Federal Court of Appeal  Cour d'appel fédérale

**Date: 20161012**

**Dockets: A-27-15**
**A-28-15**
**A-143-15**
**A-172-15**

**Citation: 2016 FCA 248**

**CORAM:** **DAWSON J.A.**
**WEBB J.A.**
**RENNIE J.A.**

**Docket: A-27-15**

**BETWEEN:**

**TEVA CANADA LIMITED**

**Appellant**

**and**

**PFIZER CANADA INC. and**
**THE MINISTER OF HEALTH and**
**THE ATTORNEY GENERAL OF CANADA**

**Respondents**

**Docket: A-28-15**

**AND BETWEEN:**

**THE ATTORNEY GENERAL OF CANADA**
**and THE MINISTER OF HEALTH**

**Appellants**

**and**

**PFIZER CANADA INC. and
TEVA CANADA LIMITED**

**Respondents**

**Docket: A-143-15**

**AND BETWEEN:**

**ATTORNEY GENERAL OF CANADA
and THE MINISTER OF HEALTH**

**Appellants**

**and**

**JANSSEN INC. and THE KENNEDY TRUST
FOR RHEUMATOLOGY RESEARCH and
HOSPIRA HEALTHCARE CORPORATION**

**Respondents**

**Docket: A-172-15**

**AND BETWEEN:**

**HOSPIRA HEALTHCARE CORPORATION**

**Appellant / (Respondent)**

**and**

**JANSSEN INC. and THE KENNEDY TRUST
FOR RHEUMATOLOGY RESEARCH**

**Respondents / (Applicants)**

**and**

**THE MINISTER OF HEALTH and**
**ATTORNEY GENERAL OF CANADA**

**Respondents / (Respondents)**

Heard at Toronto, Ontario, on May 31, 2016.

Judgment delivered at Ottawa, Ontario, on October 12, 2016.

REASONS FOR JUDGMENT BY: DAWSON J.A.

CONCURRED IN BY: WEBB J.A.
RENNIE J.A.

Federal Court of Appeal | Cour d'appel fédérale

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**Docket:A-172-15**

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**Appellant / (Respondent)**

**and**

**JANSSEN INC. and THE KENNEDY TRUST
FOR RHEUMATOLOGY RESEARCH**

**Respondents / (Applicants)**

**and**

**THE MINISTER OF HEALTH and
ATTORNEY GENERAL OF CANADA**

**Respondents / (Respondents)**

**REASONS FOR JUDGMENT**

**DAWSON J.A.**

[1] Each of the four appeals before the Court raise the following two issues. First, what is the standard of review to be applied to a decision of the Minister of Health to issue a Notice of Compliance to a generic manufacturer in circumstances when the Minister determines that the generic's drug submission is administrative in nature so that it does not trigger the notice requirement found in section 5 of the *Patented Medicine (Notice of Compliance) Regulations*, SOR/93-133 (PMNOC Regulations or Regulations)? Second, did the Federal Court err when it decided that the Minister's decisions should be set aside? This, in turn, requires consideration of whether the Minister erred in issuing two Notices of Compliance (NOC) without requiring each applicant to notify the affected patentee that the applicant was seeking a NOC.

[2] Briefly, two decisions made by the Minister are at issue on these appeals:

i. The decision of the Minister made on October 1, 2013, to issue a NOC to Teva Canada Limited for an exemestane tablet for oral administration in 25 mg strength. This is a generic version of exemestane tablets marketed by Pfizer Canada Inc. under the brand name AROMASIN.

ii. The decision of the Minister made on June 4, 2014, to issue a NOC to Hospira Healthcare Corporation for its 100 mg/vial infliximab powder for solution. This is a generic version of the 100 mg/vial infliximab powder marketed by Janssen Inc. under the brand name REMICADE.

[3] Pfizer challenged in the Federal Court the decision of the Minister to issue the NOC to Teva in respect of exemestane.

[4] For reasons cited as 2014 FC 1243, issued in the proceeding brought by Pfizer, a judge of the Federal Court found the standard of review of the Minister's decision to be correctness. The Federal Court went on to find that the Minister's interpretation of the PMNOC Regulations was incorrect (reasons, at paragraph 56). In consequence, the Minister's decision to issue the NOC to Teva in respect of exemestane was set aside.

[5] Two of the appeals before the Court relate to this decision of the Federal Court: an appeal brought by Teva in Court Docket A-27-15 and an appeal brought by the Attorney General of Canada and the Minister of Health in Court Docket A-28-15. These appeals were consolidated. As a result, a copy of these reasons will be placed in each Court file.

[6] Janssen also challenged in the Federal Court the decision of the Minister to issue a NOC to Hospira in respect of infliximab. The Federal Court issued its judgment in respect of exemestane while Janssen's application for judicial review of the Minister's decision with respect to infliximab was pending. With the consent of the parties, the Federal Court set aside the

decision of the Minister to issue the NOC to Hospira, without prejudice to any right to appeal from the judgment. This judgment was made to permit the parties to appeal the judgment and to ask that the appeals be heard together with the appeals brought against the judgment of the Federal Court with respect to exemestane.

[7] Two of the appeals before the Court relate to this judgment of the Federal Court: an appeal brought by the Attorney General of Canada and the Minister of Health in Court Docket A-143-15 and an appeal brought by Hospira in Court Docket A-172-15. These appeals were also consolidated, as a result a copy of these reasons will be placed in each Court file.

[8] The Court ordered that the consolidated appeals be heard together.

[9] For the reasons that follow, I have concluded that the Federal Court erred by reviewing the Minister's decisions on the standard of correctness. Applying the standard of reasonableness, I have concluded that the Minister's decisions were reasonable. It follows that I would allow each appeal with costs here and in the Federal Court, set aside the judgments of the Federal Court and dismiss the applications for judicial review brought in respect of the two decisions of the Minister.

[10] I begin my analysis by briefly reviewing the regulatory framework and then move to consider the drug submissions at issue in these appeals, the decision of the Federal Court and the appropriate standard of review of the Minister's decisions. Finally, I apply the appropriate standard of review to the decisions at issue.

## I. The Regulatory Framework

[11] I begin with some background context to the current regulatory regime. In 1923, the *Patent Act*, R.S.C. 1923, c. 23 was amended to introduce compulsory licensing specific to the manufacture of food and medicine. A compulsory license is a license mandated by statute that gives a licensee the right to manufacture, use, or sell a patented invention prior to the expiration of the patent.

[12] In 1992, the government introduced Bill C-91, the *Patent Act Amendment Act*, 1992, in order to amend the *Patent Act*, R.S.C. 1985, c. P-4 (Act or *Patent Act*) to implement obligations Canada had accepted under the Agreement on Trade-Related Aspects of Intellectual Property Rights and the North American Free Trade Agreement. Bill C-91 eliminated compulsory licenses issued on or after December 20, 1991 for pharmaceutical products.

[13] In order to facilitate the early entry of generic drugs to the market following the expiration of patent protection, Bill C-91 created an exception to an action for patent infringement. What is known as the "early working" exception allows a person to use a patented invention while the relevant patent is in force for the sole purpose of obtaining regulatory approval to sell a product equivalent to the patented product on the expiry of the relevant patent. The early working exception eliminated the often lengthy regulatory lag after the expiration of a patent while a generic manufacturer took the required steps to obtain a NOC.

