Date: 20070320

Docket: T-165-07

Citation: 2007 FC 300

BETWEEN:

FERRING INC.

Applicant

and

THE MINISTER OF HEALTH, APOTEX INC.
and NOVOPHARM LIMITED

Respondents

and

Docket: T-2188-06

BETWEEN:

SANOFI-AVENTIS CANADA INC.

Applicant

and

THE MINISTER OF HEALTH,
THE ATTORNEY GENERAL OF CANADA
and NOVOPHARM INC.

Respondents

and

Docket: T-2189-06

BETWEEN:

SANOFI-AVENTIS CANADA INC.

Applicant

and

THE MINISTER OF HEALTH,
THE ATTORNEY GENERAL OF CANADA
and APOTEX INC.

Respondents

and

Docket: T-2196-06

BETWEEN:

SANOFI-AVENTIS CANADA INC.

Applicant

and

THE MINISTER OF HEALTH,
THE ATTORNEY GENERAL OF CANADA
and APOTEX INC.

Respondents

and

Docket: T-2220-06

BETWEEN:

NOVOPHARM LIMITED

Applicant

and

**THE MINISTER OF HEALTH,
THE ATTORNEY GENERAL OF CANADA
and SANOFI-AVENTIS CANADA INC.**

Respondents

AMENDED REASONS FOR JUDGMENT

HUGHES J.

[1] These reasons pertain to five separate applications for judicial review argued consecutively, all of which deal with actions taken by the Minister of Health following the release of the decision of the Supreme Court of Canada in *AstraZeneca Canada Inc. v. Canada (Minister of Health),* [2006] 2 S.C.R. 560, 2006 S.C.C. 49, on November 3, 2006 (*AstraZeneca*).

[2] The core subject matter is the interpretation and application of the *Patented Medicines (Notice of Compliance) Regulations* SOR/93-133 as periodically amended (*NOC Regulations*) and in particular, section 5(1) of those Regulations. There is no doubt that the *AstraZeneca* decision had a profound effect on this subject. Influenced by that decision the Minister issued Notices of Compliance (NOC) to each of two generic drug companies Apotex Inc. and Novopharm Limited notwithstanding patents listed by innovator drug companies Ferring Inc. and Sanofi-Aventis Canada

Inc. In one instance the Minister would not issue an NOC and required Novopharm to address two patents in the context of section 5 of the *NOC Regulations*. The result of the Minister's actions is that Ferring, Sanofi-Aventis and Novopharm have brought judicial review applications in this Court seeking relief including the quashing of the decisions made against their interests and for directions to the Minister to take steps more favourable to their interests.

[3] For the reasons that follow, I find that all applications are to be dismissed, each party to bear its own costs.

History of the *NOC Regulations*

[4] The arcane nature of NOC proceedings makes it too easy to lose perspective as to the objectives of the *NOC Regulations*, their purpose and intent. The Supreme Court has offered guidance in this respect in three decisions, *AstraZeneca supra*, *Bristol-Myers Squibb Co. v. Canada (Attorney General)* [2005], 1 S.C.R. 533 (*Biolyse*), and *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)* (1998), 80 C.P.R. (3rd) 368 (*Merck Frosst*). The Federal Court of Appeal and this Court have extensively dealt with cases under the *NOC Regulations*.

[5] It is useful to begin with the *Food and Drug Regulations* C.R.C. C. 870, Part C, enacted under the provisions of the *Food and Drug Act* R.S.C. 1985, c. F-27. The objective of that Act is to bring safe and effective medicines to market so as to advance the nation's health; the law governing approval of new drugs is to ensure the safety and effectiveness of the new drugs before they can be put on the market (*AstraZeneca*, paragraph 12).

[6] An innovator drug company seeking to bring a new drug to market in Canada incurs costs not only in the research and development leading to the drug, but in the trials and testing required by the Minister in order to satisfy him that the drug is safe and effective. There is no question that in almost every instance the cost, effort and time involved are considerable, although Canada is not the only country requiring government approval of this kind and much of this cost may be spread out over several countries.

[7] The innovator company will seek approval to sell its drug in Canada, called a Notice of Compliance (NOC), by filing with the Minister a New Drug Submission (NDS). Once an NOC has been obtained, the innovator will be required to make any supplemental filings by way of a Supplemental New Drug Submission (S/NDS). Such supplemental filings may deal with a broad range of matters both administrative and technical such as name changes, merger of corporations, change in manufacturing circumstances and changes to the drug itself (*AstraZeneca*, paragraph 19).

[8] The Food and Drug legislation contemplates another body of drug companies often called generics. They seek to bring to the market in Canada what are called by the innovators "copy-cat" versions of approved drugs. The *Food and Drug Regulations* provide in section C.08.002.1 that a generic may file what is called an Abbreviated New Drug Submission (ANDS) in which the generic is only required to demonstrate that it proposes to bring to market in Canada a drug that is pharmaceutically equivalent (defined in section c.08.001.1) and bioequivalent (not defined) to the Canadian reference product. In so demonstrating, Parliament reasoned, the generic will have shown

that its drug will be equally safe and effective as the original (*AstraZeneca*, paragraph 24). Thus, the generic will not have had to expend the considerable costs in research that the innovator was required to do (*Biolyse*, paragraphs 6 and 7).

[9] The *Food and Drug Regulations* define a "Canadian reference product" in section 08.001.1 as a drug in respect of which an NOC has been granted and is marketed in Canada; where the drug is no longer marketed or for any other reason, the Minister can approve as acceptable some other drug. In the Ferring proceeding before this Court the Minister found that a drug acquired by Novopharm in the United Kingdom was acceptable. In oral argument, Ferring's counsel raised some question as to the provenance of this drug, however, this issue was not raised as an issue in its memorandum of argument or in its Notice of Application and therefore was not properly before the Court. In any event, this kind of decision is one which clearly lies with the discretion of the Minister, not the Court.

[10] Section 08.001.1 of the *Food and Drug Regulations* defines "pharmaceutical equivalent" as a new drug that, in comparison with another drug, contains identical amounts of the identical medicinal ingredients, in comparable dosage forms, but does not necessarily contain the same non-medicinal ingredients (sometimes called excipients).

[11] The *Food and Drug Regulations* do not define bioequivalence, however, all parties are agreed that in most instances this is a measure of how much of the medicinal ingredient is found in the bloodstream of a person measured over certain intervals after the medicine has been

administered. If the "profile" thus obtained is identical, within appropriate limits, as between drugs that are compared, these drugs are said to be bioequivalent. In some cases, such a test is unnecessary, for instance where the drug is administered directly into the bloodstream by injection or intended for topical application only, such as eye drops.

[12] The *Food and Drug Regulations* section C.08.004.1 provide a delay such that prior to October 5, 2006, the Minister was prohibited from issuing a NOC to a generic in respect of certain types of drugs before five years after the innovator receives its NOC. After October 5, 2006 the generic cannot apply for an NOC in respect of certain types of drugs until six years after the innovator received its NOC and the generic cannot get its NOC for at least two years after that.

[13] The Minister, upon receipt of an ANDS from a generic, is required only to examine the information provided by the generic as to the pharmaceutical equivalence and bioequivalence of its proposed drug to that of the innovator. There is no requirement that the Minister examine the data previously filed by the innovator in support of its NOC (*Bayer Inc. v. Canada (Attorney General)* (1999), 87 C.P.R.(3d) 293 (F.C.A.)). Once the Minister is satisfied as to pharmaceutical equivalence and bioequivalence the Minister has a duty to issue an NOC to the generic without delay (*Apotex Inc. v. Canada (Attorney General)*, [1994] 1 F.C. 742 (C.A.).

[14] At this point consideration must turn to the *NOC Regulations*. These Regulations lie at the intersection of the *Food and Drug Act* whose objective is to bring safe and effective drugs to the Canadian market, and the *Patent Act*, R.S.C. 1985, c.P-4 which seeks to award a temporary

monopoly to innovators who disclose their invention to the public (*AstraZeneca*, paragraph 12). It has been said that perhaps these Regulations were too hastily formulated and do not cover procedural problems which might well have been foreseen in this field of intensive competition (*Schering Canada Inc. v. Nu-Pharm Inc.* (1996), 68 C.P.R. (3d) 332 (F.C.).

[15] The *NOC Regulations* were introduced in 1993. Prior to that time Canada had a compulsory licence scheme, whereby upon making certain showings, a person could obtain a compulsory licence from the Commissioner of Patents to work in Canada inventions covered by a patent directed to a food or medicine. Compulsory licences were dropped in 1993 and replaced by the *NOC Regulations* (*Biolyse*, paragraphs 6 to 12). The Regulations are modelled rather imperfectly upon similar provisions in the United States under the *Hatch-Waxman Act*, Pub. L. No. 98-417, 98 Stat. 1585 (1984) codified as amended at 21 U.S.C.A. § 355 and 35 U.S.C.A. § 271(e) (1994), 180 A.L.R. Fed. 487 (officially cited as *Patent Laws and Drug Price Competition and Patent Term Restoration Act of 1984*).

[16] The Supreme Court in *AstraZeneca* has taken great pains to remind us that the *NOC Regulations* were enacted pursuant to section 55.2(4) of the *Patent Act* R.S.C. 1985, c.P-4, whose purpose was to permit early working of a patented invention by persons such as generic drug companies for the purpose of obtaining regulatory approval for their drugs so that they could enter the market at an appropriate time (*AstraZeneca*, paragraphs 15, 16 and 38). As stated in *Biolyse*, paragraph 50, Parliament recognized that early working provisions could be abused thus created a balance designed to strengthen the hand of patent owners against generic competitors.

[17] An earlier statement by the Supreme Court in *Merck Frosst* at paragraph 30 that the purpose of the *NOC Regulations* was simply to prevent patent infringement by delaying the issuance of an NOC until such time as their implementation in would not result in such infringement must be tempered by what has been said by that Court in *Biolyse* and *AstraZeneca* recited above. As stated in *Biolyse* at paragraph 53, it is not every use of a patented invention that will trigger *NOC Regulations*.

[18] With the objects of the *NOC Regulations* in mind, the procedure established shows that the Minister and two other parties are from time to time engaged in the process. One party is identified as a "first person" who is defined in section 2 and 4(1) of the Regulations as "a person who files or has filed a submission for, or has been issued an NOC …". This person is sometimes called the "innovator" or "brand" drug company and, as provided in section 4(2)(c) of the Regulations can be the owner of a pertinent patent or a licencee thereof, or simply be a person who has the patent owner's consent to deal with the patent in respect of the Regulations.

[19] The other party is called a "second person' and is defined in section 2 of the Regulations with reference to section 5(1). This definition is the nub of the disputes now before this Court. It is repeated in full. This definition was changed by amendments effective October 5, 2006 therefore the old and new versions are set out:

Old Version

5.(1) Where a person files or has filed a submission for a	*5.(1) Lorsqu'une personne dépose ou a déposé une*

notice of compliance in respect of a drug and compares that drug with, or makes reference to, another drug for the purpose of demonstrating bioequivalence on the basis of pharmaceutical and, where applicable, bioavailability characteristics and that other drug has been marketed in Canada pursuant to a notice of compliance issued to a first person and in respect of which a patent list has been submitted, the person shall, in the submission, with respect to each patent on the register in respect of the other drug.	*demande d'avis de conformité pour une drogue et la compare, ou fait référence, à une autre drogue pour en démontrer la bioequivalence d'après les caractéristiques pharmaceutiques et, la cas echeant, les caracteristiques en malibre de biodisponibilité, cette autre drogue ayant été commercialisée au Canada aux termes d'un avis de conformité délivré à la première personne et à l'égard de laquelle une liste de brevets a été soumise, elle doit inclure dans la demande, à l'égard de chaque brevet inserit au registre qui se rapporte à cette autre drogue :*
…	…

New Version

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 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,	*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 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 :*

… …

[20] Sometimes a “second person” is simply referred to as a “generic” however one must be careful, particularly in the circumstances of these proceedings, not to interchange those words too readily. The issue here is whether and when a “generic” becomes a “second person” as defined the the *NOC Regulations*.

