Federal Court of Appeal | Cour d'appel fédérale

Date: 20170406

Dockets: A-553-14
A-554-14

Citation: 2017 FCA 73

CORAM: **DAWSON J.A.**
RENNIE J.A.
WOODS J.A.

Docket: A-553-14

BETWEEN:

HER MAJESTY THE QUEEN

Appellant

and

APOTEX INC.

Respondent

Docket: A-554-14

AND BETWEEN:

APOTEX INC.

Appellant

and

HER MAJESTY THE QUEEN

Respondent

Heard at Toronto, Ontario, on October 25 and 26, 2016.

Judgment delivered at Ottawa, Ontario, on April 6, 2017.

REASONS FOR JUDGMENT BY: DAWSON J.A.

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

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REASONS FOR JUDGMENT

DAWSON J.A.

[1] Trazodone, also referred to as trazadone, is an antidepressant drug. On January 25, 1988, Apotex Inc. filed a submission with the Health Protection Branch of Health Canada in which it sought approval to sell a generic version of trazodone in Canada. Apotex received approval seven years later, on February 28, 1995. By that time, two generic drug manufacturers, competitors of Apotex, had received approval to sell generic versions of trazodone in Canada.

[2] In October 1998, Apotex commenced an action in damages naming Her Majesty the Queen, as representative of the Minister of Health and officials within the Health Protection Branch of Health Canada, as defendant. In these reasons the defendant is referred to as Health Canada.

[3] In its action, Apotex alleged, among other things, that in the course of considering its drug submission officials of the Health Protection Branch committed misfeasance in a public

office and also acted negligently. Apotex also alleged a breach of contract based on violation of a settlement agreement entered into between Apotex and Health Canada while Apotex' submission was under consideration.

[4] Apotex' action was bifurcated in the Federal Court. The action went to trial on the issue of liability. If required, the issue of damages was to be addressed by the Federal Court at a later date.

[5] For lengthy reasons cited as 2014 FC 1087, the Federal Court found Health Canada was liable in damages because its officials committed the torts of misfeasance in a public office and negligence. These conclusions were based on a finding that officials of Health Canada both deliberately and negligently failed to adhere to the terms of the settlement agreement referred to above. The Federal Court went on to find that Apotex' damages should be reduced on the ground that Apotex had failed to mitigate its damages. The Federal Court dismissed the claim in contract because it found that the action was commenced outside the applicable limitation period.

[6] Two appeals and a cross-appeal are brought from the judgment of the Federal Court. For the purpose of this introduction, the following summary of the issues raised on the appeals is sufficient.

[7] In its appeal (A-554-14), Apotex asserts that the Federal Court erred by:

i. failing to consider whether Health Canada committed misfeasance in a public office and negligence for reasons apart from its treatment of the settlement agreement;

ii. concluding that Apotex failed to mitigate its damages; and,

iii. concluding that the claim in contract was statute barred.

[8] In its cross-appeal, Health Canada argues that the Federal Court erred by finding there was a breach of the settlement agreement.

[9] In its appeal (A-553-14), Health Canada submits that the Federal Court erred:

i. in law in finding that the settlement agreement created a relationship of proximity;

ii. in law by failing to negate any *prima facie* duty of care based on residual policy considerations;

iii. in the alternative, by making palpable and overriding errors of fact with respect to both the standard of care and misfeasance in a public office; and,

iv. further and in the alternative, by finding misfeasance on the facts as found.

[10] These appeals were consolidated by order of the Court. In accordance with the consolidation order, a copy of these reasons shall be placed in each Court file.

[11] For the reasons which follow, I have concluded that the Federal Court committed a single error that warrants intervention by this Court: the Federal Court erred by concluding that Apotex

failed to mitigate its loss. It follows that I would dismiss Health Canada's appeal. I would allow Apotex' appeal in part and vary paragraph one of the judgment of the Federal Court to read:

> Apotex is entitled to damages to be assessed on the basis set out in the reasons of the Federal Court issued on November 18, 2014, with the exception that Apotex did not fail to mitigate its damages.

In all other respects I would dismiss Apotex' appeal and Health Canada's cross-appeal.

[12] I begin my analysis by briefly setting out the facts required to situate these appeals. I then review the decision of the Federal Court as it relates to the issues raised on these appeals and consider the standard of review to be applied to the decision of the Federal Court. Finally, I apply that standard to the issues raised in the appeals.

I. Factual Background

[13] The Minister of Health is responsible for ensuring that drugs sold in Canada are safe and effective for their intended purpose. Thus, no drug may be sold or distributed in Canada unless approved by the Minister through the issuance of a notice of compliance.

[14] The present appeals arise from events that took place between 1988 and 1995. During those years, if a research-based pharmaceutical company (also referred to as an innovator) sought approval to sell a new drug in Canada, the innovator was required to provide sufficient information and material to enable the Minister to assess the safety and effectiveness of the new drug.

[15] If, during the same period, a generic drug manufacturer wished to obtain approval to sell a generic version of a drug already available for sale in Canada, the generic manufacturer was required to establish that its product was bioequivalent to the innovator's approved drug or to establish bioequivalence to a reference product that was known to be safe and effective. Two pharmaceutical products are bioequivalent if they are pharmaceutically equivalent and if their bioavailability can be expected to be essentially the same. Bioavailability refers generally to the rate and extent to which an active pharmaceutical ingredient is absorbed from the dosage form and becomes available in the body.

[16] For the purpose of assessing bioavailability, the guidelines published in 1981 by the Health Protection Branch stated that "generally" the bioavailability of a new generic drug product would be compared to that of an "acceptable standard". The 1981 Guidelines did not define an "acceptable standard".

[17] The Federal Court found the usual, but not invariable, practice from 1988 to 1995 was for a generic drug manufacturer to test its product against the innovator's drug as approved in Canada (reasons, paragraph 26). Indeed, it was an admitted fact that during the relevant timeframe the Health Protection Branch approved six drug products on the basis of a foreign reference product.

[18] The Federal Court described the approval process as "tedious" and noted that a generic drug manufacturer could expect that it would take at least one to two years from the date its submission was filed for a notice of compliance to issue (reasons, paragraph 23).

[19] On January 25, 1988, Apotex submitted to the Health Protection Branch a new drug submission seeking approval to sell its generic version of trazodone, Apo-Trazad (later referred to as Apo-Trazadone). In its submission, Apotex sought to demonstrate that its drug was safe and effective by submitting a bioavailability study that referenced a generic drug manufactured in the United States by Barr Laboratories, referred to as "Barr Trazodone", instead of a Canadian drug. Barr Trazodone had been approved for sale in the United States on the basis of a bioavailability study comparing it with trazodone approved for sale in the United States under the brand name Desyrel. Desyrel was sold in the United States by the innovator drug company Mead Johnson and Company.

[20] With its drug submission Apotex also submitted a letter dated December 22, 1987, from Bristol Laboratories of Canada, the Canadian company approved to sell the Desyrel product in Canada, to a Canadian doctor, Dr. Rein. In the letter Bristol advised that the Canadian and American Desyrel products were identical (Joint Book of Documents, tab 24).

[21] Apotex stated that the American authorities had approved Barr Trazodone using the United States Desyrel product as a reference and that the Canadian and United States Desyrel products were identical. Therefore, Apotex submitted that because Apo-Trazadone was identical to Barr Trazodone Apotex should be permitted to use the same bioavailability studies relied upon by Barr in its American application. Put another way, Apotex submitted that if American and Canadian Desyrel were identical, the Health Protection Branch should accept the bioavailability study that demonstrated that Barr Trazodone and U.S. Desyrel were bioequivalent as proof that Apo-Trazadone and Canadian Desyrel were bioequivalent.

[22] The Health Protection Branch did not approve Apotex' new drug submission. It advised Apotex that there was a "normal requirement" for a Canadian reference product and that Barr Trazodone was not an appropriate reference product unless it could be "conclusively proven" to be identical to "a product known to the Branch," i.e. the "standard trazodone product marketed in Canada" (Joint Book of Documents, tabs 23 and 32).

[23] On February 1, 1990, the Health Protection Branch advised that it would not require a Canadian reference product if "incontrovertible and verifiable evidence can be provided to establish that the product in a foreign market is identical in all respects to the Canadian product" (Joint Book of Documents, tab 40). Thus, the Branch was prepared to accept proof that the Canadian Desyrel was identical to the American Desyrel.

[24] Apotex refused to comply. It rejected what the Health Protection Branch referred to as its "policy" that required a Canadian reference product. Apotex filed an application for judicial review on August 13, 1990, requesting an order directing that the Minister review its application without requiring that the reference product be purchased in Canada and further directing the Minister to issue a notice of compliance to Apotex (reasons, paragraph 49).

[25] This application for judicial review never proceeded to hearing because the parties reached a settlement in November 1990 and Apotex discontinued the application. The written settlement agreement is set out in full at paragraph 51 of the reasons of the Federal Court. In the settlement agreement the parties agreed that:

i. The review of Apotex' new drug submission was continuing and had not been completed for the purpose of the then applicable *Food and Drug Regulations* (C.R.C. 1978, c. 870), ("Regulations").

ii. Existing and any further data provided by Apotex to establish that its product was chemically and therapeutically equivalent to a drug product sold in Canada would be considered. For the purpose of a comparative bioavailability study "the Health Protection Branch is prepared to consider evidence to establish equivalency between Canadian and non-Canadian reference standards" (emphasis added).

[26] As the Federal Court observed at paragraph 53 of its reasons, "[t]hings did not go well" after the settlement agreement was concluded. Apotex asserted that the Health Protection Branch failed to adhere to the terms of the settlement agreement. On July 17, 1991, Apotex filed a second application for judicial review in which it sought two orders of *mandamus*. First, Apotex sought an order directing the Health Protection Branch to review its submission and assess whether the submission adequately established the required safety and effectiveness of its drug "without regard to a condition precedent to such review that the reference product tested in the comparative bioavailability study be purchased in Canada or that there be a certification from the manufacturer of the Canadian reference product that it is identical to the non-Canadian reference product". Second, Apotex sought an order directing the Health Protection Branch to issue a notice of compliance to it.

[27] The application for judicial review was dismissed by the Federal Court on the basis that it was not patently unreasonable for the Health Protection Branch to require that a new drug

submission compare the proposed generic drug against a Canadian reference product (*Apotex Inc. v. Canada (Attorney General)*, [1993] F.C.J. No. 31, 59 F.T.R. 85). The Federal Court did, however, conclude that the Health Protection Branch's refusal to consider Apotex' full submission "because of a claimed policy that bioavailability studies be done only with reference to a Canadian product" was an unlawful fettering of discretion.

