Federal Court  Cour fédérale

Date: 20100528

Dockets: T-1537-07 and T-706-10

Citation: 2010 FC 573

BETWEEN:

WELLESLEY THERAPEUTICS INC.

Applicant

- and -

MINISTER OF HEALTH (HEALTH CANADA), DIRECTOR GENERAL THERAPEUTIC PRODUCTS DIRECTORATE (HEALTH CANADA) and ATTORNEY GENERAL OF CANADA

Respondents

REASONS FOR JUDGMENT

HUGHES J.

[1] The reasons pertain to two applications for judicial review that are closely related. They are brought by the same Applicant, Wellesley Therapeutics Inc., against the same Respondents, Minister of Health (Health Canada), Director General Therapeutic Products Directorate (Health Canada) and Attorney General of Canada, whom I will collectively refer to as Health Canada. The common issue is the refusal by Health Canada to grant permission to Wellesley to market in Canada a drug containing as an active ingredient a compound known as disulfiram. For the

reasons that follow, I will dismiss application T-706-10 and allow application T-1537-07 each with costs to the prevailing party fixed at $3500.00.

[2] Disulfiram is a drug that is used in the treatment of alcoholics. Given under medical supervision, it has the effect of making the patient very sick if the patient consumes alcohol. Given in small doses it produces a massive hangover and thus serves as a deterrent to the consumption of alcohol. Large doses taken under unsupervised conditions have been reported to result in death. This drug was approved for sale by Health Canada and sold by a company named Wyeth under the brand name ANTABUSE for a period from 1949 to 2001. It was withdrawn from the Canadian market in 2001. The reason for this withdrawal appears to be unclear on the record but does not appear to be related to safety or efficacy of the drug. This drug continues to be sold in over twenty-five other countries, including the United States of America. It also continues to be available in Canada in a very limited fashion through specialty compounding pharmacies. Such limited availability means that the drug is generally not covered by provincial or federal insurance schemes except in some circumstances in British Columbia; thus, the user must pay the full cost of the drug.

[3] There are two other drugs approved for use in the treatment of alcoholism in Canada; naltrexone and acamprosate. They work by a different mechanism in that they reduce cravings for alcohol and the euphoric feeling that alcohol produces.

[4] The Applicant, Wellesley, is a small privately held company, established in 2001. Its president is Dr. Willem Wassenaar, a physician and who has occupied senior positions with

several Canadian pharmaceutical companies. He became familiar with the use of disulfiram in the treatment of alcoholism while working as a clinical physician. He believes that disulfiram is important as one of the several tools available to a physician in such treatment. When Wyeth withdrew its disulfiram product ANTABUSE from the Canadian market in 2001, Wellesley began to take steps to seek approval from Health Canada to reintroduce the product in the Canadian market. It chose the brand name ABSTAYNE for that purpose.

SELLING A DRUG IN CANADA

[5] The sale of drugs in Canada is regulated by a federal statute, the *Food and Drugs Act*, R.S.C. 1985, c. F-27 and the *Food and Drug Regulations*, C.R.C., c. 870. A drug is defined in section 2 of that *Act* to include any substance sold for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state.

> *"drug" includes any substance or mixture of substances manufactured, sold or represented for use in*
>
> *(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,*
>
> *(b) restoring, correcting or modifying organic functions in human beings or animals, or*
>
> *(c) disinfection in premises in which food is manufactured, prepared or kept;*

[6] Part C, Division 1 of the *Regulations*, section C.01.014 prohibits the sale of a drug in dosage form unless it has received and retains a Drug Identification Number (DIN) from the Minister of Health who for the purpose administering the relevant portions of the *Act* and *Regulations* operates through the Therapeutic Products Division (TPD) of Health Canada:

> *C.01.014. (1) No manufacturer shall sell a drug in dosage form unless a drug identification number has been assigned for that drug and the assignment of the number has not been cancelled pursuant to section C.01.014.6.*

[7] A party may apply for a DIN directly, in which case it must submit certain information as specified in section C.01.014.1 of the *Regulations*. This information includes such things as labelling, pharmaceutical form and other things, but nothing that is directly related to the safety or efficacy of the drug.

> *C.01.014.1. (1) A manufacturer of a drug, a person authorized by a manufacturer or, in the case of a drug to be imported into Canada, the Importer of the drug may make an application for a drug identification number for that drug.*
> *(2) An application under subsection (1) shall be made to the Director in writing and shall set out the following information:*
>
> ...

[8] A party may, alternatively, apply by making a "new drug submission" (NDS) or "abbreviated new drug submission" (ANDS) which is deemed by section C.01.014.1 (3) also to be a DIN submission:

> *(3) In the case of a new drug, a new drug submission or an abbreviated new drug submission filed pursuant to section C.08.002 or C.08.002.1 shall be regarded as an application for a drug identification number.*

[9] A "new drug" is defined in section C.08.001 of the *Regulations* to be a drug that "*has not been sold in Canada for sufficient time and in sufficient quantity to establish its safety and efficacy":*

> *C.08.001. For the purposes of the Act and this Division, "new drug" means*
> *(a) a drug that contains or consists of a substance, whether as an active or inactive ingredient, carrier, coating, excipient, menstruum*

> *or other component, that has not been sold as a drug in Canada for sufficient time and in sufficient quantity to establish in Canada the safety and effectiveness of that substance for use as a drug;*
> *(b) a drug that is a combination of two or more drugs, with or without other ingredients, and that has not been sold in that combination or in the proportion in which those drugs are combined in that drug, for sufficient time and in sufficient quantity to establish in Canada the safety and effectiveness of that combination and proportion for use as a drug; or*
> *(c) a drug, with respect to which the manufacturer prescribes, recommends, proposes or claims a use as a drug, or a condition of use as a drug, including dosage, route of administration, or duration or action and that has not been sold for that use or condition of use in Canada, for sufficient time and in sufficient quantity to establish in Canada the safety and effectiveness of that use or condition of use of that drug.*

[10] In the case of a "new drug" it may not be sold in Canada unless it has received a Notice of Compliance (NOC) as provided by section C.08.002 of the *Regulations*.

> *C.08.002. (1) No person shall sell or advertise a new drug unless*
> *(a) the manufacturer of the new drug has filed with the Minister a new drug submission or an abbreviated new drug submission relating to the new drug that is satisfactory to the Minister;*
> *(b) the Minister has issued, pursuant to section C.08.004, a notice of compliance to the manufacturer of the new drug in respect of the new drug submission or abbreviated new drug submission;*

[11] Such Notices of Compliance are familiar to those dealing in the patent area; fortunately, no patents are involved in the present applications.