[21] At this point consideration is given to section 7(1) of the transitional provisions included in the October 5, 2006 amendments to the Regulations as that section purports to affect section 5(1). It states:

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.*	*7. (1) Le paragraphe 5(1) 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 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.*

[22] The full impact of the changes to section 5(1) brought about by the October 5, 2006 amendments does not need to be addressed here since the issue in these proceedings is whether or not the particular generic at issue was a “second person’ in the circumstances of events occurring

before October 5, 2006. If the generic was not a "second person" then section 5(1) was never engaged, thus the transitional provisions are of no effect. If the generic was a "second person" then it was such a person well before October 5, 2006 and would have had to take the steps provided for by that section well before that time in any event.

[23] The process devised by the *NOC Regulations* begins with section 3(1) (of the old Regulations, it is now section 3(2), the wording is similar). That section provides for a Register upon which patents may be listed by a "first person". That section imposes a duty on the Minister not only to maintain that list, but to determine what patents may go on the list and to remove patents that have been listed improperly. That is a particular duty imposed on the Minister (*Novopharm Ltd. v. Canada (Minister of National Health and Welfare)* (1998), 78 C.P.R. (3d) 54 (FC) at paragraph 19). At this stage a generic has no role. A generic cannot compel the Minister to list or de-list a patent (*Apotex Inc. v. Canada (Minister of National Health and Welfare*), (2000), 3 C.P.R. (4th) 1 (F.C.A.)). Where an innovator challenges the Minister's decision in Court a generic has not been allowed to intervene (*Warner-Lambert Canada Inc. v. Canada (Minister of Health*), (2000), 8 C.P.R. (4th) 302 (F.C.)). At this stage a listing does not affect any particular generic.

[24] The criteria as to whether a patent is to be listed or not are set out in section 4 of the Regulations. There are a number of criteria, the most important of which for purposes of this discussion is that the patent contains a claim for the medicine or use of the medicine for which the particular NOC was granted, section 4(2)(b) of the pre-October 5, 2006 (post October 5, 2006,

Regulations section 4(2) speak of a medicinal ingredient or use of a medicinal ingredient – the distinction is not relevant here).

[25] There has been much jurisprudence discussing the nature and extent to which a link between the medicine or use provided for in the innovator's NOC must correspond to the innovation claimed in the patent sought to be listed. It need not be reviewed here. The important point to make is that there may be several NOCs respecting a drug and patents are listed as against a particular NOC.

[26] Once a patent is listed, the Minister places any application for an NOC sought by a generic in respect of the innovator's particular NOC corresponding to that list, on "patent hold". That is, the Minister will not further process the generic's application until the generic has successfully dealt with the listed patents in some way contemplated by the *NOC Regulations*, or those patents expire, or, as *AstraZeneca* points out, the generic can demonstrate that it is not a "second person" as described in the Regulations and thus does not need to address the patents at all.

[27] Previous to the decision of the Supreme Court in *AstraZeneca supra*, the practice has been that the generic would send to the listing party (the first party) a letter, usually called a notice of allegation (NOA). That notice would raise one or more of the grounds for allegation set out in section 5 of those Regulations. In brief, the grounds are:

1. the generic will wait until the patent expires;
2. the listing party was not the person entitled to list the patent;
3. the patent has expired;

4. the patent is not valid;

5. the patent will not be infringed.

[28] There is no specific provision in section 5 whereby a generic can allege, in its notice to the innovator, that the patent should not have been listed in the first place or that the generic is not required to address the patents listed at all.

[29] The innovator, upon receiving a notice of allegation can do nothing, in which case, after 45 days have expired, the Minister is free to grant an NOC to the generic. Doing nothing, or even losing proceedings subsequently instituted does nothing to impair the innovator's ability to commence and pursue an ordinary patent infringement action. The innovator may, alternatively, choose to institute proceedings under the provisions of section 6 (1) of the *NOC Regulations*. Those proceedings may engage some or all of the listed patents and some or all of the allegations raised by the generic. It is the choice of the innovator at that point.

[30] While the Minister has a duty to issue an NOC promptly under the *Food and Drug Regulations*, section 7 of the *NOC Regulations* require the Minister to wait for up to 24 months before issuing such an NOC unless it is shown that the innovator has done nothing for 45 days or that the proceedings instituted by the innovator have been concluded in favour of the generic. This is a legislated stay, it is not imposed by the Court order, it is imposed by the Regulations. In *Merck Frosst* the Supreme Court of Canada at paragraph 33 described such a stay as "draconian".

[31] Once proceedings are instituted, which in this Court is by way of a Notice of Application naming the Minister and generic as respondents, the generic may, under section 6 (5) (a) of the *NOC Regulations* move to strike the proceedings on the basis that an asserted patent should never have been listed in the first place. This is the first opportunity specifically given to the generic for doing so. Section 6 (5) (b) permits the generic to move to strike the proceedings for abuse and the like.

[32] Thus it would appear that a generic must wait until proceedings are commenced before it can engage the issue as to whether the patent should have been listed at all having regard to the provisions of section 4 of the *NOC Regulations*. As discussed, the jurisprudence indicates that a generic cannot compel the Minister directly to de-list a patent nor intervene in proceedings respecting listings brought by the innovator.

[33] The *AstraZeneca* decision, *supra* has brought a new dimension to this procedure. It has held that a generic need not address at all certain listed patents under certain circumstances.

Understanding AstraZeneca

[34] Before considering the meaning and effect of the decision of the Supreme Court of Canada in *AstraZeneca*, it is necessary to consider the processes involved in obtaining an NOC under the *Food and Drug Regulations* and the listing of patents under the *NOC Regulations*.

[35] Under the *Food and Drug Regulations* an innovator will, on seeking an NOC to market a new drug in Canada, file a great deal of information with the Minister respecting that drug's safety and effectiveness. In time, after much discussion, Ministerial approval may be given and an NOC issued. That NOC is indexed under the trade name for the drug; here in the case of Sanofi-Aventis, it is ALTACE, and in the case of Ferring, it is DDAVP. A file number is given to the submission for an NOC; however, that number can change in given circumstances. In considering the submissions the Minister refers to the subject as a "drug product" which, in accordance with the Minister's policy statements, is a term used to describe a collection of attributes concerning the drug itself, the uses for which the drug is approved and its packaging and labelling including a product monograph.

[36] The NOC that is issued will specify the manufacturer (not necessarily the actual maker but the source of the drug for the Canadian market-place), the active ingredient(s), the trade name, the permitted uses (indications) for the drug, dosage strength (e.g. 5 mg or 10 mg, etc.) and dosage form (e.g. tablets, capsules, parenteral, etc.) It is to be noted that what is not specified in the NOC itself are things like what are the non-medicinal ingredients (excipients), how the drug is actually made, or how the purity of the drug is tested.

[37] Labelling, which the Minister considers to include packaging, labels and the product monograph, is attached to the NOC. The product monograph is a document of a few score of pages, available to the public, including health professionals, that contains a great deal of technical information about the drug, specifications of the active ingredient(s), the excipients, instructions for use, precautions, certain test data and references to source material.

[38] From time to time changes are made to the drug labelling, conditions of manufacture, corporate structure of the manufacturer, uses approved for the drug and other matters. The Minister is to be kept advised as to these changes. Some changes are considered relatively trivial and the innovator simply gives notice of the change to the Minister. Other changes are considered more important and the innovator must give notice to the Minister and receive approval before making them. The most important of these changes require that a new NOC be issued before the changes can be made. Section C.08.003(2) of the *Food and Drug Regulations* sets out these changes that require a new NOC. They are:

C.08.003. (2) The matters specified for the purposes of subsection (1), in relation to the new drug, are the following:	*C.08.003. (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	*c) les spécifications de ses*

ingredients of the new drug;	*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 new drug respecting	*h) les observations faites relativement :*
(i) the recommended route of administration of the new drug,	*(i) à la voie d'administration recommandée pour la drogue nouvelle,*

[39] Some changes, such as change of name, have no effect on the drug itself. Other changes, such as changes to a method of manufacture, have potential to change the drug itself. Yet other changes, such as changes in use of the drug, do not affect the drug itself but serve to expand or vary the market for the drug. The Minister, in looking at such changes, may say that the “drug product”

(i.e. drug plus use plus packaging) has changed, but the fact remains that the chemistry of the "drug" has not.

[40] A new NOC will issue when changes occur in the areas listed in section C.08.003(2) of the Regulations set out above. Where the change is one where the manufacturer has changed or corporate entity merged or the like has happened, the file number of the NOC may change. The new NOC will bear the date of issue and certain information such as changed indications, or changed labelling or product monograph. Each new NOC is considered to incorporate all previous NOCs issued for the drug, together with the new changes.

[41] Turning to the *NOC Regulations*, they permit an innovator or its nominee to list certain patents on a Register kept by the Minister. Those are the patents that a "second person" must at a later time address. Section 4(3) of the Regulations states that the innovator must submit such a list at the time that it files a submission for an NOC. It is to be noted that any NOC submission that will serve to provide a vehicle for providing a patent list. Thus, a submission for a simple name change has been used to submit a new patent to be listed.

[42] Sections 4(4) and 4(5) of the *NOC Regulations*, as they stood pre-October 5, 2006, also permitted patents that had not yet been issued to be added to the patent list provided that the patent had been applied for before the particular NOC submission had been filed and the patent is added within 30 days from its issuance. Since there can be many NOCs in respect of a drug, section 4(5)

requires that where patents are added, the innovator must specify the particular NOC to which the patents are to apply.

[43] Another complexity must be added. Canada adheres to international conventions and treaties respecting patents, including the Paris Convention and the Patent Co-Operation Treaty (PCT). In accordance with the Convention, a party may file a preliminary patent application in a member country and, within a year, file a more substantial application and, if there is identical subject matter with the earlier application, a “priority” can be claimed for that subject matter, the effect of which would be to make certain public disclosures by third parties irrelevant for purposes of novelty or obviousness. The substantive patent application can be filed under the provisions of the PCT, which means that only one filing in one patent office takes place, usually in the United States, Europe or Japan. The applicant then receives a period of up to about three years in which it can file separate patent applications in all or whichever of the 130 or so member countries of the PCT it chooses. Canada is one such country. If an application is filed in a member country (called entering the national phase), the application is given an effective filing date of the original PCT filing. Thus, a third party will not know for up to three years whether a patent application has actually been filed in Canada but, when it is filed, the application is deemed to have been filed up to three years ago. For NOC purposes then, under section 4(4), a filing date of the patent application that precedes the NOC submission date can be deemed even though the actual filing date in Canada was later, the deemed filing date was earlier according to PCT obligations.

[44] Once the patent application is filed with the Canadian Patent Office, it is to be published within 18 months of its Canadian filing date. If that date is the deemed PCT filing date, then publications can be deemed to have occurred 18 months from the deemed filing date. As of the date of publication, actual or deemed, a conditional right to receive reasonable compensation arises which crystallizes only if a patent is actually granted with claims that are essentially identical to those of the published application (section 55(1)(b) of the *Patent Act*). A third person such as a generic could be liable for "infringement" if it sold a drug as claimed in the patent application at any time after the publication date but only if and when the patent issued with such a claim.

[45] A person applying for a patent in Canada can control, to a large measure, the speed with which a patent application proceeds through the Patent Office. An application will not be examined until the applicant requests it (*Patent Act*, section 35(1)). Responses to requests made by the examiner can be made quickly or slowly, extensions of time can be requested (*Patent Rules*, s. 26) and early examinations can be requested (*Patent Rules*, s. 28). Thus, a potential patent infringer may be left in doubt for a long time as to whether there will be a patent at all and if so, when and what it will claim. In the case of some of the Sanofi-Aventis patents at issue here, the evidence shows that it took some 10 years after the deemed Canadian application date before the patents were issued.

