

Federal Court of Appeal



Cour d'appel fédérale

Date: 20161104

Docket: A-330-15

Citation: 2016 FCA 267

**CORAM: PELLETIER J.A.
BOIVIN J.A.
RENNIE J.A.**

BETWEEN:

APOTEX INC.

Appellant

and

ELI LILLY CANADA INC.

Respondent

and

ICOS CORPORATION

Respondent

and

THE MINISTER OF HEALTH

Respondent

Heard at Toronto, Ontario, on May 5, 2016.

Judgment delivered at Ottawa, Ontario, on November 4, 2016.

REASONS FOR JUDGMENT BY:

PELLETIER J.A.

CONCURRED IN BY:

BOIVIN J.A.
RENNIE J.A.

Federal Court of Appeal



Cour d'appel fédérale

Date: 20161104

Docket: A-330-15

Citation: 2016 FCA 267

**CORAM: PELLETIER J.A.
BOIVIN J.A.
RENNIE J.A.**

BETWEEN:

APOTEX INC.

Appellant

and

ELI LILLY CANADA INC.

Respondent

and

ICOS CORPORATION

Respondent

and

THE MINISTER OF HEALTH

Respondent

REASONS FOR JUDGMENT

PELLETIER J.A.

[1] It is not often that a panel of this Court is asked to rule that another panel's decision, issued days before, was wrongly decided. But that is what we were asked to do in this appeal. We were asked to depart from the recent judgment of this Court in *Mylan Pharmaceuticals ULC v. Eli Lilly Canada Inc.*, 2016 FCA 119, [2016] F.C.J. No. 406 (QL) [*Mylan FCA*], on the ground that it did not follow the Supreme Court's decision in *Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67, [2000] 2 S.C.R. 1067 [*Whirlpool*], a case which the appellant Apotex Inc. (Apotex) says decided the major issue in this appeal and in *Mylan FCA*. This is the fourth time the Federal Courts have been called upon to rule on whether Canadian patent no. 2,226,784 (the '784 patent), which claims the use of tadalafil in the treatment of erectile dysfunction, contains "patentably distinct" claims relative to an earlier patent covering tadalafil itself, Canadian patent no. 2,181,377 (the '377 patent). In the other three cases, the Federal Courts have referred to *Whirlpool* but, for various reasons, found that it did not assist them in answering the question which the parties had put before them.

[2] It is incontrovertible that every panel of this Court speaks for the Court and that no panel of the Court sits in appeal of other panels. That said, the jurisprudence recognizes the right of the Court to overrule its prior jurisprudence in very narrow circumstances: *Miller v. Canada (Attorney General)*, 2002 FCA 370, [2002] F.C.J. No. 1375 (QL) [*Miller*]. Apotex argues that the *Miller* criteria are met in this case because *Mylan FCA* did not follow *Whirlpool*. Given this argument, it is incumbent on us to review *Whirlpool* to see if Apotex is right. Having done so, I

agree that *Whirlpool* does not settle the question of the time at which to compare the claims of the two patents in issue in an obviousness-type double patenting case.

[3] Apotex makes a further argument in support of its appeal. It argues that the Federal Court erred in finding that the disclosure in the '784 patent was sufficient to teach the person skilled in the art how to make the invention claimed, in particular the hydrate of the claimed compound. In my view, this argument is without merit.

[4] I would therefore dismiss the appeal with costs.

I. BACKGROUND

[5] This appeal arises as a result of Apotex's application for a notice of compliance (NOC) pursuant to the terms of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, which would enable it to market its generic version of tadalafil. In its notice of allegation, Apotex contended that the '784 patent, which claims a monopoly on the use of tadalafil to treat erectile dysfunction, was invalid on various grounds. In particular, Apotex alleged that the relevant claims of the '784 patent claimed nothing new or inventive relative to the claims of the '377 patent, which claimed a number of compounds including tadalafil, for use as a medicine in humans. In doing so, Apotex was relying on the judge-made doctrine of double patenting. In response to Apotex's notice of allegation, Eli Lilly Canada Inc. (Eli Lilly), the holder of the rights under the '784 patent, brought an application for an order of prohibition to prevent the Minister of Health from issuing an NOC to Apotex.