[12] Unlike a simple DIN application, in order to obtain an NOC by way of a New Drug Application a party must provide sufficient information to the Minister (Health Canada) to enable an assessment as to the safety and effectiveness of the drug, including any testing as to safety and evidence of clinical effectiveness. Section C.08.002 (2) of the *Regulations* provides, *inter alia*:

> *(2) A new drug submission shall contain sufficient information and material to enable the Minister to assess the safety and effectiveness of the new drug, including the following:*
>
> . . .
>
> *(g) detailed reports of the tests made to establish the safety of the new drug for the purpose and under the conditions of use recommended;*
> *(h) substantial evidence of the clinical effectiveness of the new drug for the purpose and under the conditions of use recommended.*

[13] Thus, an application for approval to sell a drug in Canada is considerably easier if the DIN only route can be followed. However, if the drug is considered to be a "new drug", then the NDS route leading to an NOC (and DIN) must be followed. The principal difference is that a simple DIN application alone does not require proof of safety and efficacy.

[14] The evidence of Dr. Petersen, a Division Manager in the Therapeutics Products Directorate (TPD) of Health Canada,(her affidavit paragraph 20) is that when an application for a DIN is received, the department makes an initial assessment as to whether the drug is a "new drug", if it is determined that the drug is a "new drug" then the application is diverted and must follow the more rigorous approval process. Guidelines published by TPD state:

> *A New Drug Status decision will be made on all DIN submissions. When the drug product is considered to be in New Drug Status, the applicant will be so informed, otherwise the DIN submission evaluation will proceed.*
>
> *A list of products currently regulated as New Drugs has been prepared. Although the list will not be all-encompassing due to the complexity of Division 8 of the Food and Drug Regulations, it is intended to assist applicants in identifying many new drugs.*

[15] Dr. Petersen, at paragraphs 19 and 21 of her affidavit, exemplifies such things as fluoride toothpaste, sunscreen lotions, disinfectants and anti-dandruff shampoos as those things defined as "drugs" that would normally be processed directly through the DIN process without requiring a New Drug Submission. Health Canada's Counsel, in the Memorandum of Argument filed in T-1537-07, puts it somewhat differently at paragraph 70, where Counsel says:

> *"…a "DIN submission under Division 1, which is the required route to approval for all products other than "new drugs".*

[16] Dr. Petersen admitted during cross-examination Questions 40 to 45 that a non-exhaustive list of drugs considered as "new drugs" was published by TPD and that list did not include disulfiram. She had limited knowledge as to this list.

[17] Under section C.01.014.6(1)(b) of the *Regulations,* the Minister has the power to cancel a DIN that has been assigned if the NOC has been suspended by the Minister under section C.08.006 (2) of the *Regulations*. The Minister has the power to suspend an NOC that had been issued, if, for instance, the Minister has new information giving reason to believe the drug is not safe:

> *(2) The Minister may, by notice to a manufacturer, suspend, for a definite or indefinite period, a notice of compliance issued to that manufacturer in respect of a new drug submission or an abbreviated new drug submission or a supplement to either submission, if the Minister considers*
>
> > *(a) that the drug is not safe for the use represented in the submission or supplement, a shown by evidence obtained from*
> >
> > > *(i) clinical or other experience not reported in the submission or supplement or not available to the Ministry at the time the notice of compliance as issued, or*

> *(ii) tests by new methods or tests by methods not reasonably applicable at the time the notice of compliance was issued*
>
> *(b) that, upon the basis of new information obtained after the issuance of the notice of compliance, there is lack of substantial evidence that the drug will have the effect it is represented to have under the conditions of use prescribed, recommended or proposed by the manufacturer;*

HISTORY OF WELLESLEY'S APPLICATIONS

[18] Wellesley submitted its first application for its disulfiram product ABSTAYNE in the form of a DIN application in 2002. Health Canada rejected this application on the basis that the product was in the form of a powder which Health Canada did not consider to be in final dosage form. Health Canada advised that a DIN could only be issued for a product that did not require additional processing before administration. This decision is not at issue.

[19] Wellesley reformulated its product in capsule form and, at the suggestion of Health Canada, filed its application as a New Drug Submission (NDS) on August 10, 2006. In support of this application it submitted information from the intended manufacturer, and updated scientific literature as to disulfiram. By letter dated October 10, 2006, Health Canada responded with a Screening Deficiency Notice raising a number of issues, many of which were addressed by Wellesley. On December 27, 2006, Health Canada sent a Screening Rejection Letter to Wellesley stating that the results of *"a well designed and conducted clinical trial are required. Literature references are not acceptable."* Wellesley was invited to seek a reconsideration through an internal process established by Health Canada, which it did, by letter dated January 26, 2007.

[20] Health Canada conducted a reconsideration of the matter and, by letter dated July 23, 2007, advised Wellesley that it stood by its original decision to reject the application. The letter stated, in part:

> *Upon reconsideration, the Directorate stands by the original decision that the Abstayne submission, which is based on information from the literature, does not constitute sufficient evidence of safety and effectiveness for disulfiram. There are two products currently on the market in Canada for this treatment of alcohol abuse since disulfiram was first introduced and it is the regulator's responsibility to assess the risk/benefit of disulfiram in the current Canadian context. The Bureau of Cardiology, Allergy and Neurological Science is willing to discuss the requirements of a new NDS.*

[21] In addition to this letter, Health Canada provided to Wellesley a document entitled "Issue Analysis" which was a detailed response to a variety of issues raised by Wellesley during the course of its submissions. In effect these were reasons for the rejection. This rejection is the subject of the first of these applications, T-1537-07.

[22] On November 16, 2007, Wellesley submitted a new DIN application for its disulfiram product in capsule form. It submitted four volumes of technical material, the record from the NDS application, and a number of other materials, including product monographs of two other drugs. No results of any clinical testing as such were submitted.

