



Chapter 9

Canadian Drug Patent Laws and Regulations

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9.1 Introduction

In Canada, two sets of regulations are of particular note with respect to intellectual property protection for pharmaceuticals: (i) the *Patented Medicines (Notice of Compliance) Regulations* (the “*PM(NOC) Regulations*”)¹; and (ii) data protection under the *Food and Drug Regulations*.² Both instruments are an integral part of the Government's drug patent policy, which seeks to strike an appropriate balance between encouraging continued innovation in new drugs and promoting timely access to their generic equivalents.

The *PM(NOC) Regulations* and data protection provisions of the *Food and Drug Regulations* operate in tandem in an attempt to ensure that pharmaceutical companies sell safe and effective drugs, yet are also allowed to benefit from the fruits of their labour and receive adequate patent protection for their invention. As noted by the Government of Canada in the Regulatory Impact Analysis Statement (“RIAS”) which accompanied the amendments to the data protection provisions of the *Food and Drug Regulations*, the two sets of regulations “are intended to act as a balanced set of measures, designed to work together to stabilize Canada’s intellectual property protection for drugs by ensuring a minimum period of protection and maintaining a reasonable ceiling on the maximum protection available.”³

9.2 History of Drug Patents in Canada

See “Patent Protection for Pharmaceutical Products in Canada – Chronology of Significant Events”⁴

9.2.1 Compulsory Licensing of Drugs

Prior to 1993, Canada’s patent laws permitted the issuance of compulsory licenses for the manufacturing and importation of patented medicines. A compulsory license is a statutory license that gives a licensee (typically a generic manufacturer) the right to manufacture, use or sell a patented invention before the patent expires, in exchange for the payment of a fixed royalty to the patentee. Such licenses could be granted without the consent of the patentee.

In 1923, Canada’s *Patent Act*⁵ was amended to provide for the issuance of compulsory licenses for the manufacture of food and drug patents if the medicine’s active ingredients were manufactured in Canada.

In 1969, the *Patent Act* was amended to allow compulsory licenses to be granted for the importation of medicines into Canada which, in turn, allowed generic manufacturers to import a medicine’s active ingredients and to process them into final form for sale. Royalty rates payable to a patentee were set at 4% of the retail price of the drug.

¹ *Patented Medicines (Notice of Compliance Regulations)*, S.O.R./93-133 [“*PM(NOC) Regulations*”]

² *Food and Drug Regulations*, C.R.C., c. 870, C.08.004.1 [“*Data Protection Regulations*”]

³ *Regulatory Impact Analysis Statement*, C. Gaz. II, vol. 140 no. 21 (*Regulations Amending the Food and Drug Regulations (Data Protection)*), October 18, 2006.

⁴ Margaret Smith; Government of Canada; Law and Government Division; 30 March 2000 <http://dsp-psd.pwgsc.gc.ca/Collection-R/LoPBdP/BP/prb9946-e.htm>

⁵ *Patent Act*, R.S., 1985, c. P-4 [“*Patent Act*”]

As a result of the 1969 amendments, a significant number of compulsory licenses to import were granted, leading to the development of an exceptionally strong generic industry in Canada. However, the compulsory licensing regime created an environment that was widely perceived to be inhospitable to investment in the innovative pharmaceutical industry. As a result, Canada not only experienced a substantial decrease in the growth and investment of pharmaceutical research and development, but saw the exodus of a number of innovative companies to countries abroad, leading to a reduction in the number of jobs available in the pharmaceutical industry for high-level graduates from Canadian Universities.

Consequently, in 1983 the federal Minister of Consumer and Corporate Affairs called for a rebalancing of Canada's compulsory licensing regime in order to generate growth and strengthen Canada's innovative industry.

9.2.2 1987: Bill C-22

In late 1987, Bill C-22,⁶ a bill to amend the *Patent Act*, came into force and made sweeping amendments to Canada's patent regime, including significant changes to the compulsory licensing regime. The Government's stated purpose in legislating Bill C-22 was to encourage multinational drug companies to invest in research and development in Canada.

With respect to patents generally, Bill C-22 changed the term of protection for patents, introducing a patent term of 20 years from the date on which a patent application was filed, rather than 17 years from the date the patent was issued. This change became effective in 1989.

With respect to pharmaceutical patents, Bill C-22 amended the Patent Act in three significant ways:

9.2.2.1 *Deferred Compulsory Licenses*

Bill C-22 granted drug patentees a minimum period of protection from compulsory licenses as follows:

NOC Date of Issue	Term of Protection
NOC issued after June 27, 1986	10 years protection against compulsory licenses to import 7 years of protection against compulsory licenses to manufacture.
On or before June 26, 1986 + generic NOC or compulsory license	7 years protection against compulsory license to import
On or before June 26, 1986 (no generic NOC or compulsory license issued)	8 years protection against compulsory license to import

⁶ R.S. 1985, c. 33 (3rd Supp.)

In addition, drugs which were invented and developed in Canada were granted a further form of protection; no compulsory license to import could be granted and, moreover, a compulsory license to manufacture could be granted only if, after 7 years from the date of the NOC for the drug, the patentee failed to manufacture the drug in Canada for the purpose of substantially or completely supplying the Canadian market.

9.2.2.2 *Pharmaceutical Compound Patents*

Prior to the passage of Bill C-22, patents were available only for the process used to manufacture a pharmaceutical - no patents were granted for the chemical compound or the medicine itself. Bill C-22 provided for the grant of product patents for pharmaceutical products and, consequently, protection could be sought for the product itself, regardless of the process used to manufacture it.

9.2.2.3 *Establishment of the Patented Medicines Prices Review Board*

The Patented Medicines Prices Review Board (PMPRB) was established as a federal quasi-judicial agency with a mandate to ensure that the prices of patented medicines are not excessive. The PMPRB was also charged with the responsibility of monitoring and reporting on drug price trends in Canada, as well as R&D expenditures by the innovative drug industry.

The PMPRB was granted wide-ranging statutory authority in order to fulfill its mandate, including the ability to: (i) require an innovator to lower the price of its patented medicine (ii) revoke a compulsory license; or (iii) revoke the deferral period for a given patent.

9.2.3 1991-1992 NAFTA/TRIPS

Subsequent to the passage of C-22, further developments with respect to patents took place on the international stage in the context of the negotiations of the World Trade Organization (WTO) *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS)⁷ and the *North American Free Trade Agreement* (NAFTA).⁸

The effect of NAFTA and TRIPS was and is the imposition of minimum standards of IP protection across Member States through the harmonization of domestic IP laws.

9.2.3.1 *NAFTA*

NAFTA came into effect on January 1, 1994 as an agreement between the United States, Canada and Mexico. On December 10, 1994 it was announced that agreement had been reached in principle for Chile to be admitted to the Agreement.

⁷ *Agreement on Trade-Related Aspects of Intellectual Property Rights*, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C 1869 U.N.T.S. 299 [TRIPS]. TRIPS was negotiated during the Uruguay Round trade negotiations of the General Agreement on Tariffs and Trade (GATT) from 1986 to 1994. As an agreement of the World Trade Organization (WTO), TRIPS is legally binding for all WTO Member states. Also at the Uruguay Round, the Council for TRIPS was created to monitor the operation of the agreement and governments' compliance.

⁸ *North American Free Trade Agreement*, 17 December 1992, Can. T.S. 1994 No. 2, 32 I.L.M. 289 (entered into force 1 January 1994) [NAFTA].

Article 1709(5) of NAFTA provides a patentee with the exclusive rights to use and prevent others from making using or selling a patented product without the patentees consent. Article 1709(12) provides that the term of protection of a patent is to be at least 20 years from the date a patent application is filed or 17 years from the date of issue and , moreover, provides that the term of a patent may be extended to compensate for delays incurred during the regulatory approval process.⁹

Article 1709(6) of NAFTA enables Member States to provide certain exceptions to the exclusive rights conferred by a patent, provided that the exceptions do not unreasonably conflict with the normal exploitation of the patent, and do not unreasonably prejudice the legitimate interests of the patent owner.

9.2.3.2 TRIPS

TRIPS came into being in 1994 as part of the “package deal” that emerged from the Uruguay Round negotiations of the General Agreement on Tariffs and Trade in order to:

“...reduce distortions and impediments to international trade...to promote the effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become a barrier to legitimate trade...”¹⁰

Unlike other WTO treaties, TRIPS is the first WTO treaty to impose entirely positive obligations on member states; moreover, these positive obligations are subject to enforcement and further development through the WTO dispute settlement process.¹¹

Article 28 grants a patent holder the exclusive right of “making, using, offering for sale, selling, or importing” the patented product, as well as the exclusive right to license the patented product.¹² Article 33 of TRIPS provides for a term of protection of at least 20 years from the date of a patent application.

Like Article 1709(6) of NAFTA, Article 30 of TRIPS confers a general right for members to provide limited exceptions to the exclusive rights conferred by a patent.

9.2.4 1992: Bill C-91

Bill C-91, *The Patent Act Amendment Act, 1992*¹³ was enacted in 1992 to enable Canada to meet its international obligations under NAFTA and WTO/TRIPS with respect to the protection of intellectual property. Bill C-91, which received Royal assent on February 4, 1993, provided for a number of substantial changes to Canada's patent regime:

⁹ Unlike the United States, there is no patent term restoration or supplemental protection scheme in Canada.

¹⁰ *Agreement on Trade-Related Aspects of Intellectual Property Rights*, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C 1869 U.N.T.S. 299, Preamble.

¹¹ Peter M. Gerhart, “Reflections: Beyond Compliance Theory – TRIPS as a Substantive Issue” (2000) 32 Case W.Res.J.Int'l.L. 357 at 358 [Gerhart].

¹² *Agreement on Trade-Related Aspects of Intellectual Property Rights*, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C 1869 U.N.T.S. 299, Article 28(1)(a) and (b)

¹³ *The Patent Act Amendment Act, 1992*, Statutes of Canada 1993, C. 2

9.2.4.1 **Abolition of Compulsory Licenses**

Bill C-91 abolished the compulsory license provisions of the *Patent Act* retroactive to December 20, 1991. Compulsory licences in existence before 20 December 1991, however, continued in effect and were subject to the seven- and ten-year limitation periods established under Bill C-22. Licences granted after 20 December 1991 but before the day the Act came into force were terminated when the Act became effective.

9.2.4.2 **Early Working and Stockpiling Exceptions to Infringement**

The abolishment of Canada's compulsory licensing regime caused the Government to adopt other methods of ensuring a fair balance between encouraging innovation and providing timely access to lower-cost pharmaceuticals. To do so, it created creating two exceptions to patent infringement under section 55.2 of the Patent Act. These exceptions provided that it was not an infringement to:

- (i) to use a patented invention in order to obtain regulatory approval to sell an equivalent product after the relevant patents have expired ("early working");¹⁴ or
- (ii) stockpile a generic version of a patented medicine in the period preceding the expiry of the relevant innovator patent ("stockpiling").¹⁵ The accompanying *Manufacturing and Storage of Patented Medicines Regulations* stipulated that the "stockpiling period" was six months prior to expiry of the innovator's patent.¹⁶

Both the "early working" and "stockpiling" exceptions were designed to facilitate the entry of generic products to the market by allowing a generic manufacturer to take the necessary steps during the term of the patent in order to be in a position to enter the market as soon as possible after patent expiry.

The "stockpiling" exception was subsequently repealed, along with the *Manufacturing and Storage of Patented Medicines Regulations*, following a decision of the World Trade Organization which found that the exception was inconsistent with Canada's TRIPS obligations.¹⁷

The "early working" exception remains in force and allows generic manufacturers to apply to Health Canada for approval of their product prior to expiry of the relevant patent(s), in order to be in a position to enter the market as soon as possible after patent expiry.

9.2.4.3 **Strengthening of PMPRB**

Bill C-91 also strengthened the powers of the PMPRB by granting it additional powers to, *inter alia*, order an innovator to reduce the price of its medicine and/or refund excess revenues, as

¹⁴ *Patent Act*, R.S., 1985, c. P-4, Section 55.2(1)

¹⁵ *Patent Act*, R.S., 1985, c. P-4 Section 55.2(2), *repealed*

¹⁶ *Manufacturing and Storage of Patented Medicines Regulations*, SOR/93-134

¹⁷ *Canada – Patent Protection of Pharmaceutical Products*, WT/DS114, 7 April 2000.

well as order payment of up to twice the amount of the excess revenues generated, enforceable by way of fine or imprisonment.

9.2.5 1993: Patented Medicines (Notice of Compliance) Regulations (Linkage Regulations)

At the same time that Bill C-91 was passed to amend the *Patent Act*, the Government enacted the *PM(NOC) Regulations*. The *PM(NOC) Regulations* were adopted to provide effective patent enforcement by ensuring that the early working (and, at the time, the stockpiling provision) provision did not result in the actual issuance of a generic NOC until patent expiry, or until such earlier time as a court or innovator considers justified. As stated in the Regulatory Impact Analysis Statement ("RIAS") which accompanied their passage in 1993, the creation of an early working (and, at the time, stockpiling) exception removed an exclusive right otherwise available to patentees and, therefore, the *PM(NOC) Regulations* were required to ensure that the exception is not abused by generic drug applicants seeking to sell their products during the term of a competitor's patent.¹⁸ The *PM(NOC) Regulations* attempted to prevent such abuse by linking Health Canada's ability to approve a generic drug to the patent status of the equivalent innovative product that the generic seeks to copy.

