Federal Court of Appeal | Cour d'appel fédérale

Date: 20111125

Docket: A-154-10

Citation: 2011 FCA 329

CORAM: **SEXTON J.A.**
LAYDEN-STEVENSON J.A.
STRATAS J.A.

BETWEEN:

MERCK FROSST CANADA & CO.

Appellant

and

APOTEX INC.

Respondent

Heard at Toronto, Ontario, on February 15, 2011.

Judgment delivered at Ottawa, Ontario, on November 25, 2011.

REASONS FOR JUDGMENT BY: STRATAS J.A.

CONCURRED IN BY: SEXTON J.A.
LAYDEN-STEVENSON J.A.

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REASONS FOR JUDGMENT

STRATAS J.A.

[1] Merck Frosst Canada & Co. appeals from the judgment of the Federal Court (*per* Justice O'Reilly): 2010 FC 287.

[2] The Federal Court ruled in favour of Apotex Inc's action against Merck under section 8 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, as amended. The quantum of damages to be awarded to Apotex is to be determined at a later hearing.

[3] In the course of its reasons, the Federal Court ruled that the 1998 version of section 8 of the Regulations (SOR/93-133 as amended by SOR/98-166, sections 8, 9) (the "1998 Regulations") applied to this case, and not the 1993 version of section 8 of the Regulations (SOR/93-133) (the "1993 Regulations"). Merck appeals from that ruling. Merck also submits that the Federal Court erred in fact and law in concluding that Apotex suffered a loss as a result of Merck's prohibition application.

[4] For the reasons set out below, I would dismiss Merck's appeal, with costs.

A. Background

[5] Merck listed its Canadian Patent No. 1,178,961 ("'961 Patent") concerning its norfloxacin tablets on the patent list under the 1993 Regulations.

[6] In accordance with the Regulations, on April 19, 1993 Apotex served a Notice of Allegation asserting that it would not infringe the '961 Patent. Specifically, it asserted that its norfloxacin, known as Apo-Norfloxacin, would be acquired from Novopharm Ltd. under a compulsory licence.

[7] In response to Apotex's Notice of Allegation, on May 31, 1993 Merck sought to prohibit the Minister from issuing a Notice of Compliance ("NOC") concerning Apo-Norflozacin until the

expiry of the ‘961 Patent. Under the Regulations, the Minister was prohibited from issuing a NOC at that time.

[8] The Federal Court granted prohibition and this Court dismissed an appeal from the Federal Court. In all, prohibition lasted for approximately five years, until July 9, 1998. At that time, the Supreme Court of Canada allowed an appeal from this Court and dismissed Merck’s application for prohibition: *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)*, [1998] 2 S.C.R. 193.

[9] After the Supreme Court’s decision, Apotex received its NOC and began to market Apo-Norfloxacin.

[10] Merck’s application for prohibition prevented Apotex from marketing Apo-Norfloxacin for over five years. Relying on section 8 of the Regulations, Apotex sued Merck for damages. The Federal Court awarded Apotex damages. Its reasons for doing so shall be explored below.

[11] A key issue before the Federal Court was which version of section 8 applied to govern the action. The Regulations came into force in 1993. An amendment to the Regulations came into force on March 11, 1998. The Federal Court found that section 8 of the 1998 Regulations applied, and not section 8 of the 1993 Regulations.

[12] Section 8 of the 1993 Regulations provides as follows:

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).	**8.** (1) La première personne est responsable envers la seconde personne du 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 rendu aux termes du paragraphe 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).	(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).

[13] Section 8 of the 1998 Regulations provides as follows:

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	*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

evidence that another date is more appropriate, and

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 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).

(5) Pour déterminer le montant de l'indemnité à accorder, le tribunal tient compte des facteurs 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 6(1).

B. Which version of the Regulations applies in this case?

[14] The Federal Court noted the existence of a transitional provision for the 1998 Regulations, namely subsection 9(6) of the *Regulations amending the Patented Medicines (Notice of Compliance) Regulations*, SOR/98-166 (the "transitional provision"). This transitional provision states that "section 8 of the [1998] Regulations…applies to an application pending on the coming into force of these [1998] Regulations." The 1998 Regulations came into force on March 11, 1998: *Regulations amending the Patented Medicines (Notice of Compliance) Regulations*, section 10.

[15] The Federal Court noted that Merck's prohibition application was "pending" on March 11, 1998. On March 11, 1998, the Supreme Court was considering the submissions that had been made to it. As mentioned above, four months later, on July 9, 1998, the Supreme Court released its decision. Only at that point was the matter no longer pending.

