Federal Court  Cour fédérale

Date: 20120206

Docket: T-148-11

Citation: 2012 FC 154

Ottawa, Ontario, February 6, 2012

PRESENT: The Honourable Mr. Justice de Montigny

BETWEEN:

CELGENE INC.

Applicant

and

THE MINISTER OF HEALTH

Respondent

REASONS FOR JUDGMENT AND JUDGMENT

[1] This is an application for judicial review of the decision of the Minister of Health, through the Office of the Patented Medicines and Liaison ("OPML"), whereby the Minister refused to register the Applicant's drug THALOMID on the Register of Innovative Drugs. That decision was taken on the basis that the medicinal ingredient in the drug, thalidomide, is not "innovative", contrary to subsection C.08.004.1(1) of the *Food and Drug Regulations*, CRC c 870 (the "*Regulations*"). Relevant portions of the *Regulations* are reproduced in the Annex.

[2] The Applicant, Celgene Inc., argues for its part that its drug THALOMID should be considered as an "innovative drug" despite thalidomide having been previously approved by Health Canada in 1960 and 1961. The Applicant essentially submits that the prior approvals 1) were made pursuant to an earlier version of the *Regulations* which only required safety considerations and not efficacy considerations, in contrast to the current requirements, and 2) became null and void when Health Canada withdrew thalidomide's approval for safety reasons in 1962.

[3] In essence, therefore, the Court is called upon to determine the correct interpretation of the words "previously approved" in the definition of "innovative drug" found in the Data Protection Regulations ("DPR") contained in the *Regulations*.

1. Factual Background

[4] The drug thalidomide was launched commercially by a German pharmaceutical company in October 1957. It was promoted as completely safe and was used for sleeplessness, minor ailments and was also given to thousands of pregnant women for morning sickness. In Canada, W.M.S. Merrell Company received approval for thalidomide under the brand name KEVADON on November 22, 1960 and Frank W. Homer Limited received approval for the same drug under the brand name TALIMOL on October 11, 1961.

[5] By 1959, the medical community had begun to detect a possible connection between long-term thalidomide use and polyneuritis (numbness and tingling in the hands and feet). By 1961, physicians had begun to link thalidomide with serious birth defects and deaths. In 1961 and 1962, thalidomide was dramatically withdrawn from the market worldwide because of its teratogenicity,

or capability of producing foetal malformation. Thousands of babies were born worldwide with phocomelia and other horrific conditions. Many were stillborn or died soon after birth. In Canada, the Food and Drug Directorate of the Department of Health ordered first the temporary withdrawal of KEVADON and TALIMOL in March 1962, and then its permanent withdrawal from the Canadian market one month later.

[6] The withdrawal letters sent to the manufacturers by the Department of Health stated in part:

> The acceptance of the new drug submission received by you on October 11, 1961 [November 22, 1960] is withdrawn in view of the recent evidence that raises a strong suspicion that thalidomide has a very undesirable action on the human foetus.
>
> With the withdrawal of this acceptance, thalidomide returns to the status of a new drug and must not be sold except to qualified investigators for the purpose of obtaining scientific and clinical information that could be used to support the safety of its use under conditions to be recommended by the manufacturer. Such sale does not include its sale through pharmacies.
>
> Ex. "D" to the Leshuk Affidavit, A.R., Vol. 1, Tab 28, pp. 259-265.
> Ex. "E" to the Ciesielski Affidavit, A.R. Vol. 3, Tab 67, pp. 973-976

[7] At the time, "new drug" was defined to mean:

> "New drug" means a drug that because of its
> (a) composition,
> (b) method of manufacture,
> (c) dosage, or
> (d) route of administration
> is not generally recognized by persons qualified to evaluate the safety of the drug as safe for the use for which it is proposed or recommended and includes a drug for which a new drug submission has been filed in accordance with section C.01.302 or C.01.304 but the safety of which has not been established by use for a material time or to a material extent.

> Amendment to the provisions of the *Food and Drug Regulations* relating to approval of new drugs, published January 11, 1961, SOR/61-9

[8] Thalidomide was one of two drugs the sale of which was absolutely prohibited, pursuant to the amendments enacted by Bill C-3 on December 20, 1962, which initiated the overhaul of the system for drug approval in Canada in response to the thalidomide tragedy. It remained prohibited for sale in Canada until 1984.

[9] Despite its tragic history, thalidomide was eventually found to be effective in the treatment of leprosy and other conditions, including cancer. In the early 1990s, Celgene Corporation became interested in research into the drug thalidomide and its potential uses in tuberculosis and AIDS. By 1994, Celgene Corporation was exclusively devoted to the commercialization of thalidomide to treat life-threatening diseases, including cancer and a painful condition associated with leprosy (ENL).

[10] In July 1998, the U.S. Food and Drug Administration ("FDA") approved the use of thalidomide, marketed by Celgene Corporation as THALOMID, for the acute treatment of the cutaneous manifestations of moderate to severe ENL. The FDA mandated the strongest possible restricted distribution system to prevent birth defects. Celgene Corporation created the system, known in the U.S. as the "S.T.E.P.S.®" program. In Canada, the controlled distribution system for THALOMID is known as RevAid®. Celgene Corporation developed a medical-regulatory infrastructure for approval of thalidomide that was based on clinical trials in diverse diseases. In May 2006, the FDA approved THALOMID for the treatment of patients with newly diagnosed multiple myeloma (a form of cancer).

[11] In Canada, THALOMID was first made available through Health Canada's Special Access Programme ("SAP") in 1995. This program is designed to provide exceptional access to drugs not approved for sale in Canada and essentially permits the sale of a new drug that could not otherwise be sold in Canada because it does not hold a Notice of Compliance ("NOC"). These sales are exempt from the formal, comprehensive scientific and medical review that is conducted when products are reviewed for full marketing authorization. Health Canada apparently approved the sale of THALOMID through this program in response to requests for leprosy treatment, and for treatment of other immune related conditions associated with AIDS and certain forms of cancer. The Applicant claims that Health Canada expected it to file a new drug submission ("NDS") for the drug, in view of its high profile, the high volume of requests under the SAP, and the fact that approval in the form of an NOC would better ensure safety.

[12] On May 19, 2009, Celgene did file an NDS with the Minister of Health seeking market approval for 50 mg, 100 mg, 150 mg and 200 mg strength thalidomide capsules in Canada under the trade name THALOMID, for use in the treatment of multiple myeloma. The NOC was issued on August 4, 2010.