[14] The early working exception is found in subsection 55.2(1) of the Act:

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

[15] The PMNOC Regulations were enacted in 1993 in conjunction with the amendments to the *Patent Act* that terminated compulsory licensing and created the early working exception. The Regulations were enacted in order to, among other things, prevent abuse of the early working exception. The linkage between the early working exception and the PMNOC Regulations is expressly reflected in subsection 55.2(4) of the Act. This is the provision which allows the Governor in Council to enact regulations. It authorizes the enactment of regulations considered necessary for preventing the infringement of a patent by any person who engages in the early working of the patented invention. More specifically:

| | |
|---|---|
| 55.2(4) The Governor in Council may make such regulations as the Governor in Council considers necessary for preventing the infringement of a patent by any person who makes, constructs, uses or sells a patented invention in accordance with subsection (1), including, without limiting the generality of the foregoing, regulations … | 55.2 (4) Afin d'empêcher la contrefaçon d'un brevet d'invention par l'utilisateur, le fabricant, le constructeur ou le vendeur d'une invention brevetée au sens du paragraphe (1), le gouverneur en conseil peut prendre des règlements, notamment … |
| (emphasis added) | (soulignement ajouté) |

[16] The protection provided to innovators in the PMNOC Regulations is in addition to the remedy for patent infringement under the Act.

[17] The salient features of the regulatory regime as it applies to pharmaceutical drugs such as exemestane may be briefly summarized as follows:

i. A drug manufacturer who wishes to advertise or sell a new drug in Canada must first obtain a NOC pursuant to Part C, Division 8 of the *Food and Drug Regulations*, C.R.C. c. 870. This is done by filing one of a number of types of drug submissions. A drug manufacturer is defined to include an entity who sells a drug "under their own name" (*Food and Drug Regulations*, section A.01.010).

ii. A drug approved to be marketed in Canada is assigned a unique Drug Identification Number which identifies the following characteristics of the drug: its brand name, manufacturer, medicinal ingredient or ingredients, the strength of the medicinal ingredient or ingredients, the pharmaceutical dosage form and the route of administration.

iii. Typically, an innovator drug manufacturer seeking authorization to advertise or sell a new drug in Canada files a new drug submission (NDS) pursuant to section C.08.002 of the *Food and Drug Regulations*. This type of drug submission generally requires substantial evidence of clinical trials and studies to demonstrate that the new drug is safe and effective.

iv. Another type of drug submission is an abbreviated new drug submission (ANDS), which is available under section C.08.002.1 of the *Food and Drug Regulations*. Typically, a generic drug manufacturer will file an ANDS in order to obtain a NOC. The generic manufacturer will make its own version of a previously approved brand-name drug. The brand-name drug is defined in section C.08.001.1 of the *Food and Drug Regulations* to be a "Canadian reference product". The

generic manufacturer tests its version of the Canadian reference product in order to demonstrate that the generic's version is bioequivalent to the Canadian reference product. Thus, the safety and effectiveness of the generic drug is established by demonstrating its bioequivalence to a drug whose safety and effectiveness has previously been established.

v. The PMNOC Regulations provide a mechanism by which a patent holder may delay the entry of a generic version of its patented drug onto the market. Section 4 permits an innovator who has filed a NDS and obtained a NOC to submit a patent list to the Minister in respect of the drug. If the patent or patents on the list meet the requisite criteria, the Minister may add the patent or patents to the Patent Register maintained by the Minister. The patent holder who submits a patent list is referred to as a "first-person".

vi. Thereafter, if a "second person", usually a generic drug manufacturer, seeks a NOC based on demonstrating the bioequivalence of its drug to a Canadian reference product, the second person must address each patent listed on the Patent Register in association with the Canadian reference product. The second person may address a listed patent by stating that the second person accepts that the NOC will not issue until all relevant patents expire. Alternatively, the second person may allege that a listed patent is not valid or that a listed patent will not be infringed if the second person is permitted to make, use or sell the version of the drug for which the second person seeks the NOC (subsection 5(1) of the PMNOC Regulations).

vii. A second person who alleges patent invalidity or non-infringement must then serve the first person with particulars of its allegations in a “notice of allegation”, and must prove service of the notice of allegation on the first person to the Minister (subsection 5(3) of the PMNOC Regulations).

viii. A patentee served with a notice of allegation may apply to a court for an order prohibiting the Minister from issuing a NOC until after the expiration of a patent that is the subject of the notice of allegation (subsection 6(1) of the PMNOC Regulations).

ix. A patentee’s application for prohibition under subsection 6(1) automatically triggers a statutory stay (subsection 7 of the PMNOC Regulations). During the period of the statutory stay, the Minister may not issue a NOC until one of a number of prescribed events has occurred. For example, one event that terminates the statutory stay is when a court declares that an allegation that the patent is not valid or will not be infringed by the second person is justified. Another event is when a period of 24 months elapses after the Minister receives proof that a court application has been made under subsection 6(1). Additionally, the stay triggered by the service of a notice of allegation is terminated if 45 days expires from the date a notice of allegation is served on a patentee and the patentee fails to apply for an order of prohibition under subsection 6(1) of the PMNOC Regulations.

[18] Having briefly reviewed the regulatory framework as it applies to pharmaceutical drugs such as exemestane, it is necessary to note that infliximab is a biologic, not a pharmaceutical, drug. Biologic drugs are derived through the metabolic activity of living organisms; they are

variable and structurally complex. Biologic drugs are typically manufactured from animals, microorganisms, or through the use of animals or microorganisms.

[19] The approval process for subsequent entry biologic (SEB) drugs differs in certain ways from the approval process for generic pharmaceutical drugs. The main differences may be summarized as follows:

i. The approval of a SEB is sought by filing a NDS pursuant to section C.08.002 of the *Food and Drug Regulations*. This is to be contrasted with the filing of an ANDS for the approval of a generic version of a pharmaceutical drug.

ii. In its NDS, the SEB sponsor seeks a NOC based on the demonstrated similarity of its product to a previously approved reference biologic drug. Therefore, the NDS will provide extensive data demonstrating the similarity of the subsequent entry biologic with the reference biologic drug. This reliance on the reference biologic drug reduces the required amount of clinical and non-clinical information required to demonstrate safety and efficacy.

[20] Having reviewed the regulatory framework, I now turn to review the drug submissions at issue in these appeals.

## II. The Drug Submissions

### (1) Pfizer's Supplemental New Drug Submission for AROMASIN

[21] On March 17, 2005, Pfizer filed a supplemental NDS seeking approval to market tablets containing the medicinal ingredient exemestane in 25 mg strength under the trade name AROMASIN. A NOC issued in respect of this submission on May 12, 2006.

[22] On May 12, 2006, Pfizer filed a patent list in order to list Canadian Patent No. 2,409,059 (059 patent) on the Patent Register in respect of the AROMASIN tablets in 25 mg strength.

