Federal Court  Cour fédérale

Date: 20090715

Docket: T-2100-07

Citation: 2009 FC 721

Ottawa, Ontario, July 15, 2009

PRESENT: The Honourable Mr. Justice Beaudry

BETWEEN:

APOTEX INC.

Applicant

and

THE MINISTER OF HEALTH and ASTRAZENECA CANADA INC.

Respondents

REASONS FOR JUDGMENT AND JUDGMENT

[1] This is an application for judicial review, pursuant to section 18.1 of the *Federal Courts Act*, R.S.C., 1985, c. F-7, by Apotex Inc. in respect of the refusal of the Respondent, the Minister of Health, to process Apotex's Supplementary New Drug Submission (SANDS) seeking to change the Product Monograph for its Apo-Omeprazole 20 mg capsules to add an indication for the use of the capsules in combination with antibiotics for the eradication of *H. pylori*, in accordance with Part C

of the *Food and Drug Regulations*, C.R.C., c. 870. Specifically, the Applicant seeks orders in the nature of declaration and *mandamus*.

Factual Background

[2] The Applicant, Apotex Inc., is an Ontario drug company who produces and distributes a variety of pharmaceutical products. Most of Apotex's drug products are termed "generic" in the sense that they are formulations of active medicinal ingredients which have already been brought to market by other manufacturers companies in Canada. Apotex's products are approved for sale by the Minister as therapeutically equivalent to the original brand formulation of the same active medicinal ingredient.

[3] The Respondent AstraZeneca Canada Inc. received the original Notice of Compliance (NOC) for its 20 mg Omeprazole capsules, known under the brand name LOSEC, on June 13, 1989. Eight patents were listed on the patent register under the *Patented Medicines (Notice of Compliance) Regulations* (SOR/93-133, as amended SOR/98-166, SOR/99-379, SOR/2006-242 and SOR/2008-211) (PM (NOC) Regulations) in respect of the Canadian reference product LOSEC 20 mg capsules: Canadian Patents Nos. 1,292,693 (the '693 patent), 1,302,891 (the '891 patent), 2,025,668 (the '668 patent), 2,133, 762 (the '762 patent), 1,338,377 (the '377 patent), 2,180,535 (the '535 patent), 2,186,037 (the '037 patent) and 2,284,470 (the '470 patent).

[4] On January 27, 2004, the Minister issued a NOC to Apotex in respect of submission 054341 for 20 mg Apo-Omeprazole capsules based, in part, upon a bioequivalence comparison to Respondent AstraZeneca's brand name LOSEC 20 mg capsules. On January 4, 2006, the Minister

issued a revised NOC, to reflect that AstraZeneca's drug LOSEC 20 mg served as the Canadian reference product against which Apotex made the comparisons to demonstrate bioequivalence.

[5] In obtaining this NOC, Apotex was required to address the patents listed by serving a Notice of Allegation (NOA) in respect of each patent, pursuant to the PM (NOC) Regulations. Apotex was exempted by the Court from addressing the '037 patent and the '470 patent because the PM (NOC) Regulations were not applicable, as confirmed by the Supreme Court of Canada in *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, 2006 SCC 49, [2006] 2 S.C.R. 560.

[6] In respect of the remaining NOAs, Apotex was successful in prohibition proceedings commenced by AstraZeneca in five cases (regarding the '668 patent, the '762 patent, the '693 patent, the '891 patent and the '377 patent). In respect of the sixth, the '535 patent, AstraZeneca did not commence a proceeding in response to the NOA. In respect of the '668 and the '762 patents, Apotex alleged non-infringement and asserted that it would not use, make or sell its product for the uses claimed by the two patents.

[7] On April 21, 2005, Apotex filed a supplemental submission (SANDS), supplement 098243, with the Minister, seeking approval for a proposed change to its Product Monograph for Apo-Omeprazole 20 mg capsules to add an indication for the use of the capsules in combination with antibiotics for the eradication of *H. pylori*.

[8] There were eight patents listed on the register in respect of LOSEC 20 mg capsules at the time Apotex filed its SANDS. These were the same patents which were on the register at the time that Apotex obtained its NOC for Apo-Omeprazole 20 mg capsules.

[9] Regarding its SANDS, Apotex did no further bioequivalence studies, acquired no further LOSEC 20 mg capsules and made no changes to its original submission which had led to obtaining its NOC in 2004, except that the SANDS now sought the additional indication previously omitted by which the ‘668 and ‘762 patents were attracted.

[10] Because Apotex sought approval for the additional indication, thereby attracting the ‘668 and ‘762 patents, Apotex served a NOA in respect of these two patents, alleging invalidity of the patents in order to be able to make, use and sell its Apo-Omeprazole 20 mg capsules for the patented use. A prohibition application was commenced in court file no. T-985-05 before this Court, which was dismissed by Justice Barnes on June 28, 2007 (*AstraZeneca AB v. Apotex Inc.*, 2007 FC 688, 314 F.T.R. 177).

[11] By letter dated April 28, 2005, the Minister’s officials notified Apotex that its SANDS had been transmitted for review. On July 6, 2005, Apotex was informed by letter that the examination of the supplement was complete and that the NOC would not be issued until the requirements of the PM (NOC) Regulations were met. The supplement was accordingly placed on “patent hold” on that date.

[12] In correspondence with the Office of Patented Medicines and Liaison (OPML) starting in June 2007, Apotex requested immediate issuance of the NOC on the basis of the decision in Court file no. T-985-05. Apotex argued that the remaining patents are not relevant to its SANDS, that they did not use the subject matter of any of the patents in relation to the supplemental submission, and that the patents had been addressed in relation to the NOC issued previously.

[13] The Declaration Re: Patent List (Form V) which Apotex had filed with the supplement indicated its acceptance that the NOC would not issue until the declared expiration date of each patent, so the OPML requested updated Form Vs and corresponding NOAs and proofs of service for each of the eight listed patents. Apotex then filed updated Form V's with respect to all of the patents, alleging invalidity and/or non-infringement.

[14] By letter in response dated August 15, 2007, the OPML agreed that the '668 and '762 patents (and the '535 patent, not in issue in this application) no longer barred issuance of a NOC. However, Apotex was required to address all of the remaining patents listed on the register in respect of LOSEC 20 mg capsules pursuant to section 5 of the PM (NOC) Regulations (the '693, '891, '377, '037 and '470 patents). The OPML applied its approach in light of the Supreme Court of Canada's decision in *AstraZeneca*, above, followed in *Ferring Inc. v. Canada (Minister of Health)*, 2007 FC 300, [2008] 1 F.C.R. 19 (F.C.), aff'd 2007 FCA 276, 370 N.R. 263. The Minister indicated that the OPML was "not in a position to determine whether an allegation in respect of a particular patent is justified for the purpose of section 5. Rather, such determinations are to be made by the Federal Court."

[15] By letter dated August 27, 2007, Apotex disputed the OPML's reasoning, arguing that it was contrary to the decisions of the Supreme Court of Canada in *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, 2005 SCC 26, [2005] 1 S.C.R. 533 (*Biolyse*) and *AstraZeneca*, above. Apotex argued that the OPML should compare the subject matter of the patents to that of the generic submission, determine whether they are relevant to one another and, if they are not, exempt the submission from compliance with the PM (NOC) Regulations. Apotex repeated that the patents had bee addressed in its original submission, therefore they did not have to be addressed again in relation to its SANDS.

[16] By letter dated November 26, 2007, the OPML distinguished the decisions in *Biolyse* and *AstraZeneca*, maintained the view that the OPML is not in a position to determine whether there has been early-working or infringement of a given patent and repeated that the *Regulations Amending the Patented Medicines (Notice of Compliance) Regulations*, SOR/2006-242 (the October 5, 2006 Amended Regulations) applied. In summary, the OPML considered that Apotex was required to fulfill the requirements of section 5 of the PM (NOC) Regulations in respect of the '693, '891, '377, '037 and '470 patents.

[17] This application for judicial review was commenced on December 3, 2007. AstraZeneca Canada Inc., as the innovator in respect of the patents at issue, sought to be added as a Respondent and was added, on consent, by order dated April 24, 2008.

[18] According to its Notice of Application, Apotex is not seeking judicial review of the Minister's refusal to process its SANDS. Rather, Apotex states that it is seeking orders in the nature of declaration and *mandamus*.

Legislative Framework

[19] The relevant legislative provisions are contained in Appendix A at the end of this document.

[20] In Canada, the sale of pharmaceutical products is subject to both federal and provincial regulatory control. In order to sell and to advertise for the sale of a new drug in Canada, every drug manufacturer must obtain a Notice of Compliance (NOC) for that drug from the Minister pursuant to the provisions of the *Food and Drugs Act*, R.S., 1985, c. F-27 and the *Food and Drug Regulations*.

[21] Section C.08.004 of the *Food and Drug Regulations* directs that a drug manufacturer may obtain a NOC in respect of a new drug only after submitting a New Drug Submission (NDS), filed by an innovative drug manufacturer for a new drug product, or an Abbreviated New Drug Submission (ANDS), filed by a generic company that claims its product is bioequivalent to a drug that has been previously approved (a Canadian reference product). A Canadian reference product is a drug in respect of which a NOC has been granted and is marketed in Canada (section C.08.001.1 of the *Food and Drug Regulations*).