The *PM(NOC) Regulations* were enacted pursuant to section 55.2(4) of the *Patent Act*. Section 55.2(4) of the *Patent Act* provides that:

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

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

...

(e) Generally governing the issue of a notice, certificate, permit or other document referred to in paragraph (a) in circumstances where the issue of that notice, certificate, permit or other document might result directly or indirectly in the infringement of a patent.¹⁹

The operation of the *PM(NOC) Regulations* is discussed in greater detail below.

¹⁸ Regulatory Impact Analysis Statement, (*Patented Medicines (Notice of Compliance) Regulations*), *Canada Gazette II*, vol. 127, No. 6, 1993, p. 1383

¹⁹ *Patent Act*, R.S., 1985, c. P-4, s. 55.2(4)

9.3 Overview of the Drug Approval Process in Canada

All drugs sold in Canada (including pharmaceuticals, natural health products, biologicals and radiopharmaceuticals) – both those manufactured domestically and imported – must be authorized for sale by Health Canada.

9.3.1 New Drug Submissions and Supplementary New Drug Submissions

To gain Health Canada authorization for a new drug, a manufacturer, typically an innovator, submits a New Drug Submission (“NDS”) setting out all data (obtained through rigorous clinical testing) establishing the safety and efficacy of the drug. Such submissions typically require pre-clinical, clinical, chemistry and manufacturing data. Health Canada then reviews the submitted information and evaluates the drug’s safety, efficacy and quality to determine whether it is suitable to be marketed in Canada and whether a Notice of Compliance should, accordingly, be issued.

Once a drug has been approved, any changes to the approval (e.g., change of name, packaging, product monograph) requires the manufacturer to file a Supplementary New Drug Submission (“SNDS”). Changes requiring the submission of a SNDS are those made:

- (i) in the identifying name of the drug product or the brand name;
- (ii) in the dosage form or strength of the drug product;
- (iii) in the formulation, method of manufacture, equipment, or process control of the drug product that requires supporting clinical or bioequivalence data;
- (iv) in the case of Schedule C and D drugs, in the production site, method of manufacture, equipment and process control of the drug substance or in the formulation, method of manufacture, equipment, process control or production site of the drug product;
- (v) in the labelling, including package inserts, product brochures, file cards, and product monographs of the drug product respecting, either explicitly or implicitly:
 - (a) the recommended route of administration of the drug product;
 - (b) the dosage of the drug product, and
 - (c) the claims, including indications, made for the drug product; or
- (vi) for sterile drug products, in the specifications to remove the sterility test and replace it with process parametric release.

9.3.2 Notice of Compliance

At the completion of the review, if Health Canada has authorized the new drug and its manufacturing process under the regime provided for in the *Food and Drugs Act* and *Food and Drug Regulations*, the Minister of Health (the “Minister”) will grant the manufacturer a Notice of Compliance (“NOC”) which, in turn, permits the drug to be marketed in Canada. All drugs authorized for marketing will also receive a Drug Identification Number (“DIN”) which signals to

a user that the product has undergone and passed a review of its formulation, labelling and instructions for use. A drug product may not be sold in Canada without a DIN.

If, on the other hand, there is insufficient evidence to support the manufacturer's claims of safety, efficacy or quality, a marketing authorization for the drug will not be granted and a Notice of Deficiency or a Notice of Non-Compliance is issued. A manufacturer may then submit further information to support its claim and/or may appeal a decision which declines to grant regulatory approval for a drug.

9.3.3 Abbreviated New Drug Submissions

Where a second or subsequent manufacturer, typically a generic manufacturer, seeks a Notice of Compliance on the basis of a direct or indirect comparison between its drug and the original innovative drug which has already received marketing approval (called the "Canadian Reference Product"), the generic manufacturer submits an Abbreviated New Drug Submission (ANDS) demonstrating that the generic formulation of the drug is *bioequivalent* to the brand formulation.²⁰

The ANDS typically does not contain clinical data. By establishing bioequivalence, a generic manufacturer may demonstrate the safety and effectiveness of its drug by comparison, without having to complete costly and time-consuming clinical trials.

9.4 The PM(NOC) Regulations

9.4.1 Introduction and Overview

As noted above, the *PM(NOC) Regulations* create a mechanism to prevent the infringement of patents pertaining to medicines, by prohibiting the issuance of a NOC by the Minister of Health for a potentially infringing generic product. Since their adoption, the *PM(NOC) Regulations* have been the subject of a number of amendments.²¹

The *PM(NOC) Regulations* provide a mechanism whereby the Minister may be prohibited from issuing a NOC on a submission for a generic drug for a period of up to 24 months pending a determination by a Court as to whether a second or subsequent entry drug will infringe one or more relevant patents (discussed in greater detail below).

It is important to note that a Court's decision in a PM(NOC) proceeding is not a determination of the ultimate infringement or validity of the patent(s) at issue; rather, it constitutes a determination of whether the generic's *allegations of non-infringement* were justified. Since the Court does not rule on the ultimate validity or infringement of the patent, infringement and impeachment proceedings under the *Patent Act* are still an option for an innovator where a Court does not rule in its favour.

²⁰ "Bioequivalence" is a Health Canada requirement that the active ingredient of a generic drug be absorbed into the body and metabolized in approximately the same amount over approximately the same period as the active ingredient of the innovator drug.

²¹ *Regulations Amending the Patented Medicines (Notice of Compliance) Regulations, Canada Gazette II, vol. 132; Regulations Amending the Patented Medicines (Notice of Compliance) Regulations, Canada Gazette II, vol. 133; Regulations Amending the Patented Medicines (Notice of Compliance) Regulations, Canada Gazette II, vol. 140.*

9.4.2 Operation of the pre-September 21, 2017 Regime

9.4.2.1 The Patent List (Section 4)

The *PM(NOC) Regulations* create the linkage, in part, by requiring the Minister of Health to maintain a register of patents pertaining to medicines for which NOCs have been issued (the “Patent Register”).²² The patentee or licensee who has filed a NDS or SNDS may file with the Minister a list of all the relevant patents pertaining to the submission or supplement, and these patents may then be entered on the Patent Register.

The Patent Register is updated by the innovator submitting a patent list when the innovator files an NDS or eligible SNDS. Once the NOC is issued, the Patent Register is updated so as to add the patents on the patent list.²³ The practice of listing patents on the Patent Register has been the subject of some controversy and questions have been raised regarding the appropriate timing, subject matter and relevance requirements for listed patents, resulting in a number of substantial amendments, discussed in greater detail below.

9.4.2.2 Timing Requirements for Listing

To be listed on the Patent Register, the patent must be filed with the Minister at the same time that the patentee files its NDS or a SNDS.²⁴ Where a patent has been applied for but not yet issued at the time of the submission, the patentee may list that patent within 30 days of the issuance of the patent.²⁵ For the purpose of the *PM(NOC) Regulations*, the date of issuance of the patent is considered to be the date of the grant of patent as indicated on the face of the patent.²⁶

9.4.2.3 Patent List Eligibility Requirements

In order to be listed on the Register, patents must satisfy the subject matter and relevance requirements set forth in the *Regulations*.

Subject Matter Requirement

A patent is eligible for listing against a NDS if it contains a claim to:

- (i) the approved medicinal ingredient (product or product-by-process);
- (ii) the approved formulation that contains the medicinal ingredient;
- (iii) the approved dosage form that contains the medicinal ingredient (delivery system for administering the drug); or

²² *Patented Medicines (Notice of Compliance Regulations)*, S.O.R./93-133, Section 3

²³ *Patented Medicines (Notice of Compliance Regulations)*, S.O.R./93-133, s. 3(3).

²⁴ *Patented Medicines (Notice of Compliance Regulations)*, S.O.R./93-133, s. 4(3).

²⁵ *Patented Medicines (Notice of Compliance Regulations)*, S.O.R./93-133, s. 4(4).

²⁶ *Procter & Gamble Pharmaceuticals Canada Inc. v. Canada (Minister of Health)* (2003) 33 C.P.R. (4th) 193 (F.C.A.), reversing on this ground (2003), 26 C.P.R. (4th) 180 (F.C.).

- (iv) the approved use of the medicinal ingredient.²⁷

A patent may only be listed against an SNDS where that SNDS is:

- a supplement for a change in formulation (including a change in strength);
- a supplement for a change in dosage form; or
- a supplement for a change in the use of the medicinal ingredient.

In order to be eligible for listing, the patent must contain a claim for the change that is being sought in the SNDS – i.e. a claim to (i) the approved change in formulation; (ii) the approved change in dosage form; or (iii) the approved change in the use of the medicinal ingredient.²⁸ A patent which contains claims solely for the medicinal ingredient (including polymorphs) are not eligible for listing against an SNDS.²⁹

Whether a particular SNDS supports a patent listing is determined on the basis of changes reflected in that SNDS, independent of any prior NOC.³⁰

Relevance Requirement – The 2006 Amendments

Prior to 2006, the *PM(NOC) Regulations* permitted the listing of any patent that claimed the approved medicine, its formulation, or its use; however, the patent was not required to claim the identical use or formulation contained in the regulatory submission against which the patent was sought to be listed.

On June 17, 2006,³¹ significant changes were made to these listing requirements to require patents to be relevant to the specific wording of the drug submission – that is, the patent must claim the medicinal ingredient, formulation dosage form or indication for which approval is sought – in order to be eligible for listing.³²

As noted above, a patent may only be submitted for listing on the Patent Register in respect of an SNDS if it contains a claim for the change in formulation, dosage form or use of the medicinal ingredient that is being sought for approval in the SNDS and a NOC has been issued in respect of that SNDS.³³ A SNDS filed to reflect the following changes will not support a patent listing:

²⁷ *Patented Medicines (Notice of Compliance Regulations)*, S.O.R./93-133, s. 4(2)

²⁸ *Patented Medicines (Notice of Compliance Regulations)*, S.O.R./93-133, s. 4(3)

²⁹ Health Canada, *Guidance Document: Patented Medicines (Notice of Compliance) Regulations*, available online: <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/patmedbrev/pmreg3_mbreg3-eng.php>, section 3.2.1

³⁰ *Ratiopharm Inc. v. Wyeth, Wyeth Canada and The Minister of Health*, 2007 FCA 264 per Sharlow J.A. at para. 24.

³¹ *Regulations Amending the Patented Medicines (Notice of Compliance) Regulations*, SOR/2006-242 (entered into force October 5, 2006)

³² *Patented Medicines (Notice of Compliance Regulations)*, S.O.R./93-133, section 4(2).

³³ *Patented Medicines (Notice of Compliance Regulations)*, S.O.R./93-133, section 4(3).

- change in name of the drug or the name of the drug manufacturer;³⁴
- change in the indicated use of a drug that contains a particular medicine does support a listing of a patent that contains a claim for that use of the medicine;³⁵
- process, quality control, label, safety profile changes; and
- changes to manufacturing cite.

The 2008 Amendments

The 2006 amendments to the *PM(NOC) Regulations* were not intended to be retroactive. Rather, patents included on earlier filed patent lists were to be “grandfathered” and remain subject to the listing requirements as they existed prior to June 17, 2006.³⁶

Shortly after the coming into force of the 2006 Amendments, the Supreme Court of Canada rendered its decision in *AstraZeneca Canada Inc. v. Canada (Minister of Health)* [“*Astrazeneca*”],³⁷ wherein the Court attempted to clarify the law as it related to the patents which much be addressed by a second person under section 5 of the *PM(NOC) Regulations*. In *AstraZeneca*, a patent was listed for a drug that was no longer marketed. Justice Binnie, writing for the Court, held that a second person “is only required to address the cluster of patents listed against submissions relevant to the NOC that gave rise to the comparator drug.”³⁸

Following the reasoning of Justice Binnie in *Astrazeneca*, the Federal Court of Appeal, in *Ratiopharm v. Wyeth*,³⁹ held that, in order for a patent submitted with a SNDS to be eligible for listing, there “must be relevance between the invention claimed in the patent and the change to the drug effected by the SNDS.” This finding was intended to apply to patents “grandfathered” under the 2006 amendments.

As a result of this decision, many patents submitted in full compliance with the listing requirements, as they were interpreted and applied prior to June 17, 2006, could be deleted from, or not added to, the Register, leading to increased litigation and earlier than anticipated loss of market exclusivity for a number of innovative drugs – a result which the Government

³⁴ *Ratiopharm Inc. v. Wyeth, Wyeth Canada and The Minister of Health*, 2007 FCA 264 per Sharlow J.A. at para. 25.

³⁵ *Ratiopharm Inc. v. Wyeth, Wyeth Canada and The Minister of Health*, 2007 FCA 264 per Sharlow J.A. at para. 25.

³⁶ *Regulations Amending the Patented Medicines (Notice of Compliance) Regulations*, SOR/2006-242 (October 5, 2006), section 6. Section 6 provides as follows: “Section 4 of the *Patented Medicines (Notice of Compliance) Regulations*, as enacted by section 2 of these Regulations, does not apply to patents on a patent list submitted prior to June 17, 2006”.

