Date: 20061010

Docket: A-232-06

Citation: 2006 FCA 323

CORAM: **LINDEN J.A.**
SEXTON J.A.
MALONE J.A.

BETWEEN:

Apotex Inc.

Appellant

and

Merck & Co., Inc., Merck Frosst Canada & Co., Merck Frosst Canada Ltd., Syngenta Limited, AstraZeneca UK Limited and AstraZeneca Canada Inc.

Respondents

Heard at Toronto, Ontario, on September 11 to 14, 2006.

Judgment delivered at Ottawa, Ontario, on October 10, 2006.

REASONS FOR JUDGMENT BY: MALONE J.A.

CONCURRED IN BY: LINDEN J.A.
SEXTON J.A.

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REASONS FOR JUDGMENT

MALONE J.A.

I. Introduction

[1] This is an appeal and cross-appeal from a decision of Hughes J., a Judge of the Federal Court (the Judge) dated April 26, 2006 and reported as 2006 FC 524. At issue is the validity and infringement of Canadian Patent 1,275,350 (the '350 Patent), which covers a class of compounds, including lisinopril, used in the treatment of hypertension. The '350 patent expires on October 16, 2007.

[2] There are two principal respondents, Merck & Co. Inc., which is the owner of the ‘350 Patent and its two Canadian affiliates (collectively Merck) as well as Syngenta Limited, AstraZeneca UK Limited and AstraZeneca Canada Inc. (collectively Astra). Astra is a licencee under the ‘350 Patent. Both actively sold drugs incorporating lisinopril in Canada until 2000. The appellant is Apotex Inc. (Apotex), a generic manufacturer that also markets a lisinopril product in Canada.

[3] This action was commenced in 1996 alleging that Apotex infringed claims 1, 2 and 5 of the ‘350 Patent. Apotex counterclaimed alleging invalidity of the patent. At the commencement of trial, Apotex admitted that if these claims were valid then it had infringed those claims subject to certain exemptions for lisinopril obtained from a licenced source and quantities used for exempted purposes.

[4] Hughes J. determined that Apotex had infringed each of claims 1, 2 and 5 of the ‘350 Patent, subject to certain exemptions, that Apotex was precluded from challenging the validity of those claims and that, in any event, those challenges to validity failed. Various remedies were granted that will be detailed later in these reasons.

[5] True to form, the parties have raised some 23 issues and sub-issues on the appeal and cross-appeal. However, the key question to be answered is whether a patent that meets the substantive requirements for patentability should be invalidated for an alleged failure to comply with a statutory provision during prosecution; the so-called improper divisional attack.

II. Statutory Regime

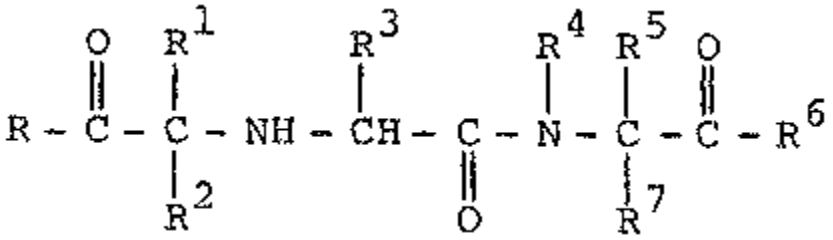
[6] Although the *Patent Act*, R.S.C. 1985, c.P-4 (the *Act*), was amended on October 1, 1989, transitional subsections 78.2(2) and (3) provide that applications filed before that date and patents arising there under, including the patent and applications at issue here, should be dealt with under its provisions as they read immediately prior to the amendments. Accordingly, unless otherwise indicated, references to the *Patent Act* in these reasons refer to the *Act* as it read immediately prior to October 1, 1989.

III. Factual Matrix

Background to the Biochemistry

[7] The patent claims under attack were issued in respect of a class of compounds discovered by Merck. The particular compounds in dispute are angiotensin converting enzyme inhibitors (ACE Inhibitors). Merck filed a United States patent application in late 1978 and a Canadian application number 341,340 (the '340 application) in late 1979. The compounds share the same general formula or "backbone," i.e. Formula I. Formula I contains seven locations, R plus R^1 through R^6, at which a choice of several chemicals or molecules may be placed. Where the compounds covered by the '340 application and all the patents derived there from differ is in the selection of chemicals and molecules which comprise each R through R^6. It was estimated by Hughes J. that easily billions of compounds could exist within this class.

[8] Formula I is depicted in the following diagram:



[9] Beginning in 1986, several divisional applications were divided out from the original ‘340 application, including the application which later matured to the ‘350 Patent. The ‘350 Patent encompasses a subset of the class of compounds covered by the original ‘340 application that includes lisinopril. Other divisionals derived from the ‘340 application are directed to other subsets of the class of compounds sharing Formula I that include two other antihypertensives, enalapril and enalaprilat.

History of the ‘350 Patent and Related Patents and Applications

[10] The first patent application resulting from Merck’s discovery of the Formula I class of compounds was United States application 968,249 filed on December 11, 1978. The ‘340 application was then filed in Canada on December 6, 1979, claiming priority from this earlier United States application. The disclosure was essentially the same as in the United States application; however, approximately 127 examples were added specifically disclosing lisinopril, enalapril and enalaprilat.

[11] In addition, there were also claims specific to each of lisinopril, enalapril and enalaprilat in the claims section of the Canadian patent application. Claims 1-3 were directed to classes of compounds. Claim 4 was specific to enalapril and Claim 5 to lisinopril. Claim 6 referred to nine

different compounds, the first of which was enalaprilat. Finally, Claim 7 was directed to a process for preparing the compounds.

[12] On February 22, 1983, United States Patent 4,374,829 issued, tracing back to the original United States priority application.

[13] As stated at paragraph 9, the ‘350 Patent is one of several patents that originated from the parent ‘340 application and whose underlying applications were “divided out” from the parent ‘340 application as divisionals. Merck divided out these applications on its own initiative. The division was not requested by the Commissioner of Patents (the Commissioner), nor did the Commissioner object when the divisional applications were filed and prosecuted.

[14] For ease of reference, the following time chronologies of the patent and divisional applications are outlined in the following tables:

Date	Patent/Application
December 11, 1978	The **initial (priority) patent** application was filed by Merck in the United States Patent Office (“U.S. Application”) and issued February 22, 1983.
December 6, 1979	The Canadian **‘340 Patent** Application was filed claiming the benefits of priority from the U.S. application (“Parent ‘340 Application”) and issued May 20, 1992.

Group	Date of Maturity	Divisional
First Group of Divisionals	October 16, 1990	Application 518,334 with claims to a class of compounds including enalapril filed on September 16, 1986. This application matured to **Patent '349**.
	May 5, 1992	Application 518,335 which included claims directed to enalaprilat filed on September 16, 1986. Ultimately matured to **Patent '313**.
Second Group of Divisionals	November 7, 1989	Application 576,715 which included claims directed to enalapril plus diuretic filed on September 7, 1988. Matured to **Patent '684**.
	November 8, 1990	Application 576,716, which included claims directed to lisinopril plus a diuretic and to uses of lisinopril alone filed on September 7, 1988. Matured to **Patent '559**.
Third Group of Divisionals	October 16, 1990	Application 607,198 which included claims directed to lisinopril filed on September 16, 1986. Matured to **Patent '350**.

Development and Commercialization of Lisinopril Products

[15] The first commercialization of lisinopril products in Canada was commenced by Merck in the early 1990s, followed closely by Astra. In October of 1990, Merck received a Notice of Compliance (NOC) from Health Canada giving it permission to market lisinopril in Canada in 5, 10, 20, and 40 milligram (mg) strength tablets.

[16] Astra then entered into an agreement with Merck, whereby Astra was licenced in respect of lisinopril products in Canada. Astra commenced selling lisinopril containing tablets in 5, 10 and 20 mg strengths in 1993.

[17] Delmar Chemicals (Delmar) manufactured lisinopril in Canada in the early 1990s under a licence from Merck in accordance with the compulsory licence scheme provided by the *Act.* Apotex obtained regulatory approval for the sale of a generic version of lisinopril tablets in a 5 mg

strength tablet in October of 1996, purchased lisinopril through an intermediary from Delmar and entered the market.

[18] In 1999, Apotex expanded its range of products to include 10 and 20 mg strengths. The entry of this additional dosage had a significant impact on sales for Merck and Astra and they essentially stopped supporting their lisinopril products in Canada in 2000.

Litigation between the Parties

[19] This is not the first litigation in which these parties have been involved. An earlier action commenced in 1991 dealt with the '349 Patent pertaining to enalapril (the Enalapril Litigation). After a lengthy trial, an appeal and several related proceedings, that patent was held to be valid and infringed by Apotex (see *Merck & Co. v. Apotex Inc.* (1994), 59 C.P.R. (3d) 133 (F.C.T.D.) and [1995] 2 F.C. 723 (C.A.)).

IV. <u>Decision Below</u>

[20] Since virtually all of the major issues decided by Hughes J. are now the subject of the appeal or cross-appeal, and will be analyzed in the issues section of these reasons, it is pointless at this juncture to summarize in detail his reasons for judgment. Accordingly, I will turn immediately to the issues before us after dealing briefly with the standard of review.

V. Standard of Review

[21] In appellate review, the nature of the question at issue determines the applicable standards of review. Questions of law are reviewable on a standard of correctness, while findings of fact or of mixed law and fact will be set aside only if it is determined that the trial judge has committed a palpable and overriding error (see *Housen v. Nikolaisen*, [2002] 2 S.C.R. 235).