[23] On May 18, 2006, the 059 patent was listed on the Patent Register. It follows that Health Canada was satisfied that the patent complied with subsection 4(2) of the PMNOC Regulations. A patent complies with this provision if, for example, the patent contains a claim for a medicinal ingredient and the medicinal ingredient was approved through the issuance of a NOC in respect of a NDS (paragraph 4(2)(*a*) of PMNOC Regulations).

### (2) Generic Medical Partners Inc.'s ANDS for MED-EXEMESTANE

[24] Of limited relevance is an ANDS filed by Generic Medical Partners Inc. (GMP) that was not properly served on Pfizer. Through administrative error this led to a short-lived NOC issued to GMP and, later, a related NOC issued to Teva. The Federal Court discussed this at paragraphs 37 to 42 of its reasons. Of greater relevance is the drug submission made by GMP that led to the NOC at issue on these appeals.

[25] On May 22, 2012, GMP filed an ANDS seeking approval to market tablets containing the medicinal ingredient exemestane in 25 mg strength under the trade name MED-EXEMESTANE. Subsequently, on August 16, 2013, GMP served a notice of allegation on Pfizer in which it made allegations in respect of the 059 patent.

[26] Although properly served with the NOC, Pfizer did not commence an application seeking prohibition pursuant to subsection 6(1) of the PMNOC Regulations.

[27] In consequence, the Minister issued a NOC to GMP on October 1, 2013.

(3) Teva's ANDS for TEVA-EXEMESTANE

[28] On June 18, 2013, Teva filed an ANDS, which cross-referenced GMP's ANDS, in which Teva sought approval to market tablets containing the medicinal ingredient exemestane in 25 mg strength under the trade name TEVA-EXEMESTANE.

[29] Teva's ANDS did not contain any data. It included a certification in which Teva certified that all aspects of Teva's drug product were identical to GMP's cross-referenced drug product except for the names of the manufacturer and the product. Teva also certified that its drug product would be manufactured in the same location as GMP's drug product, with identical specifications and procedures. Teva also included in its submission an authorization from GMP permitting the Minister to access GMP's ANDS when processing Teva's ANDS.

[30] On October 1, 2013, the Minister issued a NOC to Teva.

(4) Janssens' NOC for REMICADE

[31] On September 27, 2001, based on a NDS filed by Centocor Inc., a NOC issued to Centocor with respect to a 100 mg/vial infliximab powder for solution product marketed under the brand name REMICADE. At the same time, a Drug Identification Number was issued with respect to this medication: 02244016.

[32] On June 20, 2011, Janssen filed an administrative NDS to transfer the Drug Identification Number issued for REMICADE from Centocor to Janssen. On August 5, 2011, Janssen was issued a NOC in response to its administrative NDS and the Drug Identification Number was transferred to Janssen.

[33] With the consent of the patent owner, The Kennedy Trust for Rheumatology Research, Janssen filed a Patent List in order to list Canadian Patent No. 2,261,630 (630 patent) on the Patent Register in respect of REMICADE.

[34] On December 4, 2012, the 630 patent issued. It was listed on the Patent Register on December 6, 2012 in respect of REMICADE.

(5) Celltrion Healthcare Co. Ltd.'s NDS for INFLECTRA

[35] On November 14, 2012, Celltrion Healthcare Co. Ltd. filed a NDS seeking approval to market its subsequent entry biologic INFLECTRA which contained the medicinal ingredient

infliximab in 100 mg/vial strength in powder for solution dosage form. In its NDS Celltrion sought to demonstrate similarity between INFLECTRA and REMICADE.

[36] Celltrion's NDS nominated Hospira to be a distributor for INFLECTRA (affidavit of Beryl Chan, the Regulatory Affairs Director of Hospira, at paragraph 16).

[37] As at November 14, 2012, the filing date of Celltrion's NDS, no patent was listed on the Patent Register in respect of REMICADE. As a result, on January 15, 2014, the Minister issued a NOC to Celltrion in respect of INFLECTRA. The Minister assigned a Drug Identification Number to INFLECTRA: 02419475.

[38] Hospira was entitled to sell INFLECTRA under this NOC (affidavit of Beryl Chan, at paragraph 16).

(6) Hospira's NDS for INFLECTRA

[39] On April 7, 2014 Hospira filed a NDS cross-referencing Celltrion's NDS seeking approval to market INFLECTRA.

[40] Hospira's NDS did not contain any scientific data. It included its certification that Hospira and Celltrion had entered into a licensing agreement with respect to INFLECTRA and that pursuant to this agreement Celltrion would no longer be selling the product. In the certification Hospira certified that, except the manufacturer's name, all aspects of its drug product were identical to the cross-referenced Celltrion drug product and that the product would

be manufactured in the same location with identical specifications and procedures. As well, a letter of authorization was provided from Celltrion permitting the Minister to cross-reference its NDS when processing Hospira's NDS.

[41] The Biologics and Genetic Therapies Directorate of Health Canada concluded that because there were no changes to the previously approved drug product itself, there were no patents that Hospira was required to address (Exhibit I to the affidavit of Pino DiFranco, a Patent Officer-Legal, employed by Health Canada).

[42] On June 4, 2014 the Minister issued a NOC to Hospira in respect of its NDS for INFLECTRA. The Minister assigned the same Drug Identification Number to Hospira's INFLECTRA as had previously been assigned to Celltrion's INFLECTRA.

## III. The Decision of the Federal Court

[43] As mentioned above, the Federal Court found the standard of review of the Minister's decision to be correctness. It went on to find that the Minister's interpretation of the PMNOC Regulations was incorrect.

[44] Central to the reasoning of the Federal Court were its conclusions that:

i. the prior jurisprudence had not satisfactorily settled the applicable standard of review (reasons, at paragraphs 70-72, 105-108);

ii. the reasonableness standard of review "is presumptively applicable whenever an administrative decision-maker interprets its constituent statute or a statute or

regulation that is closely connected with its function" unless certain limited exceptions apply (reasons, at paragraphs 67, 109);

iii. notwithstanding the broad language employed by the Supreme Court in *Canadian National Railway Co. v. Canada (Attorney General)*, 2014 SCC 40, [2014] 2 S.C.R. 135, at paragraphs 59-62, to describe the deference owed to the Governor in Council when interpreting legislation closely related to its economic regulatory review function, this decision did not establish a fixed rule that the presumption of reasonableness may only be rebutted if the decision at issue falls into one of four categories. Those categories are constitutional questions, true jurisdictional questions, questions of competing jurisdiction between administrative tribunals and questions of general importance to the legal system as a whole which are outside of the decision-maker's expertise (reasons, at paragraph 88);

iv. the presumption of reasonableness may be rebutted if a contextual analysis demonstrates that Parliament did not intend the question to be left to the decision-maker to determine because the question falls more appropriately within the expertise of the reviewing court (reasons, at paragraph 104);

v. having regard to the purpose of the decision-maker, the nature of the question at issue and the expertise of the decision-maker, the presumption of reasonableness was rebutted (reasons, at paragraphs 111-120);

vi. more specifically, the Federal Court found that:

    a. nothing in the PMNOC Regulations indicated that the Governor in Council intended the issue of whether an applicant has made a "submission for an NOC" that "directly or indirectly compares" its