³⁷ *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, 2006 SCC 49 (per Binnie, J.) [“*Astrazeneca*”]

³⁸ *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, 2006 SCC 4 (per Binnie, J.) at para. 39

³⁹ *Ratiopharm Inc. v. Wyeth, Wyeth Canada and The Minister of Health*, 2007 FCA 264 per Sharlow J.A. at para. 49.

sought to avoid.⁴⁰ In an attempt to restore the original intent of the “grandfathering” provisions, the Government amended the *PM(NOC) Regulations* to clarify the specific circumstances in which a grandfathered patent may be delisted.⁴¹ The Amended Regulations provide that a patent on a patent list that was submitted prior to June 17, 2006 may not be refused for listing solely on the basis that the patent is not relevant to the submission for a notice of compliance to which the patent list relates.⁴²

a) Specific Listing Requirements

Claim for Medicinal Ingredient

The *PM(NOC) Regulations* define “claim for the medicinal ingredient” as including “a claim in the patent for the medicinal ingredient, whether chemical or biological in nature, when prepared or produced by the methods or processes of manufacture particularly described and claimed in the patent, or by their obvious chemical equivalents, and also includes a claim for different polymorphs of the medicinal ingredient, but does not include different chemical forms of the medicinal ingredient.”⁴³ As specified in the RIAS which accompanied the 2006 amendments to the *PM(NOC) Regulations*, the term “medicinal ingredient” refers to the substance in the formulation which, once administered, is responsible for the drug’s desired effect on the body.”⁴⁴

Accordingly, patents with product claims as well as product-by-process claims to the approved medicinal ingredient – including polymorphs – are eligible for listing. The RIAS which accompanied the 2006 amendments clarifies that the term “polymorph” includes “different crystalline, amorphous, hydrated and solvated forms of the approved medicinal ingredient”; however, the courts have held that claimed polymorphs must have utility as a medicine in order to be eligible for listing.⁴⁵

Conversely, claims to different chemical forms (such as salts or esters) or intermediate forms (such as active metabolites) are specifically excluded from the definition of “claim for medicinal ingredient” and therefore will not support a patent for listing on the Register. This is in line with jurisprudence pre-dating the 2006 Amendments that patents claiming intermediates or metabolites of the medicinal ingredient are ineligible for listing.⁴⁶

⁴⁰ Regulatory Impact Analysis Statement, Canada Gazette Part II, Vol. 142, No. 13, p. 1589 (*Regulations Amending the Patented Medicines (Notice of Compliance) Regulations*), June 12, 2008.

⁴¹ *Regulations Amending the Patented Medicines (Notice of Compliance) Regulations*, SOR/2008-211

⁴² *Patented Medicines (Notice of Compliance Regulations)*, S.O.R./93-133, s. 3.1(2)

⁴³ *Patented Medicines (Notice of Compliance Regulations)*, S.O.R./93-133, s.2

⁴⁴ Regulatory Impact Analysis Statement, C. Gaz. II, vol. 140 no. 21 (*Regulations Amending the Patented Medicines (Notice of Compliance) Regulations*), October 18, 2006

⁴⁵ *Abbott v. Apotex* (2005), 45 C.P.R. (4th) 81 (F.C.); aff'd (2007), 361 N.R. 308 (F.C.A.); *Abbott v. Apotex* (2007), 54 C.P.R. (4th) 356 (F.C.); aff'd 2007 FCA 187; *Abbott v. Apotex* [2007] F.C.J. No. 1072; *Abbott v. Canada (Minister of Health)* (2005), 42 C.P.R. (4th) 121 (F.C.); aff'd (2006), 350 N.R. 242 (F.C.A.).

⁴⁶ See e.g., *Merck Frosst Canada & Co. v. Canada (Minister of Health)* (2000), 7 C.P.R. (4th) 522 (F.C.), aff'd (2001), 12 C.P.R. (4th) 383 (F.C.A.), wherein the court found that a patent claiming

There must be a matching between the medicinal ingredient that has been approved through the issuance of a Notice of Compliance, and the patent claim:

- The medicinal ingredient must match that in the drug submission that was approved through the issuance of the NOC.
 - It is not enough that a claim encompasses the medicinal ingredient “L” in combination with “A” for the purposes of s. 4(2)(a) of the Regulations.⁴⁷ There must be a claim to that specific combination.
 - Likewise, a patent claim for only one medicinal ingredient does not support a listing where the underlying NOC is for a combination (synergistic or otherwise) of two or more medicinal ingredients.⁴⁸ [NTD: update with new case law]

Claim for the Formulation that Contains the Medicinal Ingredient

Under the PM(NOC) Regulations, a “claim for the formulation” means “a claim for a substance that is a mixture of medicinal and non-medicinal ingredients in a drug and that is administered to a patient in a particular dosage form.” In this regard, the term “formulation” refers to the combination of active drug and non-medicinal ingredients, such as excipients, in a final form that is administered to a patient.

With respect to formulation patents, the claimed formulation must include, as an element, the medicinal ingredient of the drug.⁴⁹ Therefore, a patent directed solely to a formulation, with no claim to the approved medicinal ingredient, is not eligible for listing on the Patent Register.⁵⁰ In addition, the formulation which is approved in the relevant NDS must be the one that is claimed in order to be able to support listing of the patent on the Register.⁵¹

Claim for the Dosage Form that Contains the Medicinal Ingredient

Prior to the 2006 Amendments, patents containing claims directed to a delivery system for the administration of a medicinal ingredient – such as, for example, a transdermal patch – were held by the Courts to be ineligible for listing.

an active metabolite could not be included on the patent list as the metabolite was not contained in the approved tablets.

⁴⁷ *Gilead Science Canada v. The Minister of Health*, 2012 FCA 254 at para. 28.

⁴⁸ *ViiV Healthcare ULC et al v. Teva Canada Limited et al*, 2014 FC 893 (F.C. per Hughes J.) at para. 89; *Gilead Sciences, Inc. v. Canada (MOH)*, 2016 FC 231 at paras. 113, 118 & 119. See however *Eli Lilly Canada Inc. v. Canada (AG)*, 2015 FCA 166 (F.C.A. per Dawson J.J.A.) at para. 107:

“... it is not necessary to require a patent to specifically name every medicinal ingredient approved through the issuance of a notice of compliance. If the patent claims the approved medicinal ingredient there will be a sufficient nexus between the patent and the subject of the notice of compliance to allow the patent to be listed.”

⁴⁹ Health Canada, *Guidance Document: Patented Medicines (Notice of Compliance) Regulations*

⁵⁰ Health Canada, *Guidance Document: Patented Medicines (Notice of Compliance) Regulations*

⁵¹ Health Canada, *Guidance Document: Patented Medicines (Notice of Compliance) Regulations*

According to the RIAS which accompanied the 2006 amendments to the *PM(NOC) Regulations*, dosage form patents merit protection in light of the significant therapeutic advantages afforded by novel dosage forms – particularly for biologic molecules, as effective administration of the medicinal ingredient often depends on the development of new and innovative delivery systems.⁵²

The *PM(NOC) Regulations* define a “claim for the dosage form” as meaning “a claim for a delivery system for administering a medicinal ingredient in a drug or a formulation of a drug that includes within its scope that medicinal ingredient or formulation.”⁵³ Examples of eligible dosage forms would include novel controlled-release tablets and capsules, implants and transdermal patches, which contain the approved medicinal ingredient or approved formulation containing the medicinal ingredient.⁵⁴ Patents claiming novel packaging which is directed at improving the drug which is delivered to a patient, as opposed to the dosage form itself, are not eligible for listing.⁵⁵

As is the case with formulation patents, a dosage form patent must claim the specific approved dosage form described in the NDS and must contain a claim that includes the approved medicinal ingredient.⁵⁶

In *Glaxosmithkline Inc. v. Canada AG*,⁵⁷ Justice Snider held that, whether a claim for a dosage form meets the listing requirements of s. 4(2)(c) is subject to a three part determination:

- (i) What does the patent claim?
- (ii) What is the approved dosage form?
- (iii) Do the claims of the patent correspond with the approved dosage form?

Claim for the Use of the Medicinal Ingredient

Under the *PM(NOC) Regulations*, a “claim for the use of a medicinal ingredient” means “means a claim for the use of the medicinal ingredient for the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms.”⁵⁸

In order to be eligible for listing, the patent must claim the approved method of using the medicinal ingredient, for an approved indication.⁵⁹ Accordingly, patents which contain a claim

⁵² Regulatory Impact Analysis Statement, C. Gaz. II, vol. 140 no. 21 (*Regulations Amending the Patented Medicines (Notice of Compliance) Regulations*), October 18, 2006

⁵³ *Patented Medicines (Notice of Compliance Regulations)*, S.O.R./93-133, section 2.

⁵⁴ Regulatory Impact Analysis Statement, C. Gaz. II, vol. 140 no. 21 (*Regulations Amending the Patented Medicines (Notice of Compliance) Regulations*), October 18, 2006

⁵⁵ *Bayer Inc. v. Canada (Minister of Health)* (2008), 68 C.P.R. (4th) 1 (F.C.) at paras 55-56. In this case, the Court construed the patent claims to be directed to the product packaging, as opposed to the transdermal patch itself, which the court held to be merely incidental.

⁵⁶ Regulatory Impact Analysis Statement, C. Gaz. II, vol. 140 no. 21 (*Regulations Amending the Patented Medicines (Notice of Compliance) Regulations*), October 18, 2006

⁵⁷ *Glaxosmithkline Inc. v. Canada AG*, 2008 FC 1416 (per Snider, J.)

⁵⁸ *Patented Medicines (Notice of Compliance Regulations)*, S.O.R./93-133, section 2

for the use of an intermediate the process of manufacturing a drug, formulation or dosage form are not eligible.⁶⁰

When attempting to list a patent against an SNDS for a change in the use of a medicinal ingredient, the patent must claim that particular use.⁶¹

9.4.2.4 Notice of Allegation (Section 5)

When the generic drug manufacturer's ANDS names a Canadian reference product and a patent is listed in respect of that Canadian reference product, the generic drug manufacturer is required by s. 5 of the *PM(NOC) Regulations* to address that patent by providing certain information to the Minister. The generic manufacturer need only address those patents which are listed on the Register as of the date that the generic manufacturer files its ANDS.⁶²

With respect to each patent listed on the Register in respect of the innovative reference drug, the generic drug manufacturer must state:

1. it is not seeking the issuance of the NOC until the patent expires;
2. the patent is not valid; or
3. the patent will not be infringed by the making using or selling of the generic product.

If the generic manufacturer alleges that the patent is not valid and/or not infringed, then the generic drug manufacturer must serve the innovator with a Notice of Allegation ("NOA") which is accompanied by a detailed statement of the factual and legal basis for the allegation.

9.4.2.5 Prohibition Proceedings (Section 6)

a) Application for Prohibition Order

If the innovator wishes to challenge the allegation of invalidity or non-infringement in the NOA, s. 6 of the *PM(NOC) Regulations* permit it to apply to the Federal Court within 45 days for an order prohibiting the Minister from issuing a NOC for the generic product prior to the expiry of the patent. Once such proceedings are commenced, the Minister is automatically precluded from issuing a NOC to the generic manufacturer for a period of 24 months, unless the time is extended by the Court or the proceedings terminated earlier. This is, in effect, like an interlocutory injunction obtained without proof of a prima facie case of infringement⁶³ or irreparable harm and becomes like a summary judgment proceeding based on affidavit evidence.

⁵⁹ Regulatory Impact Analysis Statement, C. Gaz. II, vol. 140 no. 21 (*Regulations Amending the Patented Medicines (Notice of Compliance) Regulations*), October 18, 2006

⁶⁰ See e.g. *Abbott Laboratories v. Canada (Minister of Health)* (2007), 54 C.P.R. (4th) 356 (F.C.) and *Eli Lilly v. Apotex* (1995), 63 C.P.R. (3d) 245 (F.C.) affirmed 68 C.P.R. (3d) 126.

⁶¹ *Abbott Laboratories Ltd. v. Canada (Attorney General)* (2008), 68 C.P.R. (4th) 445 (F.C.A.) at para. 47, reversing (2007), 61 C.P.R. (4th) 259 (F.C.).

⁶² *Patented Medicines (Notice of Compliance) Regulations*, S.O.R./93-133, section 5(4).

⁶³ *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)*, [10998] 2 S.C.R. 193, (per Iacobucci J.) at para. 33; cited in *Ratiopharm Inc. v. Wyeth, Wyeth Canada and The Minister of Health*, 2007 FCA 264 per Sharlow J.A. at para. 20.

On an application for a prohibition order, the innovator bears the burden of establishing that the allegations contained in the NOA are not justified and, accordingly, that an order should be granted prohibiting the Minister from granting the NOC to the generic manufacturer. However, where the generic manufacturer alleges that the process used to make the generic drug does not infringe the patented process, the generic manufacturer bears the burden of proof.⁶⁴

With respect to allegations of non-infringement, the allegations contained in the NOA are presumed to be true.⁶⁵

With respect to allegations of invalidity, there must be sufficient evidence to rebut the presumption of validity contained in subsection 43(2) of the *Patent Act*.⁶⁶ However, such evidence will be sufficient so long as it is “not clearly incapable of establishing [the] allegations of invalidity”.⁶⁷ The Federal Court of Appeal has held that the presumption of validity cannot determine the outcome of a prohibition proceeding so long as there is “any evidence that is capable of rebutting the presumption.”⁶⁸

b) Motion to Dismiss for non-eligible listing of a patent

A generic drug manufacturer cannot, by means of judicial review, obtain an order requiring the Minister to remove a patent that has been improperly listed.⁶⁹

A generic drug manufacturer may move under section 6(5)(a) of the *PM(NOC) Regulations* for an order dismissing the prohibition application in relation to improperly listed patents.⁷⁰ Such motions are heard prior to the hearing on the merits of the application.⁷¹

9.4.2.6 Stay (Section 7)

Once an application for an order of prohibition is commenced, the Minister is precluded, by section 7 of the *Regulations*, from issuing a NOC to the generic manufacturer for a period of 24 months unless or until the application is disposed of by: (i) the expiry of the patent; (ii) the court finds in favour of the generic manufacturer; or (iii) the innovator withdraws or discontinues the prohibition application. The 24 month period may be shortened or lengthened by the court in certain circumstances.⁷²

⁶⁴ *Pfizer Canada Inc. v. Novopharm Ltd.* (2005), 42 C.P.R. (4th) 502 at para. 13.