[22] With respect to discretionary decisions of a trial judge, this Court cannot intervene merely because it would have exercised the discretion in a different manner. Rather, the test for our review of the exercise of judicial discretion is whether the judge at first instance has given sufficient weight to all relevant considerations (see *Reza v. Canada*, [1994] 2 S.C.R. 394 at paragraph 20). Accordingly, a high degree of deference is accorded in matters of discretion.

VI. Issues on Appeal

Issue 1: Was the '350 Patent improperly divided out from the parent '340 application because the latter disclosed only one invention?

[23] The key to this first issue is whether the parent '340 application discloses but one invention; a class of compounds sharing the Formula I backbone of which lisinopril, enalapril and enalaprilat are examples, or are they separate inventions, one being the class of compounds itself and the other three individual compounds separately claimed within the class? (*supra* at paragraphs 10 and 11)

[24] Hughes J. approached this issue by analyzing the construction of both the '340 and '350 claims. The Judge preferred the expert evidence of Drs. Nelson and Wolfenden, called as witnesses

for Astra, who both determined that each of lisinopril, enalapril and enalaprilat were as of 1978 or 1979 inventively different from each other (Reasons for Judgment at paragraph 48). His weighing of their evidence is not under attack in the present appeal.

[25] Were it not for Canadian jurisprudence that he considered binding, Hughes J. would have followed the House of Lords' decision in *May & Baker Limited* v. *Boots Pure Drug Company Limited* (1950), 67 R.P.C. 23 (H.L.) (hereafter *May & Baker*) in finding that the '340 application disclosed only one invention. He stated:

> It is compelling, having read the specification of the '340 application as a whole, endeavouring to give a purposive construction to what is stated there, to be driven to the same conclusion as the majority of the House of Lords in *May & Baker*, namely that there is but one invention described, namely a class of compounds having the structure of Formula I in common, useful in treating hypertension, and that lisinopril, enalapril and enalaprilat are simply illustrative members of that class.

[26] Hughes J. considered himself bound by two decisions of Thurlow J. in the Exchequer Court which were upheld by the Supreme Court of Canada and considered patents similar to the '340 application, *C.H. Boehringer Sohn* v. *Bell-Craig Ltd.* [1962] Ex. C.R. 201, aff'd [1963] S.C.R. 410 (S.C.C.) and *Hoechst Pharmaceuticals of Canada Ltd.* v. *Gilbert & Co.*, [1965] 1 Ex. C.R. 710, aff'd [1966] S.C.R. 189 (S.C.C.) (hereafter *Boehringer* and *Hoechst*). His reasoning is as follows:

> Were I to approach the matter without jurisprudential constraints, I would readily find that the '340 application is directed to but one invention, a class of compounds, of which individual compounds such as lisinopril are but illustrative. However, *Boehringer* and *Hoechst, supra*, oblige me to find otherwise, on the slender basis that there was, in the '340 application not only examples but also specific claims to the individual compounds enalapril, enalaprilat and lisinopril, each of which, on the theory of those cases, is a different invention from the class. A higher court may be persuaded otherwise however, for jurisprudential integrity in this Court, I must find that the '340 application discloses separate inventions to each of the class, to lisinopril, to enalapril and to enalaprilat.

[27] In this appeal Apotex makes two central arguments designed to illustrate that the ‘340 application discloses only one invention. First, it argues that *Boehringer* and *Hoechst* are distinguishable from the present case. Alternatively, it argues that those decisions do not stand, as Hughes J. suggests, for the principle that each claim in a patent discloses a separate invention.

[28] According to Apotex, those cases were concerned with the question of whether separate subject matter, differing in scope, substance and inventiveness, could be included in separate claims in the patent and by referencing each one, still satisfy the product-by-process and patentability requirements existing in the *Act* at that time (Apotex Memorandum at paragraph 59).

[29] While the main issues were different from those in the present case, both *Boehringer* and *Hoechst* considered the same preliminary issue considered by Hughes J.; that is, whether a patent which claims both a class of compounds and an individual compound discloses a single invention or more than one invention. For example, in *Boehringer* at 211 Thurlow J. stated:

> The plaintiff, however, submitted that as a matter of construction the specification discloses two inventions, one relating to the class of substituted morpholines and the other relating to the single substance 2-phenyl-3-methylmorpholine, and it will, I think, be desirable to determine this question before approaching the question of construction of the specification in detail.

[30] Apotex also attempted to distinguish the *Boehringer* and *Hoechst* decisions because the patent involved extensive disclosure of the unique beneficial properties of the particular class members claim that were being reviewed. Apotex does not expand on this point nor does it give a pinpoint reference identifying where these extensive disclosures might be found. However, in both decisions, Thurlow J. considered the effect of separate claims for the class of compounds and the

individual compounds before embarking on a review of the specification. Therefore, whether or not the specification contained extensive disclosure about the individual compounds was irrelevant to his construction of the claims. Accordingly, given that Thurlow J. considered the same issue as Hughes J. was called upon to consider with respect to a similar patent, in my analysis, Hughes J. was correct to rely on Thurlow J.'s analysis.

[31] A second argument is that Hughes J. wrongly interpreted *Boehringer* and *Hoechst* as standing for the principle that each claim of a patent discloses a separate invention. However, in my view, Apotex is reading the reasons of Hughes J. too broadly. Nowhere does he state that those cases stand for the broad proposition that each claim in a patent represents a separate invention. Rather, his holding is much narrower; namely, in cases as in the present, where a single patent application separately claims a class of chemical compounds and a single compound within that class, each separate claim discloses a separate invention. His reasons do not address the effect of any other types of claims.

[32] Apotex also argues that Thurlow J.'s reasons in *Boehringer* and *Hoechst* cannot stand because of his later decision in the case of *Ciba-Geigy AG v. Commissioner of Patents* (1982), 65 C.P.R. (2d) 73 (F.C.A.), which is said to reject this principle. However, that case is distinguishable as the Court was considering the effect of having claims disclosing a particular substance and claims disclosing the process for making that substance in the same patent concluding that the two are aspects of the same thing and are not separate inventions. That decision did not consider the effect of separate claims for a class of compounds and the individual compound within the class and

therefore, in my view, is not inconsistent with *Boehringer* and *Hoechst* which focused only on this latter issue.

[33] One final point on this issue deserves comment. There exists some inconsistency between paragraphs 48, 187, 213 and 116 of Hughes J.'s decision. At paragraphs 48, 187 and 213, Hughes J. finds that each of lisinopril, enalapril, and enalaprilat were inventively different from each other, and if separate patent applications had been filed they would have been allowed as separate, inventively different patents. However, at paragraph 116, Hughes J., in relying upon *May & Baker*, states that he would have readily found that the '340 application is directed to but one invention, a class of compounds, of which individual compounds such as lisinopril, enalapril, and enalaprilat are but illustrative.

[34] The proceedings before the High Court of Justice in *May & Baker* involved a petition by Boots Pure Drug Company, for revocation of the patent granted to May & Baker; and a motion by May & Baker for leave to amend by way of disclaimer the complete specification upon which the patent was granted in order to delete a broad class of compounds and to insert a new claim to two specific compounds. May & Baker petitioned that Court to amend the specification by restricting its scope from the broad claim of the class of compounds to only two compounds and by insertion of a new claim to the two compounds.

[35] The issue before the Court was whether a patentee who obtains a patent for a large class of compounds can then amend the specification to significantly limit the scope and to introduce a

claim to two specific compounds of known utility, which compounds were not specifically claimed (and only exemplified) in the originally granted patent.

[36] Jenkins J. refused to permit the amendments. As a result, the decision was appealed to the Court of Appeal, who confirmed his decision. The Court of Appeal concluded that the two compounds were not claimed as the invention in the original specification. They were merely given as examples or proofs of the results said to be obtainable from every member of the genus.

[37] The House of Lords confirmed the decision of the Court of Appeal, agreeing that to permit the amendment of the specification would claim an invention substantially different from that claimed in its original form.

[38] Clearly, *May & Baker* had nothing to do with divisional practice. The patent at issue did not contain a claim to the two specific substances themselves. These two substances were not specifically named in any claims, but were only named as examples as part of a broader class. This treatment shows that *May & Baker* considered the two substances as examples of a broad inventive class. In contrast, the ‘340 application contained not only examples of lisinopril, enalapril and enalaprilat, but individual claims to each of these compounds as well.

[39] Therefore, at paragraph 116 Hughes J. failed to distinguish between the issues before the Court in *May & Baker*, that is whether an amendment to disclaim a genus and add a claim to two compounds produces a substantially different invention, and the different issue of more than one

invention raised by Apotex. This would explain the inconsistency. In any event, his ultimate conclusion was in my view correct, that the divisional of the '350 Patent was not improper. Indeed, section 36 of the *Act* calls for a divisional in the circumstances of this case and in my view, Merck and Astra were simply complying with the *Act*.

Issue 2: What are the consequences of an improper divisional?

[40] Although it is not strictly necessary to answer the above question in light of my finding that the divisional was proper, I would say that even if there was an improper divisional, the consequences are not a loss of patent rights. Rather, as found by Hughes J., the division of a patent application is primarily a procedural matter and the principle of double patenting provides a sufficient remedy in the event that more than one patent issued for the same invention.