[13] However, the Minister advised Celgene on that same date that THALOMID was not eligible for data protection because the medicinal ingredient, thalidomide, had been previously approved by the Minister in at least two drugs, KEVADON in 1960 and TALIMOL in 1961. The Minister gave Celgene thirty days in which to file written submissions on the issue.

[14] By letter dated December 6, 2010, Celgene filed written representations with the Minister. Celgene took the position that thalidomide should not be considered as having been previously approved within the meaning of C.08.004.1 of the *Regulations*. Celgene also argued that THALOMID should be added to the Register because the NDS contains new, significant and independent data.

[15] In the final decision letter dated January 5, 2011, the Minister wrote to Celgene and confirmed the decision that because thalidomide was previously approved as a drug, THALOMID was not eligible to be added to the Register of Innovative Drugs.

2. The Regulatory Framework

[16] The Minister of Health is responsible for the review of drugs in Canada under the relevant provisions of the *Food and Drugs Act*, RSC 1985, c F-27, and associated regulations. The *Food and Drugs Act* was first introduced in Canada in 1920, and by the late 1920s, the regulations were developed that established licensing requirements for drugs and gave the Minister authority to cancel or suspend a licence.

[17] Under the current regime, manufacturers who wish to advertise or sell a new drug in Canada must first obtain an NOC pursuant to Part C, Division 8 of the *Regulations*, by filing an NDS. An NDS is typically filed by an innovative drug manufacturer pursuant to section C.08.002 of the *Regulations* and usually contains voluminous clinical trial data and detailed studies. This data forms the basis on which the drug is approved for sale.

[18] An abbreviated new drug submission ("ANDS") is available under section C.08.002.1 to generic drug manufacturers who wish to copy a marketed drug without having to provide clinical data demonstrating safety and efficacy. The manufacturer must show instead that the generic drug is bioequivalent to a Canadian reference product, based on pharmaceutical and, where necessary, bioavailability characteristics.

[19] Demonstrating bioequivalence by a comparison to a Canadian reference product permits a generic drug manufacturer to establish the safety and efficacy of its product without making a direct assessment on the basis of clinical studies. In doing so, the generic drug manufacturer is relying on the information established about the Canadian reference product, as filed in the NDS by the brand name drug manufacturer, which provides the primary knowledge about the safety and efficacy of the drug and its conditions of use.

[20] There is another aspect, though, of the legislated framework within which drugs are regulated. Prior to the enactment in 1995 of the DPR found in the *Regulations*, the only obstacle to a generic drug manufacturer's ability to obtain approval of the right to market a generic drug was the existence of an unexpired patent. With the enactment of the DPR, the current version of which came into force on October 5, 2006, a generic drug manufacturer may not file a submission on the basis of a comparison to an "innovative drug" within the first six years of the eight-year period after the drug has received an NOC. In addition, the Minister may not issue an NOC to the generic drug manufacturer before the end of the eight-year period. It is these prohibitions that result in what is known as "data protection".

[21] These provisions, found in section C.08.004.1 of the *Regulations*, came into force on October 5, 2006 and were adopted pursuant to section 30(3) of the *Food and Drugs Act*, as amended. As specified in subsection C.08.004.1(2), these provisions are meant to implement Article 1711 of the *North American Free Trade Agreement* ("NAFTA") and paragraph 3 of Article 39 of the *Trade Related Aspects of Intellectual Property Rights Agreement* ("TRIPS"). Under these commitments, where a person submits undisclosed data for approval of a pharmaceutical product, and the product utilizes a new chemical entity, signatories are required to take steps to prevent other persons from making "unfair commercial use" of the data, and from relying on the data in their own applications for approval, for a reasonable period of time.

[22] The administration of the data protection provisions by the OPML is outlined in Health Canada's guidance document entitled *Data Protection under C.08.004.1 of the Food and Drug Regulations*. For the purpose of determining whether the submission filed by a generic drug manufacturer is based, directly or indirectly, on a comparison to an "innovative drug", the OPML must first consider whether the medicinal ingredient was previously approved in a drug by the Minister. This follows from the definition of an "innovative drug" in subsection C.08.004.1(1) as "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". As previously mentioned at the outset, the interpretation of this definition, and more particularly of the words "previously approved", is the nub of the present application for judicial review.

[23] The NDS that was filed for THALOMID comprised 180 volumes of data, including pharmacology and pharmacokinetic studies, toxicology studies (including toxicity, carcinogenicity and reproductive/development toxicity studies), clinical pharmacology studies and pivotal clinical trials. All of this data is claimed by Celgene to be highly sensitive proprietary and confidential information that was submitted to Health Canada in confidence, and which is maintained strictly confidential by Celgene. This is why Celgene has requested the OPML to list THALOMID on the Register of Innovative Drugs.

3. Issue

[24] The only issue in this application for judicial review is the proper interpretation to be given to the words "innovative drug" as defined in subsection C.08.004.1(1) of the *Regulations*. In determining that issue, the Court must decide whether the Minister's approval of thalidomide in 1960 and 1961 constituted an approval within the meaning of "approved" in the definition of "innovative drug". The Court is also called upon to decide whether the withdrawal of approval of thalidomide for safety reasons has the legal effect of nullifying the Minister's approval, such that the initial approval is void *ab initio*, thereby giving thalidomide the status of a new medicinal ingredient.

4. Analysis

[25] Both parties are in agreement that the issue is reviewable on a standard of correctness. The Minister's interpretation of the definition of an "innovative drug" is a pure question of law, on which the Minister has no specialized expertise. The Minister's primary expertise is in the evaluation of scientific evidence, not in the interpretation of legal provisions. In any event, this

Court has previously applied the correctness standard on at least two occasions relating to the interpretation of the definition of "innovative drug" in the DPR (see *Epicept Corporation v Canada (Minister of Health)*, 2010 FC 956 at paras 39-40, 377 FTR 29 [*Epicept Corporation*]; *Teva Canada Limited v The Minister of Health et al.*, 2011 FC 507 at para 35, 95 CPR (4d) 423 [*Teva Canada Limited*]). See also: *Bristol-Myers Squibb Co. v Canada (Attorney General)*, 2005 SCC 26 at para 36, [2005] 1 SCR 533 [*Bristol-Myers Squibb Co.*].

[26] It is trite law that the words of an Act must 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 (*Trustco Mortgage Co. v Canada*, 2005 SCC 54 at para 10, [2005] 2 SCR 601; *Interpretation Act*, RSC 1985, c I-12, s 12).