[22] An ANDS usually contains voluminous clinical trial data and detailed studies and pursuant to section C.08.002 of the *Food and Drug Regulations*, it must include descriptions of the benefits claimed, the adverse reactions experienced, the chemical composition of the ingredients and the methods of manufacture and purification, all in sufficient detail to enable the Minister to assess the safety and effectiveness of the new drug. The examination process then conducted by the Minister can take several years (*Biolyse*, above at paras. 13-15).

[23] With an ANDS, a generic company must satisfy the Minister that its generic copy of a Canadian reference product is safe and effective by comparing the two products to show that they are bioequivalent (section C.08.002.1 of the *Food and Drug Regulations*). The generic drug must be the pharmaceutical equivalent of the Canadian reference product (section C.08.001.01 of the *Food and Drug Regulations*), meaning that in comparison with the Canadian reference product, the generic drug contains identical amounts of the identical medicinal ingredients, in comparable dosage forms, but does not necessarily contain the same non-medicinal ingredients.

[24] The properties, claims, indications, conditions of use, and any other information that may be required for the optimal, safe, and effective use of a drug are described in a document called a Product Monograph. For a generic drug, the conditions of use must fall within the conditions of use of the Canadian reference product (paragraph C.08.002.1 (1)(*d*), *Food and Drug Regulations*). Thus, a generic company is required to rely on the information contained in the Product Monograph for the Canadian reference product.

[25] After a NOC has issued, any significant changes to the drug (or to the information regarding the drug contained in the previous submission) are made by filing a supplement to the NDS or ANDS (SNDS or SANDS). The supplement must also receive a NOC before the modified drug may be marketed (section C.08.003 of the *Food and Drug Regulations*).

[26] The addition of a new use for a generic drug requires such a supplemental submission (subparagraph C.08.003 (2)(*h*)(iii) of the *Food and Drug Regulations*). However, when a generic drug company files a supplemental submission seeking approval for a new use, it is not required to include material to re-establish bioequivalence with the Canadian reference product. Rather, the establishment of bioequivalence that was originally required for the approval of the generic's underlying submission is considered to remain effective.

[27] The PM (NOC) Regulations were enacted by the Governor in Council pursuant to subsection 55.2(4) of the *Patent Act*, R.S., 1985, c. P-4. For the determination of whether a drug is safe and effective, a submission enters into the drug review process conducted by the Therapeutic Products Directorate (TPD) at Health Canada. In the case of an NDS, if the Minister is satisfied that the submission demonstrates the safety and effectiveness of the drug, a NOC is issued. In the case of an ANDS, a final patent check is performed by the OPML. If the NOC would be issuable but for the operation of the PM (NOC) Regulations, the drug's sponsor is so notified. The submission is then placed on "patent hold", with no NOC issued until all the requirements under the PM (NOC) Regulations have been met. On the other hand, if the PM (NOC) Regulations present no bar, the NOC is issued forthwith. In other words, even where a generic drug has been found to be safe and

effective, the Minister may not issue a NOC where prohibited by the patent-related concerns set out in the PM (NOC) Regulations.

[28] A generic company seeking a NOC on the basis of a comparison with or reference to another drug for the purpose of demonstrating bioequivalence triggers the application of subsection 5(1) of the PM (NOC) Regulations as enacted in 2006, such that the generic company is required, in its submission, to address patents listed on the patent register in respect of the other drug.

[29] According to subsection 5(2) as enacted in 2006, the same requirements apply where a generic company files a SANDS where that supplement seeks a NOC for a change in formulation, a change in dosage form or a change in use of the medicinal ingredient. Under the 2006 Amending Regulations, subsection 5(2) applies explicitly to a generic company who has filed its SANDS prior to October 5, 2006.

[30] If patents listed in respect of the innovator's drug are to be addressed under section 5, the generic company proceeds as follows: It either states its acceptance that a NOC will not issue until each patent expires or makes an allegation, of which the most common are that the patent is invalid and that the patent will not be infringed. In practice, the generic company provides this information by filing out a "Form V: Declaration Re: Patent List" (Form V) with the submission. If it makes an allegation, the generic company also provides a notice of allegation (NOA) to the innovator, describing its allegation. A submission requiring a Form V is considered incomplete without one, as section 5 specifies that the generic company must address all relevant patents in the submission. An

incomplete submission cannot enter into the drug review process until the generic company completes it by filing the requisite Form V. If the submission is complete, it enters into the drug review process without delay.

[31] A generic company who makes an allegation must then serve a notice of allegation on the innovator under subsection 5(3) of the PM (NOC) Regulations. Within 45 days after service, an innovator may, under section 6, apply to the Federal Court for an order prohibiting the Minister from issuing a NOC until after the expiration of the patent that is the subject of the allegation.

Issue

[32] The issue to be determined in the case at bar is the following: should this application be allowed? If the answer is in the affirmative, what is the appropriate relief?

Analysis

Standard of Review

[33] Questions concerning the interpretation of the PM (NOC) Regulations are questions of law, reviewable upon a standard of correctness (*AstraZeneca*, above at para. 25; *Bayer Healthcare AG v. Sandoz Canada Inc.*, 2008 FCA 25, 375 N.R. 357 at para. 12).

Applicant's Submissions

[34] In seeking approval of its SANDS, Apotex took steps to re-address two patents on the patent register which related to the use of Omeprazole 20 mg capsules in combination with antibiotics. The

Minister agrees that Apotex has done so satisfactorily pursuant to the PM (NOC) Regulations. There is no dispute that Apotex has satisfactorily addressed the ‘668, ‘762 and ‘535 patents. The only issue at bar is whether the PM (NOC) Regulations require Apotex to re-address the remaining five patents on the patent register.

[35] The Applicant submits that the other patents on the register have no relevance to the change proposed in the SANDS and, as such, are not required to be re-addressed because they have already been addressed in the initial submission. Apotex filed no new bioequivalence studies in its SANDS but instead, it relies upon the old comparisons it had made in obtaining its NOC. Furthermore, Apotex does not seek to make any changes to its Omeprazole 20 mg capsules which could possibly change its product in a manner which would attract these patents.

[36] In obtaining its original NOC, Apotex had addressed the remaining five patents and their SANDS is based upon this NOC. The Apotex SANDS at bar is not a new submission as it is a supplement to a submission which has already been approved and the underlying NOC met the requirements of the PM (NOC) Regulations in addressing all of the remaining patents.

[37] Apotex submits that the PM (NOC) Regulations do not require it to re-address that which it has already addressed provided that there is no change in its SANDS requiring the patents to be re-addressed. There is no proposed change in Apotex’s SANDS which could possibly attract the remaining patents.

[38] The Minister's position is that he is neither required nor able to turn his mind to that issue but the jurisprudence shows that the Minister's position is incorrect. Had the Minister completed his obligations under the PM (NOC) Regulations, he would have granted Apotex its NOC. The Minister erred in interpreting Apotex's position as asking the Minister to determine whether or not any particular allegation is justified because Apotex never asked the Minister to do that. Instead, the Applicant asked the Minister to confirm that, pursuant to the PM (NOC) Regulations, Apotex was not required to re-address the five remaining patents as they had already been addressed in obtaining the initial NOC, which is the role of the Minister under the PM (NOC) Regulations.

[39] This Court and the Federal Court of Appeal have held that a generic company who has already served a NOA in respect of a ANDS is not required to re-address those patents previously addressed when filing a SANDS. In a situation involving strikingly similar circumstances, a generic company who had already served a NOA in respect of a ANDS was not required to re-address those patents when filing a SANDS where the Minister determined that no new patent issues could prevent the issuance of an NOC. The Courts further held that the Minister has the authority and the responsibility to make that determination (see *Patented Medicines (Notice of Compliance) Regulations (Re)* (1998), 152 F.T.R. 262, 81 A.C.W.S. (3d) 874 (F.C.T.D.), aff'd. (1999), 249 N.R. 110, 92 A.C.W.S. (3d) 1064 (F.C.A.) at paras. 13-16 and 28-29 (*Re Patented Medicines*)). In recent jurisprudence, this Court and the Federal Court of Appeal have confirmed the Minister's authority to determine whether particular patents do not need to be addressed by generic companies (*Ferring*, above at paras. 63-65).

Respondent Minister's Submissions

[40] The Respondent Minister of Health submits that Apotex has overlooked subsection 5(2) of the PM (NOC) Regulations, as enacted in October 2006, which explicitly invokes the application of the PM (NOC) Regulations in relation to a SANDS. In addition, Apotex's claim that it did not use the subject matter of the patents in relation to the supplement amounts to an allegation of infringement. Under the PM (NOC) Regulations, the innovator of the drug copied by Apotex is entitled either to make that determination itself or have it determined by the Court and not by the Minister.

[41] Apotex first argues that it has previously addressed the patents in its original submission which contained the bioequivalence studies; therefore, they should not have to do so again. However, this entirely disregards the provisions of subsection 5(2) of the PM (NOC) Regulations, enacted October 5, 2006, which provides that a SANDS like Apotex's triggers the application of the PM (NOC) Regulations in the same way as the ANDS itself does.

[42] Apotex's supplement is one of the types explicitly referred to in the provision, as it is a submission seeking a NOC for a change in use. Moreover, the 2006 Amending Regulations at section 7(2) make subsection 5(2) of the PM (NOC Regulations even more plainly applicable to Apotex's SANDS.