[41] Section 36 of the *Act* governs the procedure for divisional application. Subsection 36(1) provides that patents are to disclose only one invention, but that the disclosure of multiple inventions is not sufficient to invalidate the patent:

36(1) A patent shall be granted for one invention only but in an action or other proceeding a patent shall not be deemed to be invalid by reason only that it has been granted for more than one invention.	**36.(1)** Un brevet ne peut être accordé que pour une seule invention, mais dans une instance ou autre procédure, un brevet ne peut être tenu pour invalide du seul fait qu'il a été accordé pour plus d'une invention.

[42] Subsection 36(2) provides the authority for dividing out divisional applications from parent applications:

36(2) Where an application describes and claims more than one invention, the applicant may, and on the direction of the Commissioner to that effect shall, limit his claims to one invention only, and the invention or inventions defined in the other claims may be made the subject of one or more divisional applications, if those divisional applications are filed before the issue of a patent on the original application.	**36.(2)** Si une demande décrit plus d'une invention, le demandeur peut restreindre ses revendications à une seule invention, toute autre invention divulguée pouvant faire l'objet d'une demande complémentaire, si celle-ci est déposée avant la délivrance d'un brevet sur la demande originale.

[43] Subsection 36(4) provides that the divisional application is to be treated as a separate application but that it retains the filing date of the original application:

36(4) The divisional applications referred to in subsection (2) shall be deemed to be separate and distinct applications under this Act, to which the provisions thereof apply as fully as may be, and separate fees shall be paid on each of those applications and they shall bear the filing date of the original application.	**36**.**(4)** Une demande complémentaire est considérée comme une demande distincte à laquelle la présente loi s'applique aussi complètement que possible. Des taxes distinctes sont acquittées pour la demande complémentaire, et sa date de dépôt est celle de la demande originale.

[44] On appeal, Apotex urges that section 36 of the *Act* is not merely procedural and even if it is, non-compliance has the same effect as with other substantive provisions of the *Act*, namely a loss of patent rights.

[45] A review of the *Act* indicates that there are no provisions dealing with the consequences of an improper divisional. One is left therefore, to consider the purpose of section 36 and any other case law surrounding its meaning. In my analysis, the conclusions reached by the Judge are correct.

[46] First, in this case the Commissioner did not object when Merck divided out from the '340 application the claims which became the subject of the '350 Patent. As Hughes J. found, the

Commissioner implicitly approved the divisional and this decision should be given deference. Had the Commissioner rejected the divisional as improper, Merck could have reinstated the claims divided out in the parent application. To now hold that the original '340 application disclosed only one invention and therefore that the '350 Patent is invalid as an improper divisional would deny Merck the opportunity to reinstate the lisinopril claims into the parent application, which issued in 1992 without including a claim for lisinopril.

[47] Secondly, Merck and Astra point to a number of cases where the Courts have been unwilling to invalidate a patent based on non-compliance with patent prosecution procedures prior to the date of patent issuance where the Commissioner has not objected to the procedures employed: (see *Fada Radio Ltd. v. Canadian General Electric Co. Limited*, [1927] S.C.R. 520; *Aventis Pharma Inc. v. Apotex Inc.*, 2005 FC 1283 (T.D.) at paragraph 353, aff'd 2006 FCA 64, leave to appeal denied [2006] S.C.C.A. No. 136; *Beecham Canada Ltd. v. Procter & Gamble Co.* (1982), 61 C.P.R. (2d) 1 (F.C.A.)).

[48] Thirdly, Apotex has not advanced any case law showing that the consequence of an improper divisional is for that reason alone, a loss of patent rights. Apotex referred to the case *GlaxoSmithKline Inc. v. Apotex Inc.*, 2003 FCT 687, where Kelen J. found the patent at issue was an improper divisional because it did not disclose an invention different from that in the parent application. Kelen J. evidently did not consider an improper divisional alone to be enough to

invalidate the patent. Rather, he found the patent at issue void because it disclosed the same invention as the parent and therefore was invalid by virtue of double patenting. That decision is of no assistance in the present appeal.

[49] From a global perspective, when considering the harm that may result from an improper divisional, it becomes clear that the principle of double patenting provides a sufficient remedy. The harm is that two patents might issue for the same invention, giving the patentee differing monopolies. Where, as in the present case, the various divisional applications and the parent have no overlapping claims, there is no risk that a patentee will be able to extend its patent monopoly by having two patents for the same invention.

[50] In summary, Hughes J. correctly held that an improper divisional of a patent does not, in the absence of double patenting, give rise to a loss of patent rights. I would further only note that Apotex did not appeal the Judge's rejection of their double patenting argument and that issue is not before this panel.

Issue 3: Did the Judge improperly err by ignoring extrinsic evidence?

[51] Hughes J. rejected Apotex's argument that he should consider extrinsic evidence, including communications surrounding foreign patent prosecutions and statements of Merck's inventors, when construing the patents. He rejected the argument primarily on the basis that the general rule is that extrinsic evidence is inadmissible for the purpose of construing a patent specification.

[52] Apotex urges this Court to conclude that only one invention was disclosed by the ‘340 application by reference to statements made by Merck inventors and its internal documents. In my view these documents should have no bearing on this Court’s decision.

[53] As Hughes J. noted, in *Nekoosa Packaging Corp. v. AMCA International Ltd.* (1994), 56 C.P.R. (3d) 470 at 480, Robertson J.A. held that the general rule is that extrinsic evidence is inadmissible for the purpose of construing a patent specification and this must necessarily extend to the testimony of the inventor pertaining to the proper construction of the specification. Similarly, statements made by the patentee during the course of patent prosecution are not to be considered because the scope of the invention should be determined by reference to the patent itself (*P.L.G. Research Ltd. v. Jannock Steel Fabricating Co.* (1991), 35 C.P.R. (3d) 346 (F.C.T.D.), aff’d 41 C.P.R. (3d) 492 (F.C.A.)).

Issue 4: Is Section 28 of the *Act* relevant in the present appeal?

[54] Apotex argues that Merck’s claim for priority under section 28 of the *Act* from the earlier United States patent application constrains what could properly be claimed in the ‘340 application. Section 28 states that an applicant can claim priority from an earlier foreign application provided the Canadian and foreign application are for the same invention. *Boehringer* and *Hoechst* direct that the ‘340 application disclosed more than one invention because it separately claimed a class of Formula I-bearing compounds and several individual compounds.

[55] Contrary to Apotex's assertion, where a Canadian application contains material relating to subject-matter invented after the priority date, that subject-matter cannot benefit from that date. Such a defect in the priority claim will not invalidate the entire patent, but will simply result in the application bearing the Canadian filing date (see *Refrigerating Equipment Ltd. v. Drummond*, [1930] Ex. C.R. 154; *Canadian Marconi Co. v. Vera Prinzen Enterprises Ltd.* (1964), 46 C.P.R. 97 (Ex. Ct.)).

[56] As Hughes J. notes, all that a claim to priority does is to enable an applicant to claim an earlier date of filing or a notional date of invention if that became an issue. In the present appeal, there was no issue of anticipation by reason of intervening prior art between the priority date and the filing of the Canadian application. Therefore, the priority date was not at issue and cannot govern whether the parent '340 application disclosed one or more inventions.

Issue 5: Did Merck wilfully delay the prosecution of the '350 Patent?

[57] While the United States patent took less than five years to issue, the '350 Patent took almost twelve years from the filing of the original United States application, from which the '350 Patent claimed priority. Nevertheless, Hughes J. rejected the argument that the delay in issuing the '350 Patent was wilful. Importantly, he found that no evidence was tendered to show that the delay was unduly long or short. He also found that the longest delay in patent prosecution originated from the Patent Office, not Merck. Further, he refused to draw any inference from the evidence adduced by Apotex regarding lobbying for and against the abolition of the compulsory licencing scheme in Canada.

[58] I do not think this Court should interfere with Hughes J.'s reasons on this issue, as they are grounded in his analysis of the evidence before him and are a matter of considerable discretion. While Apotex lists a number of factors that might suggest that Merck did, in fact, delay prosecution of the '350 patent, in my opinion, Apotex has not succeeded in showing that Hughes J. made any palpable and overriding errors in concluding that there was no evidence of delay in the prosecution of the patent.

[59] In addition, Apotex did not point to any Canadian case law in which a patent was invalidated by reason of prosecution delay. Prosecution delay is an American concept that Apotex seeks to import into our Canadian jurisprudence. In my view, given that no underlying delay was shown in this case, this is not an appropriate case in which to consider whether this concept should be adopted in Canada.

Issue 6: Are the principles of cause of action estoppel or issue estoppel relevant in the present appeal?

[60] In their fifth amended reply and defence to counterclaim, Merck and Astra plead that Apotex was precluded on the principles of estoppel and/or abuse or process from introducing invalidity allegations that were raised or could have been raised in the Enalapril Litigation concerning the '349 Patent (*supra* at paragraph 19). Hughes J. agreed with the plaintiffs and held Apotex's invalidity allegations to be precluded by reason of estoppel.

[61] *Res judicata* has two branches, cause of action estoppel and issue estoppel. Abuse of process is a separate, but related doctrine. Hughes J. did not specify the type of estoppel on which he based his decision and consequently, Apotex's argument on appeal is that he erred in both invoking and then applying a hybrid, conflated, and legally unknown form of estoppel.

