norfloxacin as of July 2, 1993, and to import it after July 2, 1996. Novopharm entered into a supply agreement with Apotex on

November 27, 1992. Under the agreement, Novopharm and Apotex each agreed to supply the other with pharmaceutical ingredients if one of them had a license and the other did not. In this case, since Novopharm had a license for norfloxacin, Apotex was entitled, it argues, to ask Novopharm to supply norfloxacin to Apotex at Apotex's request.

[46] However, it took Apotex some time actually to convince Novopharm to go along with the arrangement. In April 1993, Apotex advised Novopharm that it intended to rely on their supply agreement to obtain norfloxacin. Details about quantities were left to a later date. Novopharm replied by asking Apotex to confirm whether Novopharm's license remained valid and there were no other patents of concern, and to address an outstanding grievance between Novopharm and Apotex about another drug (enalapril). Apotex reminded Novopharm about the terms of their mutual supply agreement, and undertook to indemnify Novopharm for any liability it might incur in responding to Apotex's request (which was part of the supply agreement anyway). Novopharm responded by stating that its license was no longer valid and, therefore, could not be relied on by Apotex under the supply agreement. Further, it pointed out that Eli Lilly was challenging the legality of the supply agreement and that Novopharm expected Apotex to reimburse Novopharm for the legal costs of defending it.

[47] The correspondence between Apotex and Novopharm continued, to and fro, for many months, indeed years. It was not until November 16, 1995 that Apotex made a formal request to Novopharm to supply it with norfloxacin. In particular, Apotex asked Novopharm to arrange for the manufacture of 2,000 kilograms of norfloxacin at Delmar. Novopharm refused. It said that the

supply agreement had been terminated and that Apotex's proposal to deal directly with Delmar rendered Novopharm's license invalid. This position was backed up by Novopharm's lawyers.

[48] Things remained quiet until 1998, until after the Supreme Court of Canada rendered its decision finding the supply agreement between Apotex and Novopharm was not an invalid sublicense and, accordingly, dismissing Merck's application for an order of prohibition. The Supreme Court of Canada issued its decision on July 9, 1998. Apotex received its NOC a week later. It then demanded material from Novopharm pursuant to the supply agreement. Within weeks, Novopharm issued purchase orders for the requested material. On August 18, 1998, Apotex received its first material from Novopharm, who had obtained the material from Cipla, a foreign source. More foreign material arrived in September. Apotex entered the market with its first sales in September 1998. Apotex received more foreign material throughout the autumn and winter of 1998-1999.

[49] Novopharm was not what one could call a willing partner. While it did supply material at Apotex's request, its compliance was no doubt a product in part of legal proceedings underway between the parties. Those proceedings led to a decision of Justice Ferrier in the Ontario Court (General Division) in January 1999, in which he upheld the supply agreement (in relation to another drug, nizatidine. See Court File No. 98-CV-157772, January 28, 1999).

[50] Based on these events, Apotex suggests that certainly as of July 2, 1996, when it would have been permitted to obtain material through foreign sources, through the combination of Novopharm's license and the supply agreement between Novopharm and Apotex, without infringing Merck's

patent rights, it was in a position to enter the market within weeks. Foreign sources were available during the relevant time frame.

[51] As for domestic sources, Apotex maintains that Novopharm would have obtained material from Delmar on Apotex's request. As discussed above, Delmar would have required a direct request from Novopharm and indemnity from Novopharm against any potential patent liability. Apotex suggests that those conditions would have been met by Novopharm because they were covered by the supply agreement between Apotex and Novopharm. In turn, Novopharm would have been indemnified by Apotex. Delmar was in a position to supply norfloxacin; the raw materials were readily available in 1993. So, Delmar-produced norfloxacin could have been put on the market by Apotex soon after Apotex received its NOC, had the Minister issued it in June 1993.

[52] Merck notes, however, that Apotex made no request of Novopharm in respect of norfloxacin until November 16, 1995. Dr. Barry Sherman for Apotex purported to direct Novopharm to arrange for the manufacture of 2000 kilograms of norfloxacin at Delmar. In fact, the draft letter he attached stated that Novopharm wished to manufacture norfloxacin at Delmar's facilities. Merck notes that Novopharm's licence was for manufacture of norfloxacin, not purchase from another manufacturer. Therefore, it was important for the parties to make arrangements that would respect the licence. The license included many terms but did not expressly include the right to have norfloxacin made by another manufacturer and sold to others. In my view, however, Novopharm's license was broad enough to permit manufacture of norfloxacin by an agent of Novopharm and sold to Apotex to make a medicine. As mentioned, Novopharm raised numerous objections to the arrangements Apotex was proposing, but none of them related to any limitations on its license.