[43] The Minister argues that the decision in *Re Patented Medicines*, above, is of no assistance to Apotex because it was based on earlier versions of the PM (NOC) Regulations which did not include the current subsection 5(2). Accordingly, Apotex's argument does not apply here and pursuant to subsection 5(2) of the PM (NOC) Regulations, the fact that Apotex has previously addressed the patents at issue, in the context of its original submission, does not exempt it from doing so in respect of its supplement.

[44] In its second argument, Apotex states that the Minister must determine that the new use is not the subject of the patents at issue, and accordingly, he must process the submission without regard to the PM (NOC) Regulations. Apotex says that the Minister must compare the subject matter of the patents at issue to the subject matter of its SANDS in order to determine that one is not relevant to the other and to exempt the submission from compliance with the PM (NOC) Regulations. To support this argument, Apotex cites the decisions in *AstraZeneca*, *Ferring* and *Re Patented Medicines*. However, the Respondent Minister submits that those cases involved different facts and different reasoning which do not apply to the facts in the case at bar or to the current legislative context. Furthermore, the responsibility for the determination that Apotex ascribes to the Minister is actually within the mandate given not to the Minister by the Governor in Council but to the Court.

[45] In deciding *AstraZeneca* and *Ferring*, the Courts developed and applied the notion of a "patent-specific analysis" to conclude that a generic company is not always required to address every patent listed against a drug it seeks to copy. However, these cases required the analysis of

issues of timing and not of issues of subject matter. In *AstraZeneca*, different versions of the innovator's drug were available on the market at different times and the Supreme Court held that the generic company was not required to address patents that had been listed in respect of the version of the innovator drug that was available only after the generic company had conducted its comparative tests. In *Ferring*, the Minister applied the timing test described in *AstraZeneca* and in three of the four instances comprised in the *Ferring* case, did not require the generic companies to address such patents and issued NOCs to them.

[46] In *Novopharm v. Sanofi-Aventis*, Court file no. T-2220-06, one of the cases contained in the *Ferring* decision (see *Ferring*, above at paras. 111 and 117), the generic company had argued, as Apotex does here, that the Minister should have applied not only a timing test, but also a test involving a comparison of the subject matter of the patents to the subject matter of the submission. The Minister refused to do so and this Court upheld that decision. Even in *AstraZeneca*, the Supreme Court recognized that if the timing test had not exempted the generic company, the patents would at least have to be addressed. However, in *AstraZeneca* and in *Ferring*, the Court did not, as stated by Apotex, extend the Minister's responsibilities to include any test involving a subject matter comparison between the innovator's patent and the generic's submission.

[47] *AstraZeneca*'s timing test has been superseded by the 2006 Amending Regulations. Prior to the decision, under the legislative provisions at issue in *AstraZeneca*, a generic company was required to address all patents listed by an innovator against the Canadian reference product, including any listed between the time the generic filed its ANDS and the issuance of the NOC. The

application of *AstraZeneca*'s timing test in cases to which the 2006 Amending Regulations apply is thus neither necessary nor appropriate.

[48] The Respondent Minister specifies that the comparison of the subject matter of the patent to that of Apotex's submission is to be made by the Court and not by the Minister. The comparison may first be made by the innovator who may decide that its patent will not be infringed and choose not to initiate an application under section 6 of the PM (NOC) Regulations upon receipt of Apotex's allegations. If it does choose to do so, the Court will determine whether Apotex's allegation that the innovator's patent will not be infringed is justified. In other words, the question that Apotex says should be determined in its favour by the Minister is the kind of question that the Governor in Council has directed to be determined in the Court proceeding resulting from the right granted to an innovator in section 6 of the PM (NOC) Regulations.

[49] The Respondent Minister notes that in *Apotex Inc. v. Canada (Attorney General),* [1994] 1 F.C. 742, (C.A.) aff'd [1994] 3 S.C.R. 1100, the Applicant sought an Order requiring the Minister of Health to issue a NOC for one of its drugs. The Court reviewed some 50 years of jurisprudence and ruled that, as affirmed by the Supreme Court, that "several principal requirements must be satisfied before *mandamus* will issue", and articulated those requirements. The law has been clearly established for many years that the Court will not issue an order of *mandamus* unless the Applicant first shows that it satisfies certain specific requirements as conditions precedent. The most fundamental of these requirements may be summarized as such: the Applicant must show that it has

a clear right to the performance of a public legal duty owed to the Applicant at the time of the hearing.

[50] Here, Apotex seeks orders requiring the Minister to process its submission immediately, and an order requiring the Minister to "prioritize" the review of its supplement "on the basis of a filing date of April 21, 2005". However, Apotex has presented neither evidence nor argument to show that it has satisfied the conditions precedent established by the jurisprudence.

Respondent's AstraZeneca's Submissions

[51] It is trite law that the words of an Act and Regulations 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 (*AstraZeneca*, above at para. 26). The duty of the courts is to give effect to the intention of the legislature as expressed in the words of the statute. This follows from the constitutional doctrine of the supremacy of the legislature when acting within its legislative powers. The fact that the words would give an unreasonable result when interpreted, however, is certainly ground for the courts to scrutinize a statute carefully to make abundantly certain that those words are not susceptible of another interpretation (*Barton No-till Disk Inc. v. Dutch Industries Ltd.*, 2003 FCA 121, [2003] 4 F.C. 67 at para. 41).

[52] Apotex submits that the Minister has misconstrued the PM (NOC) Regulations but fails to put forth any arguments relating to the applicable provisions. The Respondent AstraZeneca respectfully submits that the Minister was correct to apply subsection 5(2) of the currently enacted

PM (NOC) Regulations, specifically by virtue of subsection 7(2) of the 2006 Amending Regulations.

[53] Because Apotex's SANDS was filed on April 21, 2005, subsection 5(2) of the PM (NOC) Regulations, as currently enacted, is applicable because this subsection is triggered when the supplement seeks approval for a "change in use" of the medicinal ingredient pursuant to section C.08.003(2)(*h*)(iii) of the *Food and Drug Regulations*, as in the case of Apotex's supplement, which seeks approval for a new use of Apo-Omeprazole for the eradication of *H. pylori*.

[54] According to the plain and ordinary terms of subsection 5(2), which states that Apotex *shall* make the requisite statement or allegation with respect to each patent on the register as of October 5, 2006 in respect of AstraZeneca's LOSEC 20 mg capsules in its SANDS, the Minister's decision was correct.

[55] The Supreme Court of Canada has accepted that the general purpose of the PM (NOC) Regulations is to protect the rights of patentees by preventing generic companies from marketing their products until the expiry of all relevant patents. The Supreme Court has stated that: "It seems clear that the NOC Regulations were introduced to help generic drug companies and at the same time curb potential patent abuse by them." (*Biolyse*, above at paras. 45-47).

[56] If a generic company is not required to address a patent, the innovator will not have the opportunity to determine in Court whether the generic company will infringe their patent when they

market their product. The requirement to make an allegation under section 5 is therefore critical to the protection of the innovator's patent rights. When a generic company relying on an innovator's drug files a SANDS related to a change in formulation, a change in dosage form or a change in use, because these are substantive submissions that have the potential to bear on patent infringement, this triggers a reasonable presumption that the generic company has early-worked the invention and therefore must address the patents on the patent register.

[57] The Respondent AstraZeneca submits that the PM (NOC) Regulations cannot bear the interpretation urged by Apotex because by reading the text of subsection 5(2) in its context, mindful of the scheme and object of the PM (NOC) Regulations and the intention of Parliament, the grammatical and ordinary sense of the words does not lead to the absurd result suggested by Apotex. The interpretation of subsection 5(2) urged by Apotex would require a fundamental re-writing of the provision. Parliament wanted section 5 of the PM (NOC) Regulations to mirror the structure of section 4; therefore, it had compared the language of the two provisions. Yet, Parliament specifically chose not to include the language of subsection 4(3) in subsection 5(2) of the PM (NOC) Regulations.

[58] Requiring a generic company to address, in its SANDS, patents that may have been addressed in its initial submissions was contemplated by Parliament in drafting the 2006 Amending Regulations. These amendments include a provision (section 4.1) which allows innovators to carry forward patent lists submitted in relation to a NDS by resubmitting them in relation to a supplement to that NDS. In contrast to the language of section 5 of the PM (NOC) Regulations prior to

October 5, 2006, subsections 5(1) and 5(2) now expressly provide that the comparison to the innovator drug may occur “directly or indirectly”. In addition, the previous language that the comparison or reference be “for the purpose of establishing bioequivalence” was removed. Following this amendment, a change in use of the medicinal ingredient is now included as a triggering circumstance in subsection 5(2), notwithstanding that further bioequivalence studies are not required for such supplements.

[59] Apotex’s arguments that the supplement is based upon the original NOC and is not a new submission, that without the underlying submission the SANDS could not be applied for or approved, and that no bioequivalence studies were filed in the supplement, improperly disregard the entire scheme of the PM (NOC) Regulations. The PM (NOC) Regulations expressly treat a supplement for a new use as a separate and distinct trigger of a generic company’s obligations.