[62] Cause of action estoppel bars a party from alleging a cause of action against another if the same cause of action has already been determined by a court of competent jurisdiction (see *Angle v. Canada (Minister of National Revenue)*, [1975] 2 S.C.R. 248). Issue estoppel, on the other hand, arises where the proceeding concerns a different cause of action, but some of the issues raised have already been decided in an earlier proceeding. In *Danyluk v. Ainsworth Technologies Inc*., [2001] 2 S.C.R. 460 at paragraph 25 (hereafter *Danyluk*), the Supreme Court of Canada found that there are three preconditions to the operation of issue estoppel: that the same question has been decided; that the judicial decision which is said to create the estoppel was final; and that the parties to the judicial decision or their privies were the same persons as the parties to the proceedings in which the estoppel is raised or their privies.

[63] Counsel for Astra conceded in oral argument that cause of action estoppel could only apply if this Court found that the '340 application disclosed only one invention. Since I have already found that the '340 application discloses more than one invention, namely the class of compounds and each of lisinopril, enalapril, and enalaprilat separately, cause of action estoppel is not applicable to the present appeal.

[64] Similarly, I am satisfied that the grounds for issue estoppel have not been met. In his judgment, Hughes J. stated that the addition of Astra in this action as a licencee under the ‘350 Patent is irrelevant. With respect, I disagree. It is relevant to consider whether Astra was a privy of Merck so as to satisfy the third requirement of issue estoppel. Privies were defined by Binnie J. in *Danyluk* as somewhat elastic and that each determination should be made on a case by case basis.

[65] Astra is a licencee under the ‘350 patent. It therefore follows that since the ‘340 application discloses more than one invention, Astra did not have a participatory interest in the Enalapril Litigation so as to be considered a privy of Merck. Therefore, I find that issue estoppel should not have been applied to bar Apotex from asserting its invalidity defences.

[66] It follows from the foregoing analysis that Hughes J. erred when he determined that a valid “estoppel” existed in this case.

Issue 7: Is an injunction an appropriate remedy in the present case?

[67] The Judge granted Merck and Astra an injunction enjoining Apotex from making, using and selling lisinopril products until the expiry of the ‘350 Patent. With respect to any lisinopril products in Apotex’s possession at the time the injunction took effect, Apotex could either deliver the material up to Merck and Astra or retain the material, with an accounting for sales and hold any money received for such material in a separate trust fund. Apotex asserts that Hughes J. erred in law by awarding an injunction automatically, without proper consideration of relevant factors.

[68] The decision to award an injunction is a discretionary one entitled to considerable deference by this Court. I do not think Apotex has succeeded in showing that the Judge's exercise of that discretion warrants our interference. Apotex has provided little guidance as to the factors that should have been considered. Moreover, while Hughes J. does not specifically explain his reasons for awarding an injunction in great detail, the care with which he outlined the remedies section of his reasons militates against a finding that he did not adequately consider all relevant factors in awarding the injunction. In particular, the fact that he granted Apotex a thirty day grace period before the injunction would take effect shows he did not award the injunction automatically and without considerable thought.

[69] Moreover, in my analysis, an injunction in this case is an appropriate remedy. Not only did the Judge determine that the '350 patent was valid, but Apotex admitted infringement. Section 44 of the *Act* grants Merck the exclusive right to make, construct, use and sell its invention and clearly an injunction preventing Apotex from selling lisinopril until the expiry of the patent is necessary to protect Merck's rights.

Issue 8: Are there any statutory or common law exemptions available to Apotex?

[70] For ease of reference I would propose to deal with each of the exemptions claimed by Apotex under separate headings.

Section 56 – Material acquired before '350 Patent issued

[71] Section 56 of the *Act* provides that:

56(1) Every person who, before the issuing of a patent, has purchased, constructed or acquired any invention for which a patent is afterwards obtained under this Act has the right to use and sell to others the specific article, machine, manufacture or composition of matter patented and so purchased, constructed or acquired before the issue of the patent therefore, without being liable to the patentee or his legal representatives for so doing, but the patent shall not, with respect to other persons, be held invalid by reason of that purchase, construction or acquisition or use of the invention by the person first mentioned, or by those to whom he has sold it, unless it was the application for a patent therefore, in consequence whereof the invention became public and available to public use.	**56.(1)** Toute personne qui, avant la délivrance d'un brevet, a acheté, exécuté ou acquis une invention pour laquelle un brevet est subséquemment obtenu sous l'autorité de la présente loi, a le droit d'utiliser et de vendre à d'autres l'article, la machine, l'objet manufacturé ou la composition, de matières, spécifique, breveté et ainsi acheté, exécuté ou acquis avant la délivrance du brevet s'y rapportant sans encourir de ce chef aucune responsabilité envers le breveté ou ses représentants légaux. Toutefois, à l'égard des tiers le brevet ne peut être considéré comme invalide du fait de cet achat, de cette exécution ou acquisition ou utilisation de l'invention par la personne en premier lieu mentionnée ou par des personnes auxquelles elle l'a vendue, à moins que cette invention n'ait été achetée, exécutée, acquise ou utilisée durant une période de plus de deux ans avant la demande d'un brevet portant sur cette invention, en conséquence de quoi l'invention est devenue publique et disponible pour l'usage du public.

[72] Merck and Astra agreed that some lots of lisinopril were acquired by Apotex before October 16, 1990, the date the '350 Patent was issued and were therefore exempt from infringement by virtue of section 56. However, in contention were three lots, lot numbers P65485, P65510 and P65557 (the Delmar Batches), which were manufactured in Canada by Delmar but whose manufacture into lisinopril had not been completed before they were acquired by Apotex. Hughes J. found that with respect to these lots, Apotex was not exempt:

> While lisinopril as a molecule came into existence somewhere within each batch before October 16, 1990, until those molecules had been sufficiently isolated and purified so that Delmar could consider that it had arrived at a "*produit fini*", it cannot be said that Delmar had "purchased, constructed or acquired" the invention

> within the meaning of section 56. That did not happen with respect to either batch P65485 or P65510 until after the patent was granted.

[73] No record could be found in respect of the third lot, P65557, and accordingly, Hughes J. held that Apotex had not met its onus of proving the exemption with respect to it. With respect to batches P65485 and P655510, Apotex asserts that the jurisprudence considering the scope and application of section 56 has determined that the word 'invention' is broad enough to embrace any patentable subject-matter, whether tangible or intangible. Furthermore, the phrase "purchased, constructed or acquired" is similarly broad enough to include any means of obtaining such subject-matter.

[74] Apotex now argues that Hughes J. erred in electing to apply the principle that the patented object must be in a useable form as of the date of grant (i.e. ready to be shipped to a customer). The thrust of their argument is that this question can be answered only by concentrating on the person who purchased, constructed or acquired the subject matter rather than the use of the subject-matter itself. Apotex urges this Court to find that the relevant subject-matter in this case was the compound lisinopril, not the lisinopril dehydrate, that Delmar subsequently made using that compound.

[75] To settle this issue it is necessary to determine the meaning of 'purchase, constructed or acquired' as provided for in section 56. In *Lido Industrial Products Ltd. v. Teledyne Industries Inc.* (1981), 57 C.P.R. (2nd) 29 (C.A.) (hereafter *Lido*), the plaintiff in a patent infringement suit relied upon a patent for a shower head in which it improved its earlier invention. The defendant imported

and sold shower heads in Canada that infringed the claims of the patent. The defendant attacked the validity of the patent and asserted that it was immune from suit in respect of all the units by virtue of the present section 56 of the *Act*.

[76] In establishing whether the defendant could rely on that section, this Court held that the purpose of the section contemplates that the particular articles must actually be in existence at the date of the grant. On the evidence presented, the Court found that the appellant was entitled to the protection of that section with respect to shower heads that had already arrived in Canada, as well as other shower heads that had already been paid for and were in transit to Canada.

[77] This issue was also considered by this Court in the appeal of the Enalapril Litigation. The Court cited several decisions, *Lido* being one, and also a decision of Thurlow J. in *Libbey-Owens-Ford Glass Co. v. Ford Motor Co. of Canada Ltd.* [1969] 1 Ex. C.R. 529, aff'd [1970] S.C.R. 833 (hereafter *Libbey*). Thurlow J.'s decision concentrated on the actual use of the article purchased or acquired, rather than the article itself. He held that the right to use an article encompassed the right to use and sell products that are subsequently created by applying the article to its intended use.

[78] It follows for our purposes that the right to use a chemical compound encompasses the right to use and sell compositions that are created by applying the compound to its intended use. The fact that the use of a chemical compound may become incorporated into subsequently created products is, therefore immaterial. Accordingly, the form taken by an invention is not governing for the purpose of section 56. Pursuant to the Court in *Libbey*, the right to use an article includes the right

to use and sell things produced with that article. However, like most rules, there is also an exception. Such exception was expressed and adopted by this Court in the Enalapril Litigation.

[79] In that litigation, this Court had to decide whether Apotex's purchase of enalapril maleate prior to the granting of the '349 Patent could benefit from section 56. In delivering his decision for this Court, MacGuigan J.A. stated:

> The form taken by an invention is not governing for the purposes of s.56. Thus, if Apotex had purchased or acquired enalapril maleate in any form … it could be said to have acquired Merck's invention within the meaning of s.56. However, in the case at bar, the product which Apotex sought to purchase or acquire was pure powder. If the seller was not satisfied that the product met that description and could be delivered, Apotex could not be said to have acquired the product.

[80] Accordingly, if the seller Delmar did not consider the lots in question to be of such quality that it could be shipped prior to the grant of the '349 Patent, the enalapril maleate delivered to Apotex could not be said to be in existence for purpose of the statutory immunity. Only when it is deemed to be of proper quality could the enalapril maleate be considered to be purchased or acquired by Apotex within the meaning of that section.