⁶⁵ *GlaxoSmithKline Inc. v. Canada (Minister of Health)*, 2004 FC 116 at para. 15.

⁶⁶ *Pfizer Canada Inc. et al. v. Minister of Health*, 2006 FC 1471 at para. 28 – 31.

⁶⁷ *Pfizer Canada Inc. v. Canada (Health)*, 2007 FCA 209 at para. 109.

⁶⁸ *Abbott Laboratories v. Canada (Minister of Health)*, 2007 FCA 153 at para. 10.

⁶⁹ *Apotex Inc. v. Canada (minister of national Health and Welfare)* (2000), 3 C.P.R. (4th) 1 (F.C.A.); *Ratiopharm Inc. v. Wyeth, Wyeth Canada and The Minister of Health*, 2007 FCA 264 per Sharlow J.A. at para. 33.

⁷⁰ *Ratiopharm Inc. v. Wyeth, Wyeth Canada and The Minister of Health*, 2007 FCA 264 per Sharlow J.A. at para. 34.

⁷¹ *Ratiopharm Inc. v. Wyeth, Wyeth Canada and The Minister of Health*, 2007 FCA 264 per Sharlow J.A. at para. 36.

⁷² *Patented Medicines (Notice of Compliance Regulations)*, S.O.R./93-133, section 7(5).

In effect, the innovator receives what is tantamount to an interlocutory injunction. The Court has no discretion to lift the stay, nor to leave the contending parties to their remedies under the *Patent Act*.⁷³

9.4.2.7 Damages (Section 8)

If an innovator commences a prohibition proceeding that is ultimately unsuccessful, discontinued, withdrawn or successfully appealed, section 8 provides that the innovator is liable to the generic manufacturer for “any loss suffered” by the generic manufacturer during the period between when an NOC would have issued to the second person and the date of the dismissal, withdrawal or discontinuance of the prohibition proceeding.⁷⁴

In interpreting section 8, the Courts have held that such losses are limited to compensatory damages and do not extend to a disgorgement of the innovator’s profits.⁷⁵ Likewise, section 8 losses are limited to losses suffered by the generic during the period defined by section 8(1) and, accordingly, any losses suffered by the generic manufacturer in the period after having obtained its NOC are not compensable.⁷⁶

The Federal Court of Appeal has upheld the constitutionality of section 8 being *intra vires* the *Patent Act*, and also within the authority of Parliament.⁷⁷

In determining whether a generic manufacturer is entitled to compensation pursuant to section 8, a court must take into account “all matters it considers relevant... *including* any conduct of the first or second person which contributed to delay the disposition of the [prohibition proceeding]”.⁷⁸

9.4.2.8 Appeal from Dismissal of Prohibition Order is Moot

If the judge hearing the motion for a prohibition order dismisses it, the NOA is usually granted to the generic shortly thereafter. An appeal from an order dismissing an application for a prohibition order under the Regulations becomes moot when the Notice of Compliance is issued:⁷⁹ Once the Notice of Compliance is issued, it is no longer possible for the Court to prohibit the Minister from issuing the notice of compliance.⁸⁰

⁷³ *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, [2005] 1 S.C.R. 533, para. 24.

⁷⁴ *Patented Medicines (Notice of Compliance Regulations)*, S.O.R./93-133, section 8(1)

⁷⁵ *Merck Frosst Canada Ltd. v. Apotex Inc.*, 2009 FCA 187 at paras. 89-90. See also *Apotex Inc. v. Eli Lilly Canada Inc.* 2009 FC 378 (Tabib, P.)

⁷⁶ *Merck Frosst Canada Ltd. v. Apotex Inc.*, 2009 FCA 187 at paras. 99-102, reversing on this ground (2008), 70 C.P.R. (4th) 297 (F.C.)

⁷⁷ *Merck Frosst Canada Ltd. v. Apotex Inc.*, 2009 FCA 187

⁷⁸ *Patented Medicines (Notice of Compliance Regulations)*, S.O.R./93-133, section 8(5)

⁷⁹ *Apotex Inc. v. Bayer AG*, 2004 FCA 242, 325 N.R. 289; *Janssen Inc. v. Teva Canada Limited*, 2015 FCA 36 at para. 7; *Biovail Corporation v. Canada*, 2006 FCA 92, 348 N.R. 117 at para. 5

⁸⁰ *Janssen Inc. v. Mylan Pharmaceuticals ULC*, 2011 FCA 16, 88 C.P.R. (4th) 379 at para. 1, quoted with approval in *Amgen Canada Inc. et al v. Apotex Inc. et al*, 2016 FCA 196 (Stratas J.A., Noël C.J. and Rennie J.A. concurring) at para. 14.

Asking a court to prohibit a notice of compliance after it has issued is like asking someone to close the barn door after the horses have escaped.⁸¹

The Federal Court of Appeal should not entertain an appeal from a denial of prohibition where the patentee can bring an action for patent infringement and can assert its patent against the s. 8 claim.⁸²

9.4.3 The post-September 21, 2017 Regime

Effective September 21, 2017, the Federal government enacted new *Regulations*⁸³ to change the procedures under the *Patented Medicines (Notice of Compliance) Regulations* to fundamentally change the process from a paper-based court application to a full-blown patent infringement/validity trial, complete with documentary and oral discoveries and live testimony at trial.

Like an animal designed by committee, the former *PM(NOC)* regime was oddly eccentric and unpopular with all parties concerned. The courts had only a paper record upon which to decide often complicated technical evidence, without the aid of live expert witnesses to answer a judge's questions. The burden of proof was on the Innovator (the "first person" or patent owner) to prove that the allegations of non-infringement and invalidity made by the Generic (the "second person") in the Notice of Allegation were not justified. Appeals by Innovators from unsuccessful applications were moot, because the Notice of Compliance had already issued and could not be "un-issued". Unsuccessful applications were often followed by a patent infringement and validity lawsuits, resulting in the duplication of efforts by the parties and the court.

By agreeing to the *Canada-European Union Comprehensive Economic and Trade Agreement* ("CETA"), Canada committed to providing full appeal rights under the *Regulations* that linked the approval of generic medicines to the protection of patent rights. That commitment necessitated replacing the *PM(NOC)* court application with a single, fast-tracked, patent infringement/validity trial.

The *2017 Regulations* put a greater burden on the parties and the court to have the patent infringement/validity trial proceed to trial and a decision within 24 months.

No longer at issue will be the question as to whether the Minister of Health should be prohibited from issuing a NOC. The burdens of proof under the new regime would be consistent with those of traditional patent litigation. The proposed regulations would deem a second person to be an "interested person" who could commence invalidity proceedings as part of a counterclaim.

⁸¹ *Biovail Corporation v. Canada*, 2006 FCA 92, 348 N.R. 117 at para. 5, quoted with approval in *Amgen Canada Inc. et al v. Apotex Inc. et al*, 2016 FCA 196 (Stratas J.A., Noël C.J. and Rennie J.A. concurring) at para. 14.

⁸² *Pfizer Canada Inc. v. Apotex Inc.* (2001), 11 C.P.R. (4th) 245 at page 253 (F.C.A.); *Apotex Inc. v. Bayer AG*, *Apotex Inc. v. Bayer AG*, 2004 FCA 242, 325 N.R. 289; *Sanofi-Aventis Canada Inc. v. Apotex Inc.*, 2006 FCA 328, 53 C.P.R. (4th) 447 at para. 17; *Janssen Inc. v. Mylan Pharmaceuticals ULC*, 2011 FCA 16, 88 C.P.R. (4th) 379; *Amgen Canada Inc. et al v. Apotex Inc. et al*, 2016 FCA 196 (Stratas J.A., Noël C.J. and Rennie J.A. concurring) at para. 22.

⁸³ SOR/93-133 (the "2017 Regulations"), available at <http://laws-lois.justice.gc.ca/eng/regulations/SOR-93-133/index.html>

Wisely, the *Regulations* provide a limited number of procedural rules and otherwise leave most procedural matters to be dealt with by the Court, to evolve procedural solutions as experience develops. Also effective September 21, 2017, The Federal Court issued a *Notice to the Parties and the Profession of Guidelines for Actions under the Amended PMNOC Regulations*⁸⁴ setting out procedures to be followed under the new regime.

9.4.3.1 Certificate of Supplementary Protection (“CSP”)

In 2017, the *Patent Act* was amended to provide for a Certificate of Supplementary Protection (“CSP”) which extends the term of certain pharmaceutical patents for up to two years⁸⁵ because of the delay in obtaining governmental authorization for a product’s sale (Notice of Compliance). The CSP is analogous to the European Supplementary Protection Certificate (SPC).⁸⁶

The term extension is calculated as the lesser of:

1. the time between the filing date of the patent application and the date of Notice of Compliance minus 5 years; and
2. 2 years.⁸⁷

To be eligible for a CSP, the patent must pertain to a medicinal ingredient, or combination of medicinal ingredients, contained in a drug for which an authorization for sale of the prescribed kind was issued on or after September 21, 2017.⁸⁸ The patent can relate to medicinal ingredients or combinations of them for human and veterinary use.⁸⁹ No other CSP can have been previously issued with respect to the medicinal ingredient or the combination of medicinal ingredients.⁹⁰

An application for a CSP must be filed before the authorization for sale is issued, if the patent is granted on or before then.⁹¹

9.4.3.2 Patent Listings

The only patents or CSPs that can be listed on the respective registers (and, therefore that can be made part of a Notice of Allegation and resulting Statement of Claim) are those containing a claim for:

⁸⁴ the “2017 Guidelines”, available at [http://cas-cdc-www02.cas-satj.gc.ca/fct-cf/pdf/Notice%20-%20PMNOC%20Guidelines%20\(FINAL\)%2021sept2017%20English.pdf](http://cas-cdc-www02.cas-satj.gc.ca/fct-cf/pdf/Notice%20-%20PMNOC%20Guidelines%20(FINAL)%2021sept2017%20English.pdf)

⁸⁵ *Patent Act*, s. 116(6)

⁸⁶ https://ec.europa.eu/growth/industry/intellectual-property/patents/supplementary-protection-certificates_en

⁸⁷ *Patent Act*, s. 116(3): The certificate’s term is calculated by subtracting five years from the period beginning on the filing date of the application for the patent and ending on the day on which the authorization for sale set out in the certificate is issued, but in any event is for a maximum of two years.

⁸⁸ *Patent Act*, s. 106(1)(c)

⁸⁹ *Patent Act*, s. 105(2) to (6)

⁹⁰ *Patent Act*, s. 106(1)(e)

⁹¹ *Patent Act*, s. 106(3)

- the medicinal ingredient;
- a formulation containing the medicinal ingredient;
- the dosage form; or
- the use of the medicinal ingredient.⁹²

9.4.3.3 24 Month Timeline retained

The *2017 Regulations* continue the current practice of barring the Minister of Health from issuing a Notice of Compliance for up to 24 months from the day an action is commenced (as discussed below), plus a day.⁹³ The Minister may issue a Notice of Compliance:

- for patents and CSPs against which no allegations are made, the day after the last of them has expired;⁹⁴
- on the 46th day, if no action is commenced within 45 days of the service of a Notice of Allegation. In effect, the patent owner has not taken issue with the issuance of a Notice of Compliance for the generic product.;⁹⁵
- the day after expiry of the 24th month period after an action is brought under s. 6(1).⁹⁶ This does not apply if, when the action is brought, the plaintiff renounces the application of this paragraph (in effect, it does not want the 24 month automatic “stay” of the issuance of the Notice of Compliance, perhaps to avoid s. 8 damages if it is unsuccessful at trial);⁹⁷ or
- the day after expiry of all patents or CSPs held to be infringed as a result of an action.⁹⁸

From a Canadian perspective, 21 months to trial and a decision within 24 months would be a “fast-track” to a patent infringement/validity trial.