[53] Merck also argues that Apotex's NOA did not match its new drug submission (NDS). It suggests that Apotex would not have managed to have its norfloxacin approved in 1993, notwithstanding the Minister's letter to the contrary. In its original NDS in 1990, Apotex named Chemo Iberica as the supplier of its active ingredient. It amended the NDS in 1992 to substitute Torcan Chemical Ltd. as the source. As mentioned, the Torcan process was a more complicated four-step process compared to the patented two-step process. Nevertheless, the Torcan process was found to be an obvious variation and an infringement of Merck's patent (by Justice Rothstein, in *Merck Frosst Canada Inc*. v. *Canada* (*Minister of National Health and Welfare*), [1998] F.C.J. No. 286 (T.D.) (QL)) upheld by the Federal Court of Appeal, *Apotex Inc*. v. *Merck Frosst Canada Inc*., [1999] F.C.J. No. 206 (F.C.A.) (QL)). So Apotex could not obtain an NOC for norfloxacin by the Torcan process.

[54] Merck further submits that Apotex could not have obtained an NOC for norfloxacin made by Novopharm at Delmar using the patented process because its NDS referred to a different process. The Drug Master File (DMF) would have had to be amended, as well as the NDS, before an NOC could issue. Either way, Merck argues, Apotex could not obtain an NOC at any time prior to July 9, 1998. I am not persuaded by Merck's submissions on this point. Apotex could have made changes in source and process of manufacture relatively easily, either by informal means, particularly prior to 1994. Thereafter, Apotex would have had to advise Health Canada of a notifiable change. Substituting Delmar as the supplier would have been easily done as Delmar was already an approved manufacturer.

[55] Finally, Merck argues that Apotex's statement of claim only alleges that Delmar would have allowed Novopharm actually to manufacture norfloxacin at its plant, and makes no reference to the possibility of Apotex having access to foreign material. Paragraph 23 of the statement of claim states that Delmar was ready "to enter an arrangement with Novopharm to manufacture norfloxacin at its plant". Delmar clearly would not have allowed Novopharm employees to enter its plant and start making a drug. However, it would have permitted an arrangement whereby Novopharm could oversee production at Delmar. In my view, this potential arrangement is contemplated by paragraph 23.

[56] As for foreign sources, paragraph 22 of the statement of claim mentions Novopharm's license which permitted it to manufacture norfloxacin as of July 2, 1993 and to import it as of July 2, 1996. In my view, this allegation permitted Apotex to lead evidence about foreign sources. However, as discussed above, Apotex would have had access to domestic material from Delmar in any case through the supply agreement with Novopharm. It was not dependent on foreign material.

[57] The problems Apotex would likely have had getting Novopharm's cooperation would have slowed, not stopped, Apotex from getting on the market. As with the supply problems with Delmar, I am satisfied it would have taken Apotex up to a year to establish an arrangement with Novopharm. Litigation might well have been necessary.

III. Conclusion and Disposition

[58] In my view, therefore, Apotex has met its burden of proving that it would have entered the norfloxacin market before July 9, 1998 but for the operation of the Regulations. However, taking account of the problems with supply from Delmar, and with the supply agreement with Novopharm, I conclude that Apotex would not have been able to get on the market until one full year after it would have received its NOC, that is, as of June 10, 1994. Therefore, Apotex is entitled to be compensated for the losses it suffered between that date and July 9, 1998. I will allow Apotex's action against Merck under s. 8 of the Regulations, with costs. Determination of the quantum of damages will be made in the next phase of this trial.

JUDGMENT

THIS COURT'S JUDGMENT IS that:

1. Apotex Inc.'s action against Merck Frosst Canada & Co. under s. 8 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/98-166 is allowed, with costs.

2. The quantum of damages will be determined at a further hearing.

"James W. O'Reilly"
Judge

Annex I

Patented Medicines (Notice of Compliance) Regulations, SOR/93-133

8. (1) The first person is liable to the second person for all damage suffered by the second person where, because of the application of paragraph 7(1)(e), the Minister delays issuing a notice of compliance beyond the expiration of all patents that are the subject of an order pursuant to subsection 6(1).

(2) The court may make such order for relief by way of damages or profits as the circumstances require in respect of any damage referred to in subsection (1).

7. (1) The Minister shall not issue a notice of compliance to a second person before the latest of

[…]

(*e*) subject to subsections (2), (3) and (4), the expiration of 24 months after the receipt of proof of the making of any application under subsection 6(1), and

(4) Paragraph (1)(*e*) ceases to apply in respect of an application under subsection 6(1) if the application is withdrawn or discontinued by the first person or is dismissed by the court hearing the application.