[60] The filing of a SANDS for a change in formulation, a change in dosage form or a change in use of the medicinal ingredient creates a reasonable presumption that the submission may bear on patent infringement. Therefore, it would not be absurd to require a patent to be addressed in relation to such a supplement even if the patent was addressed in relation to the original submission. Furthermore, paragraph 6(5)(*b*) provides for a summary dismissal of a proceeding “on the ground that it is redundant, scandalous, frivolous or vexatious or is otherwise an abuse of process in respect of one or more patents”. Thus, the generic company has recourse if it believes that an application has no merit. An innovator would not have the opportunity to make submissions if such a determination would be made by the Minister alone pursuant to subsection 5(2).

[61] The Respondent AstraZeneca submits that the only authority relied upon by Apotex, *Re Patented Medicines*, does not apply to the present circumstances because that decision was based on the PM (NOC) Regulations as originally enacted in 1993, which did not include subsection 5(2).

[62] Furthermore, AstraZeneca agrees with the Minister that a consideration of whether Apotex has early-worked or infringed the patents at issue falls outside the scope of what is required of the Minister under the PM (NOC) Regulations and is a consideration for the innovator, who can then refer the matter to the Court pursuant to section 6 of the PM (NOC) Regulations. If the Minister was required to review every SANDS filed by a generic company to consider whether it is relevant to the subject matter of each patent, this would have been mentioned in the legislative scheme.

[63] Apotex's interpretation of the PM (NOC) Regulations reads in a relevance requirement into subsection 5(2), linking the subject matter of the listed patents and the generic company's drug submission. However, this Court has affirmed, following the patent-specific analysis articulated by the Supreme Court in *AstraZeneca* under the pre-amended PM (NOC) Regulations, that a generic company would always be required to address patents listed in respect of the innovator drug before the filing of the ANDS. This analysis considers the previously listed patents purely from a timing perspective (see *Ferring*, above; *Abbott Laboratories Limited v. Canada (Attorney General)*, 2008 FCA 186, 380 N.R. 40; *Pharmascience Inc. v. Canada (Minister of Health)*, 2008 FC 922, [2008] F.C.J. No. 1135 (QL)). Similar early working arguments (including that the claims are irrelevant to

Apotex's ANDS) have been rejected by the Court on a subsequent occasion (*Solvay Pharma Inc. v. Apotex Inc.*, 2008 FC 308, (2007), 323 F.T.R. 1 at para. 61).

[64] Under the current PM (NOC) Regulations, the requirement to address patents is now explicitly premised on timing and subsection 5(4) now limits the patents that are required to be addressed by a generic company to those listed as of the date it filed its regulatory submission or supplement, as the case may be. The further timing requirement that the generic company must have filed its submission before making an allegation will decrease the risk of a generic company avoiding a patent that would be infringed.

[65] The fact that a generic company was not required to address a patent in relation to its original submission in view of timing issues does not mean that its original product would not infringe such a patent. Indeed, regarding the '470 and '037 patents, the Supreme Court stated that there was no evidence before it either way as to infringement by Apotex (*AstraZeneca*, above at para. 42). Since it is premised on timing alone, section 5 of the PM (NOC) Regulations is both over and under inclusive. It is therefore not absurd that certain patents that may not ultimately be infringed are required to be addressed as this is inherent in the scheme. In the case at bar, despite Apotex's assertions, it is not plain that there will be no infringement.

[66] Apotex's argument that the Minister has the authority to determine whether particular patents do not need to be addressed is misguided. The issue raised by this application is not the Minister's authority but rather the scope of the Minister's duty in making this determination. Apotex

would impose a duty upon the Minister to consider the subject matter of the listed patents and to make a comparison to Apotex's drug submission. However, it is well established that in determining whether patents must be addressed, the Minister is acting in a purely administrative capacity. The evaluation urged by Apotex would go beyond a purely administrative role (*Ferring*, above at paras. 77-78).

[67] AstraZeneca submits that there is no absurdity in interpreting subsection 5(2) according to its ordinary meaning and requiring Apotex to address all of the remaining patents at issue. If, despite this, the Court is of the view that the Minister was required to determine whether the submission at issue relates to the subject matter of the patents, AstraZeneca submits that insofar as the Minister did not consider this factor and insofar as the necessary evidence is not before this Court to make such determination, the matter should be remitted back to the Minister to make such determination.

Analysis

[68] Pursuant to the PM (NOC) Regulations as they read prior to October 5, 2006, a generic drug company seeking a NOC on the basis of a comparison with or reference to an innovator's drug for the purpose of demonstrating bioequivalence triggers the application of subsection 5(1) such that the generic company must, in the submission, address each patent on the patent register in respect of the innovator's drug. Under the 2006 Amending Regulations, subsection 5(2) applies to a generic company who has filed a supplemental submission prior to October 5, 2006.

[69] According to subsection 5(2) of the current PM (NOC) Regulations, a generic company who files a SANDS seeking a NOC for a change in formulation, a change in dosage form or a change in use of the medicinal ingredient and the supplemental submission directly or indirectly compares the drug with, or makes reference to, another drug in respect of which patents are listed on the patent register must, in the SANDS, address each patent listed on the patent register in respect of the other drug. In all cases, when addressing the patents listed in respect of the innovator's drug under section 5, the second person (the generic company) must either state its acceptance that a NOC will not issue until each patent expires or make an allegation. As noted by AstraZeneca in their submissions, the requirement that the comparison or reference with the innovator's drug be for the purpose of establishing bioequivalence as been removed in the current PM (NOC) Regulations.

[70] Subsection 5(1) applies to generic company who file "a submission for a notice of compliance". Subsection 5(2) applies to a "supplement to a submission referred to in subsection 5(1)", whenever a generic company files a SANDS to a submission for a change in formulation, a change in dosage form or a change in use of the medicinal ingredient.

[71] Under the 2006 Amending Regulations, the PM (NOC) Regulations apply to a generic company who has filed either a submission or a supplement, as described in subsections 5(1) and 5(2), respectively, prior to October 5, 2006. The date of filing for each submission or supplement filed prior to that date is deemed to be October 5, 2006.

[72] The Supreme Court decision in *AstraZeneca* clarified the law as to which patents must be addressed by a generic company under section 5 of the PM (NOC) Regulations as they read prior to the amendments in force on October 5, 2006. Justice Binnie held at paragraph 39 that a "patent-specific analysis" is necessary and went on to determine that a generic company "is only required to address the cluster of patents listed against submissions relevant to the NOC that gave rise to the comparator drug". All patents added to the patent register in respect of the comparator drug must be addressed under subsections 5(1) and 5(2) of the PM (NOC) Regulations.

[73] Following *AstraZeneca*, the Minister developed a policy for determining whether there were patents listed in respect of an innovator drug that a generic company would not be required to address under section 5 of the PM (NOC) Regulations. The framework was summarized by Justice Hughes in *Ferring*, above at para. 63. Firstly, the Minister would determine the date upon which the generic company purchased the version of the innovator drug it used for the purpose of testing for the required bioequivalence comparison. The generic company would necessarily be required to address any patents listed prior to that purchase. As explained by Justice Simpson in *Pharmascience*, above at para. 32: "*AstraZeneca* stands for the proposition that a generic company need only address patents listed against NOC's filed at the time it purchases the comparator drug it selects for the purpose of its ANDS."

[74] Secondly, the Minister would consider each NOC issued for the innovator drug after the date of purchase, in order to determine whether the generic company had made use of any changes

made to the innovator drug since the date of purchase. If so, the generic company would be required to address patents listed after the date of purchase in relation to those changes.

[75] As a result of certain comments made by Justice Hughes in *Ferring*, the first step in the analytical framework adopted by the Minister after *AstraZeneca* was changed slightly. Instead of using, as a starting point, the date of acquisition of the innovator drug for testing purposes, the Minister would use the date of the filing of the generic company's ANDS. Thus, the generic company would always be required to address patents listed in respect of the innovator drug before the filing date of the ANDS. If an examination of NOCs issued for the innovator drug after the date indicated that the generic company had made use of changes made to the innovator drug after that date, the generic company would be required to address patents listed after that date in relation to those changes.

[76] The current PM (NOC) Regulations constitute relatively new legislation, thus far only applied on a case-by-case basis. In *Ferring* at para. 6, the Federal Court of Appeal confirmed the use of this individual approach: "We have concluded that the analytical approach adopted by the Minister in these four appeals was adequate for the factual circumstances of these cases. Whether it is adequate for all possible circumstances […] is a question upon which we express no opinion."

[77] In the case at bar, the Applicant wants a declaration from the Court that the requirements of the regulations have been satisfied and alleges that it is entitled to an order of *mandamus* because

Apotex has already addressed the remaining five patents on the register that have been listed by the Minister to be re-addressed.

[78] Apotex also argues that the Minister ought to grant the notice of compliance without requiring him to address the patents because the Minister ought to be able to decide, and should decide, that the subject matter of the patents is not the same as the subject matter of its SANDS.