9.4.3.4 Notice of Allegation

If a second person files a submission for a Notice of Compliance in respect of a drug [or for a supplement to such a submission for a change in formulation, a change in dosage form or a change in use of the medicinal ingredient⁹⁹] 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 include in the submission the required statements or allegations set out in subsection (2.1).¹⁰⁰ Subsection 2(1)(c) permits allegations that:

⁹² *2017 Regulations*, s. 4(1)(2)

⁹³ *2017 Regulations*, s. 7(1)

⁹⁴ *2017 Regulations*, s. 7(1)(a)

⁹⁵ *2017 Regulations*, s. 7(1)(c)

⁹⁶ *2017 Regulations*, s. 7(1)(d)

⁹⁷ *2017 Regulations*, s. 7(5)(b)

⁹⁸ *2017 Regulations*, s. 7(1)(e) & (f)

⁹⁹ *2017 Regulations*, s. 5(2)

¹⁰⁰ *2017 Regulations*, s. 5(1)

(i) the statement made by the first person under paragraph 4(4)(d) that the first person was the owner of the patent, or had an exclusive license to the patent or CSP, or had obtained the consent of the patent owner to list it, is false;

(ii) the patent or CSP is invalid or void;

(iii) the patent or CSP is ineligible for inclusion on the register;

(iv) the patent or CSP would not be infringed by the second person making, constructing, using or selling the drug for which the submission or the supplement is filed. This would require the second person to deal with any claims in the listed patents or CSPs (including process claims) that would be infringed if the second person made the drug. The *2017 Guidelines* state that "... where a listed patent includes claims to a process, such additional claims will need to be addressed by the second person in the Notice of Allegation (NOA) and may be part of the proceeding. However, patents solely directed to the processes for making the drug cannot be listed, and will not be involved."¹⁰¹

(v) the patent or CSP has expired, or

(vi) in the case of a CSP, the CSP cannot take effect.¹⁰²

A second person who makes such an allegation in subsection 2.1(c) must give notice of such allegation to the first person by serving on the first person a Notice of Allegation relating to the submission or supplement filed under s. 5(1) or (2) on or after its date of filing.

Under the *2017 Regulations*, the second person must provide greater detail than was previously required as to invalidity as well as non-infringement allegations. A second person has to provide a detailed legal and factual basis for any allegation the patent or certificate of supplementary protection is invalid or void¹⁰³ along with electronic copies of any document relied on in support of the allegation.¹⁰⁴ Such detail is not required for non-infringement allegations.

When serving the Notice of Allegation, the second person may request:

- contact information for any inventor¹⁰⁵; and
- laboratory notebooks, research reports or other documents that may be relevant to establish whether a particular property, advantage or use asserted by the second person to be part of the invention was established as of the filing date of the application for the patent.¹⁰⁶ Such documents must be provided in searchable electronic format (if

¹⁰¹ *2017 Guidelines*, p. 1

¹⁰² *2017 Regulations*, s. 4(4)

¹⁰³ *2017 Regulations*, s. 5(3)(b)(ii)

¹⁰⁴ *2017 Regulations*, s. 5(3)(b)(iv)

¹⁰⁵ *2017 Regulations*, s. 5(3.1)(a). Providing contact information of ex-employees may put an Innovator in breach of European privacy laws.

¹⁰⁶ *2017 Regulations*, s. 5(3.1)(b)

available; if not, then in electronic format) and, if not already in English or French, then in a either language, if available.¹⁰⁷

Once an action is commenced, the second person may bring a motion for an order requiring production of this information and documents.¹⁰⁸

With respect to non-infringement allegations, the second person must serve, along with its NOA, any portions of its submission or supplement that could be relevant for determining whether a listed patent would be infringed.¹⁰⁹ This will permit a first person or patent owner to determine whether they believe a listed patent will be infringed. Once an action is commenced, the first person may bring a motion for an order requiring production of these documents.¹¹⁰

If it is not the owner of the patent, the recipient of the Notice of Allegation must, with 5 days of receipt of the Notice of Allegation, forward copies of any documents and requests to the owners of any patents affected.¹¹¹

9.4.3.5 Confidentiality

Because some of the documents are produced before the discovery process begins, *the 2017 Regulations* allow for a party producing such documents to impose any reasonable rules for maintaining their confidentiality, as between the parties.¹¹² Such rules are binding and enforceable by the Federal Court, which may award any remedy that it considers just if they are not respected.¹¹³ On motion by the first person or the owner of the patent, the Federal Court may set aside or vary any or all of those confidentiality rules in any manner that it considers just,¹¹⁴ but only after an action is commenced. The Court does not have jurisdiction to determine a motion under s. 5(3.7) of the *Regulations* in the absence of an underlying action. Section 5(3.7) of the *Regulations* was not intended by Parliament to permit bringing a separate proceeding by way of motion or application.¹¹⁵

With respect to confidentiality, the information set out in any document ordered to be produced under subsection 6.04(1)¹¹⁶ or 6.04(2)¹¹⁷ shall be treated confidentially by the Federal Court subject to any conditions that it considers just.¹¹⁸

¹⁰⁷ *2017 Regulations*, s. 5(3.2)

¹⁰⁸ *2017 Regulations*, s. 6.04(2)

¹⁰⁹ *2017 Regulations*, s. 5(3)(b)(iii)

¹¹⁰ *2017 Regulations*, s. 6.04(1)

¹¹¹ *2017 Regulations*, s. 5(3.3)

¹¹² *2017 Regulations*, s. 5(3.5) with respect to the second person imposing confidentiality terms; s. 6.03(2) to (4) with respect to the first person imposing confidentiality terms, discussed below.

¹¹³ *2017 Regulations*, s. 5(3.6)

¹¹⁴ *2017 Regulations*, s. 5(3.7).

¹¹⁵ *Genentech, Inc. & Hoffmann-La Roche Limited v. Pfizer Canada Inc.* 2018 FC 233 (F.C. per Ayles, Proth.) at paras. 13 & 20.

¹¹⁶ portions of the submission or supplement relevant to determine infringement that are ordered to be produced.

9.4.3.6 Statement of Claim

Within 45 days of the receipt of the Notice of Allegation, a first person and/or the patent owner can sue the second person for patent infringement of any patent or CSP that is the subject of an allegation set out in that notice, on the basis of the second person's regulatory submission or supplement.¹¹⁹ As with a regular patent infringement action, if the first person is not the patent owner, the patent owner must be made a party to the lawsuit.¹²⁰

The first person must decide within the 45-day period whether it has a reasonable basis for suing the second person for patent infringement. If it does, it is obliged to proceed under these proceedings and is prohibited from bringing another action for patent infringement. If the first person did not have a reasonable basis for suing the second person for patent infringement, it can sue the second person under other proceedings.¹²¹

Presumably, the second person will not be able to argue that such infringement action, brought about 24 months before the product could be approved and sold, is not prohibited by the case law preventing *quia timet* actions where the product launch is not "imminent".

The only actions that can be joined with such proceedings are other similar actions in relation to the submission or supplement and actions brought relating to a CSP that is subsequently added to the patent register involving a patent set out in the CSP that is already at issue in that action.¹²²

When issued, the Statement of Claim shall be accompanied by a letter (presumably to the Administrator of the Federal Court) stating that the action is a NOC proceeding, and requesting that the proceeding be specially managed pursuant to s. 6.10(1) in accordance with Rules 383, 383.1 and 385, and identifying any other current proceedings before the Court involving the same drug.¹²³ The letter should also indicate if the stay of the issuance of the NOC has been renounced under s. 7(5)(b).¹²⁴

The first person must serve with the Statement of Claim, any contact information for any inventor¹²⁵ and laboratory notebooks, research reports or other documents that were requested with the Notice of Allegation, or explain the reasons for not providing them.¹²⁶ The first person

¹¹⁷ contact information of inventors and/or laboratory notebooks, research reports or other documents that may be relevant to establish whether a particular property, advantage or use asserted by the second person to be part of the invention was established as of the filing date of the application.

¹¹⁸ *2017 Regulations*, s. 6.04(3)

¹¹⁹ *2017 Regulations*, s. 6(1)

¹²⁰ *2017 Regulations*, s. 6(2)

¹²¹ *2017 Regulations*, s. 6.01

¹²² *2017 Regulations*, s. 6.02

¹²³ *2017 Guidelines*, pp. 2-3

¹²⁴ *2017 Guidelines*, p. 3

¹²⁵ *2017 Regulations*, s. 5(3.1)(a). Providing contact information of ex-employees may put an Innovator in breach of European privacy laws.

¹²⁶ *2017 Regulations*, s. 6.03

can impose on the second person reasonable rules for maintaining the confidentiality of the information provided,¹²⁷ which rules are binding and enforceable by the Federal Court¹²⁸ unless varied by the Court.¹²⁹

A Statement of Claim may be dismissed, in whole or in part, on the ground that it is redundant, scandalous, frivolous or vexatious or is otherwise an abuse of process in respect of one or more patents or CSP.¹³⁰

9.4.3.7 Notice of Intention to Respond

Within 10 days of service of the Statement of Claim, the second person shall serve and file a Notice of Intention to Respond. The second person shall indicate in the form:

- whether it intends to defend by challenging the validity of any of claims of the patent(s) asserted by the first person;¹³¹ and
- whether it intends to serve and file a counterclaim relating to the validity of any of claims of the patent(s).¹³² Where invalidity is intended to be asserted, the second person shall also indicate in the form whether it intends to serve and file a counterclaim seeking a declaration of invalidity and impeachment or whether it will defend on the basis of invalidity only.¹³³

9.4.3.8 Appointment of Case Management Judge and Trial Judge

All *PM(NOC)* actions are to be specially managed proceedings.¹³⁴ Once a Statement of Claim is filed pursuant to s. 6(1), the matter shall be referred immediately by the Registry to the Chief Justice for the appointment of a case management judge and a trial judge.¹³⁵

9.4.3.9 Case Management

The Regulatory Impact Analysis Statement says that “[e]arly and active case management will help contribute to the timely resolution of proceedings.” That is an understatement. Having a pharmaceutical patent case go to trial within 21 months and be decided within 24 months will require aggressive case management and cooperation between the parties.

The *2017 Regulations* themselves require the parties to act diligently¹³⁶ in carrying out their obligations *Regulations* and to cooperate reasonably in expediting any action or counterclaim to

¹²⁷ *2017 Regulations*, s. 6.03(2)

¹²⁸ *2017 Regulations*, s. 6.03(3)

¹²⁹ *2017 Regulations*, s. 6.03(4)

¹³⁰ *2017 Regulations*, s. 6.08

¹³¹ *2017 Guidelines*, p. 3

¹³² *2017 Guidelines*, p. 3

¹³³ *2017 Guidelines*, p. 3

¹³⁴ *2017 Regulations*, s. 6.1(1). See *Federal Courts Rules* 383, 383.1 and 385.

¹³⁵ *2017 Guidelines*, p. 2, Section II

¹³⁶ *2017 Regulations*, s. 8(1)

which they are a party.¹³⁷ Failure to do so may result in the shortening or extension of the 24 month period during which the Minister is prohibited from issuing a NOC¹³⁸ and may result in cost sanctions.¹³⁹

9.4.3.10 Agreement re Pre-Trial Procedures and Timeline

Following service of the Notice of Intention to Respond, the parties are expected to reasonably cooperate and agree on expediting pre-trial procedures pursuant to s. 6.09, including with respect to:

- the scheduling of the various steps leading up to trial;¹⁴⁰ and
- the order of evidence at trial, and the presentation of evidence at trial in a manner that could streamline the hearing, including the possibility of presenting testimony in the form of affidavits or declarations.¹⁴¹

9.4.3.11 First Case Management Conference

The case management judge shall conduct a case management conference as soon as feasible after the 10th day after the filing of proof of service of the Statement of Claim¹⁴² and no later than 28 days after the issuance of the Statement of Claim, to schedule all steps in the action in a timely and reasonable fashion and to deal with any matters of a procedural nature which should be addressed at an early stage of the proceedings.¹⁴³

Within 7 days of service of the Notice of Intention to Respond, the first person shall requisition a case management conference by letter, setting out:

a) a joint proposed timetable to govern the steps leading to the trial, including the estimated duration, proposed venue and language of the trial.¹⁴⁴ The proposed timetable shall incorporate deadlines for:

- making voluntary productions,
- serving the parties' affidavits of documents,
- requesting particulars,
- exchanging claims charts,
- completing of examinations for discovery, and
- exchanging Notices to Admit.¹⁴⁵

¹³⁷ 2017 Regulations, s. 6.09

¹³⁸ 2017 Regulations, s.7(8)

¹³⁹ 2017 Regulations, s. 6.12(2)(a) & (b)

¹⁴⁰ 2017 Guidelines, p. 3

¹⁴¹ 2017 Guidelines, p. 3

¹⁴² 2017 Regulations, s. 6.1(2)

¹⁴³ 2017 Guidelines, p. 4

¹⁴⁴ 2017 Guidelines, p. 3

¹⁴⁵ 2017 Guidelines, p. 3

In the event that counsel cannot agree on a timetable, separate submissions should be made in advance of the first case management conference.;

b) dates of mutual availability of counsel for the parties for a trial to be completed no later than 21 months from the date of commencement of the action.¹⁴⁶

c) any motions that may be contemplated by the parties, including any motions relating to protective or confidentiality orders, production pursuant to subsections 6.04(1)¹⁴⁷ and 6.04(2)¹⁴⁸ of the Regulations, and for relief pursuant to subsections 6.07¹⁴⁹ or 6.08;¹⁵⁰ and

d) the prospects for settlement.¹⁵¹

9.4.3.12 Statement of Defence (and Counterclaim)

The second person can defend the action and commence a counterclaim to invalidate any claim asserted in the action.¹⁵²

9.4.3.13 Request for Declaration that a patent or CSP is ineligible to be on the Register

A second person can bring a motion for a declaration that a patent or CSP is ineligible for inclusion on the patent register,¹⁵³ but the action is not to be dismissed solely on the basis that a patent or CSP is ineligible for inclusion on the register.¹⁵⁴

9.4.3.14 Case Management Conferences (Generally)

It is expected that any matter that may affect the orderly and expedient conduct of a NOC proceeding will be brought to the immediate attention of the case management judge.¹⁵⁵

¹⁴⁶ 2017 Guidelines, p. 3

¹⁴⁷ "... any portion of the submission or supplement that is relevant to determine if any patent or certificate of supplementary protection at issue would be infringed and any such portion that is changed."