[46] This rather long narrative of the patent process was necessary since much of the argument about the *AstraZeneca* decision has to do with "early working" of a potential invention. As can be seen, there are many unknowns involved as to if and when a patent will issue and if and when it could be placed on a patent list under the *NOC Regulations* and, if so, as against which NOC. The

issue has properly been defined as a “minefield” for a generic seeking to enter the market. The only truly relevant time for considering a patent is the date when it is listed against an NOC. Even then, as will be considered later, there may be a retroactive effect.

[47] Turning to the *AstraZeneca* decision, it is the third decision given by the Supreme Court of Canada dealing with the relatively narrow and arcane field of the *NOC Regulations*. That Court started with the case of *Merck Frosst* where at paragraph 33 of its Reasons, the statutory freeze imposed by those Regulations was described as “draconian”:

> *33.* *There may be good policy reasons for the operation of the regulatory scheme in this fashion. However, it would be manifestly unjust to subject generic drug producers to such a draconian regime without at least permitting them to protect themselves and reduce the length of the presumptive injunction by initiating the NOC process as early as possible. As I have already said, this is not inconsistent with s. 6(2) of the Regulations, which provides only that the court shall make an order of prohibition "if it finds that none of those allegations is justified" a finding which can only be made, at the earliest, on the date of hearing. Thus, an application could properly be rejected by the Federal Court as premature if the allegation made in its support is not justified at that time. This is sufficient, in my view, to discourage inappropriately premature applications. On the other hand, to interpret the Regulations in the manner urged by the respondents would effectively be to require generic drug producers to satisfy all requirements in s. 5 and then to wait up to an additional 30 months before marketing the desired product. This cannot be what was intended by the Regulations.*

[48] Eight years later the Supreme Court considered the *NOC Regulations* in *Biolyse*, *supra*. In *Biolyse* the Court explained that the *NOC Regulations* were enacted so as to permit “early working”

of a patent invention respecting a drug by permitting generics to obtain an NOC to enter the market when a patent expired and the permitted stockpiling during the term of the patent (now no longer a permitted exemption). These provisions provided to the innovator companies remedies in addition to the usual remedies under the *Patent Act*. The Court said, at paragraphs 11 and 12 of *Biolyse*:

> *11. However, having agreed to respect the 20-year monopoly granted by patents, Parliament wished to facilitate the entry of competition immediately thereafter. It acted to eliminate the usual regulatory lag of two years or more after expiry of a patent for the generic manufacturer to do the work necessary to obtain a NOC. Parliament did so by introducing an exemption from the owner's patent rights under which the generic manufacturers could work the patented invention within the 20-year period ("the early working exception") to the extent necessary to obtain a NOC at the time the patent(s) expired (s. 55.2(1)) and to "stockpile" generic product towards the end of the 20-year period to await lawful market entry (s. 55.2(2)). In order to prevent abuse of the "early working" and "stockpiling" exceptions to patent protection, the government enacted the* NOC Regulations *that are at issue in this appeal.*
>
> *12. The patent owner's remedies under the* NOC Regulations *are* in addition *to all of the usual remedies for patent infringement under the* Patent Act.

[49] One year later, the Supreme Court again addressed the *NOC Regulations* in *AstraZeneca*. At paragraph 15 of its Reasons the Court reiterated what it said in *Biolyse*, the Regulations are directed at preventing infringement by those who choose to take advantage of the “early working” provisions of section 55.2(4)d) of the *Patent Act*:

> *15. Recognizing that the "early working" and "stockpiling" exceptions could be abused, Parliament balanced creation of these exceptions with implementation of a summary procedure designed to strengthen the protection of patent owners against generic competitors* within *the 20-year patent period. The legislative solution is found in s. 55.2 of the* Patent Act *as follows:*

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. [The "early working" exception.]*

(2) It is not an infringement of a patent for any person who makes, constructs, uses or sells a patented invention in accordance with subsection (1) to make, construct or use the invention, during the applicable period provided for by the regulations, for the manufacture and storage of articles intended for sale after the date on which the term of the patent expires. [The "stockpiling" exception.]

(3) The Governor in Council may make regulations for the purposes of subsection (2), but any period provided for by the regulations must terminate immediately preceding the date on which the term of the patent expires.

(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) or (2) including, without limiting the generality of the foregoing, regulations

(a) respecting the conditions that must be fulfilled before a notice [e.g. of compliance] ... may be issued ...

(b) respecting the earliest date on which a notice [e.g. of compliance] ... may take effect ...

(c) governing the resolution of disputes between a patentee or former patentee and any person who applies for a notice [e.g. of compliance] ... as to the

> *date on which that notice ... may be issued or take effect.*
>
> *The grant of the regulation-making power in s. 55.2(4) is thus expressly limited to prevention of infringement by a person who takes advantage of the "early working" exception (s. 55.2(1)) or (until its repeal) the stockpiling exception (s. 55.2(2)).*

[50] The Court set out the issue presented by the generic (Apotex) at paragraph 18. If the generic was not in the position to "early work" a patent, how could it be subject to the Regulations at all:

> *18. If, as Apotex says, it did not have the advantage of an "early working" of the after-listed 037 and 470 patents, because they came too late and were not incorporated in any product available to Apotex to copy, it is difficult to see in principle why in respect of* those *patents Apotex should be subject to the* NOC Regulations *regime, with a consequent further delay of two years, and perhaps longer. The Apotex submission has already been pending since April 27, 1993.*

[51] The Court reviewed the provisions of section 4(5) of the *NOC Regulations* which permit a later issued patent to be based against a specific NOC. The linkage between the patent and a specific NOC was emphasized at paragraph 21:

> *21. I emphasize the words in s. 4(5) that in the case of patents added afterwards, "the first person must identify the submission to which the patent list or the amendment relates, including the date on which the submission was filed". In addition, s. 3(3) provides that "[n]o information submitted pursuant to section 4 shall be included on the register until after the issuance of the notice of compliance in respect of which the information was submitted". These provisions, it seems to me, provide an important key to understanding the scheme. Entry of the "Patent list" does not destroy the linkage between the patent and the submission(s) to which it relates, nor to the NOC to which the submission(s) are directed. Specific patents are associated with one or more NDS, ANDS or SNDS, which in turn (if approved) give rise to specific NOCs, which in turn approve a specific manufacturer's product, which a generic manufacturer may*

> *seek to copy. There is no linkage between the 037 and 470 patents and the submissions that lead to the* Losec 20 *product copied by Apotex. Those after-acquired patents were listed in relation to a SNDS dated January 22, 1999 by AstraZeneca for a new medical use for* Losec 20 *(treatment of* H. Pylori*), a use for which the Apotex product is* not *approved, and to an administrative SNDS submitted by AstraZeneca dated July 12, 2000, which submission has nothing at all to do with the technology incorporated in* Losec 20.

[52] At paragraph 22, the Court recognized that several lists in respect of several NOCs could exist. The question was to identify which NOC, therefore which list, was pertinent to the product that the generic copied:

> *22. Thus understood, the s. 4(1) patent list in relation to a medication that goes through various stages of development may become over time a list of lists, or lists within a list. Section 4(5) ensures the Minister's ability to identify the precise patents relevant to the "early working" by a generic manufacturer of its copy-cat product. This identification is important heaving regard to the limited purposes for which the* NOC Regulations *are authorized by s. 55.2(4) of the* Patent Act.

[53] The concluding sentence of paragraph 23 of the Reasons reinforces the linkage of a particular patent list to a particular NOC:

> *23. … It is not to be presumed that s. 4(5) of the* NOC Regulations *insisted on linking particular patents to particular submissions for no purpose.*

[54] This linkage is important in considering what generation of the innovator's drug the generic wishes to copy. As stated by the Supreme Court, at the last sentence of paragraph 28 of its Reasons:

> *28.* … *If Apotex claims bioequivalence with* Losec 20 *it is important to be precise about what generation of* Losec 20 *is the comparator drug.*

[55] This linkage was again emphasized in the last sentence of paragraph 34 of the Reasons which quoted from the decision of the Federal Court of Appeal in the case below:

> *34.* … *However, as Noël J.A. also conceded, "it is the actual drug, from which samples can be taken and used for comparative purposes, that is relevant to the application of subsection 5(1) of the* NOC Regulations*" (para. 46 (emphasis added)).*

[56] The Court then pointed out that the facts of the particular case before it led to the conclusion that there could have been only one drug that could have been used as a comparator, one that the innovator had discontinued marketing several years ago. This does not mean that the decision is only relevant to discontinued drugs. It simply means that, in that case, the comparator drug was easily identified. As stated in paragraph 37:

> *37. The whole obligation incurred by the generic manufacturer under the* NOC Regulations *is based on its "early working" of patents embodied in "another drug for the purpose of demonstrating bio-equivalence". The only drug that fits the description is the version of* Losec 20 *approved in the June 19, 1989 NOC.*

[57] The Supreme Court then specifically addressed "*The Broader Statutory Purpose*" of the *NOC Regulations* at paragraph 38 to 41 of its Reasons. The last sentence of paragraph 39 clearly states that the generic only needs to address that cluster of patents listed as against the particular NOC pertinent to the generation of drug which it copied:

> *39. … In my view, s. 5(1) of the* NOC Regulations *requires a patent-specific analysis, i.e. the generic manufacturer is only required to address the cluster of patents listed against submissions relevant to the NOC that gave rise to the comparator drug, in this case the 1989 version of* Losec 20.

[58] In paragraph 40, the Court recognized that if a later NOC was issued and the generic made reference to it for a specific reason, that is, for purposes of demonstrating bioequivalence, then patents listed against the later NOC would also have to be addressed:

> *40. If AstraZeneca had brought to market a* Losec 20 *product pursuant to the later NOCs and if Apotex had made reference to that modified product for the purpose of demonstrating bioequivalence, Apotex would have been required to file a notice of allegation with respect to the 037 and 470 patents.*

[59] It is important to note that the Supreme Court was quite specific in paragraph 40 as to the reason for the reference, it was for demonstrating bioequivalence. Section 5(1) of the *NOC Regulations* are specific in stating that a person is only required to take steps to issue a notice of allegation to the innovator who has listed patents (thus become a "second person") if:

- that person has filed for an NOC;
- that person has compared reference or made reference to another drug;
- for the purposes of demonstrating bioequivalence;
- and that other drug has been marketed in Canada pursuant to an NOC; and
- there is a patent list pertinent to that NOC.

[60] These requirements are cumulative. Thus, if there is no comparison or reference for the purpose of bioequivalence, section 5(1) is not triggered.

[61] If section 5(1) is not triggered, then the generic is not a "second person" and is not required to file a notice of allegation. The *NOC Regulations* do not come into play. The Supreme Court said, at paragraph 41 of its Reasons:

> *41. However, it is clear that AstraZeneca did not market any product pursuant to the subsequent NOCs and that the preconditions to any obligations of Apotex under s. 5(1) were therefore not triggered.*

Was the Minister's Position Correct?

[62] There is no specific procedure in the *NOC Regulations* whereby a generic can inform the Minister or the Minister can inform the generic that certain patents, even if properly listed, need not be addressed having regard to the particular circumstances in which the generic finds itself. There is no specific procedure in the *NOC Regulations* obliging either the generic or the Minister to bring notice of those circumstances to the listing innovator or give to the innovator it an opportunity to make submissions. Further, there is no specific provision requiring that the question as to whether the generic should address certain listed patents at all in its particular circumstances be raised or addressed in any proceedings instituted under section 6 of the *NOC Regulations*.

[63] As soon as the *AstraZeneca* decision was released in early November, 2006, the Minister, with some prompting from some generics, set about to devise a process for dealing with the question of setting a procedure for dealing with whether a generic is required to address any particular listed patent. This process is set out in affidavits of Anne Elizabeth Bowes, Associate Director of the Therapeutic Products Directorate (TPD) which is the branch of the Minister's

department dealing with the *NOC Regulations*. This process involves only ANDS applications submitted by generics prior to the change in the *NOC Regulations* of October 5, 2006. Ms. Bowes explains that it involves two steps:

1. First, the date on which the generic has purchased the comparator drug is used to determine which notices of compliance have been issued in respect of that comparator drug. The position of the Minister is that all patents listed in respect of the relevant NOC as of that date must be addressed by the generic.