[6] While these proceedings were underway, Eli Lilly faced an identical challenge from another generic, Mylan Pharmaceuticals ULC, which also alleged that the '784 was invalid by reason of double patenting. Eli Lilly's application to the Federal Court for an order of prohibition in that matter was heard in October 2014; judgement and reasons in favour of Eli Lilly, reported as 2015 FC 17, [2015] F.C.J. No. 10 (QL) [*Mylan FC*], were issued in January 2015.

[7] Eli Lilly's application for prohibition in the Apotex matter was heard in May 2015 so that the Federal Court Judge hearing that application had the benefit of the reasons in *Mylan FC* in deciding the double patenting argument. The Federal Court's reasons and judgement allowing Eli Lilly's application for an order of prohibition issued on July 20, 2015 and were reported as 2015 FC 875, 2015 F.C.J. No. 870 (QL) [*Apotex FC*].

[8] *Mylan FC* was appealed to this Court and, on April 20, 2016, *Mylan FCA* issued. This Court rejected Mylan's arguments as to double patenting. The argument turned on the date at which the comparison between the claims of the '377 and '784 patents should be made. This Court decided that the contest was between the priority dates of the two patents and, that on the facts, the choice of date did not matter as the result was the same in both cases: see *Mylan FCA* at paragraph 52. A few days later, on May 5, 2016, this appeal from *Apotex FC* was heard. In the normal course, given that the double patenting issue is identical in both cases, this Court would have simply followed *Mylan FCA* and rejected Apotex's double patenting argument on the basis that it had already decided this issue. Undeterred by this prospect, Apotex argued that *Mylan FCA* should not be followed for the reasons set out above.

[9] As noted earlier, Apotex framed its argument in terms of *Miller* where this Court identified the circumstances in which it would overrule its prior decisions. At paragraph 10 of *Miller*, this Court held that it would not overturn a prior decision unless it was “manifestly wrong, in the sense that the Court overlooked a relevant statutory provision, or a case that ought to have been followed.” If the case that ought to have been followed is a decision of the Supreme Court, the doctrine of *stare decisis* would require us to follow the Supreme Court quite apart from any dicta in *Miller*: see *Canada v. Craig*, 2012 SCC 43, [2012] 2 S.C.R. 489 at paras. 18-22.

II. THE EARLIER CASES

[10] Before reviewing the decisions in *Mylan FC* and *Apotex FC* (the Earlier Cases) which are the backdrop to this appeal, a few words about the science underlying the ‘377 and ‘784 patents are in order.

[11] Tadalafil is a member of a class of compounds known as PDE V inhibitors that interfere with an intercellular process that inhibits smooth muscle relaxation. The effect is thus to prolong smooth muscle relaxation. Smooth muscles are controlled by the autonomic nervous system, which means that they are not susceptible to voluntary control. Smooth muscles are found in various places including the heart, as well as other specialized tissue such as bronchial and vascular tissue. Smooth muscle relaxation can be useful in the treatment of conditions in which disordered smooth muscle contraction interferes with the normal functioning of human physiological systems. The ‘377 patent claims a number of compounds including tadalafil “for use in the treatment of stable, unstable and variant angina, hypertension, pulmonary

hypertension, chronic obstructive pulmonary disease, congestive heart failure, renal failure, atherosclerosis, conditions of reduced blood vessel patency, peripheral vascular disease, vascular disorders, inflammatory diseases, stroke, bronchitis, chronic asthma, allergic asthma, allergic rhinitis, glaucoma or diseases characterised by disorders of gut motility”.

[12] The tissue responsible for an erection in the human male is smooth muscle tissue. While it has long been known that an erection occurs when the penis becomes engorged with blood, it has taken some time to understand that this engorgement is the result of the relaxation of smooth muscles in structures in the penis known as *corposa cavernosa*. This understanding came to light in the period between the priority date of the ‘377 patent and the publication date of the ‘784 patent, which are the bookends for the discussion of the comparison date of the two patents.

[13] Turning now to the relevant issue in the Earlier Cases, it is undisputed that double patenting involves a comparison of the claims of the patents in issue, and not of the disclosure: *Whirlpool* at para. 63. However, before the claims can be compared, they must be construed. Construction is done from the point of view of the person skilled in the art, using the general knowledge common to such skilled persons at the material date. In the Earlier Cases, the critical issue was the date at which the claims of the two patents were to be compared, an issue whose relevance was a function of the evolution of the common general knowledge between the earliest and the latest candidates for the comparison date.