[27] When interpreting regulations it is essential to read the words in the whole context of the authorizing statute, which necessarily constrains the scope of the regulation (*Bristol-Myers Squibb Co.*, above at para 38).

[28] A contextual and purposive interpretation furthermore requires close examination of Canada's international obligations. More specifically, where domestic legislation implements an international treaty, the treaty is considered a primary aid to construction, even where there is no ambiguity (Pierre-André Côté, *The Interpretation of Legislation in Canada*, 3rd ed. (Toronto:

Thomson Canada Limited, 2000) at p 368, citing *National Corn Growers et al. v Canada (Import Tribunal)*, [1990] 2 SCR 1324 at p 1371).

[29] Counsel for the Applicant first argued that the Minister failed to apply a purposive interpretation of the DPR which, it was submitted, is to encourage and reward innovation by protecting the data an innovator must generate to obtain approval for a drug. I fully agree with that argument.

[30] It is beyond dispute that the DPR was enacted pursuant to subsection 30(3) of the *Food and Drugs Act*, which enables the Governor in Council to implement Canada's international obligations under Article 1711(5) and (6) of NAFTA and Article 39(3) of TRIPS. These provisions read as follows:

Food and Drugs Act	*Loi sur les aliments et drogues*
Regulations re the North American Free Trade Agreement and WTO Agreement	Règlements relatifs à l'Accord de libre-échange nord-américain et à l'Accord sur l'OMC
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) 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

3 of Article 39 of the Agreement on Trade-related Aspects of Intellectual Property Rights set out in Annex 1C to the WTO Agreement.

propriété intellectuelle qui touchent au commerce figurant à l'annexe 1C de l'Accord sur l'OMC.

NAFTA

1711. (5) If a Party requires, as a condition for approving the marketing of pharmaceutical or agricultural chemical products that utilize new chemical 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.

(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

ALÉNA

1711. (5) Lorsqu'une Partie subordonne l'approbation de la commercialisation de produits pharmaceutiques ou de produits chimiques pour l'agriculture qui 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) 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

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, there shall be no limitation on any Party to implement abbreviated approval procedures for such products on the basis of bioequivalence and bioavailability studies.

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 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.

Trade Related Aspects of Intellectual Property Rights Agreement

Accord sur les droits de propriété qui touchent au commerce

Section 7: Protection of Undisclosed Information

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

Section 7: Protection des renseignements non divulgués

Article 39

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,

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.	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.

[31] Article 1711 of the NAFTA and Article 39(3) of TRIPS "seek to provide protection to innovators in respect of 'undisclosed tests or other data' that they must provide to government entities in order to obtain approval for their new drugs" (*Apotex Inc v Canada (Minister of Health)*, 2010 FCA 334 at para 110, 413 NR 89 [*Apotex Inc.*]). Both treaties "…provide a scheme for protecting against the unfair commercial use of undisclosed data, the origination of which involved considerable effort" (*Epicept Corporation*, above at para 21).

[32] Counsel for the Respondent retorts that these provisions explicitly concern only those products that use "new chemical entities", and are therefore intended to protect only against unfair commercial use of data relating to new substances. Furthermore, it is argued that the language of subsection of C.08.004.1(1) implements that intention by using the term "innovative drug", as well as by limiting that term to include only medicinal ingredients in drugs that have not been previously approved. According to that reasoning, therefore, the intent of the data protection provisions is to reserve the special market exclusivity period for genuinely new and innovative medicinal ingredients, and not simply new uses of ingredients that have been previously approved for a different use.

[33] There are a number of flaws with respect to that construction of the DPR. First of all, thalidomide was not approved for any use prior to the issuance of the NOC. Indeed, it was included in Schedule "H" and then "F" of the Act and was therefore totally banned in Canada. This is not a case, therefore, where the data was collected for the different use of a drug already approved. The purpose of the DPR in requiring that the drug not be previously approved is to ensure a company is not granted data protection for something in previous use and for which no innovation was required. This is made clear by the exclusion from the scope of data protection, in the definition of "innovative drugs", of variations or minor changes to a drug previously approved such as salts, esters, solvates, polymorphs or enantiomers. The Regulatory Impact Analysis Statement explicitly states that these exclusions are aimed at preventing an innovator from seeking additional data protection for a minor change to a drug.

[34] The Guidance Document on Data Protection under C.08.004.1 of the *Regulations*, already referred to, mentions that variations other than those referred to in the definition of "innovative drugs" will be assessed on a case-by-case basis. It adds (at p. 3):

> 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 data. New and significant data is characterized as those clinical trials which provide the evidence to determine the efficacy, properties and conditions of use of the drug (eg. pivotal trials).

[35] In the case at bar, Celgene's innovation was to take something that was banned as dangerous and which had not been found to be safe and efficacious and to show it to be a useful, lifesaving drug. To do so, Celgene did not and could not rely on old data, but had to produce the very data that

had not ever been produced previously and which was required to obtain an NOC. In an uncontradicted affidavit, the Senior Director of Pharmacovigilence & Regulatory Affairs at Celgene Inc. testified that 108 volumes of data were filed with the NDS in seeking approval for THALOMID.

[36] Moreover, the purpose of the DPR is clearly to encourage and reward innovation by protecting the data an innovator must generate to obtain approval for a drug. Interpreting the DPR as proposed by Celgene is therefore completely in keeping with its purpose. While the relevant treaty provisions obligate member countries to confer the protection for pharmaceutical or agricultural products which utilize "new chemical entities", this notion is nowhere to be found in the DPR. Moreover, the focus in the treaties is clearly on the protection of "undisclosed data, the origination of which involved a considerable effort". I agree with the Applicant that to make TRIPS and NAFTA obligations meaningful, the protection must arise when approval is sought for a product containing a chemical entity that does not have approval in a drug in a particular jurisdiction. Just as a member country could not avoid the obligation to accord protection to the data filed to obtain approval in their jurisdiction because the chemical entity in the product has been approved elsewhere or is otherwise known, it would similarly be inconsistent with these treaties to refuse data protection when a chemical entity is put to an entirely new use, on the basis of extensive and genuinely new data ensuring its effectiveness and safety. In the same way as variations of a drug not included in the definition of innovative drug, new uses of previously approved ingredients must be considered on a case-by-case basis to determine how innovative they are and whether the data supporting them was "gathered at considerable cost which is not otherwise publicly available in that assembled form" (see *Canadian Generic Pharmaceutical Association v Canada (Minister of*

Health), 2009 FC 725 at paras 120-123, 348 FTR 29 rev'd on other grounds in *Apotex Inc.*, above at para 77).