[79] The Federal Court of Appeal in *Pharmascience Inc. v. Canada (Minister of Health)*, 2009 FCA 183 recently upheld by Justice Simpson in *Pharmascience Inc. v. Canada (Minister of Health)*, 2008 FC 922 and concluded that the Minister erred in law by failing to perform the patent-specific analysis mandated by the Supreme Court's decision in *AstraZeneca v. Canada (Minister of Health)*, 2006 SCC 49, [2006] 2 S.C.R. 560. In her case, Justice Simpson wrote the following at paragraphs 34 and 35:

> [34] The Minister wants to avoid the requirement to conduct the patent specific analysis mandated by the Supreme Court in *AstraZeneca*. He suggested that, if they were issues about which patents should be addressed, a prohibition proceeding should be undertaken and any such issues could then be resolved by the Court on a motion for summary judgment under subsection 6(5) of the NOC Regulations.
>
> [35] I have rejected this approach for three reasons: …

[80] The Minister states that a consideration of whether Apotex has early-worked or infringed the ‘693, ‘891, ‘377, ‘307 and ‘470 patents falls outside the scope of what is required of the Minister under the PM (NOC) Regulations. In light of *Pharmascience Inc. v. Canada (Minister of Health)*

by the Court of Appeal, I have to disagree. At paragraph 27, the Court stated: “As the respondent points out, a SANDS is not a stand-alone submission. The Minister must take into account the relationship between a particular SANDS and an earlier filed ANDS when conducting the patent specific analysis”.

[81] In the present case, the Minister did not perform the patent- specific analysis as mandated by the Supreme Court's decision in *AstraZeneca* above before determining that Apotex had to address all five remaining patents.

[82] About the relief requested by the Applicant, the proper test which must be applied to determine whether a writ of *mandamus* should issue is explained in *Dragan v. Canada (Minister of Citizenship and Immigration)*, 2003 FCT 211 at para. 39, [2003] 4 F.C. 189 (see also *Khalil v. Canada (Secretary of State)*, [1999] 4 F.C. 661 (C.A.)):

> [39] In *Apotex Inc. v. Canada (A.G.)*, [1994] 1 F.C. 742 (C.A.), aff’d [1994] 3 S.C.R. 1100, the Federal Court of Appeal conducted an extensive review of the jurisprudence relating to *mandamus* and outlined the following conditions that need to be satisfied for the Court to issue a writ of *mandamus*:
>
> (1) There must be a public legal duty to act.
> (2) The duty must be owed to the applicant.
> (3) There is a clear right to the performance of that duty, in particular:
>
> (a) the applicant has satisfied all conditions precedent giving rise to the duty;
> (b) there was (i) a prior demand for performance of the duty; (ii) a reasonable time to comply with the demand unless refused outright; and (iii) a subsequent refusal which can be either expressed or implied, e.g. unreasonable delay.

(4) No other adequate remedy is available to the applicant.
(5) The order sought will be of some practical value or effect.
(6) The Court in the exercise of discretion finds no equitable bar to the relief sought.
(7) On a "balance of convenience" an order in the nature of *mandamus* should issue.

[83] The Court is of the opinion that the Minister should perform a patent -specific analysis before taking a decision as to whether or not the applicant should address one or more of the following patents: '693, '891, '377, '307 and '470 or in the alternative issue a NOC to Apotex.

[84] Thus, the Court finds that the applicant's request for a writ of *mandamus* is premature because the Minister has no legal duty at this time to issue a NOC following Apotex's SANDS.

[85] There is no evidence before this Court to undertake the patent specific analysis as did Justice Simpson in her case. Therefore, the appropriate relief is that the matter should be remitted back to the Minister to make such determination.

JUDGMENT

THIS COURT ORDERS that the Applicant's application be allowed. The matter is remitted back to the Minister to perform a patent specific analysis as mandated by the Supreme Court's decision in *AstraZeneca v. Canada (Minister of Health)*, 2006 SCC 49, [2006] 2 S.C.R. 560. The Applicant is entitled to costs by way of a lump sum of $7,500 plus disbursements and GST as agreed by the parties. Both respondents shall pay half of the costs granted.

"Michel Beaudry"
Judge

APPENDIX A

Relevant Legislation

APPENDIX A

Relevant Legislation

Food and Drug Regulations, C.R.C., c. 870, Part C:

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 or an abbreviated 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 ou une présentation abrégée de drogue nouvelle que celui-ci juge acceptable;
(b) the Minister has issued, pursuant to section C.08.004, a notice of compliance to the manufacturer of the new drug in respect of the new drug submission or abbreviated new drug submission;	b) le ministre a, aux termes de l'article C.08.004, délivré au fabricant de la drogue nouvelle un avis de conformité relativement à la présentation de drogue nouvelle ou à la présentation abrégée de drogue nouvelle;
(c) the notice of compliance in respect of the submission has not been suspended pursuant to section C.08.006; and	c) l'avis de conformité relatif à la présentation n'a pas été suspendu aux termes de l'article C.08.006;
(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.	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) A new drug submission shall contain sufficient information and material to enable the Minister to assess the safety and effectiveness of	(2) La présentation de drogue nouvelle doit contenir suffisamment de renseignements et de matériel pour permettre au ministre d'évaluer

the new drug, including the following:

l'innocuité et l'efficacité de la drogue nouvelle, notamment :

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

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

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

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

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

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

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

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

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

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

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) detailed reports of the tests made to establish the safety of the new drug for the purpose and under the conditions of use recommended;

g) les rapports détaillés des épreuves 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

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;

form in which it is proposed that the new drug be sold;

(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 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 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 considers it necessary, bioavailability characteristics;

b) elle est bioéquivalente au produit de référence canadien d'après les caractéristiques pharmaceutiques et, si le 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 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 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 paragraphs C.08.002(2)(a) to (f) and (j) to (l);

a) les renseignements et le matériel visés aux alinéas C.08.002(2)a) à f) et j) à l);

(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 the Minister considers it necessary to assess the safety and effectiveness

(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

of the new drug, with the following information and material:

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.08.003. (1) Notwithstanding section C.08.002, no person shall sell a new drug in respect of which a notice of compliance has been issued to the manufacturer of that new drug and has not been suspended pursuant to section C.08.006, if any of the matters specified in subsection (2) are significantly different from the information or material contained in the new drug submission or abbreviated new drug submission, unless

C.08.003. (1) Malgré l'article C.08.002, il est interdit de vendre une drogue nouvelle à l'égard de laquelle un avis de conformité a été délivré à son fabricant et n'a pas été suspendu aux termes de l'article C.08.006, lorsqu'un des éléments visés au paragraphe (2) diffère sensiblement des renseignements ou du matériel contenus dans la présentation de drogue nouvelle ou la présentation abrégée de drogue nouvelle, à moins que les conditions suivantes ne soient réunies :

(a) the manufacturer of the new drug has filed with the Minister

a) le fabricant de la drogue nouvelle a déposé auprès du ministre :

(i) a supplement to that new drug submission, or

(i) soit un supplément à la présentation de drogue nouvelle,

(ii) a supplement to that abbreviated new drug submission;

(ii) soit un supplément à la présentation abrégée de drogue nouvelle;

(b) the Minister has issued a notice of compliance to the manufacturer of the new drug

b) le ministre a délivré au fabricant un avis de conformité relativement au supplément;

in respect of the supplement;

(c) the notice of compliance in respect of the supplement has not been suspended pursuant to section C.08.006; and

c) l'avis de conformité relatif au supplément n'a pas été suspendu aux termes de l'article C.08.006;

(d) the manufacturer of the new drug has submitted to the Minister specimens of the final version of any label, including any package insert, product brochure and file card, intended for use in connection with the new drug, where a change with respect to any of the matters specified in subsection (2) is made that would require a change to the label.

d) le fabricant de la drogue nouvelle a présenté au ministre, sous leur forme définitive, des échantillons de toute étiquette—y compris une notice jointe à l'emballage, un dépliant et une fiche sur le produit—destinée à être utilisée pour la drogue nouvelle, dans le cas où la modification d'un des éléments visés au paragraphe (2) nécessite un changement dans l'étiquette.

(2) The matters specified for the purposes of subsection (1), in relation to the new drug, are the following:

(2) Pour l'application du paragraphe (1), les éléments ayant trait à la drogue nouvelle sont les suivants :

(a) the description of the new drug;

a) sa description;

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

b) sa marque nominative ou le nom ou code sous lequel il est proposé de l'identifier;

(c) the specifications of the ingredients of the new drug;

c) les spécifications de ses ingrédients;

(d) the plant and equipment used in manufacturing, preparation and packaging the new drug;

d) les installations et l'équipement à utiliser pour sa fabrication, sa préparation et son emballage;

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

e) la méthode de fabrication et les mécanismes de contrôle à appliquer pour sa fabrication, sa préparation et son emballage;

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

f) les analyses effectuées pour contrôler son activité, sa pureté, sa stabilité et son innocuité;

(g) the labels used in connection with the new drug;

g) les étiquettes à utiliser pour la drogue nouvelle;

(h) the representations made with regard to the

h) les observations faites relativement :

new drug respecting

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

(ii) the dosage of the new drug,

(iii) the claims made for the new drug,

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

(v) the withdrawal period of the new drug; and

(i) the dosage form in which it is proposed that the new drug be sold.

(3) A supplement to a new drug submission or to an abbreviated new drug submission, with respect to the matters that are significantly different from those contained in the submission, shall contain sufficient information and material to enable the Minister to assess the safety and effectiveness of the new drug in relation to those matters.

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,

(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

(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.