[14] There are three dates that recur in the discussion that follows. The first is the priority date which is the date of an international filing, or of another Canadian filing, as of which a Canadian

patent application claims priority. The second is the filing date, which is the date of the filing of the patent application in the Canadian patent office. Not every patent has a priority date but all have a filing date. The last date is the publication date of the patent, which occurs at the end of a confidentiality period of 18 months – which can be shorter at the applicant’s request – which begins on the earlier of the priority date or the filing date of a patent.

[15] In addition, section 28.1 of the *Patent Act*, R.S.C. 1985 c. P-4 (the Act) provides that the date of a claim in a patent application is the filing date or, if there is one, the priority date.

Further, section 28.3 of the Act provides that the date for assessing obviousness (not necessarily obviousness double patenting) is the claim date.

[16] In *Mylan FC*, the Federal Court rejected the priority date of the ‘784 patent as the date for comparison of the claims of the two patents under discussion:

...this priority date of the '784 Patent [the later patent] cannot be the relevant date. One cannot read into the claims of the first patent more than what would have been understood by the person skilled in the art at the claim date when comparing the claims of the second patent to those of the first patent.

Mylan FC at para. 134.

[17] The Court assessed Mylan’s double patenting argument as of the priority date of the ‘377 patent. The Federal Court found that, as of that date, it would not have been obvious to a person skilled in the art that tadalafil could be used to treat erectile dysfunction, particularly via oral administration. The Court then went on to consider if the result would be different if patent comparison occurred as of the priority date of the ‘784 patent, a date that it had previously discarded. The relevant change in the state of the art was the publication of the Canadian patent

covering sildenafil (the '902 patent), the active ingredient in the drug marketed as Viagra. The Court ultimately concluded that the publication of the '902 patent did not make it obvious to a person skilled in the art that tadalafil could be used to treat erectile dysfunction.

[18] In both cases, the choice between the priority dates of the patents in question was not determinative of the double patenting issue because the claims of the '784 patent were found to be patentably distinct from those of the '377 patent as of either date.

[19] The Federal Court did not address the possibility that the comparison date might be the publication date of either of the patents, probably because the parties framed their arguments in terms of the priority date of the '784 patent: see *Mylan FC* at para. 134. As for *Whirlpool*, the Federal Court found that it was of no assistance because it did not consider the issue of the comparison date: see *Mylan FC* at para. 133.

[20] In *Apotex FC*, which is the decision under appeal, Apotex argued before the Federal Court that the comparison date was the publication date of the '784 patent while Eli Lilly argued that it was the priority date of the '377 patent: see *Apotex FC* at para. 71. The Court's work was made easier by the fact that the parties agreed on the outcome of the analysis on each of these dates. Specifically, Apotex conceded in oral argument that the claims of the '784 patent would not be obvious over the claims of the '377 patent as of the priority date of the '377 patent. On the other hand, Eli Lilly did not contest that the relevant claims of the '784 patent would be void for double patenting if the date for comparison of the claims of both patents was the publication date of the '784 patent: *Apotex FC* at paras. 72-74.

[21] Given that the Federal Court had assessed double patenting as of the priority date of the '377 patent in *Mylan FC*, Eli Lilly argued that the Court should follow that decision and assess double patenting as of the same date. This led the Federal Court to consider whether it should follow *Mylan FC* as a matter of judicial comity. A number of arguments were made in that context but, for our purposes, there are two relevant conclusions.

[22] Apotex argued that the Federal Court should depart from *Mylan FC* because in that case the Federal Court erred in not selecting the publication date of the '784 patent as the comparison date, as taught by the Supreme Court decision in *Whirlpool*.

[23] The Federal Court rejected this argument. It found that while the Supreme Court ruled that the date for construction of the claims of a patent is its publication date, it did not decide as of which date courts should decide obviousness double patenting. Furthermore, the Court held that the decision in *Whirlpool* turned on a question of the sufficiency of the evidence on the issue of obviousness: see *Apotex FC* at para. 124. As a result, any comments in *Whirlpool* dealing with the publication date in the context of the double patenting analysis were, in the Federal Court's view, simply *obiter dicta* and thus not binding on lower courts: see *Apotex FC* at para. 125.