[23] By letter dated March 29, 2010, Health Canada provided its decision to Wellesley respecting this DIN application, together with a lengthy document entitled "Issue Analysis" in which the

analysis of the issues was provided. The DIN application was rejected. Again these were in effect the reasons for the rejection. The letter stated, in part:

> *We regret to inform you that a Drug Identification Number (DIN) for Abstayne (Control#118378) will not be issued at this time since the product is considered to be a New Drug as defined in Division 8 of the Canadian Food and Drugs Regulations.*
>
> *Please refer to the following enclosed documents that further express the reasoning behind the Therapeutic Products Directorate's decision:*
>
> *Status of Disulfiram – Issue Analysis*
> *Appendix 1 – Letter to Dr. Sandu Goldstein*
> *Appendix 2 – Clinical Study Reports*
> *Appendix 3a – Interpretation of Adverse Reaction Line-Listings*
> *Appendix 3b – Summary of Canadian Reported Adverse Reactions (Disulfiram)*
> *Appendix 4 – Literature Search Results for safety of Disulfiram*
>
> *Products containing disulfiram are considered to be New Drugs, as defined in Division 8 of the Canadian Food and Drugs Act and Regulations, since they have not been sold in Canada for sufficient time and in sufficient quantity to establish safety and efficacy under the conditions of use as recommended.*
>
> *The sale of the proposed product for clinical investigation or other purposes is, in the view of the Branch, not permitted, until information is submitted and found in compliance with the above-mentioned Regulations.*

[24] This decision is the subject of the second application under consideration, T-706-10.

THE EVIDENCE

[25] In the later of the two applications, T-706-10, the Applicant filed the affidavit of Dr. Willem Wassenaar, president of Wellesley, sworn May 7, 2010, together with several exhibits, including the record filed in the earlier application, T-1537-07. Wassenaar was not cross-examined. Health Canada filed no evidence in T-706-10.

[26] In the earlier application, T-1537-07, the Applicant filed the affidavit of the same Dr. Willem Wassenaar, sworn September 18, 2007, with several exhibits; the affidavit of Dr. Peter Selby Clinical Director of the Addiction Program of the Centre for Addition Program of the Centre for Addition and Mental Health, sworn January 28, 2008, with several exhibits; and the reply affidavit of Dr. Stuart Macleod, Executive Director of the Child & Family Research Institute ,professor of paediatrics at the University of British Columbia, and sometime consultant to Health Canada with several exhibits. Parts of the Macleod affidavit had been redacted by an Order of a Prothonotary. None of these persons was cross-examined.

[27] Health Canada filed, in application T-1537-07, the Affidavit of Dr. Cathy Petersen, Division Manager, Bureau of Cardiology, Allergy and Neurological Sciences, Therapeutic Products Directorate (TPD), Health Canada, sworn April 29, 2009, with several exhibits. Dr. Petersen was cross-examined on August 27, 2009 and several exhibits marked during that cross-examination, together with a transcript of the cross-examination, were filed in the record.

[28] There were no live witnesses appearing before the Court. Having reviewed the evidence, I have no reason to doubt the credibility of any witness. I have determined that Dr. Petersen was only partially involved in the relevant activities at TPD. There seems to have been several levels of activity going on, and she was privy to or involved in only part of those activities. Her evidence therefor is based in significant measure on her review of the documents in the file at TPD. I have in mind, for instance, her answers to questions 7 through 23, and 74 through110, as illustrative of the fact that Dr. Petersen had only a limited, first-hand knowledge as to what occurred at TPD with

specific reference to Wellesley's applications. She had a general knowledge of the customary procedures followed at TPD.

[29] Counsel agreed that evidence in one application can be referred to as if it were evidence in the other.

THE ISSUES

[30] The principal issue in each application is whether the decision under review should be quashed and sent back for re-determination. I will address the particular issues raised in each case.

Standard of Review

[31] Both Counsel agreed that where the Minister (Health Canada) is entitled to exercise discretion, the standard of review is that of reasonableness. Recently, Justice O'Keefe of this Court in *Hospira Healthcare Corporation v. Canada (Attorney General) and The Minister of Health*, Feb 25, 2010, 2010 FC 213 *(Hospira)* considered the question of standard of review in respect of many of the same *Regulations* as are applicable here, and concluded at paragraph 33 that, on questions of fact and exercise of discretion, reasonableness is the appropriate standard. I agree:

> ***33*** *Previous jurisprudence of this Court has found that decisions of Health Canada on questions of fact and the exercise of discretion falling within Regulations (Part C) are entitled to deference (see Canadian Pharmaceutical Technologies International (C.P.T.) Inc. v. Canada (Attorney General), 2006 FC 708, [2006] F.C.J. No. 906 (QL) at paragraphs 11 to 17). Indeed, the safety and effectiveness of new drugs is an issue Parliament has confided to the Minister. Thus, reasonableness is the appropriate standard for both the Minister's interpretation of the Regulations as well as the Minister's ultimate decision regarding the applicant's NDS.*

[32] However, when determining jurisdiction and some other questions of law, the Court must apply a correctness standard, without deference to the decision-maker's reasoning, and to provide its own view and the correct answer. The Supreme Court of Canada instructed in *Dunsmuir v. New Brunswick*, [2008] 1 S.C.R. 190 as follows at paragraph 50:

> ***50*** *As important as it is that courts have a proper understanding of reasonableness review as a deferential standard, it is also without question that the standard of correctness must be maintained in respect of jurisdictional and some other questions of law. This promotes just decisions and avoids inconsistent and unauthorized application of law. When applying the correctness standard, a reviewing court will not show deference to the decision maker's reasoning process; it will rather undertake its own analysis of the question. The analysis will bring the court to decide whether it agrees with the determination of the decision maker; if not, the court will substitute its own view and provide the correct answer. From the outset, the court must ask whether the tribunal's decision was correct.*

[33] Thus, it is not open to a Court simply to decide if a determination by the Minister or Health Canada is reasonable, it must be correct when considering jurisdiction or some other question of law. I agree that where some question of interpretation falling within a Board's expertise is to be made, that interpretation is to be given some deference, but the Court cannot simply leave the interpretation of a *Regulation*, for instance, to the Minister alone. If the latter statement is what O'Keefe J. meant at paragraph 43 of his Reasons in *Hospira*, which I don't think he did mean, then I disagree with it.

> ***43*** *In my opinion, while the applicant's interpretation of the Regulations may have merit, the respondent Minister's view that pre-clinical and clinical data is implicitly required, is certainly a reasonable interpretation of the Regulations that falls within the range acceptable outcomes.*

[34] I understand that *Hospira* is presently under appeal.