[16] In the course of finding that Merck's prohibition application was still pending, the Federal Court relied upon a number of authorities, including *Apotex Inc. v. Syntex Pharmaceuticals International Ltd.*, 2009 FC 494. In that case, Justice Hughes found that "a judgment is final once it has been determined and issued by the…Court" and, if an appeal is taken, is "not…final until all appeals have disposed of the matter" (at paragraph 39).

[17] I agree with the result reached by the Federal Court. Merck's prohibition application was pending when the 1998 Regulations came into force. I also agree with the Federal Court that the

correct test for determining whether an application is "pending" is whether the application remains alive either at first instance, or on appeal.

[18] In this regard, I note that this Court dismissed an appeal from the main case that the Federal Court relied upon, Justice Hughes' decision in *Apotex v. Syntex*, *supra*, and this Court largely agreed with Justice Hughes' reasoning on this point: 2010 FCA 155. This Court held that "pending" means a "proceeding that is not yet finished" (at paragraph 28). It is evident that Merck's prohibition application was not yet finished as of March 11, 1998. It only finished on the date of the Supreme Court's judgment, on July 9, 1998.

[19] Merck submits that all that was pending before the Supreme Court on March 11, 1998 was an "appeal," not an "application." It says that the transitional provision, read strictly, only refers to an "application" that is "pending."

[20] I reject this submission. In a very real sense, the application was pending before the Supreme Court. The Supreme Court had the power not just to grant the appeal but also to dismiss Merck's application.

[21] The *Supreme Court Act*, R.S.C. 1985, c. S-26 governs proceedings before the Supreme Court and sets out what it may or may not do in an appeal before it. Section 45 of that Act provides that, among other things, it "may…give the judgment…that the court whose decision is appealed against [*i.e.*, this Court] should have given or awarded." This Court could have given "the

judgment…that the Trial Division should have given or awarded": *Federal Court Act*, R.S.C. 1985, c. F-7, as amended, paragraph 52(b)(*i*) (as it existed as of March 11, 1998). Therefore, the Supreme Court also had the power to give "the judgment…that the Trial Division should have given or awarded." And it did just that: see its judgment, described at paragraph 37 of its reasons. It dismissed Merck's application.

[22] The Supreme Court even had the power to amend Merck's Notice of Application for prohibition, had it found it necessary to do so: *Supreme Court Act*, section 48. That section allows the Supreme Court itself to amend the Notice of Application, or to amend it in response to an application made by any of the parties before it. From this, I would conclude that Merck's application was most definitely "pending" before the Supreme Court on March 11, 1998, even to the point where the originating document for that application, the Notice of Application, could have been amended by the Supreme Court.

[23] In support of this conclusion, I also note, as did the Federal Court (at paragraph 27), that the transitional provision is broader in its phrasing than it might have been. The transitional provision merely refers to an "application pending" when the 1998 Regulations come into force. It does not refer to an "application pending before the Federal Court" or to an "application pending before the court hearing the application."

[24] For the foregoing reasons, I conclude that Merck's application for prohibition was "pending" when the 1998 Regulations came into force. Therefore, by operation of the transitional provision in the 1998 Regulations, the 1998 Regulations apply in this case.

C. Are the 1998 Regulations invalid because they cause retroactive or retrospective effects, or interfere with vested rights, without authorization in the *Patent Act*?

[25] Despite the above, Merck nevertheless submits that the 1993 Regulations apply. It says that the 1998 Regulations are invalid and, thus, must be disregarded by this Court.

[26] It urges this result upon us because the transitional provision, as interpreted above, means that the 1998 Regulations have retroactive or retrospective effects and interfere with vested rights. Merck notes that the *Patent Act* does not authorize the making of regulations that have any of those effects or interfere with vested rights. In support of its submission, Merck points to the enabling provision for the 1998 Regulations, subsection 55.2(4) of the *Patent Act*.

[27] Subsection 55.2(4) of the *Patent Act* provides as follows:

55.2. (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) or (2) including, without limiting the generality of the foregoing, regulations	**55.2.** (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) ou (2) le gouverneur en conseil peut prendre des règlements, notamment :

(*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 under that Act;

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*) 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;

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 breveté et à laquelle elle peut prendre effet;

(*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;

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*) 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

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*) generally governing the issue of a notice, certificate, permit or other document referred to in paragraph (*a*)

e) sur toute autre mesure concernant la délivrance d'un titre visé à l'alinéa *a*) lorsque celle-ci peut avoir pour effet la

in circumstances where the issue of that notice, certificate, permit or other document might result directly or indirectly in the infringement of a patent.	contrefaçon de brevet.

