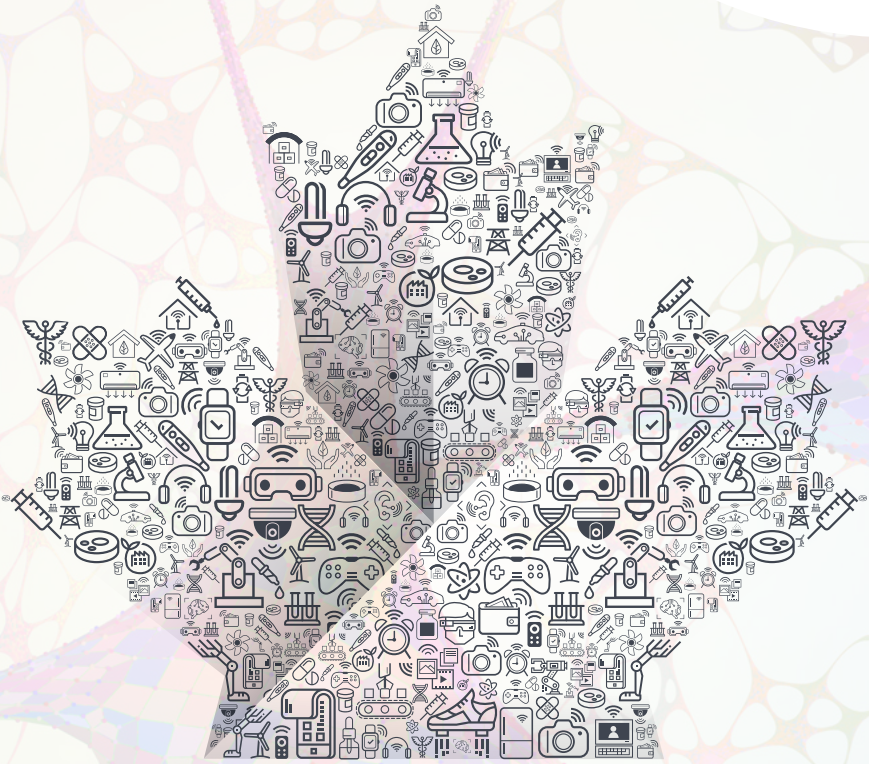

Life Sciences & Chemistry Patent Practice in Canada

A Practical Guide

Fourth Edition

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Foreword

Plans to publish an update of this book had already crystalized well before the COVID-19 global pandemic struck. As the world socially distanced, worked from home, and generally turned inwards, this rather "subject matter-specific" crisis provided a new impetus to collaborate.

Biotechnology-related inventions have been at the forefront of discussion at all points along the political spectrum, and it is clear that innovation in biotechnology is central to our global 'way out' of this pandemic – through both vaccines and treatments. A strong culture of innovation is critical to both dealing with the current pandemic and preparing for future ones.

Much has changed for the better for these inventions since the last edition of this book. Canada now has a patent term restoration regime to offset delays in regulatory approval. Longstanding subject matter eligibility issues for medical diagnostic inventions have been resolved by the Federal Court of Canada. The Supreme Court definitively quashed the problematic "promise doctrine" that felled so many patents to useful pharmaceuticals for supposed want of utility. The Canadian Intellectual Property Office (CIPO) has acknowledged significant advancements in antibody technology, leading to relaxation of unduly strict enablement and support requirements during examination. Further, the Canadian *Patent Rules* were substantively revised in 2019, changing many procedural aspects of seeking patent protection.

That said, nearly two decades on from the pioneering first edition of this book, many of our key motivations for writing remain the same. Despite an extensive chapter dedicated to biotechnology and medicines in CIPO's *Manual of Patent Office Practice (MOPOP)*, there are still many nuanced requirements and best practices in this subject matter area that are unrecorded. There also remains a dearth of formal jurisprudence from the courts specific to biotechnology patents. Further, the act of writing about one's own specialty has the incidental benefit of reinforcing one's own knowledge of the subject.

One new motivation for preparing this updated edition is a responsibility to our readership to provide current information. The eBook version of the previous edition has been downloaded thousands of times. We hope our extensive readership will continue to depend on this publication for updated in-depth information.

Now in its fourth edition, the book is directed toward a readership of patent agents/attorneys, lawyers, patent agent trainees, in-house patent counsel, technology transfer officers, and inventors specializing in the life sciences and chemistry sectors. We aim to outline the features of Canadian patent practice that are most relevant to our clients and associates in Canada and around the world. We are aware of no comparable text for the Canadian patent system. In this edition, we are also including information on various other legal specialties that relate to commercial products covered by biotechnology and chemistry patents.

We acknowledge that our readership is not limited to clients of BLG and may include other Canadian intellectual property professionals. We are privileged to have colleagues at our firm in a wide range of specialties to consult with for the benefit of our clients. If this information is helpful to other Canadian professionals who may not have colleagues in such specialties, then so much the better. Ultimately, we aspire to benefit Canadian businesses and those doing business in Canada in the life sciences and chemistry sectors, whether clients of BLG or not.

This book consists of five parts:

Part I provides an overview of the Canadian patent system, together with highlights of the procedural requirements for patent procurement and post-grant modification in Canada. Requirements specific to inventions in the life sciences and chemistry sectors are highlighted.

Part II deals with specific subject matter areas, including chemical compounds, antibodies, and life forms, to name just a few. A new section on medical devices is included. Within each section, example claim formats are provided.

Part III is devoted to regulatory issues, including the *Patented Medicines (Notice of Compliance) Regulations*, the Patented Medicine Prices Review Board, and Certificates of Supplementary Protection. A new section on advertising considerations for therapeutic products is included.

Part IV deals with disputes and includes a section on challenges to issued patents and a new section on product liability issues.

Part V is new and focuses on other forms of intellectual property protection, including trademarks, trade secrets, and plant breeders' rights.

As always, we welcome comments and suggestions from our readership with a view to improving future editions.

We hope you will find that this fourth edition possesses sufficient disclosure and more than a scintilla of utility.



Graeme Boocock **Kathleen Marsman** **Beverley Moore**

on behalf of Borden Ladner Gervais LLP

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PART 1

General Patent Practice in Canada

Chapter 1

Overview of The Canadian Patent System

1.1 Canadian Patent Law

1.1.1 Legislation, Treaties, and Guidance

Canadian patent law is established under Canadian legislation and case law. In particular, Canadian patent law is established under the *Patent Act*[1] and *Patent Rules,*[2] as well as other legislation, as discussed in subsequent chapters in this book. The Canadian Intellectual Property Office (CIPO) maintains a published *Manual of Patent Office Practice* (*MOPOP*) that establishes procedures and practices relating to the filing and prosecution of Canadian patent applications filed with CIPO.[3] *MOPOP* is a guide and should not be relied on as an authority.

Canada is a contracting state of the *Patent Cooperation Treaty* (*PCT*),[4] having regulations[5] administered under the World Intellectual Property Organization (WIPO). CIPO is a receiving office, as well as a search and examination authority, for international (*PCT*) patent applications. Canada is a party to numerous international agreements governing various aspects of patent protection for inventions, including the *Paris Convention for the Protection of Industrial Property* of 1883 (*Paris Convention*),[6] the *Canada-United States-Mexico Agreement* (*CUSMA,* previously *NAFTA*)[7], and the *Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.*[8]

1.1.2 Publication of Patent Applications

Canadian patent applications are published following an 18-month confidentiality period beginning on the earlier of the filing date of the Canadian application or the filing date of the first previously filed application from which an Applicant requests priority.[9] The international filing date of a *PCT* patent application is considered the Canadian filing date of a *PCT* patent application that enters the national phase in Canada.

1 *Patent Act,* RSC 1985 c P-4 [*Patent Act*].
2 *Patent Rules,* SOR/2019-251 [*Patent Rules*].
3 Canadian Intellectual Property Office, *Manual of Patent Office Practice*, [MOPOP]. (Ottawa: Innovation, Science and Economic Development Canada, 2019).
4 *Patent Cooperation Treaty*, 19 June 1970, 1160 UNTS 231 (entered into force 24 January 1978) [*PCT*].
5 *Regulations under the Patent Cooperation Treaty*, 19 June 1970, 1160 UNTS 231 (entered into force 1 July 2020), [*PCT Regulations*].
6 *Paris Convention for the Protection of Industrial Property,* 20 March 1883, 828 UNTS 305 (entered into force 7 July 1884), [*Paris Convention*].
7 *Canada-United States-Mexico Agreement,* 30 November 2018, Can TS 2020 No 5 (entered into force 1 July 2020) [*CUSMA*].
8 *Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure,* 28 April 1977, UNTS 1861 (entered in force 19 August 1980) [*Budapest Treaty*].
9 *Patent Act,* s 10.

1.1.3 Patent Term

The term for patents issuing from Canadian applications is 20 years from the filing date.[10] Patent term adjustment is not available in Canada for examination delays attributable to CIPO. However, a Certificate of Supplementary Protection (CSP) is a form of patent term restoration available only for inventions pertaining to medicinal ingredients requiring regulatory approval,[11] providing up to two years of patent-like protection beyond the date of patent term expiry under certain circumstances.[12]

1.1.4 Maintenance Fees

Maintenance fees are payable on an annual basis for all Canadian applications and issued Canadian patents, beginning on the second anniversary of the filing date.[13] Failure to pay a maintenance fee may result in a loss of rights if the missed fee is not paid within the available late period, together with the accompanying late fee. Reinstatement from abandonment beyond the late period is available if it can be shown that the fee remained unpaid at the end of the late period, despite due care.[14] Third-party rights to use the invention begin six months after a missed maintenance fee, permitting an exemption to infringement for activities that would otherwise constitute infringement had the maintenance fee been paid.[15]

1.2 Priority and Claim Date

1.2.1 Request for Priority

In accordance with Canada's membership in the *Paris Convention*, the *Patent Act* permits a patent application to request priority to one or more previously filed applications filed in Canada or elsewhere having a filing date within one year of the Canadian filing date.[16] If a Canadian application requests priority from a previously filed application, commonly referred to as a "priority application", the filing date of the previously filed application is commonly referred to as a "priority date", consistent with definitions of the *PCT*.[17] An application that requests priority from multiple previously filed applications may thus be said to have multiple priority dates.

10 *Patent Act*, s 44.
11 *Patent Act*, s 104. For further discussion, see Chapter 15, Certificates of Supplementary Protection (CSPs).
12 *Patent Act*, s 116(2).
13 *Patent Act*, s 27.1(1); *Patent Rules*, ss, 68, 112, Sched II.
14 *Patent Act*, ss 27.1(3), 73(1)(c); but see s 73(3). For further discussion of late or missed maintenance fees, see Chapter 2, Procedural Requirements section 2.10.1.
15 *Patent Act*, s 55.11(1).
16 *Patent Act*, s 28.4(1).
17 *PCT*, Article 2(xi), and noting that the definition of "priority date" was removed from the *Patent Act* repealed [1993, c 15, s 26] but remains in common use, consistent with the *PCT* definition.

1.2.2 Claim Date

Each claim in a Canadian application or patent has a claim date. By default, the claim date is the filing date of the Canadian application.[18] However, if priority is requested, the *Patent Act* allows each claim of a Canadian application the possibility of having as the claim date the filing date of the priority application, provided the priority application adequately describes the subject matter of the claim in question.[19]

The claims of a Canadian application may have different claim dates from each other. If priority is claimed to multiple priority applications, the claim date is determined as the earliest date among the multiple priority dates or the filing date of the Canadian application on which the claimed subject matter was adequately disclosed.[20] The claim dates of different claims may be of significance when assessing novelty and inventiveness if pertinent prior art was published after the earliest priority date but prior to the Canadian filing date.

1.2.3 Restoration of Priority

Under certain circumstances and upon request, a claim to priority can be restored to an earlier application filed up to two months prior to the one-year period preceding the Canadian filing date, provided the error of filing after the expiry of the priority period can be established as unintentional despite due care.[21]

1.3 Patentability Requirements

1.3.1 Definition of Invention

In Canada, "invention" means "any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter."[22]

In assessing whether subject matter falls within the meaning of invention under this definition, the criteria established by the Canadian courts and the *Patent Act* are as follows:[23]

a. whether the subject matter relates to a useful art as distinct from a fine art where the result produced is solely the exercise of personal skill, mental reasoning or judgment, or has only intellectual meaning or aesthetic appeal;

18 *Patent Act*, s 28.1(1).
19 *Patent Act*, s 28.1(2).
20 *Patent Act*, ss 28.1(1)(a), 28.4(4)(a).
21 *Patent Act*, s 28.4(6); *PCT Regulations*, Rule 26*bis*.3; and *Patent Rules*, s 77.
22 *Patent Act*, s 2.
23 *Tennessee Eastman Co et al v Commissioner of Patents* (1970) 62 CPR 117 (Ex Ct), aff'd [1974] SCR 111 [*Tennessee Eastman*]; *Re NV Organon Application No 003,389* (1973), 15 CPR (2d) 253 (PAB); *Patent Act*, s 27(8).

b. whether the subject matter is operable, controllable, and reproducible by the means described by the inventor so that the desired result will inevitably follow whenever the subject matter is put into practice;
c. whether the subject matter has practical application in industry, trade, or commerce; and
d. whether the subject matter is more than a mere scientific principle or abstract theorem.

The terms "art", "process", "machine", "manufacture", and "composition of matter" are not defined in the *Patent Act* or *Patent Rules*. However, court decisions provide some clarification on patentable subject matter. For example, methods of medical treatment are, in a strict sense, outside of the definition of invention and are not patentable in Canada.[24] However, a medical device and its method of operation may be patentable. Higher life forms, including plants and animals, are not patentable subject matter.[25] However, claims to a plant cell may be enforceable against an infringer possessing an entire plant.[26] Further discussions as to the patentability of subject matter within the biotechnology and chemical arts, as well as acceptable claim formats, are provided in later chapters.

1.3.2 Novelty Requirements

The *Patent Act* requires a claim to be novel. The claimed subject matter must not have been disclosed such that it was made available to the public prior to the claim date.[27]

A one-year grace period preceding the filing date of an application is allowed for subject matter disclosed to the public by the Applicant or someone obtaining knowledge directly or indirectly from the Applicant.[28] Importantly, the one-year grace period extends back from the Canadian filing date,[29] not from the earliest priority date of an application, nor from the claim date *per se* when the claim date is deemed earlier than the filing date.[30] Therefore, when a public disclosure is made by a soon-to-be Applicant, a patent application must be filed with CIPO directly or via an international application (*PCT*) within one year of the disclosure in order for a claim to the disclosed subject matter to be novel in view of the public disclosure. If the Canadian application is filed

24 *Tennessee Eastman.* For further discussion, see Chapter 8, Methods of Medical Treatments and Medical Uses.
25 *Harvard College v. Canada (Commissioner of Patents),* 2002 SCC 76. For further discussion, see Chapter 12, Living Matter (Life Forms).
26 *Monsanto Canada Inc. v. Schmeiser,* 2004 SCC 34.
27 *Patent Act,* ss 28.2(1)(a)-(b).
28 *Patent Act,* s 28.2(1)(a).
29 *Patent Act,* s 28.2(1)(a).
30 *Patent Act,* s 28.2(1)(a).

after the one-year grace period has expired, the Applicant's public disclosure is applicable as prior art against the Canadian application.

For international patent applications filed under the *PCT*, the international filing date is deemed to be the Canadian filing date.[31] The one-year grace period extends back from the international filing date and not the date of national phase entry into Canada.

While the requirement for novelty is imposed by the *Patent Act*, the test for whether a given public disclosure or a Canadian application with an earlier claim date is anticipatory of subject matter is defined by case law. A prior art publication or other public disclosure of subject matter in a way described in section 28.2 of the *Patent Act* precludes claiming the subject matter for lack of novelty only if it discloses and enables the subject matter.[32]

1.3.3 Inventiveness/Non-Obviousness

The Canadian patent system has inventiveness requirements for subject matter to be claimed in a patent. Section 28.3 of the *Patent Act* requires that the subject matter would not have been obvious on the claim date to a person skilled in the art to which it pertains. As with the provisions of the *Patent Act* requiring novelty, a one-year grace period extending back from the filing date applies to disclosures by the Applicant or someone obtaining knowledge directly or indirectly from the Applicant.[33]

While requirements for inventiveness are imposed by the *Patent Act*, the test for whether subject matter is obvious in view of a given public disclosure or combination of disclosures is defined by case law. The test for obviousness has four steps. First, the applicable person skilled in the art and the relevant common general knowledge of such person on the claim date are identified. Second, the inventive concept of the claim in question is identified. Third, the differences between the state of the art and the inventive concept are identified. Fourth, the question of whether the differences would have been obvious to the person skilled in the art on the claim date is answered.[34] In technical fields where advances are won by experimentation, the question of whether the subject matter of a claim is "obvious to try" may be considered at the fourth step of the obviousness analysis.

31 *Patent Rules*, s 161.
32 *Sanofi-Synthelabo Canada Inc. v. Apotex Inc.*, 2008 SCC 61 [*Sanofi*].
33 *Patent Act*, s 28.3.
34 *Sanofi*.

1.3.4 Utility Requirements

An invention within the meaning of section 2 of the *Patent Act* must possess utility. Utility can be either demonstrated or soundly predicted as of the Canadian filing date.[35] If relying on a sound prediction of utility, the patent must disclose both the factual basis underlying the prediction and the sound line of reasoning to the prediction.[36]

Utility is generally assessed on a claim-by-claim basis. A Canadian patent cannot be granted for something that is inoperable for the purpose for which it was designed. An Applicant must bear in mind the utility requirement when considering the scope of the claims to be pursued so as to avoid claiming any subject matter that encompasses inoperable embodiments. There is, however, no obligation on the patentee to claim the utility of the invention.[37]

1.3.5 Sufficiency of Disclosure

Section 27(3) of the *Patent Act* provides that the specification of an invention must correctly and fully describe the invention and its operation or use in such full, clear, concise, and exact terms as to enable any person skilled in the art or science to which it pertains to make, construct, or use it. There is no requirement, however, to identify the best mode of working the invention.

The skilled person must be able to understand how the subject matter of the patent is to be made or performed by reading the specification. The specification must set out the invention in sufficient detail to allow the skilled person to put it into practice. Where insufficient information is provided in the specification, the claims may be found unpatentable or invalid.[38]

1.3.6 Clarity

Section 27(4) of the *Patent Act* requires that the specification end with a claim or claims "defining distinctly and in explicit terms the subject-matter of the invention for which an exclusive privilege or property is claimed." In order to be considered patentable, the *Patent Rules* specify that a claim must be in a form that is "clear and concise"[39] so as to avoid objections based on indefiniteness. In Noranda Mines v. Minerals Separation Corp.,[40] the Exchequer Court held that, to be valid, claims must be free from avoidable ambiguity or obscurity.

35 *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77 [*Apotex v. Wellcome*].
36 *Apotex v. Wellcome.*
37 *Eli Lilly & Co v. Apotex Inc.*, 2009 FC 991, aff'd 2010 FCA 240.
38 *Noranda Mines v. Minerals Separation Corp.*, [1950] SCR 36.
39 *Patent Rules*, s 60.
40 *Noranda Mines v. Minerals Separation Corp.* (1947), Ex CR 306, at 102.

1.3.7 Scope of Invention

The *Patent Rules* require that claims be in a form that is "fully supported by the description independently of any document referred to in the description"[41] such that the scope of the claims does not exceed that of the invention described.

1.4 Unity of Invention Requirement

A patent is granted for one invention only, although a patent will not be found invalid solely on the basis that it has been granted for more than one invention.[42] The *Patent Rules* clarify that an application does not claim "more than one invention" if the subject matter defined by the claims is found to include "a group of inventions linked in such a manner that they form a single general inventive concept."[43]

When a lack of unity is raised by an Examiner and multiple claim groups are identified as defining separate inventions, an Applicant may elect a claim group to proceed further in examination, while unelected claim groups may proceed in a divisional application without susceptibility to double patenting challenges.[44]

1.5 Examination

Requesting examination of a Canadian patent application can be deferred until four years from the filing date[45] (or five years from a filing date before October 30, 2019[46]). An Examiner Requisition, commonly referred to as an "Office Action", has a four-month response deadline, extendable by two months if specific circumstances are deemed to warrant the extension.[47] If a response deadline is missed, the application becomes abandoned, with reinstatement available as a matter of right within one year. Final Actions are rare, and Examiners will provide written warning in advance. If a reply to a Final Action is rejected, the Applicant can appeal to the Patent Appeal Board (PAB), the decision of which may be appealed to the Federal Court.

1.6 Admissible File History

Under certain circumstances, response comments made during prosecution may be admitted into evidence. Section 53.1(1) of the *Patent Act* provides that in an action or proceeding pertaining to an issued patent, written

41 *Patent Rules*, s 60.
42 *Patent Act*, s 36(1). For further discussion of invention requirements in the context of divisional applications, see Chapter 2, Procedural Requirements, section 2.4.
43 *Patent Rules*, s 88.
44 *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.*, [1981] 1 SCR 504.
45 *Patent Rules*, s 81(1)(a).
46 *Patent Rules*, s 3(1).
47 *Patent Rules*, s 86(2) and s. 131(2).

communications made during prosecution may be admitted into evidence to rebut the patentee's representation regarding construction of a claim during the action or proceeding.[48]

1.7 Untrue Material Allegations, Omissions, and Additions

Section 53(1) of the *Patent Act* provides that an issued Canadian patent may be void if a material allegation in the petition is untrue. A Canadian patent may also be void if the specification or drawings contain more or less than is necessary for obtaining the patent, and the omission or addition is found to be willfully made for the purpose of misleading.[49]

While intention to mislead is difficult to prove, Applicants for Canadian patents are strongly encouraged to make efforts to ensure that the correct inventors are named in the petition to reduce the possibility that a challenge under section 53(1) of the *Patent Act* will be brought against an issued patent. Similarly, the disclosure should be reviewed prior to filing to ensure that nothing relevant to the scope of the claims is omitted and that no unnecessary addition is present that could be viewed as willfully misleading.

48 *Patent Act*, s 53.1(1). For further discussion of court proceedings, see Chapter 17, Infringement and Validity Determinations in Court.
49 *Patent Act*, s 53(1).

Chapter 2

Procedural Requirements

Significant changes to Canada's patent legislation came into force (CIF) on October 30, 2019 (the CIF date). The changes implement Canada's ratification of the *Patent Law Treaty* and bring the Canadian regulatory regime into closer conformity with international norms with respect to patent procedure. This chapter deals primarily with applications filed after the CIF date.

2.1 Filing Requirements – General

For applications filed on or after the CIF date, the following items are required to secure a filing date:

a. an indication that a Canadian patent is being sought;
b. the name of the Applicant;
c. contact information for the Applicant or its Patent Agent; and
d. a document, in any language, that on its face appears to be a description.[1]

Where an application fee is not submitted at filing, the Canadian Intellectual Property Office (CIPO) will issue a notice calling for the fee.[2] The application fee along with a late fee are due within three months of this notice.[3]

Where the description is not provided in English or French, CIPO will issue a notice calling for a translation. The English or French translation is due within two months of this notice.[4]

As an alternative to submitting the description (d), reference may be made to a previously filed application, such as a priority application.[5] A reference statement cannot be made to secure a filing date for a divisional application.[6]

The regulations require submission or making available a certified copy of any claimed priority application.[7] This must be done by the later of 16 months of the priority date and four months of the filing date.[8] The requirement can be satisfied by specifying that the application is available in an approved digital library (including the World Intellectual Property Organization (WIPO) Digital Access Service).[9] While the priority document may be in a foreign language

1 *Patent Rules*, SOR/2019-251, s 71 [*Patent Rules*].
2 *Patent Act*, RSC 1985, c P-4, s 27(7) [*Patent Act*].
3 *Patent Rules*, s 66.
4 *Patent Rules*, ss 15(3)-(4).
5 *Patent Act*, s 27.01.
6 *Patent Act*, s 27.01.
7 *Patent Rules*, s 74(1).
8 *Patent Rules*, s 74(2).
9 *Patent Rules*, s 74(1)(b); World Intellectual Property Office, "WIPO Digital Access Service – Participating Offices" (29 September 2019); Canadian Intellectual Property Office, *Manual of Patent Office Practice* (Ottawa: Innovation, Science and Economic Development Canada, 2019) s 2.02.07a, (*MOPOP*).