2. Second, where further NOC's have been issued to the innovator after the date of the purchase of the comparator drug, the Minister makes a determination as to whether the generic has made use of changes made to the comparator drug since the original date of purchase. If the generic has made use of such changes, then all patents added to the patent list subsequent to the date of purchase as are pertinent to the changes of which the generic has taken advantage must be addressed.

[64] The evidence shows that the Minister has regard to submissions made by the generic or its lawyers as to the date of purchase of the comparator drug and whether the generic has taken advantage of any subsequent NOC's issued to the innovator. As well, the Minister has regard to matters that are self evident on the record of the ANDS application by the generic, such as the date upon which data respecting the comparator drug was filed so as to establish a latest date upon which such drug could have been purchased. The "default date" for establishing the purchase of the comparator drug, in the absence of other information, is taken to be the filing date of the ANDS.

[65] I find that the policy adopted by the Minister is consistent with the reasoning of the Supreme Court of Canada in *AstraZeneca* and the applicable provisions of the *NOC Regulations* and *Food and Drug Regulations*. If I were to modify the policy, I would do so in two respects. First, the date of purchase of the comparator drug is not a date that is required by the provisions of either Regulation to be recorded or submitted. It is a date, the existence of which is known only to the generic purchasing the drug. A better date would be the filing date of the ANDS by the generic as that is a date of record and is, logically, the last date upon which the comparator drug could have been obtained by the generic. Second, with respect to the second criteria, the changes made by the generic must be those as specified in section 5(1) of the *NOC Regulations*, namely, for purposes of bioequivalence. This would be consistent with *AstraZeneca*. These suggestions, even if they had been implemented by the Minister before arriving at the decisions he did, would not have changed the results of those decisions or this decision of the Court.

TRIPS

[66] Counsel for Ferring raised in oral argument, but not in that party's factum, an assertion that Canada's *Patent Act*, including the *NOC Regulations*, failed to comply with Canada's obligations under the *Agreement on Trade Related Aspects of Intellectual Property Rights*, 1869 U.N.T.S. 299 ("TRIPS") a World Trade Organization agreement to which Canada is a signatory. This agreement was implemented into the laws of Canada by the *World Trade Organization Agreement Implementation Act*, S.C. 1994, c. 47 and appears at Annex 1C of that Act. That Act prohibits any action claiming a right claimed to arise out of the TRIPS agreement without the consent of the Attorney General of Canada. There has been no such consent in these proceedings.

[67] Article 41 of TRIPS obliges member countries such as Canada to ensure that there are effective enforcement procedures available to permit effective action to deter infringement of rights such as patent rights and to provide expeditious remedies. Ferring's counsel asserts that Canada's *Patent Act* and the *NOC Regulations* fall short of such obligations. I would be prepared to dispose of such argument summarily since it was not raised in Ferring's memorandum and was only raised in oral argument at the hearing. Such an argument would require proper evidence before it could be properly adjudicated upon. Simple assertions by counsel are insufficient.

[68] Justice Snider of this Court has rejected a similar argument recently in *Laboratoires Servier v. Apotex Inc.*, 2006 FC 1493 at paragraphs 76 to 79. I fully agree with her analysis and conclusion. Therefore, I reject the argument that the *Patent Act* and *NOC Regulations* do not comply with TRIPS. To the extent that counsel seeks to nuance this agreement to state that somehow the *NOC Regulations* must be read in a manner so as to be aggressively interpreted in enforcing patent rights in light of TRIPS. I regret that argument. I have determined the legal effect of those Regulations in accordance with the ordinary principles established in Canadian law. TRIPS affords no particular bias.

Standard of Review of Minister's Decisions

[69] It is common ground between all parties that, in a judicial review proceeding such as this, a decision of the Minister that is based on a determination of law is to be reviewed upon a standard of

correctness (*AstraZeneca*, paragraph 25). Where the Minister's decision involves factual determinations and actions based on such determinations, his decisions are entitled to deference. Kelen J. of this Court reviewed extensively the degree of deference owed to the Minister in such circumstances in *AstraZeneca Canada Inc. v. Canada (Minister of Health)* (2004), 36 C.P.R. (4th) 519 and at paragraph 36 of his Reasons concluded that the standard was that of reasonableness. That conclusion was affirmed by the Federal Court of Appeal at paragraph 2 of their Reasons reported at (2005), 40 C.P.R. (4th) 353. In such circumstances, therefore, I will apply the standard of reasonableness, that is, the Minister's decision is entitled to deference; however, it must be understood that a somewhat probing examination of the basis for the decision should be undertaken.

Was the Minister *Functus?*

[70] Ferring and Sanofi-Aventis argue that, at some point in the process, the Minister had made decisions as to the status of the generics' applications, such that the Minister could not address or re-address the issue as to whether the generics were, in fact, "second persons" within the contemplation of the *NOC Regulations*.

[71] To consider this issue, the course of the decisions to be made by the Minister should be traced. First, under the *Food and Drug Regulations*, *supra,* the Minister must examine an ANDS filed by a generic to determine if the drug is bioequivalent with the Canadian reference product (section C.08.002.1(1)(b)). Then the Minister must, based on information provided by the generic, determine if the drug is safe and effective (section C.08.002.1(2)). After completing an examination of the application and being satisfied, the Minister shall issue an NOC (section C.08.002(1)(a)). As

previously discussed, the Minister has a duty to issue the NOC without delay (*Apotex Inc. v. Canada (Attorney General)*, [1994] 1 F.C. 742 (C.A.).

[72] However, at the point where the Minister would otherwise issue an NOC, the *NOC Regulations* intervene. Section 7 of the *NOC Regulations* direct that the Minister is not to issue an NOC before the latest of:

> (a) (deleted);
>
> (b) the day on which a "second person" complies with section 5, that is, sends to the innovator who has listed patents a notice of allegation;
>
> (c) the date the patents expire;
>
> (d) a notice of allegation has been sent, 45 days have expired, and the innovator has done nothing; and
>
> (e) the innovator has taken legal proceedings and 24 months have expired.

[73] Subsequent subsections make provision for the settlement or withdrawal of legal action and expiry of relevant patents. If successful, the legal action prohibits the Minister from issuing an NOC until the relevant patents expire.

[74] Thus, where the Minister is at the point of issuing an NOC, he must have regard to relevant patents listed under the provisions of the *NOC Regulations*. If there are relevant patents, the Minister puts the application on "patent hold". Until the Supreme Court decision of *AstraZeneca*,

the “patent hold” would remain until the transpiration of events under section 7 of the *NOC Regulations*.

[75] *AstraZeneca* has told us that section 7 only applies where a generic is a “second person” as provided for in section 5(3)(d) of the *NOC Regulations*. As has happened in the cases presently before this Court, the Minister has been persuaded that the relevant generic is not such a “second person” in all cases but one.

[76] The innovators say that the Minister is *functus* and cannot visit the issue as to whether a generic is a second person since there have been events which preclude that from happening. These events are one or more of:

1. The placing of the application on “patent hold” until section 7 plays out;
2. The sending of a notice of allegation by the generic to the innovator under section 5(1); or
3. The institution of proceedings in this Court by the innovator.

[77] Neither the *Food and Drug Regulations* nor the *NOC Regulations* make any provision for the Minister to act like a tribunal, or to hear evidence, or to consider submissions or to make rulings. The Minister is not acting in a judicial or quasi-judicial role unlike that which was considered, for instance, in *Chandler v. Alberta Association of Architects*, [1989] 2 S.C.R. 848. In that case, the Supreme Court stated at pages 861 to 864 that the doctrine of *functus officio* which precludes a

tribunal from reopening a decision once made, should not be applied rigorously in respect of every sort of administrative ruling.

[78] In the present case, the Minister is acting in a purely administrative capacity, he is processing an ANDS from its submission to the issuance of an NOC. From time to time, information is provided or sought and obtained and steps are taken by the Minister. The Minister is not acting as a tribunal at all (*Novopharm Ltd. v. Canada (Minister of National Health and Welfare)* (1998), 78 C.P.R. (3rd) 54 at paragraph 16 (F.C.) and *Saskatchewan Wheat Pool v. Canada (Canadian Grain Commissioner)* (2004), 260 F.T.R. 310 at para. 24). This role is a continuing one of the type considered by the Supreme Court of Canada in *Comeau's Sea Foods Ltd. v. Canada (Minister of Fisheries and Oceans)* (1997), 142 D.L.R. (4th) 193. The Minister, as explained by the Supreme Court in *Comeau's Sea Foods* at paragraphs 39 to 51 of its Reasons, is entitled to visit and revisit circumstances from time to time as conditions change and new issues arise. It is only when the final step is taken, in that case, the issuing of a fishing licence, can the issue of *functus* arise. Here that final step is the issuance of an NOC.

[79] The process here is analogous to considerations given by the Commissioner of Patents under the *Patent Act*, *supra*, as to whether he will entertain an application for a compulsory licence (*Merck and Co. v. Brantford Chemicals Inc.* (2005), 37 C.P.R. (4th) 481 (F.C.A.)), or as to whether he will involve a person who is not the person applying for a patent at the point when the patent is allowed (*Monsanto & Co. v. Canada (Commissioner of Patents)* (2000), 1 C.P.R. (4th) 500 (F.C.)). In such

situations, the actions of the Commissioner, or here the Minister, cannot be and to be of such finality that they cannot be revisited where appropriate.

[80] Even in circumstances where the final step has been taken such as a prohibition against the Minister from issuing an NOC by a Court order, the matter has been revisited where the underlying patent has been held, in other proceedings, to be invalid (*Hoffmann-La Roche Ltd. v. Canada (Minister of Health and Welfare)*, [1999] F.C.J. No. 662 at para. 14).

[81] I find, therefore, that the Minister cannot be said to have been *functus* at any point in the process. The Minister is entitled, at a point where appropriate, to consider whether a generic is, in the circumstances of the case, a "second person" within the meaning of section 5(1) of the *NOC Regulations*.

[82] Does the fact that Court proceedings have been commenced under the provisions of section 6(1) of the *NOC Regulations* make any difference? Can the Minister consider the status of a generic as a "second person" or not, after such proceedings have been taken? Can the Minister issue an NOC once such proceedings have been taken on the basis that the generic is not, in fact, a "second person"?

[83] The *NOC Regulations* are a legislative scheme without which the Minister would be obliged to issue an NOC without delay. Section 7 imposes a legislative, not Court-ordered, stay on the issuing of an NOC until the expiry of certain events, some of which contemplate Court proceedings.

The Court proceedings would not take place at all if a generic were not a “second person”. Until the Supreme Court handed down its decision in *AstraZeneca* in November 2006, the Minister and the generic were not sufficiently alert to the issues as to what constitutes a “second person”.

[84] The Minister is charged with a duty to issue an NOC without delay. If the Minister is persuaded that a particular generic in particular circumstances is not caught up with the *NOC Regulations*, then a proper exercise of his duty, notwithstanding Court proceedings, which owe their existence only to the *NOC Regulations*, is to issue the NOC. As Reed J. said in *Hoffmann-La Roche Ltd. v. Canada (Minister of National Health and Welfare)*, [1999] F.C.J. No. 662, an order of the Court is not necessary for a Minister to issue an NOC where the patent underlying a prohibition order has been declared to be invalid. Similarly here, no Order of the Court is necessary. The mere existence of Court proceedings cannot prohibit the issuance of an NOC where the underlying basis for the Court proceedings is a nullity.

The Specific Proceedings

FERRING – T-165-07

[85] Ferring is an innovator or “first party” that markets a drug in Canada originally under the name MINIRIN and subsequently DDAVP. This drug is principally used to combat bedwetting. The first NOC for that drug was granted on March 18, 1993.

[86] Ferring challenges the decision of the Minister to issue NOCs to each of two generics, Apotex and Novopharm, on January 22, 2007. Ferring asserts that the Minister should have required that each of these generics address two patents listed by Ferring on the Register, the so-called '833 and '335 patents.