[28] Merck submits that subsection 55.2(4) of the *Patent Act* does not authorize regulations that operate retroactively or retrospectively or that interfere with vested rights.

[29] In light of the above, Merck submits that, to the extent that the transitional provision purports to give the 1998 Regulations retroactive or retrospective effect or interfere with vested rights, the transitional provision is *ultra vires* and, therefore, is of no force or effect.

[30] Merck is correct that the making of retroactive or retrospective regulations or regulations that interfere with vested rights on substantive matters must be authorized by the regulations' enabling provisions: R. Sullivan, *Sullivan on the Construction of Statutes*, 5th ed. (Markham, Ont.: LexisNexis, 2008) at pages 670 and 727; *Attorney General for British Columbia v. Parkland Private Hospital Ltd.*, [1975] 2 S.C.R. 47 at page 60; *Ass'n Internationale des commis du détail v. Commission des Relations de Travail du Québec et al.*, [1971] S.C.R. 1043 at page 1048.

[31] Merck is also correct that subsection 55.2(4) of the *Patent Act* does not authorize the making of such regulations. The wording of subsection 55.2(4) is silent on the creation of regulations that have retroactive or retrospective effects or an interference with vested rights. Given its silence,

subsection 55.2(4) must be interpreted as not authorizing such effects: *Smith v. Callander*, [1901] A.C. 297 at page 305.

[32] Further, there is no basis for implying a power to make such regulations in subsection 55.2(4). This Court so found in *Apotex Inc. v. Canada (Attorney General)*, [1994] 1 F.C. 742 at page 798 (C.A.).

[33] Therefore, in assessing the merits of Merck's submission, only one question remains to be considered: do the 1998 Regulations have retrospective or retroactive effects or interfere with vested rights?

[34] To answer this question, it is necessary to have in mind what is meant by retroactive or retrospective effects or interference with vested rights. In *Épiciers Unis Métro-Richelieu Inc., division "Éconogros" v. Collin*, 2004 SCC 59, [2004] 3 S.C.R. 257 at paragraph 46, the Supreme Court approved the following passage in E. A. Driedger, "Statutes: Retroactive Retrospective Reflections" (1978) 56 Can. Bar Rev. 264, at pages 268-69:

> A retroactive statute is one that operates as of a time prior to its enactment. A retrospective statute is one that operates for the future only. It is prospective, but it imposes new results in respect of a past event. A retroactive statute *operates backwards*. A retrospective statute *operates forwards*, but it looks backwards in that it attaches new consequences *for the future* to an event that took place before the statute was enacted. A retrospective statute changes the law from what it was; a retrospective statute changes the law from what it otherwise would be with respect to a prior event. [emphasis in original]

[35] Merck submits that applying section 8 of the 1998 Regulations to it in this case would create retroactive or retrospective effects or interfere with its vested rights. It says that on May 31, 1993 it applied for an order of prohibition and received an automatic stay, knowing that there was a risk that it would be liable to Apotex for any damage suffered by it by reason of the Minister delaying issuance of an NOC. But it says that risk was defined and framed by the rules set out in section 8 of the 1993 Regulations, the provision that was in force at the time it applied for prohibition. In effect, Merck submits that on May 31, 1993 it acquired a vested right to the benefit and burden of the rules set out in section 8 of the 1993 Regulations.

[36] Putting the submission somewhat differently and colloquially, Merck says that applying section 8 of the 1998 Regulations to it in effect "pulls the rug out from under it." Section 8 of the 1998 Regulations imposes upon it, long after it made its decision to apply for prohibition, a set of rules that is fundamentally different from the rules around which it planned its affairs. Thus, in its view, section 8 of the 1998 Regulations has a retrospective effect upon it.

[37] Merck then submits that since subsection 55.2(4) of the *Patent Act* does not authorize the making of retrospective regulations, the transitional provision that makes section 8 of the 1998 Regulations apply to it is invalid. Accordingly, in its view, section 8 of the 1993 Regulations applies to it, not section 8 of the 1998 Regulations.

[38] I reject this submission for a number of reasons.