[37] This finding bears some resemblance and is consistent with the decision of Mr. Justice Evans (as he then was) in *Bayer Inc. v Canada (Attorney General)*, [1999] 1 FC 553; conf'd (1999) 87 CPR (3d) 293). In that case, the Court had to decide, *inter alia*, whether the fact that a drug contained a chemical or biological substance found in a drug previously approved for sale in connection with an animal disease excluded it from the scope of s. C.08.004.1. As in the present case, that section only applied in respect of "a drug that contains a chemical or biological substance not previously approved for sale in Canada as a drug…" Mr. Justice Evans found that it was more consistent with the overall purposes of the statutory scheme to read in the word "human" to qualify "drug"; in other words, he found the relevant inquiry when material is filed by the innovator of a drug intended for human use was to ask whether it contains a substance that had previously been approved for sale for human use.

[38] In coming to that conclusion, Mr. Justice Evans agreed that the fact that a drug contains a substance that had been approved for use in connection with animals, had no bearing on whether it should be regarded as previously approved for sale so that it may safely be used in connection with humans. It seems to me that the same can be said of a drug that has been approved in connection with some specific uses: it cannot be inferred that this same drug can also be safely sold in connection with completely different uses, especially when its originally approved use has subsequently been banned for safety reasons.

[39] Counsel for the Applicant also raised a more technical argument, revolving around the exact meaning of the words “previously approved”. Celgene argues, essentially, that a medicinal ingredient cannot be “previously approved” where approval was revoked. In other words, Celgene contends that in withdrawing the approval of the drug submissions for thalidomide in 1962, this medicinal ingredient reverted to the status of a “new drug”, wiping the slate clean such that thalidomide now qualifies as an innovative drug.

[40] Counsel for the Respondent opposes that interpretation, arguing that withdrawing an approval or taking it back is not the same as nullifying it *ab initio*. Indeed, counsel submits that the Minister did not have the power to render the approval void *ab initio*, and that courts may only nullify executive acts in those limited cases where the executive lacked jurisdiction.

[41] I do not think it necessary to determine, for the purposes of this application for judicial review, whether the withdrawal from the market of KEVADON and TALIMOL amounted to the nullification of Health Canada’s prior approvals of thalidomide. The fact of the matter is that thalidomide was determined to be unsafe and returned to the status of a new drug. From April 6, 1962, a generic manufacturer could not submit an ANDS for approval of a generic version of thalidomide by referencing KEVADON AND TALIMOL because both drugs had reverted to a new drug status.

[42] It is equally clear that safety and effectiveness are the main considerations with respect to a drug approved for public use. This is indeed the position that was taken by the Minister in *Teva Canada Limited*, above at para 21. Would it then be fair to say that a drug, the approval of which

has been withdrawn for safety reasons, should nevertheless be considered as having been previously approved? In my view, such a finding would be entirely perverse. It is apparent that the approvals should never have been granted in view of the absence of data relating to the severe deleterious effects of the drug. This is precisely why KEVADON and TALIMOL could not be considered as "Canadian reference products" for the purpose of an ANDS. Even if these products were not voided but only withdrawn from sale, it remains that Canadians could not benefit from the discovery and development of thalidomide unless and until new medicines could be approved on the basis of new information and data demonstrating their safety and efficacy. It is to encourage the research and development of these new medicines that the DPR was enacted, so as to provide an eight-year period of market exclusivity to innovative manufacturers. This generated extensive data to ensure that a product is both safe and effective for its intended use.

[43] One last point need be made. Celgene also argues that the term "approved" in the definition of "innovative drug" should be construed as limited to approvals made pursuant to the current regulatory regime for drug approvals or earlier regimes that required both safety and efficacy considerations in the approval process. Celgene argues that the 1963 version of the *Regulations* marks the bright line between prior schemes of drug approval that are comparable to the present system, the distinguishing point being the addition of efficacy as a consideration.

[44] The Minister's prior approvals of thalidomide were made pursuant to the 1955 version of the *Regulations*. Section C.01.301 sets out the content of the submissions to be filed by a person wishing to sell a new drug, which included "detailed reports of tests made to establish the safety of the drug for the purpose and under the conditions of use recommended". There is no disagreement

between the parties that the regulatory regime in Canada was substantially overhauled as a result of the thalidomide tragedy, in order to improve safety requirements and, for the first time, to require evidence of efficacy.

[45] The Minister is no doubt correct that, generally speaking, the ministerial approval to which a legislative or regulatory provision refers, need not have been made under the current version of that provision. Since there is nothing in the definition of "innovative drug" to suggest that an approval made under an earlier version of the *Regulations* cannot come within the meaning of "approved", all that matters should therefore be that the Minister approved the drug, based on the requirements of the regulatory framework in effect at the time of the determination.

[46] It is not entirely clear, however, how far this rule should apply when prior approval has been given pursuant to a scheme that has been substantively and significantly modified over the years. Be that as it may, I am of the view that it is, at the very least, an argument reinforcing the conclusion that prior approvals of KEVADON and TALIMOL should not stand in the way of data protection for a later approved product. Submissions filed post-1963 necessarily include new and more extensive data, including data relating to efficacy, as compared to data filed in a pre-1963 submission. This, combined with the fact that 1) prior approval for thalidomide was short-lived and should never have been given at the time, 2) this new drug was effectively banned until Celgene came up with its NDS for THALOMID, and 3) approval was granted for Celgene's product on the basis of completely new studies and data, militate in favour of a declaration that THALOMID is an "innovative drug" and eligible for listing on the Register maintained pursuant to the DPR.

[47] This case is obviously quite an exceptional one. Not only are there most likely very few instances of approvals for NDS that have subsequently been withdrawn, but thalidomide has a tragic and checkered history, the likes of which are, thankfully, very rare. It is therefore to be assumed that the present decision will have a limited impact in the foreseeable future.

[48] For all of the foregoing reasons, this application for judicial review is granted, with costs to the Applicant.

JUDGMENT

THIS COURT'S JUDGMENT is that the application for judicial review is granted, with costs to the Applicant. The decision of the Minister not to add THALOMID to the Register of Innovative Drugs is therefore quashed and set aside. It is further declared that THALOMID is an "innovative drug" and eligible for listing on the Register maintained pursuant to the Data Protection Regulations as of the date of issuance of the Notice of Compliance for THALOMID, namely August 4, 2010.