(*i.e.*, other than English or French), the Patent Examiner may requisition a translation during examination.[10] If the certified copy, or access thereto, is not provided within this time frame, CIPO will issue a notice requisitioning the same within two months of the notice,[11] and a two-month extension may be available.[12]

While not required at filing, the following items are required to make an application compliant:

e. a petition;[13]
f. the name and postal address of each inventor;[14]
g. a statement of entitlement or inventorship;[15]
h. a claim or claims;[16]
i. an abstract;[17]
j. if applicable, drawings;[18] and
k. if applicable, a sequence listing that complies with the *Patent Cooperation Treaty* (*PCT*) sequence listing standard.[19]

If a required item is not submitted, CIPO will send a notice requiring the missing item within three months. Where the missing item is not submitted within this three-month period, the application will be deemed abandoned.

2.1.1 Filing Requirements – *PCT*

PCT applications entering the national phase in Canada are governed by some additional rules. On entering the national phase, an Applicant for a *PCT* application must provide CIPO with:

a. a copy of the international application, if it has not been published by the WIPO;
b. payment of the prescribed national entry fee;
c. if applicable, a translation of the application into either English or French; and
d. if applicable, any outstanding maintenance fees.

10 *Patent Rules*, s 76(1).
11 *Patent Rules*, s 74(4).
12 *Patent Rules*, s 74(6).
13 *Patent Act*, s 27(2); *Patent Rules*, ss 49, 53.
14 *Patent Rules*, s 54(1).
15 *Patent Rules*, s 54(2).
16 *Patent Act*, s 27(4); *Patent Rules*, s 49.
17 *Patent Rules*, s 55.
18 *Patent Act*, ss 27(5.1)-(5.2); *Patent Rules*, s 59.
19 *Patent Rules*, s 58.

The deadline to provide a certified copy of any priority applications, or digital access thereto, is the *PCT* national phase entry date; this requirement is usually met by the proper submission of the priority document in the international phase of the *PCT*. (The certified copy requirement does not apply to Canadian applications based on *PCT* applications having an international filing date before the CIF date.)

The deadline to enter the national phase in Canada and satisfy these requirements for a *PCT* application is 30 months after the earliest priority date. Previous regulations permitted late national phase entry up to 42 months from the earliest priority date on payment of a relatively modest late fee. Under transitional provisions, this will continue to be an option for *PCT* applications with an international filing date before the CIF date. For *PCT* applications with a filing date on or after the CIF date, however, late entry will additionally require a request for reinstatement of the Applicant's rights along with a statement that the failure to enter national phase by the 30-month deadline was "unintentional".

CIPO will not review the circumstances to determine if the failure was unintentional, leaving such a review to any litigation of the resulting patent in the Federal Court.

2.1.2 Filing Requirements – Priority Restoration

Priority restoration was not available under the previous regulations. It has become available under the new regulations for priority applications dated up to 14 months before the filing date. The priority restoration, however, must be made on or after the CIF date. Direct national applications will require a request within two months of the filing date. For *PCT* national phase applications, CIPO will recognize a request for restoration of priority that has been accepted by the *PCT* receiving office. Alternatively, a request can be submitted to CIPO within one month of national phase entry, provided that a claim to priority was made during the international phase before the later of 16 months from earliest priority and four months from the international filing date.

As in the case with late *PCT* national phase entry, a request for priority restoration submitted to CIPO will require a statement that the failure to file the application within 12 months of the priority application was "unintentional", and CIPO will not review the circumstances to determine if the failure was unintentional.

2.2 Added Subject Matter and Claiming Internal Priority

New subject matter cannot be added to the application at any time after the application is filed. New subject matter includes anything that is not reasonably inferable from the original specification or drawings. New features in the

invention, further data, or a more precise description of the invention are all considered to be new subject matter.

Any new subject matter may be included in a *new* Canadian application, which may claim priority from the earlier-filed Canadian application if it is filed within one year of the earlier-filed Canadian application. These provisions allow an Applicant to claim "internal" priority. This practice gives an Applicant the opportunity to file a patent application as early as possible after an invention has been made in order to obtain the earliest possible filing date for the disclosed subject matter. Further improvements, alterations, or additional data are included in the later-filed patent application, which then requests priority over the previously filed application. This practice allows the Applicant to retain an early claim date for the subject matter disclosed in the first application while receiving a later claim date for the new subject matter. The Applicant has the option of proceeding with both applications or abandoning the first application and proceeding with only the second application. There is no limit to the number of priority claims that may be made. This practice of claiming internal priority is similar to the U.S. continuation-in-part practice with the exception that, in Canada, there is a time limit of 12 months from the first-filed application. Once the 12-month period from the first-filed application has expired, internal priority may no longer be claimed. For the later-filed application, the patent term is calculated as 20 years from the filing date of the later-filed application.

2.3 Common Representatives

Where a patent application identifies a plurality of co-Applicants, the regulations require the identification of a "common representative" with which CIPO will correspond in the absence of an appointed Patent Agent. Among other things, the regulations empower the common representative to appoint or revoke Patent Agents, record transfers, and generally act on behalf of all of the Applicants or Patentees.

The common representative may be appointed at the national phase entry of a *PCT* application or at the filing of a direct national application. Appointing the common representative at this time will not require the signatures of the co-Applicants. After the filing date or national phase entry date, the appointment of a common representative will require all of the other Applicants or Patentees to sign an appointment notice.

In the absence of an expressly designated common representative, the regulations define a scheme for determining which Applicant or Patentee is the common representative. The common representative is the first-named

Applicant based on either the listed order or the alphabetical order, depending on whether or not certain requirements have been met.

In the case of co-Applicants, it is advisable whenever possible to identify at filing or national phase entry which co-Applicant should be the common representative, so that the appointment may be included in the application petition or national phase entry request form in order to avoid the later need for all of the co-Applicants' signatures.

2.4 Divisional Applications and Unity of Invention

In Canada, a divisional application may be filed at any time before the parent application issues to patent. The parent application can itself be a divisional application. That is, in the case of an application that is divided more than once, the first divisional application may be a parent to a subsequent divisional application. Thus, the issuance of the original, or "parent", application does not prevent further divisional applications from being filed, provided that there is at least one divisional application still pending in CIPO that describes all of the inventions. An application may be divided voluntarily by the Applicant or at the insistence of CIPO.

If CIPO raises a unity-of-invention objection and requires division, Canadian case law supports the proposition that because the division was required by the Patent Examiner, it does not constitute double patenting.[20] That is, any attack on such patents for double patenting will fail because the division was made at the request of the Patent Office. However, when an Applicant initiates the filing of a divisional application without previously receiving a unity objection, a double patenting attack is available, and has previously been successful in the courts.[21] Accordingly, it is unadvisable for an Applicant to initiate the filing of a divisional application for subject matter that has not been clearly delineated as a separate invention in a unity objection. Such an application is often referred to as an Applicant-initiated divisional, or a voluntary divisional, application.

Unity-of-invention requirements in Canada are quite broad and merely require a single general inventive concept. Various types of claims may be included in the same application without offending unity-of-invention requirements. CIPO considers the following combinations of claim categories to be acceptable within the same application:

a. a product and a process for making that product;
b. a product and a use of (or method of using) that product;

20 *Consolboard Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.*, [1981] 1 SCR 504.
21 *Glaxosmithkline Inc. v. Apotex Inc.*, 2003 FCT 687.

c. a product, a process for making that product, and a use of that product;
d. an apparatus and a process carried out on that apparatus.[22]

2.5 Requests for Examination

For applications with a filing date on or after the CIF date, a request for examination and associated fee must be submitted within four years of the filing date. For applications with a filing date before the CIF date, a request for examination and associated fee must be submitted within five years of the filing date. As a reminder, the filing date of a Canadian national phase application is considered to be the filing date of the international application.

For divisional applications, examination must be requested by the same deadline as for the parent application or, if that deadline has passed, within three months after the date on which the divisional application is actually filed.

2.6 Accelerating Examination

There are currently three options for accelerating examination in Canada.

2.6.1 Special Order

An Applicant may request expedited examination by stating that failure to advance the application is likely to prejudice the Applicant's rights, and by paying the prescribed fee. Unless publication has already occurred, the Applicant must also request early publication.

2.6.2 Patent Prosecution Highway

The Patent Prosecution Highway (PPH) program provides an alternative option for accelerating examination in Canada based on claims allowed or issued by another patent office. Currently, CIPO has established a PPH program with 30 patent offices and the Canadian Receiving Office of the *PCT*. Allowance can often be obtained within 12 months of making the request. While the basic premise of the bilateral and global agreements is the same, the specific requirements differ. One common requirement is that the PPH request must be filed before an Office Action has been issued by the Patent Office. Currently, there are no government fees.

22 *MOPOP*, s 28.08.01.

2.6.3 Green Technology

Expedited examination is also available if the application relates to "technology the commercialization of which would help to resolve or mitigate environmental impacts or to conserve the natural environment and resources." No government fee is required.

2.7 Office Action Deadlines

The response period for an Office Action is four months for both regular and accelerated examination. A two-month extension of time is available if the Commissioner of Patents considers that the circumstances justify the extension.

The extension request and extension fee must be submitted within the original response period. Requesting and receiving an extension of time in an advanced application will permanently return it to regular examination.

2.8 Final Action and Appeal

Where the Examiner and the Applicant reach an impasse, the Examiner may issue a Final Action. The Applicant may respond to the Final Action after which the Examiner may allow the application or issue a Statement of Reasons rejecting the application. The Applicant then has a right of appeal to the Patent Appeal Board (PAB).

2.9 Maintenance Fees

For all applications filed after October 1, 1989, the Applicant must pay annual maintenance fees in order to maintain the application in good standing. The first maintenance fee is due for payment on the second anniversary of the filing date and is payable every year thereafter until the patent expires.

2.10 Missed Actions, Late Fee Periods, Abandonment and Reinstatement, and Third-Party Rights

Under the previous regulations, in most cases, the failure to act by a prescribed deadline resulted in deemed abandonment of the application subject to reinstatement as of right within 12 months requiring the payment of a relatively modest additional reinstatement fee.

The new regulations introduced different abandonment-reinstatement schemes depending on whether the missed deadline is set by the filing date or is based instead on some other event.

2.10.1 Deadlines Based on the Filing Date

Deadlines set by the filing date refer to examination requests and maintenance fees. In both cases, the failure to act by the original deadline will result in the issuance of a "default notice" requiring performance of the missed act and payment of a late fee. The deadline for returning the application to good standing without providing any justification of the missed act is the later of two months from the default notice and six months from the missed deadline. Failure to return the application to good standing in time will result in abandonment where reinstatement is possible if the abandonment occurred despite the exercise of "due care". CIPO has indicated that it will adopt a "due care" practice consistent with the *PCT* guidance for receiving offices.

Regardless of the abandonment deadline established by the default notice, third-party rights will be available during the period starting six months after the missed maintenance fee or examination deadline until the application is returned to good standing. These rights are available for any party who commits, in good faith, an otherwise infringing act during this time period. Any rights obtained by the party are transferrable to others.

2.10.2 Deadlines Based Otherwise Than on the Filing Date

Deadlines that are not set based on the filing date include Office Actions. In this case, failure to timely reply to an Office Action by the deadline (or the extended deadline, as the case may be) will result in abandonment, subject to reinstatement within 12 months as of right (*i.e.*, no statement of "due care" is required). Third-party rights will not be available during this reinstatement period.

2.11 Allowance and Issue Fee Payment

The time period to pay an issue fee is four months after a Notice of Allowance is issued, with no extensions of time available. Missing this deadline will result in abandonment, with reinstatement available as of right within 12 months.

2.12 Post-Allowance Options to Continue Prosecution

Once a Notice of Allowance issues, it is no longer permitted to make substantive amendments to the claims. Reopening prosecution may be desirable when the Applicant has additional claims they want to pursue in Canada, and the Examiner has not previously been given the opportunity to assess their unity with the allowed claims. As a reminder, divisional applications are protected against double-patenting attacks if they have been filed in response to a lack-of-unity rejection.

Prosecution can be reopened if a request and fee are submitted before the four-month deadline and before the final fee is paid.

2.13 Transfers, Name Changes, Registering Documents of Title, and Corrections

An Applicant may record a transfer of rights. Where the transferor makes the request, the only requirements are the name and address of the transferee and the recordation fee. Where the transferee makes the request, evidence of the transfer, such as an executed assignment, is required.

An Applicant may also register a document relating to title. Documents that do not change the ownership at CIPO (*e.g.*, assignments related to the transfer of rights that occurred prior to national phase entry) will not be recorded by CIPO but can be registered. CIPO will simply place the document on file and will not make a recordal.

An Applicant may submit a name change request without any evidence.

The identity of an Applicant may be corrected within certain time limits. For example, corrections must be made prior to any transfers from the Applicant, and prior to publication for a direct filing or within three months of the national phase entry for *PCT* national phase applications.

Chapter 3

Biotechnology-Specific Procedural Requirements

3.1 Sequence Listings

3.1.1 General Requirements

Sequence listings in electronic form are required for all patent applications that disclose a nucleotide sequence or amino acid sequence, other than a sequence identified as forming a part of the prior art.[1] Both the electronic form and the content of the sequence listing must comply with the *PCT* sequence listing standard, which is set forth in Annex C of the *PCT Administrative Instructions*.[2] The current *PCT* standard is also sometimes referred to as the "World Intellectual Property Organization (WIPO) Standard ST.25."

For the purposes of Canadian prosecution, "nucleotide sequence" and "amino acid sequence" are given the same meaning as in the *PCT* sequence listing standard. Briefly, "nucleotide sequence" refers to an unbranched nucleotide sequence of 10 or more nucleotides, while "amino acid sequence" refers to an unbranched amino acid sequence of four or more contiguous residues.[3]

A small number of important amendments to the *Patent Rules* relating to Canadian sequence listing requirements came into force on October 30, 2019. In particular, under current Canadian practice, a sequence listing is not needed to obtain a filing date, though sequence listings may still be requisitioned if absent from an application.[4] Additionally, sequence listings are no longer considered when calculating the page count for the purposes of determining the final fee.[5]

If an application originally filed without a sequence listing is amended to include a sequence listing, or if a non-compliant sequence listing is replaced with a compliant sequence listing, the Applicant must also file a statement to the effect that the new sequence listing does not go beyond the disclosure in the application as filed.[6]

The United States Patent and Trademark Office (USPTO) offers a computer program, PatentIn, for use in preparing sequence listings. The software for this program can be downloaded by the public at no charge from the USPTO website.[7]

1 *Patent Rules*, SOR/2019-251, s 58(1) [*Patent Rules*].
2 World Intellectual Property Organization, "Administrative Instructions under the Patent Cooperation Treaty: Annex C" (1 July 2020), [*Administrative Instructions under the PCT*]
3 *Patent Rules*, s 58(5); *Administrative Instructions under the PCT*, s 2(ii).
4 *Patent Rules*, s 65.
5 *Patent Rules*, Sched 2, Item 13(b).
6 *Patent Rules*, s 58(3).
7 *United States Patent and Trademark Office.*

3.1.2 Sequence Listings and National Phase Entries

In recent CIPO practice, sequence listings filed under *Patent Cooperation Treaty* (*PCT*) Rule 5.2(a) are automatically brought forward from the international phase if they are in the appropriate electronic format in accordance with the *PCT Administrative Instructions*. However, if the sequence listing was filed for search purposes only under *PCT* Rule 13*ter*, it will not be brought forward and must be submitted along with the statement that the sequence listing does not go beyond the disclosure in the application as filed.

3.1.3 Errors in Sequence Listings

No matter how carefully the sequence listing is prepared, errors occasionally show up. Whether or not the error can be corrected depends on the circumstance and nature of the error. Like other errors in a patent application, a basis to reasonably infer the correction from the specification is required.

If the erroneous sequence is present elsewhere in the specification in a correct form (for example, in the drawings or in the description), then this usually forms an acceptable basis to reasonably infer the correction from the specification. Such a basis will likely avoid a "new matter" objection or attack under s. 38.2 of the *Patent Act*.[8] If the sequence forms part of the prior art, a correction to conform a sequence with the prior art is permitted under s. 38.2 of the *Patent Act*.

It is unlikely that a priority application can be used as the basis for correcting the erroneous sequence. Amendments to the specification and drawings must be reasonably inferred from the specification or drawings contained in the application on its filing date (and not the priority date). The filing date of a *PCT* national phase application is the international filing date.

3.2 Biological Deposits

3.2.1 Biological Material

A proper deposit of biological material will be considered as part of the specification when assessing sufficiency of disclosure. In this context, "biological material" refers to material capable of direct or indirect self-replication, such as bacteria, bacteriophages, cells in culture, hybridomas, filamentous fungi, yeasts, plant seeds, viruses, purified nucleic acid molecules, plasmids, and replication-defective cells.[9]

8 *Patent Act*, RSC 1985, c P-4, s 38.2.
9 *Patent Act*, s 38.1; Canadian Intellectual Property Office, *Manual of Patent Office Practice*, [*MOPOP*]. (Ottawa: Innovation, Science and Economic Development Canada, 2019) ss 23.06, 23.10.

3.2.2 When and How to Deposit Biological Material

Depositing biological material involves providing a sample of the material to an International Depositary Authority (IDA) *on or before* the filing date of a patent application.[10] "Filing date" refers either to the Canadian filing date; or if a *PCT* application is filed designating Canada, the international filing date. If the patent application claims priority from an earlier filed application, it is usually advisable to make the deposit before the claimed priority date whenever possible.

Once provided, the IDA will give the deposit an accession number, which an Applicant must include in the specification of their patent application along with the name of the IDA. The same information must also be provided to the Canadian Patent Office prior to the publication of the patent application,[11] which is 18 months from the earliest priority or filing date. For applications entering Canada through the *PCT*, this information must be provided to the *PCT* Office before the publication of the *PCT* application. If the information is provided in a timely manner in the international phase, this will satisfy the Canadian requirements.

Canada has a fully accredited IDA: the International Depository Authority of Canada (IDAC), located in Winnipeg, Manitoba. The IDAC stores and maintains biological deposits for patent filings in accordance with the *Budapest Treaty*, which is administered by WIPO and obliges contracting states to recognize the fact and date of a biological material deposit for patent purposes.

The IDAC accepts deposits of animal viruses at pathogenic levels 1 to 3, bacteria, bacteriophages, all mammalian cell lines, cloned genes, hybridomas, protozoa, libraries and other rDNA, plasmids, and phage vectors; also, fungi and yeasts relating to human health can be deposited. Specific details for making a deposit can be found on the IDAC's website.[12] Once an Applicant deposits a biological material, they must undertake that the deposit will not be withdrawn from the IDAC for a period of at least 30 years from the date of deposition, and for at least five years from the date of the most recent request to obtain a sample of the biological material.[13]

3.2.3 Restricting Access to a Biological Deposit

Generally, a deposited biological material becomes available to the public once the corresponding patent application publishes. However, an Applicant can

10 *Patent Rules*, s 93(1)(a).
11 *Patent Rules*, s 93(1)(b).
12 Public Health Agency of Canada, "International Depository Authority of Canada (IDAC)" (18 April 2019).
13 Regulations under the *Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure,* 27 April 1977 (entered into force on 21 October, 2002), Rule 6 and 9.

restrict public access to a deposit until either (i) their application is granted and the patent issues; or (ii) until their application is refused, withdrawn or deemed to be abandoned and no longer subject to reinstatement.[14]

To restrict access, the Applicant must submit a request to the Canadian Patent Office that the Commissioner limit access to an independent expert nominated by the Office. The Applicant must submit the request before publication of their application.[15] For applications entering Canada through the *PCT*, the Applicant must submit notice with the *PCT* Office before their application is published to restrict access during the international phase.

In respect of nominating the independent expert, the Applicant may make suggestions to the Office as to who would be a suitable expert. However, in the event that the Office and the Applicant cannot agree on an expert, the Office will consider the request to restrict access to the deposited material as having never been submitted.[16]

If access to the biological deposit has been restricted during the prosecution of the patent application, a request to lift the restriction should be submitted to the IDA once the application is allowed.

3.2.4 Accessing a Biological Deposit

To access a sample of a deposited biological material, a request must be submitted to the Canadian Patent Office. As part of the request, the requester – be it any third party or an appointed independent expert – must undertake not to make the material available to any other person, or to use the material for any purpose other than experiments that relate to the subject matter of the corresponding patent application, either until the application issues as a patent, or the application is refused, withdrawn, or deemed to be abandoned and no longer subject to reinstatement.

Once the patent application is granted and issues as a patent, any third party may make a request to obtain a sample of the deposited biological material directly to the IDA holding the deposit, unless the IDA specifically requires that an Office-certified request form be submitted indicating that the corresponding patent has issued.

Request forms for obtaining a sample of a deposited biological material are available on the Canadian Patent Office website, as well as the WIPO website

14 *Patent Rules*, s 95(1).
15 *Patent Rules*, s 96(1).
16 *Patent Rules*, s 96(2).

(*i.e.*, see Appendix 3, *Budapest Treaty*).[17] Further, detailed procedures for obtaining samples of biological materials are provided on the website for the Canadian *Manual of Patent Office Practice* (*MOPOP*) (*i.e.*, see Manual Chapter 23.11, Appendix 2).[18]

3.2.5 Biological Deposits in Patent Practice

In Canadian practice, referring to a deposited biological material in a patent application does not automatically create a presumption that the deposit is required to show sufficiency of disclosure.[19] According to the Canadian Patent Office, the fact that a deposit has been made does not mean that the invention is sufficiently described. The Office's position is that the disclosure requirement for a claim to a desired product is not met simply by reference to where a product can be found, and where a product can be clearly and explicitly defined without reference to a deposited biological material, *only* referencing the deposit is not considered a suitable substitute for sufficiency of disclosure. As much as is possible, a patent application should include both a clear and explicit product description, as well as a reference to a deposited biological material.

This also extends to allegedly anticipatory disclosures. If a prior art disclosure requires access to a biological material in order to be considered as an enabling disclosure, that biological material needs to have been reliably available to a skilled person before the claim date of the patent application in order for the disclosure to be anticipatory.[20]

17 Guide to the Deposit of Microorganisms under the *Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure*, 25 September 1980, Appendix 3.
18 *MOPOP*, Appendix 2 Steps for Obtaining Samples of Biological Materials.
19 *Patent Act*, s 38.1(2).
20 *MOPOP*, s 23.06.02.

Chapter 4

Challenges at The Canadian Intellectual Property Office and Post-Grant Modifications

4.1 Introduction

There may be circumstances in which changes to a granted patent are required. While there are provisions in the *Patent Act* that permit this, each applies to only a particular set of circumstances. Some provisions are only available to the Patentee, while others may be used by third parties wishing to challenge applications or patents.

For example, a Patentee may need to correct clerical errors or may need disclaim subject matter that was included by error. A Patentee may wish to seek reissuance of a granted patent, which permits amendments to the patent to properly disclose and claim the invention. The Patentee may also apply to the Federal Court to vary entries in the records of the Canadian Intellectual Property Office (CIPO).

The *Patent Act* also contains provisions that permit a third party to challenge a patent or an application through CIPO itself. For example, at the application stage, a third party can file relevant prior art with CIPO that it considers to bear on the patentability of an application.

Any member of the public (including the Patentee) can request re-examination of a granted patent by filing pertinent prior art and paying a fee. Re-examination may therefore be used in a "corrective" manner by the Applicant, when new prior art comes to light, or may be used by a third part to challenge a patent.