The DIN Decision

[35] This question pertains to application T-706-10. The decision at issue is set out in Health Canada's letter of March 29, 2010. The operative part of that letter states:

> *We regret to inform you that a Drug Identification Number (DIN) for Abstayne (Control#118378) will not be issued at this time since the product is considered to be a New Drug as defined in Division 8 of the Canadian Food and Drugs Regulations.*
>
> . . .
>
> *Products containing disulfiram are considered to be new Drugs, as defined in Division 8 of the Canadian Food and Drugs Act and Regulations, since they have not been sold in Canada for sufficient time and in sufficient quantity to establish safety and efficacy under the conditions of use as recommended.*

[36] In brief Health Canada did not consider that the disulfiram drug had not been sold in Canada:

> *"…for sufficient time and in sufficient quantity to establish safety and efficacy…"*

[37] To this extent, the decision repeats the language of section C.08.001 (a) of the *Regulations* set out earlier, which I repeat:

> *C.08.001. For the purposes of the Act and this Division, "new drug" means*
> *(a) a drug that contains or consists of a substance, whether as an active or inactive ingredient, carrier, coating, excipient, menstruum or other component, that has not been sold as a drug in Canada for sufficient time and in sufficient quantity to establish in Canada the safety and effectiveness of that substance for use as a drug;*

[38] This DIN application was filed by Wellesley in November 2007. Its position was set out in a cover letter from its representative, Scientific Affairs Consultants Inc., dated November 26, 2007. The position was that disulfiram had been on the Canadian market for fifty years, and is still available elsewhere; it has been available for "sufficient" time and in "sufficient" quantity to prove its safety and effectiveness. Scientific literature references to support this position were provided. That letter states, in part:

> *Disulfiram was first used in 1949. In Canada, disulfiram entered the market in 1966 under the trademark Antabuse® by Wyeth Canada. Various mergers lead to pharmaceutical plant closings and the decision to discontinue the marketing of Antabuse® (250 mg and 500 mg) by Wyeth Canada on May 7th, 2001. Currently, there is no approved disulfiram in Canada but it has been available through compounding pharmacies. Disulfiram is approved and available in the United States and Europe from manufacturers other than Wyeth.*
>
> *This DIN submission represents a re-entry of disulfiram to the Canadian market. Wellesley believes a DIN submission should be sufficient for health Canada to evaluate and potentially approve this old drug. A new drug submission should not be necessary to assess disulfiram considering its long history of safe and effective use. According to the regulations a new drug is defined as a 'drug which has not been sold for that use or condition of use in Canada for sufficient time and in sufficient quantity to establish in Canada the safety and effectiveness of that substance for use as a drug'. This is certainly not the case for disulfiram. In fact, disulfiram is still approved and available in major jurisdictions such as the United States and Europe which further attests to its usefulness and ultimately its favourable risk/benefit profile.*
>
> *A brief review of recent clinical studies conducted with disulfiram has been summarized in volume 1, page 61 of this submission. While it is acknowledged that this review may be selective to modern better controlled studies we also acknowledge that it does not work for every alcoholic. However, disulfiram, like many other drugs, remains effective for selected patients. Even Health Canada, in its report of 1999, Best Practices Substance Abuse Treatment and Rehabilitation, has endorsed the use of disulfiram for selected populations. Therefore, efficacy from either a clinical or biopharmaceutical*

> *viewpoint should not be a deterrent for the review this DIN application.*
>
> *Safety information should also not deter the review of this application. Considering the length of time that disulfiram has been on the Canadian (as well as other markets) the safety profile is well established and known. We have reviewed Health Canada's safety database on disulfiram, which is available online. There is nothing in that database to suggest or indicate that the drug has an unfavourable safety profile.*
>
> . . .
>
> *A rough estimate of ADRs from disulfiram was between 1 per 200 to 2000 per treatment year, which corresponds to an intermediate rate of adverse reactions along with many other drugs (Enghusen Poulsen et al 1992]. Therefore, the safety profile of disulfiram is well known, similar to other drugs, and should not deter Health Canada from accepting this DIN submission.*
>
> *In summary, Wellesley believes that Abstayne® is not a new drug because disulfiram has a long safety and efficacy history. This history has a favourable risk/benefit ratio. The active ingredient in Abstayne®, disulfiram (USP, Ph. Eur), is pharmaceutically equivalent to disulfiram (USP, Ph. Eur) by definition. Abstayne® also contains 98% disulfiram. Disulfiram does not exhibit complex kinetics. Therefore, there is no scientific justification for Health Canada not to accept this application as a DIN submission.*

[39] Health Canada, as previously described, provided a lengthy document entitled "Status of Disulfiram – Issue Analysis" with its letter of March 29, 2010. That Issue Analysis begins:

> *Status of Disulfiram – Issue Analysis*
>
> *Overview*
>
> *The object of this analysis is to assess the status of disulfiram for drug submission review purposes under the Food and Drug Regulations. In particular, this review will consider whether disulfiram meets the definition of "new drug" set out in C.08.001 of the Regulations. If disulfiram meets the "new drug" definition, approval for marketing in Canada requires the filing of a "new drug submission" pursuant to the provisions of Part C, Division 8 of the Regulations. If disulfiram does not meet the definition, approval may*

be obtained by filing of a "DIN submission" pursuant to the provisions of Part C, Division 1.

For the purpose of this analysis, the relevant portion of C.08.001 defines new drug as:

> *(a) a drug that contains or consists of a substance, whether as an active or inactive ingredient, carrier, coating, excipient, menstruum or other component, that has not been sold as a drug in Canada for sufficient time and in sufficient quantity to establish in Canada the safety and effectiveness of that substance for use as a drug.*

In light of the above, the focus of this analysis will be on the post-market history of disulfiram and whether that history establishes the safe and effective use of the drug. To that end, this analysis will consider the arguments and evidence provided by Wellesley Therapeutics in support of the view that disulfiram is not a "new drug" as well as other evidence available to Health Canada not referenced by Wellesley Therapeutics in its submission material.

Product Information

Disulfiram was introduced to the Canadian market by Wyeth Pharmaceuticals Inc. in 1949 under the brand name Antabuse. On May 27th, 2001, Wyeth voluntarily discontinued marketing Antabuse in Canada.

Wellesley Therapeutics now seeks approval for a disulfiram product under the name Abstayne. Wellesley asserts that its product is not a "new drug" and is properly regulated under Division 1 of the Regulations.

Of note, a review of internal material reveals that health Canada notified ICN Canada Ltd. on may 15, 1984 that disulfiram was considered to be a "new drug" subject to regulation under Division 8 (Appendix 1). Although the letter does not outline the scientific basis for the position that disulfiram is a new drug, it does indicate that Health Canada considered disulfiram to be a new drug 16 years prior to its withdrawal from the Canadian market.

