Federal Court  Cour fédérale

Date: 20100924

Docket: T-2009-09

Citation: 2010 FC 956

Ottawa, Ontario, September 24, 2010

PRESENT: The Honourable Mr. Justice Near

BETWEEN:

EPICEPT CORPORATION

Applicant

and

THE MINISTER OF HEALTH

Respondent

and

CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION

Intervener

REASONS FOR JUDGMENT AND JUDGMENT

[1] This is an application for judicial review of a decision of the Minister of Health under the data protection provisions of the *Food and Drug Regulations*, C.R.C., c. 870, as amended on October 5, 2006 by SOR/2006-241 (the *Regulations*). The Minister advised the Applicant on

November 2, 2009 that its product CEPLENE® is not an “innovative drug” pursuant to subsection C.08.004.1(1) of the *Regulations* (the Decision).

[2] For the reasons set out below the application is dismissed.

I. Background

A. *The Parties*

[3] The Applicant is a specialty pharmaceutical company that focuses on unmet medical needs in cancer treatment and pain management. The Applicant markets the product CEPLENE (histamine dihydrochloride), which is used for remission maintenance therapy in acute myeloid leukemia. CEPLENE was approved for sale in Europe in 2008, with submissions under review in Canada and pending in the United States.

[4] The Respondent is the Minister of Health (the Minister). The Minister has exclusive legislative jurisdiction with respect to the approval of drugs, confirmed by the *Food and Drugs Act*, R.S.C. 1985, c. F.-27 (the *Act*), and the *Regulations*. Health Canada produces various guidelines and policy statements on issues such as the drug approval process in Canada and the application of the data protection regulations.

B. *The Drug Approval Process in Canada*

[5] It is important to understand several aspects of the way drugs are regulated in Canada.

[6] A “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 (see the *Act*, section 2).

[7] “New drugs” are regulated under Part C, Division 8 of the *Regulations*. A “new drug” is defined in C.08.001 as a drug that contains a substance, combination of substances, or use which has not been sold in Canada for sufficient time and in sufficient quantity to establish in Canada the safety and effectiveness of that substance, combination, proportion, use or condition of use, for use as a drug.

[8] To market a “new drug” in Canada, the manufacturer must have, *inter alia*, a Notice of Compliance (NOC).

[9] To gain a NOC, a manufacturer must file a New Drug Submission (NDS). The NDS must contain sufficient information and material to enable the Minister to assess the safety and effectiveness of the “new drug”, including substantial evidence of its clinical effectiveness (see C.08.002(2) of the *Regulations*).

[10] The NDS typically consists of evidence from pivotal trials, which are trials of high scientific quality which provide basic evidence to determine the efficacy, properties and conditions of use for the drug. These trials are well-planned, designed, and usually controlled studies conducted and analyzed by qualified investigators. It is on the basis of this information that the "new drug" is approved. There are provisions for making changes to the "new drug" or the NDS that are not relevant to this proceeding. This material is typically undisclosed and proprietary.

[11] A generic manufacturer who wishes to copy a marketed drug without having to provide clinical data demonstrating safety and effectiveness may file an Abbreviated New Drug Submission (ANDS) under section C.08.002.1. The ANDS must show that the generic drug is the bioequivalent of a Canadian reference product, which is, *inter alia*, a drug that has received a NOC. The generic manufacturer relies on the information established about the Canadian reference product, as filed in the NDS, which provides the primary knowledge about the safety and effectiveness of the drug and the conditions of use.

[12] To market a drug that is a "new drug" or a "drug" a manufacturer must have a Drug Identification Number (DIN). A DIN is an eight digit numerical code that identifies drug product characteristics, including manufacturer, brand name, medicinal ingredient, dosing, pharmaceutical form, and route of administration (see C.01.014.1(2) of the *Regulations*). The DIN is used to track or recall a drug in the event of an adverse drug reaction in a population.

[13] A DIN submission must contain a Drug Submission Application Form, a DIN Submission Certification and specific product information. To receive a DIN, the manufacturer must file sufficient data to allow the Minister to evaluate the safety and efficacy of the drug for its intended use. A DIN Submission does not require substantial evidence of clinical effectiveness, voluminous clinical trial data, or detailed studies.

[14] Natural health and homeopathic products have been regulated under the *Natural Health Products Regulations*, SOR/2003-196, since January 1, 2004. Prior to this such products were regulated under the DIN process. Manufacturers of these products are required to file a Product License Application and obtain a product license number. The product license submissions are not required to contain pivotal trials or voluminous clinical trial data and detailed studies.

[15] Therefore, to market a "new drug" in Canada, a manufacture needs, *inter alia*, a NOC and a DIN, and is subject to Division 8 of the *Regulation*s. To market a "drug" in Canada, a manufacturer needs, *inter alia*, a DIN, but not a NOC. An application for a DIN is regulated primarily under Part C, Division 1 of the *Regulations*.

C. *The Data Protection Provisions*

[16] The "data protection" provisions at issue are found in section C.08.004.1 of the *Regulations*. These provisions came into force on October 5, 2006 and are administered by the Office of the Patented Medicines and Liaison (OPML), Health Canada. The provision provides for an eight year

term of market exclusivity after the first NOC is issued, replacing the old five-year period which had been effectively abolished by *Bayer Inc. v. Canada (Attorney General)* (1998), 84 C.P.R. (3d) 129; 155 F.T.R. 184 (F.C.T.D.), aff'd (1999), 87 C.P.R. (3d) 293; 243 N.R. 170, (F.C.A.), leave to appeal to the S.C.C. refused. The Minister is also required to maintain a register of innovative drugs, which has been named the Register of Innovative Drugs.