4.2 Corrections to Issued Patents

Clerical errors referred to errors that arose in the mechanical process of writing or transcribing.[1] Previously, section 8 of the *Patent Act* stated that clerical errors in any instrument of record in CIPO do not invalidate the instrument and may be corrected with the permission of the Commissioner of Patents.[2] Section 8 has now been repealed and a new scheme for correcting errors has been introduced.

This new scheme is set out in sections 104-111 of the *Patent Rules*. Some of these provisions are restricted to correcting errors in the names of Applicants or inventors in an application for a patent.[3] However, corrections may be made after a patent has been issued, within certain time frames pursuant to other provisions. The primary focus of these latter rules is on correcting "obvious errors".[4]

1 See for example, *Scannex Technologies, LLC v. Canada (Attorney General)*, 2009 FC 1068 at para 26.
2 *Patent Act*, RSC 1985, c P-4, s 8 [*Patent Act*].
3 *Patent Rules*, SOR/2019-251, ss 104-106 [*Patent Rules*].
4 *Patent Rules* SOR/2019-251.

For instance, section 107 allows the Commissioner on his or her own initiative, or by request of the Patentee, to correct an error made by the Commissioner in the patent, specifications or drawings if it is obvious that something other than what is contained therein was intended and nothing other than the correction could have been intended, based on the documents that were in the possession of CIPO on the day the patent issued.[5] It is a requirement that either the Commissioner exercise this initiative or that the request be made by the Patentee within 12 months after the day on which the patent is issued.[6]

A similar provision allows the Commissioner to correct errors made by the re-examination board (see section 4.7 below) in a certificate, although in that case the timeline is six months from the day on which the certificate was issued.[7]

There are additional requirements to be met when the error is not made by either the Commissioner or the re-examination board. Section 109 of the *Patent Rules* sets out that the Commissioner must, on the request of the Patentee, correct an error in the name of the Patentee or an inventor included in the patent, if the correction does not change their identity.[8] Likewise, the Commissioner must also correct an error in the specification or the drawings referenced in the patent if it would have been obvious to a person skilled in the art from the specification or drawings that something other than the error was intended and that nothing other than the correction could have been intended.[9]

However, there are a number of conditions that must be met by a request under section 109. First, the request must be made not later than 12 months after the day on which the patent is issued.[10] Second, the request must contain:

a. an indication that a correction of an error is being requested;
b. the number of the patent concerned;
c. the correction to be made; and
d. new pages to replace the pages altered by the correction, if the error is in the specification or the drawings and the error was not made by the Commissioner.[11]

Third, unlike sections 107 and 108, section 109 also requires that the Patentee pay a fee for each patent referred to in the request for correction.[12] The Commissioner can waive the fee associated with a request for correction where

5 *Patent Rules*, s 107.
6 *Patent Rules*, s 107.
7 *Patent Rules*, s 108.
8 *Patent Rules*, s 109(1)(a).
9 *Patent Rules*, s 109(1)(b).
10 *Patent Rules*, s 109(1).
11 *Patent Rules*, s 109(2).
12 *Patent Rules*, s 109(1), Schedule 2, Item 24.

the error was made by the Commissioner.[13] If the request does not include the required content or the fee, the Commissioner must send a notice to the Patentee and must correct the error if the Applicant complies with the notice not later than three months after its date and if the error falls within section 109(1).[14]

The Commissioner is not authorized under section 3(1) of the *Patent Rules* to extend the times for correcting an error in an issued patent.[15] If a correction is made under sections 107-109, the Commissioner must issue a certificate setting out the correction,[16] and the correction is considered to have been made on the day on which the patent was issued (if made under sections 107 or 109)[17] or the day on which the certificate was issued (if made under section 108).[18] The Commissioner can also correct an obvious error made in a certificate issued under section 111(1).[19]

4.3 Disclaimers

A disclaimer under section 48 of the *Patent Act* allows a Patentee to renounce one or more claims or portions thereof where, by accident, inadvertence or mistake, the Patentee claimed more than it was entitled to.[20] New matter may not be added to a claim to limit it in the context of a disclaimer. Further, a disclaimer may not be used to broaden the claim(s).

The Patentee is entitled to disclaim anything included by accident, inadvertence or mistake at any time during the term of the patent. The Court has held that a mistake as to law is sufficient for the purposes of section 48.[21] The Patentee can disclaim all or part of a claim.

The Commissioner of Patents does not have any discretion to refuse to accept a disclaimer.[22] However, if the disclaimer is challenged, the Patentee must prove the mistake, accident or inadvertence on a balance of probabilities.[23]

A disclaimer is only permitted to narrow the scope of the claim. The Federal Court of Appeal (FCA) has held that if a disclaimer broadens the scope of the claim, it is invalid.[24] Thus, a disclaimer cannot introduce new inventive elements,

13 *Patent Rules*, s 140(1).
14 *Patent Rules*, ss 109(3)-(4).
15 *Patent Rules*, s 110.
16 *Patent Rules*, s 111(1).
17 *Patent Rules*, ss 107(2), 109(5).
18 *Patent Rules*, s 108(2).
19 *Patent Rules*, s 111(2).
20 *Patent Act*, s 48.
21 *Pfizer v. Apotex*, 2007 FC 971 at para 40, aff'd on other grounds (without comment on this point) 2009 FCA 8.
22 *Richards Packaging Inc. v. Canada (Attorney General)*, 2008 FCA 4 at paras 9, 12, aff'g 2007 FC 11.
23 *Hershkovitz v. Tyco Safety Products Canada Ltd.*, 2010 FCA 190 at para 43 [*Hershkovitz*], aff'g 2009 FC 256.
24 *Hershkovitz* at paras 23-25.

but it is permitted to introduce new essential elements, because that can narrow the scope of the patent.[25]

The *Patent Act* sets out that no disclaimer affects any action pending at the time when it is made, unless there is unreasonable neglect or delay in making it.[26] However, the Federal Court has considered a disclaimer that was filed after the commencement of an action but noted this timing as one factor indicating that the disclaimer was improper.[27]

In the context of proceedings pursuant to the *Patented Medicines (Notice of Compliance) Regulations*, the FCA has held that the date for assessing the justification of a Notice of Allegation (NOA) is the date of the hearing of the prohibition proceeding.[28] Thus, a Patentee is permitted to file a disclaimer after receiving an NOA and to have the disclaimed patent considered in the prohibition proceeding.[29] However, the generic company is also permitted to challenge the disclaimer in the proceeding.[30]

Caution should be taken to ensure that disclaimers filed meet all the statutory requirements to avoid irreparable damage to the patent holder. The Courts have held that if a disclaimer is found to be invalid, the Patentee can still be bound by the admission that the original patent claimed more than it was entitled to, with the result that the claims will be invalid for overbreadth.[31] Accordingly, filing a disclaimer carries a risk of invalidating the patent in the event that the disclaimer is successfully challenged.

4.4 Reissue

Reissuance allows a Patentee to attempt to correct deficiencies in an issued patent, in order for it to properly disclose and claim the invention. Unlike a disclaimer, reissuance can potentially broaden the scope of the claims. However, the purpose is to ensure that the patent granted accurately reflects what the Applicant intended to claim, and not to add new subject matter.

A Patentee may apply for the reissue of a patent within four years of the issue date. The legislative basis for the reissue of a patent is found in section 47 of the *Patent Act*, which sets out the conditions necessary for reissue and the procedure for reissue itself,[32] as well as provides for the possibility that reissue

25 *Hershkovitz* at para 35.
26 *Patent Act*, s 48(4); see also *Canadian Celanese Ltd. v. B.V.D. Co. Ltd.* [1939] 2 DLR 289 at 294 (UK JCPC).
27 *Distrimedic Inc. v. Dispill Inc.*, 2013 FC 1043 at para 234.
28 *Abbott Laboratories v. Canada (Minister of Health)*, 2010 FCA 168 at paras 44, 52, citing *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)*, [1998] 2 SCR 193.
29 *Sanofi-Aventis v. Hospira Healthcare Corp.*, 2009 FC 1077 at paras 121-122 [*Sanofi-Aventis*].
30 *Sanofi-Aventis*, at para 131.
31 See for example, *Hershkovitz*, at paras 46-47.
32 *Patent Act*, s 47(1).

may occur where the patent is the subject of an ongoing lawsuit.[33] Reissuance can also be sought for an expired patent that is set out in a certificate of supplementary protection, in which case the reissued patent remains expired but the reissuance establishes the rights granted under the certificate.[34]

The prerequisites for the reissue of a patent require:

a. that the application for reissue be for the *same invention* as that of the original patent;
b. that the patent be deemed to be "defective or inoperative" on the basis of insufficient description and specification, or by the Patentee's claiming more or less than they had a right to claim as new; and
c. that this error arose from inadvertence, accident or mistake.[35]

The scope of the phrase "deemed defective or inoperative" is to be determined with respect to the intention of the inventor. Cases where an inventor failed to claim protection due to a lack of recognition of an invention did not qualify for reissue.[36]

A series of cases considered the scope of the phrase "deemed defective or inoperative" and concluded that a patent must be valid, even if deficient, to be corrected by reissue.[37] Reissue therefore cannot correct a fundamentally invalid patent. With respect to "inadvertence, accident, or mistake," whether or not a "mistake" has occurred is determined with reference to the intention of the inventor[38] and may have been made either by the inventors themselves or by patent counsel.[39] The intention of the inventors has been determined with respect to their experience in the patent process,[40] by objective evidence such as the text of the patents,[41] from action taken in an equivalent U.S. patent[42] and from examination of non-party patent agents,[43] notwithstanding potential difficulties arising from solicitor-client privilege.[44]

33 *Patent Act*, s 47(2).
34 *Patent Act*, s 47(1.1).
35 *Patent Act*, s 47(1); see also *Northern Electric Co. v. Photo Sound Corp.*, [1936] SCR 649 [*Northern Electric*].
36 *Northern Electric*, at 658-659.
37 *Farbwerke Hoechst AG vormals Meister Lucius & Bruning v. Canada (Commissioner of Patents)*, [1966] SCR 604 [*Farbwerke*]; *Burton Parsons Chemicals, Inc. v. Hewlett-Packard (Canada) Ltd.* (1974), [1976] 1 SCR 555 [*Burton Parsons*]; *Creations 2000 Inc. v. Canper Industrial Products Ltd.* (1988), 22 FTR 180 (TD) *[Creations 2000]*; aff'd [1990] FCJ No 1029 (CA).
38 *Farbwerke*, at 614, citing *Northern Electric* at 667. Section 50 is a citation to the *Patent Act*, RSC 1952, c 203 *[Patent Act 1952]*, which, as recited in *Farbwerke* at 608, is substantively similar to s 47(1).
39 *Mobil Oil Corp. v. Hercules Canada Inc.* (1994), 82 FTR 211 (TD) [*Mobil Oil TD*], rev'd in part (1995), 98 FTR 319 (CA) [*Mobil Oil CA*], leave to appeal to SCC refused, 25012 (16 May 1996).
40 *Northern Electric*, at 661, 665-66; *Curl-Master Mfg Co. Ltd. v. Atlas Brush Ltd.*, [1967] SCR 514 [*Curl-Master*].
41 *Mobil Oil TD* at 499; *Mobil Oil TD* was affirmed on this point; see *Mobil Oil CA* at 481-82, 489.
42 *Mobil Oil TD* at 499-500.
43 *Grand Tank (International) Inc. v. Brown*, 2004 FC 1355 [*Grand Tank*].
44 *Grand Tank* at para 11. It is implicit, both through mention of solicitor-client privilege and through acknowledgment that the patent agents "at one time or another, provided legal counsel to the Plaintiffs," that each of the patent agents was also a lawyer.

Case law suggests that the reissue of a patent must be done with consideration of possible prejudice to the public, who may have relied on the original patent.[45]

Reissue may be appropriate where the Patentee failed to address relevant prior art in the original patent, even in the case of subsequently discovered prior art.[46]

An application for reissue may occur where the original patent is the subject of an ongoing law suit, and section 47(2) of the *Patent Act* sets out that the reissuance has no effect on any pending litigation in so far as the claims of the original and reissued patents are identical.[47] The Courts have held that this means that there must be at least one claim at issue that is "identical" in the original and reissued patents.[48] The claims do not need to be literally "identical", the focus instead is on whether the scope of the reissue claim has been changed over that of the original claim.[49]

An application for reissuance must be in the prescribed form and set out the reasons why the patent should be deemed defective or inoperative; the manner in which the error arose from inadvertence, accident or mistake; and when and how the Patentee gained knowledge of the new facts giving rise to the application. The Patentee should provide its best evidence in the application, which should include objective proof of the Applicant's intentions.

An application to reissue a patent must be accompanied by the fee prescribed by the *Patent Rules*.[50] However, the Commissioner has the discretion to waive this fee, if the error necessitating the application was the result of an error made by the Commissioner and if the circumstances justify it.[51]

CIPO will then form a Reissue Board, which will determine if the application meets the requirements for reissuance. If so, the proposed reissued patent will then be examined for compliance with the *Patent Act* and *Patent Rules*. If the Reissue Board finds that the application does not comply with section 47, it will issue an office letter explaining the basis for this finding. The Patentee may then respond to this letter with arguments, further evidence or amendments, and can also withdraw the application.[52] Issues between the Patentee and Reissue Board that cannot be resolved may be forwarded to the Patent Appeal Board

45 *Creations 2000* at 406.
46 *Flexi-Coil Ltd. v. FP Bourgault Industries Air Seeder Division Ltd.* (1990), 36 FTR 149 (TD) *[Flexi-Coil TD]*, aff'd (1991), 35 CPR (3d) 154 (FCA).
47 *Patent Act*, s 47(2).
48 *Warner-Lambert Co. v. Wilkinson Sword Canada Inc.* (1988), 21 CPR (3d) 145 at 146-147; *Stamicarbon B.V. v. Urea Casale SA*, 2002 FCA 10 at paras 14-15 [*Stamicarbon*], rev'g in part [2001] 1 FC 172.
49 *Stamicarbon* at para 22.
50 *Patent Act*, s 47(1); *Patent Rules*, s 119, Schedule 2, item 28.
51 *Patent Rules*, s 140(2).
52 Canadian Intellectual Property Office, *Manual of Patent Office Practice*, (Ottawa: Innovation, Science and Economic Development Canada, 2019), at 31.01.07 [*MOPOP*].

(PAB) and the Commissioner. The decision of the Commissioner to grant or refuse reissuance can be appealed, but by virtue of section 47, this decision is discretionary even if all the conditions set out therein are met.[53]

A Patentee may also obtain multiple reissued patents each relating to distinct portions of the original invention by filing multiple applications.[54] The test for reissuance would need to be met by each application, and the resulting patents would need to respect the prohibition on double patenting.

4.5 Recordal Proceedings

Section 52 of the *Patent Act* provides that the Federal Court has jurisdiction, on the application of the Commissioner or any interested person, to order that any entry in the records of CIPO relating to the title of a patent be varied or expunged. "Title" has been broadly interpreted by the Courts to include matters relating to the root of title, and section 52 has been used to vary entries in the records of CIPO, such as assignments and grants.[55] Additionally, the Courts have held that section 52 can be used to add or remove inventors' names, as inventorship is a matter relating to the root of title.[56]

Under section 27 of the *Patent Act*, a patent for an invention can be applied for by the inventor or the inventor's legal representative.[57] The owner of a patent is, in the first instance, the Applicant and thereafter any assignee. If a patent or application is assigned, the Patentee or Applicant can request that the Commissioner record the transfer, as can the transferee.[58] A challenge to ownership or the validity of an assignment may be commenced by way of an application for declaratory relief and for variation or expungement of the record. The Court has also held that affidavit evidence from the relevant inventors and assignors is not necessarily required in a section 52 application, although it is commonly provided and is of assistance to the Court.[59]

The FCA has held that the Federal Court does have the jurisdiction to grant relief under section 52, even when the underlying dispute is dependent on the interpretation of a contract between the litigants.[60] The Federal Court had previously taken the position that such contractual issues were beyond its statutory

53 *Patent Act*, s 47(1); *Farbwerke* at 613.
54 *Patent Act*, s 47(3).
55 See for example, *Micromass UK Ltd. v. Canada (Commissioner of Patents)*, 2006 FC 117 at paras 13-15; and *Everlight Electronics Co., Ltd. v. Canada (Attorney General)*, 2017 FC 1108 at para 3.
56 See, for example, *Imperial Oil Resources Ltd. v. Canada (Attorney General)*, 2015 FC 1218; and *Qualcomm Inc. v. Canada (Commissioner of Patents)*, 2016 FC 1092.
57 *Patent Act*, s 27(1).
58 *Patent Act*, ss 49(2) – (3).
59 *Copperhead Industrial Inc. v. Canada (Attorney General)*, 2018 FC 311.
60 *Salt Canada Inc. v. Baker*, 2020 FCA 127 at paras 47-48 [*Salt*].

jurisdiction.[61] However, following the FCA's decision in *Salt Canada Inc. v. Baker*, it is clear that the Federal Court can interpret agreements and other instruments if necessary to carry out the task Parliament has given it through section 52.[62]

Section 52 applications may also be available to resolve the two most difficult ownership issues — disputes as to who is an inventor and disputes as to whether the invention was made in the course of employment or other contractual obligation that would oblige the inventor to assign the invention to his or her employer or counterpart.[63] In determining who is or is not an inventor, the Courts have considered the criteria set out in section 31(3) and 31(4) of the *Patent Act*.[64]

4.6 Filings of Prior Art at CIPO ("Protests")

Before the 1989 amendments to the *Patent Act*, prior art was filed against a third-party application as a "protest", and this terminology persists even though the scope of what may be submitted by third parties has changed.

Today, a third party may challenge the patentability of a party's patent application by filing with CIPO prior art that the third party believes has a bearing on the patentability of any claim in a pending patent application.[65] The prior art must be accompanied by an identification of the claim(s) against which the proponent believes the prior art is relevant and an explanation of its relevance to the pending claim. No fee is required.[66]

Under section 34.1 of the *Patent Act*, applicable prior art is limited to patents, published patent applications and printed publications. Printed publications may include not only journal articles but also newspaper articles or advertisements for a particular product.

Filings of prior art are often quite free form in practice. When based on a counterpart submission made in another country, some protests cite art outside the scope of that prescribed by section 34.1 and/or contain arguments or affidavits that extend beyond the mere explanation of relevance required by section 34.1. Even though CIPO tends not to reject such submissions, no weight should be given to this extraneous material by the examiner.

Other than the original identification of the relevance of the prior art, the third party cannot discuss the prior art with the examiner and cannot make oral

61 *Farmobile, LLC v. Farmers Edge Inc.*, 2018 FC 1269; *RLP Machine & Steel Fabrication Inc. v. DiTullio*, 2001 FCT 245 (TD).
62 *Salt*.
63 See for example, *Electec Ltd. v. Comstock Canada* (1991), 45 FTR 241 (TD).
64 *Imperial Oil Resources Ltd. v. Canada (Attorney General)*, 2015 FC 1218; *Qualcomm Inc. v. Canada (Commissioner of Patents)*, 2016 FC 1092.
65 *Patent Act*, s 34.1.
66 *Patent Act*, s 34.1.

representations to the examiner. The examiner has no authority to correspond with anyone other than the agent of record. The examiner is therefore not able to discuss the art or its relevancy with the protesting party. The protesting party receives an acknowledgment that the filing of the prior art will become part of CIPO file but will receive no further communication from CIPO. The onus is on the protesting party to continue to monitor the patent application file to review any steps taken by an examiner.

Once the prior art becomes part of the CIPO file record, the Applicant will receive a notice and the examiner will review the submission to determine whether the prior art is, in fact, relevant to the claims in the application. If the examiner determines that the prior art is relevant, a further Office Action will issue on that basis. Where the prior art calls into question the patentability of an invention for which a notice of allowance has been sent but the patent has not yet been issued, the notice of allowance will be withdrawn prior to the issuance of the Office Action. If the examiner determines that the prior art is not relevant, they will simply take no further action with respect to it. No further notice is given to the protesting party. The protesting party may file further submissions of prior art in response to any representations made by the Applicant, or in response to the examiner's determination that the prior art is not relevant.

The limited role of the protesting party can be a significant disadvantage. While the protesting party does not have an opportunity to discuss the prior art with the examiner, the Applicant is able to do so. That said, the Federal Court has rejected the argument that deference should be given to an examiner's decision in relation to protests.[67] While the Courts may still take into account the examiner's views on prior art references filed under section 34.1, the presumption of the validity of the patent would not be strengthened.

Additionally, the recent introduction of a provision[68] permitting the admission in an action or proceeding into evidence of a written communication prepared during prosecution of the application may have an impact on the significance of prior art filings under section 34.1. Positions taken in response to prior art raised during prosecution may become admissible to rebut representations made by the Patentee regarding claims construction in later court proceedings. It is unclear to what extent the Courts may similarly consider the positions taken by third parties in submitting prior art during prosecution.

67 *Pollard Banknote Ltd. v. BABN Technologies Corp., 2016 FC 883* at paras 128-134.
68 *Patent Act*, s 53.1.

4.7 Re-examination

Any member of the public, including the Patentee, may request the re-examination of any claim of a patent.[69] Re-examination may be requested only on patents issuing from applications filed after October 1, 1989.

Re-examination of a patent is initiated by the filing of a request for re-examination, along with applicable prior art and the prescribed fee. The applicable prior art consists of patents, applications for patents open to public inspection and printed publications.[70] The request for re-examination must set forth the pertinence of the prior art and explain how the prior art applies to the claim or claims being re-examined. [71]

When the re-examination is requested by someone other than the Patentee, CIPO will send a copy of the request to the Patentee.[72] At this point, the requesting party no longer plays an active role in the re-examination, and the requesting party does not have an opportunity to make further submissions either orally or in writing. CIPO may, however, copy the requestor on correspondence to the Patentee, if the requestor is not the Patentee.

After the request for re-examination is received, CIPO will establish a Re-examination Board, consisting of at least three persons, at least two of whom must be employees of CIPO.[73] Generally, the Board will consist of a PAB member and two examiners from CIPO who have experience in the art or science to which the invention belongs.

The Board has three months to determine whether the request for re-examination raises a substantial new question of patentability. This must be a validity issue that was not previously considered during the prosecution of the application or any other prior proceeding, and that is substantially different from the issues previously considered. Typically, this will involve new prior art references, although it can also include prior art considered previously but applied in a different manner. For instance, prior art could be considered as part of an obviousness objection, when previously it was considered for anticipation.

Where the Board determines that no new question of patentability of a claim is raised, it will notify the requesting party of this decision. This decision is final and not subject to appeal or review either by the requesting party or by the Patentee, whether a substantial new question of patentability is found or not.[74]

69 *Patent Act*, s 48.1(1).
70 *Patent Act*, s 48.1(1).
71 *Patent Act*, s 48.1(2).
72 *Patent Act*, s 48.1(3).
73 *Patent Act*, s 48.2.
74 *Patent Act*, s 48.2(3); *Cusitar v. Canada (Attorney General)*, 2019 FC 1641 at para 32.

Where the Re-examination Board determines that the request for re-examination does raise a substantial new question affecting the patentability of a claim, the Board will notify the Patentee of this decision and the reasons for it. The Patentee then has three months to submit a reply to the Board setting out any submissions it wishes to make on the issue of the patentability of the claim.[75] After receipt of a reply from the Patentee or the expiry of the three-month time limit, the Board will proceed to re-examine the claim in issue. Re-examination proceedings must be completed within 12 months after the receipt of the reply from the Patentee containing submissions on the issue of patentability of the claim, or 15 months after the Board sends notice of its decision if the Patentee does not reply.[76] In making submissions, the Patentee may propose amendments or new claims but may not enlarge the scope of the claims.[77]

On conclusion of a re-examination proceeding, the Re-examination Board will issue a certificate having one of the following effects:[78]

a. cancellation of any claim of the patent determined to be unpatentable;
b. confirmation that any claim of the patent is patentable; or
c. incorporation into the patent of any proposed amendment or new claim determined to be patentable.