¹⁴⁸ contact information for the inventors and/or "any laboratory notebook, research report or other document that may be relevant to determine whether a particular property, advantage, or use asserted by the second person to be part of the invention was established as of the filing date of the application for the patent."

¹⁴⁹ a declaration that a patent or certificate of supplementary protection is ineligible for inclusion on the register.

¹⁵⁰ a dismissal of the action on the basis that it is redundant, scandalous, frivolous or vexatious or is otherwise an abuse of process in respect of one or more patents or certificates of supplementary protection.

¹⁵¹ 2017 Guidelines, p. 4

¹⁵² 2017 Regulations, s. 6(3)

¹⁵³ 2017 Regulations, s. 6.07

¹⁵⁴ 2017 Regulations, s. 6.07(3)

¹⁵⁵ 2017 Guidelines, p. 4

Counsel should ensure that they will be reasonably available for case management conferences, to complete discoveries on a timely basis and for an expedited trial.¹⁵⁶

Counsel will be expected to have conferred among themselves before requesting any case management conference or bringing any motion.¹⁵⁷ The case management judge may require that a case management conference be held before any motion is brought.¹⁵⁸

Unless otherwise ordered or directed by the case management judge:

- a) the parties shall provide timely advance notice to the party to be examined of their respective discovery plans, including requests for the production of additional documents and possible lines of questioning;¹⁵⁹
- b) the parties shall provide timely production of documents in advance of the examination;¹⁶⁰
- c) the parties shall consider the use of requests to admit facts prior to taking discovery so as to shorten discovery where possible.¹⁶¹

It is expected that interlocutory procedures including any appeals shall be completed sufficiently in advance of the deadlines agreed to by counsel or fixed by the Court.¹⁶²

The parties may seek interlocutory relief, including an extension of scheduling deadlines, by letter if on consent or unopposed, subject to the sole discretion of the case management or trial judge.¹⁶³

9.4.3.15 Further Procedures

Interlocutory orders made in the action or counterclaim can be appealed within 10 days of the order,¹⁶⁴ but only to the Federal Court of Appeal, and only with leave of that court.¹⁶⁵ Leave applications are governed by Federal Courts Rules 352 to 356.

The party that brings the action is obliged to provide the Minister with court documents as the case proceeds.¹⁶⁶

¹⁵⁶ 2017 Guidelines, p. 4

¹⁵⁷ 2017 Guidelines, p. 4

¹⁵⁸ 2017 Guidelines, p. 4

¹⁵⁹ 2017 Guidelines, p. 4

¹⁶⁰ 2017 Guidelines, p. 4

¹⁶¹ 2017 Guidelines, p. 4

¹⁶² 2017 Guidelines, p. 4

¹⁶³ 2017 Guidelines, p. 4

¹⁶⁴ 2017 Regulations, s. 6.11(2)

¹⁶⁵ 2017 Regulations, s. 6.11(1)

¹⁶⁶ 2017 Regulations, s. 6.13

9.4.3.16 Claim Construction and Claim Charts

Early claim construction can result in a reduction of the claims being asserted at the trial, or even lead to settlement of the entire proceeding.¹⁶⁷ Therefore, the parties will be required to exchange claims charts in a format prescribed by the Court.¹⁶⁸ A case management conference should be requisitioned with a view to limiting claim construction issues.¹⁶⁹

9.4.3.17 Trial Management Conference

Given the active role of the Court in case management, no pre-trial conferences shall be held in NOC proceedings.¹⁷⁰

A trial management conference shall be requisitioned by the parties pursuant to Rule 270 of the Rules forthwith upon the trial dates being fixed to deal with matters relating to the conduct of the trial.¹⁷¹

All affidavits will have to be served and filed in accordance with the schedule fixed by the Court and, unless a prior order is made, the witness should be available for cross-examination at the trial.¹⁷²

If any fact evidence is decided to be adduced at trial by *viva voce* testimony then an outline of the areas of testimony of any facts witnesses who are expected to appear at the trial will also need to be submitted in advance of trial in accordance with the schedule fixed by the Court, with such witnesses being made available for cross-examination at trial.¹⁷³ Where it is agreed by the parties that certain fact evidence may be introduced without cross-examination, parties are encouraged to adduce stipulations of such evidence to streamline the necessity for trial testimony.¹⁷⁴

Demonstrative evidence sought to be used should be exchanged by the parties at least 30 days prior to the trial.¹⁷⁵ Objections to any demonstrative evidence must be raised with the Court at least 20 days prior to the trial. No additional demonstrative evidence will be allowed at the trial.¹⁷⁶

¹⁶⁷ 2017 Guidelines, p. 4
¹⁶⁸ 2017 Guidelines, p. 4
¹⁶⁹ 2017 Guidelines, p. 4
¹⁷⁰ 2017 Guidelines, p. 3
¹⁷¹ 2017 Guidelines, p. 5
¹⁷² 2017 Guidelines, p. 5
¹⁷³ 2017 Guidelines, p. 5
¹⁷⁴ 2017 Guidelines, p. 5
¹⁷⁵ 2017 Guidelines, p. 5
¹⁷⁶ 2017 Guidelines, p. 5

At least 30 days prior to the trial, a further trial management conference should be held to discuss, among other things, the identification of the patents and/or claims that remain in issue and any specific claim construction disputes that still exist.¹⁷⁷

9.4.3.18 Trial

At the request of, and at a time specified by, the trial judge, the parties shall provide a tutorial session in a form to be agreed to by the parties or on direction of the Court.¹⁷⁸

The Court will expect parties to complete trials within two weeks, unless the Court determines that additional time is required.¹⁷⁹

For trial, the parties will be expected to adduce their evidence-in-chief¹⁸⁰ by way of affidavit, subject to variation by the case management judge or the trial judge prior to trial.¹⁸¹

9.4.3.19 Damages

The proposed Regulations would continue to allow a second person to seek compensation for losses suffered during the period they were kept off the market as a result of an unsuccessful or discontinued proceeding.¹⁸² All plaintiffs would be made jointly and severally (or solidarily – a Quebec term) liable for any loss suffered by the second person starting after the later of either the date of service of the NOA (a change from the previous start date) or the date when the NOC would have issued in the absence of the Regulations.¹⁸³ Liability is no longer limited to losses suffered prior to a specified end date.

9.5 Canada's Access to Medicines Regime (Bill C-9)

On August 2, 2003, the General Council of the World Trade Organization set forth a decision allowing member countries to issue compulsory licenses for the production of generic versions of pharmaceutical products, for the sole purpose of export to nations which require the drug to combat public health crises.¹⁸⁴ Essentially, the decision allows a country to waive its obligations under section 31(f) of TRIPS, which mandates that compulsory licenses are to be used “predominantly for the supply of the domestic market of the Member authorizing such use.”

On May 14, 2004, the Canadian Parliament approved Bill C-9, *An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chretien Pledge to Africa Act)*.¹⁸⁵ In doing so, Canada

¹⁷⁷ 2017 Guidelines, p. 5

¹⁷⁸ 2017 Guidelines, p. 4

¹⁷⁹ 2017 Guidelines, p. 3

¹⁸⁰ Interestingly, this is not limited to expert evidence and, therefore, would include fact witnesses.

¹⁸¹ 2017 Guidelines, p. 5

¹⁸² 2017 Regulations, s. 8(1)

¹⁸³ 2017 Regulations, s. 8(2)

¹⁸⁴ WTO, *Agreement on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, Decision of the General Council of 30 August 2003, WT/L/540

¹⁸⁵ Bill C-9, *An Act to amend the Patent Act and the Food and Drugs Act*, 3d Sess., 37th Parl. 2004. The Bill added sections 21.01 – 21.2 to the Canadian *Patent Act*.

became the first country to implement the WTO decision. Bill C-9 amended the *Patent Act* by adding a number of new sections that pertain to the use of patents for international humanitarian purposes in order to address public health concerns. The stated purpose of the regime is to facilitate

...access to pharmaceutical products to address public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.¹⁸⁶

The regime contemplated under section 21 of the *Patent Act*, known as the Canada Access to Medicines Regime (CAMR), permits the Commissioner of Patents to grant a compulsory license to an applicant who submits an application that meets a series of conditions set out section 21.01-21.2 of the *Patent Act* and in the corresponding regulations.¹⁸⁷ The scheme permits the export of fifty-six defined products¹⁸⁸ to all WTO countries¹⁸⁹ and all non-WTO least developed countries. The compulsory license or "authorization" will permit the licensee to "make, construct and use a patented invention solely for purposes directly related to the manufacture of the pharmaceutical product named in the application" and sell it for export to a country listed in Schedules 2, 3, or 4 of the *Patent Act* and named in the application.¹⁹⁰ Once a compulsory license is issued, it will remain valid for 2 years with a one-time opportunity for renewal.¹⁹¹

In addition to the requirements of the *Patent Act*, the applicant for a compulsory license must comply with the requirements of the *Food and Drugs Act* and the *Food and Drug Regulations*. In order to implement Bill C-9, the *Food and Drug Regulations* were amended by the addition of a new division (Division 7), entitled "Sale of Drugs for the Purposes of Implementing the General Council Decision."

¹⁸⁶ *Patent Act*, R.S., 1985, c. P-4, s. 21.01.

¹⁸⁷ *Use of Patented Products for International Humanitarian Purposes Regulations*, SOR/2005-143

¹⁸⁸ Bill C-9, *An Act to amend the Patent Act and the Food and Drugs Act*, 3d Sess., 37th Parl., 2004. As enacted, Schedule 1 of Bill C-9 included a list of 56 defined products that are principally derived from the WHO's Model List of Essential Medicines, and, upon the recommendation of 2 federal Ministers and the final decision of the federal Cabinet, other pharmaceuticals may be added to the list. The list currently includes a number of HIV/AIDS drugs, antibiotics, as well as some older, off-patent drugs.

¹⁸⁹ WTO, *Agreement on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, Decision of the General Council of 30 August 2003, paragraph 1(b) provides that the Agreement is potentially open to all Member States, it being understood "that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.

¹⁹⁰ Schedule 2 lists all countries that have been identified by the UN as "least-developed countries". Schedule 4 lists WTO members that have agreed to use the system as importers only in the event of a national emergency or circumstances of extreme urgency. Schedule 3 lists WTO members that are not listed in Schedules 2 or 4, and that have not opted out of the system and includes some potentially large markets as China, India and Brazil.

¹⁹¹ *Patent Act*, R.S., 1985, c. P-4, ss.21.09 and 21.12. Moreover Sections 21.1 and 21.11 provide that the use of a patented invention under an authorization is non-exclusive and generally non-transferable.

In September 2007, Canada became the first WTO member to authorize export of a generic version of the antiretroviral TRIAVIR® to Rwanda, by Apotex Inc., under CAMR. The production and export of Apo-Triavir has been the only use of the CAMR legislation since its adoption.

9.6 *Data Protection*

In addition to the protection afforded by the *PM(NOC) Regulations*, section C.08.004.1 of the *Food and Drug Regulations* creates a regulatory framework to protect the clinical data submitted by an innovator in support of its drug regulatory submissions, by providing new drugs with a guaranteed minimum period of market exclusivity.

9.6.1 *History of Data Protection in Canada*

Canada first introduced data protection provisions into the *Food and Drug Regulations* on August 16, 1995.¹⁹² Both NAFTA and TRIPS provide a scheme for protecting against unfair commercial use of what would otherwise be undisclosed data and oblige Health Canada to protect the use of undisclosed tests or other data submitted in order to obtain marketing approval for pharmaceutical products based on new chemical entities.¹⁹³ The intent of this protection was and is to allow the data innovator to protect the investments made in the development of the product by allowing a period of market exclusivity.

The data protection provisions of NAFTA and TRIPS relate broadly to what are generally known as *trade secrets*. More specifically, the provisions outline a member state's obligations in the particular instance where such trade secret data is submitted to a government agency as a precondition for obtaining marketing approval.

¹⁹² SOR/95-411, s. C.08.004.1.

¹⁹³ Generally speaking, Canadian courts have held that, while Parliament is presumed not to intend to legislate contrary to international treaties or general principles of international law, where the legislation is clear, one need not and should not look to international law. See e.g., *Pfizer Canada Inc. v. Canada (Attorney General)*, 2003 FCA 138. More recently, the Federal Court has rejected arguments to the effect that Canadian laws, in particular the *PM(NOC) Regulations*, must be read in a manner so as to be interpreted as enforcing patent rights in light of TRIPS and, holding instead, that the legal effect of the *PM(NOC) Regulations* are to be determined in accordance with the ordinary principles established in Canadian law. See e.g., *Laboratoires Servier v. Apotex Inc.*, 2006 FC 1493 (per Snider, J.) and *Ferring Inc. v. Canada (Minister of Health)*, 2007 FC 300 (per Hughes, J.). Notwithstanding the foregoing, the Regulatory Impact Analysis Statements which accompanied the 2006 amendments to the data protection provisions of the *Food and Drug Regulations*, *supra*, note 3, are clear that the amendments are intended to clarify and effectively implement Canada's *North American Free Trade Agreement* ("NAFTA") and the *Trade-Related Aspects of Intellectual Property Rights* ("TRIPS") obligations with respect to the protection of undisclosed test or other data necessary to determine the safety and effectiveness of a pharmaceutical or agricultural product which utilizes a new chemical entity. It remains to be seen what impact the provisions of NAFTA and TRIPS will have on the judicial interpretation of the amended data protection provision of the *Food and Drug Regulations* in light of the Government's apparent, as expressed, intention in enacting the amendments.