[81] In the present case, therefore, Apotex cannot be said to have purchased or acquired the Delmar Batches until they obtained title to them. If the Delmar Batches were of a finished product, title would have passed to Apotex and Apotex could then claim the statutory benefit. However, that is not the case here. At trial, Dr. Dickinson, President of Delmar, testified that they were not satisfied that the Delmar Batches met the description of the lisinopril Apotex sought to purchase. The lisinopril had not yet been isolated as a solid and still had to undergo purification steps followed by drying, before it could be released as a finished product. These steps were eventually undertaken

but it was not until October 23, 1990 and November 7, 1990 that the Delmar Batches were packaged and ready for delivery.

[82] As a result, title could not pass to Apotex until the product was in a deliverable state (i.e. October 23, 1990 and November 7, 1990). By that time, the '350 Patent was already granted to Merck (October 16, 1990) and Apotex's right to reap the benefit of section 56 was already extinguished.

Exemption for Lots under Compulsory Licence

[83] Apotex claimed the benefit of a compulsory licence granted to Delmar while certain compulsory licence provisions were in force under the *Act*. Although compulsory licences granted after December 20, 1991 were terminated, transitional provisions in the *Patent Act Amendment Act*, 1992, S.C. 1993, c. 2 (*Amendment Act*), provide that rights under licences granted after December 20, 1991 would continue until February 14, 1993:

12(1) Every licence granted under section 39 of the former Act on or after December 20, 1991 shall cease to have effect on the expiration of the day preceding the commencement day, and all rights or privileges acquired or accrued under that licence or under the former Act in relation to that licence shall thereupon be extinguished.	**12.(1)** Toute licence accordée au titre de l'article 39 de la loi antérieure le 20 décembre 1991 ou après cesse d'être valide à l'expiration du jour précédent la date d'entre en vigueur et les droits et privilèges acquis au titre de cette licence ou de la loi antérieure relativement à cette licence s'éteignent.
(2) For greater certainty, no action for infringement of a patent lies under the *Patent Act* in respect of any act that is done before the commencement day under a licence referred to in subsection (1) in accordance with the terms of that licence and sections 39 to 39.17 of the former Act.	**(2)** Il ne peut être intenté d'action en contrefaçon d'un brevet sous le régime de la *Loi sur les brevets* à la date d'entrée en vigueur, au titre d'une licence visée au paragraphe (1) et conformément aux articles 39 à 39.17 de la loi antérieure ou à cette licence.

[84] Delmar held a compulsory licence (Delmar Licence) under which it manufactured batches of lisinopril. Some of the batches were produced and sold to a Panamanian company prior to February 14, 1993 (the Commencement Day). These batches were then sold to Apotex well after the Commencement Day. The current issue is whether Apotex could take the benefit of the Delmar Licence despite the fact that the lisinopril was acquired after the extinguishment of the licence.

[85] As with the construction of the '340 application, Hughes J. would have held in favour of Apotex had he not been bound by precedent. In his view, the licence, even if extinguished, still ran with the goods made before the licence was extinguished. However, he concluded that he was bound by an earlier decision of this Court dealing with a very similar licence granted to Delmar for the manufacture of enalapril where the Court concluded that Apotex was precluded from raising a compulsory licence defence because the argument had previously been rejected and no special circumstances had arisen that would permit re-litigation of the issue. He wrote:

> Since the Federal Court of Appeal in *Apotex Inc. v. Merck & Co.* (2002) 19 C.P.R. (4th) 163 *supra* in a decision involving the same parties, Apotex and Merck, in respect of a compulsory licence identical in terms with that at issue here, involving a patent which arose from the same parent application ('340) as the '350 patent here, has decided that Apotex was prevented from re-litigating the issue of the licence, I am compelled to say likewise. Apotex cannot, now, raise the '350 compulsory licence as a defence to infringement.

[86] Apotex now argues that no form of estoppel was ever raised by Merck and Astra in any pleading and no argument was ever advanced at trial to suggest that it was estopped from asserting that the subject lots were exempt from infringement. Therefore, it was not open to Hughes J. to make a finding on a point not raised in the pleading and where no evidence had been provided.

[87] I will first deal with Apotex's assertion that since no form of estoppel was ever plead by the Merck and Astra, Hughes J. erred in relying on *res judicata* as to the issue of the Delmar Licence. In the text, *The Law of Evidence in Canada* (Markham: Butterworths Canada Ltd., 1999), Sopinka states that it is well established that estoppel by *res judicata* must be pleaded. The leading statement on the necessity to plead *res judicata* is an ancient Supreme Court of Canada decision, *Cooper et al. v. Molsons Bank* (1896), 26 S.C.R. 611, where it was stated by Chief Justice Strong that:

> Under the system of pleading introduced by the Judicature Act, it has been decided that *res judicata* as a defence, or as a reply to a counter claim, must be specifically pleaded.

[88] I agree with Apotex that it was not open to Hughes J. to raise and decide this unpleaded issue. Accordingly, the Judge was incorrect in determining that Apotex was barred as a result of issue estoppel from relying on the Delmar Licence. Although Justice Hughes dismissed this exemption on the ground of *res judicata*, he still went on to state that:

> Should a higher Court wish to consider this issue afresh, my view is that the licence, even if extinguished, still runs with goods made before the licence was extinguished. As stated in *Eli Lilly*, *supra*, this affords a good defence to infringement.

In my respectful opinion, Hughes J. was wrong in making such a finding.

[89] In *Apotex Inc. v. Merck & Co*, [2003] 1 F.C. 242 (C.A.), this Court considered the law with respect to the rights inherent in patented material purchased from a licenced vendor. Apotex argued that the Supreme Court in *Eli Lilly and Co. v. Apotex Inc.*, [1998] 2 S.C.R. 129 (hereafter *Eli Lilly*) changed the law with respect to this issue. Apotex asserted that *Eli Lilly* stood for the proposition that use rights exist *in rem*, and are not consequently affected by extinguishment of the compulsory licence under which the goods were sold.

[90] On a review of Iacobucci J.'s decision in *Eli Lilly*, this Court held that Apotex's reasoning was erroneous. Iacobucci J.'s reasons only disclose that sale of licenced material by a licencee to an unlicenced purchaser passes the right to do with the material as the purchaser sees fit without fear of infringement, subject at all times to explicit restrictions in the licence itself. Iacobucci J. never addressed how the consequences of the statutory extinguishment of the licence affect the licencee or any unlicenced purchaser. On this basis alone, *Eli Lilly* was found to be distinguishable.

[91] Clearly, *Eli Lilly* did not change the law that a licensor's legal rights extinguish with the licence itself, and any use following that extinguishment would be subject to a potential action for infringement. I would agree with Merck and Astra that the Delmar licence did not run with the goods, and therefore, any rights that Apotex may have had, extinguished on the expiry date of the licence. Although my analysis on this issue differs from that of Hughes J., our conclusions are the same; specifically, that Apotex cannot rely on the Delmar Licence. On that basis, I would dismiss this ground of appeal.

Does the Limitation Period bar any lawful exemptions?

[92] Hughes J. found Apotex was able to rely on the 'regulatory use' exemption provided by subsection 55.2(1) of the *Act* (Post Oct 1/89), and the common law 'fair dealing' exemption as defences to infringement. However, he held that because those defences were not pleaded until Apotex amended its defence and counterclaim on January 26, 2006, the exemptions applied only to the six years prior to the pleading amendment.

[93] Section 39 of the *Federal Courts Act*, R.S.C. 1985, c.F-7 (*FCA*) provides for a six year limitation period where the action at issue is not confined to one province:

39(1) Except as expressly provided by any other Act, the laws relating to prescription and the limitation of actions in force in a province between subject and subject apply to any proceedings in the Federal Court of Appeal or the Federal Court in respect of any cause of action arising in that province.	**39.(1)** Sauf disposition contraire d'une autre loi, les règles de droit en matière de prescription qui, dans une province, régissent les rapports entre particuliers s'appliquent à toute instance devant la Cour d'appel fédérale ou la Cour fédérale dont le fait générateur est survenu dans cette province.
(2) A proceeding in the Federal Court of Appeal or the Federal Court in respect of a cause of action arising otherwise than in a province shall be taken within six years after the cause of action arose.	**(2)** Le délai de prescription est de six ans à compter du fait générateur lorsque celui-ci n'est pas survenu dans une province.

[94] Since 1993, section 55.01 of the *Act* (Post Oct 1/96), has provided a limitations provision that reads as follows:

55.01 No remedy may be awarded for an act of infringement committed more than six years before the commencement of the action for infringement.	**55.01** Tout recours visant un acte de contrefaçon se prescrit à compter de six ans de la commission de celui-ci.

[95] Hughes J. found that Apotex's manufacture and sale of lisinopril took place in a number of provinces and therefore provincial limitations periods referenced in subsection 39(1) were not applicable. However, it is not clear whether he chose a six-year limitation period on the basis of subsection 39(2) of the *FCA* or section 55.01 of the *Act*:

> The *Patent Act* now contains specific provisions as to limitations. Section 55.01 provides that no remedy may be awarded for an act occurring more than six years previous. The *Federal Court Act* (*sic*) R.S.C. 1985, s.39 provides that if no other limitation period is provided, provincial limitation periods apply where activity is confined to a single province, otherwise the period is six years. While Apotex's tablet manufacturing business is located in Ontario, it obtained material from Quebec and from abroad, it sells across Canada and exports product. No one

> province can be said to be uniquely involved. The six year limitation period is appropriate.