[17] The relevant data protection provisions are set out as such:

(1) The following definitions apply in this section.	(1) Les définitions qui suivent s'appliquent au présent article.
[…]	[…]
(2) This section applies to the implementation of Article 1711 of the North American Free Trade Agreement [NAFTA], as defined in the definition "Agreement" in subsection 2(1) of the *North American Free Trade Agreement Implementation Act*, and of paragraph 3 of Article 39 of the Agreement on Trade-related Aspects of Intellectual Property Rights [TRIPS]set out in Annex 1C to the World Trade Organization Agreement, as defined in the definition "Agreement" in subsection 2(1) of the *World Trade Organization Agreement Implementation Act*.	(2) Le présent article s'applique à la mise en œuvre de l'article 1711 de l'Accord de libre-échange nord-américain, au sens du terme « Accord » au paragraphe 2(1) de la Loi de mise en œuvre de *l'Accord de libre-échange nord-américain*, et du paragraphe 3 de l'article 39 de l'Accord sur les aspects des droits de propriété intellectuelle qui touchent au commerce figurant à l'annexe 1C de l'Accord sur l'Organisation mondiale du commerce, au sens du terme « Accord » au paragraphe 2(1) de la Loi de mise en œuvre de *l'Accord sur l'Organisation mondiale du commerce*.
(3) If a manufacturer seeks a notice of compliance for a new drug on the basis of a direct or indirect comparison between	(3) Lorsque le fabricant demande la délivrance d'un avis de conformité pour une drogue nouvelle sur la base

the new drug and an innovative drug,	d'une comparaison directe ou indirecte entre celle-ci et la drogue innovante :
(a) the manufacturer may not file a new drug submission, a supplement to a new drug submission, an abbreviated new drug submission or a supplement to an abbreviated new drug submission in respect of the new drug before the end of a period of six years after the day on which the first notice of compliance was issued to the innovator in respect of the innovative drug; and	a) le fabricant ne peut déposer pour cette drogue nouvelle de présentation de drogue nouvelle, de présentation abrégée de drogue nouvelle ou de supplément à l'une de ces présentations avant l'expiration d'un délai de six ans suivant la date à laquelle le premier avis de conformité a été délivré à l'innovateur pour la drogue innovante;
(b) the Minister shall not approve that submission or supplement and shall not issue a notice of compliance in respect of the new drug before the end of a period of eight years after the day on which the first notice of compliance was issued to the innovator in respect of the innovative drug.	b) le ministre ne peut approuver une telle présentation ou un tel supplément et ne peut délivrer d'avis de conformité pour cette nouvelle drogue avant l'expiration d'un délai de huit ans suivant la date à laquelle le premier avis de conformité a été délivré à l'innovateur pour la drogue innovante.
[…]	[…]
(5) Subsection (3) does not apply if the innovative drug is not being marketed in Canada.	(5) Le paragraphe (3) ne s'applique pas si la drogue innovante n'est pas commercialisée au Canada.
[…]	[…]
(9) The Minister shall maintain a register of innovative drugs	(9) Le ministre tient un registre des drogues innovantes, lequel

that includes information relating to the matters specified in subsections (3) and (4).	contient les renseignements relatifs à l'application des paragraphes (3) et (4).

[18] The data protection provisions are enacted under subsection 30(3) of the *Act*. This subsection authorizes the implementation of certain parts of NAFTA and TRIPS. Subsection 30(3) is set out as such:

30 (3) Without limiting or restricting the authority conferred by any other provisions of this Act or any Part thereof for carrying into effect the purposes and provisions of this Act or any Part thereof, the Governor in Council may make such regulations as the Governor in Council deems necessary for the purpose of implementing, in relation to drugs, Article 1711 of the North American Free Trade Agreement or paragraph 3 of Article 39 of the Agreement on Trade-related Aspects of Intellectual Property Rights set out in Annex 1C to the WTO Agreement.	30 (3) Sans que soit limité le pouvoir conféré par toute autre disposition de la présente loi de prendre des règlements d'application de la présente loi ou d'une partie de celle-ci, le gouverneur en conseil peut prendre, concernant les drogues, les règlements qu'il estime nécessaires pour la mise en oeuvre de l'article 1711 de l'Accord de libre-échange nord-américain ou du paragraphe 3 de l'article 39 de l'Accord sur les aspects des droits de propriété intellectuelle qui touchent au commerce figurant à l'annexe 1C de l'Accord sur l'OMC.

[19] The relevant data protection provision from NAFTA is located at Article 1711:

5. If a Party requires, as a condition for approving the marketing of pharmaceutical or agricultural chemical products that utilize new chemical	5. Lorsqu'une Partie subordonne l'approbation de la commercialisation de produits pharmaceutiques ou de produits chimiques pour l'agriculture qui

entities, the submission of undisclosed test or other data necessary to determine whether the use of such products is safe and effective, the Party shall protect against disclosure of the data of persons making such submissions, where the origination of such data involves considerable effort, except where the disclosure is necessary to protect the public or unless steps are taken to ensure that the data is protected against unfair commercial use.

comportent des éléments chimiques nouveaux, à la communication de données non divulguées résultant d'essais ou d'autres données non divulguées nécessaires pour déterminer si l'utilisation de ces produits est sans danger et efficace, cette Partie protégera ces données contre toute divulgation, lorsque l'établissement de ces données demande un effort considérable, sauf si la divulgation est nécessaire pour protéger le public, ou à moins que des mesures ne soient prises pour s'assurer que les données sont protégées contre toute exploitation déloyale dans le commerce.