It should also be noted that, despite this assertion from Health Canada, disulfiram is not currently listed on the New Drug List. However, as products are generally only added to the New Drug List after the issuance of a Notice of Compliance (NOC), in the absence

of an approved new drug submission, a product would not typically have the opportunity to be added to this list.

In its application, Wellesley argues that the long marketing history of disulfiram has established the safety and effectiveness of the drug. In support of this position, Wellesley has provided 41 literature references speaking to safety and efficacy issues. They have also included a Non-clinical and Clinical Overview with their submission that summarizes the references provided. The list of references is included as Appendix 2.

l. Overview of clinical information provided in support of Safety and Efficacy of ABSTAYNE

Review of Clinical Overview for ABSTAYNE

Efficacy overview

(Here there follows an analyses of several literature references cited by Wellesley. It is noted that Wellesley provided no clinical trial data.)

Safety overview

(Again, several literature references were reviewed.)

Canada Post-market safety date

(A review of "adverse events" was made, some 56 such events were considered.)

Literature search for safety date

(Health Canada undertook its own literature search and reviewed that literature.)

Reviewer's Conclusion of Safety Overview

Based on the arguments above, the company has failed to establish clear data on the incidence and type of adverse reactions that could occur in patients taking disulfiram treatment, and has also failed to establish a "safety margin" for patients who take concomitant alcohol. In addition, no risk mitigation measures have been proposed that may help reduce the risk of adverse reactions associated with the drug. The clinical overview that was provided lacks sufficient

detail, only provides information on published studies and case reports, and fails even to provide all of the available published information that could contribute to the establishment of a safety profile on the drug. Therefore, they have clearly failed to establish the safety profile of the drug.

Review of supporting references

(A review of further references was given.)

Comparator Products for the same indication

(Two other products REVIVA (naltrexone) and CAMPRAL (acamprosate) were considered. In the course of that consideration, the following statement was made):

…the regulator must not only consider the benefit/risk profile of the drug that is under review, but also the relative benefit/risk profile of that product compared to other products for the same indication. Historically, there are numerous cases of products with a long marketing history that have been removed from the Canadian market due to the discovery or characterization of serious adverse events, or because of the advent of newer, safer alternatives to treat the same illness.

. . .

The following conclusion was made:

Overall Risk/Benefit conclusion from data provided

After review of the materials submitted by Wellesley, and examination of additional information referenced above it is evident that the post-marketing experience with disulfiram is such that its safe and effective use has not been established. The company's assertion that the drug is not a new drug, does not take into account all the available evidence. While there is some evidence of limited efficacy of disulfiram as an adjunct to behavioural therapy, this has not been well-established. In addition, Wellesley has failed to provide sufficient detail on the safety of disulfiram. They have not provided a rationale for exclusion of a large body of literature evidence of safety issues with the product, and have failed to properly analyze the case report data available in Canada.

In the face of limited evidence of efficacy, even limited toxicity can assume importance in establishing a benefit/risk profile. Serious

> *safety issues identified with disulfiram include hepatotoxicity, cardiovascular side effects, serious skin reactions, neuropsychiatric reactions, and sudden death. Several of these adverse reactions are idiosyncratic in nature (unpredictable) and therefore are very difficult to mitigate through pharmacovigilance systems, or even through close medical supervision.*
>
> *Wellesley has also failed to account for the other available therapies that have come to market that appear to have improved benefit/risk profiles relative to disulfiram. Although the benefit/risk profile of disulfiram may not have changed relative to the disulfiram product that was previously marketed its relative benefit/risk compared to other pharmacologic interventions for management of alcoholism has. Given the borderline efficacy noted in the poorly designed trials, and anecdotal and trial evidence of serious safety issues, the benefit/risk profile for this product does not appear favourable based on the evidence reviewed.*

[40] In argument, Wellesley's Counsel made the following points in urging that the decision should be set aside:

a. Health Canada failed to give proper consideration to the fact that a fifty-year track record in Canada with millions of doses should in and of itself constitute "sufficient" time and quantity to make safety and efficacy self-evident.

b. Health Canada made a selective and incorrect analysis of the literature references.

c. Health Canada was fixated upon a requirement for clinical test data when none is required in a DIN application.

d. Health Canada made improper references to other available products.

e. Health Canada failed to consider the affidavit evidence submitted as part of the record in T-1537-07.

[41] I will consider each of these points in turn.

(1) Health Canada failed to give proper consideration to the fact that a fifty-year track record in Canada with millions of doses should in and of itself constitute "sufficient" time and quantity to make safety and efficacy self-evident.

[42] On the face of it, Wellesley makes an attractive argument in saying that surely fifty years of use and millions of doses is sufficient to make safety and efficacy self-evident, particularly since at no time did Health Canada require the previous seller of the product to withdraw the product or justify its continuing sale in Canada or make any adjustments to the product or its labelling.

[43] Counsel for Health Canada makes a very candid argument in saying that listing criteria and analytical and testing techniques of fifty years ago are not those of today. It is difficult to monitor every drug that has been approved. An appropriate time to revisit whether a drug should be approved is when one party has discontinued its sale and another party seeks approval to sell.

[44] Further, Health Canada's Counsel argues, the Issue Analysis provided by Health Canada is responsive to the submissions made by Wellesley's representative. The points raised, including the sufficiency of time and doses and the literature presented, have been reviewed. In addition, Health Canada sought out and reviewed other literature.

[45] I am satisfied that the use of the word “sufficient” in section C.08.001 of the Regulations does not mean that the simple passage of a long period of time or administration of a great many doses in and of itself dictate that the Minister must be satisfied as to safety and efficacy. The word “sufficient” implies a standard that may be variable, depending upon the circumstances. The *Concise Oxford Dictionary* defines the word in saying *“sufficing, adequate esp. in amount or number to the need, enough”*. It is appropriate for Health Canada, as the need arises including, as in the present circumstances, when it becomes expedient to do so, to make an assessment as to whether the time and quantity is “sufficient” in and of itself to determine safety and efficacy. In this case, Health Canada determined that such sufficiency did not exist. I find no reviewable error in that determination. Health Canada’s decision was reasonable.

(2) Health Canada made a selective and incorrect analysis of the literature references.