A certificate issued by the Re-examination Board is attached to the patent and becomes part of it. Where a certificate has been issued, it may:[79]

a. cancel any claim but not all claims of the patent, in which case the patent shall be deemed to have been issued from the date of grant in the corrected form;
b. cancel all claims of the patent, in which case the patent shall be deemed never to have been issued; or
c. amend any claim in the patent or incorporate a new claim in the patent, in which case the amended claim or new claim shall be effective from the date of the certificate for the unexpired term of the patent.

Any decision by the Re-examination Board set out in the certificate is subject to appeal by the Patentee to the Federal Court. An appeal must be taken within three months from the date of the certificate's issuance. A requesting party who is not the Patentee has no right of appeal.[80]

75 *Patent Act*, s 48.2(5).
76 *Patent Act*, s 48.3(3).
77 *Patent Act*, s 48.3(3).
78 *Patent Act*, s 48.4.
79 *Patent Act*, s 48.4.
80 *Patent Act*, s. 48.4(5).

PART 2

Subject Matter-Specific Considerations

Chapter 5

Chemical Compounds

5.1 Overview

This chapter covers jurisprudence and best practices of broad relevance to inventions in the chemical, biological, and pharmaceutical arts.

In Canadian practice, compounds, compositions, products, processes, systems, and kits, including polymers, agricultural chemicals, pharmaceuticals, and cosmetics, are all patentable subject matter.[1] A compound is considered to be a composition of matter, and thus falls within the definition of an invention. Synthetic as well as naturally occurring compounds may be the subject of a patent claim, provided that other patentability criteria are met.[2] Compounds that occur naturally but that have utility in an isolated and purified form may be patented, provided they are claimed in a state other than a naturally occurring one.

It is recommended that any feature that has potential importance be represented by its own claim. Since Canada is a country that uses a "fence" approach to patent claims, rather than a "signpost" approach (such as that used in Japan), it is advisable to have a variety of claims in the application. In this way, if a broad claim becomes invalidated in a court action, there will be narrower claims to fall back on.

5.2 Types of Claims

The Canadian Intellectual Property Office (CIPO) accepts most claim styles, such as Jepson-type claims and European-type claims using "characterizing" language to distinguish those parts of the claim that are old from those parts that are new. Such language may be somewhat limiting, however, when interpreting the claims from an infringement or validity standpoint.[3]

5.2.1 Compounds

Chemical compounds may be claimed generically by defining a class, or as individual compounds. A compound may be defined (1) by structure, (2) in terms of physical or chemical properties, and/or (3) by the process by which it is made (product-by-process). Preferably, the compound is defined by its structure. No matter which way it is defined, the product must be distinguished from all other known products.[4]

1 *Patent Act*, RSC 1985, c P-4, s 2 [*Patent Act*].
2 See Chapter 1, Overview of the Canadian Patent System, section 1.3, "Patentability Requirements".
3 *Stamicarbon BV v. Urea Casale SA* (2001), 8 CPR (4th) 206 (FCTD), rev'd on other grounds by 2002 FCA 10.
4 Canadian Intellectual Property Office, *Manual of Patent Office Practice*, (Ottawa: Innovation, Science and Economic Development Canada, 2019) s 16.08 [*MOPOP*].

Compounds defined by structure typically include empirical formulae, structural formulae, or chemically acceptable names. Low molecular weight molecules are most often claimed according to structural features, including functional groups.

When the structure is not known, it is possible to claim compounds by way of their novel properties or composition.[5] For example, novel antibiotic compounds having an as yet undetermined complex structure may be claimed by way of physical properties and spectra, such as NMR (nuclear magnetic resonance) spectroscopy and IR (infrared) absorption spectroscopy.

Functional language may be used where appropriate, but acceptance by CIPO will depend on the context. In particular, CIPO policy states[6] that:

> the question to be asked [is]: "can the person skilled in the art practice, in view of the description, the full breadth of the claimed invention without recourse to undue experimentation or inventive ingenuity?" … If the means to effect the defined function are common general knowledge, the functional limitation is unlikely to be objectionable. Where few or only one means is known to effect the function, however, broad functional language would direct the claimed invention to be practised in ways that have not been fully described or enabled and consequently would be objectionable …

The relevant case law is equally clear that the use of functional language in a claim – for example, in the form of a desired result – to define an invention is not *per se* objectionable, and the desired result can serve as a functional limitation on the claim.[7]

A product-by-process claim defines the claimed product wholly or partly in terms of the process by which is it made. The process limitations may be included within the product claim itself or the whole claim may be made dependent on another claim directed to the process.[8]

Products that are already known may not be claimed by making them dependent on a new process.[9] Only the process itself may be claimed. In Canada, this limitation on product-by-process claims is not generally a concern. If a novel product is made by a patented process, then the product is assumed to infringe the process claim, absent evidence to the contrary, even if the

5 *MOPOP*, s 16.08.
6 *MOPOP*, s 14.05.01.
7 *Burton Parsons Chemicals Inc. v. Hewlett-Packard (Canada) Ltd.*, (1974), [1976] 1 SCR 555 [*Burton Parsons*]; *Chu v. University of Houston*, 112 CPR (4th) 41 (PAB).
8 *MOPOP*, s 16.08.01.
9 *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61 [*Sanofi*].

process is effected outside Canada and the product is then imported into Canada.[10]

Both geometric and optical isomers may be claimed. A claim to a compound that is capable of isomerism, but that is not defined in terms of any of its isomers, will generally be regarded to include all of the isomers, including racemic mixtures. Where appropriate, it is also possible to specify the isomer intended by using conventional isomer notation.

For naturally occurring compounds, the claimed subject matter must be distinguished from the form in which the compound occurs naturally.

5.2.2 Compositions

According to CIPO, a "composition", by definition, comprises at least two ingredients.[11] A claim to a composition must therefore include not only the novel compound but also a second ingredient, which forms the composition. This second ingredient may be inert, such as a carrier.

Compositions containing known compounds can be patented as can new uses for known compounds. In *Rohm & Haas Co. v. Canada (Commissioner of Patents)*,[12] a fungicidal composition containing known salts as "active ingredients" was found to be patentable. However, a method could not be claimed in this case, because a known method is not made novel by applying a new substance to it. The invention may reside in a new use, as in *Shell Oil Co. v. Canada (Commissioner of Patents)*,[13] where the use is an unobvious use in that an unexpected result is achieved.

A composition that comprises a known compound in combination with a mere diluent is not considered patentable subject matter if no new use is established. In *Farbwerke Hoechst AG v. Canada (Commissioner of Patents)*,[14] the patent application contained composition of matter claims relating to an anti-diabetic composition of sulphonyl urea diluted by a carrier. The same Applicant had already received patents to protect the undiluted compound. The Court held that the dilution of the compound does not result in further invention and a patent to protect the diluted form was not granted.

When claiming alloys, CIPO prefers that all of the possible ingredients be specifically mentioned in the broad claim. That is, if a particular ingredient

10 *Patent Act*, s 55.1; *Eli Lilly & Co. v. Apotex Inc., 2009* FC 991, at paras 270-341, aff'd 2010 FCA 240, leave to appeal to SCC refused, docket no. 33946 (5 May 2011).
11 *MOPOP*, s 16.04.
12 *Rohm & Haas Co. v. Canada (Commissioner of Patents)*, [1959] Ex CR 153.
13 *Shell Oil Co. v. Canada (Commissioner of Patents)*, [1982] 2 SCR 536 [*Shell Oil*].
14 *Farbwerke Hoechst AG v. Canada (Commissioner of Patents)*, [1964] SCR 49.

appears as an additional ingredient in a subsidiary claim, that ingredient should be mentioned in the broad claim. Generally, optional components may be claimed as up to X percent rather than from 0 to X percent. Furthermore, the alloy composition may be made up to 100 percent by including such terms as "balance trace elements" and/or "unavoidable impurities". If significant, the broad claims should include a maximum allowable amount for one or more critical impurities.

5.2.3 Methods and Processes

A method is a series of steps to be followed in order to achieve a desired result. CIPO distinguishes between methods and processes; the latter includes a method as well as the substance to which the method is applied.[15]

In the instance of a known compound prepared by a new process, an Applicant may obtain claims to the novel process. In *Hoffmann-La Roche Ltd. v. Canada (Commissioner of Patents)*,[16] a patent was sought for a new process of making aldehydes. Although the aldehydes themselves could not be claimed as new, it was established that the Applicant would nonetheless have a monopoly in respect of aldehydes made according to the patented process. Although process claims can be difficult to enforce, section 55.1 of the *Patent Act* provides that in an action for infringement of a patent granted for a process for obtaining a new product, any product that is the same as the new product shall, in the absence of proof to the contrary, be considered to have been produced by the patented process. This relieves some of the initial evidentiary burden from the Patentee when enforcing process claims for new products and requires the alleged infringer to offer evidence of non-infringement. It is not, however, helpful with respect to process claims for old products.

Process claims are also patentable where minor modifications to a known synthetic process are made. In *Halocarbon (Ont.) Ltd. v. Farbwerke Hoechst AG*,[17] claims related to a process for producing isohalothane under liquid-phase conditions at a temperature of 50°C were refused by CIPO as obvious modifications. However, the Court found that the prior art did not point a skilled person to this modification. The Court therefore upheld the claims on the basis that a scintilla of inventiveness was found in the process modifications and, consequently, the modifications were patentable over the prior art. This decision

15 *MOPOP*, s 16.10.01.
16 *Hoffman-LaRoche Ltd. v. Canada (Commissioner of Patents)*, [1955] SCR 414 [*Hoffman-La Roche*].
17 *Halocarbon (Ont) Ltd. v. Farbwerke Hoechst AG*, [1979] 2 SCR 929.

reinforces the low standard of inventiveness required to overcome obviousness rejections. A mere scintilla of inventiveness is all that is needed.[18]

Process claims may also be patentable even though the generic method used is classical.[19] Thus, a claim to a process that consists of applying a known method to chemically react known substances is patentable, provided that the method has never before been applied to these substances and results in a new, useful, and unobvious product. In *Ciba Ltd. v. Canada (Commissioner of Patents)*,[20] the Court held the process to be new by virtue of the novelty of the end product even though the reaction used was a standard, classical reaction.

Essential steps in a process for synthesis of a compound must be recited in a claim. The decision of *Wellcome Foundation Ltd. v. Apotex Inc.*[21] related to methoxy and anilino intermediates in a process for trimethoprim production. An essential step in the process was omitted – that is, isolating the final product. Claims were drawn broadly, with up to 10 million possible compounds being synthesized according to the process. The burden of proof was on the attacker to show inoperability of any particular embodiment of the process, and this was not met. However, because the isolation step was omitted, it was held that a claim to the process of preparing an intermediate was invalid because a process that works but has no reasonable prospect of commercial or industrial application lacks utility.

CIPO prefers to see specific process steps. Therefore, a claim such as "a process for coating a substrate that comprises the novel coating composition of claim 1" would be required to be amended to read "a process for coating a substrate that comprises the step of coating the substrate with the coating composition of claim 1." The latter actively recites a process step rather than leaving it to be included by inference.

5.2.4 Use

A "use" falls within the category "art," and is thus patentable subject matter. A use is distinguished from a method in that the latter involves directing the person skilled in the art to take a step or series of steps to arrive at the desired result. In contrast, a use may not require any specific step or steps to be followed.

18 See Chapter 17, Infringement and Validity Determinations in Court, sections 17.6.2 "Obviousness/Inventiveness," and 17.6.4 "Utility and Sound Prediction".
19 *MOPOP*, s 16.10.01.
20 *Ciba Ltd. v. Canada (Commissioner of Patents)*, [1959] SCR 378.
21 *Wellcome Foundation Ltd. v. Apotex Inc.* (1991), 47 FTR 81 (FCTD) [*Apotex FCTD*].

A new use of a known compound may be patentable in Canada where the use is new and unobvious. In *Shell*, claims were directed to a composition containing a known compound for use as a plant growth regulator. The use of the compound as a plant growth regulator was not previously known. A claim was directed to the plant growth regulator but included the element of use within the preamble of the claim. The Court upheld the claim as patentable because the use of the known compound was new and unobvious.[22] In *Re Application for Patent by Wayne State University*,[23] it was established that a new medical use of a compound could be patented even though the compound had another known medical use. However, products that are already known may not be claimed by making them dependent on a new process.[24] Medical "use" claims are discussed in detail in Chapter 8, Methods of Medical Treatment and Medical Uses.

5.2.5 Commercial Package and Kit

Commercial package claims are a commonly accepted claim format in Canada. A commercial package claim may contain a single component, a plurality of the same component, one or more different components, or any combination thereof, and is typically a claim directed to a compound or composition together with instructions for use of the compound or composition. Examples of claim formats that are acceptable in Canada follow in section 5.7, below.

A kit claim must also be directed to at least two elements, either two compounds or compositions, or at least one compound or composition, together with instructions for the use of the compound(s) or composition(s).

5.3 Sound Prediction and Utility

Claims may be directed to a large class of compounds or to a more specific subset. Not all members of the claimed class of compounds need to be exemplified in the specification in order to obtain patent protection under Canadian law. It is sufficient if a smaller number of compounds are exemplified as long as the class of compounds claimed is a reasonable or sound prediction from the data provided in the specification. This principle was established in *Monsanto Co. v. Canada (Commissioner of Patents)*,[25] in which the Commissioner of Patents rejected claims to chemical compounds useful in preventing premature vulcanization in the production of vulcanized rubber

22 Shell Oil.
23 *Application for Patent by Wayne State University, Re* (1988), 22 CPR (3d) 407 (PAB and Comm of Pat) [*Wayne State*].
24 Hoffman-La Roche.
25 *Monsanto Co. v. Canada (Commissioner of Patents),* [1979] 2 SCR 1108.

dienes. The rejection was made on the basis that the claims were broader than the disclosure. One of the claims covered 126 potential compounds, although only three compounds had been tested and exemplified in the specification. The Court allowed the claims on the basis that sound predictions of utility were reasonable in the absence of evidence to the contrary. The Court held that the claims could be rejected only if it was established that the claimed subject matter included embodiments that lacked the utility or if the claimed subject matter was not a sound prediction, from the perspective of one skilled in the art, based on the exemplifications in the specification.

The issue of sound prediction resurfaced in *Apotex Inc. v. Wellcome Foundation Ltd.*[26] Apotex challenged the validity of Glaxo/Wellcome's patent directed to AZT (a drug for treating HIV/AIDS) on the basis that the necessary utility had not been established as of the priority date of the patent and that the claims covered more than the invention. Apotex asserted that Glaxo/Wellcome did not have sufficient information about AZT to predict that it could be successfully used in the treatment and prophylaxis of HIV/AIDS. However, the Court held that Glaxo/Wellcome had soundly predicted the utility of AZT in humans on the basis of *in vitro* data. The Court established a "doctrine of sound prediction" that aimed to "balance the public interest in early disclosure of new and useful inventions, even before their utility has been fully verified by tests, and the public interest in avoiding cluttering the public domain with useless patents and granting monopoly rights in exchange for speculation or misinformation."

The doctrine of sound prediction has three components. First, there must be a factual basis for the prediction. Second, the inventor must have at the date of the patent application *(i.e.*, the filing date) an articulable and "sound" line of reasoning from which the desired result can be inferred from the factual basis. Third, there must be proper disclosure. The soundness (or otherwise) of the prediction is a question of fact. The doctrine of sound prediction, in its nature, presupposes that further work remains to be done. The doctrine of sound prediction does not include a lucky guess or mere speculation.

Apotex[27] states that there must be evidence as of the filing date that can demonstrate or provide a sound basis for predicting the invention's utility. Research performed post-filing for the purpose of buttressing a patent's utility is not permitted. This principle has been adopted in subsequent decisions.

26 *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77 [*Apotex SCC*].
27 *Apotex FCTD* at para 80.

For example, the Federal Court stated:[28]

> Where a patent is challenged for inutility, a patentee must establish either that the utility of the patent is demonstrated or soundly predicted as of the Canadian filing date. Evidence of demonstrated utility may be and often is tendered that goes beyond the disclosures set out in the patent. However, such evidence must relate to the state of events as of the date the patent was applied for; evidence occurring after the filing date is not permissible.

While section 2 of the *Patent Act* states that an invention by definition must be "useful", there is no requirement in the Act that the invention's utility must be disclosed in the specification. The Supreme Court of Canada stated in its 2017 *Esomeprazole* decision that "a patentee is not required to disclose the utility of the invention to fulfill the requirements of section 2".[29]

These decisions have implications for claims in all areas of chemical subject matter. Currently, the onus is on the examiner to provide evidence that a broad claim is not based on sound predictions of utility, even if very few embodiments of the broad class of subject matter claimed have been tested or exemplified in the specification. In *Ciba-Geigy v. Canada (Commissioner of Patents)*,[30] relating to processes for making new amines, only two processes were exemplified in the specification. The Commissioner rejected the claims to the processes as untested and, thus, speculative. The decision in *Monsanto* was relied on, and it was affirmed that a claim of this type should be rejected only if there is evidence of a lack of utility or if the claim is not based on a sound prediction. That the claimed processes were subsequently shown to work was considered evidence that the claims were based on sound and reasonable prediction. The Court found that if the prediction made at the time of filing the patent application turned out to be true, it ought to be considered well founded at the time it was made. The Patent Appeal Board has also recently considered post-filing evidence to support a finding that monoclonal antibodies directed to a novel antigen were soundly predicted.[31] However, CIPO has been reluctant to accept *ex post facto* evidence of utility, particularly where an application as filed does not, in the eyes of the examiner, soundly predict that utility.

When an Applicant claims a broad class of compounds while providing exemplification for a small number of them, it runs the risk of including embodiments that lack utility. If some of the compounds falling within the claim

28 *Eli Lilly Canada Inc. v. Apotex Inc.*, 2015 SC 1016 at para 121.
29 *AstraZeneca Canada Inc. v. Apotex Inc.*, 2017 SCC 36 at para 58.
30 *Ciba-Geigy v. Canada (Commissioner of Patents)* (1982), 65 CPR (2d) 73 (FCA).
31 *Immunex Corporation Patent Application No 583,988*, *Re* (2011), 89 CPR (4th) 34 (PAB).

lack utility for the intended purpose set out in the specification, the claim may be found invalid. In *Société des usines chimiques Rhône-Poulenc v. Jules R. Gilbert Ltd.*,[32] claims to a process for making tripelennamine, an antihistamine, were in question. One of the claims related to the synthesis of a class of compounds and salts thereof. Certain isomers formed according to the process claim were shown to be ineffective for the intended purpose. The Court held the claim invalid because it covered isomers that were useless as well as those that were useful.

The Federal Court has held in other cases that claims must be read in view of a skilled person in the art, and therefore where the skilled person would clearly recognize that a compound could not be used for the intended purpose, the compound must be excluded from the claim. In *Burton Parsons Chemicals Inc. v. Hewlett-Packard (Canada) Limited*,[33] claims in the patent were directed to electrically conducting cream that was topically applied to the skin to promote conductivity in obtaining an electrocardiogram. Certain of the claimed salts were inappropriate for use on human skin. The Court found that a skilled person would immediately recognize such compounds to be inappropriate for use on human skin and, therefore, would not use them for such a purpose. The Court read the claim to exclude these compounds from the claim and upheld it as valid.

A claim to a broad class of compounds drawn on the premise of "reasonable prediction" cannot be interpreted to anticipate an undisclosed embodiment of the broad class that was not suggested in the claims or disclosure, should another party apply for patent protection for the embodiment. In *Re G.D. Searle & Co. Patent Application No. 2,152,792*,[34] Searle filed a U.S. priority document claiming a broad class of anti-inflammatory furanones. The Canadian patent application, claiming the benefit of the Searle priority application,[35] contained claims to a specific subclass of furanones that were also described in a co-pending Canadian patent application filed by Merck Frosst Canada Inc. The Merck Frosst application was filed after the priority date but before the Canadian filing date of the Searle application. Because neither the Searle priority document nor the Searle application was publicly available prior to the Merck Frosst filing date, neither of the Searle documents could be cited for the purpose of obviousness of the Merck Frosst claims under section 28.3 of the *Patent Act*. However, the Searle application was citable with regard to

32 *Société des usines chimiques Rhone-Poulenc v. Jules R Gilbert Ltd.,* [1968] SCR 950.
33 *Burton Parsons*.
34 *GD Searle & Co Patent Application No 2,152,792, Re* (1999), 4 CPR (4th) 244 (PAB and Comm of Pat).
35 See Chapter 1, Overview of the Canadian Patent System, section 1.2, "Priority and Claim Date".

novelty (section 28.2(1)(d) of the *Patent Act*), but only with respect to the broad class of furanones, because only these had specific support in the priority application. It was held that although the broad claim to the class of furanones could be obtained by Searle, the embodiments claimed by Merck, which were not exemplified by Searle, were not anticipated by the Searle application. This case points to the need for support in a priority application with regard to a composition-of-matter claim in order to obtain a valid claim date. Furthermore, it serves as a reminder that a priority document, such as a provisional application, will not be interpreted to extend to non-disclosed subject matter.

A distinction may be made between sound prediction and obviousness. The test for sound prediction involves the inventor as the relevant person, someone who is inventive by definition. In assessing sound prediction, common general knowledge as well as previous private work known to the inventor are pertinent. To meet the test for sound prediction, there must be more than a lucky guess, but certainty is not required – a reasonable prediction is sufficient. In contrast, in making an assessment of obviousness, the relevant person is a person of ordinary skill in the art with no imagination (that is, not inventive). In assessing obviousness, common general knowledge published before the claim date is of relevance. To meet the test for obviousness, it must be very plain that the subject matter would or would not work; a reasonable prediction is not sufficient.[36]

Care must also be taken to clearly identify the broadest aspect of the invention within the description in terms of, for example, process parameters such as temperature and pressure ranges, possible functional groups, and ranges of components in a composition. All other parameters, whether optional or within the broad aspect of the invention, should be identified as optional or other features of the invention. Unnecessary use of restrictive terms in the description, such as “must be included,” should be avoided because CIPO will use such terminology to reject claims excluding the seemingly mandatory element as too broad in view of the disclosure.

5.4 Selection Patents

Canadian practice allows the patenting of a smaller class of novel compounds that is a subset of a larger known class of compounds. Such a patent is referred to as a selection patent.[37] In *Sanofi*, the Supreme Court of Canada unanimously confirmed that a selection patent is permissible under the

36 *Sanofi-Aventis Canada Inc. v. Apotex Inc.*, 2009 FC 676.
37 *IG Farbenindustrie AG's Patents, In re* (1930), 47 RPC 289.

Patent Act. The Court stated that a selection patent "does not in its nature differ from any other patent", and its validity should be evaluated by the usual statutory criteria, such as novelty and inventiveness. The Court held that "a system of genus and selection patents is acceptable in principle." The Court followed a 1930 U.K. case in finding that they must meet three criteria: (1) there must be a substantial advantage to be secured or disadvantage to be avoided by the use of the selected members, (2) the whole of the selected members must possess the advantage in question, and (3) the selection must be in respect of a quality of a special character peculiar to the selected group. If further research revealed a small number of unselected compounds possessing the same advantage, that would not invalidate the selection patent. However, if research showed that a larger number of unselected compounds possessed the same advantage, the quality of the compound claimed in the selection patent would not be of a special character. The Court also made it clear that the specification of a selection patent must define in clear terms the nature of the special characteristic that is possessed by the selection claimed.[38]

In *Eli Lilly Canada Inc. v. Novopharm Ltd.*, the Court held that no freestanding ground of attack that a patent is not a valid selection patent exists. A selection patent is the same as any other patent. Its validity is vulnerable to attack on any of the grounds set out in the *Patent Act*.[39]

Subset compounds can therefore be patented if it is established that they have some substantial advantage or utility over the larger known class, all selected members have the advantage, and the advantage is not an obvious one. The unobvious advantage may be a new use for the compounds. It may also include the previous use of the known compounds, but at a much-improved level. For example, where a large class of compounds has been shown to be useful in the treatment of cancer, a subset of the compounds may be patentable for the treatment of cancer where the reactivity or supporting data are significantly improved from that of the known class, so that it can be shown that the subset reacts in a different manner from the known class. In such instances where the subset compounds are known but the use is novel, only "method", "use", and "compound for use" claims would be available.