[28] The Federal Court also characterized the Health Protection Branch's manner of dealing with Apotex "to have been maladroit, at times dissembling if not actually misleading." This said, the Federal Court did not believe that the Branch "acted in bad faith or with malice."

[29] Following the second application for judicial review, the Health Protection Branch re-reviewed Apotex' submissions, and on April 8, 1994, concluded that Apotex had not "adequately established the bioequivalence of Canadian and U.S. Desyrel drug products."

[30] Apotex then provided further studies which were reviewed in June of 1994. Upon review of these further studies, the Health Protection Branch reviewer concluded in a "draft" report dated June 23, 1994, (Joint Book of Documents, tab 164) that:

> In light of the acknowledgement of chemical equivalence, the nature of the drug substance, and the results of comparative dissolution analyses in a variety of media over the physiological pH range, I have no outstanding concerns regarding the potential inequivalence of U.S. and Canadian marketed Desyrel.

[31] On December 16, 1994, the Health Protection Branch reviewer signed a report which contained only slight revisions to the "draft report". In it he concluded:

> In light of the Crown's acknowledgement of chemical equivalence, the nature of the drug substance, and the results of comparative dissolution analyses in a

> variety of media over the physiological pH range, I conclude that no basis remains for articulating concerns regarding the potential inequivalence of U.S. and Canadian marketed Desyrel.

[32] By January 3, 1995, one of the reviewer's superiors had read the report. She sent a short note to the reviewer asking how the Health Protection Branch might "extricate" itself from the matter.

[33] Thereafter, a lawyer with the Department of Justice sent what the Federal Court characterized to be "a peculiar letter" to Apotex' lawyers. The letter indicated that Health Canada was attempting to expedite the review of the drug submission. The letter also requested that Apotex sign a release, a copy of which was enclosed, releasing Her Majesty and others from "any and all manner of claims, actions, causes of action, debts".

[34] Afterwards, senior counsel at the Department of Justice advised that Health Canada would not seek any agreement which would limit any recourse which Apotex might properly have against Health Canada.

[35] On February 28, 1995, Apotex received its notice of compliance. No explanation has been provided for the lengthy delay between the draft and final reports or the significant delay between the final report and the issuance of the notice of compliance.

II. The Decision of the Federal Court

[36] The Federal Court began by reviewing the process for obtaining drug approval in Canada during the period from 1988 to 1995, and the usual practices of Health Canada during that period. The Court then reviewed in some detail the dealings between the parties. Helpfully, the Court tabulated the more relevant documents and events in a 38-page schedule to the reasons.

[37] In the course of its reasons the Federal Court made a number of findings of fact, including the following which are relevant to the issues raised on these appeals:

i. There was, at the relevant time, a general understanding, at least within the Health Protection Branch, that a Canadian reference product was required to establish the bioavailability, and hence the bioequivalence of a generic drug. This understanding was not reduced to writing until 1989, after Apotex' drug submission was received. This understanding was not an express requirement of either the *Food and Drugs Act*, R.S.C. 1985, c. F-27 or the Regulations (reasons, paragraphs 29 to 33).

ii. There was little evidence to support the Health Protection Branch's assertion that it had a "long-standing" policy of requiring a Canadian reference product. The Health Protection Branch was inconsistent in applying its "policy". However, there was no evidence that the Branch discriminated against Apotex in this regard (reasons, paragraphs 26, 71).

iii. In January 1989, early in the process, the Director of the Bureau of Human Prescription Drugs, Dr. G. Johnson, sent a memorandum to the Director General

of the Drugs Directorate "which clearly draws the lines that [were] followed throughout the history of this matter" (reasons, paragraph 39). The Director of the Bureau wrote:

> Therefore, on the basis of science alone, I am inclined to accept the arguments advanced by Apotex. However, we should also examine the possibility that we may be establishing a precedent if we follow this course of action that could see us forced to accept similar arguments from around the world. What is to prevent, for example, Apotex from commissioning a bioavailability study comparing the French brand of a product as the standard? If we accept the arguments advanced in this particular case, we could have a difficult time not allowing this type of study. This could be the start of a process that would see us lose control over the generic submissions.
>
> [Emphasis added]

iv. The Health Protection Branch knew that the American reference product Apotex relied upon was identical to its Canadian counterpart, because the Branch had approved the Canadian innovator's drug using data provided from the innovator's U.S. product. However, Health Protection Branch officials refused to look at the Canadian innovator's file because of an unwritten internal policy which directed that officials not look at the data submitted by the innovator for the purpose of evaluating the submission of a generic who subsequently sought approval to sell the same drug. Thus, the Health Protection Branch required Apotex to prove to the Branch that which it already knew to be true (reasons, paragraphs 46 and 25).

v. At the time the settlement agreement was concluded the only outstanding issue between the parties was that of bioavailability. Apotex believed that it could demonstrate bioavailability by equivalency, whereas the Health Protection Branch required identicality. The settlement agreement "clearly" stated that the Health

Protection Branch would look at the matter from the point of view of equivalency (reasons, paragraph 54).

vi. Thereafter, the Health Protection Branch did not follow the terms of the settlement agreement. The Branch "stayed on a path whereby they were insisting upon identicality." The Branch was "less than full and forthright in its dealings with Apotex." There was a deliberate attempt by the Branch "to stick to its position as to identicality while conveying to Apotex a sense that it was willing to be flexible, which it was not" (reasons, paragraph 55).

vii. Apotex was led to believe that if it submitted "a bit more data" to the Health Protection Branch, particularly with respect to dissolution rates, this would be sufficient to satisfy the Branch (reasons, paragraph 56).

viii. Despite asserting to Apotex that it was prepared to accept evidence as to the equivalency of the American and Canadian reference products, the Health Protection Branch was only prepared to consider evidence as to bioavailability with reference to a Canadian reference product (reasons, paragraph 71).

ix. The Health Protection Branch unlawfully fettered its discretion by refusing to consider Apotex' full submissions on the basis that a Canadian reference product was required (reasons, paragraph 71).

x. The Health Protection Branch misled Apotex into the belief that the Branch was willing to receive further data and review it on the basis of equivalency when the Branch was not willing to do so (reasons, paragraph 71).

xi. The Health Protection Branch made a deliberate attempt to frustrate Apotex' submission for a notice of compliance. There appeared to have been "endless

circling around the internal idea that a Canadian reference product must be used, and the insistence that Apotex must prove the impossible – identicality" (reasons, paragraph 95).

xii. Apotex wished to make its Apo-Trazadone submission a test case about whether a non-Canadian drug product could be used as a reference. "In no way was Apotex the victim that it purports to be" (reasons, paragraphs 105, 107).

xiii. While the words "careless and unconcerned about accuracy" could be applied to the testimony of Mr. Rowsell, the then Director of the Bureau of Pharmaceutical Surveillance, all of the remaining fact witnesses called on behalf of the Health Protection Branch "tried their best to be honest, but somewhat embarrassed, about the facts and evidence as to what went on some twenty to twenty-eight years ago" (reasons, paragraph 106).

xiv. The Health Protection Branch "was inefficient, hopelessly bureaucratic, dissembling and clumsy" (reasons, paragraph 108).

[38] The Federal Court went on to conclude that officials of the Health Protection Branch committed the tort of misfeasance in a public office. Officials were aware, since the date of the settlement agreement, that the Branch was to consider Apotex' submission on the basis of equivalency - yet the Branch ignored this requirement. Further, there was an effort to conceal this from Apotex. This constituted bad faith. Further, the Health Protection Branch was aware that its conduct would likely injure Apotex (reasons, paragraphs 117-119).

[39] Next, the Federal Court considered the tort of negligence. It found that the settlement agreement transformed the relationship between the Health Protection Branch and Apotex such that the Branch owed Apotex a duty of care. But for the settlement agreement, no duty of care would have been owed to Apotex. The Federal Court further found that no residual policy concerns, particularly concerns about indeterminate liability and the discretionary nature of the Branch's decisions, negated the existence of the duty of care. Finally, the Federal Court found that the actions of the Health Protection Branch breached the requisite standard of care. The breach occurred when officials insisted on assessing Apotex' submission on the standard of identicality, rather than the agreed-upon standard of equivalency (reasons, paragraphs 123-131).

[40] Next, the Federal Court determined that Apotex' claim for breach of contract failed because it was brought outside the applicable six year limitation period. The action was commenced on October 9, 1998. Thus, in order to be within the limitation period any breach of contract must have taken place after October 9, 1992. However, the Federal Court found that by April or July 1991, Apotex was aware of, and possessed knowledge of, sufficient facts to be aware that the Branch had breached the terms of the settlement agreement. Thus, the action was commenced outside the applicable limitation period (reasons, paragraphs 136-138).

[41] Finally, the Federal Court considered the issue of mitigation. The Federal Court first considered when Apotex' damages began to accrue. The Federal Court inferred that Apotex ought to have received its notice of compliance on November 26, 1991, one year after the settlement agreement was entered into. Therefore the Court found that Apotex' damages began to accrue as of that date.

[42] The Federal Court went on to conclude that Apotex' damages ought to be reduced because it did not take reasonable steps to avoid its loss. Specifically, the Federal Court found that a reasonable person would have taken steps to mitigate their damages by July 2, 1991. This was the date on which the Federal Court found that Apotex wrote to the Health Protection Branch advising that it would mitigate its damages for another drug (Apo-Zidovudine) by testing that drug against a Canadian reference product. As of that date, Apotex should have re-tested Apo-Trazadone using a Canadian reference standard. Had it done so, Apotex "may have received" its notice of compliance between 15 to 18 months later. It followed that in assessing damages, the starting date was November 26, 1991, but the termination date was mid-November 1992 (reasons, paragraphs 147-163).

III. Standard of Review

[43] The standards of review applicable to the issues raised on these appeals are as described by the Supreme Court in *Housen v. Nikolaisen*, 2002 SCC 33, [2002] 2 S.C.R. 235. The standard of review to be applied to questions of law is correctness. Findings of fact and inferences of fact are to be reviewed on the basis of palpable and overriding error. Findings of mixed fact and law are to be reviewed on the same deferential standard unless an extricable legal error can be demonstrated, in which event such error is reviewed on the correctness standard.