[96] In my view, on a plain reading of both subsection 39(2) of the *FCA* and section 55.01 of the *Act*, neither is applicable to limit the Apotex defences of infringement. Subsection 39(2) of the *FCA* refers exclusively to the time limit imposed upon a plaintiff to bring a proceeding and it makes no mention of a time limit for raising a defence. Similarly, the wording of section 55.01 of the *Act* is also straightforward: 'no remedy may be awarded for an act of infringement committed more than six years before the commencement of the action for infringement.' Clearly, these limitation periods apply only to a plaintiff alleging infringement and not to a defendant.

[97] Therefore, in my view, Hughes J. erred in limiting Apotex's exemption from infringement to the six years prior to when Apotex amended its pleadings. No limitation period applies to any lawful exemptions claimed by Apotex.

VII. Issues on Cross-Appeal

Exemptions

Issue 1: Is Apotex entitled to the regulatory use exemption under section 55.2(1) of the *Act*?

[98] Subsection 55.2(1) of the *Act* (Post Oct 1/89), reads as follows:

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.	**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.

[99] The primary ground of appeal here is that subsection 55.2(1) exempts only uses of the patented product prior to market entry and necessary to obtain a NOC. Once the generic, such as Apotex, enters the market, they argue that the exemption no longer applies.

[100] I do not agree. On a plain reading of subsection 55.2(1) it is clear that the provision is not limited to pre-market regulatory approval. In *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, [2005] 1 S.C.R. 533, the Supreme Court of Canada held that after abolishing the compulsory licensing regime, Parliament's desire to facilitate the entry of generic drugs into the market immediately after the expiry of a patent motivated the enactment of subsection 55.2(1). However, nowhere does the Supreme Court of Canada say that this was the only motivation behind subsection 55.2(1). Moreover, had Parliament intended to limit the application of that subsection to a NOC context, it would have limited the exemption to materials required for compliance with laws relating to NOCs, rather than the broader reference to any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product.

[101] In support of their submission, Merck and Astra also argue that subsection 55.2(1) is an exemption from the primary purpose of the *Act*, which they say is to protect the exclusive rights of a patentee, and therefore should be strictly construed. Again, I do not agree. In *Apotex Inc. v. Wellcome Foundation*, [2002] 4 S.C.R. 153 (S.C.C.) at paragraph 37, that Court held that patent law

seeks to find a balance between encouraging innovation and sharing the products of innovation with the public, rather than simply seeking to protect the patentee:

> A patent, as has been said many times, is not intended as an accolade or civic award for ingenuity. It is a method by which inventive solutions to practical problems are coaxed into the public domain by the promise of a limited monopoly for a limited time. Disclosure is the *quid pro quo* for valuable proprietary rights to exclusivity which are entirely the statutory creature of the *Patent Act*.

[102] Moreover, in *Harvard College v. Canada (Commissioner of Patents)*, [2002] 4 S.C.R. 45, the Supreme Court of Canada also acknowledged that the manner in which Canada has administered its patent regime reveals that the promotion of ingenuity has at times been balanced against other considerations. Subsection 55.2(1) is, accordingly not an exemption from the purpose of the *Act*, but is an integral part thereof by seeking to balance the rights of patentees with those of the public. Accordingly, I can see no basis for strictly construing subsection 55.2(1) as Merck and Astra suggest.

[103] Merck and Astra also submit that because none of the samples taken by Apotex were actually submitted to any regulatory body, Apotex is not entitled to rely on the subsection 55.2(1) exemption. However, the wording of subsection 55.2(1) does not support this submission. Any samples which are reasonably related to the development and submission of information under legislation or regulations are exempt by the provision. It does not limit the exemption to information actually submitted.

[104] In summary, Hughes J. did not err in his conclusion that subsection 55.2(1) applies to exempt Apotex from infringement with respect to incoming raw material and finished products

stored by Apotex in the event they are required for future reference in accordance with regulatory governmental requirements.

Issue 2: Is Apotex entitled to the common law fair dealing exemption?

[105] Merck and Astra argue that the Judge erred in law in finding that a fair dealing exemption to infringement exists, apart from the narrow exemption recognized in *Smith Kline & French Inter-American Corp. v. Micro Chemicals Ltd.*, [1972] S.C.R. 506 (hereafter *Micro Chemicals*), namely, that the experimental use defence only operates in the context of compulsory licencing where the uses are bona fide. Further, it is said that the Judge overlooked the fact that the activities at issue were conducted to further Apotex's business interests and was therefore, commercial in nature.

[106] They also rely on a decision of the Supreme Court of Canada in *Monsanto Canada Inc. v. Schmeiser*, [2004] 1 S.C.R. 902 (hereafter *Monsanto*). In that case, the Court considered the word 'use' in section 42 of the *Act*. The provision reads as follows:

42. Every patent granted under this Act shall contain the title or name of the invention, with a reference to the specification, and shall, subject to this Act, grant to the patentee and the patentee's legal representatives for the term of the patent, from the granting of the patent, the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used, subject to adjudication in respect thereof before any court of competent jurisdiction.	**42.** Tout brevet accordé en vertu de la présente loi contient le titre ou le nom de l'invention avec renvoi au mémoire descriptif et accorde, sous réserve des autres dispositions de la présente loi, au breveté et à ses représentants légaux, pour la durée du brevet à compter de la date où il a été accordé, le droit, la faculté et le privilège exclusif de fabriquer, construire, exploiter et vendre à d'autres, pour qu'ils l'exploitent, l'objet de l'invention, sauf jugement en l'espèce par un tribunal compétent.

[107] That Court ultimately rejected an approach to infringement litigation that has regard to whether the defendant has benefited or profited from the activity. In doing so, it determined that use

is not restricted to profitable uses, but also extends to all acts that otherwise further an infringer's business interests.

[108] Merck and Astra submit that this approach is consistent with the test applied in the United States Courts (see *Madey v. Duke University* (2002), 64 USPQ 2d 1737 (Fed. Cir. (C.A.)). In the United States, it has been held that the profit or non-profit status of the user is not determinative. One must also have regard to whether the act is in furtherance of the alleged infringer's business and is not for amusement, to satisfy idle curiosity, or for a strictly philosophical inquiry.

[109] I reject this assertion that the *Micro Chemicals* exception is limited and only applies as an adjunct to the grant of compulsory licences. Although the grant of a compulsory licence was at issue in *Micro Chemicals*, certainly it did not form the basis of the exemption. Moreover, the case *Frearson v. Loe* (1878), 9 Ch. D. 48, was relied on by the Supreme Court in *Micro Chemicals*, and in that case, the grant of a compulsory licence was not at issue. In my analysis, all that is required is that the infringing product was made merely by way of bona fide experiment, and not with the intention of selling and making use of the product in the commercial market.

[110] Merck and Astra argue in the alternative, that if an exemption does exist at law, apart from a right to apply for a compulsory licence, such an exception should be strictly limited. In this respect, they urge the application of the United States test. They allege that so long as the act is in

furtherance of the alleged infringer's legitimate business, and is not solely for amusement, to satisfy idle curiosity or for a strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defence.

[111] Following the Supreme Court of Canada in *Micro Chemicals*, the Judge was called upon to determine whether Apotex's use in making the patented substances was not for profit, but rather to establish that it could manufacture a quality product in accordance with the specifications disclosed in the application for patent. In this case, Hughes J. found that there had been use of lisinopril in ongoing research and development of alternate formulae, alternate techniques for tablet making and the like. On the present record, I am inclined to agree with Hughes J. that this ongoing research should be exempt as it meets the test in *Micro Chemicals,* particularly, because Apotex was trying to establish if it could manufacture a quality product.

[112] In any event, even if this Court applied the United States test in this case, I am satisfied that Apotex's research was used to satisfy their curiosity as to whether they could in fact manufacture a product with the specifications disclosed in the application of the '350 Patent.

[113] Finally, it is submitted that once the user had proceeded beyond the experimental and testing phase and has taken steps to manufacture, promote and sell the product, the fair dealing exception no longer applies. While this proposition is true, Hughes J. did not find that this occurred with the use of lisinopril in the development of alternate formulae and alternate techniques for tablet making. Since he was in the position, as trial judge, to examine the evidence, he should be accorded

deference as to this finding of fact. Accordingly, I can see no reason to interfere with his decision to exempt such lisinopril from infringement under the regulatory use exemption provided for by subsection 55.2(1) of the *Act*.

Remedies

[114] It is well established that this Court must show considerable deference to trial judges' choice of remedy and should only interfere where the trial judge has committed an error of law or principle (*Doucet-Boudreau v. Nova Scotia (Minister of Education)* [2003] 3 S.C.R. 3 at paragraph 87).

[115] Hughes J. determined that certain remedies for infringement should be awarded to both Merck and Astra. These remedies are as follows:

(1) Damages, the quantum of which were to be determined upon a reference;

(2) Apotex, its directors, officers, employees, agents and all those under its direction or control were enjoined from further infringement of the '350 Patent during its term commencing as of the 26th day of May 2006. Apotex was required effective that date to commence keeping an account of all lisinopril products it acquired, used, or sold since the delivery of his Reasons and was to place all funds received in respect of such products in a separate trust account subject to further order.

(3) Apotex was also required to deliver up to Merck and Astra or destroy under oath all lisinopril products in its possession as of and after May 26, 2006 except for those exempted. However, Apotex could retain certain lisinopril products for use in

accordance with the lawful exemptions or for use after the expiry of the '350 Patent if it provided an accounting and gave an undertaking to place all sums received in a trust account subject to further order.