38 *Sanofi.*
39 *Eli Lilly Canada Inc. v. Novopharm Ltd.,* 2010 FCA 197.

5.5 Unity

CIPO takes the position that claims directed to a product, a process for making a product, a use of the product and an apparatus specially adapted to carry out the process may generally be prosecuted together in the same application.[40]

In the case of a novel compound prepared by a process in which one or more of the intermediates are also novel, CIPO takes the position that it is usually possible to keep the claims for the intermediates in the same application as claims to the final compound. Claims directed to a final product and an intermediate product used in the preparation of the final product may be claimed independently in the same application when there is sufficient structural similarity between the two, when the intermediate product does not have an additional use different from the final product and when the final product can be manufactured directly or via a small number of other intermediates from the intermediate product.[41]

5.6 Claim Language

5.6.1 Markush and Alternative Language

Markush format provides a list of alternatives and is worded akin to "selected from the group consisting of … A, B … and C." Similarly, language such as "A, B, or C" (that is, alternative language) also provides a format for reciting alternatives. Although these claim formats are both accepted by CIPO, such language may not always be advisable in view of some case law.

For example, in *Abbott Laboratories v. Canada (Minister of Health)*,[42] a claim was directed to a process using a solvent chosen from a Markush group of 17 listed solvents. The claims were found to lack utility when three of the listed solvents were selected. The Court held that elements of a Markush grouping cannot be considered alternatives within the scope of section 27(5) of the *Patent Act*, the relevant portion of which provides that when a claim defines the subject matter of an invention in the alternative, each alternative is a separate claim for the purpose of determining utility. The Court found that the patent holder was unable to prove that allegations that the claim was invalid

40 *MOPOP*, s 14.02; See Chapter 2, Procedural Requirements, section 2.4, "Divisional Applications and Unity of Invention".
41 *MOPOP*, s 21.08.05.
42 *Abbott Laboratories v. Canada (Minister of Health)*, 2005 FC 1095 [*Abbott 1*].

were unjustified.[43] In a subsequent decision, Abbott again failed to prove that allegations that a Markush claim was invalid on similar grounds were unjustified.[44]

Both *Abbott #1* and *Abbott #2* were Notice of Compliance (NOC) proceedings, and it is therefore questionable whether these decisions will impact Patent Office policy.[45] Nonetheless, the results of the *Abbott* proceedings have resulted in increased uncertainty for Applicants for Canadian patents and their agents.

It may therefore be advantageous to divide up subject matter covered by lists and collective terms into separate claims. Any commercially significant embodiment of the invention should be expressly and separately disclosed and claimed. CIPO does not charge excess claim fees, and prospective Patentees should consider claiming embodiments of varying scope to capture broad, intermediate and specific subject matter.

5.6.2 Terminology

Common rejections from CIPO include those based on terminology that CIPO considers ambiguous or indefinite.[46] CIPO will routinely reject claims, at least initially, containing terms such as "substituted" and "protecting group" if the terms are not further defined in the claim. If these terms are further defined in the specification, the specification may be referred to in order to argue against such a rejection. When substituents are defined as a class of compounds, CIPO will reject open-ended definitions. These include terms such as "alkyl" and "aryl", where the number of carbon atoms in the alkyl or aryl group is not specified. A functional limitation such as "lower alkyl" may sometimes be acceptable as a suitable limitation to overcome such a rejection if it can be shown that "lower" has a known meaning in the art or is defined in the description. Such limitations are not always successful, however, and it is frequently necessary to specify the number of carbon atoms in the group. Terms such as "hetero" may also be rejected for the requirement to limit the term to the specific hetero-atoms contemplated. Similar objections may be made to broad definitions of heterocyclic compounds. Care should therefore be taken to incorporate sufficient details of substituents into the application so

43 *Abbott 1* was a hearing pursuant to the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 [*PMNOC Regulations*]. In Notice of Compliance [NOC] proceedings, there is an onus on the patent holder (Abbott in this case) to prove that an allegation of invalidity is not justified. See Chapter 13, Data Protection and the Patented Medicines (Notice of Compliance) Regulations, section 13.6.3, "Burden Is on a Balance of Probabilities".

44 *Abbott Laboratories v. Canada (Minister of Health),* 2005 FC 1332.

45 *Eli Lilly Canada Inc v. Novapharm Ltd.,* 2007 FCA 359. See Chapter 13, Data Protection and the *Patented Medicines (Notice of Compliance) Regulations*, section 13.6.2, "Action in the Federal Court".

46 See Chapter 1, section 1.3, "Patentability Requirements", and Chapter 17, Infringement and Validity Determinations in Court, section 17.6.6, "Ambiguity".

that any such objections may be overcome without unduly limiting the scope of the claim. When a clear description of the term is provided in the description, argument that it is appropriate to construe the claim in view of the specification, citing *Whirlpool Corp. v. Camco Inc.*,[47] may overcome such objections.

5.6.3 Claim Dependencies

Rules of claim dependency are more liberal in Canada than in the U.S. and some other jurisdictions. Any number of dependencies are permitted. However, CIPO is strict about the wording of such multiple dependencies and the preambles of claims. Wording such as "according to any previous claim" is not acceptable because previous claims must be referred to by number, such as "according to any one of claims …" In addition, as discussed above, CIPO does not charge excess claim fees, or fees for multiple dependencies.

5.6.4 Antecedents

CIPO takes a strict approach to antecedents. Thus, a set of claims that is acceptable in other countries may meet antecedent objections from a Canadian examiner. All terms referred to in a claim must be introduced with the indefinite article "a" or "an" (or with no article where appropriate) prior to being referred to with a definite article – for example, "the" or "said." The introduction of a term may be within a dependent claim or in a parent claim on which the dependent claim depends.

5.6.5 Negative Limitations

CIPO often objects to claims containing negative expressions such as "not being ...", "not having ..." and, "not requiring ..." While negative claiming is not preferred, it is permissible where it is the clearest method of claiming the invention.[48]

5.6.6 Relative Terms

CIPO often objects to claims containing "relative" expressions, such as "high", "average", "thin", and "strong". The Patent Office generally requires that the meaning of such relative terms be defined in terms of a numerical value or relative to another element of the claim.[49]

47 *Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67.
48 *MOPOP*, s 16.03.03.
49 *MOPOP*, s 16.03.02.

5.7 Claim Formats

a. *Composition of matter claim reciting a formula or structural feature*
   - A compound having formula (I)[50] …
   - A compound comprising core A with functional group B present in position C, D, or E.[51]

b. *Composition of matter claim reciting a chemical name*
   - A composition of matter claim reciting a chemical name of a new compound generally uses naming conventions in accordance with IUPAC[52] nomenclature.
   - A product of the formula X or a pharmaceutically acceptable salt thereof.

c. *Composition of matter claim reciting a characterizing property*
   - A compound having the following H-NMR spectrum[53] …

d. *Composition of matter claim for a naturally occurring compound*
   - A compound of formula (I)[54] isolated from plant J having a purity greater than value K.

e. *Composition of matter in admixture*
   - A composition comprising a compound of formula (I) in admixture with a diluent or carrier.[55]

f. *Commercial package claim*
   - A commercial package comprising a compound of formula (I)[56] together with instructions for use in the treatment of condition P.[57]

g. *Process claim for preparation of a compound*
   - A process for forming a compound of formula (I)[58] comprising the steps of L and M.

50 Formula (I) should be inserted in the claim.
51 The formula may or may not be inserted in the claim.
52 International Union of Pure and Applied Chemistry.
53 A table characterizing peaks may be inserted in the claim.
54 Formula (I) should be inserted in the claim.
55 Formula (I) should be inserted in the claim.
56 Formula (I) should be inserted in the claim.
57 The claim format was found acceptable in *Wayne State*.
58 Formula (I) should be inserted in the claim.

h. *Product-by-process claim*
   - A compound of formula (I)[59] prepared according to the process of claim 1.
   - A compound of formula (I)[60] prepared by a process comprising the steps of L and M.

i. *Use-limited composition of matter claim, including EPC 2000 style*
   - A compound of formula (I)[61] for use in purpose N.
   - A composition comprising a compound of formula (I)[62] together with a suitable carrier for use in purpose N.
   - A compound X for use in the treatment of Y.[63]
   - A pharmaceutical composition X for use in the treatment of Y.[64]

j. *Canadian- or German-type "use" claim*
   - Use of a compound of formula (I)[65] for treatment of condition P.[66]

k. *Swiss-type "use" claim*
   - Use of a compound of formula (I)[67] for preparation of a medicament useful in treatment of condition P.[68]

l. *Method claim*
   - A method for regulation of function L comprising the step of providing a compound of formula (I)[69] …

m. *Kit claim*
   - A kit comprising a first container comprising a compound of formula (I)[70] and a second container …

59 Formula (I) should be inserted in the claim.
60 Formula (I) should be inserted in the claim.
61 Formula (I) should be inserted in the claim.
62 Formula (I) should be inserted in the claim.
63 *Apotex Inc. v. Wellcome Foundation Ltd.* (2000), 186 FTR 274 (FCA) [*Apotex v Wellcome*].
64 *Apotex v. Wellcome*.
65 Formula (I) should be inserted in the claim.
66 The claim format was found acceptable in *Wayne State*.
67 Formula (I) should be inserted in the claim.
68 This claim format may be useful to claim similar subject matter to that claimed as a method of medical treatment in other jurisdictions.
69 Formula (I) should be inserted in the claim. This claim format may be rejected where it recites similar subject matter as that claimed as a method of medical treatment in other jurisdictions.
70 Formula (I) should be inserted in the claim.

Chapter 6

Biopolymers: DNA, RNA, and Protein Molecules

6.1 Overview

Biopolymers, such as nucleic acids and proteins, are eligible for patenting in Canada provided that the standard criteria for patentability are met. This area has not been extensively litigated, and there is a dearth of specific guidance from the courts as to requirements. The Canadian Intellectual Property Office (CIPO) has set forth its guidelines for examination in Chapter 23 of the *Manual of Patent Office Practice* (*MOPOP*), drawing largely on other subject matter areas.

In practice, CIPO requires real utility to be shown for a biopolymer claim. Frivolous utilities, such as the use of an oligonucleotide as a probe to locate similar sequences, are generally not acceptable unless it can be shown that such a utility has a real-world application – for example, in diagnostics.

Claims including homology-based assertions of utility or function – for example, reciting a threshold "percent identity" to a specific sequence possessing the required utility – are acceptable under Canadian practice. However, if an examiner has reason to believe that a claimed sequence is not adequately supported or is not adequately similar to the specific sequence possessing the utility, the claim will be rejected. If the recited threshold of percent identity is set so low as to encompass sequences that do not possess the required utility, the claim will be rejected. Likewise, a claim covering mutants or variants based on a reference sequence may be rejected if an examiner feels that certain sequence changes would impact function, or if undue experimentation would be required to determine whether a given sequence would fall within or outside the scope of the claim. Usually, mutants and variants of a specific sequence cannot simply be claimed in general terms together with a functional limitation. However, mutants and variants of a specific sequence may nevertheless be acceptable claim subject matter if adequate structural qualification of permitted changes or substitutions to the sequence is provided.

It is always advantageous to illustrate utility using *in vitro* or *in vivo* examples.

6.2 Description And Utility

An adequate description of a biopolymer must be disclosed in an application in order for the biopolymer to be patentable. CIPO requires that a biopolymer be explicitly defined, such as by structure, formula, chemical name, or physical properties.

Many patent applications directed to biopolymers rely on a sequence listing to fulfill written description requirements. However, if such a biopolymer has not been fully characterized, physical or chemical properties may be relied

upon for description of the invention, such as with an unsequenced protein having a known physical function (the approach of defining a biopolymer in terms of physical properties was more common in the years before sequencing technology became routine). In such cases, the physical properties must be adequate to describe what the biopolymer *actually is*, not merely *what it does*. An examiner may reject a claim that uses functional language if it causes the scope of the claim to be overly broad; for example, if a skilled person in the art would require an inventive effort to practice the full scope of the claim. A combination of physical or chemical properties will most likely be necessary to distinguish it over prior art compounds. If a protein or nucleic acid can be sequenced, it is preferable to do so and include this data in the patent application.

Chapter 14 of *MOPOP* indicates that common general knowledge need not be comprehensively disclosed in a patent application for the purposes of sufficiency; describing an assay by literature reference is sufficient.[1] However, where techniques are relatively new or being practised by relatively few labs, jurisprudence from the antibody field suggests that it is best to describe such methods in detail.[2]

Where the utility of certain claimed biopolymers is not explicitly disclosed or illustrated in an application but is nevertheless predicted, the court-created doctrine of sound prediction may be relied upon (see Chapter 17 for more information on sound prediction). CIPO looks for a factual basis, as well as a "sound line of reasoning", to ascertain whether a claim is a reasonable extrapolation over the presented experimental evidence. Where the factual basis and sound line of reasoning are based on data that is not part of the common general knowledge, then disclosure of the factual basis and sound line of reasoning will likely be required to support sound prediction.

6.3 Guidance On Specific Biopolymer-Related Subject Matter

A naturally occurring protein effective as an enzyme was claimed according to physical function and these claims were upheld in the case of *Continental Soya Company Limited v. Short Milling Company Limited*.[3] The Supreme Court of Canada considered the validity of claims to a naturally occurring soybean enzyme effective in bleaching flour. It was determined that the definition of invention in the *Patent Act* included such an enzyme within the meaning of a

1 Canadian Intellectual Property Office, *Manual of Patent Office Practice*, (Ottawa: Innovation, Science and Economic Development Canada, 2019), s 14.02 [*MOPOP*].
2 *Sloan-Kettering Institute for Cancer Research Patent Appn No 2,072,017, Re* (2009), 82 CPR (4th) 33 (PAB).
3 *Continental Soya Co. Ltd. v. Short Milling Company (Canada)*, [1942] SCR 187.

manufacture or composition of matter. Although the bleaching enzyme already existed in nature, in its isolated and purified state it was considered useful and novel, and thus patentable. In this case, details of the biopolymer sequence were not required because an amino acid sequence could not have been determined at that time.

A biopolymer must be claimed in a way other than its naturally occurring state, such as in an isolated or purified form. Thus, it seems reasonable to assume that a patent claim directed to an isolated or purified human gene sequence will not be infringed merely by possessing the gene in the human genome. Manipulating a cell naturally containing the gene is unlikely to infringe such a patent claim if the gene is not being used in the isolated or purified state claimed. Unlike in the U.S., jurisprudence surrounding these issues has been limited in Canada. At the time of publication, there has been no decision in Canada excluding isolated genes from patent eligibility. The validity of isolated gene patents was raised in an action in the Federal Court brought by the Children's Hospital of Eastern Ontario.[4] However, the action was settled.

Isolated disease-linked gene sequences are often claimed in the context of a diagnostic product for detection of the disease (see Chapter 10, Medical Diagnostics). For example, claims to a nucleotide sequence tethered to a gene chip are allowable in principle in Canada. Likewise, claims to biomarker panels and their use in diagnostic applications are allowable in principle. Although CIPO typically requires specific clinical indications to be set forth, broader disease-related applications may be claimed if there is an underlying molecular mechanism common to a class of diseases.

In the case of a known sequence that is modified in such a way as to possess a new utility, such as with polymorphisms and mutations linked to a disease or a pharmacogenomic trait, a sequence can be characterized by the sequence change. In the case of single nucleotide polymorphisms (SNPs), a sequence is characterized in terms of the change in its sequence, because it differs from a reference sequence.

Proteins are appropriate subject matter for a patent claim, provided that they are claimed in an isolated form. First-generation proteins isolated from a natural source, and second-generation proteins produced by recombinant DNA technology, protein engineering, or an equivalent process are both within the realm of patentable subject matter. If a first-generation protein is already known, second-generation proteins must be structurally distinguishable in order to be patentable. Although there is no Canadian jurisprudence to direct this practice,

4 *Children's Hospital of Eastern Ontario v. Transgenomic, Inc. et al* (14 May 2015), T-2249-14.

CIPO is of the view that first-generation and second-generation proteins are equivalent.

Nucleotide sequences may comprise coding and/or non-coding sequences and may be variously defined as polynucleotides, DNA, or RNA. They also may be double-stranded, single-stranded, or partially double-stranded. Sequences can sometimes be defined functionally in a patent claim, although this is often an area of argument with examiners. For example, a particular sequence may be defined as coding for a peptide, a promoter region, or a transcription initiation site. A sequence or part of it may also act as a linker or adaptor molecule enabling nucleotide sequences to be linked together, usually in the same reading frame. A nucleotide sequence may be defined in terms of another nucleotide sequence with which it will hybridize under defined conditions, although this may provoke an argument with an examiner about clarity of scope. For this reason, it is advisable that Applicants ensure that hybridization conditions are clearly defined in the specification. Furthermore, a claim will be rejected on the ground of lack of utility if a DNA sequence complementary to a coding sequence is claimed, because only the coding sequence itself is considered to have utility. If a utility can be demonstrated for the complementary sequence, other than for locating the coding sequence to which it hybridizes, then it may be possible to claim such a complementary sequence.

Cloning or expression vectors, such as plasmids, are acceptable claim subject matter. Claims to these aspects of an invention are useful because genetic material is often stored or deposited in this form, rather than in cells, because cells tend to age and die. In the course of aging and dying, cells can corrupt the nucleotide sequences they contain. Cloning vehicles, such as viruses, often behave more like chemicals than life forms. They are often modified, may be chimeric and may be semi-autonomous from the chromosomal complement of the cell in which they are inserted. Claims to these aspects of an invention are narrower than claims to the sequences themselves but are broader than claims to cells and microorganisms.

If it can be shown that a genetic rearrangement, with or without the addition of heterologous material, of a chromosome or of the genetic complement of an organism has an unexpected benefit, it may be worth seeking patent protection. A modified chromosome, a novel chromosome, or a complete genetic complement of chromosomes may each be claimed subject matter. Subcomponents of chromosomes, such as centromeres, telomeres, and regulatory elements, are patentable – especially if modified or isolated – provided that the other requirements of novelty, inventiveness, and utility are met.

Processes for the formation of biopolymers are considered patentable – for example, for effecting the formation of a protein encoded by a DNA sequence. Methods, processes, and uses involving known biopolymers are considered patentable. In the case where such a method pertains to the treatment of a pathological state, the appropriate claim format under Canadian practice recites a "use," as discussed in more detail in Chapter 8, Medical Treatments and Medical Uses.

6.4 Claim Formats

A biopolymer may be claimed as a composition of matter simply by reciting a sequence in the claim or by making reference to a sequence within the sequence listing contained in the description. With such a claim, acceptable levels of similarity or conservative substitutions may be specified, often in conjunction with a functional limitation. Alternatively, in lieu of providing a sequence, a biopolymer may be claimed by referring to a characterizing feature such as a sequence to which the biopolymer hybridizes or binds, by a measurable property or by a process used to prepare it. A biopolymer can also be claimed in combination with a vector or a host cell. Process, method, and use claims involving the biopolymer may also be appropriate. Kits or other commercial packages involving biopolymers may be claimed.

As mentioned, to date, biopolymer patents have not been extensively litigated in Canada. Prospective Canadian Patentees would do well to consider including a wide variety of claim types in their applications.

Examples of claim formats include:

a. *Composition of matter claim by sequence*

- An isolated oligonucleotide comprising the nucleotide sequence 5' CAGCCAGGATGGAG 3'.
- A DNA molecule consisting of the nucleotide sequence represented by SEQ ID NO:1.
- An isolated DNA molecule comprising the nucleotide sequence represented by SEQ ID NO:1.
- A polynucleotide encoding a protein consisting of the amino acid sequence represented by SEQ ID NO:2 (if the protein is not naturally occurring).
- An isolated polynucleotide encoding a protein consisting of the amino acid sequence represented by SEQ ID NO:2 (if the protein is naturally occurring).

- An isolated nucleotide comprising the nucleotide sequence represented by SEQ ID NO:1 or an allelic variant thereof.
- An isolated nucleotide consisting of the nucleotide sequence represented by SEQ ID NO:3 comprising nucleotide G substituted at position 300.
- A cDNA comprising the nucleotide sequence represented by SEQ ID NO:1.
- A vector comprising the nucleotide sequence represented by SEQ ID NO:1.
- A recombinant host cell comprising the nucleotide sequence represented by SEQ ID NO:1.

b. *Composition of matter claim referring to biological deposit*

Note: the biological deposit must be fully identified in the description at the time of filing.

- A cloning vehicle comprising ATCC accession number 12345.

c. *Composition of matter claim specifying function, hybridization, or percent identity*

- An isolated DNA sequence which hybridizes to the complement of the nucleotide sequence represented by SEQ ID NO:1 under conditions of high stringency,* and which is substantially identical to the nucleotide sequence represented by SEQ ID NO:2.
- An isolated DNA sequence with at least 80 percent identity to the nucleotide sequence represented by SEQ ID NO:2, which hybridizes with the nucleotide sequence represented by SEQ ID NO:1 under stringent* conditions.
- A DNA sequence encoding a protein having an amino acid sequence represented by SEQ ID NO:1, or a sequence that hybridizes to the complement of such a DNA sequence under hybridization conditions of 50%C and 0.9M NaCl followed by washing in 1X SSC at 55%C.
- A PCR amplimer comprising a first oligonucleotide primer consisting of 18-25 contiguous nucleotides between position 1 and position 50 of the nucleotide sequence represented by SEQ ID NO:1, and a second oligonucleotide primer consisting of 18-25 contiguous nucleotides complementary to the nucleotide sequence represented by SEQ ID NO:1 between positions 200 to 250.
- A transmembrane protein isolated from microbe C which binds to receptor D.

- A transmembrane protein comprising at least 85 percent identity with the amino acid sequence represented by SEQ ID NO:1, and which binds to receptor D.

d. *Composition of matter claim reciting distinguishing feature*
   - An isolated DNA sequence from gene A having polymorphism E leading to a restriction fragment pattern shown in Figure 1.

e. *Composition of matter claim defining a sequence by a process for preparation*
   - Protein F prepared according to a process comprising steps G and H.

f. *Process claim for preparation of a biopolymer*
   - A process for isolating protein F comprising steps G and H.
   - A process for preparing the DNA sequence of claim 1 comprising the steps of:
     i. reverse transcribing RNA, which complements part of the DNA sequence of claim 1 to form a partial DNA sequence; and
     ii. ligating the partial DNA sequence resulting from step (i) to at least one other partial DNA sequence comprising the balance of the DNA sequence of claim 1.

g. *Method claim involving a sequence*
   - A method for transforming a plant comprising the step of transfection with a vector comprising the nucleotide sequence represented by SEQ ID NO:1.

h. *Use claim for treatment involving a sequence*
   - Use of an oligonucleotide comprising the nucleotide sequence represented by SEQ ID NO:1 for treatment of disease I.
   - Use of a therapeutically effective amount of a protein having the amino acid sequence represented by SEQ ID NO:1 for treatment or prevention of disease I.

i. *Kit claim involving a sequence*
   - A kit for detection of disease I comprising the nucleotide sequence represented by SEQ ID NO:1 and directions for detecting binding with gene A.

* In view of frequently encountered Patent Office objections, it is highly advisable to ensure that these hybridization conditions are clearly defined in the patent specification.

Chapter 7

Antibodies

7.1 Overview

There is, perhaps, no other area of Canadian patent examination that has undergone such a favourable reversal of fortunes in recent time as that of antibodies. Canadian examination in this technical area is now much more responsive to developments in the state of the art, making it easier, in some cases, to claim antibodies that have not yet been made; provided that a novel epitope is described, there is no requirement to have actually produced antibodies to meet enablement and written description requirements if production methods were conventional at the filing date. The corollary is that prior art objections will tend to ensue for claims to a general class of antibodies directed to a known epitope.