IV. Misfeasance in a Public Office

[44] I begin by setting out the legal principles relevant to the tort of misfeasance and then turn to the errors asserted by both Apotex and Health Canada.

A. *The tort of misfeasance in a public office*

[45] As neither party asserts any error in the Federal Court's articulation of the elements of this tort, as set out at paragraph 113 of its reasons, a brief description of the constituent elements of the tort is sufficient.

[46] The leading authority in Canada is *Odhavji Estate v. Woodhouse*, 2003 SCC 69, [2003] 3 S.C.R. 263. The Supreme Court explained that the tort is based on the rationale that the rule of law requires that executive or administrative powers "'may be exercised only for the public good' and not for ulterior and improper purposes" (paragraph 26).

[47] There are two constituent elements to the tort. First, there must be deliberate, unlawful conduct in the exercise of public functions. Second, there must be awareness on the part of the official that his or her conduct is unlawful and is likely to injure the plaintiff (paragraph 32). The requirement that the official must be aware that his or her conduct is unlawful is a reflection of the principle that misfeasance in a public office requires an element of bad faith or dishonesty (paragraph 28).

[48] The tort may arise in one of two ways. First, it may arise out of the conduct of a public office that is specifically intended to injure a person, or a class of persons. Second, it may arise out of the conduct of a public officer who acts knowing both that the officer has no power to do the act complained of and that the act is likely to injure the plaintiff. In either instance, a plaintiff must prove each of the tort's constituent elements (paragraph 22).

[49] Common to each element of the tort is the requirement that a public officer must have engaged in deliberate and unlawful conduct in his or her capacity as a public officer (paragraph 23). An act may be unlawful because an official acted in breach of a statutory provision, or in excess of the powers granted, or for an improper purpose (paragraph 24).

[50] I now turn to consider Apotex' appeal.

B. *Apotex' appeal*

(1) The Federal Court failed to consider liability arising apart from the settlement agreement

[51] Apotex asserts that the Federal Court erred in law by confining its analysis to Health Canada's conduct following the conclusion of the settlement agreement. Apotex further asserts that the Health Protection Branch engaged in three related acts of misfeasance prior to the settlement agreement. These acts are said to be the Health Protection Branch's:

- insistence on a Canadian reference product when there was no such statutory or regulatory requirement;
- assertion of a long-standing policy that prohibited reliance on a foreign reference product when no such policy existed; and
- insistence that Apotex prove the Canadian and American Desyrel products were identical, notwithstanding that the Branch had already reached this conclusion.

[52] I begin by rejecting the assertion that the Federal Court erred in law by confining its analysis to conduct subsequent to the conclusion of the settlement agreement.

[53] The reasons of the Federal Court were structured so that from paragraphs 7 to 101 the Court reviewed the entire history of the dealings between the parties, culminating with the issuance of the notice of compliance on February 28, 1995. At paragraphs 102 to 108 the Court set out its "overall view" of the circumstances of the case.

[54] As part of its overall view, the Court concluded that the Health Protection Branch was, particularly during the years up to 1993, an inefficient, badly run bureaucracy. The bureaucracy possessed unwritten policies such as those respecting the use of non-Canadian reference drugs and those respecting whether third-party files could be accessed in order to confirm information contained in those files. No one wanted to make a decision and consultation took place without end (reasons, paragraph 103). This view of the Health Protection Branch was consistent with the Court's finding, at paragraph 71 (on page 38), that while the Health Protection Branch "was inconsistent in applying its 'policy' with respect to insistence upon a Canadian reference product. […] there is no evidence that Apotex was subject to discrimination in that regard."

[55] The Court then moved to consider misfeasance, holding that since the date of the settlement agreement the Health Protection Branch knew that it was to consider Apotex' submission on the basis of equivalency and further holding that "[u]pon entering into the Settlement Agreement with Apotex, [the Health Protection Branch] acted in bad faith" (reasons, paragraphs 117 and 118).

[56] This was a finding that it was only after Health Canada entered into the settlement agreement that its conduct rose to the level of deliberate, unlawful conduct in the exercise of

public functions. The Federal Court did not err in law by failing to consider pre-settlement agreement conduct. On the whole of the evidence it only found bad faith to arise after completion of the settlement agreement.

[57] With respect to the pre-settlement conduct that Apotex asserts constitutes misfeasance, as explained in *Odhavji*, the tort of misfeasance requires an element of bad faith or dishonesty. A public officer must engage in deliberate and unlawful conduct in that capacity. The Federal Court declined to find bad faith or dishonesty prior to the conclusion of the settlement agreement. It found that the Health Protection Branch's insistence on a Canadian reference product prior to the settlement agreement did not constitute discrimination. Accordingly, it could not be said that the Health Protection Branch's insistence was deliberate and unlawful conduct in the exercise of public functions. Rather, as evidenced in the Johnson memorandum quoted above at paragraph 37 (iii), the Health Protection Branch was concerned about the policy ramifications that would flow from accepting non-Canadian reference products. Acting on that concern was in accordance with the proper exercise of the Branch's powers.

[58] Apotex has failed to show a palpable and overriding error on the part of the Federal Court in its appreciation of the evidence surrounding the conduct and intent of the Health Protection Branch prior to the settlement agreement.

C. *Health Canada's appeal*

[59] On its appeal, Health Canada asserts four palpable and overriding errors of fact, one error of law and one error of mixed fact and law. During oral argument counsel for Health Canada

advised that it withdrew the argument contained in its memorandum of fact and law that misfeasance must, as a matter of law, arise from a breach of a specific statutory duty.

[60] For the following reasons I reject the argument that the Federal Court erred in fact, in law or in mixed fact and law.

(1) The asserted errors of fact

[61] The four alleged errors of fact are said to be the Court's findings that:

- The Health Protection Branch deliberately examined Apotex' submission on the standard of identicality contrary to the settlement agreement.
- Health Protection Branch officials knew that the Canadian and American Desyrel products were identical.
- Health Protection Branch officials misled Apotex into believing that the Branch was willing to review further data.
- Apotex submitted data in 1990 that demonstrated equivalence.

[62] I begin my analysis by observing that considerable deference is owed to findings of fact made by a trial judge. Thus, findings of fact are reviewed on the standard of palpable and overriding error. A palpable error is one that is plainly seen. An overriding error is one that affects the judge's assessment of the facts. It is difficult to establish palpable and overriding error. Thus, it has been said that it is not enough to pull at leaves and branches but to leave the tree standing. Rather, the tree must fall (*Canada v. South Yukon Forest Corporation*, 2012 FCA 165, 431 N.R. 286, at paragraph 46).

(a) *The Health Protection Branch deliberately examined Apotex' submission on the standard of identicality contrary to the settlement agreement*

[63] Health Canada complains that the Federal Court failed to identify the evidence relied upon to make this finding and failed to indicate that it considered the evidence to the contrary. However, a Court is not required to extensively catalogue the evidence before it. A Court's mere reliance upon the evidence of some witnesses over others by itself does not form the basis of a reasonable belief that the Court forgot, ignored or misconceived the evidence in a way that influenced its conclusions (*Housen*, paragraph 46).

[64] In the present case, there was ample evidence to support the finding of the Federal Court that the Health Protection Branch examined Apotex' submission on the standard of identicality. Some of the evidence is referred to at paragraphs 53-59 and 71 of the Court's reasons. To illustrate:

- On November 5, 1990, Apotex submitted additional data to show the equivalence of Canadian and American Desyrel (Joint Book of Documents, tab 53). The additional data was reviewed by Dr. Cheriyan, a Chemistry Specialist with the Health Protection Branch. This was agreed by the parties to be the only review of the data which was conducted prior to Health Canada's letter of December 20, 1990. This letter advised Apotex that the data it submitted was not sufficient to establish the equivalency of the Canadian and non-Canadian reference standards (Agreed Statement of Facts, paragraph 15). In the memorandum prepared by Dr. Cheriyan which outlined the result of his review, he concluded that the data "does not unambiguously prove that the two formulations are identical and I

recommend that Apotex be advised accordingly." His memorandum goes on to make numerous references to identicality (Joint Book of Documents, tab 63).

- In cross-examination, Mr. Rowsell confirmed that he understood Dr. Cheriyan to have applied the identicality standard to his review of Apotex' data (transcript October 27, 2014, page 902, line 26).
- Apotex' expert, Dr. Kibbe, understood from his review of the relevant documents that Dr. Cheriyan had applied the standard of identicality to his review of the data (transcript October 22, 2014, page 495, line 10 to page 496, line 16).

[65] No palpable and overriding error of fact has been demonstrated on the record before the Federal Court.

(b) *Health Protection Branch officials knew that the Canadian and American Desyrel products were identical*

[66] Health Canada argues that this conclusion was reached "in the total absence of evidentiary support, and by failing to address evidence to the contrary" (memorandum of fact and law, paragraph 84).

[67] Again, I find there was ample evidence to support the finding of the Federal Court:

- In his memorandum of January 20, 1989, Dr. Johnson wrote that it was not "illogical" to conclude that the bioavailability study provided by Apotex with its new drug submission "is applicable to the Apotex and Bristol products marketed in Canada" (Joint Book of Documents, tab 21) He went on to state:

> This point is further strengthened by the fact that the Mead Johnson product, in addition to being identical to the Bristol product, was in fact the product mainly used in carrying out pivotal studies performed in the U.S., which [studies] were also submitted in support of the Canadian NDS for Desyrel. [Emphasis added]

- At trial, Mr. Rowsell confirmed that Dr. Johnson had reviewed the Desyrel new drug submission in order to learn what data had been provided in support of the submission (transcript October 27, 2014, page 831, lines 24 to 28).
- Apotex had provided with its new drug submission a letter from Bristol Laboratories, the company that markets Desyrel in Canada, confirming that the Canadian and American Desyrel products were identical. At trial, Mr. Rowsell admitted that the Health Protection Branch could have confirmed the reliability of the letter's contents directly with Bristol Laboratories (transcript October 27, 2014, page 835, line 22 to page 836, line 24).

[68] No palpable and overriding error has been shown.

(c) *Health Protection Branch officials misled Apotex into believing that the Branch was willing to review further data*

[69] Again, Health Canada complains that the Federal Court failed to address conflicting evidence that the Health Protection Branch's reviews and re-reviews were conducted on the basis of equivalence. Again, I am satisfied that the finding of the Federal Court was amply supported on the evidence.