(4) Pre-judgment interest, not compounded, was allowed on the award of damages at the average annual rate established by the Bank of Canada as the minimum rate at which it makes short term advances to the banks listed in Schedule I of the *Bank Act*, R.S.C. 1985, c. B-1;

(5) Post judgment interest was allowed bearing the annual rate of five per cent not to be compounded; and

(6) Costs were to be spoken to.

[116] Hughes J. refused their request for an award of profits and for so-called elevated damages thirty per cent above normal.

Issue 3: Whether Merck and Astra are entitled to a delivery up or destruction order?

[117] Merck and Astra now argue that in allowing Apotex the option of retaining lisinopril products, Hughes J. created a *de facto* stockpiling exception, allowing Apotex to immediately resume sales from stockpiled lisinopril once the '350 Patent expired. They point to Canada's obligations under the *Trade Related Aspects of Intellectual Property Rights Agreement* (TRIPS), 1869 U.N.T.S. 299, and the fact that in response to an unfavourable report on Canada's compliance with TRIPS by the World Trade Organization Panel on Canada – Protection of Pharmaceutical

Products – Parliament repealed subsections 55.2(2) and (3) of the *Act*. Those subsections had allowed third parties to manufacture and store patented pharmaceuticals six months before the expiry of the relevant patents, in a practice known as stockpiling.

[118] As Apotex correctly points out, those subsections effectively deemed infringing conduct to be non-infringing and were directed to third parties who would sell the stockpiled goods after patent expiry for their own benefit. In the present case, however, Apotex was permitted to retain only the infringing product that Hughes J. found to be exempt under subsection 55.2(1) and the fair dealing exception.

[119] At paragraph 113, *supra*, I already noted that once a user has proceeded beyond the experimental and testing phase, the fair dealing exception no longer applies. Moreover, at paragraph 104, *supra*, I found that the only lisinopril product exempt under subsection 55.2(1) is in respect of incoming raw material and finished products stored by Apotex in the event they are required for future reference in accordance with regulatory requirements. Therefore, in my analysis, I would direct that all such lisinopril product not used for exempt purposes must be delivered up to Merck and Astra, or destroyed under oath.

[120] I would add that this modified delivery up or destruction order seems to be just the type of reasonable limit on an patentee's exclusive rights contemplated by Article 30 of TRIPS:

Article 30 - *Exceptions to Rights Conferred*	**Article 30** - *Exceptions aux droits conférés*
Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.	Les Membres pourront prévoir des exceptions limitées aux droits exclusifs conférés par un brevet, à condition que celles-ci ne portent pas atteinte de manière injustifiée à l'exploitation normale du brevet ni ne causent un préjudice injustifié aux intérêts légitimes du titulaire du brevet, compte tenu des intérêts légitimes des tiers.

[121] A second argument is that Hughes J.'s delivery-up or destruction award was not a remedy available to him. It is argued that subsection 20(2) of the *FCA* limits the Court's ability to grant remedies to those known to common law or equity and that Hughes J.'s award goes beyond the normally recognized remedy. In addition, Merck submits that Hughes J.'s award is contrary to the purpose of a destruction or delivery-up award.

[122] I do not agree with Merck's interpretation of subsection 20(2) of the *FCA*. The subsection reads as follows:

20(2) The Federal Court has concurrent jurisdiction in all cases, other than those mentioned in subsection (1), in which a remedy is sought under the authority of an Act of Parliament or at law or in equity respecting any patent of invention, copyright, trade-mark, industrial design or topography referred to in paragraph (1)(a).	**20.(2)** Elle a compétence concurrente dans tous les autres cas de recours sous le régime d'une loi fédérale ou de toute autre règle de droit non visés par le paragraphe (1) relativement à un brevet d'invention, un droit d'auteur, une marque de commerce, un dessin industriel ou une topographie au sens de la *Loi sur les topographies de circuits intégrés*.

[123] Section 20 falls under the section of the *FCA* entitled "Jurisdiction of Federal Court" and is concerned with the Court's jurisdiction to hear and decide intellectual property matters. Nothing therein suggests that it is intended to limit a judge's creativity in fashioning appropriate remedies.

[124] Therefore, I can agree with Hughes J. to the extent that Apotex is permitted to retain exempted lisinopril product only. All other lisinopril product is to be delivered up or destroyed under oath by December 31, 2006, in order to comply with Canada's obligation under TRIPS.

Issue 4: Monies held in trust by Apotex

[125] Merck argues that Hughes J. erred in ordering that monies received by Apotex as of April 26, 2006 be paid into a trust account established by Apotex. Instead, Merck argues that the Judge should have ordered that the monies be paid into court.

[126] It follows from my analysis above that since Apotex cannot sell any of the exempt lisinopril products it retains, there is no need to decide whether money should be paid into court, or whether a trust account established by Apotex is sufficient. In the present circumstances, any monies presently held in trust should be subject to an accounting and paid to Merck and Astra by December 31, 2006.

Issue 5: Are Merck and Astra to be afforded an election between profits and damages?

[127] Once a patentee has successfully demonstrated infringement, the Court has the discretion to grant the patentee's choice of remedies pursuant to section 57 of the *Act.* If a judge thereby refuses

the award of an accounting of profits, damages are available pursuant to section 55. There is no presumption that the patentee is entitled to an election, rather a trial judge has complete discretion in deciding whether or not to grant this equitable remedy (see *AlliedSignal Inc. v. Du Pont Canada Inc.* (1995), 61 C.P.R. (3d) 417 (F.C.A.)); Apotex Inc. v. Merck & Co. et al. (1996), 70 C.P.R. (3d) 183 (F.C.A.)).

[128] Merck and Astra claim Hughes J. erred in refusing to allow them to elect an accounting of profits, rather than damages, as a remedy for Apotex's infringement. Their argument is premised on two alleged errors. First, they argue that in reaching this conclusion, Hughes J. relied on two irrelevant factors: the pace of the litigation and their failure to compete with Apotex's infringing products. Secondly, if this Court finds those factors to be relevant, they further assert that they were not responsible for the slow pace of the litigation and that they did in fact compete with Apotex.

[129] With respect to the first argument concerning irrelevant factors, the parties have not pointed to any authority precluding the Court from considering these two factors or enumerating the factors that must be considered. In *Beloit Canada Ltd. v. Valmet-Dominion Inc.* (1997), 73 C.P.R. (3d) 321 (F.C.A) (hereafter *Beloit*), this Court held that it was within the discretion of the trial judge to take into consideration the equitable results of the election of an accounting of profits based on the complexity and length of proceedings among other considerations. In other cases, the Court noted that other panels have identified circumstances under which an accounting of profits may reasonably be refused, such as excessive delay and misconduct on the part of the patentee.

However, nowhere does the Court say that these are the only factors that might reasonably be considered.

[130] In *Lubrizol Corp. v. Imperial Ltd.* (1992), 45 C.P.R. (3d) 449 (F.C.A.) (hereafter *Lubrizol*), this Court at page 474 approved the decision of a trial judge who considered the time taken by the plaintiff to commence the action and whether the infringing products competed with those of the plaintiff's:

> The award of the option of an election of profits is, in any event, clearly discretionary …
>
> > As a general rule, an appellate court will not interfere with the exercise of a discretion by a trial judge unless the judge has proceeded upon some erroneous principle, or some misapprehension of the facts, or where the order is not just and reasonable. (*Friends of the Oldman River Society v. Canada (Minister of Transport)* (1990), 68 D.L.R. (4th) 375 at p. 400, [1990] 2 F.C. 18, 5 C.E.L.R. (N.S.) 1 (C.A.).)

[131] These authorities support the view that a plaintiff's delay in initiating an action is a proper ground for refusing the election of an accounting of profits. In my view, delay in prosecuting an action once the action has been initiated has the same effect as a delay in bringing the action and therefore, should likewise be an appropriate ground for refusing the election.

[132] Nor have the parties pointed to any authority that a plaintiff's attempt to compete is a relevant consideration in awarding or refusing to award an accounting of profits. In arguing that their failure to compete with Apotex should not be a relevant consideration, Merck and Astra point to the fact that by competing they would drive down Apotex's profits, thereby reducing the amount they would be able to recover from Apotex on account of profits. With respect, I do not find that

argument persuasive. Had they made efforts to compete aggressively against Apotex, it is not certain that Apotex would have lowered prices or would have earned profits less than those already earned. Moreover, while the profits earned by Apotex on account of a decrease in market share might have been lower had they attempted to compete, Merck and Astra would themselves be earning profits in place of Apotex's lost profits.

[133] In summary, because the Courts have not settled conclusively on the factors that must be taken into account and because a trial judge has considerable discretion in determining whether an accounting of profits should be awarded, I cannot conclude on this record that this Court should interfere with the Judge's holding on the basis that he considered irrelevant factors.

[134] Two other collateral arguments bear comment. During oral argument, counsel indicated that there were over seventy-two pre-trial motions and other proceedings over a ten year period which on its face would indicate a highly contested proceeding and no undue delay. However, on closer inspection, there was a great deal of inaction during the first three years of this litigation that consequently lead to a status review hearing followed by the long and contentious series of motions. Accordingly, on this record, I cannot conclude that Hughes J. erred in finding that Merck and Astra left this action to proceed in a leisurely fashion.

[135] On the issue of their failure to compete, Astra concedes that it stopped competing. Merck, on the other hand, points to affidavit evidence used in Apotex's subsequent and unsuccessful attempt to stay the judgment of Hughes J., which indicates that Merck did in fact set prices closer to

those of Apotex. In my view, this evidence should have been placed in front of the Judge below and I choose to ignore it on the basis that Merck has not proceeded with due diligence.