6. Each Party shall provide that for data subject to paragraph 5 that are submitted to the Party after the date of entry into force of this Agreement, no person other than the person that submitted them may, without the latter's permission, rely on such data in support of an application for product approval during a reasonable period of time after their submission. For this purpose, a reasonable period shall normally mean not less than five years from the date on which the Party granted approval to the person that produced the data for approval to market its product, taking account of the nature of the data and the person's efforts and expenditures in producing them. Subject to this provision,

6. Chacune des Parties prévoira, en ce qui concerne les données visées au paragraphe 5 qui lui sont communiquées après la date d'entrée en vigueur du présent accord, que seule la personne qui les a communiquées peut, sans autorisation de cette dernière à autrui, utiliser ces données à l'appui d'une demande d'approbation de produit au cours d'une période de temps raisonnable suivant la date de leur communication. On entend généralement par période de temps raisonnable, une période d'au moins cinq années à compter de la date à laquelle la Partie en cause a donné son autorisation à la personne ayant produit les données destinées à faire approuver la

there shall be no limitation on any Party to implement abbreviated approval procedures for such products on the basis of bioequivalence and bioavailability studies.	commercialisation de son produit, compte tenu de la nature des données, ainsi que des efforts et des frais consentis par cette personne pour les produire. Sous réserve de cette disposition, rien n'empêchera une Partie d'adopter à l'égard de ces produits des procédures d'homologation abrégées fondées sur des études de bioéquivalence et de biodisponibilité.

[20] The relevant data protection provision from TRIPS is located at Article 39:

3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.	3. Lorsqu'ils subordonnent l'approbation de la commercialisation de produits pharmaceutiques ou de produits chimiques pour l'agriculture qui comportent des entités chimiques nouvelles à la communication de données non divulguées résultant d'essais ou d'autres données non divulguées, dont l'établissement demande un effort considérable, les Membres protégeront ces données contre l'exploitation déloyale dans le commerce. En outre, les Membres protégeront ces données contre la divulgation, sauf si cela est nécessaire pour protéger le public, ou à moins que des mesures ne soient prises pour s'assurer que les données sont protégées contre l'exploitation déloyale dans le commerce.

[21] NAFTA and TRIPS each provide a scheme for protecting against the unfair commercial use of undisclosed data, the origination of which involved considerable effort. NAFTA also provides the data originator with a reasonable period of market exclusivity of not less than five years.

[22] In *Canadian Generic Pharmaceutical Assn. v. Canada (Minister of Health)*, 2009 FC 725; 77 C.P.R. (4th) 407, Justice Leonard Mandamin held that subsection 30(3) of the *Act* and the data protection provisions of the *Regulations* are intra vires as a valid exercise of the federal constitutional power under the regulation of trade and commerce and that section C.08.004.1 of the *Regulations* was rationally connected with subsection 30(3) of the *Act* and within the regulatory authority Parliament has given to the Governor in Council. This decision has been appealed to the Federal Court of Appeal (see Court File No. A-360-09).

[23] The object and purpose of the data protection provisions were described in the Regulatory Impact Analysis Statement (RIAS) (see *Canada Gazette Part II*, vol. 140, No. 21 (2006-10-18). The relevant portions are reproduced here:

Description	Description
The amendments to section C.08.004.1 of the *Food and Drug Regulations* ("Regulations") are intended to provide new drugs with an internationally competitive, guaranteed minimum period of market exclusivity of eight years. An additional six months period of data protection is	L'objet des modifications à l'article C.08.004.1 du *Règlement sur les aliments et drogues* (le « règlement ») consiste à accorder aux drogues nouvelles une position concurrentielle sur les marchés internationaux et une période d'exclusivité de marché garantie d'une durée de huit

available for innovative drugs that have been the subject of clinical trials designed and conducted for the purpose of increasing the knowledge of the behaviour of the drug in pediatric populations.

ans. Une période de six mois supplémentaires de protection des données est possible dans le cas des drogues ayant fait l'objet d'essais cliniques conçus et menés dans le but d'accroître les connaissances sur le comportement du médicament chez les populations pédiatriques.

[…]

[…]

Background

Contexte

The amendments to section C.08.004.1of the *Food and Drug Regulations* are intended to clarify and effectively implement Canada's *North American Free Trade Agreement* ("NAFTA") and the *Trade-Related Aspects of Intellectual Property Rights* ("TRIPS") obligations with respect to the protection of undisclosed test or other data necessary to determine the safety and effectiveness of a pharmaceutical or agricultural product which utilizes a new chemical entity. […] In keeping with the provisions, the government has decided to provide this protection by allowing the innovator, or the originator of the data submitted for regulatory approval, to protect investments made in the development of the product by providing a period of market exclusivity.

Les modifications à l'article C.08.004.1 le règlement visent à clarifier et à mettre en oeuvre, de façon efficace, les engagements du Canada en vertu de *l'Accord de libre-échange nord-américain* (ALÉNA) et les aspects des droits de propriété intellectuelle qui touchent au commerce (ADPIC) en matière de protection des données de tests non divulgués ou d'autres données nécessaires afin de déterminer l'innocuité et l'efficacité d'un produit pharmaceutique ou agricole qui comporte une nouvelle entité chimique. […] Dans l'esprit de ces dispositions, le gouvernement a décidé d'accorder cette protection en permettant à l'innovateur ou au premier auteur des données soumises à l'approbation réglementaire de protéger l'investissement fait dans le développement du produit en

prévoyant une période d'exclusivité du marché

Amendment to C.08.004.1

The government is introducing an eight-year term of data protection for innovative drugs with a six-year no-filing period within the eight-year term of data protection. As a result, Canada will now provide for a six-year period (within the eight-year term) where a generic manufacturer, seeking to copy an innovative drug, will not be permitted to file a new drug or abbreviated new drug submission with the Minister. This will be followed by a no-marketing period of two years during which the Minister will not grant a notice of compliance to that generic manufacturer. This additional two-year period is generally reflective of the period of time required to approve a drug submission, as well as the time required for a generic manufacturer to meet its obligations under the *Patented Medicines (Notice of Compliance) Regulations* ("PM(NOC) Regulations"). The introduction of these changes will provide an adequate incentive for innovators to invest in research, and to develop and market their products in Canada. It will also bring Canada in-line with a system similar to that of other jurisdictions in respect of the