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

(ii) à sa posologie,

(iii) aux propriétés qui lui sont attribuées,

(iv) à ses contre-indications et à ses effets secondaires,

(v) au délai d'attente applicable à celle-ci;

i) sa forme posologique proposée pour la vente.

(3) Le supplément à la présentation de drogue nouvelle ou à la présentation abrégée de drogue nouvelle doit contenir, à l'égard des éléments qui diffèrent sensiblement de ce qui figure dans la présentation, les renseignements et le matériel nécessaires pour permettre au ministre d'évaluer l'innocuité et l'efficacité de la drogue nouvelle relativement à ces éléments.

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) 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) 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.

Patented Medicines (Notice of Compliance) Regulations, SOR/93-133:

4. (1) A first person who files or who has filed a new drug submission or a supplement to a new drug submission may submit to the Minister a patent list in relation to the submission or

4. (1) La première personne qui dépose ou a déposé la présentation de drogue nouvelle ou le supplément à une présentation de drogue nouvelle peut présenter au ministre, pour

supplement for addition to the register.

adjonction au registre, une liste de brevets qui se rattache à la présentation ou au supplément.

(2) A patent on a patent list in relation to a new drug submission is eligible to be added to the register if the patent contains

(2) Est admissible à l'adjonction au registre tout brevet, inscrit sur une liste de brevets, qui se rattache à la présentation de drogue nouvelle, s'il contient, selon le cas :

(a) a claim for the medicinal ingredient and the medicinal ingredient has been approved through the issuance of a notice of compliance in respect of the submission;

a) une revendication de l'ingrédient médicinal, l'ingrédient ayant été approuvé par la délivrance d'un avis de conformité à l'égard de la présentation;

(b) a claim for the formulation that contains the medicinal ingredient and the formulation has been approved through the issuance of a notice of compliance in respect of the submission;

b) une revendication de la formulation contenant l'ingrédient médicinal, la formulation ayant été approuvée par la délivrance d'un avis de conformité à l'égard de la présentation;

(c) a claim for the dosage form and the dosage form has been approved through the issuance of a notice of compliance in respect of the submission; or

c) une revendication de la forme posologique, la forme posologique ayant été approuvée par la délivrance d'un avis de conformité à l'égard de la présentation;

(d) a claim for the use of the medicinal ingredient, and the use has been approved through the issuance of a notice of compliance in respect of the submission.

d) une revendication de l'utilisation de l'ingrédient médicinal, l'utilisation ayant été approuvée par la délivrance d'un avis de conformité à l'égard de la présentation.

(3) A patent on a patent list in relation to a supplement to a new drug submission is eligible to be added to the register if the supplement is for a change in formulation, a change in dosage form or a change in use of the medicinal ingredient, and

(3) Est admissible à l'adjonction au registre tout brevet, inscrit sur une liste de brevets, qui se rattache au supplément à une présentation de drogue nouvelle visant une modification de la formulation, une modification de la forme posologique ou une modification de l'utilisation de l'ingrédient médicinal, s'il contient, selon le cas :

(a) in the case of a change in formulation, the patent contains a claim for the changed formulation that has been approved through the issuance of a notice of compliance in respect of the supplement;

a) dans le cas d'une modification de formulation, une revendication de la formulation modifiée, la formulation ayant été approuvée par la délivrance d'un avis de conformité à l'égard du supplément;

(b) in the case of a change in dosage form, the

b) dans le cas d'une modification de la forme

patent contains a claim for the changed dosage form that has been approved through the issuance of a notice of compliance in respect of the supplement; or

posologique, une revendication de la forme posologique modifiée, la forme posologique ayant été approuvée par la délivrance d'un avis de conformité à l'égard du supplément;

(c) in the case of a change in use of the medicinal ingredient, the patent contains a claim for the changed use of the medicinal ingredient that has been approved through the issuance of a notice of compliance in respect of the supplement.

c) dans le cas d'une modification d'utilisation de l'ingrédient médicinal, une revendication de l'utilisation modifiée de l'ingrédient médicinal, l'utilisation ayant été approuvée par la délivrance d'un avis de conformité à l'égard du supplément.

(4) A patent list shall contain the following:

(4) La liste de brevets comprend :

(a) an identification of the new drug submission or the supplement to a new drug submission to which the list relates;

a) l'identification de la présentation de drogue nouvelle ou du supplément à la présentation de drogue nouvelle qui s'y rattachent;

(b) the medicinal ingredient, brand name, dosage form, strength, route of administration and use set out in the new drug submission or the supplement to a new drug submission to which the list relates;

b) l'ingrédient médicinal, la marque nominative, la forme posologique, la concentration, la voie d'administration et l'utilisation prévus à la présentation ou au supplément qui s'y rattachent;

(c) for each patent on the list, the patent number, the filing date of the patent application in Canada, the date of grant of the patent and the date on which the term limited for the duration of the patent will expire under section 44 or 45 of the Patent Act;

c) à l'égard de chaque brevet qui y est inscrit, le numéro de brevet, la date de dépôt de la demande de brevet au Canada, la date de délivrance de celui-ci et la date d'expiration du brevet aux termes des articles 44 ou 45 de la Loi sur les brevets;

(d) for each patent on the list, a statement that the first person who filed the new drug submission or the supplement to a new drug submission to which the list relates is the owner of the patent or has an exclusive licence to the patent, or has obtained the consent of the owner of the patent to its inclusion on the list;

d) à l'égard de chaque brevet qui y est inscrit, une déclaration portant que la première personne qui a déposé la présentation de drogue nouvelle ou le supplément à une présentation de drogue nouvelle qui s'y rattachent en est le propriétaire, en détient la licence exclusive ou a obtenu le consentement du propriétaire pour l'inclure dans la liste;

(e) the address in Canada for service, on the first person, of a notice of allegation referred to in paragraph 5(3)(a) or the name and address in Canada of another person on whom service may

e) l'adresse au Canada de la première personne aux fins de signification de l'avis d'allégation visé à l'alinéa 5(3)a) ou les nom et adresse au Canada d'une autre personne qui peut en

be made with the same effect as if service were made on the first person; and

recevoir signification comme s'il s'agissait de la première personne elle-même;

(f) a certification by the first person that the information submitted under this subsection is accurate and that each patent on the list meets the eligibility requirements of subsection (2) or (3).

f) une attestation de la première personne portant que les renseignements fournis aux termes du présent paragraphe sont exacts et que chaque brevet qui y est inscrit est conforme aux conditions d'admissibilité prévues aux paragraphes (2) ou (3).

(5) Subject to subsection (6), a first person who submits a patent list must do so at the time the person files the new drug submission or the supplement to a new drug submission to which the patent list relates.

(5) Sous réserve du paragraphe (6), la première personne qui présente une liste de brevets doit le faire au moment du dépôt de la présentation de drogue nouvelle ou du supplément à une présentation de drogue nouvelle qui s'y rattachent.

(6) A first person may, after the date of filing of a new drug submission or a supplement to a new drug submission, and within 30 days after the issuance of a patent that was issued on the basis of an application that has a filing date in Canada that precedes the date of filing of the submission or supplement, submit a patent list, including the information referred to in subsection (4), in relation to the submission or supplement.

(6) La première personne peut, après la date de dépôt de la présentation de drogue nouvelle ou du supplément à une présentation de drogue nouvelle et dans les trente jours suivant la délivrance d'un brevet faite au titre d'une demande de brevet dont la date de dépôt au Canada est antérieure à celle de la présentation ou du supplément, présenter une liste de brevets, à l'égard de cette présentation ou de ce supplément, qui contient les renseignements visés au paragraphe (4).

(7) A first person who has submitted a patent list must keep the information on the list up to date but, in so doing, may not add a patent to the list.

(7) La première personne qui a présenté une liste de brevets doit tenir à jour les renseignements y figurant, mais ne peut toutefois y ajouter de brevets.

(8) The Minister shall insert on the patent list the date of filing and submission number of the new drug submission or the supplement to a new drug submission in relation to which the list was submitted.

(8) Le ministre inscrit sur la liste de brevets la date de dépôt et le numéro de la présentation de drogue nouvelle ou du supplément à une présentation de drogue nouvelle qui se rattache à la liste présentée.

5. (1) If a second person files a submission for a notice of compliance in respect of a drug and the submission directly or indirectly compares the drug with, or makes reference to, another drug

5. (1) Dans le cas où la seconde personne dépose une présentation pour un avis de conformité à l'égard d'une drogue, laquelle présentation, directement ou indirectement, compare celle-ci à

marketed in Canada under a notice of compliance issued to a first person and in respect of which a patent list has been submitted, the second person shall, in the submission, with respect to each patent on the register in respect of the other drug,

une autre drogue commercialisée sur le marché canadien aux termes d'un avis de conformité délivré à la première personne et à l'égard de laquelle une liste de brevets a été présentée — ou y fait renvoi —, cette seconde personne doit, à l'égard de chaque brevet ajouté au registre pour cette autre drogue, inclure dans sa présentation :

(a) state that the second person accepts that the notice of compliance will not issue until the patent expires; or

a) soit une déclaration portant qu'elle accepte que l'avis de conformité ne sera pas délivré avant l'expiration du brevet;

(b) allege that

b) soit une allégation portant que, selon le cas :

(i) the statement made by the first person under paragraph 4(4)(d) is false,

(i) la déclaration présentée par la première personne aux termes de l'alinéa 4(4)d) est fausse,

(ii) the patent has expired,

(ii) le brevet est expiré,

(iii) the patent is not valid, or

(iii) le brevet n'est pas valide,

(iv) no claim for the medicinal ingredient, no claim for the formulation, no claim for the dosage form and no claim for the use of the medicinal ingredient would be infringed by the second person making, constructing, using or selling the drug for which the submission is filed.