While certain restrictive local nuances remain, there are a number of accepted claiming conventions that usually permit Applicants to obtain a scope of claim coverage commensurate with their commercial aims.

7.2 Background and Legal Framework

CIPO's examination policies for antibody claims are governed almost exclusively by a series of decisions of the Commissioner of Patents, rendered by the Patent Appeal Board (PAB), which CIPO considers to be precedential.

For many years, examination practices were constrained by a 1995 decision of the Commissioner of Patents in *Re Institut Pasteur*, in which claims to monoclonal antibodies and hybridomas secreting them were refused because neither had been made.[1] The decision hinged on statements from an academic textbook, taken somewhat out of context, indicating that if production was straightforward then the field of immunology would have produced "all kinds of cures". *Pasteur* was then applied as a static policy for many years to reject any claim covering a monoclonal (or more specialized) antibody that had not been made.

It was not until 2008 that the PAB acknowledged that the precedential value of the *Pasteur* decision had diminished in view of advances in the state of the art.[2] In 2009, claims to non-exemplified chimeric antibodies were allowed by the PAB in an application that described a corresponding murine monoclonal antibody for which a biological deposit had been made.[3] The PAB accepted that the skilled person could start with the deposited hybridoma and carry out the necessary genetic manipulation.

1 *Institut Pasteur Patent Application, Re* (1995), 76 CPR (3d) 206 (PAB) [*Pasteur*].
2 *Central Sydney Area Health Service Patent Appn No 605,669, Re* (2008), Commissioner's Decision 1283 (PAB).
3 *Sloan-Kettering Institute for Cancer Research Patent Appn No 2,072,017, Re* (2009), 82 CPR (4th) 33 (PAB).

In 2010, the PAB allowed claims to monoclonal antibodies defined by reference to an epitope sequence, even though the antibodies had not been made.[4] The PAB stated that:[5]

> … the skilled person would appreciate that monoclonal antibodies can be adequately described based on a combination of a structural description of the antigen, functional identity between the antibody and antigen, and knowledge of predictable production methods.

Examination practices for humanized antibodies remained unchanged until 2016, when the above rationale for monoclonal antibodies was extended by the PAB.[6] The subject application described the production of murine monoclonal antibodies specific for human glypican-3 by immunization with a specific peptide, the sequence of which was disclosed. Two murine antibodies demonstrated high binding affinity, with additional data supporting utility in the treatment of liver and lung cancer. Notably, the sequences of these antibodies were not provided in the application, though a biological deposit had been made. The PAB allowed claims to the humanized antibodies, acknowledging both the fully characterized antigen and the straightforward production methods. In rendering its decision, the PAB was explicit that its previous decisions were fact-specific and were not intended to impose rigid rules for examination. The PAB explained:[7]

> The evolution of [common general knowledge] is an important factor for assessing whether the disclosure in this case is sufficient to enable a person skilled in the art to practice the invention as claimed without displaying inventive ingenuity or undertaking undue experimentation as of the relevant date.

Following the decision, examination practices became much more adaptive to the facts of a given application, and CIPO's *Manual of Patent Office Practice (MOPOP)* was updated to include revised guidelines.[8]

4 *Re Immunex Corporation Patent Application No 583,988* (2011), 89 CPR (4th) 34 (PAB) [*Immunex*].
5 *Immunex* at para 67.
6 *Re Chugai Seiyaku and Kabushiki Kaisha Patent Application No 2,451,493* (2016), Commissioner's Decision 1398 *[Chugai]*.
7 *Chugai* at para 36.
8 Canadian Intellectual Property Office, *Manual of Patent Office Practice*, (Ottawa: Innovation, Science and Economic Development Canada, 2019) s 23.07 *[MOPOP]*.

7.3 Patentability Requirements for Antibodies

7.3.1. Disclosure and Enablement

Claims to antibodies must be supported by a specification that describes and enables the claimed invention as of the filing date of an application. *MOPOP* provides a non-exhaustive list of factors to be considered when determining whether or not claims to antibodies are enabled:[9]

- whether the Applicant actually prepared [an antibody];
- where [an antibody] had not been prepared;
  - whether the target antigen to which the [antibody] specifically binds was fully characterized,
  - the availability and/or ease of production of the antigen,
  - whether there is an absence of any indications that the Applicant was unable to produce [an antibody] or that one of skill in the art would be unable to reproducibly make [an antibody] to the target antigen, or
  - whether there is an absence of any indications that undue experimentation or undue adaption of known core steps would be necessary for preparing [an antibody].
- whether the scope of [an antibody] claim in respect to the antigen is appropriate.

A list of factors is also provided for determining whether or not a specification provides a correct and full description:[10]

- whether there was a full characterization of the target antigen to which [the antibody] specifically binds;
- if not, whether the Applicant actually prepared [the antibody] and provided a full characterization thereof;
- if not, whether the Applicant prepared [an antibody] and deposited a hybridoma which produces the antibody, in accordance with the *Patent Rules*, on or before the filing date of the application…; and
- whether the scope of an antibody claim with respect to the antigen is appropriate.

The specification need not set out a detailed procedure for producing an antibody provided that the core steps are well known to one of ordinary skill in the art, such that the claimed antibodies could be produced at the filing date

9 *MOPOP*, s 23.07.02a; (the list is provided in a section concerning monoclonal antibodies, but is later referenced for the assessment of other antibody sub-types).
10 *MOPOP*, s 23.07.02a.

without undue experimentation or inventive ingenuity. Such a description may be required if there was technical difficulty in producing the antibody. Each application is to be considered on its merits.

CIPO's approach considers ongoing change in the state of the art. The availability of claims to non-exemplified antibodies of a particular sub-type, directed to a defined target sequence, will therefore depend on the routineness of their production. In a 2016 training presentation, CIPO indicated that production methods for murine monoclonal, human, and humanized antibodies became routine in 1992, 2000, and 2002, respectively, with applications having filing dates prior to these dates to be considered on a case-by-case basis.[11] As new antibody-based technologies develop, it may fall to Applicants to establish when production methods for more specialized subclasses became routine, bearing in mind that such arguments may also impact inventiveness (see 7.3.2).

7.3.2. Novelty and Inventiveness

If an antigen is known or obvious at the filing date, then claims to a general class of antibodies reactive with that antigen will also be considered obvious if production methods were routine at that time.[12] The same will be said if the prior art discloses antibodies directed to a structurally related target, such that they cross-react with the claimed antigen.[13]

Claims to specific antibodies are usually available in these circumstances, provided that the antibody is adequately distinguished by sequence, by reference to a specific hybridoma or by an activity that is adequately different from that of foregoing antibodies.[14] A non-obvious difference is sufficient; a linked "technical effect" is not a general requirement. Accordingly, CIPO has adopted what has been termed a "structural non-obviousness approach". In practice, this means that claims to antibodies having novel complementarity determining region (CDR) sequences are held to be inventive over a prior disclosure of a general class, or another specific antibody directed to the same epitope.

7.3.3. Utility

A "mere scintilla" of utility is required under Canadian law.[15] In many cases, the utility of an antibody directed to a particular target will be self-evident.

11 Anik Marquis, "*MOPOP* Chapter 17 – antibodies" (2016) at 5 [*Marquis*].
12 *MOPOP*, s 23.07.
13 *MOPOP*, s 23.07.
14 *MOPOP*, s 23.07.02b.
15 *MOPOP*, s 23.07.05.

7.4 Antibodies Defined By Sequence

Antibodies can be claimed by sequence; for example, by reference to CDR sequences, variable heavy (V_H) and variable light (V_L) chain sequences or complete sequences. Given the lack of excess claim fees in Canada, Applicants should always consider including additional claims that *specifically* cover *each* commercial embodiment separately. Such claims may provide advantages with respect to enforcement.

As a matter of policy, CIPO does not accept claims encompassing sequence variation in CDRs.[16] Accordingly, CIPO does not permit claims to recite a percent identity to reference CDR sequences, claims that define only a subset of the CDRs or claims that cover CDR combinations that have not been tested. Sequence variation outside of the CDRs is much less contentious and is therefore easier to claim in the absence of working examples.

CIPO's view is that CDR sequences are critical to the formation of an active binding site and that even minor changes to these sequences could vastly impact this activity.[17] A claim defining an antibody by sequence must therefore minimally define a complete set of intact CDR sequences, with no possibility of sequence modifications, additions or deletions. What constitutes a "complete" set is determined according to the type of antibody. Accordingly, it is understood that single domain antibodies (sdAbs), such as shark and camelid sdAbs, need only define three CDRs.

Even when an application describes different antibodies having similar CDR sequences, it is typical for Applicants to be restricted to the precise scope of the tested variants. Claims specifying a percent identity based on observed variation are not permitted.

This remains CIPO's position even when the claims specify an exact binding activity. Accordingly, this is one area of antibody examination policy that has not kept pace with scientific understanding. Examiners often rely on a 1982 publication by Rudikoff *et al*. to support this position.[18] However, it is well established that CDR mutations can be tolerated.[19] CIPO's policy is also difficult to reconcile with its much more flexible treatment of antibody fragments, humanized variants, and antibodies defined by competitive binding, all of which entail testing following modification. The policy stands in stark contrast to

16 *MOPOP*, s 23.07.
17 *MOPOP*, s 23.07.
18 S Rudikoff et al., "Kappa Chain Joining Segments and Structural Diversity of Antibody Combining Sites" (1980) 77:7 PNAS at 4270.
19 G Boocock, "Antibody Examination Practice at the Canadian Patent Office: Immune to Change?" (2013) 29:2 Canadian Intellectual Property Reporter 225 (see section 3.1.1).

CIPO's treatment of enzymes, and proteins more generally, claims to which are routinely allowed to encompass sequence variation when accompanied by an appropriate functional qualifier.

Despite this, Applicants can most often achieve protection for variants by including claims to antibodies defined by competitive binding (see 7.7.2).

7.5 Antibody Fragments and Multivalent Constructs

Claims to various types of antibody fragments and multivalent constructs, including those that are engineered, are generally permitted provided that the fragments or constructs comprise a complete paratope, and provided that the paratope is adequately defined.[20]

Where a "fragment" is not one of established class, it is usually required that a functional qualification be recited in the claim, such as an indication that the fragment retains "the same binding activity" as the parent molecule from which it is derived. Phrases such as "*substantially* the same binding activity" are usually objected to as indefinite on a policy basis.

Claims to subunits that do not comprise a complete paratope typically garner objections for over breadth or lack of utility. This practice usually extends to nucleic acid molecules encoding an individual V_H or V_L chain.

7.6 Antibodies Defined By Reference to a Biological Deposit

Antibodies may be defined by reference to a biological deposit, *e.g.*, for a hybridoma cell line that secretes it.[21]

However, if sequences of the antibody produced by a deposited cell line are not disclosed in an application, it is generally not permissible to claim specific sequences of the antibody or nucleic acid molecules that encode them. *MOPOP* states that "a deposit of biological material is not a substitute for a full and correct description".[22]

That said, it is possible to claim a humanized version of a non-human monoclonal antibody defined by reference to biological deposit, even if the antibody has not been sequenced.[23]

20 *MOPOP*, s 23.07.03.
21 *MOPOP*, s 23.07.02c.
22 *MOPOP*, s 23.07.02c.
23 *Chugai* at para 43.

The relative simplicity of sequencing compared to humanization is apparently not considered.

7.7 Antibodies Defined By Functional Features

7.7.1. Epitope Binding

If a novel epitope is fully described in an application, CIPO will generally accept claims to various antibody sub-types defined by binding to the epitope in circumstances in which production methods were considered to be routine at the time of filing. This includes polyclonal, monoclonal, chimeric, humanized and fully human antibodies.

It is often required that the binding to the epitope be qualified as “specific” in the claims to avoid reading on non-specific antisera.

Claims involving discontinuous or conformational epitopes may pose initial challenges during examination but can usually be obtained if it can be shown that the identified residues meaningfully define the epitope.

7.7.2. Competitive Binding

Claims to antibodies that compete with an exemplified reference antibody for binding to a target protein or epitope are generally accepted. In these claims, CIPO considers that the epitope is meaningfully defined by a combination of the structure of the target molecule, specific binding activity of the reference antibody, and routine methods through which antibodies can be raised to the former and screened for the latter.

This claim format has several advantages. First, it notionally covers antibodies comprising modifications in CDR sequences, which are otherwise difficult to claim (see 7.4). The format may provide protection for an epitope, even when its precise location within a target antigen is not known at the time of filing. Thus, it provides a means for protecting antibodies to conformational epitopes when detailed mapping has not yet taken place. It may also provide a way to protect epitopes comprising post-translational modifications.

CIPO will usually require the reference antibody to be defined quite exactly. As this parameter is merely part of a set of test conditions, such features are generally not unduly limiting to the competing antibodies themselves. The reference antibody may be defined by sequence, though CIPO also permits the

reference antibody to be one produced by a deposited cell line, even when the latter antibody has not been sequenced.[24]

7.7.3. Affinity, Specificity and Other Functional Properties

If a particular antigen is known or antibodies to the antigen have been previously raised, claims to specific antibodies directed to the same target may still be available if they can be distinguished by a functional property, such as affinity, specificity, potency, or some other characteristic variable.[25] Such claims will typically garner greater scrutiny of support and enablement requirements.

7.8 New Methods Of Production, Libraries, And Constructs

For inventions relating to new methods of production, to antibody libraries, and to constructs comprising antibodies or portions thereof, it is often the case that the precise sequence details of a specific antibody are not at the point of invention and are therefore not part of the broadest claims. For example, the properties of a chimeric antigen receptor (CAR) construct having a novel architecture may not be tied to the specifics of the antibody paratope that it comprises.

Claims to such inventions may be objected to initially in Canadian examination if there is an initial misunderstanding as to the nature of the invention. Such objections may be influenced by CIPO's general preference for specific structural definitions for biopolymer claims, and its restrictive practice of requiring full and non-modified CDR sequences to be claimed when the invention lies in a novel antibody. Nevertheless, it is usually possible to secure claims commensurate with the scope of the invention if it can be clarified and explained that the specific sequence details of the antibodies used in experiments are not material to the broadest aspects of invention. Fortunately, the flexibility of Canadian examination provides Applicants with the opportunity to make their case without significant risk of a Final Action.

24 *MOPOP*, s 23.07.02c.
25 *MOPOP*, s 23.07.

7.9 Methods Of Use, Uses, Kits And Commercial Packages

Claims may also be obtained for methods, uses, kits, and commercial packages involving application of the antibody (with the exception of methods directed to medical treatments). Usually, these claims will indicate the associated assay, diagnosis, or treatment. Claims to second indication uses may also be available. Kit and commercial package-type claims may provide coverage of tangible items for second indication inventions and may be easier to enforce than method or use claims.

7.10 Claim Formats

When an invention lies in a novel antibody or epitope, there are a number of ways to claim antibodies:

a. *By defining the sequence of the antibody*

1. An anti-albumin antibody comprising:
   - a CDR1 consisting of the sequence according to SEQ ID NO:1,
   - a CDR2 consisting of the sequence according to SEQ ID NO:2,
   - a CDR3 consisting of the sequence according to SEQ ID NO:3,
   - a CDR4 consisting of the sequence according to SEQ ID NO:4,
   - a CDR5 consisting of the sequence according to SEQ ID NO:5, and
   - a CDR6 consisting of the sequence according to SEQ ID NO:6.
2. The anti-albumin antibody according to claim 1, comprising a heavy chain that is at least 90% identical to the sequence according to SEQ ID NO:7 and a light chain that is at least 90% identical to the according to SEQ ID NO:8.
3. The anti-albumin antibody according to claim 2, wherein the heavy chain comprises the sequence according to SEQ ID NO:7 and the light chain comprises the sequence according to SEQ ID NO:8.
4. The anti-albumin antibody according to claim 1, comprising the sequence of SEQ ID NO: 9.
5. A shark sdAb comprising:
   - CDR1 consisting of the sequence according to SEQ ID NO:10,
   - a CDR2 consisting of the sequence according to SEQ ID NO:11, and
   - a CDR3 consisting of the sequence according to SEQ ID NO:12,

b. *By specific binding to a novel epitope*

6. An antibody that specifically binds to an epitope in human serum albumin, wherein the epitope consists of SEQ ID NO: 13.
7. An antibody that specifically binds to human serum comprising SEQ ID NO: 14, wherein the antibody binds to a conformation epitope therein comprising residues at positions 12, 34, 56, 78, and 90, and does not comprise residues at positions 55 and 88.

c. *By further defining the antibody type*

8. The anti-albumin antibody according to any one of claims 1 to 4, 6, and 7, which is a monoclonal antibody.
9. The anti-albumin antibody according to any one of claims 1 to 4, 6, and 7, which is a bispecific antibody.
10. The anti-albumin antibody according to any one of claims 1 to 4, 6, and 7, which is a chimeric antibody.
11. The anti-albumin antibody according to any one of claims 1 to 4, 6, and 7, which is a humanized antibody.

d. *By defining a fragment comprising a complete paratope*

12. A fragment of the anti-albumin antibody as defined in any one of claims 1 to 4, 6, and 7, which comprises the same binding activity as the anti-albumin antibody.
13. An Fab fragment of the anti-albumin antibody as defined in any one of claims 1 to 4, 6, and 7.
14. An $F(ab')_2$ fragment of the anti-albumin antibody as defined any one of claims 1 to 4, 6, and 7.
15. A single-chain variable fragment (scFv) comprising:

    - a CDR1 consisting of the sequence according to SEQ ID NO:1,
    - a CDR2 consisting of the sequence according to SEQ ID NO:2,
    - a CDR3 consisting of the sequence according to SEQ ID NO:3,
    - a CDR4 consisting of the sequence according to SEQ ID NO:4,
    - a CDR5 consisting of the sequence according to SEQ ID NO:5, and
    - a CDR6 consisting of the sequence according to SEQ ID NO:6.

e. *By defining a construct comprising a complete paratope*

16. A chimeric antigen receptor (CAR) comprising the shark sdAB as defined in claim 5.

f. *By reference to hybridoma*

17. A murine anti-albumin monoclonal antibody produced by a cell line deposited with Authority X under Accession No. Y.
18. A humanized variant of the murine anti-albumin monoclonal antibody as defined in claim 17.

g. *By other functional properties*

19. The antibody of any one of claims 1 to 18, comprising an affinity of at least X and a specificity of at least Y.

d. *By competitive binding with a reference antibody*

20. An antibody that competes for specific binding to albumin with the anti-albumin antibody as defined in claim 1 or with the murine anti-albumin monoclonal antibody as defined in claim 17.

Chapter 8

Medical Treatments and Medical Uses

8.1 Overview

In Canada, the Courts have found that methods of medical treatment do not fall within the meaning of "invention" as set out in the *Patent Act*. As such, method claims reciting active steps of medical treatment are not permitted.

It is usually possible to obtain protection for medical treatment-related subject matter in the form of an appropriate "use" claim. New medical uses of known compounds, often referred to as "second medical use" or "second indication" claims, also constitute patent-eligible subject matter in Canada.

However, "use" claims limited by certain features can be problematic when those features are interpreted as transforming the claim into an impermissible method of medical treatment. Both Canadian law and examination policy in this area are nuanced and complex.

8.2 Background

8.2.1. Supreme Court Jurisprudence

Tennessee Eastman[1] is a landmark 1972 decision of the Supreme Court of Canada (SCC) with respect to the non-patentability of medical and surgical methods. This decision turned on former section 41(1) of the *Patent Act*, which established a general prohibition on patent claims to substances prepared or produced by chemical processes and intended for food or medicine. The method claims struck down by the SCC were presented in a format that attempted to circumvent this prohibition. This provision has long since been repealed, but the FCA subsequently accepted that *Tennessee Eastman* established that methods of medical treatment are non-patentable,[2] and the decision has subsequently been applied, interpreted and arguably expanded by lower courts and by CIPO.

In 2002, claims to a new use for a previously known compound were affirmed by the SCC in *Apotex v. Wellcome.*[3]

These two strands of SCC jurisprudence concerning methods of medical treatment and medical uses are in tension with one another.

The interpretation and application of legal precedent has led to contradictions in Canadian patent practice. Professor Norman Siebrasse has argued that excluding methods of medical treatment from patentability lacks a principled basis.[4]

1 *Tennessee Eastman Co et al v Commissioner of Patents*, [1974] SCR 11.
2 *Imperial Chemical Industries Ltd. v. Canada (Commissioner of Patents)*, [1986] 3 FC 40 (FCA) [*Imperial Chemical*].
3 *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77.
4 Norman Siebrasse, "A Rule Without a Principle: Patentability of Methods of Medical Treatment" (19 January 2015).

8.2.2. Jurisprudence Concerning Dosage Ranges vs. Fixed Dose Amounts

Subsequent decisions of the court have established a further distinction between use claims that require or prevent the exercise of professional skill or judgement of a medical practitioner, and those that do not. The former have been held to be ineligible subject matter, and the latter eligible. The approach de-emphasizes claim category in favour of scrutiny of a claim's technical features. For example, medical use claims comprising a dosage range have been interpreted as impermissible methods of medical treatment, even when no method *per se* is claimed. In some cases, the Federal Court appears to have been influenced in its decision-making by a concern about inhibiting physicians from taking decisions in patient care, apparently overlooking the fact that if such decisions were actually available to physicians prior to the invention then the claim would be invalid for reason of anticipation or obviousness.

Medical "use" claims have been interpreted as *being* methods of medical treatment despite the fact that no method *per se* is claimed.

In the 2006 *Axcan* decision,[5] the Court was asked to consider invalidity allegations with respect to a patent claiming the use of 13 to 15 mg of Ursodiol per kg of the patient's weight per day, for the treatment of primary biliary cirrhosis. The Court held that a patent claim over a dosage range of a known drug for a known use is not a vendible product and, therefore, is not patentable. The Court stated at paragraph 46:

> It is up to the physician based on his or her knowledge of the patient's rate of metabolism and other factors to determine the appropriate daily dosage. I cannot, for a moment, contemplate that Axcan could claim exclusive property in the dosage and sue a physician for prescribing Ursodiol for the treatment of PBC at a dosage less than 13 mg/kg/day or greater than 15 mg/kg/day.

Since the emphasis in the patent at issue was on the dosage range rather than on an actual dosage, the Court accepted the invalidity allegations.

Merck[6] stands in contrast to *Axcan*. Here, the Court upheld claims directed to a dosage form of alendronate monosodium trihydrate. The claim was for tablets with a strict dosing regime and the "how and when" of administration were not part of the patent. The Court found that the claims covered a vendible product and *not* a patent ineligible method of medical treatment.

5 *Axcan Pharma Inc. v. Pharmascience Inc.*, 2006 FC 527.
6 *Merck & Co. Inc. v. Apotex Inc.*, 2005 FC 755.

In the decision of the FC in *Janssen*,[7] the claims covered a use of galantamine to treat Alzheimer's disease in a specific titration regimen. In this case, galantamine was a known compound that had been previously used to treat Alzheimer's disease and was to be provided to Alzheimer's subjects in lower dosages with an advantageous effect. The claims were held to be directed to a method of medical treatment. The Court stated at paragraph 26:

> … a patent claim over a method of medical treatment that, by its nature, covers an area for which a physician's skill or judgment is expected to be exercised is not patentable in Canada. This would include the administration of a drug whereby the physician, while relying upon the dosage advice of the patentee, would still be expected to be alert and responsive to a patient's profile and to the patient's reaction to the compound.

The Court stated at paragraph 52:

> By attempting to monopolize an effective titration regimen for galantamine, the '950 Patent interferes with the ability of physicians to exercise their judgment in the administration of generic versions of the drug. This is because, absent a license from Janssen, any physician attempting to administer a generic version of galantamine to treat Alzheimer's disease by the method claimed by the '950 Patent would infringe.