[46] Wellesley’s Counsel in argument took the Court through some, but not all, of the analyses of the scientific literature as set out in Health Canada’s “Issue Analysis” in an effort to point out that parts of such literature may have been overlooked, or misinterpreted, or dealt with selectively so as to stress only matters unfavourable to disulfiram. There is no affidavit or other evidence in the record to support Counsel’s critique. I have myself reviewed the literature references and while I agree to some extent with Counsel’s submissions, I cannot, as a judge and not as a person skilled in the area, come to a conclusion that the analyses made and conclusions reached by Health Canada are unreasonable, let alone so unreasonable that the decision must be set aside.

(3) Health Canada was fixated upon a requirement for clinical test data when none is required in a DIN application.

[47] The "Issue Analysis" did comment upon the fact that no clinical test data had been presented. It is true that a DIN submission does not require such data. However, the decision under review determined that the application could not be treated as a DIN application because there was insufficient information, whether by passage of time, number of doses, or by the literature references for Health Canada to determine safety and efficacy. Health Canada made no reviewable error in stating that more information would be needed and that clinical test data would be desirable.

(4) Health Canada made improper references to other available products.

[48] The "Issue Analysis" made reference to two other drugs used in the treatment of alcoholism. Health Canada in that Analysis stated that it must not only consider the benefit/risk profile of the drug in question, but the relative benefit/risk profile of that product compound to other products for the same indication. I can find no basis in the *Act* or the *Regulations* for such a requirement. It may be desirable, it may be useful, but nowhere is it a requirement.

[49] Dr. Petersen said that DIN applications were usually considered where the product in question was something like a fluoride toothpaste or sunscreen lotion. The Court can take judicial notice that there are hundreds of competitive products of this nature offered for sale in Canada. There is no evidence that Health Canada, before approving another such product on a DIN

application, makes a comparison with the many others already approved for sale. Even if it were to do so, neither the *Act* nor the *Regulations* establish any criteria by which the risk/benefit of the candidate product is to be measured as against the others, or the threshold to be met before approval is given.

[50] Here, Health Canada did state that two other products were already approved and available for use in treating alcoholism in Canada. However, I find that this was not a determinative factor by which Health Canada made its decision. It was not an error to mention the point. I find that it did not play a vital role in the reaching of the decision. There is no basis on this ground to set aside the decision.

(5) Health Canada failed to consider the affidavit evidence submitted as part of the record in T-1537-07.

[51] Nowhere in the decision letter or in the Issues Analysis does Health Canada refer to the record filed in application T-1537-07, which record was submitted to Health Canada by Wellesley as part of the materials in support of its DIN application. In particular, Health Canada does not refer to any of the affidavits of Drs. Wassenaar, Selby, or Macleod, or the statements made in their affidavits.

[52] Those affidavits, to the extent that they would be relevant at all to the DIN application is opinion, not factual. No new scientific information or data is provided. The application is not a hearing. Health Canada does not receive and consider opinion evidence as a Court would, nor is it

required to assess, weigh or balance such evidence. As a matter of good practice, it should have clearly acknowledged that it received such evidence; however, the apparent failure to consider such evidence does not constitute a reasonable error.

[53] In summary, I find that Health Canada made no errors in reaching its decision not to treat the application as a DIN application that are of such significance as would require the decision to be set aside and re-determined.

The NDS Decision

[54] This question pertains to application T-1537-07. The decision at issue is set out in Health Canada's letter dated July 23, 2007 with the accompanying Issue Analysis Summary.

[55] In this case, Wellesley had filed the application as an NDS application, thus there was no initial conversion from a DIN to an NDS application. Wellesley filed submissions essentially the same as in the DIN application, relying on scientific literature and the fact that the drug had been sold in large quantise in Canada for over fifty years, and was still available elsewhere. Health Canada insisted upon more; it wanted clinical test data.

[56] In this instance, we do not have the initial submissions made by Wellesley in filing the NDS application. The record does contain the rejection letter dated October 20, 2006 provided by Health Canada following the initial screening process, entitled Screening Deficiency Notice. It says, in part:

> *9) Please provide the results of well designed and conducted clinical trials supporting the use of your drug in the context of currently available therapies.*

[57] The cross-examination of Dr. Petersen, particularly her answers to questions 7 to 16, reveal that at this stage, the person doing the initial screening would not have looked at the scientific literature provided. That person would simply have observed that no clinical trial data had been provided and not looked at anything else.

[58] Wellesley responded to the Screening Deficiency Notice, but did not provide any clinical trial data. Health Canada sent a Screening Rejection Letter to Wellesley on December 27, 2006 reiterating its request for clinical trial data:

> *In consultation with the Central Nervous System Division (CNS) of the Bureau of Cardiology, Allergy, and Neurological Sciences, it has been determined that in order to assess the risk/benefit of your drug, the results of well designed and conducted clinical trials are required. Literature references are not acceptable.*

[59] The cross-examination of Dr. Petersen previously referred to makes it clear that Health Canada still had not made any review of the literature submitted.

[60] Wellesley then asked for a re-consideration. The cross-examination of Dr. Petersen makes it clear that even at this stage, the submissions, including the literature provided, had not been reviewed. In fact, it had never been reviewed until she prepared her affidavit submitted in these proceedings. I repeat the question put and answers given at questions 18 through 23 of her cross-examination:

> *18 Q. Where did it go from there? After that point, Wellesley asked for reconsideration. Correct?*
>
> *A. Yes. I have seen the papers. I was not there.*
>
> *19 Q. Were you involved at all in the reconsideration process?*
>
> *A. No, I was not. I was on leave at some time. I believe my director at that time represented me. I was not at the reconsideration at all.*
>
> *20 Q. During that process, there still would be no review of the actual application because of the same issue that thee were no clinical trials. Is that correct?*
>
> *A. No. The name of the drug was known, Abstayne. Disulfiram is well known. I would have known the name of the drug. I have seen it in the literature.*
>
> *21 Q. So you were familiar with the drug, but was there any actual review done beyond this rejection at the initial screening stage?*
>
> *A. No.*
>
> *22 Q. Not as part of the reconsideration process.*
>
> *A. No, because we don't review publications. We don't review them.*
>
> *23 Q. Again, you said that was relying on the provisions in the Food and Drugs Act Regulations.*
>
> *A. That's right.*

[61] There is no express provision in the *Act* or *Regulations* requiring that clinical trials be conducted and resulting data be provided to Health Canada. Counsel for Health Canada informed the Court that Health Canada relies on its interpretation of sections C.08.002 (2)(g) and (h) of the *Regulations*, which I will repeat, to state that an NDS application must include clinical test data:

> *(2) A new drug submission shall contain sufficient information and material to enable the Minister to assess the safety and effectiveness of the new drug, including the following:*
>
> . . .
>
> *(g) detailed reports of the tests made to establish the safety of the new drug for the purpose and under the conditions of use recommended;*
> *(h) substantial evidence of the clinical effectiveness of the new drug for the purpose and under the conditions of use recommended.*

[62] Clinical testing is a rigorous and often expensive and time-consuming process. The affidavit of Dr. Macleod, particularly at paragraphs 27 to 29, points out the frailties of many clinical trials, particularly when compared to a long history of actual use by the public. Dr. Petersen's cross-examination, particularly in answer to questions 191 to 196, for the first time makes it clear what the nature of the tests were and the data that Health Canada hoped to review. This was never clearly expressed by Health Canada in the course of its dealing with the Wellesley NDS application prior to the launch of these legal proceedings.