– I –

[39] First, some of Merck's oral and written submissions seem to suggest that it had a vested right to the continuance of the law as it stood at the time it decided to apply for an order for prohibition. As a general proposition, this is not the law of Canada: *Gustavson Drilling (1964) Limited v. The Minister of National Revenue*, [1977] 1 S.C.R. 271 at page 282. No one has a vested right or an enforceable claim to the continuance of the substantive standards in laws, even in situations where expectations to that effect have been encouraged: *Reference Re Canada Assistance Plan (B.C.)*, [1991] 2 S.C.R. 525.

– II –

[40] There is a rebuttable presumption of validity that applies in cases where regulations are alleged to exceed the scope of the law-making power set out in the parent statute: see Sullivan, *supra* at page 458. In this case, this means that the burden is on Merck to demonstrate that the application of the 1998 Regulations creates retroactive or retrospective effects, or interferes with a vested right. As is evident from this section of my reasons, I find that Merck has not discharged that burden.

– III –

[41] Merck submits that this case is similar to *Thiessen v. Manitoba Public Insurance Corp.* (1990), 66 D.L.R. (4th) 366 (Man. C.A.). In that case, a regulation contained an express limit on damages, but the regulation was later repealed. The Manitoba Court of Appeal held that the

defendant had a vested right in the limit on damages under the old regulation. Therefore, in its view, the new regulation, which purported to remove that limit, was retrospective.

[42] *Thiessen* is different from the case at bar. When Merck decided to apply for prohibition, it knew that it was potentially subject to an action for damages. When Merck made that decision, section 8 of the 1993 Regulations did not give Merck any rights, such as an affirmative defence or liability cap, that were repealed by the 1998 Regulations. *Thiessen* is a case where, unlike this case, such a right – a liability cap – was repealed by later legislation.

– IV –

[43] Merck submits that section 8 of the 1998 Regulations greatly expanded liability for damages and created new rights for "second persons" such as Apotex.

[44] It is not necessary in this case to define fully the content of section 8 of the 1998 Regulations. Suffice to say, Merck's submission in this case overshoots the mark.

[45] Accompanying the 1998 Regulations was a Regulatory Impact Analysis Statement: Canada Gazette Part II, vol. 132, no. 7 at page 1056. It is appropriate to take into account this Statement as an aid to determining the meaning of the 1998 Regulations: *Bristol-Myers Squibb Co. v. Canada (A.G.)*, 2005 SCC 26 at paragraph 46, [2005] 1 S.C.R. 533; *Apotex Inc. v. Merck & Co. Inc.*, 2009

FCA 187 at paragraph 47; *Teva Canada Limited v. Sanofi-Aventis Canada Inc.*, 2011 FCA 149 at paragraph 13, *per* Sharlow J.A. (dissenting but not on this point). That Statement declared:

> **Specifying circumstances in which damages or costs can be awarded.** A clearer indication is given to the court 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, and the factors that may be taken into account in calculating damages. The court may also award costs to either a generic manufacturer or a patentee, including solicitor and client costs, as appropriate, consistent with Federal Court Rules.

[46] This passage in the Regulatory Impact Analysis Statement suggests that the 1998 Regulations did not work a revolution in the substantive content of section 8 of the 1993 Regulations. Instead, it was aimed at providing a "clearer indication" of the circumstances in which damages could be awarded.

[47] In this way, the 1998 Regulations, for the most part, made aspects of the section 8 of the 1993 Regulations clearer by declaring, with greater specificity, the bases of liability for damages. Legislation that largely declares the state of an earlier, uncertain law is not retrospective.

[48] This is well-illustrated by a relatively recent decision of the English Chancery Division: *Westminster City Council v. Haywood*, [2000] 2 All E.R. 634. Before the court in that case were certain regulations and an "explanatory note" issued alongside the Regulations. The court found the "explanatory note" admissible for the purpose of determining the mischief that the regulations before it were meant to address. Similar to the Regulatory Impact Analysis Statement in this case,

the “explanatory note” before the court in *Westminster* suggested that the purpose of the regulations was to “clarify the extent of the jurisdiction” of a pensions ombudsman.

[49] In the course of its reasons, the court in *Westminster* stated that if the regulations simply clarified matters, they would be merely “declaratory.” In its view, legislation that is merely declaratory of rights existing before is not retrospective: see paragraph 19. It turned out that, as a matter of interpretation, the regulation before the court did much more than simply clarify the state of the former law. Nevertheless, the point established by *Westminster* is clear: section 8 of the 1998 Regulations, as a largely clarifying provision or a provision that largely attempts to declare what the law has been, is not retroactive or retrospective, nor does it interfere with earlier vested rights.