[70] Mr. Rowsell swore an affidavit in opposition to Apotex' second application for judicial review in which he swore that:

> 33. In accordance with the settlement agreement, we reviewed all of the material submitted by Apotex. The director was not persuaded that the reference standard used by Apotex was equivalent to a product marketed for sale in Canada, and was not persuaded that the evidence submitted respecting Apo-Trazad was sufficient to establish that the product was safe and effective as required by regulation C.08.002.
>
> 34. In spite of an inadvertent reference to the usual requirement that Canadian and foreign reference products be "identical" in my letter dated December 6, 1990 to Dr. Sherman, which is marked as Exhibit "C" to his affidavit sworn July 10, 1991, the Department has consistently kept an open mind in reviewing the submissions presented by Apotex relative to establishing that the reference standards are equivalent, and we have made every effort to abide by both the letter and spirit of the settlement agreement, as stated in the letter from Department of Justice Counsel to Apotex's Counsel referred to in paragraph 29 herein.
>
> [Emphasis added]

[71] The second application for judicial review was heard by Mr. Justice MacKay of the Federal Court.

[72] At the trial of this action Mr. Rowsell was cross-examined on the evidence he provided before Justice MacKay in the second application for judicial review:

> Q. You represented to Justice MacKay that a review against equivalency had been conducted while at the same time reprimanding a staff member because he had erroneously said that in a letter [to] Dr. Sherman; true?
>
> A. Yes.
>
> Q. In Paragraph 34 you say:
>
> "In spite of an inadvertent reference the department has always kept an open mind in reviewing the submission presented by Apotex relative to establishing that standards are equivalent."

And then you said:

"We have made every effort to abide by both the letter and spirit of the settlement."

Do you see that?

A. Yes.

Q. And that was to conduct an equivalency review?

A. Yes.

Q. But you knew when you swore that affidavit that your department had not neither in spirit or letter or fact abided by the agreement and you reprimanded your department for that?

A. Yes.

Q. And you didn't tell Justice MacKay?

A. No.

Q. You didn't produce, as part of this record, the Cheriyan review?

A. No.

Q. You had it?

A. Yes.

Q. Looking back at this affidavit now, many years later, cooler heads sometime prevail when you're out of the rough battle of the day?

A. Yes.

Q. Do you wish you had told Justice MacKay an equivalency review hadn't been done? That would have been more complete; right?

A. Yes.

[Emphasis added]

[73] Thus, Mr. Rowsell admitted at trial that he misled the Federal Court, and by extension Apotex, by suggesting that the Health Protection Branch was prepared to review additional data

on the standard of equivalence in compliance with the spirit and the letter of the settlement agreement.

[74] There was sufficient evidence to support the finding that Apotex was misled by the Health Protection Branch.

(d) *Apotex submitted data in 1990 that demonstrated equivalence*

[75] Apotex' expert, Dr. Kibbe, opined that as of November 5, 1990, Apotex had established equivalency between the Canadian and non-Canadian reference standards. The Federal Court accepted this evidence which it referred to as "uncontradicted evidence" (reasons, paragraph 56).

[76] Health Canada asserts at paragraph 91 of its memorandum of fact and law:

> […] In cross-examination, Apotex's expert conceded that any definition of equivalence must account for therapeutic equivalence – that is, equivalent *in vivo* results when administered to different patients. The data submitted with the McKeag Memo was solely to establish chemical equivalence between the reference products. None of the evidence before the court suggests that the 1990 FTIR data purported to establish therapeutic equivalence. The trial judge committed a palpable and overriding error in adopting a bare assertion in the Kibbe Affidavit, which was contradicted by other aspects of his evidence.
>
> [Emphasis added]

[77] The reference to the "McKeag Memo" is a reference to a memorandum prepared by Apotex and provided to Health Canada on or about November 5, 1990.

[78] It is, in my view, inaccurate to characterize the data submitted with the McKeag memo on November 5, 1990, to consist solely of Fourier-Transform infrared (FTIR) spectra data

submitted to establish chemical equivalence. This is so because, as explained by Dr. Kibbe, the McKeag memo also incorporated results from dissolution studies.

[79] Dr. Kibbe's opinion, which the Federal Court accepted, was:

> 28. I am advised that settlement discussions took place in early November 1990. I am advised that the settlement discussions concerning the application and Apotex's Apo-Trazad submission culminated in a settlement agreement dated November 26, 1990. I have been provided with a copy of that agreement which is attached as Exhibit "Q".
>
> 29. The Settlement Agreement confirmed that the review of the Apo-Trazad submission was still ongoing and had not been completed and then stated:
>
> > Any existing and further data provided by Apotex to establish that Apo-trazad is chemically and therapeutically equivalent to a drug product sold in Canada will be considered. For the purposes of a comparative bioavailability study, the Health Protection Branch is prepared to consider evidence to establish equivalency between Canadian and non-Canadian reference standards.
>
> 30. Accordingly, HPB was no longer requiring a direct comparison establishing identicality between the Apotex product and the Canadian reference product. Instead, HPB was prepared to rely on the bioequivalence study Apotex had conducted against the U.S. reference products, so long as Apotex could establish "equivalency" between the U.S. reference standard and the Canadian reference standard. Equivalency means that two products can be expected to behave in the same manner in terms of therapeutic outcome, whether or not they are identical in all respects.
>
> Did Apotex Provide Sufficient Evidence to Establish Equivalency between Canadian and Non-Canadian Reference Standards?
>
> *The November 5, 1990 Equivalency Evidence*
>
> 31. In materials attached at Exhibit "R", dated November 5, 1990, [the "McKeag Memo"] which I am advised were provided to HPB during settlement negotiations, Apotex provided the results of a detailed comparison between two lots of the Canadian reference standard and four lots of the U.S. reference standard. Fourier-Transformed infrared analysis was conducted. This type of analysis is a well-known and dependable way to determine if two solids contain the same ingredients and can be used to establish chemical equivalence. The results showed that all six lots examined did indeed use the same excipients (inactive ingredients). In conjunction with the information Apotex provided

> regarding uniformity of the tablets, the results showed that all six lots were chemically and physically equivalent. (footnote omitted)
>
> 32. Apotex also discussed the results of dissolution testing. Dissolution testing is important because it is the best *in vitro* (not in the body) test to determine the release characteristics of a product. In fact, once a product is approved for market, the only testing which is done to ensure that future batches are the same as the batch that was approved, is *in vitro* testing. Accordingly, the dissolution comparison Apotex conducted between the Canadian and U.S. reference standards is the same sort of testing the manufacturers of those products would perform on their own products to ensure batch to batch consistency.
>
> 33. Dissolution testing measures how quickly the medicine (known as the active ingredient or active pharmaceutical ingredient – in this case trazodone) is released from the dosage form. The correspondence from Apotex states that all lots were at least 95% dissolved in 15 minutes. This clearly indicates that the drug products are immediate release formulations which perform identically *in vitro* and, therefore, should perform identically *in vivo* (in the body).
>
> 34. Because the products being compared are immediate release products (as opposed to delayed-release or extended-release products) and contain the same excipients, there is virtual certainty that their performance *in vivo* is unlikely to be affected by any deviation in the manufacturing process (if any existed). In both products, trazodone would be released from the formulation very quickly upon ingestion and then the trazodone, which is undoubtedly the same in both products, would be absorbed by the patient in the ordinary course. After release of the trazodone from the tablet, that absorption would be expected to take place at the same rate and to the same extent regardless of in which reference product it was when ingested. (footnote omitted)
>
> 35. In my opinion, the evidence provided by Apotex on November 5, 1990 clearly established equivalency between Canadian and non-Canadian reference standards.
>
> [Emphasis omitted]
>
> [Underlining added]

[80] Two points emerge.

[81] First, contrary to the submission of Health Canada, Dr. Kibbe defined equivalency in terms of therapeutic outcome as seen at paragraph 30 of his opinion.

[82] Second, it is correct that the FTIR spectra data was relied upon to establish the Canadian and American reference standards were chemically and physically equivalent. But it was the dissolution testing of the chemically identical products that established equivalency in terms of therapeutic outcome.

[83] No palpable and overriding error has been demonstrated in the Court's finding that in 1990 Apotex submitted data that established equivalence.

(2) The asserted errors of law and mixed fact and law

(a) *The Federal Court concluded that a breach of contract amounts to misfeasance*

[84] First, Health Canada argues that the Federal Court erred in law by concluding that a breach of contract amounts to misfeasance. Relying on *Saskatchewan Power Corporation v. Swift Current (City)*, 2007 SKCA 27, [2007] 5 W.W.R. 387, at paragraph 33, Health Canada argues that once the Court found it to be liable for breach of contract it was not open to the Court to find liability in misfeasance for the same conduct.

[85] I disagree.

[86] In *Saskatchewan Power* the Court of Appeal concluded that the Chambers Judge below had erred by concluding that a claim in misfeasance should be struck out on the basis it was redundant because the loss claimed was "already covered" by a claim for breach of contract. The Chambers Judge contravened the principle that the parties are entitled to plead in the alternative,

and it was possible that the claim based in contract would fail while the claim based in misfeasance would succeed.

[87] This decision does not support Health Canada's submission. While a plaintiff may not be compensated twice for the same loss, this circumstance did not arise in the present case as the claim based in contract was found to be statute barred.

[88] Further, Health Canada's submission is contrary to the general principle that where conduct *prima facie* supports an action in contract and in tort, a party may sue in either or both, subject to any limit that the parties have placed on that right in their contract (*BG Checo International Ltd. v. British Columbia Hydro and Power Authority*, [1993] 1 S.C.R. 12 at page 26, 99 D.L.R. (4th) 577).

[89] In the present case, the settlement agreement did not limit Apotex' right to sue in tort.

(b) *The facts as found by the Federal Court do not amount to misfeasance*

[90] Next, Health Canada argues that the Federal Court erred in finding misfeasance on the facts found by it. Health Canada submits that the Health Protection Branch's "scepticism about Apotex's data was fuelled by an overarching concern for ensuring the drug's safety and effectiveness" (memorandum of fact and law, paragraph 99). It is said to be unreasonable to suggest that the Branch's desire to meet the Minister's obligation to the public can be indicative of bad faith or malice against Apotex.

[91] Again I disagree.

[92] The Federal Court found that the Health Protection Branch knew that it was required to evaluate Apotex' submission on the basis of equivalency but it did not do so. Further, the Court found that the Health Protection Branch attempted to conceal or dissemble that fact (reasons, paragraph 126). The Federal Court also found that the Health Protection Branch deliberately sought to frustrate Apotex' submission for a notice of compliance (reasons, paragraph 95). These findings establish bad faith as bad faith is described in *Odhavji* and also establish that officials of Health Canada acted in circumstances where they knew that they were acting beyond their mandate and that injury to Apotex was likely. This deliberate and unlawful conduct establishes misfeasance in a public office.