Modification à l'article C.08.004.1

Le gouvernement instaure désormais une période de protection des données de huit années pour les médicaments novateurs et une période de six années de non-dépôt comprise dans la période de huit années de protection. Ainsi, le Canada accordera une période d'une durée de six années (à l'intérieur de la période de huit années) de protection des données au cours de laquelle le fabricant du produit générique cherchant à copier le médicament novateur ne pourra pas déposer de présentation de drogue nouvelle ou de présentation abrégée de drogue nouvelle au ministre. Cela sera suivi d'une période de non-commercialisation de deux années au cours de laquelle le ministre ne délivrera pas d'avis de conformité au fabricant du produit générique. Cette période supplémentaire d'une durée de deux années représente, en règle générale, la période de temps requise afin d'approuver une présentation de drogue, ainsi que la période de temps que requière un fabricant de produit générique afin de respecter ses obligations en vertu du *Règlement sur les médicaments brevetés (avis de conformité)*. La mise en oeuvre

no-filing period.

de ces modifications incitera les innovateurs à investir dans la recherche ainsi qu'à développer et à commercialiser leurs produits au Canada. Le Canada harmonisera ainsi son système avec ceux des autres pays en ce qui a trait à la période de non-dépôt.

[…]

[…]

Innovative Drug

Drogue innovante

The definition of "innovative drug" specifically prohibits innovators from obtaining additional terms of data protection for variations of medicinal ingredients. The list of variations is not exhaustive, but rather meant to give examples of the types of variations not considered for protection. The exclusion of variations of a previously approved medicinal ingredient from the scope of protection was introduced to avoid the granting of an additional eight years of protection where an innovator seeks approval for a minor change to a drug. For other arguable variations not included in the list, such as metabolites, an assessment will be made as to whether or not approval is being sought primarily on the basis of previously submitted clinical data (i.e. without the support of new and significant clinical [sic] data) or not. This position is consistent with both NAFTA

La définition de « drogue innovante » interdit spécifiquement aux innovateurs d'obtenir une période supplémentaire de protection des données du fait qu'ils ont varié les ingrédients médicinaux. La liste des variations n'est pas exhaustive, mais se veut plutôt une liste d'exemples des types de variations qui n'avaient pas été prises en compte en matière de protection. L'exclusion de variations d'un ingrédient médicinal préalablement approuvé de la portée de la protection a été adoptée afin d'éviter l'octroi d'une période de protection supplémentaire de huit années quand un innovateur tente de faire approuver une modification mineure à un médicament. Pour d'autres variations douteuses qui ne sont pas incluses sur la liste, comme les métabolites, une évaluation sera effectuée dans le but de déterminer si oui ou non l'approbation demandée

and TRIPS which only require the granting of protection for undisclosed data, the origination of which involved a considerable effort.

est principalement fondée sur des données cliniques préalablement soumises (c.-à-d. sans l'appui de données cliniques nouvelles et significatives). Cette position est conforme à l'ALÉNA et aux dispositions des ADPIC qui n'exigent l'octroi d'une protection que pour les données non divulguées, dont la création nécessite un effort considérable.

[…]

[…]

Triggering mechanism

The triggering mechanism is intended to capture generic and second entrant manufacturers that are seeking to rely on direct or indirect comparison between their drug and the innovative drug. As was observed by the Supreme Court of Canada in *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, 2005 SCC 26,such direct or indirect comparisons would exclude submissions in which the submission sponsor does not rely on another manufacturer's safety and efficacy data in seeking approval under the *Food and Drug Regulations*. This is consistent with Article 1711 of NAFTA and paragraph 3, Article 39 of TRIPS, since there would be no unfair commercial use of data or the reliance on such data for the approval of the product. The mechanism is intended to capture both

Mécanisme déclencheur

Le mécanisme déclencheur vise à assujettir les fabricants de médicaments génériques et les deuxièmes fabricants qui tentent de se fonder sur la comparaison directe ou indirecte entre leur drogue et une drogue innovante. Comme l'a mentionné la Cour suprême du Canada, dans l'affaire *Brystol-Myers Squibb Co. c. Canada (Procureur général)*, 2005 CSC 26, de telles comparaisons directes ou indirectes excluraient les présentations dans lesquelles le parrain de la présentation ne se fie pas aux données d'innocuité et d'efficacité d'un autre fabricant afin d'obtenir une approbation en vertu du règlement. Cela est conforme à l'article 1711 de l'ALÉNA ainsi qu'au paragraphe 3 de l'article 39 des ADPIC, du fait qu'il n'y aurait pas d'utilisation déloyale de données ou de

submissions that fall under the abbreviated new drug submission provisions and submissions that are filed under the new drug submission provisions, so long as there is a direct or indirect comparison with the innovative drug.	fondement sur ces données pour obtenir l'approbation du produit. Le mécanisme cherche à englober les présentations assujetties aux dispositions qui s'appliquent aux présentations abrégées de drogues nouvelles et à celles qui sont soumises en vertu des dispositions visant les drogues nouvelles, dans la mesure où l'on a établi une comparaison, qu'elle soit directe ou indirecte, avec la drogue innovante.

D. *Histamine Dihydrochloride and CEPLENE*

[24] The medicinal ingredient in CEPLENE is histamine dihydrochloride. This medicinal ingredient has been previously approved in several "drugs", all of which were approved using the DIN process or the current method under the *Natural Health Products Regulations*.