product to that of another innovator be left to the Minister or officials within Health Canada (reasons, at paragraph 113);

b. indeed, the regulatory and statutory context indicated that the issue is not to be left to Health Canada because the Minister enjoys no discretion as to whether to issue a NOC (reasons, at paragraph 114); and,

c. the Governor in Council left to the Court the ultimate determination of whether a NOC should issue under the PMNOC Regulations. The Court's role is inconsistent with application of the reasonableness standard to the Minister's decisions. Further, the case was similar to that in *Takeda Canada Inc. v. Canada (Minister of Health)*, 2013 FCA 13, 440 N.R. 346 where the dissenting judge rebutted the presumptive application of the reasonableness standard on the basis that the question before the Minister was purely legal, the Minister had no experience in legal interpretation and nothing in the legislation suggested deference should be given to the Minister's decision (reasons, at paragraphs 116-118);

vii. the Federal Court then turned to the application of the correctness standard to the decision of the Minister, recognizing that the applicable statutory and regulatory provisions were to be interpreted in a purposive manner (reasons, at paragraphs 121, 131);

viii. the Federal Court rejected the notion that the purpose of the PMNOC Regulations "is to allow the 'early working'" of a patented drug by a generic drug manufacturer. These Regulations exist not only to allow early working but also to balance the interest in promoting early access to less expensive generic drugs with

the interest of patentees in obtaining proper protection for their patented inventions. It is irrelevant to the objects of subsection 5(1) of the PMNOC Regulations that Teva did not take advantage of the early working exception. Once "the purpose of the PMNOC Regulations is properly understood, it supports the conclusion that a company in the position of Teva must comply with subsection 5(1) of the Regulations" (reasons, at paragraphs 133-136);

ix. the Federal Court rejected the argument that Teva's administrative drug submission did not come within the scope of subsection 5(1) of the PMNOC Regulations. The Federal Court could not distinguish the decisions of this Court in *Nu-Pharm Inc. v. Canada (Attorney General)* (1998), 80 C.P.R. (3d) 74, [1998] F.C.J. No. 274 (*Nu-Pharm 1*); and *Merck & Co., Inc. v. Canada (Attorney General*) (2000), 179 F.T.R. 278, 5 C.P.R. (4th) 138 (*Nu-Pharm 2*) (together the *Nu-Pharm* decisions). The Federal Court viewed these cases to indicate that "subsection 5(1) of the PMNOC Regulations exists to require all generic companies who obtain their rights through a licence to address an innovator company's patent on the Patent Register created by the Regulations, whether they make a direct or an indirect comparison to the innovator's product". Further, just as in the present cases, in the *Nu-Pharm* decisions the generic company had acquired the right to produce the drug in question under a license from another generic company and filed a submission that made a direct or indirect comparison to an innovator's drug (reasons, at paragraphs 137, 141);

x. the Federal Court rejected the submission that the situation before the Court was identical to that before the Court in *GlaxoSmithKlein Inc. v. Canada (Attorney*

*General)*, 2004 FC 1302, 38 C.P.R. (4th) 27 (*Glaxo*) where the Federal Court held that the administrative new drug submissions filed in that case did not engage the PMNOC Regulations because such submissions were not "submissions" within the meaning of subsection 5(1) of the PMNOC Regulations. In the Federal Court's view, the decision was distinguishable because in *Glaxo* the generic company had complied with subsection 5(1) of the PMNOC Regulations and had served a notice of allegation on the innovator company and the Judge's comments relied upon by the Attorney General were *obiter* (reasons, at paragraph 142); and,

xi. finally, the Federal Court found that the cases interpreting the meaning of "submission" in the context of section 4 of the PMNOC Regulations for the purpose of listing a patent on the Patent Register are inapplicable to the issues in this case - the concerns about an innovator company extending its entitlements under the Regulations through administrative filings do not arise in this case (reasons, at paragraph 143).

## IV. The Standard of Review to be applied to the Decision of the Federal Court

[45] It is well-settled, and not in contention on these appeals, that when reviewing a decision of the Federal Court made in the context of an application for judicial review, this Court is required to determine whether the Federal Court identified the appropriate standard of review and then properly applied the standard (*Agraira v. Canada (Public Safety and Emergency Preparedness)*, 2013 SCC 36, [2013] 2 S.C.R. 559, at paragraph 45).

V. Did the Federal Court err when it identified the appropriate standard of review to be correctness?

[46] I agree with the Federal Court that the prior jurisprudence had not satisfactorily determined the standard of review to be applied to the decisions of the Minister. I reject the submissions of the respondents Pfizer, Janssen and The Kennedy Trust that decisions such as *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, 2005 SCC 26, [2005] 1 S.C.R. 533, at paragraph 36 (*Biolyse*) and *AstraZeneca v. Canada (Minister of Health)*, 2006 SCC 49, [2006] 2 S.C.R. 560, at paragraph 25 selected the standard of review in a manner binding upon this Court and the Federal Court. As the Federal Court correctly noted, in *Agraira*, at paragraph 48, the Supreme Court instructed that the standard of review cannot be seen to be satisfactorily established "if the relevant precedents appear to be inconsistent with recent developments in the common law principles of judicial review". In my view this is the case in the present appeals because both *Biolyse* and *AstraZeneca* were decided without regard to the presumption of reasonableness articulated in cases such as *Alberta Teachers' Association v. Alberta (Information and Privacy Commissioner)*, 2011 SCC 61, [2011] 3 S.C.R. 654, at paragraph 39.

[47] I also agree with the Federal Court that the presumption of reasonableness may be rebutted when a contextual analysis reveals Parliament's intent "not to protect the tribunal's jurisdiction in relation to certain matters; the existence of concurrent and non-exclusive jurisdiction on a given point of law is an important factor in this regard" (*Mouvement laïque québécois v. Saguenay (City)*, 2015 SCC 16, [2015] 2 S.C.R. 3, at paragraph 46; citing, *Tervita Corp. v. Canada (Commissioner of Competition)*, 2015 SCC 3, [2015] 1 S.C.R. 161, at paragraphs 35-36 and 38-39; *McLean v. British Columbia (Securities Commission)*, 2013 SCC

67, [2013] 3 S.C.R. 895, at paragraph 22; *Rogers Communications Inc. v. Society of Composers, Authors and Music Publishers of Canada*, 2012 SCC 35, [2012] 2 S.C.R. 283, at paragraph 15).

[48] Where my analysis diverges from that of the Federal Court is that in my view a contextual analysis does not rebut the presumption of reasonableness.

[49] The Federal Court relied upon the following considerations to rebut the presumption of reasonableness:

i. the Minister has no discretion whether to issue a NOC. The Minister may not issue a NOC until the criteria in section 7 of the PMNOC Regulations are met (reasons, at paragraph 114);

ii. the Governor in Council left the ultimate decision of whether a NOC should issue under the PMNOC Regulations to the Court, because the Federal Court is required to adjudicate applications for prohibition. This role is inconsistent with reasonableness review (reasons, at paragraph 116); and,

iii. the question was purely legal, and nothing in the PMNOC Regulations suggests that deference should be given to the Minister's interpretation of the Regulations (reasons, at paragraph 118).