[93] To conclude, I see no basis on which to interfere with the findings of the Federal Court with respect to misfeasance in a public office.

V. Negligence

[94] I begin my analysis by setting out the legal principles relevant to the tort of negligence and then turn to the errors asserted by both Apotex and Health Canada.

A. *The tort of negligence*

[95] Traditionally, the proper remedy for breach of a statutory duty by a public authority is judicial review. To date, the law does not recognize a cause of action against a government

authority for the negligent breach of a statutory duty (*Holland v. Saskatchewan*, 2008 SCC 42, [2008] 2 S.C.R. 551, at paragraphs 8 and 9).

[96] It follows, and the parties agree, that the viability of an action in negligence against Health Canada must be determined by application of the principles articulated in *Anns v. Merton London Borough Council*, [1978] A.C. 728 (H.L.), as adopted and refined by the Supreme Court in *Cooper v. Hobart*, 2001 SCC 79, [2001] 3 S.C.R. 537 (*Cooper-Anns* test).

[97] The *Cooper-Anns* test is a two stage test. The first stage of the test requires consideration of foreseeability, proximity and policy. Two questions arise: First, was the harm that resulted the reasonably foreseeable consequence of the defendant's act? Second, are there reasons why the duty of care should not be imposed in the situation at issue? This stage focuses on factors arising from the relationship between the plaintiff and the defendant.

[98] At the first stage, more than mere foreseeability is required. The parties must also be sufficiently proximate. "Proximity" describes the type of relationship in which a duty of care to guard against foreseeable negligence may be imposed. As explained by the Supreme Court in *Hercules Managements Ltd. v. Ernst & Young*, [1997] 2 S.C.R. 165, and quoted with approval by the Supreme Court in *Cooper* at paragraph 33, proximity connotes that:

> […] the circumstances of the relationship inhering between the plaintiff and the defendant are of such a nature that the defendant may be said to be under an obligation to be mindful of the plaintiff's legitimate interests in conducting his or her affairs.
>
> [Emphasis in the original]

[99] This means that it is just and fair, having regard to the relationship between the parties, to impose a duty of care upon the defendant. Defining the proximity of the relationship may involve looking at the expectations, representations, reliance and interests involved. That is, one looks at the factors that demonstrate the closeness of the relationship between the plaintiff and the defendant (*Cooper*, at paragraphs 30-34).

[100] The applicable legislative scheme plays a role when determining whether a government authority owes a *prima facie* duty of care. A duty of care may be alleged to arise explicitly or implicitly from the legislative scheme. Or, a *prima facie* duty of care may be said to arise from the interactions between the claimant and the government authority, where such a duty is not negated by the legislative scheme (*R. v. Imperial Tobacco Canada Ltd.*, 2011 SCC 42, [2011] 3 S.C.R. 45, at paragraphs 43-44). Where a statute is geared to, for example, regulating an industry:

> […] it may be difficult to infer that the legislature intended to create private law tort duties to claimants. This may be even more difficult if the recognition of a private law duty would conflict with the public authority's duty to the public: see, e.g., *Cooper* and *Syl Apps*. As stated in *Syl Apps*, "[w]here an alleged duty of care is found to conflict with an overarching statutory or public duty, this may constitute a compelling policy reason for refusing to find proximity".

(*Imperial Tobacco*, paragraph 44)

[101] At the second stage of the *Cooper-Anns* test, the question is whether there are residual policy considerations outside the relationship of the parties that may negate the imposition of a duty of care (*Cooper*, at paragraph 30).

[102] The defendant bears the burden of establishing a countervailing residual policy consideration under the second stage of the *Cooper-Anns* test (*Childs v. Desormeaux*, 2006 SCC 18, [2006] 1 S.C.R. 643, at paragraph 13).

[103] I now consider Apotex' appeal.

B. *Apotex' appeal*

(1) The Federal Court failed to consider liability arising apart from the settlement agreement

[104] Apotex asserts that the Federal Court erred by failing to conduct an analysis of whether the Health Protection Branch was liable in negligence apart from its liability in relation to the settlement agreement. Apotex says that had the Court done so, it would have concluded that the relationship between Apotex and the Health Protection Branch was sufficiently close and direct to give rise to a duty of care at any time after Apotex' new drug submission was filed. Apotex also points out that the Federal Court did not undertake an analysis of the governing legislation or the nature of the specific relationship between Apotex and the Health Protection Branch.

[105] I begin my analysis by agreeing that the Federal Court's analysis on the issue of proximity was sparse. After referencing and quoting the applicable jurisprudence, the Federal Court wrote at paragraph 123:

> Here, were it not for the Settlement Agreement, I would find that [Health Protection Branch] was not in a position where it owed a duty of care to Apotex over and above any duty owed to any other pharmaceutical company seeking approval to sell a drug in Canada. However, the Settlement Agreement changed all that. By stating to Apotex that it would examine Apotex's submissions on the

> basis of equivalency, [Health Protection Branch] put itself in a special relationship with Apotex and owed a duty of care not only to examine Apotex's submissions on that standard, but also to be open and transparent as to what it had done (*Central Trust Co. v Rafuse*, [1986] 2 SCR 147 at para 49). [Health Protection Branch] failed on both counts and acted negligently in doing so, I address the standard of care below. The answer to the first of the *Cooper/Anns* questions is yes.
>
> [Emphasis added]

[106] I also agree that the Federal Court ought to have expressly considered the legislative scheme. Did the legislation contemplate a duty of care, preclude a duty of care, or conflict with the existence of a duty of care, as discussed by the Supreme Court in *Imperial Tobacco*?

[107] This said, I disagree that the Federal Court failed to consider whether the Health Protection Branch owed a *prima facie* duty of care apart from the settlement agreement. Read fairly, the Federal Court found insufficient proximity between the parties to give rise to a duty of care until the parties entered into the settlement agreement. The question then becomes whether that conclusion was correct in law?

[108] In my view, it was correct for the following reasons.

[109] Paragraph 30(1)(*o*) of the *Food and Drugs Act* authorizes the Governor in Council to make regulations respecting, among other things, the testing of new drugs and the definition of what is a "new drug".

[110] The Regulations prohibit the sale of a new drug unless the manufacturer of the new drug has filed a new drug submission with the Minister "in a form and having a content satisfactory to

the Minister" and the Minister has issued a notice of compliance to the manufacturer (subparagraphs C.08.002(1)(a) and (b)).

[111] During the years in issue, the new drug submission had to include such information as the Director of the Health Protection Branch required, including "detailed reports of the tests made to establish the safety of the new drug for the purpose and under the conditions of use recommended" and "substantial evidence of the clinical effectiveness of the new drug for the purpose and under the conditions of use recommended" (subparagraphs C.08.002(2)(g) and (h) of the Regulations).

[112] The Minister was required to issue a notice of compliance if satisfied that the new drug submission complied with the requirements of the Regulation (paragraph C.08.004(1) of the Regulations).

[113] I accept that the paramount concern of the legislative regime was concern for the safety and efficacy of the drugs sold to Canadians.

[114] Nonetheless, from this review of the legislative scheme I take the following. First, the *Food and Drugs Act* and Regulations are neutral with respect to the existence of a *prima facie* duty of care. They neither establish nor negate the existence of a duty of care.

[115] Second, given that the legislation is directed to public health and safety through the regulation of drug manufacturers, it is difficult to infer that Parliament intended Health Canada

to owe a *prima facie* duty of care to all drug manufacturers with respect to all new drug submissions. Given the discretion vested by the Regulations in the Health Protection Branch, albeit a discretion which must be exercised lawfully, I find that requiring the Branch to be mindful of Apotex' economic interests when exercising its discretion would place the Health Protection Branch in a position of conflict between its obligation to Apotex and the duty it owes to the public.

[116] Thus, I find no *prima facie* duty of care to arise explicitly or implicitly from the legislative scheme.

[117] It follows that I must now consider whether a *prima facie* duty of care arose from the interactions between Apotex and the Health Protection Branch prior to the settlement agreement and, if so, whether anything in the legislation negates the existence of such a duty of care.

[118] Apotex argues that this legislative regime required and resulted in an ongoing dialogue between a drug manufacturer and the Health Protection Branch – particularly in cases such as the present one where repeated requests were made for more information and responses were provided. The nature of Apotex' relationship with the Health Protection Branch is said to bear all of the hallmarks of a proximate relationship that gives rise to a *prima facie* duty of care.

[119] I disagree.

[120] In *Taylor v. Canada (Attorney General)*, 2012 ONCA 479, 111 O.R. (3d) 161, the Ontario Court of Appeal observed that findings of proximity based on the interactions between a regulator and a plaintiff are of necessity fact-specific. Based on its review of the jurisprudence, the Court concluded that there are two important factual features in cases where a *prima facie* duty of care has been found. One of those features is relevant to the present case. That is where "the facts demonstrate a relationship and connection between the regulator and the individual that is distinct from and more direct than the relationship between the regulator and that part of the public affected by the regulator's work" (*Taylor*, paragraph 80).

[121] I agree.

[122] In my view, the interactions Apotex points to in order to establish a proximate relationship amount to no more than the regular interactions between the Health Protection Branch and any drug manufacturer. It follows that the relationship was not distinct from, and more direct than, the Health Protection Branch's relationship with any drug manufacturer.

[123] Apotex has failed to show that the Federal Court erred in its conclusion that the relationship between the Health Protection Branch and Apotex prior to the settlement agreement did not give rise to a *prima facie* duty of care.

C. *Health Canada's appeal*

[124] Health Canada argues on its appeal that the Federal Court:

i. erred in law by finding that the settlement agreement created a relationship of proximity;

ii. erred by failing to negate any *prima facie* duty of care based on residual policy considerations; and,

iii. in the alternative, erred by making palpable and overriding errors of fact which led the Federal Court to find a breach of the standard of care.

[125] I reject these submissions for the following reasons.

(1) The settlement agreement did not create a relationship of proximity

[126] Health Canada argues that the settlement agreement did not transform the legal relationship between the Health Protection Branch and Apotex. Rather, the settlement agreement confirmed the way the parties expected the Health Protection Branch to do its job. Health Canada also argues that imposing a private law duty of care is inconsistent with its role as regulator.