[25] Health Canada deemed CEPLENE as a "new drug" and the Applicant filed their NDS on August 5, 2009. The NDS is 124 volumes in size and includes a large amount of material and data from comprehensive Phase II and Phase III clinical trials. The CEPLENE NDS contains a large amount of undisclosed clinical and non-clinical test data to support its safety and efficacy. The Applicant requested that Health Canada add CEPLENE to the Register of Innovative Drugs once approved.

[26] The Applicant has submitted one patent for listing on the Patent Register with respect to CEPLENE and this patent expires in 2010. Therefore, the Applicant is relying on the market exclusivity provided by data protection to protect its product in Canada following the issuance of a NOC.

E. *The Decision Under Review*

[27] By letter dated August 27, 2009 the OPML, on behalf of the Minister, expressed the preliminary view that CEPLENE is not an "innovative drug" and would not be added to the Register of Innovative Drugs. The Applicant was given 30 days to make responding submissions to the Minister. The Applicant provided such submissions on September 24, 2009.

[28] On November 2, 2009, the OPML, on behalf of the Minister, confirmed its preliminary view that CEPLENE is not an "innovative drug" and would not be added to the Register of Innovative Drugs (the Decision).

[29] In the Decision, the Minister stated that:

- The word "drug" in subsection C.08.004.1(1) of the Regulations is defined under the Act and is not limited to drugs which receive a NOC and are approved under Division 8;

- The medicinal ingredients histamine and histamine dihydrochloride have previously received DINs as they have been previously approved in several drugs by the Minister;

- The definition of “innovative drug” contemplates that medicinal ingredients not previously approved in “any drug” are to be considered in the assessment of eligibility of data protection, and not just those drugs that receive a NOC;
- That the OPML’s position is in keeping with the purpose of the data protection provisions;
- That while CEPLENE’s NDS submissions contain new clinical data and the use is unrelated to the uses of histamine which have been previously approved, the nature or extent of the data becomes relevant only where it is unclear as to whether or not the drug meets the definition of “innovative drug”.

F. *The Evidence*

[30] Both the Applicant and Respondent filed affidavit evidence.

[31] The Applicant filed evidence from John V. Talley, Jr., Chief Executive Officer and Director of EpiCept. Mr. Talley’s affidavit introduced the preliminary decision and Decision and their related submissions into the record. Mr. Talley was not cross-examined.

[32] The Respondent filed evidence from Anne Elizabeth Bowes, Director of the Office of Patented Medicines and Liaison, Therapeutic Products Directorate, Heath Products and Food Branch at Health Canada. Ms. Bowes is responsible for the administration of section C.01.004.1 of the *Regulations*. In her affidavit Ms. Bowes reviewed the regulatory scheme for drug submissions. Ms. Bowes was cross-examined.

[33] The Respondent also provided the Applicant with documents pursuant to Rule 317 of the *Federal Court Rules*, SOR/2004-283, s. 2. which encompassed the Minister's Record on this decision. The documents provided included a note to file listing previously approved products containing histamine or salts of histamine dihydrochloride, as identified on the Minister's internal Drug Product Database; an excerpt from the US Pharmacopia Dictionary of USAN and International Drug Names on "histamine dihydrochloride", and an excerpt from the Merck Index, 14th Edition, on "histamine".

II. Issue

[34] There is one issue in this matter: Did the Minister err in determining that CEPLENE is not an "innovative drug" pursuant to subsection C.08.004.1(1) of the *Regulations*?

III. Standard of Review

[35] In *Dunsmuir v. New Brunswick*, 2008 SCC 9, [2008] 1 S.C.R. 190, and *Canada (Minister of Citizenship and Immigration) v. Khosa*, 2009 SCC 12; [2009] 1 S.C.R. 339 the Supreme Court set out two standards of review for administrative decisions: reasonableness and correctness.

[36] I will undertake a standard of review analysis to determine the standard of review to be used as this is the first time this amended provision has been interpreted.

[37] Pursuant to my direction of July 30, 2010 the Applicant and Respondent made written submissions as to the appropriate standard of review. Both the Applicant and the Respondent agree that the issue to be determined in this matter is a question of law, namely the interpretation of the definition of “innovative drug” under subsection C.08.004.1 (1) of the *Regulations*.

[38] The Court in *Dunsmuir*, above, summarized various factors to be considered in the standard of review analysis of a question of law.

> 55 A consideration of the following factors will lead to the conclusion that the decision maker should be given deference and a reasonableness test applied:
>
> - A privative clause: this is a statutory direction from Parliament or a legislature indicating the need for deference.
> - A discrete and special administrative regime in which the decision maker has special expertise (labour relations for instance).
> - The nature of the question of law. A question of law that is of "central importance to the legal system ... and outside the ... specialized area of expertise" of the administrative decision maker will always attract a correctness standard (*Toronto (City) v. C.U.P.E.*, [2003] 3 S.C.R. 77, at para. 62). On the other hand, a question of law that does not rise to this level may be compatible with a reasonableness standard where the two above factors so indicate.
>
> 56 If these factors, considered together, point to a standard of reasonableness, the decision maker's decision must be approached with deference in the sense of respect discussed earlier in these reasons.

[39] I agree with the Parties' apparent shared view that when these factors are distilled they would be applied to this matter in the following way:

> i. There is no privative clause in the *Regulations* or the *Food and Drugs Act*, R.S.C. 1985, c. F-27 ("*Act*")
>
> ii. The statutory interpretation of the definition of "innovative drug" is a pure question of law.
>
> iii. Under the *Act* and *Regulations*, the Minister has jurisdiction with respect to the approval of drugs. However, the Minister has no expertise in deciding pure questions of law, as explained below.
>
> iv. The Court is as well placed as the Minister to determine the proper statutory interpretation of the *Regulations*.