[50] Declaratory or clarifying legislation, which corrects defects in the earlier legislation, does not implicate the concerns associated with retrospective or retroactive legislation and may even bolster the known purposes of the earlier legislation: see C.J.G. Sampford et al., *Retrospectivity and the Rule of Law* (Oxford: Oxford University Press, 2006) at pages 233 and 266, and see also Jill E. Fitch, “Retroactivity and Legal Change: An Equilibrium Approach” (1996-1997) 110 Harv. L. Rev. at page 1088. Such declaratory or clarifying legislation is not evidence of a change of approach by legislators, but rather a desire to ensure that earlier laws “reflect the principles [legislators] had in mind and communicated when the law was passed”: Sampford, *Retrospectivity and the Rule of Law*, *supra* at page 273.

[51] It follows then that I agree with the Federal Court judge's conclusion at paragraph 26 of his reasons:

> …[A]s the 1998 [Regulatory Impact Analysis Statement] 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.

– V –

[52] As mentioned above, the task before us is to consider whether the 1998 Regulations have retrospective or retroactive effects or interfere with vested rights. In carrying out that task, we must keep front of mind the reasons why courts decline to enforce regulations that cause retrospective or retroactive effects or interfere with vested rights and that are not authorized by statute to do those things.

[53] The concern of courts about unauthorized regulations that cause retrospective or retroactive effects or interfere with vested rights is founded upon aspects of the rule of law. "Citizens choose how to act in the belief that the state will impose the legal consequences determined by the legal text discoverable at that time and not on other texts which were not in existence at the time of the relevant action": Sampford et al., *Retrospectivity and the Rule of Law*, *supra* at page 98. It is unfair to change the rules later and catch those who planned their affairs under the former law: *British Columbia v. Imperial Tobacco Canada Ltd.*, 2005 SCC 49 at paragraph 71, [2005] 2 S.C.R. 473;

E. Edinger, “Retrospectivity in Law” (1995) 29 U.B.C. L. Rev. 5, at page 13; Joseph Raz, “The Rule of Law and its Virtue” (1977), 93 L.Q.R. 195 at page 198; Andrew P. LeSueur, et al., *Principles of Public Law*, 2nd ed. (London: Cavendish Publishing Limited, 1999) at page 425.

[54] In *Imperial Tobacco*, the Supreme Court held that retrospective or retroactive laws are not unconstitutional by that reason alone. However, the unfairness of such laws underlies the “rules of statutory interpretation that require the legislature to indicate clearly any desired retroactive or retrospective effects”: *Imperial Tobacco*, at paragraph 71. Such rules ensure that the legislature has turned its mind to such effects and “determined that the benefits of retroactivity [or retrospectivity] outweigh the potential for disruption or unfairness”: *Landgraf v. USI Film Products*, 511 U.S. 244 at page 268 (1994), cited in *Imperial Tobacco* at paragraph 71 by the Supreme Court.

[55] From this, it would be unfair and would trigger the concern about retroactive or retrospective laws if Merck planned its affairs in reasonable reliance upon a definite, concrete set of rules set out in section 8 of the 1993 Regulations, and then the 1998 Regulations purported to change those rules. If that were the case, one might conclude that the 1998 Regulations unfairly “pulled the rug out” from under Merck. But is that what happened here?

[56] In my view, no. When Merck applied for prohibition and made itself potentially subject to an action for damages, it acquired for itself a “black box” of potential liability. I offer three reasons for that conclusion.

[57] First, under subsection 8(2) of the 1993 Regulations, the Court had a broad discretion to make "such order for relief by way of damages or profits as the circumstances require." Evidently, the rules and bases for the calculation of damage under section 8 remained to be worked out through judicial clarification. When it brought its prohibition application, Merck would have reasonably expected that there would be future clarifications in the law, at least by courts interpreting the provision.

[58] Second, Merck applied for prohibition on May 31, 1993, at an early time in the history of the 1993 Regulations. At that time, no significant cases interpreting section 8 of the 1993 Regulations had been decided. It is fair to assume, given the complexity of the wording of section 8 of the 1993 Regulations and the 1993 Regulations themselves, that any decision by Merck to launch an application for prohibition and accept the potential of section 8 liability on May 31, 1993 was pregnant with risk. At that time, Merck should have reasonably expected that there would be clarification in the law later, at least by courts interpreting the provision, if not by the Governor in Council through amending regulations.