Règlement sur les médicaments brevetés (avis de conformité), DORS/93-133

8. (1) La première personne est responsable envers la seconde personne de tout préjudice subi par cette dernière lorsque, en application de l'alinéa 7(1)(e), le ministre reporte la délivrance de l'avis de conformité au-delà de la date d'expiration de tous les brevets visés par une ordonnance rendue aux termes du paragraphe 6(1).

(2) Le tribunal peut rendre toute ordonnance de redressement par voie de dommages-intérêts ou de profits que les circonstances exigent à l'égard de tout préjudice subi du fait de l'application du paragraphe (1).

7. (1) Le ministre ne peut délivrer un avis de conformité à la seconde personne avant la plus tardive des dates suivantes :

[…]

e) sous réserve des paragraphes (2), (3) et (4), la date qui suit de 24 mois la date de réception de la preuve de présentation de la demande visée au paragraphe 6(1);

(4) L'alinéa (1)*e*) cesse de s'appliquer à l'égard de la demande visée au paragraphe 6(1) si celle-ci est retirée ou fait l'objet d'un désistement par la première personne ou est rejetée par le tribunal qui en est saisi.

Annex II

Patented Medicines (Notice of Compliance) Regulations, SOR/98-166	*Règlement sur les médicaments brevetés (avis de conformité)*, DORS/98-166
8. (1) If an application made under subsection 6(1) is withdrawn or discontinued by the first person or is dismissed by the court hearing the application or if an order preventing the Minister from issuing a notice of compliance, made pursuant to that subsection, is reversed on appeal, the first person is liable to the second person for any loss suffered during the period	8. (1) Si la demande présentée aux termes du paragraphe 6(1) est retirée ou fait l'objet d'un désistement par la première personne ou est rejetée par le tribunal qui en est saisi, ou si l'ordonnance interdisant au ministre de délivrer un avis de conformité, rendue aux termes de ce paragraphe, est annulée lors d'un appel, la première personne est responsable envers la seconde personne de toute perte subie au cours de la période :
(*a*) beginning on the date, as certified by the Minister, on which a notice of compliance would have been issued in the absence of these Regulations, unless the court is satisfied on the evidence that another date is more appropriate; and	*a*) débutant à la date, attestée par le ministre, à laquelle un avis de conformité aurait été délivré en l'absence du présent règlement, sauf si le tribunal estime d'après la preuve qu'une autre date est plus appropriée;
(*b*) ending on the date of the withdrawal, the discontinuance, the dismissal or the reversal.	*b*) se terminant à la date du retrait, du désistement ou du rejet de la demande ou de l'annulation de l'ordonnance.
(2) A second person may, by action against a first person, apply to the court for an order requiring the first person to compensate the second person for the loss referred to in subsection (1).	(2) La seconde personne peut, par voie d'action contre la première personne, demander au tribunal de rendre une ordonnance enjoignant à cette dernière de lui verser une indemnité pour la perte visée au paragraphe (1).
(3) The court may make an order under this section without regard to whether the first person has commenced an action for the infringement of a patent that is the subject matter of the application.	(3) Le tribunal peut rendre une ordonnance aux termes du présent article sans tenir compte du fait que la première personne a institué ou non une action pour contrefaçon du brevet visé par la demande.
(4) The court may make such order for relief by way of damages or profits as the circumstances require in respect of any loss referred to in subsection (1).	(4) Le tribunal peut rendre l'ordonnance qu'il juge indiquée pour accorder réparation par recouvrement de dommages-intérêts ou de profits à l'égard de la perte visée au paragraphe (1).
(5) In assessing the amount of compensation the court shall take into account all matters that	(5) Pour déterminer le montant de l'indemnité à accorder, le tribunal tient compte des facteurs

it considers relevant to the assessment of the amount, including any conduct of the first or second person which contributed to delay the disposition of the application under subsection 6(1).

9. (6) Section 8 of the Regulations, as enacted by section 8, applies to an application pending on the coming into force of these Regulations.

Patent Act, R.S.C. 1985, c. P-4

Burden of proof for patented process

Exception

55.2 (1) It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product.

(2) and (3) [Repealed, 2001, c. 10, s. 2]

Regulations

(4) The Governor in Council may make such regulations as the Governor in Council considers necessary for preventing the infringement of a patent by any person who makes, constructs, uses or sells a patented invention in accordance with subsection (1), including, without limiting the generality of the foregoing, regulations
(*a*) respecting the conditions that must be fulfilled before a notice, certificate, permit or other document concerning any product to which a patent may relate may be issued to a patentee or other person under any Act of Parliament that regulates the manufacture, construction, use or sale of that product, in addition to any conditions provided for by or

qu'il juge pertinents à cette fin, y compris, le cas échéant, la conduite de la première personne ou de la seconde personne qui a contribué à retarder le règlement de la demande visée au paragraphe (1).