9.6.2 The Former Data Protection Regime

The former regulations, in theory, provided for a five-year period of market exclusivity (generic drug approval would be deferred by a corresponding period).¹⁹⁴ This protection was provided on the basis that data or information filed in the innovator's submission supported Health Canada's approval of the new drug submission.

However, former section C.08.004.1 was interpreted very narrowly by Canadian Courts such that it rarely, if ever, was triggered.

Under former section C.08.004.1, the data protection exclusivity period arose when the Minister of Health examined and relied on an innovator's undisclosed data in order to grant a NOC to a generic manufacturer. However, to receive a NOC in Canada, a generic manufacturer need only demonstrate bioequivalence by comparing its generic product to the innovator's product. Therefore, in actual practice, the Minister typically did not actually examine the data contained in the innovator's submission in order to grant a NOC for a generic product. This fact led the Federal Court of Appeal, in the 1998 case of *Bayer Inc. v. Canada (Attorney General)*,¹⁹⁵ to conclude that data protection did not arise where bioequivalence forms the basis of a generic submission and, as a result, the five-year term of data protection was rendered inapplicable (moreover, the Court saw the overall scheme and purpose of the regulatory regime was to reduce the cost of drugs by facilitating approval of generic drugs, and that the argument put forward by Bayer would undermine this purpose by imposing a delay on the issuance of NOCs to generic manufacturers). This narrow interpretation of the data protection provisions of the *Food and Drug Regulations* opened the door for generic drug manufacturers to seek marketing authorization for generic drugs that rely for their safety and efficacy on the previous filings and approvals of the innovative drug manufacturer.

9.6.3 2006 Amendments

On October 5, 2006, the Government of Canada enacted amendments to the data protection provisions of the *Food and Drug Regulations* to include more robust data protection provisions for innovative drugs.¹⁹⁶

¹⁹⁴ Section **C.08.004.1** of the *Food and Drug Regulations*, as it then was, read as follows: (1) *Where a manufacturer files a new drug submission, an abbreviated new drug submission, a supplement to a new drug submission or a supplement to an abbreviated new drug submission for the purpose of establishing the safety and effectiveness of the new drug for which the submission or supplement is filed, and the Minister examines any information of material filed with the Minister, in a new drug submission, by the innovator of a drug that contains a chemical or biological substance not previously approved for sale in Canada as a drug, and the Minister, in support of the manufacturer's submission or supplement, relies on data contained in the information or material filed by the innovator, the Minister shall not issue a notice of compliance in respect of that submission or supplement earlier than five years after the date of issuance to the innovator of the notice of compliance or approval to market that drug, as the case may be, issued on the basis of the information or material filed by the innovator for that drug.*

¹⁹⁵ *Bayer Inc. v. Canada (Attorney General)* (1998), 87 C.P.R. (3d) 293 (F.C.A.)

¹⁹⁶ *Regulations Amending the Food and Drug Regulations (Data Protection)*, SOR/2006-241 (October 5, 2006)

The 2006 amendments, which introduced the automatic prohibition approach to generic drug submissions implemented in similar jurisdictions such as the U.S. and Europe, provide new and “innovative” brand-name drugs with a guaranteed minimum period of market exclusivity of eight years, with a further six months of data exclusivity available for drugs that have been the subject of pediatric studies designed and conducted with the purpose of increasing knowledge about the drug in pediatric age groups in which it may be used.

Under the current Data Protection regime, generic manufacturers will be subject to a six-year period (within the eight-year exclusivity term) where the generic manufacturer, seeking to copy an innovative drug, is not permitted to file a new drug or abbreviated new drug submission with the Minister. This six-year period will then be followed by a “no-marketing period” of two years during which the Minister will not grant a NOC to that generic manufacturer. According to the RIAS which accompanied the 2006 amendments, this additional two-year period is generally reflective of the period of time required to approve a drug submission, as well as the time required for a generic manufacturer to meet its obligations under the *PM(NOC) Regulations*.¹⁹⁷

9.6.4 The Current Regime - Details of Operation

9.6.4.1 Scope of Protection: “Innovative” Drugs

The current Data Protection regime applies solely to so-called “innovative” drugs, which are defined by section C.08.00401(1) to be drugs that contain a medicinal ingredient not previously approved in Canada and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph.

Therefore, under the definition of an “innovative” drug, pharmaceuticals containing a medicinal ingredient(s) that has been previously approved¹⁹⁸ in Canada will not be afforded protection under the current regime.¹⁹⁹

The definition of “innovative drug” specifically prohibits innovators from obtaining additional terms of data protection for variations of medicinal ingredients. Health Canada has indicated that the list of variations is not exhaustive, but rather meant to give examples of the types of variations not considered for protection. For other arguable variations, such as metabolites or pro-drugs, an assessment will be made on a case-by-case basis as to whether or not approval is being sought primarily on the basis of previously submitted clinical data or not.²⁰⁰

¹⁹⁷ Regulatory Impact Analysis Statement, C. Gaz. II, vol. 140 no. 21 (*Regulations Amending the Food and Drug Regulations (Data Protection)*), October 18, 2006

¹⁹⁸ See *Canada (Health) v. Celgene Inc.* (2013 FCA 43) where thalidomide was a medicinal ingredient that had received regulatory approval and was held to have been “previously approved” for the purposes of the Regulations.

¹⁹⁹ It should be noted that drugs containing medicinal ingredients previously approved for veterinary uses will not qualify for additional protection if submitted as human drugs since the protection is only available for the first approval. Biologics and radiopharmaceuticals are also included in these provisions. See Health Canada, Guidance Document: “*Data Protection under C.08.004.1 of the Food and Drug Regulations*”, 24 March 2009, available online: <http://www.hc-sc.gc.ca/dhp-mpps/prodpharma/applic-demande/guide-ld/data_donnees_protection-eng.php>.

²⁰⁰ Health Canada, Guidance Document: “*Data Protection under C.08.004.1 of the Food and Drug Regulations*”, 24 March 2009

With respect to combination drugs, the Guidance Document provides that a combination drug, having at least one ingredient which is an innovative drug and for which a data protection term is still in effect, will receive data protection for the innovative drug in the combination until the expiry of the original data protection period of that innovative drug. Combinations of previously approved medicinal ingredients are not eligible for an additional period of data protection.²⁰¹

9.6.4.2 Requirement for Marketing In Canada

Data protection for innovative drugs under the current regime is available only where the innovative drug has received regulatory approval (i.e., received marketing authorization from Health Canada in the form of a NOC) and is actually marketed in Canada.²⁰²

Drugs that are withdrawn from the market by the innovator will no longer be eligible for data protection. According to the RIAS which accompanied the 2006 amendments, this rule has been implemented to ensure that a generic drug is not blocked from entering the market where an innovative drug has been withdrawn prior to the expiry of its term of data protection.²⁰³

9.6.4.3 Register of Innovative Drugs

Pursuant to Section C.08.004.1(9), the Minister of Health maintains a "Register of Innovative Drugs" which contains information respecting innovative drugs that are eligible for data protection. Innovative drugs are added to the Register after they receive a NOC.²⁰⁴

The Register of Innovative Drugs may be accessed online at http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/regist/reg_innov_dr-eng.php, and includes, *inter alia*, information respecting the name of the drug, the medicinal ingredient, and the date on which the data protection and, where applicable, the pediatric extension, will terminate.

9.6.4.4 Term of Protection

Under section C.08.004.1(3)(b), a NOC may not be issued to a second or subsequent entry drug manufacturer which seeks a NOC on the basis of a direct or indirect comparison between the second or subsequent entry drug and an innovative drug, until the expiry of a period of eight years after the day on which the first NOC was issued to the innovator in respect of the innovative drug.

In addition to the eight-year term of data protection, a further six month extension is available under Section C.08.004.1(4) if an innovator includes, in its NDS, or any supplement to that NDS filed within the first five years of the eight-year data protection period, results of clinical trials which were designed and conducted with the purpose of increasing knowledge about the use of

²⁰¹ Health Canada, Guidance Document: "Data Protection under C.08.004.1 of the Food and Drug Regulations", 24 March 2009

²⁰² *Food and Drug Regulations* (C.R.C., c. 870), section C.08.004.1(5).

²⁰³ Regulatory Impact Analysis Statement, C. Gaz. II, vol. 140 no. 21 (*Regulations Amending the Food and Drug Regulations (Data Protection)*), October 18, 2006

²⁰⁴ According to the RIAS which accompanied the amendments, the Register of Innovative Drugs was introduced as a "transparency measure" to provide both transparency and predictability for Canadian pharmaceutical companies.

the innovative drug in pediatric populations.²⁰⁵ The RIAS which accompanied the 2006 amendments to the Data Protection Regulations elaborates on the scope of data required to qualify for the pediatric extension. In particular, the data must meet the definition of “clinical trial” set out in the *Food and Drug Regulations*,²⁰⁶ and the goal of such studies, as reflected in the study hypothesis, objectives, design and conduct, must be to “increase knowledge about the behaviour of the drug in pediatric populations that will assist health professionals, parents, caregivers, and patients in making informed choices about drug therapy.”²⁰⁷

9.6.4.5 Six-Year “No File” Period

As noted above, where a manufacturer seeks a NOC on the basis of a direct or indirect comparison between the new drug and an innovative drug, the manufacturer is prohibited under Section C.08.004.1(3)(a) from filing the submission for six years from the date of issuance of the NOC for the innovative drug.²⁰⁸

Generally, any such submissions received by the Minister within this six-year period will be rejected; however, the manufacturer will be provided with a preliminary decision by letter informing it of the intent to reject the submission and granting the manufacturer a 30-day period to make representations in response. If, following consideration of the representations, the Minister remains of the view that the submission cannot be filed, then the submission will be returned to the manufacturer at its expense.

A subsequent manufacturer seeking a NOC on the basis of a direct or indirect comparison to the innovative drug would include a manufacturer filing an ANDS. In that case, the innovative drug is typically the Canadian Reference Product. However, the provision is also intended to include New Drug Submissions that seek a NOC for a drug that contains the same medicinal ingredient as an innovative drug, on the basis of a comparison to the innovative drug, including subsequent entry biologics.²⁰⁹

²⁰⁵ Section C.08.004.1(1) of the *Food and Drug Regulations* (C.R.C., c. 870) defines “pediatric populations” as follows: premature babies born before the 37th week of gestation; full-term babies from 0 to 27 days of age; and all children from 28 days to 2 years of age, 2 years plus 1 day to 11 years of age and 11 years plus 1 day to 18 years of age.

²⁰⁶ “Clinical trial” is defined in Division 5 of the *Food and Drug Regulations* as “an investigation in respect of the drug for use in humans that involves human subjects and that is intended to discover or verify the clinical, pharmacological or pharmacodynamic effects of the drug, identify any adverse events in respect of the drug, study the absorption, distribution, metabolism and excretion of the drug, or ascertain the safety or efficacy of the drug” (*Food and Drug Regulations* (C.R.C., c. 870), s. C.05.001).

²⁰⁷ Regulatory Impact Analysis Statement, C. Gaz. II, vol. 140 no. 21 (*Regulations Amending the Food and Drug Regulations (Data Protection)*), October 18, 2006

²⁰⁸ However, under Section C.08.004.1(8) of the *Food and Drug Regulations*, an innovator may consent to the submission of a drug manufacturer who seeks a Notice of Compliance on the basis of a direct or indirect comparison between the new drug and an innovative drug. A letter of consent signed by the innovator company must be submitted with the submission of the authorized manufacturer specifically providing authorization to file the submission within the protection period.

²⁰⁹ Health Canada, Guidance Document: “*Data Protection under C.08.004.1 of the Food and Drug Regulations*”, 24 March 2009

9.6.4.6 Exemption Under Canada's Access to Medicines Regime

An exemption from the six-year "no file" period is available under Section C.08.004.1(7) to allow a subsequent manufacturer to file a drug submission under Canada's Access to Medicines Regime.²¹⁰

Although such drug submissions can be submitted within the no-filing period, the NOC will not be issued until the expiry of the data protection term. For second person submissions filed within the six-year period, for the purposes of the *Patented Medicines (Notice of Compliance) Regulations*, the date of filing is deemed to be six years after the date of issuance of the first person's Notice of Compliance.²¹¹

9.6.4.7 Transitional Provisions

The current Data Protection Regulations apply only to marketed innovative drugs in respect of which a NOC issued on or after June 17, 2006. According to the transitional provisions of the Data Protection Regulations, any innovative drug which received a NOC prior to June 17, 2006 remains subject to Canada's former data protection regime described above.

9.6.5 Court Challenges to the Data Protection Regulations

On November 14, 2006, the Canadian Generic Pharmaceutical Association (CGPA), an industry association representing Canadian manufacturers of generic drugs, filed a legal challenge to the current Data Protection regime, that sought a declaration that the amended Data Protection Regulations are *ultra vires* the Government to legislate, on the basis that they exceed the requirements of NAFTA and Canada's obligations under TRIPS.²¹²

A second challenge was subsequently filed by the generic drug manufacturer Apotex Inc., who brought an application for judicial review attacking the provisions on the basis that they are designed to protect the unfair commercial use of trade secrets and undisclosed data and, therefore, surpass the limits of federal authority.²¹³

Both challenges were heard together by the Federal Court on December 16, 2008. Eli Lilly Canada Inc. and Rx&D participated as interveners on behalf of Canada's research-based pharmaceutical industry. On July 17, 2009, the Federal Court rendered a decision upholding the *Data Protection Regulations* as being constitutionally valid and dismissed the challenges of the CGPA and Apotex, Inc.²¹⁴

²¹⁰ *Patent Act, supra*, note 7, ss. 21.01 to 21.2 on the Use of Patents for International Humanitarian Purposes to Address Public Health Problems.