[127] In my view, the settlement agreement did transform the relationship between the parties. Prior to the settlement agreement the parties were at a stalemate over the issue of bioavailability. Apotex believed it could demonstrate bioavailability by equivalency – the Health Protection Branch required proof of identicality. During the meeting that led to the settlement, Mr. Rowsell made statements to Dr. Sherman of Apotex which Mr. Rowsell intended Apotex to rely upon when entering into the settlement agreement (transcript October 27, 2014, page 884, line 17 to page 885, line 8). By entering into the settlement agreement, the Health Protection Branch agreed to look at the matter "from the point of view of equivalency" (reasons, paragraph 54).

[128] The settlement agreement put Apotex in a different relationship with the Health Protection Branch with respect to the Apo-Trazadone drug submission. The Health Protection Branch agreed to review the submission on the standard of equivalency – a departure from its usual practice. Apotex was entitled to assume that the Health Protection Branch would carry out the obligation it agreed to assume.

[129] As contemplated in *Taylor*, the settlement agreement created a relationship and connection between the Health Protection Branch and Apotex that was distinct and more direct than the relationship between the Health Protection Branch and other drug manufacturers which submitted drug submissions. This established the requisite proximity.

[130] Nor do policy considerations negate a finding of a *prima facie* duty of care at the first stage of the *Cooper-Anns* test. The Health Protection Branch made an informed, voluntary decision to evaluate the Apo-Trazadone drug submission considering evidence which would establish equivalency between Canadian and non-Canadian reference standards. It must be assumed that the Health Protection Branch did so believing that such an evaluation, properly conducted, would ensure drug safety and efficacy.

[131] Health Canada cannot now say that imposing a duty of care on it to comply with its agreement would have any chilling effect upon it as regulator.

(2) The Federal Court failed to negate a *prima facie* duty of care based on residual policy considerations

[132] Health Canada argues that at the second stage of the *Cooper-Anns* test the Federal Court erred by failing to negate the imposition of a duty of care on two bases: the Health Protection Branch made policy decisions which should be accorded deference and the imposition of a duty of care carries the potential for indeterminate liability.

[133] At trial, Health Canada argued that when deciding whether to issue a notice of compliance, it applied a broad discretion under the *Food and Drugs Act* and Regulations. The discretion was exercised in the area of public policy related to the health and safety of the public. It further argued that the existence of such discretion should preclude tort liability. The Federal Court rejected this argument at paragraph 126 of its reasons.

[134] I agree with the conclusion of the Federal Court.

[135] I have rejected the argument that the Health Protection Branch owed a duty of care to all drug companies with respect to all new drug submissions – proximity only arose from the settlement agreement. It follows that the question does not arise whether the imposition of a duty of care would affect the broad discretion vested in the Health Protection Branch when it reviews a drug submission.

[136] The Federal Court found that the Health Protection Branch agreed to do one thing, chose to do another and then attempted to conceal this from Apotex (reasons, paragraph 126). It cannot be credibly argued that in so acting the Health Protection Branch was making a policy decision.

[137] The Federal Court also rejected the argument that recognizing a duty of care would raise the spectre of indeterminate liability. In the Federal Court's view, the liability that arose from the settlement agreement was unique and would not open the door to indeterminate liability (reasons, paragraph 127).

[138] In *Design Services Ltd. v. Canada*, 2008 SCC 22, [2008] 1 S.C.R. 737 the Supreme Court considered the residual policy concern of indeterminate liability. At paragraph 62, the Court paraphrased Chief Justice Cardozo of the Court of Appeals of New York, and concluded that "care must be taken to find that a duty is recognized only in cases where the class of plaintiffs, the time and the amounts are determinate" (see also *Imperial Tobacco*, at paragraph 100).

[139] Looked at in this light, imposing a duty of care in circumstances when a government actor chooses to enter into a contract and then breaches the agreement, limits both the potential class of claimants and the time in which liability may be affixed. The class of claimants is confined to those privy to the contract. The time in which liability may be affixed is limited by the applicable limitation period. Further, in most, if not all cases, the government actor is able to control its conduct so as to avoid or limit liability.

[140] The Federal Court did not err in rejecting the spectre of indeterminate liability.

(3) The Federal Court made palpable and overriding errors that led it to conclude that the Health Protection Branch breached the settlement agreement

[141] In oral argument Health Canada identified for the first time the palpable and overriding errors of fact it relied upon. Health Canada asserted that the Federal Court:

i. misunderstood the new drug submission; it particularly misunderstood where Apo-Trazadone was to be made and whether the Canadian and American Desyrel products were identical;

ii. confused equivalence with therapeutic equivalence;

iii. erred by finding the data submitted in November 1990 was reviewed on the standard of identicality; and,

iv. erred by failing to consider the data filed after November 1990 when determining that the Health Protection Branch breached the settlement agreement.

[142] I have already dealt with and dismissed the submissions that the Federal Court erred by finding that the Canadian and American Desyrel products were identical, by finding the November 1990 data was reviewed on the standard of identicality, and by finding that the data submitted in November 1990 established equivalence.

[143] This leaves for consideration the submissions that the Federal Court erred by misunderstanding where Apo-Trazadone was to be made and by confusing equivalence with therapeutic equivalence.

[144] I acknowledge that at paragraph 35 of its reasons the Federal Court stated that Apotex had advised the Health Protection Branch that its generic product would be manufactured in the United States by a company owned by it, Barr Laboratories. This does not appear to be correct. Apotex intended to manufacture its product in Canada.

[145] In my view, this error was not material to the decision of the Federal Court. This is because Dr. Johnson, in his memorandum of January 20, 1989 (Joint Book of Documents, tab 21) observed:

> Since Barr Laboratories are owned by Apotex, they can presumably provide evidence that the Barr product and the proposed Apotex product are identical from a chemistry and manufacturing standpoint.

[146] No evidence has suggested any material difference between Barr Trazodone and Apo-Trazadone that would have influenced the Federal Court's appreciation of the evidence.

[147] Nor am I persuaded that the Federal Court misunderstood that the settlement agreement required therapeutic equivalence. At paragraph 51 of its reasons, the Court quoted the settlement agreement which required data "to establish that Apo-trazad is chemically and therapeutically equivalent to a drug product sold in Canada". It cannot reasonably be presumed that the Federal Court ignored this.

[148] I have previously found that Dr. Kibbe defined equivalency in terms of therapeutic outcome and that the Federal Court did not err by relying on his evidence to conclude that Apotex had established equivalency in terms of therapeutic outcome in November 1990.

[149] To conclude, I see no basis on which to interfere with the findings of the Federal Court with respect to negligence.

VI. Mitigation

[150] I begin by setting out the legal principles that underlie the concept of mitigation and then consider the errors asserted by Apotex.

A. *The concept of mitigation*

[151] The concept of mitigation may be succinctly expressed: a plaintiff is not entitled to recover compensation for loss that could have been avoided by taking reasonable action. Pursuant to this concept, any loss is disallowed when the loss flows from the plaintiff's inaction, as opposed to the defendant's wrong.

[152] What constitutes reasonable action is in every case a question of fact, depending on the particular circumstances of the plaintiff and the case. This said, as is the case with the concept of remoteness, a finding that a plaintiff ought to have mitigated its loss is not a simple question of fact because it also involves a legal conclusion.

[153] The burden of establishing the failure to mitigate is on the defendant. The defendant must show both that the plaintiff failed to make reasonable efforts to mitigate and that mitigation was possible (*Southcott Estates Inc. v. Toronto Catholic District School Board*, 2012 SCC 51, [2012] 2 S.C.R. 675, at paragraph 24).

[154] In case of doubt, the plaintiff will generally receive the benefit of the doubt on the ground that a defendant should not be overly critical of a plaintiff's good-faith effort to avoid difficulties caused by the defendant's wrongful act (S. M. Waddams, *The Law of Damages*, looseleaf (Toronto: ON: Thomson Reuters Canada, 1991) at paragraph 15.140). In *Banco de Portugal v. Waterlow & Sons, Ltd.*, [1932] A.C. 452 (H.L.) Lord Macmillan expressed this concept as follows (at page 506):

> Where the sufferer from a breach of contract finds himself in consequence of that breach placed in a position of embarrassment the measures which he may be driven to adopt in order to extricate himself ought not to be weighed in nice scales at the instance of the party whose breach of contract has occasioned the difficulty. It is often easy after an emergency has passed to criticise the steps which have been taken to meet it, but such criticism does not come well from those who have themselves created the emergency. The law is satisfied if the party placed in a difficult situation by reason of the breach of a duty owed to him has acted reasonably in the adoption of remedial measures, and he will not be held disentitled to recover the cost of such measures merely because the party in breach can suggest that other measures less burdensome to him might have been taken.
>
> [Emphasis added]

[155] This principle applies equally to cases where there has been a tortious act. Thus, a plaintiff's conduct is not weighed against a single standard of objective reasonability.

[156] I now consider Apotex' appeal.

B. *Apotex' appeal*

(1) The Federal Court erred in its appreciation of the onus of proof

[157] At paragraphs 151 to 154 of its reasons, the Federal Court set out the legal principles applicable to the issue of mitigation. At paragraph 154 it wrote that "[o]nus has no role to play in assessing mitigation; the duty of the Court is to look at the evidence in the record and determine whether and when it was appropriate to mitigate the losses claimed." The Federal Court cited *Chopra v. Canada (Attorney General)*, 2007 FCA 268, [2008] 2 F.C.R. 393, at paragraphs 40 to 42 as authority for this proposition.

[158] In my respectful view, the Federal Court erred in its appreciation of the *Chopra* decision and erred in law by concluding that onus had no role to play in assessing mitigation. In *Chopra*, this Court was making the point that the question of onus only arises factually when one must decide which party bears the consequence of a gap in the evidentiary record which prevents a necessary finding of fact from being made. In any event, the decision of the Supreme Court in *Southcott* is dispositive: the defendant must establish that the plaintiff failed to make reasonable efforts to mitigate the loss.

[159] While Apotex asserts a number of other errors on the part of the Federal Court, in my view it is only necessary to consider whether the Federal Court erred by requiring Apotex to accede to the use of a Canadian reference product in order to mitigate its loss.