[136] In summary, Merck and Astra do not have a *prima facie* right to an account of profits as the case law is clear that the choice between the two remedies cannot be left entirely to the successful plaintiff. In conclusion, given that the decision to award an accounting of profits is a discretionary decision, which is entitled to deference, Merck and Astra have not, in my analysis, shown that this Court should depart from the Judge's refusal to allow them to elect between and an accounting of profits and damages.

Issue 6: Pre-Judgment Interest

[137] Subsections 36(2) and (5) of the *FCA* grant complete discretion to Hughes J. to award pre-judgment interest at any rate that he considers reasonable in the circumstances. The Judge granted pre-judgment interest on the award of damages at the average annual rate established by the Bank of Canada. Merck and Astra had been seeking the average annual bank rate plus 1.5%, or in the alternative, a fixed rate of 5.75% with interest compounded to reflect modern commercial reality.

[138] Merck and Astra now argue that Hughes J. erred by ordering a rate of pre-judgment interest that is too low to properly account for commercial reality. Instead, it should be set at five per cent per annum, the minimum rate set out in section 3 of the *Interest Act*, R.S.C. 1985, c.I-15. That provision provides that whenever any interest is payable by the agreement of parties or by law, and no rate is fixed, the rate of interest shall be five per cent per annum. Moreover, compound interest

is said to be necessary to properly compensate them and to prevent Apotex from receiving a windfall benefit.

[139] Subsection 36(5) permits the Court to consider the conduct of the proceedings or any other relevant consideration in determining the entitlement to and the rate of pre-judgment interest. That subsection states:

36(5) The Federal Court of Appeal or the Federal Court may, if it considers it just to do so, having regard to changes in market interest rates, the conduct of the proceedings or any other relevant consideration, disallow interest or allow interest for a period other than that provided for in subsection (2) in respect of the whole or any part of the amount on which interest is payable under this section.	**36.(5)** La Cour d'appel fédérale ou la Cour fédérale, selon le cas, peut, si elle l'estime juste compte tenu de la fluctuation des taux d'intérêt commerciaux, du déroulement des procédures et de tout autre motif valable, refuser l'intérêt ou l'accorder pour une période autre que celle prévue à l'égard du montant total ou partiel sur lequel l'intérêt est calculé en vertu du présent article.

[140] Judicial discretion as to the appropriate rate and period for which interest will run is said to assist the court in controlling the litigation process and to avoid inappropriate compensation (see *Wellcome Foundation Ltd. v. Apotex Inc.* (1992), 40 C.P.R. (3d) 361 at 366 (F.C.T.D.)). In this case, Hughes J. found that Merck and Astra 'essentially threw in the towel and left this action to proceed in a leisurely fashion.' It seems obvious to me that the Judge was considering subsection 36(5) when he exercised his discretion and set the pre-judgment interest rate as set out above.

[141] I would also note that section 3 of the *Interest Act* is applicable only when there is no provision made in an applicable statute or in an agreement and no mechanism is provided by which a rate can be fixed. That section reads as follows:

3. Whenever any interest is payable by the agreement of parties or by law, and no rate is fixed by the agreement or by law, the rate of interest shall be five per cent per annum.	**3.** Chaque fois que de l'intérêt est exigible par convention entre les parties ou en vertu de la loi, et qu'il n'est pas fixé de taux en vertu de cette convention ou par la loi, le taux de l'intérêt est de cinq pour cent par an.

[142] It follows that the application of the *Interest Act* in this case depends upon the occurrence of two factors, namely, that interest be payable by law and that no rate of interest is fixed by law.

[143] With respect to the issue of whether the rate of interest is here fixed by law, the words 'fixed by law' should be given a liberal construction (see *British Pacific Properties Ltd. v. British Columbia (Minister of Highways & Public Works)*, [1980] 2 S.C.R. 283). In essence, whether a statute under which interest is payable prescribes the rate or whether the rate is remitted to a judge for determination, the rate ultimately awarded arises under law and is said to be 'fixed by law.' Section 3 of the *Interest Act*, therefore, does not apply to the present case and Hughes J. correctly fixed the interest rate accordingly. I am satisfied that he did not err when he awarded pre-judgment interest at the average annual rate established by the Bank of Canada.

[144] With respect to whether interest should be compounded, paragraph 36(4)(b) of the *FCA* provides a complete answer. It states:

36(4) Interest shall not be awarded under subsection (2),	**36.(4)** Il n'est pas accordé d'intérêts aux termes du paragraphe (2),
(b) on interest accruing under this section	**(b)** sur les intérêts accumulés aux termes du présent article;

[145] Therefore, Hughes J. did not err in refusing to award compound interest.

Issue 7: Post Judgment Interest

[146] It is argued that the post judgment interest rate should mirror the pre-judgment interest rate (i.e. the average annual bank rate plus 1.5%), or in the alternative, a fixed rate of 5.75%. Furthermore, an award of compounded post-judgment interest would allow full compensation when the award is finally paid and would discourage Apotex from delaying payment of the judgment award.

[147] The same considerations apply here as were relevant to pre-judgment interest. An award of compound interest and the rate of interest is completely discretionary and are matters that are to be weighed by the Judge. I can see no basis to conclude that Hughes J. erred in awarding simple post judgment interest in this case.

Issue 8: Whether Astra is entitled to elevated/exemplary/punitive damages?

[148] This ground of appeal is advanced solely by Astra. Merck and Astra had sought elevated, exemplary and/or punitive damages as Apotex had sold product beyond the prior acquired inventory to which it was limited under the NOC. The Judge declined to grant such an award on the basis that the matter had not been expressly pleaded.

[149] Rule 182(a) of the *Federal Court Rules*, SOR/98-106, states that every statement of claim shall specify the nature of any damages claimed. In *Whiten v. Pilot Insurance Co.*, [2002] 1 S.C.R.

595 (hereafter *Whiten*) the Supreme Court considered whether punitive damages were properly pleaded. In rendering the decision for the Court, Binnie J. held that one of the purposes of a statement of claim is to alert the defendant to the case it has to meet, and if at the end of the day the defendant is surprised by an award against it that is a multiple of what it thought was the amount in issue, there is an obvious unfairness.

[150] Clearly, punitive or exemplary damages must be pleaded. Astra asserts, however, that only after other damages are awarded are they required to present evidence on the subject of punitive damages. In asserting such a proposition, they rely on *Lubrizol Corp* v. *Imperial Oil Ltd.* (1996), 67 C.P.R. (3d) 1 (FCA). In that case, the Court had to determine whether exemplary damages should be awarded. In doing so, Stone and Linden JJ.A. held that the Court cannot decide whether exemplary damages are required until after it decides whether the general damages were insufficient for punishment and deterrent purposes. In other words, the Court must first assess the general damages.

[151] In my view, this case merely states that the Court will not turn its mind to a consideration of punitive or exemplary damages until all other damages are awarded. It is noteworthy that in *Lubrizol*, the Statement of Claim had pleaded for exemplary or punitive damages and counsel's opening address at trial referred to the claim for exemplary damages. Since such damages were pleaded, it was open to the Court in *Lubrizol* to decide whether or not they should be granted.

[152] I can find no basis to conclude that Hughes J erred in failing to award punitive or exemplary damages in the circumstances of this case.

VIII. Conclusion

[153] The appeal should be allowed in part on the issues of the limitation period for exemptions and estoppel and the judgment of Hughes J. on those issues should be set aside. The cross-appeal should be allowed in part on the issues of stockpiling and monies held in trust, and the judgment of Hughes J. on those issues should be set aside.

[154] On the appeal, Merck and Astra were largely successful and are therefore, entitled to their respective costs to be taxed at the upper level of Column IV for one senior and one junior counsel each. On the cross-appeal, Apotex was largely successful, and are therefore, should be entitled to its costs to be taxed at the upper level of Column IV for one senior and one junior counsel only.

"B. Malone"
J.A.

“I agree.
A.M. Linden J.A.”

“I agree.
J. Edgar Sexton J.A.”

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-232-06

(APPEAL FROM THE JUDGMENT OF THE HONOURABLE MR.JUSTICE HUGHES, DATED APRIL 26,2006 (FILE NO.T-2792-96))

STYLE OF CAUSE:	**Apotex Inc. and Merck & Co., Inc., Merck Frosst Canada & Co., Merck Frosst Canada Ltd., Syngenta Limited, AstraZeneca UK Limited and AstraZeneca Canada Inc.**
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CONCURRED IN BY:	Linden, J.A. Sexton, J.A.
DATED:	October 10, 2006

APPEARANCES:

H.B.RADOMSKI, DAVID M.SCRIMGER,NANDO DE LUCA,MILES HASTIE	FOR THE APPELLANT /
JUDITH ROBINSON,PATRICK E.KIERANS,JORDANA SANFT FOR MERCK;	FOR THE RESPONDENTS MERCK INC.ET AL.
GUNARS A.GAIKIS,J.SHELDON HAMILTON,NANCY P.PEI FOR ASTRAZENECA	FOR THE RESPONDENTS ASTRAZENECA ET AL.

SOLICITORS OF RECORD:

GOODMANS LLP, TORONTO,ONTARIO	FOR THE APPELLANT
OGILVY RENAULT, MONTREAL QUEBEC	FOR THE RESPONDENT MERCK INC.
SMART & BIGGAR, TORONTO	FOR THE RESPONDENT ASTRAZENECA ETAL