[63] It is clear from the cross-examination of Dr. Petersen in response to questions 20 to 23 previously set out, that even at the reconsideration stage, no substantive examination of the

Wellesley submission, including the literature, had been considered. The letter provided to Wellesley following reconsideration, dated July 23, 2007, stated in part:

> *Upon reconsideration, the Directorate stands by the original decision that the Abstayne submission, which is based on information from the literature, does not constitute sufficient evidence of safety and effectiveness for disulfiram. There are two products currently on the market in Canada for the treatment of alcohol abuse since disulfiram was first introduced and it is the regulator's responsibility to assess the risk/benefit of disulfiram in the current Canadian context. The Bureau of Cardiology, Allergy and Neurological Sciences is willing to discuss the requirements of a new NDS.*

[64] The accompanying Issue Analysis Summary addressed the issue as to the requirement for clinical test data only briefly, as well as the issue as to other products on the market. It said:

> *Issue 1*
>
> *Sponsor: Since disulfiram has been on the market in Canada for over 50 years and has been used effectively for that period, to define disulfiram as a new drug is contrary to the definition of a "new drug".*
>
> *The Food and Drug Act defines a drug as including "any substance" and C.08.001 states:*
>
> *"For the purposes of this Act and this Division "new drug" means: "(a) a drug that contains or consists of a substance, whether as an active or inactive ingredient, carrier, coating, excipient, menstruum or other component, that has not been sold in Canada for a sufficient time and in sufficient quantity to establish in Canada the safety and effectiveness of that substance for use as a drug."*
>
> *Disulfiram was recently designated as a "new drug" by Health Canada without rational justification.*
>
> *Office of Science: The previously available disulfiram product, Antabuse, has been discontinued by the innovator. The issue of new drug status was the subject of an appeal in 2003 and is not eligible for further discussion within the context of the present reconsideration request.*

Issue 2

Sponsor: The first quoted paragraph suggests that the submission does not comply with the requirements of the Food and Drugs Regulations but it does not detail what the requirements are and the shortfalls of the submission.

Office of Science: The letter has indicated that the basis for non-compliance is the submission of literature references rather than full clinical study reports. Literature references are a poor substitute for full clinical study reports, as they do not typically include detailed methodology or the full set of expected data tabulations, listings, and appendices. Re-analyses of the submitted data are not possible and data for individual patients are not available.

Issue 3

Sponsor: The second paragraph refers to a consultation with the CNS Division.

a. What was the nature of the consultation?
b. What was the input from CNS?

Office of Science: The regulatory project manager has stated that "in consultation with the Central Nervous System Division (CNSD) of the Bureau of Cardiology, Allergy, and Neurological Sciences, it has been determined that in order to assess the risk/benefit of your drug, the results of well designed and conducted clinical trials are required. Literature references are not acceptable." There is no documentation to review concerning this consultation.

Issue 4

Sponsor: The decision goes on to state "…it has been determined that in order to assess the risk/benefit…"

a. What is the nature of the risk/benefit to be determined?
b. The risk/benefit is well established in Canada after 50 years of use. No clinical trial can add anything new to the risk/benefit profile. Why after 50 years of use in Canada are literature references not acceptable?

Office of Science: The risk-benefit of many currently or previously marketed drugs may be subject to re-evaluation when new therapeutic options with improved efficacy or safety become available or when information emerges to generate new or intensified safety concerns. Because of improved practices in efficacy assessments and drug safety monitoring, it is likely that new clinical

trials could contribute information relevant to the risk-benefit assessment.

Issue 5

Sponsor: While disulfiram was introduced to the Canadian market at a time when the amount of data required for submission was substantially less than required today, this does not make it a new drug. Health Canada accepted the safety and efficacy of disulfiram when Health Canada issued DIN numbers to Wyeth in the recent past.

Office of Science: Health Canada can reassess the risk-benefit of marketed or previously marketed drugs whenever relevant new information arises. With the advent of new therapeutic options for the treatment of alcohol abuse, health Canada is justified in preferring a re-assessment of the risk-benefit balance for this drug.

Issue 6

Sponsor: Health Canada has not made it clear to the sponsor why it has not accepted the submission under the process set out in Section C.08.0021 i.e. 'the filing of an abbreviated new drug submission.

Office of Science: Health Canada must accept the submission as an abbreviated new drug-submission because there is no Canadian reference product.

Issue 7

Sponsor: The availability or non-availability of a pharmaceutical product for the treatment of alcohol abuse has important social policy considerations and cannot be arbitrarily dismissed.

Office of Science: TPD recognises that alcohol abuse is a major public health problem in Canada. Two products are currently approved in Canada for this indication; naltrexone and acamprosate.

[65] The reference in the response to Issue 1 to an appeal in 2003 is a reference to the original DIN (powder) application by Wellesley. The only discussion of the matter by Health Canada that

Counsel could direct the Court to is a paragraph in Health Canada's Rejection Letter – Screening, dated December 30, 2002 which says:

> *Please inform all your Canadian clients that products containing Disulfiram are considered to be New Drugs as defined in Division 8 of the Canadian Food and Drugs Regulations since they have not been sold in Canada for sufficient time and in sufficient quantity to establish safety and efficacy under the conditions of use recommended.*

[66] It is clear from these documents and the evidence of Dr. Petersen that:

a. When Health Canada received Wellesley's NDS application, some person doing the initial screening observed that it contained no clinical test data. No further analyses of the application or accompanying literature were made even at the later reconsideration stage.

b. Health Canada has a general practice of rejecting NDS applications that do not contain clinical test data.

c. Health Canada at no time during the process told Wellesley what sort of clinical test data it specifically required.

d. Health Canada put forward as one of the two reasons for rejecting Wellesley's application the evidence of two other drugs directed to the treatment of alcoholism. At no time did Health Canada direct its mind to the different manner in which disulfiram was used compared to the manner in which these two drugs were used in

> such treatment, or to the desirability of having several options available to the professional administering such treatment.