"Yves de Montigny"
Judge

Annex

Food and Drug Regulations (C.R.C., c. 870)	*Règlement sur les aliments et drogues* (C.R.C., ch. 870)
New Drugs	Drogues nouvelles
C.08.001. For the purposes of the Act and this Division, "new drug" means	**C.08.001**. 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 that substance for use as a drug;	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 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.

C.08.001.1. For the purposes of this Division,

C.08.001.1. Les définitions qui suivent s'appliquent au présent titre.

"Canadian reference product" means

« équivalent pharmaceutique » S'entend d'une drogue nouvelle qui, par comparaison à une autre drogue, contient les mêmes quantités d'ingrédients médicinaux identiques, sous des formes posologiques comparables, mais pas nécessairement les mêmes ingrédients non médicinaux. (pharmaceutical equivalent)

« produit de référence canadien » Selon le cas :

(a) a drug in respect of which a notice of compliance is issued under section C.08.004 or C.08.004.01 and which is marketed in Canada by the innovator of the drug,

a) une drogue à l'égard de laquelle un avis de conformité a été délivré en application des articles C.08.004 ou C.08.004.01 et qui est commercialisée au Canada par son innovateur;

(b) a drug, acceptable to the Minister, that can be used for the purpose of demonstrating bioequivalence on the basis of pharmaceutical and, where applicable, bioavailability characteristics, where a drug in respect of which a notice of compliance has been issued under section C.08.004 or C.08.004.01 cannot be used for that purpose because it is no longer marketed in Canada, or

b) une drogue jugée acceptable par le ministre et qui peut être utilisée pour la détermination de la bioéquivalence d'après les caractéristiques pharmaceutiques et, le cas échéant, les caractéristiques en matière de biodisponibilité, lorsqu'une drogue pour laquelle un avis de conformité a été délivré en application des articles C.08.004 ou C.08.004.01 ne peut être utilisée à cette fin parce qu'elle n'est plus commercialisée au Canada;

(c) a drug, acceptable to the Minister, that can be used for the purpose of demonstrating bioequivalence on the basis of pharmaceutical and, where applicable, bioavailability characteristics, in comparison to a drug referred to in paragraph (a); (*produit de référence canadien*)

c) une drogue jugée acceptable par le ministre qui peut être utilisée pour la détermination de la bioéquivalence d'après les caractéristiques pharmaceutiques et, le cas échéant, les caractéristiques en matière de biodisponibilité, par comparaison à une drogue visée à l'alinéa a). (*Canadian reference product*)

"pharmaceutical equivalent" means a new drug that, in comparison with another drug,

« spécifications » S'entend de la description détaillée d'une drogue nouvelle et de ses

contains identical amounts of the identical medicinal ingredients, in comparable dosage forms, but that does not necessarily contain the same non-medicinal ingredients; *(équivalent pharmaceutique*)

ingrédients, notamment :

"specifications" means a detailed description of a new drug and of its ingredients and includes

(a) a statement of all properties and qualities of the ingredients that are relevant to the manufacture and use of the new drug, including the identity, potency and purity of the ingredients,

a) la liste des propriétés et des qualités des ingrédients qui ont trait à la fabrication et à l'emploi de la drogue nouvelle, y compris leur identité, leur activité et leur pureté;

(b) a detailed description of the methods used for testing and examining the ingredients, and

b) la description détaillée des méthodes d'analyse et d'examen des ingrédients;

(c) a statement of the tolerances associated with the properties and qualities of the ingredients. (*spécifications*)

c) la liste des tolérances relatives aux propriétés et aux qualités des ingrédients. (*specifications*)

C.08.002. (1) No person shall sell or advertise a new drug unless

C.08.002. (1) Il est interdit de vendre ou d'annoncer une drogue nouvelle, à moins que les conditions suivantes ne soient réunies :

(a) the manufacturer of the new drug has filed with the Minister a new drug submission, an extraordinary use new drug submission, an abbreviated new drug submission or an abbreviated extraordinary use new drug submission relating to the new drug that is satisfactory to the Minister;

a) le fabricant de la drogue nouvelle a, relativement à celle-ci, déposé auprès du ministre une présentation de drogue nouvelle, une présentation de drogue nouvelle pour usage exceptionnel, une présentation abrégée de drogue nouvelle ou une présentation abrégée de drogue nouvelle pour usage exceptionnel que celui-ci juge acceptable;

(b) the Minister has issued, under section C.08.004 or C.08.004.01, a notice of compliance to the manufacturer of the new drug in respect of the submission;

b) le ministre a délivré au fabricant de la drogue nouvelle, en application des articles C.08.004 ou C.08.004.01, un avis de conformité relativement à la présentation;

(c) the notice of compliance in respect of the submission has not been suspended pursuant

c) l'avis de conformité relatif à la présentation n'a pas été suspendu aux termes

to section C.08.006; and

(d) the manufacturer of the new drug has submitted to the Minister specimens of the final version of any labels, including package inserts, product brochures and file cards, intended for use in connection with that new drug, and a statement setting out the proposed date on which those labels will first be used.

(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:

(a) a description of the new drug and a statement of its proper name or its common name if there is no proper name;

(b) a statement of the brand name of the new drug or the identifying name or code proposed for the new drug;

(c) a list of the ingredients of the new drug, stated quantitatively, and the specifications for each of those ingredients;

(d) a description of the plant and equipment to be used in the manufacture, preparation and packaging of the new drug;

(e) details of the method of manufacture and the controls to be used in the manufacture, preparation and packaging of the new drug;

(f) details of the tests to be applied to control the potency, purity, stability and safety of the new drug;

(g) detailed reports of the tests made to

de l’article C.08.006;

d) le fabricant de la drogue nouvelle a présenté au ministre, sous leur forme définitive, des échantillons des étiquettes — y compris toute notice jointe à l’emballage, tout dépliant et toute fiche sur le produit — destinées à être utilisées pour la drogue nouvelle, ainsi qu’une déclaration indiquant la date à laquelle il est prévu de commencer à utiliser ces étiquettes.