[50] I begin my analysis by rejecting the respondents' submission that the argument for reasonableness review rests on the incorrect characterization of the PMNOC Regulations as the Minister's home statute. While I agree that these regulations are enacted pursuant to the *Patent Act* which falls under the Minister of Industry, not Health, this is too narrow a view of the

prevailing jurisprudence. The presumption of reasonableness applies when an administrative decision-maker is interpreting not just its home statute, but also when the decision-maker is interpreting "statutes closely connected to its function" (*Dunsmuir v. New Brunswick*, 2008 SCC 9, [2008] 1 S.C.R. 190, at paragraph 54). This applies equally to regulations such as the PMNOC Regulations that are closely connected to the function of the Minister of Health.

[51] Having concluded that it should be presumed that the decision of the Minister interpreting the PMNOC Regulations is reviewable on the standard of reasonableness, neither the fact that this raises a legal question nor the fact that the PMNOC Regulations do not suggest deference point away from the reasonableness standard.

[52] Since *Dunsmuir*, the Supreme Court has stated that the interpretation of unclear language in an administrative decision-maker's home statute (or regulation) is usually best left to the administrative decision-maker (*McLean*, at paragraph 43). The proper inquiry is whether the PMNOC Regulations evidence Parliament's intention that decisions of the Minister interpreting the Regulations be reviewed on a less deferential standard of review (*Tervita*, at paragraphs 38-39).

[53] I can find no indication of such intention in the PMNOC Regulations.

[54] I also disagree that the role of the Court in the PMNOC Regulations is inconsistent with reasonableness review, and disagree that this case is "somewhat similar to *Rogers Communications Inc.* in which Justice Rothstein for the majority applied the correctness standard

to the review of the Copyright Board's interpretation of its constituent Act on the basis that the Board and the courts shared concurrent jurisdiction under the statute…" (reasons, at paragraph 117).

[55] The Minister has exclusive jurisdiction to decide whether a drug submission filed by a second person makes a comparison with a Canadian reference product so as to require the second person to address a patent listed on the Patent Register. It is only if this question is answered by the Minister in the affirmative, a notice of allegation is served by the second person, and a prohibition application is commenced by the first person that the Minister is prohibited from issuing a NOC under paragraph 7(1)(*e*) of the Regulations (section 7 PMNOC Regulations).

[56] Aside from the Court's potential role on an application for judicial review of a Ministerial decision made under section 5, the PMNOC Regulations provide a role for the Court as a first instance decision-maker only under section 6: where a first person has initiated an application for prohibition it is for the Court to determine whether the allegations contained in a second person's notice of allegation are justified. On an application for prohibition, the Court does not consider whether section 5 ought to have been triggered in the first place. It follows that in a prohibition application there is no possibility of conflicting interpretations between the Minister and the Court with respect to whether section 5 was triggered.

[57] In my view, the question of whether a drug submission triggers section 5 of the PMNOC Regulations is a question of mixed fact and law. It is well-settled that reasonableness is the standard of review to be applied to such questions (see, for example, *Tervita*, at paragraph 40).

[58] In *Dunsmuir*, at paragraph 68, the Supreme Court recognized that where there is a discrete or special administrative regime in which the decision-maker has special expertise, that decision-maker is entitled to deference. In my view Health Canada, and through it the Minister, are required on a regular basis to interpret section 5 of the Regulations. For example, the Minister is required to determine whether to issue a NOC or to place a drug submission on patent hold. In *AstraZeneca*, the Supreme Court required the Minister to conduct a patent-specific analysis when applying subsection 5(1) because a "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" (*AstraZeneca*, at paragraph 39).

[59] It follows from the nature of the question and the Minister's expertise that the decisions at issue should be reviewed on the standard of reasonableness.

[60] I now turn to the second issue.

VI. Was it unreasonable for the Minister to conclude that section 5 of the PMNOC Regulations was not engaged by the drug submissions at issue such that NOCs should issue to Teva and Hospira?

[61] Because the Federal Court did not apply the appropriate standard of review it is necessary for this Court to apply the appropriate standard of review, reasonableness, to the decisions of the Minister. This said, it is helpful to review the conclusions that led the Federal Court to its determination that the decisions of the Minister were incorrect.

[62] The pertinent conclusions of the Federal Court on this point were as follows:

i. the Federal Court rejected the notion that the purpose of the PMNOC Regulations "is to allow the 'early working'" of a patented drug by a generic drug manufacturer. These Regulations exist not only to allow early working but also to balance the interest in promoting early access to less expensive generic drugs with the interest of patentees in obtaining proper protection for their patented inventions. Therefore it was irrelevant to the objects of subsection 5(1) of the PMNOC Regulations that Teva did not take advantage of the early working exception (reasons, at paragraphs 133-135);

ii. the Federal Court rejected the argument that Teva's administrative drug submission did not come within the scope of subsection 5(1) of the PMNOC Regulations. The Federal Court could not distinguish the *Nu-Pharm* decisions of this Court. These cases held that "subsection 5(1) of the PMNOC Regulations exists to require all generic companies who obtain their rights through a licence to address an innovator company's patent on the Patent Register created by the Regulations, whether they make a direct or an indirect comparison to the innovator's product". Just as in the *Nu-Pharm* decisions, Teva "filed a submission that makes a direct or indirect comparison" to a first person's drug (reasons, at paragraphs 137, 141);

iii. the Federal Court rejected the submission that the situation before the Court was identical to that before the Court in *Glaxo*, where the Federal Court held that the administrative new drug submissions filed in that case did not engage the PMNOC Regulations, because in *Glaxo* the generic company had complied with subsection 5(1) of the PMNOC Regulations and had served a notice of allegation

on the innovator company. Moreover, the comments relied upon by the Attorney General were *obiter* (reasons, at paragraph 142); and,

iv. finally, the Federal Court found that the cases interpreting the meaning of "submission" in the context of section 4 of the PMNOC Regulations for the purpose of listing a patent on the Patent Register were inapplicable to the issues in this case - the concerns about an innovator company extending its entitlements under the Regulations through administrative filings did not arise in this case (reasons, at paragraphs 143).

[63] I will deal with each point in turn.

[64] First, I disagree that it is irrelevant for the purpose of subsection 5(1) of the PMNOC Regulations whether Teva or Hospira took advantage of the early working exception.

[65] In *Biolyse*, the Supreme Court considered the situation where Bristol-Myers Squibb had a number of patents related to new and useful formulations and methods of administration of the drug paclitaxel. Bristol-Myers Squibb did not have a patent on paclitaxel itself – a drug discovered by the National Cancer Institute of the United States and then put into the public domain. Bristol-Myers Squibb argued that, pursuant to what was then subsection 5(1.1) of the Regulations, a generic manufacturer was required to address its patents simply because its formulation contained paclitaxel and the offending Biolyse product was bioequivalent to Bristol-Myers Squibb's product.

[66] At first instance, the Federal Court had found that the Biolyse product had been properly characterized as an innovator drug. Notwithstanding, the Federal Court found the Biolyse product to be captured by subsection 5(1.1) of the Regulations.