[59] Third, it is fair to say that section 8 of the 1993 Regulations is notorious in judicial circles for its obscurity of meaning. There are many judicial statements to that effect.

[60] For those statements, one can start with the Federal Court judge in the case at bar. The Federal Court judge candidly stated (at paragraph 13) that the meaning of section 8 of the 1993 Regulations "eludes me." He described the section as "murky." In saying this, he cited Justice

Hugessen's observation in this Court that section 8 of the 1993 Regulations is "particularly obscure in its meaning": *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)* (1994), 55 C.P.R. (3d) 302 at page 316 (F.C.A.). In that case, Justice Hugessen also expressed relief that he did not have to interpret the section (at page 316).

[61] There are more such statements. Recently, this Court agreed with Justice Hugessen's observation that section 8 is "particularly obscure in its meaning": *Apotex v. Syntex, supra* at paragraph 34. This Court added (at paragraph 34) that "[i]t may well not be possible to find an interpretation [of section 8 of the 1993 Regulations] that resolves all the contingencies." In *Apotex v. Syntex, supra*, the Federal Court (*per* Justice Hughes) stated (at paragraph 59) that "Courts in the past have been fortunate enough to be able to avoid interpreting that section." Somewhat earlier, this Court considered that section 8 raised "difficult questions" of interpretation: in *Apotex Inc. v. Eli Lilly and Co.*, 2004 FCA 358 at paragraph 16.

[62] I wholeheartedly and emphatically agree with all of these statements. To say the least, the full meaning of section 8 of the 1993 Regulations is enigmatic and puzzling.

[63] Before us, the parties presented us with two competing interpretations of section 8 of the 1993 Regulations, each plausible and each possessing strengths, but each having certain unsatisfactory, irresolvable anomalies and difficulties.

[64] I have examined the competing interpretations and have given them much consideration over a long period of time. Following the accepted method of statutory interpretation – examining the plain words, viewing the plain words in the content of other provisions of the Act and Regulations, and considering the purpose of the Act and Regulations – I conclude that reaching a satisfactory conclusion on the definitive meaning of all aspects of section 8 of the 1993 Regulations is a formidable task.

[65] It is true that some individual cases have reached conclusions about limited aspects of section 8 of the 1993 Regulations based on the specific facts before them. But having attempted to examine and consider in depth all aspects of section 8 of the 1993 Regulations, only one thing is clear to me. Anyone looking at this provision – as Merck undoubtedly did before it applied for prohibition on May 31, 1993 – would conclude that those applying for prohibition under the 1993 Regulations were acquiring for themselves a “black box” of potential liability under section 8.

[66] In such an unusual circumstance, it cannot be said that the 1998 Regulations “pulled the rug out” from under Merck. Instead, when Merck brought its application for prohibition on May 31, 1993, the legal environment was fundamentally uncertain. Merck knew or should have known on May 31, 1993 that clarifications of section 8 of the 1993 Regulations, whether at the behest of the courts or by way of regulatory amendment, were entirely possible and perhaps even quite likely while its prohibition application was pending before the courts.

[67] It follows that I disagree with Merck's submission, at paragraph 68 of its memorandum of fact and law, that when it "brought its application for a prohibition order under the 1993 Regulations, its legal situation became individualized, tangible and concrete" and that its legal situation became "sufficiently constituted to give rise to a vested right." Instead, when it brought its application, Merck's legal situation was fundamentally uncertain. When it brought its application, Merck acquired for itself a "black box" of potential liability.

[68] Therefore, I conclude that the 1998 Regulations cannot be said to be retroactive or retrospective or interfere with any vested rights of Merck. Accordingly, I agree with the Federal Court judge that the 1998 Regulations are authorized by subsection 55.2(4) of the *Patent Act*, are valid, and apply in this case.

D. Did the Federal Court err in fact and in law in concluding that Apotex suffered loss as a result of Merck's prohibition application?

[69] The Federal Court found that Apotex suffered loss as a result of Merck's prohibition application. Apotex established, to the satisfaction of the Federal Court, that it was prevented from getting into the norfloxacin market because of Merck's prohibition application. In establishing this, Apotex satisfied the Federal Court that, on the balance of probabilities, it would have had access to an available supply of non-infringing norfloxacin.

[70] The Federal Court found (at paragraphs 38 and 39) that it only needed to examine whether Apotex could have entered the market with material obtained from Novopharm under Novopharm's

compulsory licence with Merck and under a reciprocal agreement between Apotex and Novopharm to supply licensed material on request.