[67] At this point, I must consider specifically the decision of O'Keefe J. of this Court in *Hospira*, recognizing that this decision is under appeal. In reaching a determination as to what he described as Issue 2: *Does section C.08.002 of the Regulation mandate the submission of clinical trial data as part of a New Drub Submission*? O'Keefe J. wrote the following at paragraphs 38, 43 and 46:

> *[38] The NDS rejection makes it clear that in Health Canada's view the Regulations require pre-clinical and clinical data to be submitted with an NDS. The respondent Minister maintains this position and submits that even if the Regulations do not explicitly require pre-clinical and clinical data, they do so at least implicitly.*
>
> . . .
>
> *[43] In my opinion, while the applicant's interpretation of the Regulations may have merit, the respondent Minister's view that pre-clinical and clinical data is implicitly required, is certainly a reasonable interpretation of the Regulations that falls within the range acceptable outcomes.*
>
> . . .
>
> *[46] Therefore, the impugned decision should stand and should not be interfered with on the application of the reasonableness standard to the Minister's interpretation of its home statute and related regulations.*

[68] With all due respect, I disagree with O'Keefe J. if he has determined that, as a matter of statutory (regulatory) interpretation, section C.09.002 *requires* clinical test data. I would agree with him that Health Canada would be acting reasonably and within the scope of that *Regulation* if it asked for clinical test data in order to satisfy itself as to the safety and efficacy of a candidate drug. I

disagree if that section means that all NDS applications, regardless of circumstances, *must* be accompanied by clinical test data. It is a difference between can and must.

[69] The distinction that I have made is important here because in the present case, no analysis was ever made by Health Canada as to Wellesley's submission, no regard was given to the arguments raised, no review of the literature was conducted. Health Canada simply shut its mind to the application, even on reconsideration, as soon as it was determined that no clinical test data was submitted.

[70] Further, in the present case, Health Canada never took the trouble to advise Wellesley as to the kind of clinical test data it was interested in receiving. This is unlike *Hospira* and the Apotex case discussed by O'Keefe J. at paragraphs 52 and 54 of his Reasons:

> *[52] In Apotex Inc. v. Canada (Minister of Health), 2009 FC 452, [2009] F.C.J. No. 577 (QL) (Apotex 2009) Mr. Justice Phelan dealt with a similar issue. Apotex's ANDS for aspirin had been rejected by the Minister because the data from two of its clinical test subjects did not meet the Minister's standards, reflected in Health Canada's guidelines. Apotex defended its drug, asserting that the defective reference drug caused the errors. One year later, on reconsideration, Health Canada confirmed the rejection. Apotex then charged that the Minister had fettered his discretion by rigidly adhering to his guidelines. Mr. Justice Phelan disagreed and held first that the published guidelines allowed for exceptions and second, that the Minister analyzed Apotex's submissions and specifically explained its concerns. At paragraph 35 he stated:*
> *It is not unreasonable, nor is it intransigence, for the Minister to demand compliance with the Guidelines in the absence of a clear indication that an alternative approach is required.*
>
> . . .
>
> *[54] Even if the August 17, 2006 decision and the December 19, 2006 are viewed as being so intertwined as to be reviewed*

> *together, the claim that the Minister fettered his discretion cannot be accepted. It is clear from the record that, like Apotex 2009 above, the particular circumstance of the applicant was considered extensively before the Minister finally decided that it would apply its policy to require clinical data. The applicant alleges that it was in consultations with Health Canada for 22 months to determine if alternative criteria could be accepted in its NDS. In the end, Health Canada decided it would not define or accept such alternative criteria. It is not open for the applicant to now argue its particular circumstances were not taken into account, or that the Minister was legally obliged to make an exception.*

[71] The second aspect to Health Canada's decision is the reference to competitive drugs already approved for sale in Canada. As discussed with respect to the DIN application, there is nothing in the *Act* or *Regulations* requiring any consideration as to alternatives, nor is there any criteria by which they are to be measured. There is no evidence that the Minister looked very deeply into these alternatives. No consideration was given to a comparison of the mechanisms by which they work. No consideration was given to the desirability of having alternatives available to the caregiver.

[72] I find, given the mechanical rejection of the application at the initial stage and forever thereafter simply because of the lack of clinical test data and the reliance on the availability of two other approved drugs with no consideration as to the mechanisms by which they worked, or the desirability of the alternatives, that Health Canada's decision to reject Wellesley's NDS application was unreasonable. It must be set aside and returned for review on its merits by consideration of the application including the submissions made and the literature provided and with full regard as to how the alternative drugs work, and to the desirability of having a number of alternatives available. Such review should be conducted and supervised by persons not involved in the decision under review.

CONCLUSION AND COSTS

[73] As a result, I will dismiss application T-706-10, and allow application T-1537-07 and send the matter back for reconsideration as set out in the previous paragraph.

[74] I have received submissions as to costs from Counsel for each party. Counsel for the Applicant's submissions go beyond submissions just as to the costs, and attempt to re-argue part of the case. I have not taken such re-argument into account in arriving at my decision as to the substantive matters. Applicant's Counsel essentially argues that the Applicant, if successful, is entitled to substantial costs and disbursements, but should not have to pay any costs if unsuccessful. I do not agree with such an argument. Success or loss in an application is often a close matter. Here, Counsel for all parties were fair and helpful. The case for all parties was well prepared and argued. Costs are usually intended as a partial defrayal of expenses and fees. They are not to assuage any moral outrage one party or the other may harbour whether justified or not.

[75] I agree with the Respondent's Counsel that costs in the sum of $3,500.00, payable to the successful party in each case, is appropriate.

"Roger T. Hughes"

Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1537-07 and T-706-10
STYLE OF CAUSE:	WELLESLEY THERAPEUTICS INC. v. MINISTER OF HEALTH (HEALTH CANADA), DIRECTOR GENERAL THERAPEUTIC PRODUCTS DIRECTORATE (HEALTH CANADA) and ATTORNEY GENERAL OF CANADA
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	MAY 19, 2010
REASONS FOR JUDGMENT:	HUGHES J.
DATED:	MAY 28, 2010

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