(2) La présentation de drogue nouvelle doit contenir suffisamment de renseignements et de matériel pour permettre au ministre d’évaluer l’innocuité et l’efficacité de la drogue nouvelle, notamment :

a) une description de la drogue nouvelle et une mention de son nom propre ou, à défaut, de son nom usuel;

b) une mention de la marque nominative de la drogue nouvelle ou du nom ou code d’identification projeté pour celle-ci;

c) la liste quantitative des ingrédients de la drogue nouvelle et les spécifications relatives à chaque ingrédient;

d) la description des installations et de l’équipement à utiliser pour la fabrication, la préparation et l’emballage de la drogue nouvelle;

e) des précisions sur la méthode de fabrication et les mécanismes de contrôle à appliquer pour la fabrication, la préparation et l’emballage de la drogue nouvelle;

f) le détail des épreuves qui doivent être effectuées pour contrôler l’activité, la pureté, la stabilité et l’innocuité de la drogue nouvelle;

g) les rapports détaillés des épreuves

establish the safety of the new drug for the purpose and under the conditions of use recommended;

effectuées en vue d'établir l'innocuité de la drogue nouvelle, aux fins et selon le mode d'emploi recommandés;

(h) substantial evidence of the clinical effectiveness of the new drug for the purpose and under the conditions of use recommended;

h) des preuves substantielles de l'efficacité clinique de la drogue nouvelle aux fins et selon le mode d'emploi recommandés;

(i) a statement of the names and qualifications of all the investigators to whom the new drug has been sold;

i) la déclaration des noms et titres professionnels de tous les chercheurs à qui la drogue nouvelle a été vendue;

(j) a draft of every label to be used in conjunction with the new drug;

j) une esquisse de chacune des étiquettes qui doivent être employées relativement à la drogue nouvelle;

(k) a statement of all the representations to be made for the promotion of the new drug respecting

k) la déclaration de toutes les recommandations qui doivent être faites dans la réclame pour la drogue nouvelle, au sujet

(i) the recommended route of administration of the new drug,

(i) de la voie d'administration recommandée pour la drogue nouvelle,

(ii) the proposed dosage of the new drug,

(ii) de la posologie proposée pour la drogue nouvelle,

(iii) the claims to be made for the new drug, and

(iii) des propriétés attribuées à la drogue nouvelle,

(iv) the contra-indications and side effects of the new drug;

(iv) des contre-indications et les effets secondaires de la drogue nouvelle;

(l) a description of the dosage form in which it is proposed that the new drug be sold;

l) la description de la forme posologique proposée pour la vente de la drogue nouvelle;

(m) evidence that all test batches of the new drug used in any studies conducted in connection with the submission were manufactured and controlled in a manner that is representative of market production; and

m) les éléments de preuve établissant que les lots d'essai de la drogue nouvelle ayant servi aux études menées dans le cadre de la présentation ont été fabriqués et contrôlés d'une manière représentative de la production destinée au commerce;

(n) for a drug intended for administration to food-producing animals, the withdrawal period of the new drug.

n) dans le cas d’une drogue nouvelle destinée à être administrée à des animaux producteurs de denrées alimentaires, le délai d’attente applicable.

(3) The manufacturer of a new drug shall, at the request of the Minister, provide the Minister, where for the purposes of a new drug submission the Minister considers it necessary to assess the safety and effectiveness of the new drug, with the following information and material:

(3) Le fabricant de la drogue nouvelle doit, à la demande du ministre, lui fournir, selon ce que celui-ci estime nécessaire pour évaluer l’innocuité et l’efficacité de la drogue dans le cadre de la présentation de drogue nouvelle, les renseignements et le matériel suivants :

(a) the names and addresses of the manufacturers of each of the ingredients of the new drug and the names and addresses of the manufacturers of the new drug in the dosage form in which it is proposed that the new drug be sold;

a) les nom et adresse des fabricants de chaque ingrédient de la drogue nouvelle et les nom et adresse des fabricants de la drogue nouvelle sous sa forme posologique proposée pour la vente;

(b) samples of the ingredients of the new drug;

b) des échantillons des ingrédients de la drogue nouvelle;

(c) samples of the new drug in the dosage form in which it is proposed that the new drug be sold; and

c) des échantillons de la drogue nouvelle sous sa forme posologique proposée pour la vente;

(d) any additional information or material respecting the safety and effectiveness of the new drug.

d) tout renseignement ou matériel supplémentaire se rapportant à l’innocuité et à l’efficacité de la drogue nouvelle.

C.08.002.1. (1) A manufacturer of a new drug may file an abbreviated new drug submission or an abbreviated extraordinary use new drug submission for the new drug where, in comparison with a Canadian reference product,

C.08.002.1. (1) Le fabricant d’une drogue nouvelle peut déposer à l’égard de celle-ci une présentation abrégée de drogue nouvelle ou une présentation abrégée de drogue nouvelle pour usage exceptionnel si, par comparaison à un produit de référence canadien :

(a) the new drug is the pharmaceutical equivalent of the Canadian reference product;

a) la drogue nouvelle est un équivalent pharmaceutique du produit de référence canadien;

(b) the new drug is bioequivalent with the Canadian reference product, based on the pharmaceutical and, where the Minister

b) elle est bioéquivalente au produit de référence canadien d’après les caractéristiques pharmaceutiques et, si le

considers it necessary, bioavailability characteristics;

ministre l’estime nécessaire, d’après les caractéristiques en matière de biodisponibilité;

(c) the route of administration of the new drug is the same as that of the Canadian reference product; and

c) la voie d’administration de la drogue nouvelle est identique à celle du produit de référence canadien;

(d) the conditions of use for the new drug fall within the conditions of use for the Canadian reference product.

d) les conditions thérapeutiques relatives à la drogue nouvelle figurent parmi celles qui s’appliquent au produit de référence canadien.