[87] A complete list of relevant events is attached at Schedule A. However, for purposes of the present analysis, as instructed by the Supreme Court in *AstraZeneca*, the following events are relevant:

- March 18, 1993 – First NOC issued to Ferring;
- September 19, 2000 – A further NOC issued to Ferring for a new indication for the drug Patent 1, 232, 839 was listed against this NOC;
- April 20, 2004 – Novopharm acquires a comparator drug which is a United Kingdom version of DDVAP found acceptable by the Minister;
- October 19, 2004 – Apotex acquires a Canadian version of DDVAP as a comparator drug;
- December 14, 2004 – Novopharm files its ANDS with the Minister;
- February 16, 2005 – Patent 1,232,839 expires;
- September 6, 2005 – Apotex files its ANDS with the Minister;
- November 21, 2005 – A further NOC issued to Ferring respecting a new manufacturing process and slightly adjusted formulation;
- December 7, 2005 – The '833 patent was added to the list respecting the November 21, 2005 NOC;

- February 8, 2006 – The '335 patent was added to the list respecting the November 21, 2005 NOC;
- June 27-28, 2006 – Apotex sends a notice of allegation on Ferring respecting the '335 and '833 patents;
- August 11, 2006 – Ferring commences proceedings under section 6(1) of the *NOC Regulations* against Apotex;
- October 31, 2006 – Novopharm's application is put on "patent hold";
- November 3, 2006 – *AstraZeneca* decision released;
- January 23, 2007 – The Minister issues NOC to each of Apotex and Novopharm.

[88] As can be seen, when each of Apotex and Novopharm purchased their comparator drugs and when each filed their ANDS, the NOC that was extant at the time was that of September 14, 2000. The '833 and '335 patents were not added until the further NOC granted to Ferring on November 21, 2005. That further NOC could not have been used by either Apotex or Novopharm for purposes of bioequivalence since bioequivalence studies would have been filed with their ANDS which preceded November 21, 2005.

[89] Thus, in accordance with *AstraZeneca*, the Minister, in doing a patent specific analysis, needed to look only at patents listed against the NOC extant as of the filing of the ANDS by the generics (or purchase date of comparator drugs). The only relevant patent listed there was a Canadian patent 1,232,839, which expired on February 16, 2005. Thus, no relevant patent remained in respect to any NOC relevant to the generics.

[90] The fact that Apotex had sent a notice of allegation and proceedings had been instituted by February is, as previously determined, irrelevant. Novopharm had never sent a notice of allegation and no proceedings had been commenced.

[91] I find that the Minister's decisions respecting Apotex and Novopharm were correct.

Duty of Fairness

[92] Ferring makes a further argument that the decisions of the Minister were made without warning to Ferring and giving it an opportunity to be heard. This, argues Ferring, is unfair and contrary to the principles of natural justice.

[93] The Minister submits that the decision is administrative in nature and there is nothing in the *NOC Regulations* or *Food and Drug Regulations* that obliges him to advise an innovator who has listed patents as to whether a generic is seeking an NOC or to afford the innovator a right to be heard before a decision is made.

[94] The parties refer to the Supreme Court of Canada decision in *Baker v. Canada (Minister of Citizenship and Immigration)* (1999), 174 D.L.R. (4th) 193 at paragraphs 21 to 28 for the purposes of considering what the duty of fairness might require in any particular circumstances. L'Heureux-Dube J. said in the majority decision at paragraph 21 of that decision that the concept is eminently variable and depends on the particular circumstances in each case. In paragraph 23 she stated that the closer a procedure is to a judicial process, the more likely it would be that there would be

procedural protection, such as that afforded a litigant. Second, the terms of the particular legislation must be considered. A third consideration is the importance to the individual affected. Fourth is the legitimate expectation of persons challenging the decision. Fifth is the choice of procedure afforded to the decision maker.

[95] In considering these criteria: first, the decision of the Minister to grant an NOC, including whether a generic is caught up in section 5(1) is administrative in nature; second, the Regulations do not specify any form of notice or hearing being afforded to others; third, an innovator is affected by the decision in that it may lose an opportunity to institute proceedings under the *NOC Regulations*, thus losing an opportunity to gain a two-month stay, however, this is an exceptional remedy and cannot be considered to be available as of right; fourth, there is nothing in the Regulations such as would give an expectation to an innovator to be consulted and heard before an NOC is given to a generic other than to receive a notice of allegation if and when the generic is obliged as a "second person" under section 5(1) to send such a notice, otherwise all proceedings are confidential as between the generic and the Minister; fifth, there is no choice given to the Minister as to whether to engage the innovator or not.

[96] There is no history of the Minister notifying an innovator or affording it an opportunity to be heard during the process of granting an NOC to a generic. There is a reference, in the Trial Division Reasons in the *AstraZeneca* case (2004), 36 C.P.R. (4th) 519 at paragraphs 55 and 56, to communications between the Minister and the innovator. A review of the record in that case indicates that the Minister wrote to the innovator on January 13, 2004, without disclosing that there

was a pending NOC submission from a generic. The Minister simply requested information as to whether the innovator's LOSEC 20 capsules had been marketed in Canada since the date of its NOC on June 4, 1999. The innovator was not asked to make submissions of any kind as to the impact that the failure to market might have. There was no hearing of any kind conducted by the Minister; there was a simple request for information.

[97] The Minister was not required to inform Ferring as to a generic's pending NOC submission; in fact, that submission is to remain confidential. Nor was the Minister required to afford Ferring an opportunity to be heard before making a decision as to whether the provisions of section 5(1) of the *NOC Regulations* applied to the generic, or to issue an NOC to the generic.

Status of Ferring to Seek Judicial Review

[98] Novopharm takes issue as to the status of Ferring to seek judicial review of the Minister's decision that Novopharm was not a "second party" as defined in section 5(1), whereby Novopharm received the NOC it sought without engaging the provisions of the *NOC Regulations*.

[99] Section 18.1 of the *Federal Courts Act*, R.S.C., 1985, c. F-7 affords any person "directly affected" by a decision of a federal board, commission or other tribunal the right to seek judicial review of that decision. As discussed in respect of sections 3(1) of the *NOC Regulations*, a generic is not afforded an opportunity to intervene in proceedings respecting the listing of a patent or to seek de-listing since, at that point, no particular generic can be seen to be "directly affected". This is consistent with the law expressed in *Rothmans of Pall Mall Canada Ltd. v. Canada (Minister of*

National Revenue – M.N.R.), [1976] 2 F.C. 500 (F.C.A.) that a person who is simply a member of a class generally affected by a decision, without more, has no status to seek judicial review (see also *Apotex Inc. v. Canada (Governor in Council)*, 2007 FC 232).

[100] It has been found that a mere economic interest is insufficient to support status to seek judicial review (*Aventis Pharma Inc. v. Canada (Minister of Health)* (2005), 45 C.P.R. (4th) 6 at para. 13). That decision was appealed but the appeal was not proceeded with. In that case, the innovator, Aventis, had apparently failed to list its patent in a timely fashion. The generic Novopharm was awarded an NOC by the Minister. Aventis sought judicial review of that decision. The Minister sought to strike out those portions of Aventis' application challenging the issuance of an NOC.

[101] The Aventis decision, particularly from paragraphs 9 to 19, indicates that Aventis first argued before a Prothonotary of this Court that the Minister had, in issuing an NOC, acted unfairly in respect of his analysis as to safety and effectiveness. At the Trial Court level Aventis shifted ground and argued that it had a *de facto* monopoly that was destroyed by the issuance of an NOC to a generic, thus it was a "person interested" in seeking judicial review of the decision to issue that NOC. It was held at paragraph 13 that the fact that Aventis did not gain the opportunity to invoke the NOC proceedings was insufficient so as to afford it status to seek judicial review.

[102] I make the same finding here. As far as Novopharm is concerned, Ferring had no right to be given notice or an opportunity to be heard before the Minister made a determination that the

generic, in its particular circumstances, did not have to engage the *NOC Regulations*. Ferring retains all of its NOCs and its patent listing, they are unaffected. Ferring retains the right to commence patent infringement proceedings. Ferring simply lost an opportunity to commence NOC proceedings in the Court, just as Aventis had no such right. This is merely a commercial interest.

[103] Therefore, I find that Ferring, in the circumstances, has no status to seek judicial review as against Novopharm. This is a further reason why Ferring's application will be dismissed as against Novopharm. Apotex did not raise this issue.

Sanofi-Aventis: General

[104] Sanofi-Aventis is an innovator or "first party" that markets a drug in Canada under the name ALTACE (ramapril). It has been directed toward treatment of hypertension. The first NOC for the drug was received by Sanofi-Aventis on October 8, 1993. Sanofi-Aventis subsequently was granted four Canadian patents, two described as the '387 patent and the '549 patent were directed toward treatment of patients with increased risk of cardiovascular event, these are the so-called HOPE patents. It also received two other patents called '089 and '948 directed to other uses which have been called non-HOPE in these proceedings. Sanofi-Aventis has received an NOC that would permit it to market ALTACE for the HOPE indication but has not received such approval for the non-HOPE indications. Thus, it has four patents but can only market the product for the uses claimed in two of them.

[105] Two generics, Apotex and Novopharm, want to market their generic versions of ALTACE in Canada but only for old uses. They say that they do not want to market them for the HOPE or non-HOPE indications.

[106] The Minister issued an NOC to Apotex on December 12, 2006. However, the Minister maintained that Novopharm had to address the non-HOPE patents by way of notice of allegation under section 5(1) of the *NOC Regulations*. Sanofi-Aventis and Novopharm have applied for judicial review of these decisions. Those applications will now be dealt with specifically.

SANOFI-AVENTIS V. NOVOPHARM – T-2188-06
NOVOPHARM V. SANOFI-AVENTIS – T-2220-06

[107] These two proceedings are closely related and can be addressed together. Attached as Schedule B is a more complete listing of relevant events; however, the following are the most pertinent:

- October 8, 1993 – Sanofi-Aventis receives its first NOC respecting ALTACE;
- February 13, 2001 – Sanofi-Aventis receives a further NOC respecting ALTACE (submission 066094);
- June 22, 2001 – Novopharm purchases ALTACE for use as a comparator drug;
- December 24, 2001 – Novopharm files an ANDS for its generic version of ALTACE;
- October 14, 2003 – Novopharm's submissions approved but put on "patent hold";
- November 6, 2003 – Sanofi-Aventis granted a further NOC (submission 082094);

- November 10, 2003 – The '089 patent (non-HOPE) added to patent list respecting NOC 066094;
- June 25, 2004 – the '948 patent (non-HOPE) added to patent list respecting NOC 066094;
- March 17, 2005 – The '549 patent (HOPE) added to patent list respecting NOC 082026;
- June 28, 2005 - '387 patent (HOPE) added to patent list respecting NOC 082094;
- September 14, 2005 – Novopharm serves a notice of allegation on Sanofi-Aventis respecting the two HOPE and two non-HOPE patents;
- October 31, 2005 – Sanofi-Aventis commences NOC proceedings in the Court respecting all four patents;
- November 3, 2006 – *AstraZeneca* decision released;
- December 8, 2006 – The Minister advises Novopharm (copying Sanofi-Aventis) that Novopharm was no longer required to address the HOPE patents but was required to address the non-HOPE patents;
- December 15, 2006 – Sanofi-Aventis initiates judicial review proceedings T-2188-06 respecting the Minister's decision that Novopharm did have to address the HOPE patents;
- December 15, 2006 – Novopharm commences judicial review proceedings respecting the Minister's decision that it did have to address the non-HOPE patents.

[108] Not relevant to this determination is an ANDS filed by Novopharm for 1.25 mg. version of its generic drug, nor is another patent, 1,341,206 which has been dealt with in other proceedings at the trial level and is awaiting a decision of the Court of Appeal.