[160] The Federal Court found that Apotex "knew it could mitigate its losses by conducting tests using a Canadian reference standard. It did precisely that in respect of Apo-Zidovudine" (reasons, paragraph 155). Had Apotex done so, it would have cost between $200,000 and $300,000 and taken three to six months (reasons, paragraph 157). The Court found a "reasonable person, thinking in terms of economics" would have chosen to re-test Apo-Trazadone's bioavailability against a Canadian reference product (reasons, paragraph 161). Had Apotex done so, it may have received its notice of compliance in between 15 to 18 months (reasons, paragraph 162).

[161] As noted above, in any case what is reasonable depends on the particular circumstances of the plaintiff and the case.

[162] Perhaps because of its failure to appreciate the applicable onus of proof, the Federal Court did not review the actions Apotex did take after it became aware that Health Canada was acting contrary to the settlement agreement in order to consider whether Apotex made reasonable efforts to mitigate. Instead, the Federal Court went directly to its conclusion that "Apotex knew it could mitigate its losses by conducting tests using a Canadian reference standard" (reasons, paragraph 155). In my view it was an error of law for the Federal Court to dictate a single, reasonable course of action and to fail to consider the reasonableness of Apotex' actual course of conduct.

[163] As a result of this failure it is necessary to review Apotex' conduct in order to assess the reasonableness of its course of conduct.

[164] Looking at the totality of the evidence, the following chronology emerges:

January 25, 1988	The Health Protection Branch received Apotex' submission for a notice of compliance for Apo-Trazadone (reasons, paragraph 1).
August 24, 1989	The Health Protection Branch wrote to Apotex insisting that a Canadian reference product is required (Joint Book of Documents, tab 32). The Federal Court finds that by this point "the battle lines had been drawn" (reasons, paragraph 44).
From May 1989 to July 1990	Correspondence is exchanged between Apotex and the Health Protection Branch wherein both sides stick to their positions concerning the appropriate reference product (see, for example, Joint Book of Documents, tabs 23, 24, 29, 32, 38, 39, 40, 41, 44, 45, 46, 47, 48, 49, 50, 51).
August 13, 1990	The first application for judicial review is filed by Apotex. Apotex sought an order directing the Minister to review its submission without requiring that the reference product be purchased in Canada and to issue a notice of compliance (Joint Brief of Judicial Review Documents from Court File No. T-2276-90, tab 1).
November 26, 1990	The settlement agreement was signed by counsel for the Health Protection Branch and delivered to Apotex: the Health Protection Branch agreed that it was "prepared to consider evidence to establish equivalency between Canadian and non-Canadian reference standards" (Joint Book of Documents, tab 60).
April 1991	The date by which Apotex was found by the Federal Court to possess sufficient facts to be aware that the Health Protection Branch was acting in breach of the settlement agreement (reasons, paragraph 138).
April 25, 1991	Apotex wrote to the Health Protection Branch advising it had found three other examples where drugs had been approved without the requirement of a Canadian reference product and saying that "Apotex is now suffering substantial damages". If the Health Protection Branch failed to confirm "within a matter of days" that Apotex's bioavailability study using the U.S. reference product would suffice, Apotex would initiate an action founded on "bad faith and on a refusal to comply with the settlement agreement." Apotex also stated that it would "claim damages flowing from the delay in review and approval" (Joint Book of Documents, tab 83).
May 10, 1991	Apotex wrote to the Health Protection Branch advising that it intended to mitigate its damages with respect to Apo-Zidovudine by

	using a Canadian reference product (Joint Book of Documents, tab 87).
July 2, 1991	Apotex again wrote to the Health Protection Branch urging it to comply with the settlement agreement and threatening to pursue both *mandamus* and an action in damages if the Health Protection Branch did not comply (Joint Book of Documents, tab 102). The Federal Court concluded that Apotex should have taken mitigative action as of this date (reasons, paragraph 161).
July 17, 1991	Apotex filed a second application for judicial review seeking an order directing the Minister to review its drug submission without imposing a condition precedent that a bioavailability study be conducted comparing Apo-Trazadone to a Canadian reference product, and if such review was satisfactory, directing the issuance of a notice of compliance (Joint Brief of Judicial Review Documents from Court File No. T-1877-91, tab 1).
March 22 to 24, 1992	Apotex' second judicial review application was heard by the Federal Court (Joint Brief of Judicial Review Documents from Court File No. T-1877-91, tab 19).
January 19, 1993	The Federal Court dismissed Apotex' application for judicial review (Joint Brief of Judicial Review Documents from Court File No. T-1877-91, tab 19).
February 8, 1993	Apotex appealed the decision of the Federal Court (Joint Brief of Judicial Review Documents from Court File No. T-1877-91, tab 20).
October 12, 1993	The new Executive Director of the Drugs Directorate sent a "very strong" memorandum to the Health Protection Branch stating that Apotex was "owed a full explanation" (Exhibit 8, reasons, paragraph 74).
April 8, 1994	The Health Protection Branch conducted a "re-review" of Apotex' submission and concluded that Apotex had "not adequately established the bioequivalence of Canadian and U.S. Desyrel drug products." Thereafter, the Health Protection Branch wrote to Apotex advising that no notice of compliance would issue (Joint Book of Documents, tab 159).
May 16, 1994	A meeting took place between representatives of Apotex and the Health Protection Branch. The Health Protection Branch advised that "the Directorate was not intransigent and would seriously consider further data." The Health Protection Branch "also emphasized that this case was a watershed for many issues; policy definitions are appropriately made subsequent to a scientific process rather than as a consequence of litigation" (Joint Book of

	Documents, tab 160).
May 31, 1994	Further studies were provided by Apotex to the Health Protection Branch (Joint Book of Documents, tab 162).
June 23, 1994	The Health Protection Branch concluded that it had no outstanding concerns that should prevent the issuance of a notice of compliance (Joint Book of Documents, tab 164). However, the Health Protection Branch did not communicate this conclusion to Apotex.
October 17, 1994	Apotex contacted the Health Protection Branch to ascertain the status of its submission. It was advised the next day that the matter is "currently under discussion with legal counsel" (Joint Book of Documents, tab 172).
December 16, 1994	A report concluding there were no outstanding concerns was signed by the Health Protection Branch. The report repeated the findings of the June 23, 1994 report (Joint Book of Documents, tab 197).
February 28, 1995	Apotex received its notice of compliance (Joint Book of Documents, tab 224).

[165] What emerges from this chronology is that on the date the Federal Court found that Apotex should have taken mitigative action, Apotex wrote to Health Canada threatening both *mandamus* and an action in damages. Within 15 days of that date Apotex commenced an application for *mandamus*. This application was pursued on a timely basis. In addition to filing an appeal from the negative decision of the Federal Court, Apotex continued to press Health Canada.

[166] As a result of such pressure, the October 12, 1993 memorandum was sent which stated that Apotex was owed a full explanation and expressed the "feeling" of the new Director of the Drugs Directorate that "our practices and maybe even our policies have been inconsistent".

[167] On January 4, 1994 (Joint Book of Documents, tab 144), Apotex' counsel wrote to counsel for Health Canada advising that Apotex had obtained Health Canada documents through one or more access to information applications. Counsel advised that from a review of that documentation, it was apparent that the review of Apotex' drug submission:

> […] has always been conducted without regard to the settlement agreement and the underlying principles thereto. More precisely, your client has failed to review the dissolution data submitted in conjunction with and in light of the finding of chemical equivalence of the U.S. and Canadian reference brands.
>
> [Emphasis added]

[168] It followed that Health Canada:

> […] has failed not only to abide by the terms of the settlement agreement but to discharge its statutory obligation.

[169] This was "vividly exemplified":

> […] in a memorandum dated April 15, 1992 from M. Ward, Senior Drug Evaluator, to W.M. Nitchuk. […] the memorandum illustrates the basic error and confusion which your client has been making and suffering throughout the process. In the first full paragraph of the memorandum, Ward states that:
>
> > "It is generally accepted that comparative dissolution profile analysis cannot replace comparative bioavailability studies as a means of establishing "bioequivalence" between two different products unless an in-vitro/in-vivo correlation has been demonstrated." [emphasis in original]
>
> The statement is correct insofar as it reads. Apotex has never taken the position that comparative dissolution data for different products would be sufficient in the absence of a comparative bioavailability. However, the case at hand does not involve "different" products. Your client has conceded that the U.S. and Canadian reference products are the same, that is, are chemically equivalent, if not identical.
>
> [Emphasis in original]

[170] On February 9, 1994 counsel for Apotex wrote to counsel for Health Canada setting the "parameters for resolution [of the dispute] which we have discussed" (Joint Book of Documents, tab 150). Correspondence followed between counsel and, as noted above, on May 16, 1994 the parties met. On May 31, 1994, Apotex provided further dissolution data (Joint Book of Documents, tab 162). By June 23, 1994, Health Canada had no outstanding concerns with respect to the clinical equivalence of the American and Canadian Desyrel product (Joint Book of Documents, tab 164). On February 28, 1995, the notice of compliance issued to Apotex. As explained above at paragraph 35, no explanation was provided for the delay between June 23, 1994 and February 28, 1995.

[171] It is apparent that throughout this chronology, Apotex never sat on its rights. Notwithstanding, Health Canada argues that Apotex' conduct does not constitute reasonable mitigation because "[i]nsisting that a party allegedly in breach honour a contractual term cannot constitute mitigation" (memorandum of fact and law, paragraph 88).

[172] This said, Health Canada does acknowledge that in "rare situations" a failure to mitigate is justifiable (memorandum of fact and law, paragraph 90). This arises where a plaintiff has a substantial and legitimate interest in seeking specific performance of a defendant's obligation.

[173] Thus, in *Asamera Oil Corporation Ltd. v. Sea Oil & General Corporation et al.*, [1979] 1 S.C.R. 633, 89 D.L.R. (3d) 1, the Supreme Court considered the claim of a party that sought the return of a number of shares in a corporation and argued it was not obliged to mitigate its loss by purchasing replacement shares in the market. Rather, the claimant argued that it was entitled to

seek specific performance of the contract to return the shares and that during the period it relied upon an interim injunction restraining the sale of the shares it did not have to take into account the losses flowing from its failure to purchase replacement shares and mitigate those losses.

[174] The Supreme Court found that, as a matter of law, the principle of mitigation ought to prevail unless there was "a substantial and legitimate interest represented by specific performance" (Supreme Court Reports, page 667). Therefore, when the evidence revealed "a substantial and legitimate interest in seeking performance as opposed to damages, then a plaintiff will be able to justify his inaction" (Supreme Court Reports, pages 668-669).

[175] This principle was reiterated in *Semelhago v. Paramadevan*, [1996] 2 S.C.R. 415, 28 O.R. (3d) 639, at pages 429-430 of the Supreme Court Reports.