[67] Subsection 5(1.1) then in force provided:

| | |
|---|---|
| 5.(1.1) Subject to subsection (1.2), where subsection (1) does not apply and where a person files or has filed a submission for a notice of compliance in respect of a drug that contains a medicine found in another drug that 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 included on the register in respect of the other drug containing the medicine, where the drug has the same route of administration and a comparable strength and dosage form, | 5.(1.1) Sous réserve du paragraphe (1.2), lorsque le paragraphe (1) ne s'applique pas, la personne qui dépose ou a déposé une demande d'avis de conformité pour une drogue contenant un médicament que l'on trouve dans une autre drogue qui a été commercialisée au Canada par suite de la délivrance d'un avis de conformité à la première personne et à l'égard de laquelle une liste de brevets a été soumise doit inclure dans la demande, à l'égard de chaque brevet inscrit au registre visant cette autre drogue contenant ce médicament, lorsque celle-ci présente la même voie d'administration et une forme posologique et une concentration comparables : |
| (*a*) state that the person accepts that the notice of compliance will not issue until the patent expires; or | *a*) soit une déclaration portant qu'elle accepte que l'avis de conformité ne soit pas délivré avant l'expiration du brevet; |
| (*b*) allege that | *b*) soit une allégation portant que, selon le cas : |
| (i) the statement made by the first person pursuant to paragraph 4(2)(c) is false, | (i) la déclaration faite par la première personne aux termes de l'alinéa 4(2)*c*) est fausse, |
| (ii) the patent has expired, | (ii) le brevet est expiré, |
| (iii) the patent is not valid, or | (iii) le brevet n'est pas valide, |
| (iv) no claim for the medicine itself | (iv) aucune revendication pour le |

| | |
|---|---|
| and no claim for the use of the medicine would be infringed by the making, constructing, using or selling by that person of the drug for which the submission for the notice of compliance is filed. | médicament en soi ni aucune revendication pour l'utilisation du médicament ne seraient contrefaites advenant l'utilisation, la fabrication, la construction ou la vente par elle de la drogue faisant l'objet de la demande d'avis de conformité. |
| (emphasis added) | (soulignement ajouté) |

[68] The majority of the Supreme Court made a number of key points when rejecting Bristol-Myers Squibb's submission:

i. the scope of a regulation is constrained by its enabling legislation (reasons, at paragraph 38). It followed that the Regulations had to be read in the light of subsection 55.2(4) of the Act;

ii. while the word "submission" provided the "gateway" into subsection 5(1.1), the term was not defined in the Regulations (reasons, at paragraph 40);

iii. reading the Regulations in the light of subsection 55.2(4), it followed that the Regulations were directed to persons who made use of a "patented invention" (reasons, at paragraph 52);

iv. not every use of a patented invention triggered the Regulations. Subsection 55.2(4) was directed to preventing infringement by persons who use "the patented invention" for the "early working" exception. This is all the Governor in Council is authorized to regulate (reasons, at paragraph 53);

v. the fact paclitaxel was found in the Biolyse product did not mean that Biolyse "took advantage of" Bristol-Myers Squibb's inventions for the purpose of "early working" a generic copy in anticipation of the expiration of the Bristol-Myers Squibb patents (reasons, at paragraph 54);

vi. the interpretation of subsection 5(1.1) sought by Bristol-Myers Squibb went well beyond the provision's purpose of preventing generic manufacturers from hiding their reliance on innovator drugs by putting forward as a reference drug another generic manufacturer's product. "If the approval of the generic drug is related to the work of another drug manufacturer in respect of which a patent list has been filed (as in the *Nu-Pharm* type situations), it will be caught by s. 5(1.1)." (reasons, at paragraph 65).

[69] On this last point, the Supreme Court's reference to the "*Nu-Pharm* type situations" shows that when making this statement the Supreme Court had in its contemplation the situation where a second generic relies on the drug submission of a first generic who did not comply with subsection 5(1) of the Regulations. In *Nu-Pharm* the first generic neither served a notice of allegation nor was required to deal with subsection 5(1) because no patent was listed against its Canadian reference product.

[70] Subsequently, in *AstraZeneca* the Supreme Court made the following points of relevance to these appeals:

i. the Court reiterated that the grant of the regulation-making power in subsection 55.2(4) of the Act is expressly limited to prevention of infringement by a generic manufacturer who takes advantage of the early working exception (reasons, at paragraph 15);

ii. for the purpose of considering a generic manufacturer's obligations under subsection 5(1) of the PMNOC Regulations, the important aspect of *Biolyse* was

the emphasis it placed on the need to interpret the Regulations "with careful regard to the limited purposes" set out in subsection 55.2(4) of the Act (reasons, at paragraph 16);

iii. if Apotex did not early work two after-listed patents because they were not incorporated into any product available to Apotex to copy, it was difficult to see why Apotex should be required to comply with the Regulations in respect of those patents (reasons, at paragraph 18);

iv. a supplementary NDS may be submitted for either substantive or purely administrative reasons (reasons, at paragraph 19);

v. the "whole obligation incurred by the generic manufacturer under the [PMNOC Regulations] is based on its 'early working' of patents embodied in 'another drug for the purpose of demonstrating bio-equivalence'" (reasons, paragraph 37); and,

vi. when a generic is erroneously required to comply with the Regulations, the balance struck by Parliament between making safe and effective drugs available to the public and preventing abuse of the early working exception is undermined (reasons, at paragraph 39).

[71] In sum, because Apotex did not make use of the patented inventions taught by the patents at issue Apotex did not fall within the mischief aimed at by the PMNOC Regulations (*AstraZeneca*, at paragraph 38).

[72] Subsequently, in reliance upon *AstraZeneca*, this Court has held that the Minister must attempt to determine whether a listed patent was early worked before requiring a generic to

address a listed patent (*Canada (Health) v. Pharmascience Inc.*, 2009 FCA 183, 392 N.R. 315, at paragraphs 25-26).

[73] Given the Supreme Court's observation in *AstraZeneca*, at paragraph 18, that unless Apotex had taken advantage of early working patents whose inventions were incorporated into Apotex' reference product it was difficult to see why Apotex should be subject to the Regulations, the question of whether Teva or Hospira early worked the relevant patents was a relevant consideration.

[74] This is particularly pertinent to Hospira which cross-referenced its drug submission to that of Celltrion. As a matter of law, Celltrion could not have early worked Janssen's patented invention for infliximab: Janssen's 630 patent was issued and listed after Celltrion filed its NDS. Nor did Hospira use Celltrion's INFLECTRA as a Canadian reference product in the usual fashion in order to demonstrate bioequivalence. Hospira's drug product was Celltrion's drug product.

[75] Next, I am not persuaded that the *Nu-Pharm* decisions cannot be distinguished from the cases before the Federal Court.