[24] The second relevant conclusion is found at paragraph 135 of the Federal Court's reasons where the following appears:

The issue of the correct date for undertaking the double patenting analysis is therefore moot as the same result obtains if the analysis is undertaken as of the priority date of either the 377 Patent or of the 784 Patent. Given the comity principle and the lack of authority on the point, I prefer not to make a firm determination on the point as under either of the two possible dates the same result obtains.

[25] This conclusion anticipates and is based upon a careful analysis of the evidence as to the common general knowledge of the person skilled in the art as of these two dates: see *Apotex FC* at paras. 136-68.

[26] In the end result, the Federal Court found that, whether one chose one priority date or the other as the comparison date, the claims of the '784 patent were patentably distinct from the claims of the '377 patent. Apotex's allegations of double patenting were therefore dismissed.

[27] Given the pleadings of the parties and the findings of the Federal Court in *Apotex FC*, the sole double patenting issue in this appeal is whether, as Apotex asserts, *Whirlpool* decided that the date for comparison of the claims of the patents in a double patenting case is the publication date of the later of the two patents. If Apotex is correct, both *Apotex FC* and *Mylan FCA* (and, by extension, *Mylan FC*) are wrongly decided.

III. WHAT DID WHIRLPOOL DECIDE?

[28] The issue in *Whirlpool* was whether the claims of the later patent, the '734 patent, which claimed flexible vanes on a dual action washing machine agitator were patentably distinct from the claims of the earlier patent, the '803 patent, which simply claimed "vanes" on a dual action agitator. A dual action agitator was a washing machine agitator which had an upper agitator which forced water and the washing machine load onto the lower agitator which rotated back and forth. In the '734 patent, the upper agitator came in two varieties: continuous operation and intermittent operation. Only the claims relating to intermittent dual action machines were in issue in the double patenting analysis.

[29] Binnie J., writing for the Court, began his analysis with a careful examination of the date at which the claims of a patent should be construed. He held that the correct date was the publication date of the patent. All the patents in suit in *Whirlpool* were issued prior to October 1, 1989 and were therefore subject to the terms of the “old” *Patent Act*. Under that Act, the publication date of a patent was its issue date. As noted earlier, the publication date of a patent under the current regime is at the end of the confidentiality period.

[30] Binnie J. then went on to address the issue of the construction of the ‘803 patent. He noted that, contrary to the usual case, the party challenging the patent was arguing for a broad interpretation of the claims of the patent while the patent holder argued for a narrow interpretation of those claims. This was so, he said, because of the appellant’s desire “to broaden the ‘803 patent to set up their argument for the invalidity of the later ‘734 patent”: *Whirlpool* at para. 51. Binnie J. reviewed the trial judge’s reasons and found that, in light of the evidence, it was open to the trial judge to conclude that as of the date of issuance of the patent (and thus, its publication) the claims of the ‘803 patent referred only to rigid vanes.

[31] The next step in the analysis was the construction of the ‘734 patent. This was done under the heading of “If the ‘803 Patent Claims Properly Construed do not include Flex Vanes, is the ‘734 Patent Nevertheless Invalid Because of Double Patenting.” Binnie J. began this analysis by setting out the law as to double-patenting and, in particular, the distinction between “same invention” double patenting and “obviousness” double patenting. The latter, wrote Binnie J., “prohibits the issuance of a second patent with claims that are not patentably distinct from those of the earlier patent.”: *Whirlpool* at para. 66.

[32] Having set out the law, Binnie J. turned to the evidence. Once again deferring to the trial judge's conclusions, he wrote that:

What distinguished '734 technology from '803 technology in respect of the intermittent drive claims was the substitution of flex vanes for rigid vanes, as the trial judge noted at pp. 189-90: "[t]he essence of the invention is the unique wash system produced by the combination of flex vanes with dual action agitation".

Whirlpool at para. 69.