[176] In the present case, Apotex regularly interacted with Health Canada with respect to new drug submissions. Dr. Sherman testified that Apotex developed most of its generic products in Canada and therefore, as a matter of convenience, it used Canadian reference products to establish bioequivalence and bioavailability. However, when a generic product was developed outside of Canada, Apotex established bioequivalence using studies done in the foreign market. Thus, Dr. Sherman could point to four instances between September 1976 and 1995 when Apotex had obtained a notice of compliance using a foreign reference product. It was his understanding that "every time we, or to the best of our knowledge anyone else, submit a submission using a foreign reference it was acceptable except only for Spirozide" (transcript October 21, 2014, page 299, line 11 to page 302, line 26). Apotex had a clear business interest in

establishing that foreign reference products were, as a matter of general principle, acceptable. As the Federal Court found, Apotex made its Apo-Trazad submission a test case as to whether a non-Canadian reference product could be used as a reference (reasons, paragraph 105).

[177] At the same time, Health Canada recognized that Apotex had raised an important point of principle. Thus, as previously discussed, in his memo of January 20, 1989 to the Director of the Drugs Directorate, Dr. Johnson acknowledged the scientific basis of Apotex' position that it ought to be able to rely on the foreign reference product. He wrote:

> Therefore, on the basis of science alone, I am inclined to accept the arguments advanced by Apotex. However, we should also examine the possibility that we may be establishing a precedent if we follow this course of action that could see us forced to accept similar arguments from around the world. What is to prevent, for example, Apotex from commissioning a bioavailability study comparing the French brand of a product as the standard? If we accept the arguments advanced in this particular case, we could have a difficult time not allowing this type of study. This could be the start of a process that would see us lose control over the generic submissions.
>
> [Emphasis added]

This was reiterated by Health Canada late in the process. As noted above, at the meeting between representatives of Health Canada and Apotex on May 16, 1994, officials from Health Canada "emphasized that this case was a watershed for many issues."

[178] It follows that this was not a case where Apotex clung to a point of principle without regard to the consequences. Both Apotex and Health Canada recognized that the availability of recourse to a foreign reference product raised an important issue of principle. While the Federal Court recognized that "battle lines" were drawn, it erred by ignoring this important issue of principle and by considering only the economics involved in a single drug submission. The issue

in dispute transcended a single drug submission and was directly linked to Apotex' strategic and economic interests.

[179] The evidence establishes that Apotex had a substantial and legitimate interest in pursuing its claim for *mandamus*, a claim that would, in effect, require Health Canada to abide by the settlement agreement and specifically perform its obligation to consider evidence to establish the bioequivalency of the Canadian and the American reference standards.

[180] Thus, in the rather unique circumstances of this case, Apotex' choice to pursue litigation was reasonable. It did not fail to mitigate its loss and it was an error of principle to require Apotex to mitigate its loss by requiring it to abandon its right to have the Health Protection Branch consider evidence to establish the bioequivalence of the Canadian and American reference standards and by requiring Apotex to do the very thing the settlement agreement was intended to avoid: a new bioavailability test using a Canadian reference product.

[181] Had Apotex so proceeded and obtained a notice of compliance, the issuance of the notice of compliance would have rendered moot the issue of the suitability of a foreign reference product. It follows that in any subsequent drug submission the suitability of a foreign reference product would remain a live issue; in the words of the Federal Court, the "battle lines" would be drawn again.

[182] Apotex' ongoing interest in having Health Canada accept the notion of foreign reference products in appropriate cases was a substantial and legitimate interest Apotex was entitled to pursue through *mandamus* properly instituted and prosecuted.

[183] While this is sufficient to set aside the decision of the Federal Court on mitigation, a brief comment is warranted on the Federal Court's reliance on Apotex' conduct with respect to Apo-Zidovudine.

[184] In the case of Apo-Zidovudine, Apotex had not obtained any agreement from the Health Protection Branch that it would consider evidence to establish equivalence between the Canadian and non-Canadian reference standards. To block the impasse Apotex chose to re-test. This is distinguishable from the present case. In the present case, the impasse had been resolved by settlement agreement.

[185] For these reasons I would vary the judgment of the Federal Court so as to remove its conclusion that Apotex failed to mitigate its loss. Thus, the reference or trial to establish the extent of Apotex' damages should proceed on the basis that Apotex did not fail to mitigate its loss.

VII. Contract

A. *Apotex' claim in contract*

[186] Apotex asserted at trial that the Health Protection Branch breached the settlement agreement by continuing to insist, internally, upon applying the standard of identicality when assessing bioequivalence. The Federal Court found that the settlement agreement required review on the standard of equivalence and that the Health Protection Branch failed to apply that standard. I have found those findings to be supported by the evidence.

[187] However, the Federal Court found Apotex' claim for breach of contract was barred by the application of the applicable limitation period. The Federal Court found that Apotex was aware of the breach of the settlement agreement by April 1991. This finding was based on correspondence from Apotex to the Health Protection Branch dated April 25, 1991, July 2, 1991 and July 31, 1991 (Joint Book of Documents, tabs 83, 102 and 111).

B. *Apotex' appeal*

[188] On its appeal Apotex asserts that while it "clearly suspected that the [Health Protection Branch] was not acting in compliance with the settlement agreement, it did not know the critical facts necessary to establish the specific breach of contract at issue here" (Apotex' memorandum of fact and law, paragraph 107).

[189] The Federal Court's finding that Apotex was aware of the breach of the settlement agreement by April 1991 was a finding of fact which is entitled to deference. Looking at the correspondence relied upon by the Federal Court, Apotex wrote on April 25, 1991:

> As you know, we brought an action in the Federal Court in August 1990, which was withdrawn only after we arrived at a settlement agreement. The agreement was that the U.S. reference could be used, along with evidence to establish the equivalence of the Canadian and U.S. references. In the course of the settlement discussions, we provided Mr. Rowsell with IR spectral comparisons and dissolution comparisons, as further evidence that the formulations of the U.S. and Canadian references were the same, and he confirmed that this data was the type of further data needed.
>
> In the course of settlement discussions, we received assurances that [Health Protection Branch] would comply with the agreement and review our submission in good faith.
>
> […]
>
> Apotex is now suffering substantial damages from the delay in review and approval of Apo-Trazadone.
>
> We ask that you reconsider your position and confirm that our bioavailability study using the reference purchased in the U.S. will suffice. If we do not receive such confirmation within a matter of days, we will have no alternative but to initiate another action in the Federal Court founded, inter alia, on bad faith and on refusal to comply with the settlement agreement.
>
> [Emphasis added]

On July 2, 1991:

> The essence of the Settlement Agreement was that we would abandon the use of a foreign reference in cases where the foreign and Canadian references are not the same, and [Health Protection Branch] would accept the foreign references when it appears that the foreign and Canadian references are the same and that appearance is confirmed by laboratory comparisons. In the course of the discussions as to what would suffice, I tendered to Mr. Rowsell I.R. and dissolution comparisons, which Mr. Rowsell stated to be exactly the sort of data which was needed to provide the extra assurance that the U.S. and Canadian references were equivalent.

> We have now complied with the terms of the Agreement by providing (for both trazadone and zidovudine) extensive comparisons which confirm the U.S. and Canadian references indistinguishable.
>
> Instead of now accepting these two products in compliance with the Agreement, Mr. Rowsell has reverted to the position that laboratory comparisons will not suffice and that approval can be obtained only on the basis of certification by the originator or a bioavailability study against the reference purchased in Canada. This position was stated very explicitly by Mr. Rowsell to Dr. Spino in a telephone conversation on June 26, 1991, and is also clear from the contents of Mr. Rowsell's letter of June 21, 1991. Mr. Rowsell has thus repudiated the Settlement Agreement. It is particularly irritating that Mr. Rowsell at the same time purports to be honoring the Agreement. Clearly, the essence of the Agreement was [to] be that our products would be approved if the data confirmed the references to be indistinguishable.
>
> [Emphasis added]

And on July 31, 1991:

> […] It was well understood by both parties (as it should be understood by you), that if the laboratory comparisons confirm that the references are chemically equivalent, it follows that they are therapeutically equivalent. Given that Mr. Rowsell specifically stated in the settlement discussions that our comparative IR and dissolution data was exactly the sort of additional data needed, and given that he subsequently confirmed to me that such was the understanding, it appears to me inconceivable that Mr. Rowsell will now purport that the agreement was otherwise.
>
> […]
>
> I believe that each and every one of the "comments" made by you is untenable. Moreover, taken together they appear to demonstrate an intransigent refusal to act in good faith.
>
> [Emphasis added]

[190] The content of the correspondence is such that I see no palpable and overriding error in the Federal Court's finding that by April 1991, Apotex was aware that the Health Protection

Branch was acting in breach of the settlement agreement and that Apotex was suffering damage as a result.

[191] It follows that I would dismiss this aspect of Apotex' appeal.

C. *Health Canada's cross-appeal*

[192] Health Canada repeats its arguments that the Federal Court misapprehended the evidence in order to find there was a breach in the settlement agreement. I have previously dealt with these submissions. No further analysis is required in circumstances where I have concluded in any event that the cause of action in contract is statute barred.

VIII. Conclusion

[193] For the reasons above I would dismiss Health Canada's appeal. I would allow Apotex' appeal in part and vary paragraph one of the judgment of the Federal Court to read:

> Apotex is entitled to damages to be assessed on the basis set out in the reasons of the Federal Court issued on November 18, 2014, with the exception that Apotex did not fail to mitigate its damages.

[194] In all other respects I would dismiss Apotex' appeal and Health Canada's cross-appeal.

[195] Health Canada has been wholly unsuccessful on its appeal and cross-appeal and Apotex has in largest part been unsuccessful on its appeal. It is, in my view, appropriate in these circumstances that each party bear their own costs. It follows that I would not award costs on the appeals or cross-appeal.

"Eleanor R. Dawson"

J.A.

"I agree.
Rennie J.A."

"I agree.
WoodsJ.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-553-14
STYLE OF CAUSE:	HER MAJESTY THE QUEEN v. APOTEX INC.
AND DOCKET:	A-554-14
STYLE OF CAUSE:	APOTEX INC. v. HER MAJESTY THE QUEEN
PLACE OF HEARING:	TORONTO, ONTARIO
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CONCURRED IN BY:	RENNIE J.A. WOODS J.A.
DATED:	APRIL 6, 2017

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