[109] The rationale for the Minister's decision was set out in the last two pages of his letter of December 8, 2006 as follows:

> *Novopharm purchased the comparator drug, ALTACE, on June 22, 2001.*
>
> *NOCs were issued to sanofi-aventis on October 8, 1993, October 30, 1994, June 5, 1996, December 31, 1996 and February 13, 2001 for the comparator drug in respect of submission numbers 08257, 24206, 043465, 033131 and 066094, respectively. The '948 patent was added to the Patent register in respect of all of these submissions. The '089 patent was added in respect of all the submissions except for 08257 As a result, both the '948 and '089 patents must be addressed under subsections 5(1) and 5(2) of the* PM(NOC) Regulations.
>
> *After the date of purchase of the comparator drug, an NOC was issued to sanofi-aventis on November 6, 2003 in respect of submission number 082094. Both the '549 and '387 patents were added to the Patent Register in respect of this submission. Both patents, along with the '948 and '089 patents, are currently the subject of an ongoing application for an order of prohibition in T-1979-06. Since Novopharm's ANDS has been on patent hold since October 14, 2003, it has not made use of the changes made to the comparator drug as a result of submission 082094. Therefore, Novopharm does not have to address the '549 and '387 patents.*
>
> *Note, however, that at this time, the TPD is unable to issue an NOC to Novopharm for the products noted above, as, in our view, we are bound by the 24 month stay imposed by the* PM(NOC) Regulations *in respect of the prohibition proceeding in T-1979-06. You will, therefore, be required to dispose of that proceeding prior to the issuance of an NOC.*

[110] This rationale is consistent with the direction given by the Supreme Court in *AstraZeneca*. Patents that have been listed in respect of an NOC that was in existence at the time when the comparator drug was acquired (here it could equally have been the date Novopharm filed its ANDS as either date was after NOC 066094 and before NOC 082094). The Minister performed a patent specific analysis, linking the relevant patents to the relevant NOC as directed in *AstraZeneca*.

[111] Novopharm argues that it is irrational to require that it address the two non-HOPE patents since, it argues, they could not have "early worked" these patents. Novopharm argues that it has never sought approval from the Minister for an NOC that would include the non-HOPE uses. Second, it argues, Sanofi-Aventis itself never received an NOC for non-HOPE uses. Third, Novopharm argues that it obtained its reference product before the non-HOPE patents had issued. Fourth and fifth, Novopharm argues that AstraZeneca requires a technology-related examination of each patent and it did not adopt the technology. Sixth, Novopharm argues that since these patents are related to use and not a medicine itself, bioequivalence is not a factor, only clinical studies indicating patents, thus there is no bioequivalence.

[112] As to all of Novopharm's arguments, the last sentence of *AstraZeneca* paragraph 39 is pertinent:

> *39.* … *In my view, s. 5(1) of the* NOC Regulations *requires a patent-specific analysis, i.e. the generic manufacturer is only required to address the cluster of patents listed against submissions relevant to the NOC that gave rise to the comparator drug, in this case the 1989 version of* Losec 20.

[113] With this statement is mind, sections 4(4) and 4(5) of the *NOC Regulations* pre-October 5, 2006 (the new Regulations contain similar provisions as sections 4(5) and 4(6)) must be considered:

4 (4) A first person may, after the date of filing of a submission for a notice of compliance and within 30 days after the issuance of a patent that was issued on the basis of an application that has a filing date that precedes the date of filing of the submission, submit a patent list, or an amendment to an existing patent list, that includes the information referred to in subsection (2).	*4 (4) La première personne peut, après la date de dépôt de la demande d'avis de conformité et dans les 30 jours suivant la délivrance d'un brevet qui est fondée sur une demande de brevet dont la date de dépôt est antérieure à celle de la demande d'avis de conformité, soumettre une liste de brevets, ou toute modification apportée à une liste de brevets, qui contient les renseignements visés au paragraphe (2).*
(5) When a first person submits a patent list or an amendment to an existing patent list in accordance with subsection (4), the first person must identify the submission to which the patent list or the amendment relates, including the date on which the submission was filed.	*(5) Lorsque la première personne soumet, conformément au paragraphe (4), une liste de brevets ou une modification apportée à une liste de brevets, elle doit indiquer la demande d'avis de conformité à laquelle se rapporte la liste ou la modification, en précisant notamment la date de dépôt de la demande.*

[114] These provisions allow patents to be listed against a previous NOC provided that the application for the patent was filed before that NOC application was filed and the patent is submitted for listing within 30 days of its issuance. As we have seen, some patent applications can linger in the Patent Office for 10 years or so which means that there is plenty of potential for listing newly issued patents against old NOCs.

[115] Time and again it has been said that the *NOC Regulations* are not a masterpiece of logic or draughtmanship. They say what they say.

[116] *AstraZeneca* tells us that a generic must address patents "linked to" the NOC that is relevant to the comparator drug. The fact that later issued patents can be listed in respect of that NOC is an artifact of the way the *NOC Regulations* are drafted.

[117] Novopharm will have to address these patents, and did, in a notice of allegation. Sanofi-Aventis has instituted proceedings in respect of those allegations. The matter will have to be determined in this Court in accordance with the *NOC Regulations*.

SANOFI-AVENTIS V. APOTEX – T-2189-06 AND T-2196-06

[118] These are proceedings involving Sanofi-Aventis and another generic, Apotex. A more complete listing of events is set out in Schedule C; however, the following events are most pertinent:

- October 8, 1993 – Sanofi-Aventis receives its initial NOC for ALTACE;
- October 2002 – Apotex purchases samples of ALTACE for use as a comparator drug;
- July 22, 2003 – Apotex files an ANDS for its generic version of ALTACE;
- November 6, 2003 – Sanofi-Aventis receives a further NOC pursuant to its submission 082094;

- March 17, 2005 – The 2,382,549 (HOPE) patent was added to the list respecting NOC 082094;
- June 28, 2005 – The 2,382,387 (HOPE) patent was added to the list respecting NOC 082094;
- November 29, 2005 – Apotex serves Sanofi-Aventis with a notice of allegation respecting the two HOPE patents;
- January 17, 2006 – Sanofi-Aventis commences NOC proceedings in this Court respecting the two HOPE patents;
- October 2006 – Sanofi-Aventis revises its product monograph;
- November 3, 2006 – The *AstraZeneca* decision is released;
- December 8, 2006 – Apotex revises its draft product monograph to incorporate some but not all changes made by Sanofi-Aventis in its revised monograph;
- December 12, 2006 – The Minister issues an NOC to Apotex;
- December 14, 2006 – Apotex revises its product monograph to remove certain material.

[119] As can be seen, as of the date that Apotex acquired the comparator drug, October 2002, and as of the date it filed its ANDS, July 22, 2003, none of the HOPE or non-HOPE patents were on any patent list respecting any NOC issued to Sanofi-Aventis. Subsequently, the two non-HOPE patents '089 and '948 were added to an earlier NOC dated February 13, 2001 as a result of the retroactive provisions of sections 4(5) and 4(6) of the *NOC Regulations*. Those patents are no longer at issue since Sanofi-Aventis proceedings in respect of them were dismissed. The remaining two patents, the

HOPE patents '549 and '387, were added to an NOC dated November 6, 2003 which was subsequent to the filing by Apotex of its ANDS.

[120] Having regard to the *AstraZeneca* decision, the Minister, in his December 8, 2006 letter to Apotex, does not need to address the two HOPE patents since they were not listed in respect of any NOC in existence at the time Apotex filed its ANDS.

[121] The Minister further said in his letter of December 8, 2006 that since Court proceedings were still extant, those proceedings had to be terminated before an NOC issued. As I have found, he was not correct in this regard. In any event, the Minister changed his mind, and issued an NOC to Apotex on December 12, 2006. As I have found, the Minister was not *functus* and could issue that NOC.

[122] Sanofi-Aventis raises an issue concerning Apotex's product monograph. They say that as of December 12, 2006, when the NOC was issued, the product monograph which was attached to the NOC contained material copied from Sanofi-Aventis' monograph which could suggest that Apotex was encouraging the use of its product for the HOPE indications. This issue, says Sanofi-Aventis, means that the Minister should have left the matter for the Court to decide.

[123] The Minister's letter of December 13, 2006, to Apotex shows that he considered the product monograph. In discussing the two HOPE patents at the third page of that letter, he said:

> *Those patents were added in respect of Sanofi-Aventis S/ANDS number 082096 for a change to the product monograph for*

> *ALTACE. A comparison of the Sanofi-Aventis product monograph with the Apotex product monograph shows that Apotex has not incorporated the change.*

From the Minister's letter of December 13, 2006 to Sanofi-Aventis' lawyer, it is clear that before issuing the NOC to Apotex, written and oral submissions were made by Sanofi-Aventis' counsel to the Minister and he considered them.

[124] The Affidavit of Hems, Director of Regulatory Affairs for Apotex, sworn February 12, 2007, sets out the history of a succession of draft product monographs filed by Apotex with the Minister and how, in many respects, wording from Sanofi-Aventis' product monographs as they existed from time to time, was copied. As explained by Hems at paragraphs 8 to 17 of his affidavit, typically the monographs of a generic are not significantly different from that of the reference brand.

[125] Hems explains that language specific to HOPE indications had been in draft Apotex monographs since Apotex's initial filing of its ANDS. This language was copied from an earlier Sanofi-Aventis monograph of 2001, that is, from a monograph that predates the issuances of the HOPE patents and their addition to a later NOC, by about three years.

[126] In October 2003 Apotex added the phrase:

> *… and for the management of patents at increased risk of cardiovascular events.*

to a section of the monograph dealing with Action and Clinical Pharmacology (Hems calls this the "A and CP" language). That monograph of October 2003 also contained what Hems calls "Plasma Language" which is not associated with HOPE. It says:

> *Following a single administration of up to 5 mg of Ramipril, plasma concentrations of ramipril and tamiprilat increase in a manner that is greater than proportional to dose; after a single administration of 5 mg to 20 mg of ramipril the plasma concentrations for both are dose-proportional. The non-linear pharmacokinetics observed at the lower doses of ramipril can be explained by the saturable binding of ramiprilat to ACE.*

[127] The December 12, 2006 monograph was attached to Apotex's NOC materials, the old HOPE language of 2001 as well as the October 2003 A and CP language and the Plasma Language. While irrelevant, Apotex removed the HOPE and A and CP language from a revised monograph submitted to the Minister on December 14, 2006. This, however, was after the issuance to Apotex of the NOC about which Sanofi-Aventis now makes an issue. Hems was cross-examined and his evidence was not impaired.

[128] The issue before this Court is whether the Minister's decision to issue the NOC was reasonable having regard to the state of Apotex's NOC as of December 12, 2006. There is no doubt that the Minister had the monograph before him and had received whatever submissions Sanofi-Aventis wanted to make. There is no evidence as to the oral submissions of Sanofi-Aventis' counsel to the Minister, but there is in evidence that counsel's letter to the Minister of December 11, 2006 where, particularly at pages 2 to 4, the monograph is addressed at length.

[129] The considerations given by the Minister to the monograph is set out at paragraphs 66 and 67 of the affidavit of Ann Bowes, previously referred to, sworn February 9, 2007. She says:

> *66. Both the '549 and '387 patents were added in respect of Sanofi's S/NDS 082094. As described above in paragraphs 43-49, the S/NDS was filed in order to, first, add wording to the "Action and Clinical Pharmacology" section, and second, make an addition to the "Management of Patients at Increased Risk of Cardiovascular Event" indication of the product monograph for ALTACE. While the first change was approved, the second was not. Furthermore, an examination of Apotex's approvable product monograph on patent hold, showed that Apotex did not incorporate this change. Apotex's draft product monograph is attached as Exhibit "P".*
>
> *67. In any event, none of the changes that were introduced to Sanofi's product monograph as a result of S/NDS 082094 reflected a change to the drug product, ALTACE, such that Apotex would have to address the '549 and '387 patents.*

[130] Ms. Bowes was cross-examined on her affidavit and nothing in the transcript changes what was said above or impairs it in any way.

[131] Apotex submitted the Affidavit of Dr. Gordon Moe, a cardiologist, who provided an affidavit testifying that the Plasma language had no relationship to the HOPE study or HOPE patents. He was cross-examined and this testimony was not impaired.