9. (6) L'article 8 du même règlement, édicté par l'article 8, s'applique aux demandes qui sont pendantes à la date d'entrée en vigueur du présent règlement.

Loi sur les brevets, L.R., 1985, ch. P-4

Assimilation à une action en contrefaçon

Exception

55.2 (1) Il n'y a pas contrefaçon de brevet lorsque l'utilisation, la fabrication, la construction ou la vente d'une invention brevetée se justifie dans la seule mesure nécessaire à la préparation et à la production du dossier d'information qu'oblige à fournir une loi fédérale, provinciale ou étrangère réglementant la fabrication, la construction, l'utilisation ou la vente d'un produit.

(2) et (3) [Abrogés, 2001, ch. 10, art. 2]

Règlements

(4) Afin d'empêcher la contrefaçon d'un brevet d'invention par l'utilisateur, le fabricant, le constructeur ou le vendeur d'une invention brevetée au sens du paragraphe (1), le gouverneur en conseil peut prendre des règlements, notamment :
a) fixant des conditions complémentaires nécessaires à la délivrance, en vertu de lois fédérales régissant l'exploitation, la fabrication, la construction ou la vente de produits sur lesquels porte un brevet, d'avis, de certificats, de permis ou de tout autre titre à quiconque n'est pas le breveté;
b) concernant la première date, et la manière de la fixer, à laquelle un titre visé à l'alinéa *a*) peut être délivré à quelqu'un qui n'est pas le

under that Act;
(*b*) respecting the earliest date on which a notice, certificate, permit or other document referred to in paragraph (*a*) that is issued or to be issued to a person other than the patentee may take effect and respecting the manner in which that date is to be determined;
(*c*) governing the resolution of disputes between a patentee or former patentee and any person who applies for a notice, certificate, permit or other document referred to in paragraph (*a*) as to the date on which that notice, certificate, permit or other document may be issued or take effect;
(*d*) conferring rights of action in any court of competent jurisdiction with respect to any disputes referred to in paragraph (*c*) and respecting the remedies that may be sought in the court, the procedure of the court in the matter and the decisions and orders it may make; and
(*e*) generally governing the issue of a notice, certificate, permit or other document referred to in paragraph (*a*) in circumstances where the issue of that notice, certificate, permit or other document might result directly or indirectly in the infringement of a patent.

breveté et à laquelle elle peut prendre effet;
c) concernant le règlement des litiges entre le breveté, ou l'ancien titulaire du brevet, et le demandeur d'un titre visé à l'alinéa *a*), quant à la date à laquelle le titre en question peut être délivré ou prendre effet;
d) conférant des droits d'action devant tout tribunal compétent concernant les litiges visés à l'alinéa *c*), les conclusions qui peuvent être recherchées, la procédure devant ce tribunal et les décisions qui peuvent être rendues;
e) sur toute autre mesure concernant la délivrance d'un titre visé à l'alinéa *a*) lorsque celle-ci peut avoir pour effet la contrefaçon de brevet.

Constitution Act, 1867, (U.K.), 30 & 31 Victoria, c. 3

EXCLUSIVE POWERS OF PROVINCIAL LEGISLATURES

Subjects of exclusive Provincial Legislation

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,

…

13. Property and Civil Rights in the Province.

Loi constitutionnelle de 1867 (R.-U.), 30 & 31 Vict., c. 3

POUVOIRS EXCLUSIFS DES LÉGISLATURES PROVINCIALES

Sujets soumis au contrôle exclusif de la législation provinciale

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. La propriété et les droits civils dans la province.

Federal Courts Act, R.S.C. 1985, c. F-7

Loi sur les Cours fédérales, L. .R., 1985, ch.

F-7

Appeals from Federal Court

27. (1) An appeal lies to the Federal Court of Appeal from any of the following decisions of the Federal Court:

(*a*) a final judgment;

(*b*) a judgment on a question of law determined before trial;

(*c*) an interlocutory judgment; or

(*d*) a determination on a reference made by a federal board, commission or other tribunal or the Attorney General of Canada.

Appels des jugements de la Cour fédérale

27. (1) Il peut être interjeté appel, devant la Cour d'appel fédérale, des décisions suivantes de la Cour fédérale :

a) jugement définitif;

b) jugement sur une question de droit rendu avant l'instruction;

c) jugement interlocutoire;

d) jugement sur un renvoi d'un office fédéral ou du procureur général du Canada.

FEDERAL COURT

NAME OF COUNSEL AND SOLICITORS OF RECORD

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