[40] In his submissions the Respondent emphasizes that, given the recent jurisprudence found in *Khosa*, above, in some circumstances the standard of reasonableness is the appropriate standard to apply even to a question of law. Deference to the decision-maker may be required where the question of law is within the decision-maker's specialized area of expertise and is not of central importance to the legal system generally even where there is no privative clause. These are the facts in the present case. I agree that this would seem to be the current state of law. However, in this matter both the Applicant and the Respondent also agree that the Minister of Health does not have any particular expertise that would place him in a better position to determine the proper statutory interpretation of the *Regulations* than the Court. Accordingly, the appropriate standard of review is correctness.

IV. Discussion

[41] The Applicant argues that the Minister misinterpreted the relevant provisions of the Regulations. They take the position that the Minister's interpretation would prevent "new drugs", such as CEPLENE from obtaining data protection where unrelated homeopathic products containing the same or a similar medicinal ingredient have been approved previously. The Applicant states that this interpretation is contrary to the plain and ordinary language of the *Regulations* and the object and purpose of the overall scheme.

[42] The Respondent takes the position that the CEPLENE cannot be considered an innovative drug as is required and therefore the Minister properly refused to list CEPLENE on the Register of Innovative Drugs.

A. *Meaning of the Term "Innovative Drug"*

[43] It is necessary to interpret the definition of the term "innovative drug".

[44] The approach to modern statutory interpretation was set out by the Supreme Court in *Trustco Mortgage Co. v. Canada*, [2005] 2 S.C.R. 601, 2005 SCC 54: the words of an Act are to be read in their entire context and in their grammatical and ordinary sense harmoniously with the scheme of the Act, the object of the Act, and the intention of Parliament. Finding the correct interpretation requires a purposive analysis giving such fair, large and liberal construction and

interpretation as best ensures the attainment of the Act's objectives (see *Rizzo and Rizzo Shoes Ltd. (Re)*, [1998] 1 S.C.R. 27; 154 D.L.R. (4th) 193, *Interpretation Act*, R.S.C. 1985, c.1-12, s. 12).

[45] I am also mindful of the fact that one cannot interpret a regulation the same way as a statutory provision. When interpreting regulations it is necessary to read the words in the whole context of the authorizing statute and the scope of a regulation is constrained by its enabling legislation (see *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, [2005] 1 S.C.R. 533, 2005 SCC 26 at paragraph 38).

[46] In coming to my conclusion in this application I have also relied on the RIAS statement that accompanied the new regulations. The RIAS statements are often used as a guide to Parliamentary intention as to the purpose and effect of those regulations, although they are not part of the regulations themselves (*Bristol-Myers Squibb Co. v. Canada (Attorney General)*, above, see also *RJR-MacDonald Inc. v. Canada (Attorney General)*, [1994] 1 S.C.R. 311, [1994] S.C.J. No. 17 at pp. 352-53; *Friesen v. Canada*, [1995] 3 S.C.R. 103, [1995] S.C.J. No. 71 at paragraphs. 63-64). I note that the RIAS were used as an aid in interpreting the previous subsection C.08.004.1(1) of the *Regulations*, the provision in place prior to the current impugned provision (see *Bayer Inc. v. Canada (Attorney General)* (1999), 87 C.P.R. (3d) 293; 243 N.R. 170 (F.C.A.), at paragraph 10).

[47] It is with these principles in mind that I interpret the definition of the term “innovative drug” in this provision.

(1) Intent of the Provision

[48] Considering subsection 30(3) of the *Act*, the *Regulations*, the RIAS, and the relevant portions of NAFTA and TRIPS, as set out above, I have come to the following conclusions with regard to the intent of the impugned provision:

i. Data protection is available for “new drugs” only.

ii. The amendments were intended to clarify and implement NAFTA and TRIPS for the protection of undisclosed test or other data necessary to determine the safety and effectiveness of a pharmaceutical or agricultural product which utilizes a new chemical entity.

iii. The former regulation was amended to provide an adequate incentive for innovators to invest in research, and to develop and market their products in Canada, and bring Canada in-line with a system similar to that of other jurisdictions in respect of the no-filing period.

iv. The definition of "innovative drug" specifically prohibits innovators from obtaining additional terms of data protection for variations of previously approved medicinal ingredients. This exclusion was introduced to avoid the granting of an additional eight years of protection where an innovator seeks approval for a minor change to a drug.

v. If the submission of undisclosed test or other data is a condition for approving the marketing of a drug and determining whether the use of such products are safe and effective, and the origination of which requires considerable effort, as a condition of approving the marketing of a drug, then Canada shall protect such data against unfair commercial use.

[49] In coming to these conclusions, I find support in the recent decision by Justice Mandamin in *Canadian Generic Pharmaceutical Association*, above, at paragraph 78 to 79, where he considered the purpose and legal effect of the data protection provision to be as such:

> 78 Considering the Data Protection Regulation, the stated purpose, its legal and economic effects, and the language of NAFTA and TRIPS, I conclude that the purpose of the Data Protection Regulation is the implementation of the specific provisions of NAFTA and TRIPS. The legal effect is the protection of the NDS information submitted by innovator drug companies and its intended effect is the balancing of commercial considerations, protecting the research and development costs for new drugs by innovator drug manufacturers on one hand and achieving lower drug costs by the eventual introduction of generic drugs by generic drug manufacturers on the other hand.
>
> 79 I conclude that the pith and substance of the Data Protection Regulation is the balancing of commercial considerations between the protection of an innovator drug manufacturer's investments in preparing the NDS information in order to obtain an NOC for a new drug and the eventual NOC approval of generic drug manufacturer's ANDS for a lower cost generic version of the new drug.

(2) The Definition

[50] The term “innovative drug” is set out in section C.08.004.1 of the *Regulations* as:

“innovative drug” means a drug that contains a medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph.	« drogue innovante » S’entend de toute drogue qui contient un ingrédient médicinal non déjà approuvé dans une drogue par le ministre et qui ne constitue pas une variante d’un ingrédient médicinal déjà approuvé tel un changement de sel, d’ester, d’énantiomère, de solvate ou de polymorphe.