[132] Dr. Bernard Sherman, President of Apotex, provided an affidavit testifying that all HOPE language was removed from the product monograph just after the NOC was issued to avoid any suggestion of impropriety. Sanofi-Aventis apparently chose not to cross-examine Dr. Sherman.

[133] Sanofi-Aventis filed the affidavit of Laurent-Didier Jacobs, its Vice President of Medical Affairs. He traced some of the history of Sanofi-Aventis' and Apotex's product monographs but drew no conclusions. He was not cross-examined.

[134] Considering the decision of the Minister and the record before him as well as the evidence of the parties, it is clear that the Minister's decision as to the Apotex product monograph was reasonable. The Minister has expertise in these matters and consideration of product monographs is part of what the Minister is required to do. It cannot be said, for purposes of judicial review, that the decision should be set aside.

[135] Therefore, the decision of the Minister to grant an NOC to Apotex will not be set aside.

Conclusion and Costs

[136] As a result, I find that the Minister's decision in each case, was correct; therefore, each application for judicial review will be dismissed. Further, Ferring's application against Novopharm, as part of T-165-07, will be dismissed on a second ground, raised only by Novopharm, that Ferring lacked status to seek judicial review.

[137] As to costs, I will make no order. Each party will bear its own costs. These are the first opportunities any party has had to deal with the effects of the Supreme Court decision in *AstraZeneca* and no party should be penalized in costs for having taken or defended these proceedings.

"Roger T. Hughes"
Judge

SCHEDULE A

	CHRONOLOGY OF EVENTS **T-165-07, *Ferring Inc. v. Apotex Inc et al***
1950's	Desmopressin discovered
Feb. 16 1988	CA 1,232,839 issued to Ferring for DDAVP tablet formulation
1989	Ferring first markets DDAVP in Canada as nasal spray
March 18, 1993	First NOCs issued to Ferring for 0.1 and 0.2 mg DDAVP desmopressin tablets (Old Formulation)
April 13, 1993	Ferrings CA 1,232,839 added to Patent Register
1995	Ferring first markets DDAVP desmopressin tablets in Canada
Sept 14, 2000	NOC issued to Ferring for DDAVP "new indication"
April 20, 2004 (alleged in Novopharm letter dated Dec 22, 2004 to the Minister)	Novopharm purchases U.K comparator drug (DDAVP desmopressin tablets)
April 30, 2004	Ferring files '833 Patent application in Canada
July 19, 2004	Ferring files '335 Patent application in Canada
Oct. 19, 2004	Apotex acquires DDAVP product for bioequivalence studies
November 2004	Apotex bioequivalence studies are completed
November 11, 2004	'833 patent application published
December 14, 2004	Novopharm files its ANDS for 0.1 and 0.2 mg Novo-Desmopressin tablets with Form V and agrees to wait until the expiry of the CA 1,232,839
January 25, 2005	335 patent application published
February 16, 2005	Ferring's CA 1,232,839 expired
February 24, 2005	Ferring's SNDS for change in manufacturing process & change in manufacturing process
August 2, 2005	'833 Patent issues to Ferring
August 5, 2005	Ferring files Form IV's with the Minster in which '833 patent was listed re: the DDAVP SNDS
September 6, 2005	Apotex files submissions for ANDS for Apo-desmopressin tablets
November 21, 2005	NOC issues to Ferring for change in manufacturing process (new formulation) (097275)
December 7, 2005	'833 added to Patent Register "new formulation"

January 31, 2006	'335 Patent issues to Ferring
February 6, 2006	Ferring file Forms IV's with the Minister in which the '335 patent was listed re: DDAVP SNDS
February 8 2006	Ferring's '335 added to Patent Register "new formulation"
May/June 2006	Ferring starts selling DDAVP tablets pursuant (new formulation) to second NOC & stops selling tablets pursuant to the first NOC
May 2006	Apotex commences judicial review for Minister decision to address '833, '335 Patents
June 27, 28, 2006 (Ferring receives NOA's on June 30, 2006)	Apotex serves Ferring with two Notices of Allegation addressing '335 & '833 Patents, respectively
July 31, 2006	Apotex Product monograph & ANDS complete
August 2, 2006	Apotex ANDS on "Patent Hold"
August 11, 2006	Ferring files two Notices of Application s.6(1) in response Apotex's NOAs
September 8, 2006	NOC issues to Ferring for new DDAVP MELT, CA 2,484,724 is listed on Patent Register
Oct 5, 2006	*PM(NOC) Regulations* are amended
October 27, 2006	Novopharm product monograph & ANDS complete
October 31, 2006	Novopharm ANDS on "Patent Hold"
December 5, 2006	Ferring discontinues Notice of Application re: '335 Patent ('833 ongoing)
Nov 3, 2006	SCC releases *AstraZeneca* 2006 SCC 49
November 2006	Ferring starts selling DDAVP MELT
January 22, 2007	Minister's official advises all parties that it reconsidered the status of the ANDS; Apotex and Novopharm do not have to address the '833, '335 patents; NOC issue to Apotex & Novopharm
January 29, 2007	This judicial review is commenced

SCHEDULE B

	CHRONOLOGY OF EVENTS **T-2188-06** ***Sanofi-Aventis v. Minister of Health and Novopharm*** **T-2220-06 ,** ***Novopharm Limited v. Minister of Health and Sanofi-Aventis***
August 11, 1989	**Sanofi-Aventis** '089 Priority application is filed
August 10, 1990	**Sanofi-Aventis** filed the patent application for the '089 patent (Non-HOPE)
November 27, 1990	**Sanofi-Aventis** '948 priority application is filed.
February 12, 1991	**Sanofi-Aventis** '089 application is published
November 26, 1991	**Sanofi-Aventis** filed the patent application for the '948 patent. (Non-HOPE)
May 28, 1992	**Sanofi-Aventis** '948 application is published
October 8, 1993	**Sanofi-Aventis** received its first Notice of Compliance for ALTACE 1.25 mg, 2.5 mg, 5 mg, and 10 mg capsules.
January, 1994	**Sanofi-Aventis** commences sales of ALTACE
September 30 1994	**Sanofi-Aventis** receives NOC for ALTACE Capsules, 1.25mg, 2.5, 5mg 10mg "Provides for a revised manufacturing process" (24206)
June 5, 1996	**Sanofi-Aventis** receives NOC for ALTACE Capsules "Angiotensin converting enzyme inhibitor" (043465)
December 31, 1996	**Sanofi-Aventis** receives NOC for ALTACE 1.25, 2.5, 5, 10mg "treatment following acute myocardial infarction" (033131)
August 22, 1999	**Sanofi-Aventis '**387 priority application is filed
August 30, 1999	**Sanofi-Aventis '**549 priority application is filed
April 2, 2000	**Sanofi-Aventis** filed an S/NDS, submission 066094, to approve a new indication for ALTACE, namely the "management of patients at increased risk of cardiovascular events".
August 25, 2000	**Sanofi-Aventis** filed the patent (PCT) application for the '387 patent. (HOPE Indication)
August 30, 2000	**Sanofi-Aventis** filed the patent (PCT) application for the '549 patent. (HOPE Indication)
February 13, 2001	**Sanofi-Aventis** receives NOC for ALTACE SNDS, submission 066094. The "Indications and Clinical Use" section was updated to include the subsection "Management of Patients at Increased Risk of Cardiovascular Events".
March 8, 2001	'387, '549 PCT applications are published
May 8, 2001 ******Sanofi-Aventis and Minister give purchase date as June 22, 2001	**Novopharm** purchases ALTACE (the "comparator drug") samples - it subsequently used for its bioequivalence studies.
December 24,2001 (date received by Minister December 27, 2001)	**Novopharm** files ANDS 075408 for Novo-ramipril 2.5 mg, 5 mg and 10 mg capsules. The ANDS included Form Vs, stating Novopharm would await expiry of the 3 patents then on the Register.
November 12, 2002	**Sanofi-Aventis** '948 patent issues.

December 10, 2002	**Sanofi-Aventis** files its Form IV's to list the '948 patent against the submissions 066094, 24206, 043465, 033131 and NDS 08257
January 14, 2003	**Sanofi-Aventis** '089 patent issues.
January 15, 2003	**Sanofi-Aventis** filed S/NDS 082094 for a further update to the ALTACE capsules Product Monograph. The S/NDS had two purposes (Changes 1 & 2 or ALTACE 2003): (1) to update the "Action and Clinical Pharmacology" section to add new wording: "...and for the management of patients at increased risk of cardiovascular events" (2) to update the "Management of Patients at Increased Risk of Cardiovascular Event" indication in the product monograph, to further define the stroke patient population by specifying "fatal stroke". The proposed indication was as follows: "ALTACE may be used to reduce the risk of myocardial infarction, stroke (including fatal stroke) or cardiovascular death in patients over 55 years..."
February 14, 2003	**Sanofi-Aventis** files its Form IV's to list the '089 patent against the submissions 066094, 24206, 043465, 033131
June 9, 2003	The **Minister**'s officials, in respect of S/NDS for Changes 1 and 2 (082094) (1) approved the proposed update to the "Action and Clinical Pharmacology" section of the product monograph to include the wording "...and the management of patients at increased risk of cardiovascular events". (2) Denied the proposed inclusion of "(including fatal stroke)" to the "Management of Patients at "Increased Risk of Cardiovascular Events" indication, for two reasons. First, in the view of the Minister's experts, the HOPE study was not designed to evaluate the incidence of fatal stroke in patients at higher risk of cardiovascular events treated with ramipril. Second, the prevention of fatal stroke was considered to be a new indication, requiring new clinical data, and required an NDS.
October 14, 2003	**Novopharm's** ANDS 075408 for Novo-ramipril 2.5 mg, 5 mg and 10 mg capsules was found satisfactory and was placed on "patent hold".
November 6, 2003	**Sanofi-Aventis** was issued a NOC in respect of S/NDS 082094 to update the Product Monograph (for Changes 1 & 2 but not "fatal stroke")
November 10, 2003	**Sanofi-Aventis** '089 patent was added to the Register re: submission for 1994-2001 submissions 066094, 24206, 043465, 033131, which received NOC's
June 25, 2004	**Sanofi-Aventis** '948 patent was added to the Patent Register re: submissions for 1993-2001 for NOC submissions 066094, 24206, 043465, 033131 and NDS 08257
March 15, 2005	**Sanofi-Aventis** '549 patent issues, entitled "Use of inhibitors of the renin-angiotensin system in the prevention of cardiovascular events".
March 17, 2005	**Sanofi-Aventis** '549 patent was added to the Register in respect of the S/NDS 082094 and the issued NOC updating the product monograph.