[71] The Federal Court noted (at paragraph 39) that this Court concluded that this supply agreement amounted to an improper sublicense (see (1996), 67 C.P.R. (3d) 455 (F.C.A.)) but the Supreme Court reversed that finding in its July 9, 1998 decision in *Merck Frosst Canada Inc.*, *supra*. Therefore, the Federal Court concluded (at paragraph 39) that "the supply agreement created a means by which Apotex could, at least in theory, enter the norfloxacin market without infringing Merck's patent rights."

[72] The Federal Court also noted obstacles in the way of Apotex entering the norfloxacin market with norfloxacin supplied by Novopharm (at paragraphs 40-57). Examining all of the evidence, the Federal Court concluded that the obstacles "would have slowed, not stopped, Apotex from getting on the market." The Federal Court concluded (at paragraph 58):

> 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.

[73] Merck submits that the Federal Court erred in two main respects.

[74] First, Merck submits that the Federal Court had no evidentiary basis for finding (in paragraph 58 of its reasons) that Apotex would have been able to get Apo-Norfloxacin on the

market by June 10, 1994. It adds that the trial judge committed a palpable and overriding error of fact in concluding that Apotex could have obtained norfloxacin from Novopharm at any time before July 9, 1998.

[75] In assessing Merck's submission, it must be remembered that the Federal Court had to assess Apotex's damages on the basis of a hypothetical question: what would have happened had Merck not brought an application for prohibition? On this question, the Federal Court heard evidence from five witnesses on what would have happened under that hypothetical situation. In order to assess what would have happened under that hypothetical situation, the Federal Court had to consider the evidence in a holistic way. As both parties accept, the standard of review for such a factual determination is that of palpable and overriding error.

[76] The requirement that factual determinations stand on appeal unless palpable and overriding error makes considerable sense, especially in a complex case such as this. As the Court of Appeal for Ontario stated in *Waxman v. Waxman* (2004), 186 O.A.C. 201 at paragraphs 294-295 and 336, in words apposite to this case:

> In a case as…factually complex as this case, appellate judges are very much like the blind men in the parable of the blind men and the elephant. Counsel invite the court to carefully examine isolated parts of the evidence, but the court cannot possibly see and comprehend the whole of the narrative. Like the inapt comparisons to the whole of the elephant made by the blind men who felt only one small part of the beast, appellate fact-finding is not likely to reflect an accurate appreciate of the entirety of the narrative. This case demonstrates that the "palpable and overriding" standard of review is a realistic reflection of the limitations and pitfalls inherent in appellate fact-finding.

> Despite the benefit of detailed reasons for judgment, lengthy and effective argument by counsel, and many hours of study, we are entirely satisfied that we cannot possibly know and understand this trial record in the way that the trial judge came to know and understand it. [His] factual determinations are much more likely to be accurate than any that we might make.
>
> …..
>
> Many of the "no evidence" submissions made by the appellants are, on closer examination, arguments that there was not enough evidence to support findings of fact made by the trial judge. The sufficiency of evidence is not open to review.

[77] In my view, there was sufficient evidence upon which the Federal Court could have made the factual findings it did, and those findings are not susceptible to review in this Court.

[78] Merck concentrates part of its attack on an alternative way in which Apotex said it could have obtained norfloxacin, namely from a company in which it was a minority shareholder, Delmar Chemicals Inc. Merck says that Delmar was unable to manufacture sufficiently pure norfloxacin using a non-infringing process, and that there was no evidence to suggest that the use of the patented process would have avoided impurity problems. Merck has not pointed this Court to any evidence of impurity problems in Delmar's manufacture of norfloxacin. Further, the Federal Court had evidence before it upon which it could conclude (at paragraph 43) that in the hypothetical world where Merck had not brought an application for prohibition, Delmar would have been ready in June 1993 to start providing Apotex with norfloxacin by way of Apotex's supply agreement with Novopharm.

[79] In any event, the Federal Court correctly pointed out (at paragraph 37) that it only needed to consider whether Apotex could have entered the market with material obtained from Novopharm

under its compulsory licence. As Novopharm held a compulsory licence for norfloxacin, it was entitled to source what would generally be considered "infringing" supplies of norfloxacin, and to sell it in Canada, without infringing Merck's rights under the '961 Patent. As summarized above, the Federal Court, based on the evidence before it regarding what would likely happen in what I have called the "hypothetical world," reached conclusions regarding how Novopharm would have behaved had Apotex asked it in 1993 to supply norfloxacin. I cannot say that the Federal Court's conclusions are unsupported by the evidence.