In another *Merck* case,[8] the patent claimed the use of 1.0 mg of the drug for the treatment of male baldness, which the Court construed as a daily dosage. The claims were held to be directed to a vendible product and not a method of medical treatment. At paragraph 114, the Court stated:

> … a distinction must be made between claims that rely upon the skill and judgment of a medical practitioner and those that deal with a vendible product, be it a scalpel, X-ray machine or 1 mg tablet that are to be used or prescribed for use by such practitioner. In the present case, we have a 1.0 mg tablet taken as a daily dose. No skill or judgment is brought to bear. It is a vendible product and not a method of medical treatment.

7 *Janssen Inc. v. Mylan Pharmaceuticals ULC*, 2010 FC 1123.
8 *Merck & Co. v. Pharmascience Inc.*, 2010 FC 510.

More recent court decisions have generally followed the distinction set by earlier cases between claims involving dosage or timing ranges and those that do not.[9] At times, the approach has been quite nuanced, such that it was not apparent that a claim did or did not involve a timing range until specific terms within the claims were construed by the Court in light of expert evidence.[10]

8.2.3. Other Decisions Concerning Subject Matter Eligibility of Method Claims

Other decisions from the Patent Appeal Board (PAB) and the Federal Court have established specific guidance as to whether or not a claimed method is or is not a method of medical treatment. These determinations have been highly fact dependent. From a practical perspective, the importance of some of these distinctions has diminished in view of the availability of "use" claims and in view of subsequent policy developments at CIPO (see 8.4).

Select decisions are briefly summarized below:

- In *Re Application of Revici*,[11] methods of eliminating the desire for tobacco involving the administration of a specific compound to the body held to be non-patentable by the PAB, which reasoned that any substance used for modifying organic functions in humans or animals was a medicine in the broad sense, and thus any method involving manipulation of organic function constituted a medical treatment.
- In *Imperial Chemical Industries*,[12] claims directed to a method of cleaning dental plaque from teeth were held to be non-patentable because the leading function of the invention was medical given the widespread incidence of dental diseases in the population.
- In *Commissioner's Decision #1086*,[13] a method of surgically implanting a device into a uterus to occlude the oviduct was held to be non-patentable because the skill of a medical practitioner was required.
- *Commissioner's Decision #1108*[14] concerned claims involving a method of passing blood from an individual through an extracorporeal device for the removal of pathogens. The PAB found that the claims were directed to patentable diagnostic and extracorporeal method rather than to a therapeutic method.

9 See *Sanofi-Aventis Canada Inc. v. Hospira Healthcare Corp.*, 2009 FC 1077 [*Sanofi-Aventis*]; *Novartis Pharmaceuticals Canada Inc. v. Cobalt Pharmaceuticals Company*, 2014 FCA 17; *Abbott Laboratories (Bermuda) Ltd., Re*, 2014 FC 1251 [*Abbott*].
10 See *Sanofi-Aventis*; *Abbott*.
11 *Application of Revici, Re* (now Patent No. 1,134,748) (1981), 71 CPR (2d) 285 (PAB).
12 *Imperial Chemical Industries v. Canada (Commissioner of Patents)* (1986), 9 CPR (3d) 289 (FCA).
13 *Patent Appn No 329,163* (1986), Commissioner's Decision 1086.
14 *Patent Appn No 319,105* (1987), Commissioner's Decision 1108.

- *Commissioner's Decision #1114*[15] concerned a method of increasing skin cell turnover through the application of various formulations to the skin. The PAB reasoned that the method dealt with living tissue and was designed to improve the capacity of the body by treating it to produce new cells at an improved rate, and was therefore primarily a method of medical treatment
- The *Goldenberg* application[16] concerned a method of locating a tumour through parenteral administration of antibodies into the body. The PAB concluded that the use of radio-labelled antibodies as tumour markers would not have a therapeutic effect. Therefore, the claims were not directed to a method of medical treatment in the strict sense and were allowed.
- In the 1988 decision of *Wayne State*,[17] the claims were directed to the use of a known compound for an inventive purpose: reducing tumour cell metastasis. In view of Supreme Court jurisprudence concerning the general patent eligibility of inventions involving new uses, the PAB found "use" claim format should be allowed. The claims issued in the Wayne State patent also included commercial package claims comprising the compound of interest together with instructions for use in the specified treatment. This claim format has been accepted ever since.
- In the *General Hospital Corp*. decision,[18] the PAB concluded that methods of preventing pregnancy are not methods of medical treatment in the strict sense because pregnancy is not a disease.
- In the *Senenteck* decision,[19] the PAB allowed claims directed to a method of treating skin cells to reduce the effects of aging, accepting the argument that aging is a natural condition of the human body, not a disease.

8.3 CIPO's Practice Notices

In 2015, CIPO released a Practice Notice providing guidance to its examiners for the assessment of medical "use" claims.[20] The Practice Notice applied CIPO's then-contemporaneous "problem and solution" approach to identify the "essential elements" (as CIPO understands the term) of a claim. Under the 2015 Practice Notice, medical "use" claims were divided into those that addressed the problem of "what" to use for treatment and those that addressed "how" a patient was to be treated. The former were generally considered to be

15 *Patent Appn No 347,547* (1988), Commissioner's Decision 1114.
16 *Patent of Goldenberg, Patent Appn, Re* (1988), 22 CPR (3d) 159 (PAB).
17 *Wayne State University Patent Appn, Re* (1988), 22 CPR (3d) 407 (PAB).
18 *General Hospital Corp Patent Appn No 532,566, Re* (1996), 74 CPR (3d) 544 (PAB).
19 *Senenteck plc, Re* (1997), 77 CPR (3d) 321 (PAB).
20 Canadian Intellectual Property Office, "Archived – Patent Notice: Revised Examination Practice Respecting Medical Uses – PN 2015-01" (March 18, 2015).

patentable, while the latter were said to improperly prevent, interfere with or require the professional skill of a physician.

Claims limited by dosage or timing ranges were said to be ineligible subject matter, while claims limited by discrete amounts were said to be eligible subject matter because no discretion was required. However, the 2015 Practice Notice also extended into areas that had never been formally tested by the courts, stating without any basis, *e.g,* that treatment of a new patient sub-population was inherently anticipated by prior treatment of a broader group encompassing the sub-population.[21]

Following the decision of the Federal Court in *Yves Choueifaty v. Canada (Attorney General)* 2020 FC 837,[22] which held that the problem and solution approach was incorrect, CIPO published new examination guidelines in November 2020 ("the 2020 guidelines") for computer-implemented inventions, medical diagnostic methods and medical use claims.[23]

The 2020 guidelines provide only one example scenario relevant to this area:

> *The specification describes the new use of compound X to treat peptic ulcers. The description also discloses a titration regime for determining the appropriate dosage of X for an individual patient. In this case, the titration regime is used to minimize side-effects and ensure patient tolerability to X. This requires monitoring by a physician to know when adjustments to the dosage are needed for each patient.*

Two example claims are provided:

1. *Use of compound X to treat peptic ulcers.*
2. *The use of claim 1, wherein X is for administration at a first dosage of 6 to 8 mg/day for a period of about 2 to 10 weeks, and a final dosage of 16 to 24 mg/day.*

Claim 1 is held to be eligible subject matter as follows:

> *… As none of the elements of the actual invention encompass a method of medical treatment or otherwise restrict, prevent, interfere with, or require the exercise of the professional skill and judgment of a medical professional, the subject-matter defined by the claim is patentable subject-matter*.

21 Canadian Intellectual Property Office, "Examples of purposive construction analysis of medical use claims for statutory subject-matter evaluation" (June 1, 2015),.
22 *Yves Choueifaty v. Canada (Attorney General)*, 2020 FC 837.
23 Canadian Intellectual Property Office, "Patentable Subject-Matter under the *Patent Act*" (November 3, 2020).

Claim 2 is held to be ineligible:

> *… Dependent claim 2 differs from claim 1 in that claim 2 includes an element that limits the use of X to a first dosage period covering a range of dosages, and a final dosage range. This amounts to a titration regime since the medical professional is expected to monitor individual patients and make adjustments to the dosage and/or dosage period. The subject-matter defined by the claim is not patentable subject-matter because this element restricts, prevents, interferes with, or requires the exercise of the professional skill and judgment of a medical professional.*

The unfavorable assessment of claim 2 contrasts with the 2015 guidelines, which held dependent claims to be eligible subject matter if the corresponding independent claim was eligible subject matter. At present, it is unclear if the teaching of the description factors into the above analysis and if a different conclusion could be reached in other circumstances.

Overall, the current 2020 examination guidelines are much less detailed and much less prescriptive than their 2015 counterpart guidelines as far as medical "use" claims are concerned.

During examination, Applicants may be required to amend claims reciting dosage or timing ranges to instead specify discrete values. Canada has no excess claims fees and a flexible basis for amendment, and it is therefore usually possible to include several parallel independent claims reciting different values.

8.4 Claim Formats

Three main types of "use" claims are available in Canada for inventions involving medicaments: the Canadian-type "use" claim (reciting "a use of X for treatment of Y"); the Swiss-type "use" claim (reciting "a use of X for preparation of a medicament for treatment of Y"); and the use-limited product claim (reciting "a compound X for use in treating Y"). The "commercial package" format (reciting "a commercial package comprising X and instructions for use in Y") is also available. These claim types are particularly useful in seeking patent protection for second medical indication claims to protect the use of known compounds for a new purpose, but they are also available for a first medical indication of a new compound.

Typically, claims to methods of medical treatment permitted in other jurisdictions, such as the U.S., can be converted to a "use" format for Canada. A method claim can usually be converted to one or more of the above claim

types, even if specific terms such as “use”, “commercial package” and “preparation of a medicament” are not explicitly stated in the application as filed. Timing of such amendments is relatively flexible.

Regardless of format, claims that broadly recite the use of a compound or composition for *any* therapeutic treatment will generally not be permitted. Such claims must be amended to recite a *particular* indication against which the compound or composition is to be used. This is the case regardless of whether the compound or composition is itself new or known. Functionally defined clinical indications, such as “a diseased caused by over-expression of gene Z” or “a condition associated with iron deficiency” can be problematic from the perspective of breadth and/or definiteness; CIPO tends to require precise definitions.

Conversion of claims into an acceptable format for Canada generally requires that all active and invasive steps be removed or else rephrased into more passive language. Unlike Europe, the mere fact that the claim is directed to a patentable category of subject matter is not enough in and of itself if other problematic claim features are present.

Strategies for converting claims may involve the following:

- Active steps from method claims may be placed into the past tense when converted to “use” format. For example, a step of “obtaining cells from a subject” prior to other action being taken would be viewed as invasive and may be restated as a use in relation to “cells *obtained* from a subject”.
- Therapeutic effects may be stated in a “for” clause, *e.g.*, “A use… *for* bone repair”, “A use… *for* promotion of clotting”.
- Methods involving a step of co-administration may be formulated as a use of two medicines, or of a combination.
- Methods involving sequential administration of drugs X and Y may require that the use be defined “for treatment of a subject *previously* treated with X” or “for use *prior to* Y”. The inclusion of active sequential steps is not permitted. When appropriate, Applicants should consider claiming both the use of drug Y for treatment of a patient who has *previously* received drug X, and also the use of drug X for treatment of a patient who is *later to receive* drug Y.
- Where a mode of administration is recited as a method step, such as “orally administering to a patient”, the corresponding “use” claim may state that the composition “is *orally administrable*”, that the composition “is *formulated for oral administration*” or simply that the composition “is *for oral administration*”.

Under CIPO's examination practices, claims including dosage ranges or timing ranges are usually not accepted. Applicants should consider adding claims reciting *discrete* dosage amounts and *specific* time intervals relevant to their commercial activities.

If an invention pertains primarily to a physical manipulation of a subject's body by a health care provider, seeking patent protection can be difficult, but may not be impossible. If a medical device is used in order to achieve a desired manipulation, there may be a way to claim a use of the device without use of active steps.

Exemplary claim types available in Canada are shown below, including "use" claims, use-limited product claims and commercial package claims.

a. *Swiss-type "use" claim:*
   - Use of compound X for preparation of a medicament for treatment of disease Y.

b. *Canadian- or German-type "use" claim:*
   - Use of compound X for treatment of disease Y.

c. *Use-limited product claim:*
   - A compound X for use in treatment of disease Y.
   - A composition comprising compound X, together with a pharmaceutically acceptable diluent or carrier, for use in treatment of disease Y.
   - A pharmaceutical composition in a dosage unit form suitable for oral or parenteral administration for reducing metastasis and neoplastic growth in a mammal, which comprises X in admixture with a suitable pharmaceutically acceptable diluent or carrier.

   (Adapted from claim 1 considered *Wayne State*.[33])

d. *Commercial package claim:*
   - A commercial package comprising compound X and instructions for use in treatment of disease Y.

Chapter 9

Medical Devices

9.1 Overview

Section 2 of the Canadian *Patent Act* defines "invention" as "any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement [therein]".[1] Medical devices *per se* generally fall within the category of "machine" and thus constitute patent-eligible subject matter. Medical devices may also figure as elements in other categories of invention, and the subject matter eligibility thereof depends on the requirements applicable to each such category. Accordingly, drafting claims to provide robust coverage for medical device technologies must take into account the subject matter eligibility requirements for the different categories of invention which involve medical devices.

9.2 Claiming Medical Devices

In general, the patent-eligibility of claims involving medical devices depends substantially on the extent to which a claim defines a prohibited category of invention. Prohibited categories and activities include methods of medical treatment, steps of surgery, and any claim requiring the exercise of professional skill or judgement. Though not necessarily considered patent-ineligible, medical device claims which incorporate an algorithm at the point of invention may also face subject matter eligibility issues, as outlined in Chapter 12.

In general, however, medical device claims directed to the device itself are regarded to be patent-eligible, including when defined for use for a medical or surgical purpose. Acceptable claims take the typical format, such as:

1. (eligible) A medical device comprising elements A, B, and C.
2. (eligible) A device for purpose X, the device comprising: elements A, B, and C.

In practical terms, the patent-eligibility of uses and methods that employ medical devices depends on the extent to which a claim includes an active treatment step or surgical step, or defines downstream therapeutic effects. As discussed in greater detail in Chapter 8, methods of medical treatment which "cure, prevent or ameliorate an ailment or pathological condition, or treat a physical abnormality or deformity such as by physiotherapy or surgery" are considered patent-ineligible.[2] However, the practical application of this prohibition is highly nuanced.

1 *Patent Act*, RSC 1985, c P-4, s 2.

2 See Canadian Intellectual Property Office, *Manual of Patent Office Practice*, (*MOPOP*), (Ottawa: Innovation, Science and Economic Development Canada, 2019) s. 23.03.01.

Subject matter is considered to be patent-ineligible when a claim defines a step of medical administration or surgical intervention, or defines a practical therapeutic benefit beyond the purpose specified by the word "for". The same considerations therefore apply when claiming methods of treatment and surgery using medical devices. For example, the Patent Appeal Board (PAB) of the Canadian Intellectual Property Office (CIPO) has concluded that a claimed method for delivering a *healing* substance to a targeted place in the gastrointestinal tract using a device is nevertheless directed to an ineligible method of medical treatment, due to the *therapeutic benefit* implied by the claim.[3]

Claims of the following formats may face challenges during examination for being directed to methods of medical treatment:

3. (ineligible) A method of treating a patient using a medical device X, the method comprising steps D, E, and F.
4. (ineligible) A use of a suturing device X for treating a patient having disease Y… comprising suturing an incision with the suturing device X…
5. (likely ineligible) A use of a drug pump device X for delivery of drug Y to a patient having disease Z, wherein the patient experiences an increase in circulating levels of the drug Y.

In the above example, claims 3 and 4 would be problematic due to the inclusion of active and/or invasive steps – this despite claim 4 being in a "use" format. Claim 5 would likely be problematic because it defines therapeutic effects beyond the purpose specified by the word "for".

Uses of a device are acceptable, however, when they define a medical or surgical purpose but do not include method steps:

6. (eligible) A use of a medical device X for surgical purpose Y, the device comprising elements A, B, and C.
7. (eligible) A use of a medical device X for treating a patient having disease Y, the medical device comprising elements A, B, and C.

Thus, for example, claim 5 could be rendered less problematic by removing active language and rephrasing this as a purpose:

8. (likely eligible) A use of drug pump device X for increasing circulating levels of drug Y of a patient having disease Z.

3 *Decision 1388* (August 5, 2015), Commissioner of Patents in the Canadian Patent Office.

Converting method claims to a suitable use format is a common requirement in Canada. Given the many nuances in this area, even use claims permitted in other jurisdictions may require significant adjustment for Canadian examination.

Conversion may not be necessary for methods involving medical devices for treating *non-pathological* conditions, including treating ageing, pregnancy, baldness, and wrinkles, which are not considered prohibited subject matter.[4] Similarly, claims that do not provide a practical therapeutic benefit including methods "of diagnosing a disease or medical condition, whether practiced *in vitro* or *in vivo*, of treating an animal solely to derive an economic benefit, or for achieving a cosmetic result" may be patent-eligible.[5] For example, the PAB concluded that the use of ophthalmic lenses for reducing or preventing progression of myopia was not a method of medical treatment for the reason that myopia is not a disease but rather a natural human condition.[6, 7] The PAB, citing the Federal Court,[8] found that such claims are directed to patent-eligible subject matter (see section 8.2.3 for other examples). Method claims may therefore be drafted as follows, or as a corresponding use form:

9. (eligible) A method of treating non-pathological condition Y using a medical device, the method comprising steps D, E, and F.
10. (eligible) A method of cosmetic/non-invasive procedure Y using a medical device, the method comprising steps D, E, and F.

Claims 9 and 10 would be eligible provided that none of steps D, E, and F is invasive or surgical in nature. Given the subtleties in this practice, and the fact that much remains formally untested in court, the inclusion of use claims should be considered as a best practice.

9.3 Regulatory Considerations

As discussed in greater detail in Chapter 13, a patent may be added to a Patent Register maintained by the Minister of Health if the patent contains a claim for an approved medicinal ingredient, a formulation containing the medicinal ingredient, a dosage form thereof, or a use thereof. Doing so may provide the patentee with certain advantages pursuant to the *Patented Medicines (Notice of Compliance) (PMNOC) Regulations*.

4 *MOPOP*, s 23.03.01.
5 *MOPOP*, s 23.03.01.
6 *Decision 1491* (August 5, 2019), Commissioner of Patents in the Canadian Patent Office.
7 *Decision 1493* (August 16, 2019), Commissioner of Patents in the Canadian Patent Office.
8 *Visx Incorporated v. Nidek Co.*, (1999) 181 FTR 22 (FC).

With respect to medical devices, however, Canadian courts have distinguished between "delivery systems" and "payloads":

> The attempts to define "claim for the use of the medicine itself" on the basis of whether the ingredients are mixed, or the presence of physical devices, all point to a more fundamental distinction between a delivery system and that which is delivered by that system. […] Does the patent protect the delivery system or does it protect the payload? […] If the patent protects the delivery system, then it does not contain a claim for the medicine itself, or the use of the medicine, even if it contains a reference to the medicine as payload.[9]

For example, a patent protecting a patch type medical device for transdermal administration of fentanyl was not eligible for listing on the Patent Register, as the patent contained no claim for the medicine itself.[10] A number of granted patents have been denied listing on, or have been removed from, the Patent Register, as the claims have been construed to be directed to delivery systems rather than the payloads themselves.[11, 12, 13, 14, 15] Accordingly, claims directed to a medical device that nevertheless recite an approved medicinal ingredient may not be eligible for listing on the Patent Register.

9 *GlaxoSmithKline Inc. v. Canada (Attorney General)*, 2005 FCA 197, at paras 42-44.
10 *Janssen-Ortho Inc. v. Canada (Minister of Health)* (2003), 229 FTR 268 confirmed by (2004) FCJ No. 242 (FCA), leave to appeal to the SCC denied, August 26, 2004.
11 *Novartis Pharmaceuticals Canada Inc. v Canada (Minister of Health)*, 2003 FCA 299.
12 *Procter & Gamble Pharmaceuticals Canada Inc. v Canada (Minister of Health)*, 2006 FC 411.
13 *GlaxoSmithKline Inc. v Canada (Attorney General)*, 2006 FCA 347.
14 *Abbott Laboratories Ltd. v Canada (Health)*, 2008 FC 919.
15 *Novartis Pharmaceuticals Canada Inc. v Canada (Attorney General)*, 2012 FC 836.

Chapter 10

Medical Diagnostics

10.1 Overview

Until recently, claims to diagnostic inventions were subjected to unfavourable examination policies of the Canadian Intellectual Property Office (CIPO). At the time of writing, CIPO has published new examination guidelines that appear to restore a more reasonable state of affairs for many inventions in this field.

10.2 History

In 2009, the Patent Appeal Board (PAB) rejected the Amazon One-Click application, and, in doing so, created a "form and substance" test for subject matter eligibility that focused on the discrete "contribution", *i.e.*, the subset of *individually* novel elements that remained after elements in the prior art were subtracted from the claims. This test was applied by CIPO not only to computer-implemented inventions, but also to inventions in the diagnostic realm. Diagnostic claims were routinely rejected when the contribution was deemed to be a correlation, which was said to be a patent ineligible mental step.

Ultimately, this approach was struck down in 2011 for inconsistencies with jurisprudence.[1]

In 2015, after significant delay, CIPO published a new "problem and solution" approach for the assessment of subject matter eligibility. This approach evaluated only the subset of claim features that provided the solution to a "problem", narrowly defined based on common general knowledge. The 2015 approach effectively subtracted prior art at the outset of the analysis. Though couched in the language of Supreme Court of Canada (SCC) jurisprudence for claims construction, the 2015 approach was very different. Once again, the approach was applied to both computer-implemented inventions and medical diagnostics.

For diagnostics, claims were held either to address a "data analysis problem" or a "data acquisition problem". When the former was identified, claims were routinely rejected as allegedly limited to a mere correlation. When the latter was identified, claims were interpreted as being limited to the step of measuring the analyte, and prior art objections inevitably ensued when the analyte was known.

The reason for parallel treatment of diagnostic and computer-related subject matter throughout the years is not entirely clear. However, the influence of the former on the latter parallels the impact of the United States Supreme Court decision concerning business methods in *Bilski v. Kappos*[2] on subsequent

1 *Amazon.com, Inc. v. Canada (Commissioner of Patents)*, 2011 FCA 328.

2 *Bilski v. Kappos*, 561 US 593 (2010).

decisions in the medical arts, such as *Mayo v. Prometheus*.[3] CIPO's briefing documents prepared for the government's Associate Deputy Minister of Innovation, Science and Economic Development Canada in 2018 described CIPO's approach as intermediate to that of the United States Patent and Trademark Office and the European Patent Office.[4] It is also notable that some CIPO policymakers expressed concerns about the impact of diagnostic patents on existing diagnostic tests within the health care system.[5]

In 2020, the Federal Court struck down the "problem and solution" approach and instructed CIPO to follow the SCC on claims construction.[6]

CIPO published new examination guidelines in November 2020 ("the 2020 guidelines") covering computer-implemented inventions, medical diagnostic methods and medical use claims.[7] While CIPO's latest approach again departs from jurisprudence, the new guidelines appear to signal a long-awaited and positive change to the treatment of diagnostic inventions during examination.

10.3 CIPO's 2020 Examination Guidelines

CIPO's new guidelines state that the "problem and solution" approach of 2015 should no longer be followed, and that claims should be construed in accordance with the principles set out by the SCC in *Free World Trust v. Électro Santé Inc.*[8] and *Whirlpool Corp. v. Camco Inc*.[9] In line with this, the guidelines acknowledge the importance of the intent of the inventor as to which elements of a claim are considered to be essential, and indicate that "all elements set out in a claim are presumed essential unless it is established otherwise or is contrary to the language used in the claim."