[33] In light of this construction, were the claims of the '734 patent "patentably distinct" from the claims of the '803 patent? This question led to a discussion of the evidence of the competing experts in the case. The trial judge had discounted the evidence of the appellant's expert on the basis that he had little experience with dual action agitators, an assessment with which Binnie J. agreed. On the other hand, Binnie J. found the respondent's expert should not have been relied upon because he was an engineer who had worked in the respondent's product development group. Binnie J. found that he was, therefore, not a "satisfactory proxy for the 'ordinary worker'": see *Whirlpool* at para. 70. The 'ordinary worker' is the person skilled in the art, sometimes referred to as the person of ordinary skill in the art – often identified by the acronym POSITA.

[34] Binnie J.'s discussion of the state of the art is the basis for Apotex's argument that the comparison date is the publication date of the later patent. After having confirmed that the trial judge was entitled to reject the evidence of the respondent's expert because he was a member of the respondent's product development group, Binnie J. turned to the qualifications of the appellant's expert who had no experience with dual action washing machines. Binnie J. set out the factual context:

At the date the '734 patent issued (February 17, 1981), dual action machines no longer constituted esoteric technology intelligible only to the initiated. Dual action machines had been public since June 1975 – almost six years prior to issuance of the '734 patent. The '401 and '803 "dual action" patents had issued in Canada on January 2, 1979, and March 6, 1979, respectively, and in the United States considerably earlier than that. They were not prior art opposable to the validity of the '734 patent because they were co-pending in the Canadian Patent Office, but by 1981 dual action machines and the earlier patents were nevertheless well known and available to those with "a practical interest in the subject matter of [the] invention" (Catnic, *supra*, at p. 242).

Whirlpool at para. 73.

[35] In the next paragraph, Binnie J. continued his analysis of the weakness of the appellant's witness' evidence:

The trial judge was concerned, as I read his opinion, that Mr. Mellinger's testimony was not supported by the level of practical understanding of dual action washing machines that by 1981 was common knowledge among the skilled workers who were interested in this end of the washing machine business. Dual action agitators were, after all, big news for these people in the late 1970s.

[36] *Whirlpool* at para. 74. Apotex has fastened on the repeated references to 1981, the publication date of the '377 patent, to argue that Binnie J. would have assessed double patenting as of that date. At this point in his analysis, Binnie J. has already settled on the construction of the '734 patent: see *Whirlpool* at para.69. These references to 1981 occur in the context of the ability of the parties' experts to comment on whether the change from rigid to flexible vanes was obvious. Apotex argues that this demonstrates Binnie J.'s intention to decide the question of double patenting as of the date of the publication date of the later of the two patents.

[37] While this line of argument has a certain appeal, there are a number of factors which lead away from the conclusion urged by Apotex. It is, in my view, improbable that Binnie J. would

settle a significant point in the law of double patenting by implication and without addressing it directly. The care taken to justify the publication date of a patent as the date at which it is to be construed suggests that if Binnie J. intended to decide the issue of the comparison date of the claims of the patents in an obviousness double patenting suit, he would do so explicitly.

[38] Furthermore, the issue of the comparison date in double patenting cases had not arisen previously in the Supreme Court jurisprudence, nor in the works of the text book writers. It would be surprising, to say the least, if Binnie J. purported to deal with a novel question by implication. This is all the more so when one considers that the issue was there to be addressed if the Court chose to do so. Binnie J. flagged the fact that the state of the common general knowledge had evolved between the date of the date of the invention, the date of the filing of the '734 patent, and the latter's publication date: see *Whirlpool* at para. 55. In those circumstances, I can only conclude that Binnie J.'s reticence on the point was deliberate and that he did not intend to settle that particular question.

[39] For these reasons, I do not agree that *Whirlpool* has decided that the date at which the claims of the two patents in issue in a double patenting case are to be compared is the date of publication of the later patent. This remains an open question.

[40] I might add that the analysis in the Earlier Cases, in *Mylan FCA*, and in this case was driven by the fact that the parties chose to frame the issue in terms of the date for comparison of the claims of the patents in issue. Having conducted the analysis on the basis chosen by the parties, we should not be taken as having decided that this framework for analysis is the correct

one. The fact that this issue has not arisen in this form in the past may be an indication that there may be other ways to approach it. Perhaps, the Court, having construed the claims of each of the patents with the assistance of the persons skilled in the art, simply compares the claims and decides whether the later claims are patentably distinct from the earlier claims on the basis of the insights which it has gained in the course of the construction of the patents. This appears to be what was done in *Commissioner of Patents v. Farbwerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning*, [1964] S.C.R. 49, 1966 CanLII 66, and more recently in *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61, [2008] 3 S.C.R. 265. This is not to argue that this approach is any more correct than the comparison date approach but rather that, going forward, parties should not feel that they are locked into the framework chosen by the parties in these cases.