(2) An abbreviated new drug submission or an abbreviated extraordinary use 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:

(2) La présentation abrégée de drogue nouvelle ou la présentation abrégée de drogue nouvelle pour usage exceptionnel doit contenir suffisamment de renseignements et de matériel pour permettre au ministre d’évaluer l’innocuité et l’efficacité de la drogue nouvelle, notamment :

(a) the information and material described in

a) les renseignements et le matériel visés :

(i) paragraphs C.08.002(2)(a) to (f) and (j) to (l), in the case of an abbreviated new drug submission, and

(i) aux alinéas C.08.002(2)a) à f) et j) à l), dans le cas d’une présentation abrégée de drogue nouvelle,

(ii) paragraphs C.08.002(2)(a) to (f) and (j) to (l) and subparagraphs C.08.002.01(2)(b)(ix) and (x), in the case of an abbreviated extraordinary use new drug submission;

(ii) aux alinéas C.08.002(2)a) à f) et j) à l) et aux sous-alinéas C.08.002.01(2)b)(ix) et (x), dans le cas d’une présentation abrégée de drogue nouvelle pour usage exceptionnel;

(b) information identifying the Canadian reference product used in any comparative studies conducted in connection with the submission;

b) les renseignements permettant d’identifier le produit de référence canadien utilisé pour les études comparatives menées dans le cadre de la présentation;

(c) evidence from the comparative studies conducted in connection with the submission that the new drug is

c) les éléments de preuve, provenant des études comparatives menées dans le cadre de la présentation, établissant que la drogue nouvelle :

(i) the pharmaceutical equivalent of the Canadian reference product, and

(i) d’une part, est un équivalent pharmaceutique du produit de référence

canadien,

(ii) where the Minister considers it necessary on the basis of the pharmaceutical and, where applicable, bioavailability characteristics of the new drug, bioequivalent with the Canadian reference product as demonstrated using bioavailability studies, pharmacodynamic studies or clinical studies;

(ii) d'autre part, si le ministre l'estime nécessaire d'après les caractéristiques pharmaceutiques et, le cas échéant, d'après les caractéristiques en matière de biodisponibilité de celle-ci, est bioéquivalente au produit de référence canadien selon les résultats des études en matière de biodisponibilité, des études pharmacodynamiques ou des études cliniques;

(d) evidence that all test batches of the new drug used in any studies conducted in connection with the submission were manufactured and controlled in a manner that is representative of market production; and

d) les éléments de preuve établissant que les lots d'essai de la drogue nouvelle ayant servi aux études menées dans le cadre de la présentation ont été fabriqués et contrôlés d'une manière représentative de la production destinée au commerce;

(e) for a drug intended for administration to food-producing animals, sufficient information to confirm that the withdrawal period is identical to that of the Canadian reference product.

e) dans le cas d'une drogue destinée à être administrée à des animaux producteurs de denrées alimentaires, les renseignements permettant de confirmer que le délai d'attente est identique à celui du produit de référence canadien.

(3) The manufacturer of a new drug shall, at the request of the Minister, provide the Minister, where for the purposes of an abbreviated new drug submission or an abbreviated extraordinary use new drug submission the Minister considers it necessary to assess the safety and effectiveness of the new drug, with the following information and material:

(3) Le fabricant de la drogue nouvelle doit, à la demande du ministre, lui fournir, selon ce que celui-ci estime nécessaire pour évaluer l'innocuité et l'efficacité de la drogue dans le cadre de la présentation abrégée de drogue nouvelle ou de la présentation abrégée de drogue nouvelle pour usage exceptionnel, les renseignements et le matériel suivants :

(a) the names and addresses of the manufacturers of each of the ingredients of the new drug and the names and addresses of the manufacturers of the new drug in the dosage form in which it is proposed that the new drug be sold;

a) les nom et adresse des fabricants de chaque ingrédient de la drogue nouvelle et les nom et adresse des fabricants de la drogue nouvelle sous sa forme posologique proposée pour la vente;

(b) samples of the ingredients of the new drug;

b) des échantillons des ingrédients de la drogue nouvelle;

(c) samples of the new drug in the dosage form in which it is proposed that the new drug be sold; and

c) des échantillons de la drogue nouvelle sous sa forme posologique proposée pour la vente;

(d) any additional information or material respecting the safety and effectiveness of the new drug.

d) tout renseignement ou matériel supplémentaire se rapportant à l'innocuité et à l'efficacité de la drogue nouvelle.

(4) For the purposes of this section, in the case of an abbreviated new drug submission, a new drug for extraordinary use in respect of which a notice of compliance has been issued under section C.08.004.01 is not a Canadian reference product.

(4) Pour l'application du présent article, dans le cas d'une présentation abrégée de drogue nouvelle, la drogue nouvelle pour usage exceptionnel à l'égard de laquelle un avis de conformité a été délivré en application de l'article C.08.004.01 n'est pas un produit de référence canadien.

C.08.004. (1) Subject to section C.08.004.1, the Minister shall, after completing an examination of a new drug submission or abbreviated new drug submission or a supplement to either submission,

C.08.004. (1) Sous réserve de l'article C.08.004.1, après avoir terminé l'examen d'une présentation de drogue nouvelle, d'une présentation abrégée de drogue nouvelle ou d'un supplément à l'une de ces présentations, le ministre :

(a) if that submission or supplement complies with section C.08.002, C.08.002.1 or C.08.003, as the case may be, and section C.08.005.1, issue a notice of compliance; or

a) si la présentation ou le supplément est conforme aux articles C.08.002, C.08.002.1 ou C.08.003, selon le cas, et à l'article C.08.005.1, délivre un avis de conformité;

(b) if that submission or supplement does not comply with section C.08.002, C.08.002.1 or C.08.003, as the case may be, or section C.08.005.1, notify the manufacturer that the submission or supplement does not so comply.

b) si la présentation ou le supplément n'est pas conforme aux articles C.08.002, C.08.002.1 ou C.08.003, selon le cas, ou à l'article C.08.005.1, en informe le fabricant.

(2) Where a new drug submission or abbreviated new drug submission or a supplement to either submission does not comply with section C.08.002, C.08.002.1 or C.08.003, as the case may be, or section C.08.005.1, the manufacturer who filed the submission or supplement may amend the submission or supplement by filing additional information or material.

(2) Lorsqu'une présentation de drogue nouvelle, une présentation abrégée de drogue nouvelle ou un supplément à l'une de ces présentations n'est pas conforme aux articles C.08.002, C.08.002.1 ou C.08.003, selon le cas, ou à l'article C.08.005.1, le fabricant qui l'a déposé peut le modifier en déposant des renseignements ou du matériel supplémentaires.

(3) Subject to section C.08.004.1, the Minister shall, after completing an examination of any additional information or material filed in respect of a new drug submission or an abbreviated new drug submission or a supplement to either submission,

(3) Sous réserve de l’article C.08.004.1, après avoir terminé l’examen des renseignements et du matériel supplémentaires déposés relativement à une présentation de drogue nouvelle, à une présentation abrégée de drogue nouvelle ou à un supplément à l’une de ces présentations, le ministre :

(a) if that submission or supplement complies with section C.08.002, C.08.002.1 or C.08.003, as the case may be, and section C.08.005.1, issue a notice of compliance; or

a) si la présentation ou le supplément est conforme aux articles C.08.002, C.08.002.1 ou C.08.003, selon le cas, et à l’article C.08.005.1, délivre un avis de conformité;

(b) if that submission or supplement does not comply with the requirements of section C.08.002, C.08.002.1 or C.08.003, as the case may be, or section C.08.005.1, notify the manufacturer that the submission or supplement does not so comply.

b) si la présentation ou le supplément n’est pas conforme aux articles C.08.002, C.08.002.1 ou C.08.003, selon le cas, ou à l’article C.08.005.1, en informe le fabricant.