[76] In my view, the *Nu-Pharm* decisions must be read in the context of their unique factual circumstances. There, Apotex, the first generic, filed its drug submission before the PMNOC Regulations were enacted. Apotex therefore obtained its NOC without addressing the relevant patent. In the present case, GMP complied with the Regulations by serving a notice of allegation

upon Pfizer. GMP's NOC issued only after Pfizer failed to challenge GMP's allegations of invalidity and non-infringement. Celltrion was not obliged to address any patent because none was listed against REMICADE. In *Nu-Pharm* this Court was not required to consider the position of a second generic which was licensed to sell a first generic's drug by a first generic who either complied with the Regulations or was not required to address any listed patent.

[77] Moreover, I accept the submission that decisions that pre-date *Biolyse* and *AstraZeneca* must be read with care. Thus, in *Biolyse* the "*Nu-Pharm* type" situation was distinguished from that where a generic did not early work the patented invention (*Biolyse*, reasons at paragraph 65). Further, any interpretation of the Regulations not limited to preventing infringement occurring as a result of the early working exception will exceed the scope of regulation-making authority conferred by subsection 55.2(4) of the Act.

[78] Next, I am not persuaded that the *Glaxo* decision is distinguishable on the basis articulated by the Federal Court. I reach this conclusion for the following reasons.

[79] First, I disagree with the Federal Court that in *Glaxo* "the generic company … had complied with subsection 5(1) of the Regulations and had served [a notice of allegation] on the innovator company in respect of whose product it had undertaken a comparison" (reasons, at paragraph 142). Apotex, the generic, did not serve a notice of allegation on either 3M Canada (whose product AiromirÔ Apotex cross-referenced in its drug submission) or GlaxoSmithKline (a patent holder that alleged Apotex' product contained the same medicine as its product Ventolin). This is apparent from the fact that Apotex had entered into a licensing agreement with

3M which allowed Apotex to sell 3M's product under its own name (*Glaxo* reasons, at paragraph 16) and from the fact the Federal Court found that the Minister had properly issued a NOC to Apotex without requiring it to serve a notice of allegation on GlaxoSmithKline (*Glaxo* reasons, at paragraph 72).

[80] Second, I disagree with the Federal Court that in *Glaxo* the Federal Court's conclusion that the administrative NDS did not engage the PMNOC Regulations was *obiter*. As evidenced by paragraph 73 of the *Glaxo* reasons, the Federal Court's reliance upon Apotex' comparison with 3M's product was only in the event it was wrong in its primary conclusion that the Regulations did not apply to the administrative NDS.

[81] The final reason given by the Federal Court for its conclusion that Teva had directly or indirectly compared its product to AROMASIN so that its drug submission fell within subsection 5(1) of the Regulations was that cases that had interpreted the meaning of "submission" in the context of section 4 of the Regulations were inapplicable because "the concerns about an innovator company's extending its entitlements under the Regulations through administrative filings do not arise in this case" (reasons, at paragraph 143). Again, I respectfully disagree.

[82] Returning to the decision of the Supreme Court in *Biolyse*, the Supreme Court was required to interpret the word "submission" in the then current version of subsection 5(1.1) of the Regulations. To do so, the Court looked to subsection 4(1) of the Regulations, a provision the Court characterized to be a "reciprocal provision" to then subsection 5(1.1) (*Biolyse*, at paragraph 61). At paragraphs 57-61 Justice Binnie wrote:

> 57 The word "submission" is used in various places in the NOC Regulations. In particular, the text of s. 4(1) provides the template on which s. 5(1.1) is modelled. The relevant words in s. 4(1) are:
>
> > 4.(1) A person who files or has filed a submission for, or has been issued, a notice of compliance in respect of a drug that contains a medicine ...
>
> 58 … The Federal Court has consistently held that the word "submission" in s. 4(1) does not include all submissions. It does not include a *supplementary* NDS. (*Bristol-Myers Squibb Canada Inc. v. Canada (Attorney General)* (2001), 10 C.P.R. (4th) 318 (F.C.T.D.), at paras. 13, 19 and 21, aff'd (2002), 16 C.P.R. (4th) 425, 2002 FCA 32; *Ferring Inc. v. Canada (Attorney General)* (2003), 26 C.P.R. (4th) 155, 2003 FCA 274, at para. 18; *Toba Pharma Inc. v. Canada (Attorney General)* (2002), 21 C.P.R. (4th) 232, 2002 FCTD 927, at para. 34; *AstraZeneca Canada Inc. v. Canada (Minister of Health)* (2004), 36 C.P.R. (4th) 58, 2004 FC 736, at paras. 39-40).
>
> 59 Applying a purposive interpretation, the Federal Court in these cases held that to read "submission" in s. 4(1) to include all NDSs would allow innovator companies to sidestep the time limits applicable to patent lists by the simple expedient of submitting a supplementary New Drug Submission (SNDS) making corporate or technical changes to their filing (*Bristol-Myers*, at para. 19). Such a result would not be consistent with the scheme of the *NOC Regulations* as a whole. In my view, this purposive approach is correct.
>
> 60 The parallel words in s. 5(1.1) are:
>
> > 5.(1.1) ... where a person files or has filed a submission for a notice of compliance in respect of a drug that contains a medicine ...
>
> 61 The text of s. 5(1.1) closely tracks the language of s. 4(1). It is a reciprocal provision in the sense that s. 4(1) sets up the patent list that the person subject to s. 5(1.1) must circumnavigate. Section 5(1.1) should therefore receive a similarly purposive interpretation. The word "submission" should also be construed so as to fulfill the purposes laid out in s. 55.2(4) of the *Patent Act*.

[83] In my view, on the basis of this analysis the Federal Court erred in law by failing to apply the jurisprudence which interpreted "submission" as used in subsection 4(1) of the Regulations when interpreting "submission" in subsection 5(1) of the Regulations.

[84] Having rejected the arguments advanced by the Federal Court it remains to be considered whether the Minister reasonably decided that the drug submissions filed by Teva and Hospira did not trigger the notice requirement found in subsection 5(1) of the Regulations.

[85] To begin, I agree with the Federal Court that there is more than one reasonable interpretation of subsection 5(1) of the Regulations (reasons, at paragraph 56).

[86] I accept the submission that the purposive interpretation of the word "submission" articulated in *Biolyse* requires consideration of each submission in issue in order to determine whether it is a submission that triggers sections 4 or 5 of the Regulations.

[87] Thus, in *Hoffmann-La Roche Ltd. v. Canada (Minister of Health)*, 2005 FCA 140, [2006] 1 F.C.R. 141, this Court found that some drug submissions are excluded from the scope of section 4 of the Regulations. Examples of such submissions were those made because of a change in the brand-name of a drug, or a change in the name of the manufacturer of the drug, or a change in the manufacturing site. Justice Sharlow wrote at paragraph 25 that:

> … A change in the name of a drug or a drug manufacturer, or a change of manufacturing site, cannot possibly be relevant to any potential claim for infringement of a patent for a medicine found in the drug. There is no justification for permitting patent holders to use such a change to enhance the advantage they obtain under the *Patented Medicines (Notice of Compliance) Regulations*. Thus, a supplemental new drug submission is outside the scope of section 4 if it is filed to reflect a change in the name of a drug or a drug manufacturer, or a change of manufacturing site.