(iv) elle ne contreferait aucune revendication de l'ingrédient médicinal, revendication de la formulation, revendication de la forme posologique ni revendication de l'utilisation de l'ingrédient médicinal en fabriquant, construisant, utilisant ou vendant la drogue pour laquelle la présentation est déposée.

(2) If a second person files a supplement to a submission referred to in subsection (1) seeking a notice of compliance for a change in formulation, a change in dosage form or a change in use of the medicinal ingredient and the supplement directly or indirectly compares the drug with, or makes reference to, another drug that has been marketed in Canada under a notice of compliance issued to a first person and in respect of which a patent list has been submitted, the second person shall, in the supplement, with respect to each patent on the register in respect of the other drug,

(2) Dans le cas où la seconde personne dépose un supplément à la présentation visée au paragraphe (1), en vue d'obtenir un avis de conformité à l'égard d'une modification de la formulation, d'une modification de la forme posologique ou d'une modification de l'utilisation de l'ingrédient médicinal, lequel supplément, directement ou indirectement, compare celle-ci à une autre drogue commercialisée sur le marché canadien aux termes de l'avis de conformité délivré à la première personne et à l'égard duquel une liste de brevets a été présentée — ou y fait renvoi — ,

cette seconde personne doit, à l'égard de chaque brevet ajouté au registre pour cette autre drogue, inclure dans son supplément :

(a) state that the second person accepts that the notice of compliance will not issue until the patent expires; or

a) soit une déclaration portant qu'elle accepte que l'avis de conformité ne sera pas délivré avant l'expiration du brevet;

(b) allege that

b) soit une allégation portant que, selon le cas :

(i) the statement made by the first person under paragraph 4(4)(d) is false,

(i) la déclaration présentée par la première personne aux termes de l'alinéa 4(4)d) est fausse,

(ii) the patent has expired,

(ii) le brevet est expiré,

(iii) the patent is not valid, or

(iii) le brevet n'est pas valide,

(iv) no claim for the medicinal ingredient, no claim for the formulation, no claim for the dosage form and no claim for the use of the medicinal ingredient would be infringed by the second person making, constructing, using or selling the drug for which the supplement is filed.

(iv) elle ne contreferait aucune revendication de l'ingrédient médicinal, revendication de la formulation, revendication de la forme posologique ni revendication de l'utilisation de l'ingrédient médicinal en fabriquant, construisant, utilisant ou vendant la drogue pour laquelle le supplément est déposé.

(3) A second person who makes an allegation under paragraph (1)(b) or (2)(b) shall

(3) La seconde personne qui inclut l'allégation visée à l'alinéa (1)b) ou (2)b) doit prendre les mesures suivantes :

(a) serve on the first person a notice of allegation relating to the submission or supplement filed under subsection (1) or (2) on or after its date of filing;

a) signifier à la première personne un avis de l'allégation à l'égard de la présentation ou du supplément déposé en vertu des paragraphes (1) ou (2), à la date de son dépôt ou à toute date postérieure;

(b) include in the notice of allegation

b) insérer dans l'avis de l'allégation :

(i) a description of the medicinal ingredient, dosage form, strength, route of administration and use of the drug in respect of which the submission or supplement has been filed, and

(i) une description de l'ingrédient médicinal, de la forme posologique, de la concentration, de la voie d'administration et de l'utilisation de la drogue visée par la présentation ou le supplément,

(ii) a detailed statement of the legal and factual basis for the allegation;

(ii) un énoncé détaillé du fondement juridique et factuel de l'allégation;

(c) include in the material served a certification by the Minister of the date of filing of the submission or supplement; and

c) joindre à la signification une attestation par le ministre de la date du dépôt de la présentation ou du supplément;

(d) serve proof of service of the documents and information referred to in paragraphs (a) to (c) on the Minister.

d) signifier au ministre la preuve de toute signification des documents et renseignements visés aux alinéas a) à c).

(4) A second person is not required to comply with

(4) La seconde personne n'est pas tenue de se conformer :

(a) subsection (1) in respect of a patent added to the register in respect of the other drug on or after the date of filing of the submission referred to in that subsection, including a patent added under subsection 3(5); and

a) au paragraphe (1) en ce qui concerne tout brevet ajouté au registre à l'égard de l'autre drogue — y compris celui ajouté aux termes du paragraphe 3(5) — à la date de dépôt de la présentation visée au paragraphe (1) ou à toute date postérieure;

(b) subsection (2) in respect of a patent added to the register in respect of the other drug on or after the date of filing of the supplement referred to in that subsection, including a patent added under subsection 3(5).

b) au paragraphe (2) en ce qui concerne tout brevet ajouté au registre à l'égard de l'autre drogue — y compris celui ajouté aux termes du paragraphe 3(5) — à la date de dépôt du supplément visé au paragraphe (2) ou à toute date postérieure.

(5) For the purposes of subsections (3) and (4), if subsection (1) or (2) applies to a submission or supplement referred to in paragraph C.07.003(b) of the Food and Drug Regulations, if the drug to which the comparison or reference is made is an innovative drug within the meaning of subsection C.08.004.1(1) of those Regulations and if the date of filing of the submission or supplement is less than six years from the day on which the first notice of compliance was issued in respect of the innovative drug, the deemed date of filing of the submission or supplement is six years after the date of issuance of the notice of compliance.

(5) Pour l'application des paragraphes (3) et (4), si les paragraphes (1) ou (2) s'appliquent à l'égard d'une présentation ou d'un supplément à une telle présentation visés à l'alinéa C.07.003b) du Règlement sur les aliments et drogues et que la drogue faisant l'objet de la comparaison ou du renvoi est une drogue innovante, au sens du paragraphe C.08.004.1(1) du même règlement, et si la date de dépôt de la présentation ou du supplément est de moins de six ans après la date de délivrance du premier avis de conformité à l'égard de cette drogue innovante, la date de dépôt est réputée être la date qui suit de six ans celle de la délivrance.

(6) A second person who has served a notice of

(6) La seconde personne qui a signifié l'avis

allegation on a first person under paragraph (3)(a) shall retract the notice of allegation and serve notice of the retraction on the first person within 90 days after either of the following dates:

(a) the date on which the Minister notifies the second person under paragraph C.08.004(3)(b) of the Food and Drug Regulations of their non-compliance 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 of those Regulations; or

(b) the date of the cancellation by the second person of the submission or supplement to which the allegation relates.

(7) A first person who has applied for a prohibition order under subsection 6(1) in response to a notice of allegation shall, if the notice is retracted in accordance with subsection (6), apply without delay for a discontinuance of the proceedings.

6. (1) A first person may, within 45 days after being served with a notice of allegation under paragraph 5(3)(a), apply to a court for an order prohibiting the Minister from issuing a notice of compliance until after the expiration of a patent that is the subject of the notice of allegation.

(2) The court shall make an order pursuant to subsection (1) in respect of a patent that is the subject of one or more allegations if it finds that none of those allegations is justified.

(3) The first person shall, within the 45 days referred to in subsection (1), serve the Minister with proof that an application referred to in that subsection has been made.

(4) Where the first person is not the owner of

d’allégation à la première personne en vertu de l’alinéa (3)a) doit retirer celui-ci et signifier un avis du retrait à la première personne dans les quatre-vingt-dix jours qui suivent :

a) soit la date à laquelle le ministre a informé la seconde personne, aux termes de l’alinéa C.08.004(3)b) du Règlement sur les aliments et drogues, de sa non-conformité aux articles C.08.002, C.08.002.1 ou C.08.003, selon le cas, ou à l’article C.08.005.1 du même règlement;

b) soit la date de l’annulation par la seconde personne de sa présentation ou de son supplément faisant l’objet de l’allégation.

(7) La première personne qui demande une ordonnance d’interdiction en vertu du paragraphe 6(1) en réponse à l’avis d’allégation doit, dans le cas où l’avis est retiré aux termes du paragraphe (6), demander dans les plus brefs délais un désistement des procédures.

6. (1) La première personne peut, au plus tard quarante-cinq jours après avoir reçu signification d’un avis d’allégation aux termes de l’alinéa 5(3)a), demander au tribunal de rendre une ordonnance interdisant au ministre de délivrer l’avis de conformité avant l’expiration du brevet en cause.

(2) Le tribunal rend une ordonnance en vertu du paragraphe (1) à l’égard du brevet visé par une ou plusieurs allégations si elle conclut qu’aucune des allégations n’est fondée.

(3) La première personne signifie au ministre, dans la période de 45 jours visée au paragraphe (1), la preuve que la demande visée à ce paragraphe a été faite.

(4) Lorsque la première personne n’est pas le

each patent that is the subject of an application referred to in subsection (1), the owner of each such patent shall be made a party to the application.

propriétaire de chaque brevet visé dans la demande mentionnée au paragraphe (1), le propriétaire de chaque brevet est une partie à la demande.