[51] The parties agree that CEPLENE contains a medicinal ingredient and I dismiss the argument that the term "approved …by the Minister" is relevant to this matter (see below). The parties do not take issue with the fact that the "drug" cannot be a variation.

[52] At the heart of this issue is the meaning to be ascribed to the term "drug" as it is referred to the second time in the definition. Can the second reference to a drug be read down to be limited to approved "new drugs" or does it include all approved "drugs". The word "drug" appears twice:

> "innovative drug" means a drug [referred to as Drug 1] that contains a medicinal ingredient not previously approved in a drug [referred to as Drug 2] by the Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph."

[53] The Applicant and Respondent agree that "Drug 1" should be a "new drug", but differ on the interpretation of "Drug 2".

(3) <u>The Applicant's Position</u>

[54] The Applicant advocates that the definition be read as such (the Applicant's Definition):

> "innovative drug" means a [new] drug that contains a medicinal ingredient not previously approved in a [new] drug by the Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph."

[55] Based on this reading, Drug 2 would take on the definition of a “new drug” as set out in Division 8 of the *Regulations*, and therefore would exclude consideration of drugs approved under a DIN or the *Natural Health Products Regulations*.

[56] The Applicant argues that this reading reflects the fact that “innovative drug” is defined in Division 8 of the *Regulations*, the Division that only applies to “new drugs” and the fact that only “new drugs” fall within the scope of products eligible for data protection. The Applicant states that this interpretation reflects the overall context and is consistent with the grammatical and ordinary meaning of subsection C.08.004.1(1).

[57] The Applicant states that the Respondent’s position is incorrect as it creates an illogical result: “drugs” that were never eligible for data protection and approved without substantial evidence of safety and efficacy could prevent a “new drug” from obtaining the benefit of data protection. According to the Applicant, this is against the presumption of coherence as it would give the term drug two different meanings in the definition of “innovative drug” and is inconsistent with a plain reading and the context of the provision.

[58] The Applicant also states that the Respondent’s position violates the presumption of absurdity as it would result in histamine products that were approved by way of a DIN and therefore not required to submit extensive clinical data, to bar a “new drug”, with such data, from data protection.

(4) The Respondent's Position

[59] The Respondent advocates that the definition be read as such (the Respondent's Definition):

> "innovative drug" means a [new] drug that contains a medicinal ingredient not previously approved in a [any] drug by the Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph."

[60] Based on this reading, Drug 2 takes on the definition as set out in section 2 of the *Act*, and includes all products approved through a DIN or an approval process under the *Natural Health Products Regulations*. The Respondent argues that this interpretation complies with the plain and ordinary reading of the regulation, and that all "drugs" must be considered in the assessment of eligibility for data protection.

[61] The Respondent argues that as a drug that obtains a DIN is an "approved" drug and will be refused if, *inter alia*, the drug is believed to be unsafe or ineffective for its intended purpose, then a plain and ordinary reading of the provision would include products captured under the definition "drug" in Drug 2.

V. Analysis

[62] While the Applicant's interpretation and arguments are compelling, in the end they must fail. Drug 1 is to be interpreted as "new drug" and Drug 2 is to be interpreted as any "drug", as set out in section 2 of the *Act*.

[63] The Applicant's position is based on the argument that the data protection regulations are to protect the extensive clinical data performed to gain approval for a "new drug". However, as set out in the relevant NAFTA and TRIPS provisions, the *Regulations* are to protect "new chemical entities". Not all "new drugs" are "new chemical entities".

[64] A new drug is defined in C.08.001 as a drug that contains a substance, combination of substances, or use which has not been sold in Canada for sufficient time and in sufficient quantity to establish in Canada the safety and effectiveness of that substance, combination, proportion, use or condition of use for use as a drug:

For the purposes of the Act and this Division, "new drug" means	Pour l'application de la Loi et du présent titre, « drogue nouvelle » désigne :
(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	a) une drogue qui est constituée d'une substance ou renferme une substance, sous forme d'ingrédient actif ou inerte, de véhicule, d'enrobage, d'excipient, de solvant ou de tout autre constituant, laquelle substance n'a pas été vendue comme drogue au Canada pendant assez longtemps et en

that substance for use as a drug;	quantité suffisante pour établir, au Canada, l'innocuité et l'efficacité de ladite substance employée comme drogue;
(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	b) une drogue qui entre dans une association de deux drogues ou plus, avec ou sans autre ingrédient, qui n'a pas été vendue dans cette association particulière, ou dans les proportions de ladite association pour ces drogues particulières, pendant assez longtemps et en quantité suffisante pour établir, au Canada, l'innocuité et l'efficacité de cette association ou de ces proportions employées comme drogue; ou
(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 of 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.	c) une drogue pour laquelle le fabricant prescrit, recommande, propose ou déclare un usage comme drogue ou un mode d'emploi comme drogue, y compris la posologie, la voie d'administration et la durée d'action, et qui n'a pas été vendue pour cet usage ou selon ce mode d'emploi au Canada pendant assez longtemps et en quantité suffisante pour établir, au Canada, l'innocuité et l'efficacité de cet usage ou de ce mode d'emploi pour ladite drogue.

[65] I agree that the purpose of the regulation is to protect the extensive clinical data created by innovators. However, the protection is not for all drugs, but for “new chemical entities”. A drug that

has been approved by the DIN process or the process under the *Natural Health Products Regulations* cannot be said to be a “new chemical entity” that has not been approved.