[88] Later, in *Hoffmann-La Roche Ltd. v. Canada (Minister of Health)*, 2006 FCA 335, [2007] 3 F.C.R. 102, this Court concluded that a supplement to a NDS made only to reflect changes in

the name of the drug manufacturer could not support an application to list a patent. This was because:

> 37 There is a debate between the parties as to the proper characterization of the April 30, 1998 submission. Counsel for Roche characterizes it as a new drug submission and not a supplement to a new drug submission, because it was filed to obtain a notice of compliance that would permit Roche for the first time to market Bondronat. Counsel for the Minister argues that the April 30, 1998 submission is what it purports to be, an "administrative" submission or, in other words, a supplement to the new drug submission originally filed by Boehringer Canada, reflecting a change in the name of the corporation that would market Bondronat. The Minister treated the April 30, 1998, submission as a supplement within the scope of section C.08.003 of the *Food and Drug Regulations*, but not a supplement that engaged the Minister's obligation to assess the safety or effectiveness of the drug.
>
> 38 I can find no fault with the Minister's characterization of the April 30, 1998 submission. On that date there was an existing notice of compliance for Bondronat that had been issued to Boehringer Canada. The April 30, 1998 submission reflected a proposed change in the name of the entity that would be marketing Bondronat, which would require that the labels be changed to identify Roche rather than Boehringer Canada as the source of the drug (see paragraph C.08.003(2)(g) of the *Food and Drug Regulations*).

[89] Consistent with this jurisprudence, when characterizing a drug submission the focus should be upon the drug product itself. The question should be whether the changes reflected in the drug submission give rise to a new or different basis for asserting that a particular product is infringing.

[90] In the case of Teva, GMP possessed a NOC that entitled it to sell MED-EXEMESTANE tablets. GMP then licensed Teva to sell its tablets. This required Teva to obtain its own NOC. Teva did not submit any data in support of its application. Instead, it certified that its drug product was identical to GMP's drug except for the name of the manufacturer and the product. It also certified that its drug product would be manufactured in the same location as GMP' s drug

product, with identical specifications and procedures. No evidence supports the submission that Teva "early worked" Pfizer's patented invention.

[91] In this circumstance, I cannot conclude that the Minister's interpretation of subsection 5(1) of the Regulations was unreasonable. Teva sought approval to market a product identical to that which GMP was already entitled to market – in this circumstance it was not unreasonable for the Minister to decline to confer on Pfizer the robust advantages conferred on an innovator by the Regulations. Pfizer elected not to challenge GMP's notice of allegation. To require Teva to serve a new notice of allegation on Pfizer for the identical product would, in effect, allow Pfizer to challenge Teva's later notice of allegation on the basis of Pfizer's assessment of competitive considerations; considerations unrelated to the nature of Teva's drug product. Importantly, it must be remembered that the issuance of a NOC to Teva does not provide any defence to an action for patent infringement brought by Pfizer. Pfizer may sue if Teva's product infringes Pfizer's patent.

[92] This conclusion is, in my view, consistent with the decision of the Federal Court in *Glaxo* where, in my view, the Court's conclusion that Apotex' drug submission did not trigger the requirement to address listed patents was founded on the evidence that Apotex certified that all aspects of its submission were identical to 3M's submission in respect of AiromirÔ "except for a change in the manufacturer/sponsor's name and/or product name and that the product will be manufactured in the same location with identical specifications and procedures" (*Glaxo* reasons, at paragraph 20).

[93] This conclusion is also consistent with how supplementary drug submissions are treated under subsection 5(2) of the PMNOC Regulations. Under this provision, a supplement to a drug submission triggers the requirement to address listed patents only when there is a change in formulation, a change in dosage form, or a change in the use of the medical ingredient. Changes of an administrative nature do not trigger the need to address listed patents.

[94] For the same reasons, I find that the Minister of Health's decision to issue a NOC to Hospira was reasonable.

[95] Celltrion possessed a NOC that permitted it to sell INFLECTRA in Canada and Celltrion's NDS named Hospira as a distributor for INFLECTRA. Hospira then filed a NDS cross-referencing Celltrion's NDS in which it sought approval to market INFLECTRA. Its NDS did not contain any scientific data. Rather, it included Hospira's certification that pursuant to the licensing agreement it had been agreed that Celltrion would no longer sell INFLECTRA and its additional certification that, except for the name of the manufacturer, all aspects of its drug product were identical to Celltrion's product and its product would be manufactured in the same location with identical specifications and procedures to that of Celltrion's drug.

[96] Again, any potential infringement of the 630 patent by Hospira may be addressed in infringement proceedings.

## VII. Conclusion

[97] For these reasons, I would allow the appeals and set aside the judgments of the Federal Court.

[98] Pronouncing the judgments the Federal Court should have made, I would order that the application for judicial review of the decision of the Minister of Health brought by Pfizer in the Federal Court in Court Docket T-1703-13 be dismissed, and Pfizer should pay one set of costs to Teva and one set of costs to the Attorney General and the Minister of Health both in this Court and in the Federal Court. I would further order that the application for judicial review of the decision of the Minister of Health brought by Janssen and The Kennedy Trust in the Federal Court in Court Docket T-1516-14 be dismissed and Janssen and The Kennedy Trust should pay one set of costs to Hospira and one set of costs to the Attorney General and the Minister of Health both in this Court and in the Federal Court.

"Eleanor R. Dawson"
J.A.

"I agree.
Wyman W. Webb J.A."

"I agree.
Donald J. Rennie J.A."

**FEDERAL COURT OF APPEAL**

**NAMES OF COUNSEL AND SOLICITORS OF RECORD**

| | |
|---|---|
| **DOCKETS:** | A-27-15, A-28-15, A-143-15 and A-172-15 |
| **DOCKET:** | A-27-15 |
| **STYLE OF CAUSE:** | TEVA CANADA LIMITED v. PFIZER CANADA INC. and THE MINISTER OF HEALTH and THE ATTORNEY GENERAL OF CANADA |
| **AND DOCKET:** | A-28-15 |
| **STYLE OF CAUSE:** | THE ATTORNEY GENERAL OF CANADA and THE MINISTER OF HEALTH v. PFIZER CANADA INC. and TEVA CANADA LIMITED |
| **AND DOCKET:** | A-143-15 |
| **STYLE OF CAUSE:** | ATTORNEY GENERAL OF CANADA and THE MINISTER OF HEALTH v. JANSSEN INC. and THE KENNEDY TRUST FOR RHEUMATOLOGY RESEARCH and HOSPIRA HEALTHCARE CORPORATION |
| **AND DOCKET:** | A-172-15 |
| **STYLE OF CAUSE:** | HOSPIRA HEALTHCARE CORPORATION v. JANSSEN INC. and THE KENNEDY TRUST FOR RHEUMATOLOGY RESEARCH v. THE MINISTER OF HEALTH and ATTORNEY GENERAL OF CANADA |
| **PLACE OF HEARING:** | TORONTO, ONTARIO |
| **DATE OF HEARING:** | MAY 31, 2016 |

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| **REASONS FOR JUDGMENT BY:** | DAWSON J.A. |
| **CONCURRED IN BY:** | WEBB J.A.<br>RENNIE J.A. |
| **DATED:** | OCTOBER 12, 2016 |

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