(5) Subject to subsection (5.1), in a proceeding in respect of an application under subsection (1), the court may, on the motion of a second person, dismiss the application in whole or in part

(5) Sous réserve du paragraphe (5.1), lors de l'instance relative à la demande visée au paragraphe (1), le tribunal peut, sur requête de la seconde personne, rejeter tout ou partie de la demande si, selon le cas :

(a) in respect of those patents that are not eligible for inclusion on the register; or

a) les brevets en cause ne sont pas admissibles à l'inscription au registre;

(b) on the ground that it is redundant, scandalous, frivolous or vexatious or is otherwise an abuse of process in respect of one or more patents.

b) il conclut qu'elle est inutile, scandaleuse, frivole ou vexatoire ou constitue autrement, à l'égard d'un ou plusieurs brevets, un abus de procédure.

(5.1) In a proceeding in respect of an application under subsection (1), the court shall not dismiss an application in whole or in part solely on the basis that a patent on a patent list that was submitted before June 17, 2006 is not eligible for inclusion on the register.

(5.1) Lors de l'instance relative à la demande visée au paragraphe (1), le tribunal ne peut rejeter tout ou partie de la demande pour la seule raison qu'un brevet inscrit sur une liste de brevets présentée avant le 17 juin 2006 n'est pas admissible à l'inscription au registre.

(6) For the purposes of an application referred to in subsection (1), if a second person has made an allegation under subparagraph 5(1)(b)(iv) or (2)(b)(iv) in respect of a patent and the patent was granted for the medicinal ingredient when prepared or produced by the methods or processes of manufacture particularly described and claimed in the patent, or by their obvious chemical equivalents, it shall be considered that the drug proposed to be produced by the second person is, in the absence of proof to the contrary, prepared or produced by those methods or processes.

(6) Aux fins de la demande visée au paragraphe (1), dans le cas où la seconde personne a fait une allégation aux termes des sous-alinéas 5(1)b)(iv) ou 5(2)b)(iv) à l'égard d'un brevet et que ce brevet a été accordé pour l'ingrédient médicinal préparé ou produit selon les modes ou procédés de fabrication décrits en détail et revendiqués dans le brevet ou selon leurs équivalents chimiques manifestes, la drogue qu'elle projette de produire est, en l'absence d'une preuve contraire, réputée préparée ou produite selon ces modes ou procédés.

(7) On the motion of a first person, the court may, at any time during a proceeding,

(7) Sur requête de la première personne, le tribunal peut, au cours de l'instance :

(a) order a second person to produce any portion

a) ordonner à la seconde personne de produire

of the submission or supplement filed by the second person for a notice of compliance that is relevant to the disposition of the issues in the proceeding and may order that any change made to the portion during the proceeding be produced by the second person as it is made; and

(b) order the Minister to verify that any portion produced corresponds fully to the information in the submission or supplement.

(8) A document produced under subsection (7) shall be treated confidentially.

(9) In a proceeding in respect of an application under subsection (1), a court may make any order in respect of costs, including on a solicitor-and-client basis, in accordance with the rules of the court.

(10) In addition to any other matter that the court may take into account in making an order as to costs, it may consider the following factors:

(a) the diligence with which the parties have pursued the application;

(b) the inclusion on the certified patent list of a patent that should not have been included under section 4; and

(c) the failure of the first person to keep the patent list up to date in accordance with subsection 4(7).

les extraits pertinents de la présentation ou du supplément qu'elle a déposé pour obtenir un avis de conformité et lui enjoindre de produire sans délai tout changement apporté à ces extraits au cours de l'instance;

b) enjoindre au ministre de vérifier si les extraits produits correspondent fidèlement aux renseignements figurant dans la présentation ou le supplément déposé.

(8) Tout document produit aux termes du paragraphe (7) est considéré comme confidentiel.

(9) Le tribunal peut, au cours de l'instance relative à la demande visée au paragraphe (1), rendre toute ordonnance relative aux dépens, notamment sur une base avocat-client, conformément à ses règles.

(10) Lorsque le tribunal rend une ordonnance relative aux dépens, il peut tenir compte notamment des facteurs suivants :

a) la diligence des parties à poursuivre la demande;

b) l'inscription, sur la liste de brevets qui fait l'objet d'une attestation, de tout brevet qui n'aurait pas dû y être inclus aux termes de l'article 4;

c) le fait que la première personne n'a pas tenu à jour la liste de brevets conformément au paragraphe 4(7).

Regulations Amending the Patented Medicines (Notice of Compliance) Regulations, SOR/2006-242:

TRANSITIONAL PROVISIONS

DISPOSITIONS TRANSITOIRES

7. (1) Subsection 5(1) of the *Patented Medicines (Notice of Compliance) Regulations*, as enacted by section 2 of these Regulations, applies to a second person who has filed a submission referred to in subsection 5(1) prior to the coming into force of these Regulations and the date of filing of the submission is deemed to be the date of the coming into force of these Regulations.

(2) Subsection 5(2) of the *Patented Medicines (Notice of Compliance) Regulations*, as enacted by section 2 of these Regulations, applies to a second person who has filed a supplement to a submission referred to in subsection 5(2) prior to the coming into force of these Regulations and the date of filing of the supplement is deemed to be the date of the coming into force of these Regulations.

7. (1) Le paragraphe 5(1) du *Règlement sur les médicaments brevets (avis de conformité)*, édicté par l'article 2 du présent règlement, s'applique à toute seconde personne qui a déposé la présentation visée à ce paragraphe avant l'entrée en vigueur du présent règlement, et la date de dépôt de cette présentation est réputée être la date d'entrée en vigueur du présent règlement.

(2) Le paragraphe 5(2) du *Règlement sur les médicaments brevetés (avis de conformité)*, édicté par l'article 2 du présent règlement, s'applique à toute seconde personne qui a déposé le supplément à une présentation visée à ce paragraphe avant l'entrée en vigueur du présent règlement, et la date de dépôt de ce supplément est réputée être la date d'entrée en vigueur du présent règlement.

Patent Act, R.S., 1985, c. P-4:

55.2 (1) It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product.

(2) and (3) [Repealed, 2001, c. 10, s. 2]

(4) The Governor in Council may make such regulations as the Governor in Council considers necessary for preventing the infringement of a patent by any person who makes, constructs, uses or sells a patented invention in accordance with subsection (1), including, without limiting the generality of the foregoing, regulations

55.2 (1) Il n'y a pas contrefaçon de brevet lorsque l'utilisation, la fabrication, la construction ou la vente d'une invention brevetée se justifie dans la seule mesure nécessaire à la préparation et à la production du dossier d'information qu'oblige à fournir une loi fédérale, provinciale ou étrangère réglementant la fabrication, la construction, l'utilisation ou la vente d'un produit.

(2) et (3) [Abrogés, 2001, ch. 10, art. 2]

(4) Afin d'empêcher la contrefaçon d'un brevet d'invention par l'utilisateur, le fabricant, le constructeur ou le vendeur d'une invention brevetée au sens du paragraphe (1), le gouverneur en conseil peut prendre des règlements, notamment :

(a) respecting the conditions that must be fulfilled before a notice, certificate, permit or other document concerning any product to which a patent may relate may be issued to a patentee or other person under any Act of Parliament that regulates the manufacture, construction, use or sale of that product, in addition to any conditions provided for by or under that Act;

a) fixant des conditions complémentaires nécessaires à la délivrance, en vertu de lois fédérales régissant l'exploitation, la fabrication, la construction ou la vente de produits sur lesquels porte un brevet, d'avis, de certificats, de permis ou de tout autre titre à quiconque n'est pas le breveté;

(b) respecting the earliest date on which a notice, certificate, permit or other document referred to in paragraph (a) that is issued or to be issued to a person other than the patentee may take effect and respecting the manner in which that date is to be determined;

b) concernant la première date, et la manière de la fixer, à laquelle un titre visé à l'alinéa a) peut être délivré à quelqu'un qui n'est pas le breveté et à laquelle elle peut prendre effet;

(c) governing the resolution of disputes between a patentee or former patentee and any person who applies for a notice, certificate, permit or other document referred to in paragraph (a) as to the date on which that notice, certificate, permit or other document may be issued or take effect;

c) concernant le règlement des litiges entre le breveté, ou l'ancien titulaire du brevet, et le demandeur d'un titre visé à l'alinéa a), quant à la date à laquelle le titre en question peut être délivré ou prendre effet;

(d) conferring rights of action in any court of competent jurisdiction with respect to any disputes referred to in paragraph (c) and respecting the remedies that may be sought in the court, the procedure of the court in the matter and the decisions and orders it may make; and

d) conférant des droits d'action devant tout tribunal compétent concernant les litiges visés à l'alinéa c), les conclusions qui peuvent être recherchées, la procédure devant ce tribunal et les décisions qui peuvent être rendues;

(e) generally governing the issue of a notice, certificate, permit or other document referred to in paragraph (a) in circumstances where the issue of that notice, certificate, permit or other document might result directly or indirectly in the infringement of a patent.

e) sur toute autre mesure concernant la délivrance d'un titre visé à l'alinéa a) lorsque celle-ci peut avoir pour effet la contrefaçon de brevet.

FEDERAL COURT

NAME OF COUNSEL AND SOLICITORS OF RECORD

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