[41] That said, on the basis of my conclusion as to what *Whirlpool* decided, I find that Apotex's argument that *Mylan FCA* was wrongly decided fails; there is no reason for us to depart from it.

IV. INSUFFICIENCY

[42] Apotex's second ground of appeal is that the Federal Court erred in its conclusion that the specification of the '784 patent taught a person skilled in the art how to proceed from the manufacture of tadalafil itself to a solvate of tadalafil, more specifically a hydrate. The distinction between a solvate and a hydrate was set out by the Federal Court at paragraph 23 of its reasons:

A solvate is a physical form of a chemical compound that is a crystalline solid containing a solvent incorporated within the crystal structure. A hydrate is a solvate in which the incorporated solvent is water.

[43] The specification itself does not teach how this is to be done. Apotex's evidence tended to show that a person skilled in the art would have to engage in experimentation beyond what would be considered routine and the results were not guaranteed. The Federal Court acknowledged that further steps would have to be taken to get from tadalafil to a hydrate of tadalafil but accepted the evidence of Eli Lilly's expert that this was a matter of routine experimentation.

[44] Apotex relies upon a number of the Supreme Court decisions including *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)*, [1989] 1 S.C.R. 1623 at 1638, 1989 CanLII 64:

The description must be such as to enable a person skilled in the art or the field of the invention to produce it using *only the instructions contained in the disclosure* ... and once the monopoly period is over, to use the invention as successfully as the inventor could at the time of his application.

[Emphasis added.]

[45] This passage was repeated with approbation in *Teva Canada Ltd. v. Pfizer Canada Inc.*, 2012 SCC 60, [2012] 3 S.C.R. 625 at paras. 51, 71 [*Sildenafil*]. In *Sildenafil*, the patent was found deficient because the person skilled in the art would have had to conduct a minor research project to arrive at the invention: see *Sildenafil* at para. 75.

[46] The Federal Court found that the dispute as to the sufficiency of the disclosure was an evidentiary problem. Apotex disagrees and argues that the Federal Court erred in law in

accepting that the disclosure was adequate. In my view, applying the legal test for sufficiency of disclosure to the facts of this case is a question of mixed law and fact, reviewable on the standard of palpable and overriding error. The Federal Court relied on the same authorities as Apotex did in setting the test for sufficiency. The difference in their positions consists in applying that test to the facts of the case. This, in turn, turned on the Federal Court's preference for the evidence of Eli Lilly's expert as opposed to that of Apotex's expert. We are not in a position to second-guess the Federal Court's assessment of the expert evidence.

[47] In my view, Apotex's arguments on this portion of the appeal also fail.

V. CONCLUSION

[48] I would therefore dismiss the appeal with costs.

"J.D. Denis Pelletier"

J.A.

"I agree
Richard Boivin J.A."

"I agree
Donald J. Rennie J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET: A-330-15

STYLE OF CAUSE: APOTEX INC. v. ELI LILLY
CANADA INC. AND ICOS
CORPORATION

PLACE OF HEARING: TORONTO, ONTARIO

DATE OF HEARING: MAY 5, 2016

REASONS FOR JUDGMENT BY: PELLETIER J.A.

CONCURRED IN BY: BOIVIN J.A.
RENNIE J.A.

DATED: NOVEMBER 4, 2016

APPEARANCES:

Andrew Brodtkin
Sandon Shogilev
Jordan D. Scopa

FOR THE APPELLANT
APOTEX INC.

Jamie Mills
Chantal Saunders

FOR THE RESPONDENT
ELI LILLY CANADA INC. AND
ICOS CORPORATION

SOLICITORS OF RECORD:

Goodmans LLP
Toronto, Ontario

FOR THE APPELLANT
APOTEX INC.

Borden Ladner Gervais LLP
Ottawa, Ontario

FOR THE RESPONDENT
ELI LILLY CANADA INC. and
ICOS CORPORATION

William F. Pentney
Deputy Attorney General of Canada

FOR THE RESPONDENT
THE MINISTER OF HEALTH