(4) A notice of compliance issued in respect of a new drug on the basis of information and material contained in a submission filed pursuant to section C.08.002.1 shall state the name of the Canadian reference product referred to in the submission and shall constitute a declaration of equivalence for that new drug.

(4) L’avis de conformité délivré à l’égard d’une drogue nouvelle d’après les renseignements et le matériel contenus dans la présentation déposée conformément à l’article C.08.002.1 indique le nom du produit de référence canadien mentionné dans la présentation et constitue la déclaration d’équivalence de cette drogue.

C.08.004.1 (1) The following definitions apply in this section.

C.08.004.1 (1) Les définitions qui suivent s’appliquent au présent article.

“abbreviated new drug submission” includes an abbreviated extraordinary use new drug submission. (présentation abrégée de drogue nouvelle)

« 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. (innovative drug)

“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

« population pédiatrique » S’entend de chacun des groupes suivants : les bébés prématurés nés avant la 37e semaine de gestation, les bébés menés à terme et âgés de

previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph. (drogue innovante)

0 à 27 jours, tous les enfants âgés de 28 jours à deux ans, ceux âgés de deux ans et un jour à 11 ans et ceux âgés de 11 ans et un jour à 18 ans. (pediatric populations)

“new drug submission” includes an extraordinary use new drug submission. (présentation de drogue nouvelle)

« présentation abrégée de drogue nouvelle » S’entend également d’une présentation abrégée de drogue nouvelle pour usage exceptionnel. (abbreviated new drug submission)

“pediatric populations” means the following groups: premature babies born before the 37th week of gestation; full-term babies from 0 to 27 days of age; and all children from 28 days to 2 years of age, 2 years plus 1 day to 11 years of age and 11 years plus 1 day to 18 years of age. (population pédiatrique)

« présentation de drogue nouvelle » S’entend également d’une présentation de drogue nouvelle pour usage exceptionnel. (new drug submission)

(2) This section applies to the implementation of Article 1711 of the North American Free Trade Agreement, 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 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 the new drug and an innovative drug,

(3) Lorsque le fabricant demande la délivrance d’un avis de conformité pour une drogue nouvelle sur la base 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

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

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

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.

(4) The period specified in paragraph (3)(b) is lengthened to eight years and six months if

(4) Le délai prévu à l'alinéa (3)b) est porté à huit ans et six mois si, à la fois :

(a) the innovator provides the Minister with the description and results of clinical trials relating to the use of the innovative drug in relevant pediatric populations in its first new drug submission for the innovative drug or in any supplement to that submission that is filed within five years after the issuance of the first notice of compliance for that innovative drug; and

a) l'innovateur fournit au ministre la description et les résultats des essais cliniques concernant l'utilisation de la drogue innovante dans les populations pédiatriques concernées dans sa première présentation de drogue nouvelle à l'égard de la drogue innovante ou dans tout supplément à une telle présentation déposé au cours des cinq années suivant la délivrance du premier avis de conformité à l'égard de cette drogue innovante;

(b) 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, the Minister determines that the clinical trials were designed and conducted for the purpose of increasing knowledge of the use of the innovative drug in those pediatric populations and this knowledge would there-by provide a health benefit to members of those populations.

b) le ministre conclut, avant l'expiration du délai de six ans qui suit la date à laquelle le premier avis de conformité a été délivré à l'innovateur pour la drogue innovante, que les essais cliniques ont été conçus et menés en vue d'élargir les connaissances sur l'utilisation de cette drogue dans les populations pédiatriques visées et que ces connaissances se traduiraient par des avantages pour la santé des membres de celles-ci.

(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.

(6) Paragraph (3)(a) does not apply to a subsequent manufacturer if the innovator consents to the filing of 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 by the subsequent manufacturer before the end of the period of six years specified in that paragraph.

(6) L'alinéa (3)a) ne s'applique pas au fabricant ultérieur dans le cas où l'innovateur consent à ce qu'il dépose une présentation de drogue nouvelle, une présentation abrégée de drogue nouvelle ou un supplément à l'une de ces présentations avant l'expiration du délai de six ans prévu à cet alinéa.

(7) Paragraph (3)(a) does not apply to a subsequent manufacturer if the manufacturer files an application for authorization to sell its new drug under section C.07.003.

(7) L'alinéa (3)a) ne s'applique pas au fabricant ultérieur s'il dépose une demande d'autorisation pour vendre cette drogue nouvelle aux termes de l'article C.07.003.

(8) Paragraph (3)(b) does not apply to a subsequent manufacturer if the innovator consents to the issuance of a notice of compliance to the subsequent manufacturer before the end of the period of eight years specified in that paragraph or of eight years and six months specified in subsection (4).

(8) L'alinéa (3)b) ne s'applique pas au fabricant ultérieur dans le cas où l'innovateur consent à ce que lui soit délivré un avis de conformité avant l'expiration du délai de huit ans prévu à cet alinéa ou de huit ans et six mois prévu au paragraphe (4).

(9) The Minister shall maintain a register of innovative drugs that includes information relating to the matters specified in subsections (3) and (4).

(9) Le ministre tient un registre des drogues innovantes, lequel contient les renseignements relatifs à l'application des paragraphes (3) et (4).

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-148-11
STYLE OF CAUSE:	CELGENE INC. v THE MINISTER OF HEALTH
PLACE OF HEARING:	Ottawa, ON
DATE OF HEARING:	November 21, 2011
REASONS FOR JUDGMENT AND JUDGMENT:	de MONTIGNY J.
DATED:	February 6, 2012

APPEARANCES:

William Vanveen Wendy Wagner	FOR THE APPLICANT
Eric Peterson	FOR THE RESPONDENT

SOLICITORS OF RECORD:

Gowling Lafleur Henderson LLP Ottawa, ON	FOR THE APPLICANT
Myles J. Kirvan Deputy Attorney General of Canada Ottawa, ON	FOR THE RESPONDENT