²¹¹ Health Canada, Guidance Document: "*Data Protection under C.08.004.1 of the Food and Drug Regulations*", 24 March 2009. See also, Health Canada, *Guidance Document: Patented Medicines (Notice of Compliance) Regulations*, available online: <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide/ld/patmedbrev/pmreg3_mbreg3-eng.php>

²¹² *Canadian Generic Pharmaceutical Association v. Governor in Council (The) et al.*, Federal Court file T-1976-06, filed November 14, 2006.

²¹³ *Apotex Inc. v. Governor in Council et al.*, Federal Court file T-2047-06, filed November 22, 2006.

²¹⁴ *Canadian Generic Pharmaceutical Association v. Canada (Health)*, 2009 FC 725 (per Mandamin, J.)

9.7 **Biologics**

A biologic is a type of drug derived from biological sources; more specifically, through the metabolic activity of living organisms.²¹⁵

Biologics are large and complex molecules. Because they are made through biological processes, they tend to be heterogeneous, (varying in structure). Their structure is usually sensitive to changes in the manufacturing conditions, so care must be taken to maintain manufacturing conditions or a different product may result. It is said, “the process is the product”.²¹⁶

Biologics are regulated by Divisions 3, 4 and 8 of Part C of the *Canadian Food And Drugs Regulations* and are specifically listed in Schedule D to the *Canadian Food and Drugs Act*. They include:

- Individual products
 - Snake venom
 - Anterior pituitary extracts
 - Urokinase
- Product classes
 - Immunizing agents
 - Allergenic substances used for the treatment or diagnosis of allergic or immunological diseases
 - Monoclonal antibodies, their conjugates and derivatives
- Drugs obtained by recombinant DNA procedures
- Drugs, other than antibiotics, prepared from micro-organisms
- Blood components
 - Blood and blood derivatives, except cord blood and peripheral blood that are a source of lymphohematopoietic cells for transplantation
 - Human plasma collected by plasmapheresis
- Cytokines

²¹⁵ Health Canada Fact Sheet: Subsequent Entry Biologics in Canada, http://www.hc-sc.gc.ca/dhp-mpps/alt_formats/hpfb-dgpsa/pdf/brgtherap/fs-fi_seb-pbu_07_2006-eng.pdf, p. 1.

²¹⁶ Health Canada Fact Sheet: Subsequent Entry Biologics in Canada, http://www.hc-sc.gc.ca/dhp-mpps/alt_formats/hpfb-dgpsa/pdf/brgtherap/fs-fi_seb-pbu_07_2006-eng.pdf, p. 1.

- Interferon
- Protein hormones
 - Insulin
 - Glucagon
 - Gonadotrophins
 - Aprotinin (bovine pancreatic trypsin inhibitor, BPTI)
 - Secretin
 - Cholecystokinin
- Gene therapy products

Biologics, due to their complex molecular nature, may be quite sensitive to manufacturing process changes or changes in the surrounding environment. Changes to manufacturing protocol, source materials, equipment or facilities can result in significant unexpected changes to the final product. Consequently, no two biologics are identical.

9.7.1 Regulatory Approval for Biologics

In order to sell or distribute a biologic in Canada, a Notice of Compliance (“NOC”) and Drug Identification Number (“DIN”) must be issued to the biologic’s sponsor.

9.7.2 Subsequent Entry Biologics (SEBs)

9.7.2.1 Overview

A Subsequent Entry Biologic (SEB), is a biologic drug that enters the market subsequent to a version previously authorized in Canada and with demonstrated *similarity* to a reference biologic drug. A submission for marketing authorization of an SEB relies, in part, on available information about the reference biologic drug in order to present a reduced dossier of the clinical data required to obtain for marketing approval.²¹⁷ SEBs are not simply “generic biologics” and the authorization of an SEB is not a declaration of pharmaceutical or therapeutic equivalence with the reference biologic product.²¹⁸

The concept of an SEB does not apply to a biologic drug submission which is based on independent clinical trials and where the basis of the submission does not seek marketing authorization based on comparisons to a previously approved biologic drug.

²¹⁷ Health Canada, *Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biologics (SEBs)*, March 5, 2010, available online: < http://www.hc-sc.gc.ca/dhp-mps/brgtherap/applic-demande/guides/seb-pbu/notice-avis_seb-pbu_2010-eng.php>

²¹⁸ Health Canada, *Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biologics (SEBs)*., section 1.3

Health Canada has recently released a guidance document entitled *Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biologics (SEBs)* (hereinafter, the “*SEB Guidance*”),²¹⁹ which represents Health Canada’s position regarding a regulatory approval pathway for SEBs in Canada.²²⁰

9.7.2.2 Regulatory Approval

Health Canada has stated that SEBs, like all biologic drugs, are subject to the existing framework set out in section C.08.002 of *Food and Drug Regulations* and, therefore, will be approved through the existing New Drug Submission (NDS) pathway under the *Food and Drug Regulations*.²²¹

a) Reference Product

According to the *SEB Guidance*, an SEB would only be authorized for sale based on a submission that makes a direct or indirect comparison to an innovator biologic authorized for sale in Canada for the purposes of demonstrating similarity. In the NDS, the SEB manufacturer must clearly identify the product that the SEB is subsequent to.²²² The SEB manufacturer has the responsibility of demonstrating that the chosen reference product is suitable to support the SEB submission.

Although the reference product should be authorized for sale and marketed in Canada, the *SEB Guidance* provides that, in certain circumstances, a manufacturer may be permitted to use a foreign reference product to demonstrate similarity between an SEB and a product authorized for sale in Canada. If a non-Canadian reference product is used, the manufacturer must demonstrate that the foreign reference product is a suitable proxy and the submission should clearly explain the link between the reference product and the product authorized for sale in Canada. Other factors to be considered in determining whether a non-Canadian reference product may be used include, but are not limited to, whether the foreign reference product is associated with sufficient information and data to support the submission and whether it is from a jurisdiction that has a relationship with Health Canada.²²³

b) Data Set

As noted above, an SEB relies in part on prior information regarding safety and efficacy that is deemed relevant in light of a demonstration of similarity to the reference biologic drug. According to the *SEB Guidance*, a demonstration of similarity does not necessarily signify that the quality attributes of the two products being compared are identical, but that they

²¹⁹ Health Canada, *Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biologics (SEBs)*, March 5, 2010,

²²⁰ Health Canada, *Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biologics (SEBs)*, section 1.1

²²¹ Health Canada, *Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biologics (SEBs)*, section 2.1.1

²²² Health Canada, *Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biologics (SEBs)*, section 2.1.2

²²³ Health Canada, *Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biologics (SEBs)*, section 2.1.3

are highly similar with two consequences: 1) that the existing knowledge of both products is sufficient to predict that any differences in quality attributes should have no adverse impact upon safety or efficacy of the SEB; and 2) that non-clinical and clinical data previously generated with the reference biologic drug is relevant to the SEB. The *SEB Guidance* provides that, in addition to the full chemistry and manufacturing data package required for all biologic drugs, an SEB application should also provide extensive data demonstrating similarity with the chosen reference product, including biological and analytical side-by-side characterization studies of the drug substance or, if appropriate, comparability studies using the formulated drug products. Final determination of similarity can include a combination of analytical testing, biological assays, as well as clinical and non-clinical data.²²⁴

If similarity can be established between the SEB and the reference product, then the SEB submission may be filed with a reduced dossier of clinical and pre-clinical data. Although a full clinical data set is not required, the *SEB Guidance* provides that comparative pre-clinical and clinical trials are required in order to establish pharmacokinetic and pharmacodynamics profiles as well as safety and efficacy.

If, however, similarity to the reference product cannot be established through chemistry and manufacturing bio-comparability exercises, then a reduced dossier of the clinical and pre-clinical data required to obtain marketing approval cannot be justified and, consequently, the product cannot be considered to be an SEB. For such products, the submission should presumably be filed as a standard New Drug Submission with a full set of independent clinical and pre-clinical data in support of the submission.

9.7.2.3 Intellectual Property Protection

Health Canada has stated that all SEBs are subject to existing laws and regulations as outlined in the *PM(NOC) Regulations*, the *Data Protection Regulations* and their related Health Canada guidance documents - *Guidance Document: Patented Medicines (Notice of Compliance) Regulations*, and *Guidance Document: Data Protection under C. 08.004.1 of the Food and Drug Regulations*, (the “*PM(NOC) Regulations Guidance*” and “*Data Protection Guidance*”, respectively).²²⁵

The *SEB Guidance Document* was published concurrently with amendments to the *Health Canada Data Protection Guidance Document* and the *Health Canada PM(NOC) Regulations Guidance Document*, discussed in greater detail below.

As noted above, NDSs which are based on independent clinical trials, and which are not comparative in nature, do not fall within the purview of Health Canada's SEB framework and, accordingly, do not trigger the relevant provisions of the *PM(NOC) Regulations* or *Data Protection Regulations*.

²²⁴ Health Canada, *Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biologics (SEBs)*, section 2.3

²²⁵ Health Canada, *Guidance Document: Data Protection under C. 08.004.1 of the Food and Drug Regulations*, and *Guidance Document: Patented Medicines (Notice of Compliance) Regulations*, both of which are available online at Health Canada's website <<http://www.hc-sc.gc.ca>>.

a) Patent Protection

Health Canada has amended its *PM(NOC) Regulations Guidance* to expressly provide that section 5 of the *PM(NOC) Regulations* is intended to capture all submissions approved on the basis of a direct or indirect comparison with, or reference to, another drug – including NDSs submitted in accordance with the *SEB Guidance* that demonstrate similarity with a biologic drug marketed in Canada – and in respect of which there are patents listed on the Patent Register.²²⁶

Accordingly, where an SEB manufacturer seeks an NOC on the basis of a comparison with an innovative biologic, the SEB manufacturer will be required to fulfill the requirements for second persons under the *PM(NOC) Regulations*.²²⁷

In addition, the *PM(NOC) Guidance* provides that SEB submissions based on a comparison to a non-Canadian reference product in order to justify a reduced clinical and non-clinical dossier - including supplemental submissions for a change in formulation, dosage form or use of the medicinal ingredient - will likewise fall within the purview of section 5 of the *PM(NOC) Regulations* and, consequently, will trigger their application.²²⁸

In determining whether or not there has been a comparison with a drug that would trigger application of the *PM(NOC) Regulations*, the Office of Patented Medicines and Liaison (OPML) will look for a demonstration of similarity to the chosen reference biologic drug. If there is any uncertainty, the *PM(NOC) Guidance* directs the OPML to contact the relevant review bureau.²²⁹

b) Data Protection

Health Canada has amended its Data Protection Guidance to expressly provide that section C.08.004.1(3) of the *Food and Drug Regulations* applies to new drug submissions – including those for SEBs, seeking an NOC for a drug on the basis of a comparison to an innovative drug. The *Data Protection Guidance* further provides that a submission containing a demonstration of similarity to a reference biologic drug is considered to be a comparison within the meaning of section C.08.004.1(3). Accordingly, where an SEB manufacturer seeks an NOC on the basis of a comparison with an innovative biologic, the SEB manufacturer will not be permitted to file the submission for six (6) years from the date of issuance of the NOC for the innovative biologic.²³⁰

In addition, the *Data Protection Guidance* provides that SEB submissions based on a comparison to a non-Canadian reference product will likewise fall within the purview of section

²²⁶ Health Canada, *Guidance Document: Patented Medicines (Notice of Compliance) Regulations*, available online: <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-id/patmedbrev/pmreg3_mbreg3-eng.php>, section 3.4.1

²²⁷ Health Canada, *Guidance Document: Patented Medicines (Notice of Compliance) Regulations*, section 3.4.1

²²⁸ Health Canada, *Guidance Document: Patented Medicines (Notice of Compliance) Regulations*, section 3.4.1.

²²⁹ Health Canada, *Guidance Document: Patented Medicines (Notice of Compliance) Regulations*, section 3.5.1

²³⁰ Health Canada, *Guidance Document: Data Protection under C. 08.004.1 of the Food and Drug Regulations*, section 3.1

C.08.004.1(3) and, consequently, will be rejected for filing within the six-year period from the date of issuance of the NOC for the Canadian reference biologic drug.²³¹

9.8 Conclusion

In conclusion, pharmaceutical patents in Canada are subject to a number of complex statutory schemes and regulatory regimes not applicable to patents generally. These legislative and regulatory regimes reflect the Government's attempt at a balancing act – namely, the promotion of innovation, research and development by allowing innovators to benefit from a period of market exclusivity, while fostering early and effective competition to ensure that Canadians have access to drugs at reasonable prices.

To achieve this end, Canada's pharmaceutical patent laws and regulations have been subject to a number of sweeping amendments and interpretations. It will remain to be seen whether further steps will be required to enable this process from achieving its intended goals.

²³¹ Health Canada, *Guidance Document: Data Protection under C. 08.004.1 of the Food and Drug Regulations*, section 3.1