[80] As for the Federal Court's selection of June 10, 1994 as the relevant date, I consider it to be supported by the Federal Court's holistic assessment of the evidence regarding what might have happened in the hypothetical world where Merck had not brought its application for prohibition. Similarly, I find that there was some evidence upon which the Federal Court could conclude that Apotex could have obtained norfloxacin from Novopharm at the relevant time. This evidence is well-summarized at paragraphs 65-96 of Apotex's memorandum of fact and law.

[81] Merck offers a second submission to support its view that the Federal Court erred in concluding that Apotex suffered loss as a result of Merck's prohibition application. Merck says that Apotex could not have acquired norfloxacin from Novopharm under its supply agreement based on manufacture by Delmar or any other third party manufacturer. It says that would have constituted an illegal sublicence because the compulsory licence did not include "have-made" rights.

[82] In my view, this submission is barred by the doctrines of *res judicata* and issue estoppel: *Danyluk v. Ainsworth Technologies Inc.*, [2001] 2 S.C.R. 460. The Supreme Court disposed of this submission in *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)*, [1998] 2 S.C.R. 193 and the case argued with it, *Eli Lilly & Co. v. Novopharm Ltd.*, [1998] 2 S.C.R. 129. As mentioned above, the Federal Court also so found (see paragraph 39 of its reasons).

[83] It is evident that the Supreme Court determined that the supply agreement between Apotex and Novopharm was not an illegal sublicence and that Apotex could arrange for the drug to be manufactured by a supplier of its choice, direct Novopharm to acquire the drug from that supplier, and then require Novopharm to sell it the drug, for it to resell under its NOC. This is seen at paragraph 78 of the *Eli Lilly* decision:

> Pursuant to the terms of the contract as it stands, Apotex is simply permitted to direct Novopharm to the third party manufacturer which it favours and with whom it has negotiated terms, which would then oblige Novopharm to deal with that manufacturer and acquire the patented medicine on the terms negotiated. Despite this considerable degree of control by Apotex, it remains the case that separate entities are involved, that Apotex is in no way ultimately responsible for the supply of goods that Novopharm will eventually sell to it, and that a legitimate and de facto transfer of property must occur between Novopharm and the third party before any propriety rights can be acquired by Apotex.

[84] The chain of contracting ultimately used by Apotex and Novopharm was expressly contemplated by the Supreme Court and expressly found not to be a breach of the compulsory licence or an illegal sublicence: see also *Merck Frosst*, *supra* at paragraph 20.

[85] In paragraph 106 of its memorandum of fact and law, Merck suggests that Apotex's designated supplier would need "the power of representation and the power to affect the legal position of the principal [Novopharm]" in order to be Novopharm's agent for the purpose of manufacturing the norfloxacin that Novopharm was licensed to manufacture. There is no indication in *Merck Frosst* or *Eli Lilly*, both *supra*, that that is so.

[86] I would add that in both *Merck Frosst* and *Eli Lilly*, Apotex argued these points in its written submissions and was rebutted by written submissions made by Eli Lilly. In *Eli Lilly* at paragraph 91, the Supreme Court sided with Apotex, deciding that Novopharm was entitled to "manufacture the medicine itself or through Canadian agents." The Supreme Court in *Eli Lilly* rejected the very submissions that Merck makes to this Court and has ruled that the chain of contracting in this case was permissible.

E. Proposed Disposition

[87] For the foregoing reasons, I conclude that the Federal Court correctly determined that section 8 of the 1998 Regulations applies in this case and that the Federal Court did not commit any reviewable error in its determination of the period of damages for which Merck is liable.

[88] Therefore, I would dismiss the appeal, with costs.

"David Stratas"

J.A.

“I agree
J. Edgar Sexton J.A.”

“I agree
Carolyn Layden-Stevenson J.A.”

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-154-10
APPEAL FROM AN ORDER OF THE HONOURABLE JUSTICE O'REILLY DATED MARCH 12, 2010, NO. T-411-01	
STYLE OF CAUSE:	Merck Frosst Canada & Co. v. Apotex Inc.
PLACE OF HEARING:	Toronto, Ontario
DATE OF HEARING:	February 15, 2011
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CONCURRED IN BY:	Sexton and Layden-Stevenson JJ.A.
DATED:	November 25, 2011

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