[66] Therefore, prior to considering if the material filed is new confidential data, the Minister must consider if the data is with regard to a “new chemical entity”. If this is established in the positive, then the Minister must then consider if the data is undisclosed test or other data necessary to determine the safety and effectiveness of a pharmaceutical or agricultural product.

A. *Presumption of Coherence and Against Absurdity*

[67] The Applicant argues that to interpret Drug 1 narrowly as “new drug”, and broadly for Drug 2, to mean “any drug”, is incoherent.

[68] In *Bell ExpressVu Limited Partnership v. Rex*, [2002] 2 S.C.R. 559; 2002 SCC 42 at paragraph 27, the Supreme Court has described the doctrine of coherence as such:

> 27 The preferred approach recognizes the important role that context must inevitably play when a court construes the written words of a statute: as Professor John Willis incisively noted in his seminal article "Statute Interpretation in a Nutshell" (1938), 16 Can. Bar Rev. 1, at p. 6, "words, like [page581] people, take their colour from their surroundings". This being the case, where the provision under consideration is found in an Act that is itself a component of a larger statutory scheme, the surroundings that colour the words and the scheme of the Act are more expansive. In such an instance, the application of Driedger's principle gives rise to what was described in R. v. Ulybel Enterprises Ltd., [2001] 2 S.C.R. 867, 2001 SCC 56, at para. 52, as "the principle of interpretation that presumes a harmony, coherence, and consistency between statutes dealing with the same subject matter". (See also Stoddard v. Watson, [1993] 2

> S.C.R. 1069, at p. 1079; Pointe-Claire (City) v. Quebec (Labour Court), [1997] 1 S.C.R. 1015, at para. 61, per Lamer C.J.)

[69] Based on this statement on the doctrine of coherence, the issue is that the interpretation of the regulation be coherent with "statutes dealing with the same subject matter". Interpreting the regulations in the manner set out by the Respondent ensure that the regulation is not incoherent with the other statues dealing with the same subject matter, namely the definition of "new drug" and subsection 30(3) of the *Act*. While interpreting Drug 1 and Drug 2 in a different manner within the same regulation is not desirable, the result is more coherent and consistent with the other statutes and regulations dealing with the same subject matter than the case of interpreting the two references to drugs as meaning the same thing, either "any drug" or "new drug".

[70] The Applicant also argues that the interpretation advanced by the Respondent violates the presumption against absurdity. It is their position that it is absurd that "drugs" approved by DIN submissions or product license application alone, on the basis of minimal data requirements, may prevent "new drugs" approved by NDS, on the basis of new and significant data, from being eligible for data protection.

[71] This interpretation is not absurd. The interpretation mirrors the fact, as set out in the *Act* and *Regulations*, that there are different classifications of drugs. Relevant for this matter, there are "drugs", "new drugs", and "innovative drugs".

[72] At its core, the Applicant's argument is that it is absurd that a "drug" approved by the process of a DIN submission, without substantial data and pivotal trial data, can prevent a "new drug", with substantial data, from data protection. However, when it is remembered that data protection is to protect "new chemical entities", the outcome is not absurd.

B. *Previous Decision in Bayer*

[73] According to the Applicant, their position is more in line with the interpretation of the former data protection regulations as set out by Justice John Evans for the Federal Court and Justice Marshall Rothstein for the Court of Appeal in *Bayer*, above. In that matter, Justice Evans, as later affirmed by the Court of Appeal, held that reading the words "human" into the regulation was proper so that a drug that was marketed for animals could not block data protection for the same drug to be marketed for humans. Justice Evans wrote that the Minister's position was literal and a-contextual and that adding the word "human" was more consistent with the overall statutory approach.

[74] However, I do not see my reasons as being inconsistent. First, the "drugs" that are cited by the Minister are for human use. Second, the NOC scheme sets out three different categories of "new drugs": (a) a new substance, (b) a new combination, and (c) a new use. Therefore, the scheme itself already categorizes "new drugs". Subsection 30(3) of the Act authorizes the implementation of the relevant articles from NAFTA and TRIPS, which the RIAS explains are meant to protect the data of

products utilizing “new chemical entities”, clearly addressing category (a) of “new drugs”. Therefore, this interpretation fits with the approach set out by Parliament.

C. *Issue of Approval by the Minister*

[75] The Applicant argues that the phrase “not previously approved in a drug by the Minister” in subsection C.08.004.1(1) can only be understood as a reference to a “new drug” as “drugs” approved under a DIN are approved by the Director (see C.01.014.2(1) of the *Regulations*), while “new drugs” are approved by the Minister (see C.08.004(1) of the *Regulations*).

[76] The Respondent argues that in respect of most functions, legislated references to a Minister are to be read as though referring to an appropriate official (*Comeau's Sea Foods Ltd. v. Canada (Minister of Fisheries and Oceans)*, [1997] 1 S.C.R. 12, [1997] S.C.J. No. 5; *Interpretation Act*, above, subsection 24(2)).

[77] I agree with the Respondent. The provision can be read that the approval may be conducted by the responsible official. Therefore, in this case, the use of the terms “Minister” and “Director” in the two regulatory provisions is not material to the outcome of this matter.

[78] In this case, the medicinal ingredient in CEPLENE is histamine dihydrochloride. Histamine dihydrochloride is an old ingredient and therefore CEPLENE falls under the definition of a “new drug” in subsection (c), a new use but not a new substance or chemical entity. There are several

products with this medicinal ingredient, or a variation thereof, which have been approved for sale in Canada under either the DIN process or the *Natural Health Products Regulations*.

JUDGMENT

THIS COURT ORDERS AND ADJUDGES that this application is dismissed. Counsel for the Applicant, Respondent and Intervener in this matter all agreed that given that these specific regulatory provisions have not been previously considered by the Court that there should be no Order as to costs. I agree with this position and as such there will be no order as to costs.

" D. G. Near "
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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