June 21, 2005	**Sanofi-Aventis** '387 patent issues, entitled "Pharmaceutical formulations and use thereof in the prevention of stroke, diabetes and/or congestive heart failure".
June 28, 2005	**Sanofi-Aventis** '387 patent was added to the Register in respect of the S/NDS 082094 and its NOC updating the product monograph.
August 26, 2005 (Minister's date August 30, 2005)	**Novopharm** filed S/ANDS for Novo-ramipril 1.25 mg capsules. The S/ANDS included a new Form V in respect of the '206 patent and new Form Vs in respect of the '089, '948, '549 and '387 patents.
September 12, 2005	**Novopharm** served a notice of allegation in respect of the '206 patent
September 14, 2005 (Minister's date September 12, 2005)	**Novopharm** served a NOA in respect of the '089, '948, '549 and '387 patents (NON-HOPE and HOPE patents). Novopharm attaches draft product monograph for NOVO-RAMIPRIL dated August 26, 2005 which includes ALTACE Change #2
September 20, 2005	'206 Patent is invalid for lack of sound prediction *Aventis Pharma Inc. v. Apotex Inc. et. al.* 2005 FC 1283, aff'd 2006 FCA 64 (February 13, 2006)
October 31, 2005	**Sanofi-Aventis** filed an application to the Federal Court in T-1965-05, under section 6 of the *NOC Regulations*, for an order prohibiting the Minister from issuing a NOC until expiry of the '206 patent.
November 2, 2005	**Sanofi-Aventis** filed an application to the Federal Court in T-1979-05, under section 6 of the *NOC Regulations*, for an order prohibiting the Minister from issuing a NOC until expiry of the '089, '948, '549 and '387 patents – the Use patents
May 29, 2006	**Sanofi-Aventis** receives an NOC for transfer of ownership
August 3, 2006 (August 2, 2006 date by Minister)	**Novopharm's** S/ANDS 100859 for Novo-ramipril 1.25 mg capsules was found satisfactory and was placed on "patent hold".
September 25, 2006	**Sanofi-Aventis's** application in Court File No. T-1965-05 in respect of the '206 patent was dismissed. (A notice of appeal was filed on September 29, 2006; the application in T-1979-05 remains pending.)
October 5, 2006	*PM (NOC) Regulations* are amended
November 3, 2006	The Supreme Court of Canada released the *AstraZeneca* decision, 2006 SCC 49
November 6, 2006	**Novopharm's** counsel wrote to the Minister's officials, stating that in light of the *AstraZeneca* decision Novopharm was not required to address the '089, '948, '549 and '387 patents, and requesting the issuance of a NOC for Novo-ramipril. Further correspondence followed.
December 8, 2006	**Novopharm** and **Sanofi-Aventis** were informed that the Minister had reconsidered the patent hold status of Novopharm's ANDS for its 2.5 mg, 5 mg, and 10 mg capsules of Novo-ramipril: **Novopharm** would be required to address the '089 and '948 patents under subsections 5(1) and 5(2) of the *NOC Regulations*, but not the '549 or '387 patent.
December 12, 2006	**Sanofi-Aventis** initiated the application in T-2188-06 for judicial review of the Minister's decision of December 8, 2006 in respect of the '549 and '387 patents.
December 15, 2006	**Novopharm** initiated the application in T-2220-06 for judicial review of the Minister's decision of December 8, 2006 in respect of the '089 and '948 patents.
December 15, 2006	**Novopharm** withdrew its notice of allegation in respect of the '549 and '387 patents

SCHEDULE C

	CHRONOLOGY OF EVENTS **T-2189-06, T-2196-06, *Sanofi-Aventis v. Minister of Health and Apotex***
August 10, 1990	**Sanofi-Aventis** filed the patent application for the '089 patent (Non-HOPE)
November 26, 1991	**Sanofi-Aventis** filed the patent application for the '948 patent. (Non-HOPE)
October 8, 1993	**Sanofi-Aventis** received its first Notice of Compliance for ALTACE 1.25 mg, 2.5 mg, 5 mg, and 10 mg capsules.
October 8, 1993 (Oct 29, 2003 date of revision)	**Sanofi-Aventis** Product Monograph ALTACE ® (ramipril) capsules 1.25, 2.5, 5 and 10mg "Pharmacologic Classification, Angiotensin Converting Enzyme Inhibitor, Action and Clinical Pharmacology"
October 24, 2003 – date of revision	**Sanofi-Aventis** Product Monograph ALTACE (ramipril capsules), 1.25, 2.5, 5, 10mg
January, 1994	**Sanofi-Aventis** commences sales of ALTACE
August 22, 1999	**Sanofi-Aventis '**387 priority application is filed (**HOPE Indication**)
August 30, 1999	**Sanofi-Aventis '**549 priority application is filed **(HOPE Indication**)
April 2, 2000	**Sanofi-Aventis** filed an S/NDS, submission 066094, <u>to approve a new indication</u> for ALTACE namely the "management of patients at increased risk of cardiovascular events".
August 25, 2000	**Sanofi-Aventis** filed the patent (PCT) application for the '387 patent. (HOPE Indication)
August 30, 2000	**Sanofi-Aventis** filed the patent (PCT) application for the '549 patent. (HOPE Indication)
February 5, 2001 – date of revision (Oct 8, 1993, Dec 23, 1996)	**Sanofi-Aventis** Product Monograph ALTACE (ramipril) capsules 1.25, 2.5, 5, 10mg "Pharmacologic Classification, Angiotensin Converting Enzyme Inhibitor, Action and Clinical Pharmacology"
February 13, 2001	**Sanofi-Aventis** received a Notice of Compliance for the S/NDS 066094, with The "Indications and Clinical Use" section was updated to include the subsection "Management of Patients at Increased Risk of Cardiovascular Events"
March 8, 2001	'387, '549 PCT applications are published
October 2002	**Apotex** purchases ALTACE samples
November 12, 2002	**Sanofi-Aventis** was granted the '948 patent.
January 14, 2003	**Sanofi-Aventis** was granted the '089 patent.
January 15, 2003	**Sanofi-Aventis** filed S/NDS 082094 for a further update to the ALTACE capsules <u>product monograph</u>. The S/NDS had two purposes (Changes 1 & 2 or ALTACE 2003) (1) to update the "Action and Clinical Pharmacology" section to add new wording: "...and for the management of patients at increased risk of cardiovascular events" (2) to update the "Management of Patients at Increased Risk of Cardiovascular Event" indication in the product monograph, to further define the stroke patient population by specifying "fatal stroke". The proposed indication was as follows: "ALTACE may be used to reduce the risk of myocardial infarction, stroke

	(including fatal stroke) or cardiovascular death in patients over 55 years..."
June 9, 2003	The **Minister**'s officials, in respect of S/NDS for Changes 1 and 2 (082094) (1) approved the proposed update to the "Action and Clinical Pharmacology" section of the product monograph to include the wording "...and the management of patients at increased risk of cardiovascular events". (2) Denied the proposed inclusion of "(including fatal stroke)" to the "Management of Patients at "Increased Risk of Cardiovascular Events" indication, for two reasons. First, in the view of the Minister's experts, the HOPE study was not designed to evaluate the incidence of fatal stroke in patients at higher risk of cardiovascular events treated with ramipril. Second, the prevention of fatal stroke was considered to be a new indication, requiring new clinical data.
July 31,2003	**Apotex** files ANDS for APO-RAMIPRIL based on comparative bioequivalence studies with ALTACE; July 25, 2003 draft APO-RAMIPRIL Product Monograph includes HOPE Indication
November 6, 2003	**Sanofi-Aventis** was issued a NOC in respect of S/NDS 082094 (Changes 1 & 2) ("2003 Altace") to update the product monograph. The associated product monograph differs from the Altace 2001 in two ways: "management of patients at increased risk of cardiovascular events; and inclusion of "plasma language"
November 10, 2003	**Sanofi-Aventis'** '089 patent was added to the Register in respect of S/NDS 066094 and its NOC.
April 6, 2004	**Apotex** Product Monograph updated to correspond to PM dated October 29, 2003, of ALTACE 2003
April 20 2004	**Apotex's** ANDS put on "Patent Hold"; draft APO-RAMIPRIL Product Monograph includes HOPE Indication and Change #2
April 21, 2004	**Apotex** prepares Product monograph for APO-RAMIPRIL capsules 1.25, 2.5, 5, and 10mg "Therapeutic Classification: Angiotensin Converting Enzyme Inhibitor – Actions and Clinical Pharmacology"
June 25, 2004	**Sanofi-Aventis'** '948 patent was added to the Patent Register in respect of S/NDS 066094 and its NOC
March 15, 2005	**Sanofi-Aventis** '549 patent issues, entitled "Use of inhibitors of the renin-angiotensin system in the prevention of cardiovascular events".
March 17, 2005	**Sanofi-Aventis** '549 patent was added to the Register in respect of the S/NDS 082094 and its NOC. (re: Altace 2003)
June 21, 2005	**Sanofi-Aventis'** '387 patent issues, entitled "Pharmaceutical formulations and use thereof in the prevention of stroke, diabetes and/or congestive heart failure".
June 28, 2005	**Sanofi-Aventis'** '387 patent was added to the Register in respect of the S/NDS 082094 and its NOC. (re: Altace 2003)
November 2, 2005	**Sanofi-Aventis** filed an application to the Federal Court in T-1979-05, under section 6 of the *NOC Regulations,* for an order prohibiting the Minister from issuing a NOC until expiry of the '089, '948, '549 and '387 patents – the Use patents

November 29, 2005	**Apotex's** Notice of Allegation re: HOPE Patents
January 17, 2006	**Sanofi-Aventis** commences proceedings under *Regulations* (T-87-06) re: Nov 29, 2005 NOA
October 2006	**Sanofi-Aventis** updates its ALTACE product monograph
October 5, 2006	*PM (NOC) Regulations* are amended
November 3, 2006	The Supreme Court of Canada released the *AstraZeneca* decision 2006 SCC 49
November 30 2006	**Apotex** commences series of requests for issuance of NOC in light of *AstraZeneca*
December 8, 2006	**Apotex** Product Monograph updated to correspond to ALTACE Product Monograph October 2006 product monograph
December 8, 2006	**Minister** advises **Apotex** that it need not address Patents but must dispose of T-87-06 before an NOC can issue
December 8, 2006	**Apotex** submits further updated APO-RAMIPRIL PM dated Dec 6, 2006; includes HOPE Indication, reference to the ALTACE Oct 2006 PM and changes #1 and #2.
December 10-12, 2006	**Sanofi-Aventis and Apotex** request reconsideration of Dec 8, 2006 decision supported by written representations
December 12, 2006	**Minister** advises Apotex that NOC can be issued following withdrawal of NOA Minister issues NOC for APO-RAMILPRIL and sends it to Apotex, enclosing a PM Apotex's PM dated Dec 12, 2006 includes HOPE indication, Changes #1 and #2, and reference to comparative bioavailability studies Sanofi-Aventis commences judicial review of Dec 8, 2006 decision (T-2189-06)
December 12, 2006	NOC issues to Apotex for Apo-ramipril
December 13, 2006	**Minister** advises Sanofi-Aventis that an NOC has issued to Apotex Sanofi-Aventis commences T-2196-06
December 14, 2006	**Apotex** removes all HOPE study language from the Apo-ramipril product monograph.

FEDERAL COURT

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	T-165-07
STYLE OF CAUSE:	FERRING INC. and THE MINISTER OF HEALTH ET AL
PLACE OF HEARING:	Toronto, Ontario
DATE OF HEARING:	March 1-2, 2007
REASONS FOR JUDGMENT:	Hughes, J.
DATED:	March 20, 2007

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FEDERAL COURT

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	T-2188-06
STYLE OF CAUSE:	SANOFI-AVENTIS CANADA INC. v. MINISTER OF HEALTH, THE ATTORNEY GENERAL OF CANADA, and NOVOPHARM
PLACE OF HEARING:	Toronto, Ontario
DATE OF HEARING:	March 5, 2007
REASONS FOR JUDGMENT:	Hughes J.
DATED:	March 20, 2007

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FEDERAL COURT

NAME OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	T-2189-06
STYLE OF CAUSE:	SANOFI-AVENTIS CANADA INC. and THE MINISTER OF HEALTH ET AL
PLACE OF HEARING:	Toronto, Ontario
DATE OF HEARING:	March 8-9, 2007
REASONS FOR JUDGMENT:	Hughes, J.
DATED:	March 20, 2007

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FEDERAL COURT

NAME OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	T-2196-06
STYLE OF CAUSE:	SANOFI-AVENTIS CANADA INC. and THE MINISTER OF HEALTH ET AL
PLACE OF HEARING:	Toronto, Ontario
DATE OF HEARING:	March 8-9, 2007
REASONS FOR JUDGMENT:	Hughes, J.
DATED:	March 20, 2007

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FEDERAL COURT

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	T-2220-06
STYLE OF CAUSE:	NOVOPHARM LIMITED v. MINISTER OF HEALTH,THE ATTORNEY GENERAL OF CANADA,and SANOFI-AVENTIS CANADA INC.
PLACE OF HEARING:	Toronto, Ontario
DATE OF HEARING:	March 6, 2007
REASONS FOR JUDGMENT:	Hughes J.
DATED:	March 20, 2007

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