The guidelines place new emphasis on a statutory prohibition under subsection 27(8) of the *Patent Act*, which indicates that, "No patent shall be granted for any mere scientific principle or abstract theorem."

The guidelines also introduce the concept of an "actual invention", which is different to what is claimed:

> An element of a claimed invention that is identified as essential for establishing the fences of the monopoly under purposive

3 *Mayo v. Prometheus*, 566 US 66 (2012).
4 Innovation, Science and Economic Development Canada, "Background Information for Associate Deputy Minister David McGovern" (2018).
5 Borden Ladner Gervais LLP, "CIPO's Examination Guidelines for Medical Diagnostic Methods Turn Three" (2018).
6 *Yves Choueifaty v. Canada (Attorney General)*, 2020 FC 837.
7 Canadian Intellectual Property Office, "Patentable Subject-Matter under the *Patent Act*" (November 3, 2020) [*Patentable Subject Matter*, CIPO].
8 *Free World Trust v. Électro Santé Inc.*, 2000 SCC 66 [*Free World Trust*].
9 *Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67.

> construction is not necessarily part of the actual invention. For example, an element may be an essential element of a claim only because the applicant intended to limit the scope of the monopoly being claimed to less than what the applicant actually invented. An element may thus be an essential element of the claim because the applicant intended it to be essential even though it has no material effect on the working of the invention. Such an element would not form part of the actual invention because the fact that it has no material effect on the working of the invention means it does not cooperate with other elements of the claimed invention [emphasis added].[10]

Under the 2020 guidelines, it is CIPO's "actual invention" that must meet subject matter eligibility requirements. Accordingly, the claims are construed to determine essential elements, but only the subset of elements deemed to be part of the "actual invention" are assessed for subject matter eligibility.

This dichotomy could be seen to fit with jurisprudence insofar as a patentee is never required to claim its entire invention. However, the concept of an "actual invention" is not part of the SCC's purposive construction and is difficult to reconcile with the SCC's fundamental principle that the claims define the invention.

CIPO's scrutiny of the "actual invention" against subject matter eligibility requirements also strikes at the SCC's affirmation, in *Shell Oil*, that valid patent claims can be based on a patent ineligible abstract idea. In this regard, the SCC stated:

> A disembodied idea is not *per se* patentable. But it will be patentable if it has a method of practical application.[11]

It is also notable that the SCC test for essentiality is based on how substitution or omission of a claim element would affect the working of the invention:

> In some instances, the precise elements of the "fence" may be crucial or "essential" to the working of the invention as claimed; in others the inventor may contemplate, and the reader skilled in the art appreciate, that variants could easily be used or substituted without making any material difference to the working of the invention.[12]

10 *Patentable Subject-Matter*, CIPO.
11 *Shell Oil Co. v. Commissioner of Patents* (1982), 67 CPR (2d) 1 (SCC), at p 14.
12 *Free World Trust*.

According to the SCC, an element is essential if its substation or omission affects the working of the invention. In contrast to this, CIPO appears to contemplate essential elements that *do not* have a material effect on the invention.

10.4 Diagnostic Methods

Setting aside the questionable legal basis of the 2020 guidelines, their practical result appears to be favourable for diagnostic inventions. The new guidelines acknowledge that many diagnostic methods specify a physical step of testing or quantifying an analyte. The guidelines state that this element may cooperate with other features, including a correlation, to form a single "actual invention" that constitutes patentable subject matter. This contrasts markedly with CIPO's previous approach, which held such combinations to be non-cooperative aggregations.

Two example claims provided distinguish between a physical step of *measuring* an analyte (claim 1) and a step of merely *receiving information* about the analyte (claim 2):

1. A method of diagnosing whether a human subject is at risk for developing cancer, comprising:
   a. measuring the level of X in a biological sample from the subject; and
   b. comparing said level to the level of a non-cancerous reference sample, wherein an increase in the level of X relative to said reference indicates the subject is at risk for cancer.
2. A method of diagnosing whether a human subject is at risk for developing cancer, comprising:
   a. receiving a report summarizing the level of X in a sample from the subject; and
   b. comparing said level to the level of a non-cancerous reference sample, wherein an increase in the level of X relative to said reference indicates the subject is at risk for cancer.13

Claim 1 is said to relate to an "actual invention" that comprises a physical step that renders it patentable subject matter:

> It is apparent that in order to arrive at a diagnosis of cancer risk, the measuring element, comparing element and correlation element must cooperate together. Thus, the actual invention of claim 1 consists of a combination of all of these elements. Recognizing

13 Canadian Intellectual Property Office, "Examples of Patentable Subject-Matter" (November 3, 2020).

> that step a) is directed to physically measuring the level of X in the sample, this satisfies the physicality requirement and makes the subject-matter of the claim patentable subject-matter.

In contrast, the "receiving a report" step of claim 2 is said not to provide the required physicality, resulting in a lack of eligible subject matter:

> In order to arrive at the diagnosis in this claim, the receiving element, comparing element and correlation element cooperate together to form a single actual invention. In order to be found patentable, the actual invention must have physical existence or manifest a discernible physical effect or change. As none of the elements in the actual invention provide this physicality, the subject-matter of the claim is not patentable subject-matter.

On its face, the new approach appears to accept, as patentable subject matter, a diagnostics claim that certainly would have been objected to under previous practice.

It appears that claims to many diagnostics inventions would now meet CIPO's physicality requirement, and that many others could be amended to do so by making the step of collecting data overtly active and physical. That said, diagnostic inventions that rely on data from biological signals could continue to face challenges, depending on how the term "physical" is interpreted.

Much will be learned as CIPO examiners apply the new guidelines to various types of claims.

10.5 Personalized Medicine and Precision Medicine

Personalized medicine is the tailoring of medical decisions, practices, interventions, and products to an individual patient based on predicted response or risk. Precision medicine carries a similar meaning, but notionally prioritizes the decision making based on the *characteristics* of a patient over personalization *per se*. Both approaches aim to concentrate treatment on patients who are likely to benefit.

Personalized and precision medicine claims may be divided into two categories: (1) those that specify actual *treatment* and (2) those that focus on use for *decision making* prior to treatment.

The first category cannot be claimed as a "method" due to Canada's judicially created exception to the patentability of methods of medical treatment (see Chapter 8). However, such inventions may be amenable to protection in "use" format provided that nothing active beyond the "for treatment" clause is recited.

Claims in the second category are less problematic is this regard and may be amenable to presentation as methods that diagnose susceptibility to a particular treatment or invention or predict treatment outcome. Such claims should be carefully drafted to avoid language such as "obtaining a sample from a subject", and to instead refer to manipulation of a sample previously "obtained" from the subject.

At the time of writing, it is not entirely clear how CIPO intends to treat claims to personalized or precision "uses".

CIPO's 2015 examination guidelines contained an example claim covering a "use" of a therapeutic agent for treatment of a patient subgroup having a particular genotype. The "use" was said to be inherently anticipated because the patient subgroup was part of a larger group that had previously received the same therapeutic agent. The 2015 examination indicated, without supporting legal references or rationale, that such a claim would not qualify as a selection. The 2015 Practice Notice has now been archived. This point was not incorporated into CIPO's *MOPOP*, nor is it addressed in the 2020 examination guidelines.

10.6 Companion Diagnostics

A companion diagnostic is a diagnostic test to be used in combination with a therapeutic agent to determine its applicability to a specific individual and may be thought of as a special subset of personalized or precision medicine inventions.

Companion diagnostics are amenable to protection with medical "use" format claims (see Section 11.5). When it is important to have coverage for a vendible product comprising a combination of a pharmaceutical agent and a diagnostic, Applicants may also wish to consider the "kit" and "commercial package" formats, both of which may comprise diagnostic reagents and/or instructions for use as a second component.

10.7 Claim Formats

Sample claim formats are provided below.

a. *Diagnostic Methods*

- A method of diagnosing condition X comprising:
  - isolating DNA from a patient sample;
  - sequencing a single nucleotide polymorphism, SNP123; and
  - diagnosing condition X if an adenine is present at SNP123.

- A method of analyzing a tissue sample from a subject to diagnose cancer in the subject, the method comprising:
  - homogenizing a tissue sample in a suspension to produce a homogenate;
  - separating the homogenate into a soluble fraction from an insoluble fraction;
  - reacting the soluble fraction with antibody specific for an antigen; and
  - detecting specific binding of the antibody with the antigen;

wherein specific binding of the antibody to the antigen indicates the presence of a tumour expressing the antigen.

- A method of determining breast cancer tumour grade comprising:
  - extracting RNA from a tumour sample; and
  - performing array-based hybridization with said RNA to measure global gene expression,

wherein:

(a) increased expression of genes A1 and A2 relative to a normal control is indicative of a grade III tumour;

(b) increased expression of the gene A1 and unchanged or decreased expression of the gene A2 relative to said normal control is indicative of a grade II tumour; and

(c) unchanged or decreased expression of the genes A1 and A2 relative to said normal control is indicative of a grade I tumour.

b. Personalized/Precision Medicine – Decision making

- A method of predicting an adverse reaction to drug X comprising:
  - measuring the level of protein Y in a sample obtained from a subject;
  - comparing the level to a threshold value; and
  - determining that the patient is at risk of the adverse reaction if the measured level exceeds the threshold value.
- A use of a measurement of protein Y in a sample from a patient for determining if the patient is a candidate for treatment with drug X.

c. *Personalized/Precision Medical – Treatment*
   - A use of drug X for treatment of a patient comprising mutation Y in gene Z.
   - A use of drug X for preparation of a medicament for treatment of a patient comprising mutation Y in gene Z.
   - A drug X for use in treatment of a patient comprising mutation Y in gene Z.

d. *Companion Diagnostics: Kits and Commercial Packages*
   - A kit comprising drug X, together with reagents for detecting the quantity of protein Y in a sample urine.
   - A commercial package comprising drug X, together with instructions for treatment of a patient having mutation Y in cytochrome P450 reductase.

Chapter 11

Computer-Implemented Inventions

11.1 Introduction

In Canada, the patentability of computer-implemented inventions is determined substantiality based on the same principles as all inventions generally. Neither the governing legislation nor jurisprudence creates a specific exception for this category of invention. Thus, as with all inventions, in order to be patentable, a claimed computer-implemented invention must be not only novel and unobvious over the prior art, it must also be patent eligible, meaning that it falls within one of the so-called "statutory categories of invention" defined in the governing legislation – namely art, process, machine, manufacture, or composition of matter.[1] In the electrical and computer arts, methods of all kinds fall generally into the categories of art or process, devices fall generally into the category of machine, and computer-readable media fall within the category of manufacture.

There exists no legislative provision that excludes from patent eligibility any particular category of technology.[2] As such, the principles to be applied when making such a determination are agnostic with respect to technology type, at least in theory. In the case of inventions in the electrical and computer arts, how such principles are applied depends largely on whether the inventive contribution resides exclusively in data processing or information transformation, or instead requires interaction of physical agents and entities in order to produce the desired result.

11.2 Case Law

11.2.1 Basic Requirements

The *Patent Act* contains only a single provision that defines a categorical exclusion from patent eligibility, namely that "no patent shall be granted for any mere scientific principle or abstract theorem" ("the abstract ideas prohibition").[3] Thus, the courts have held that while a disembodied idea is not patent eligible, a practical method of application of the idea may be patent eligible.[4]

Canadian courts have found that calculations and mathematical formulae *per se* are encompassed by this prohibition, and that mental operations and processes,[5] plans or information transformations involving no change to underlying physical entities,[6] schemes or rules (including in relation to games)

1 *Patent Act*, RSC 1985, c P-4 ["*Patent Act*], s 2, *sv* "invention".
2 Including so called 'business methods': see *Re Amazon.com Inc.*, 2011 FCA 328 at para 60[*Amazon*].
3 *Patent Act*, s 27(8).
4 See *Shell Oil Co. v. Canada (Commissioner of Patents)*, [1982] 2 SCR 536 at para. 40.
5 See *Schlumberger Ltd. v. Canada (Patent Commissioner)*, [1982] 1 FC 845 at para 5. (FCC-AD) [*Schlumberger*]
6 See *Lawson v. Canada (Commissioner of Patents)* (1970), 62 CPR 101 at para 60 (Ex Ct) [*Lawson*].

involving a conventional use of known equipment[7] and computer programs *per se*[8] are not encompassed by the statutory categories.

The courts have held that, in general, subject matter is patent eligible if, when performed or employed, it involves some physical existence or manifestation of a discernible effect or change ("the physicality standard").[9] A computing device configured to perform an algorithm appears to meet this standard, since it has physical existence and the performance of an algorithm by it typically manifests a discernible effect or change in at least some physical state of matter. The courts have also held, however, that the performance of patent ineligible subject matter (*e.g.*, calculations and mathematical formulae) by computing devices does not render the subject matter patent eligible.[10] Much of the uncertainty in the treatment of computer-implemented inventions thus involves how the courts and the Canadian Patent Office have attempted to reconcile both of these principles, particularly in connection with subject matter where the inventive concept resides in an algorithm which resolves ultimately to calculations and mathematical formulae.

11.2.2 Purposive Construction

Part of this attempt has involved "purposive construction", a procedure required by the governing case law to be performed prior to all determinations of validity or infringement, including determinations as to whether or not claimed subject matter falls within one of the statutory categories of invention.

The "purposive construction" procedure was set forth by the Supreme Court of Canada (SCC) in the year 2000 companion cases of *Free World Trust c. Électro Santé Inc.*[11] and *Whirlpool Corp. v. Camco Inc.*[12] In these cases, the Court formulated a test (the *Free World Trust* test) for determining when subject matter not falling within the scope of a claim strictly construed would nevertheless be encompassed by the claim. The procedure involves a determination as to whether each claim element is to be regarded as "essential" or "non-essential". When a claim element is considered "essential", there is infringement only if the subject matter reads on the claim element as strictly interpreted. When a claim element is considered "non-essential", however, there may be infringement even if the subject matter constitutes a variant not encompassed by the claim element as strictly interpreted. To this end, the

7 See *Progressive Games Inc. v. Canada (Commissioner of Patents)* (1999), 3 CPR (4th) 517 (FCC-TD).
8 See *Apple Computer Inc. Mackintosh Computers Ltd.*, [1987] 1 FC 173 at para 97 (FCC-TD), aff'd [1988] 1 FC 673,(FCC-AD), aff'd [1990] 2 SCR 209.
9 See *Amazon* at para 71; *Lawson*, at para 29.
10 See *Schlumberger*.
11 *Free World Trust v. Électro Santé Inc.*, 2000 SCC 66 [*Free World Trust*].
12 *Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67.

Free World Trust test asks two questions: 1) whether it is clear based on a purposive construction of the words of the claim that the claim element at issue was clearly not intended to be essential, *i.e.*, that it was intended to be interpreted so as to include variants; and 2) whether a skilled person would have understood that the invention would have worked in the same way whether it used the claim element strictly construed or the allegedly infringing variant (in other words, the claim element is "functionally substitutable").

In view of an unfortunate usage by the SCC of "and" rather than "or" in the formulation of the *Free World Trust* test, and despite clarification by later court decisions,[13] the Canadian Patent Office interpreted the test in such a way as to conclude that a functionally substitutable claim element could be found non-essential, and omitted, even if such a conclusion would be clearly contrary to the objective intention of the Applicant.[14] On this basis, the Office formulated examination guidelines[15] designed to enable a finding that claimed subject matter is patent ineligible even if it meets the physicality standard when the inventive concept resides in the implemented algorithm. The former guidelines employed a problem-solution approach, asking what "problem" was addressed by the application, what "solution" was taught by the application, and by identifying as "essential" (within the framework of the *Free World Trust* test) only those claim elements required for that "solution", with the remaining elements being deemed "non-essential" and omitted. In practice, the former guidelines operated to isolate the inventive contribution from the claimed subject matter and assess only it against the statutory categories. In the case of inventions wherein the inventive contribution resided in an algorithm, the former guidelines typically resulted in the conclusion that the "problem" was not a "computer problem" when the computing device was used in a conventional way, that the "solution" therefore did not require the device, and that it was instead a disembodied algorithm, or idea, not falling within one of the statutory categories.[16]

The former guidelines were overruled by the Federal Court in the case of *Choueifaty v. Canada (Attorney General)* ("*Choueifaty*")[17] as contravening the

13 See *Bauer Hockey Corp. v. Easton Sports Canada Inc.*, 2010 FC 361 at para 144, aff'd 2011 FCA 83; and *Shire Canada Inc. v. Apotex Inc.*, 2016 FC 382 at paras 136-138.

14 See *IGT Patent Appn No 2,237,438* (2013), 2013 Carswell Nat 5532 (PAB).

15 These guidelines were published by the Patent Office in 2013 as Practice Notices identified as PN2013-02 and PN2013-03, on the website of the Patent Office at https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr03626.html (accessed February 9, 2021) and https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr03627.html (accessed February 9, 2021).

16 See Canadian Intellectual Property Office, *Manual of Patent Office Practice*, (Ottawa: Innovation, Science and Economic Development Canada, 2019), (*MOPOP*), s 12.02 [*MOPOP*] concerning the Office's guidelines intended to implement the *Free World Trust* test, and also *MOPOP* s 22 dealing with computer-implemented inventions.

17 In *Choueifaty v. Canada (Attorney General)*, 2020 FC 837 [*Choueifaty*].

governing jurisprudence. The claimed subject matter at issue related to a computer-implemented financial method involving processing data concerning groups of securities to maximize an anti-benchmark ratio for one of them. In particular, the Court held that the Canadian Patent Office's employment of a problem-solution analysis was in error, as well as the effect of the guidelines to find claim elements non-essential despite the Applicant's intention expressed or implicit in the text of the claims.[18]

While, as discussed below, the Canadian Patent Office subsequently issued replacement guidelines ("the 2020 guidelines"),[19] there is as yet case law which assesses their validity or otherwise provides guidance with respect to specific subject matter. It is reasonable to expect, however, that such replacement guidelines may be applied in such a way as to maintain at least some aspects of the former guidelines.

11.3 Patent Office Examination Guidelines

11.3.1 Generally

The *Manual of Patent Office Practice* ("*MOPOP*"), the Canadian Patent Office's primary examination guidelines document, sets forth the Office's position with respect to subject patent eligibility.[20] In view of the above-discussed overruling of the Office's previous examination guidelines with respect to the patent eligibility of computer-implemented inventions, the Office issued replacement guidelines[21] that have not yet been integrated into *MOPOP*.

The current examination guidelines (the Guidelines) acknowledge, in accordance with the *Free World Trust* test, that claim elements cannot be found non-essential contrary to the Applicant's intention as expressed or implicit in the text of the claims. They also repudiate the previous employment of any assessment of a "contribution" of a claim, or of a "technological solution to a technological problem", or of the use of the problem-solution approach in the identification of essential elements when applying the *Free World Trust* test.

Instead, the 2020 guidelines employ the concept of an "actual invention" consisting of either a single element or a combination of elements that provide

18 *Choueifaty* at paras 39-40.
19 Available on the Canadian Patent Office's website at https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr04860.html (accessed February 9, 2021).
20 Available at https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/h_wr00720.html (accessed February 9, 2021). The Office's guidelines with respect to 'purposive construction' and the *Free World Trust* test are set forth in *MOPOP*, s 12.02, and with respect to computer-implemented inventions are set forth in *MOPOP*, s 22.
21 See at footnote 19, *supra*

a solution to a problem. According to the Guidelines, in order to be both patent eligible and not fall within the above-noted abstract ideas prohibition, claimed subject matter must be limited to or narrower than an "actual invention" that meets the physicality standard and relates to the manual or productive arts.

The Guidelines emphasize that while a claim element may be essential in accordance with the *Free World Trust* test, inasmuch as such conclusion accords with the Applicant's intention, it may nevertheless have no material effect on the working of the "actual invention", as in the case of a superfluous limitation or "self-inflicted wound". In a footnote, the Guidelines assert that if a claim is broader than the "actual invention", then it would contravene a particular provision of the *Patent Act* generally asserted in connection with lack of clarity,[22] but also asserted in connection with exhaustive combinations where the claim exceeds the immediate and cooperating environment of the inventive contribution. The Guidelines seem to suggest, therefore, that where particular claim elements do not form an overall combination with remaining elements to produce new and unexpected results, then those particular claim elements may be found not to form a part of the "actual invention" and the claim would be indefinite as defining an exhaustive combination.

In connection specifically with computer-implemented inventions, the Guidelines assert that even if a computing device is an essential element in accordance with the *Free World Trust* test, it may not form a part of the "actual invention". In this connection, the Guidelines assert that if the computing device is used merely in a well-known manner to perform an algorithm, and such performance does not solve any problem in the functioning of the device, then the device and algorithm will not be regarded to form a single "actual invention" and the subject matter will be regarded to offend the abstract ideas prohibition.

The Guidelines present examples that provide a measure of clarification.[23] In particular, the examples seem to indicate that when a claim defines means or steps for data collection in the form of measurements of physical systems, and the collected data is processed by a computing device performing an algorithm, the combination will be regarded to be the "actual invention" and the subject matter patent eligible. Similarly, when a claim defines processing of received data by a computing device performing an algorithm and also defines performance of physical activity based on the processing results, the combination will likewise be regarded to be the "actual invention" and the subject matter patent eligible. The examples emphasize, however, that

22 *Patent Act*, s 27(4).

23 The examples are presented on the Canadian Patent Office's website at https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr04861.html (accessed February 9, 2021).

conventional data receiving means or steps, or conventional output means or steps (such as a displaying step), would be regarded not to form a part of the "actual invention", and thus a claim defining performance of an algorithm by a computing device with only conventional data receiving and output or display steps would be regarded to offend the abstract ideas prohibition.

The Guidelines indicate, however, that when the performance of an algorithm by a computing device solves a problem in the functioning of the device, the algorithm-device combination will be regarded to be the "actual invention", as opposed to the algorithm alone, and thus constitute patent eligible subject matter. A further example provided in the Guidelines indicates that where a new algorithm requires fewer instructions than known methods, such that the performance of the algorithm requires less processing power, the performance of the algorithm will be regarded to solve a problem in the functioning of the computing device, which will therefore form a part of the "actual invention", and hence the performance of the algorithm by the computing device will be regarded to constitute patent eligible subject matter even if only conventional data receiving and output or display steps are involved.

At the time of writing, only a single decision of the Commissioner of Patents has been issued that elaborates or provides insight as to how the Office intends to apply the replacement Guidelines in practice. In the *Choueifaty* appeal mentioned above, the Court, having overruled the previous examination guidelines, remanded the appeal back to the Commissioner. In its reconsideration, the Patent Appeal Board (PAB) and Commissioner accepted evidence that the claimed algorithm permitted the desired optimization to be performed with significantly less processing and greater speed than by a different algorithm. On this basis, it concluded that the algorithm thereby improved the functioning of the computer used to run it, and consequently the computer and algorithm together formed a single "actual invention" falling within the patent eligible "statutory categories" of invention. While the PAB's decision does not exceed the particular facts of the case, it is noteworthy that the invention concerned a financial data processing method, and the claims regarded to be patent eligible recited only conventional data receiving steps, and no output or display steps.

It is expected that further elaboration of the principles set forth in the replacement Guidelines will follow in the coming months as further appeals of final rejections by patent examiners are adjudicated by the Commissioner of Patents.

11.3.2 Special Topics

MOPOP sets forth the Canadian Patent Office's position with respect to subject matter patent eligibility in connection with a number of special topics.

11.3.2.1 Graphical User Interfaces

Specifically, the Office takes the position that a graphical user interface (GUI) is an arrangement of visual elements for display on a screen constituting information having purely intellectual or aesthetic significance which does not constitute patent eligible subject matter, and thus claims to GUIs *per se* or of a computer-readable medium providing the GUI are typically found to be patent ineligible. A GUI integrated in a combination with otherwise patent eligible subject matter may also be patent eligible, and thus a claim to a computing device configured with a GUI which interoperates with other functionality of the device to solve a problem related to computing function may be considered patent eligible.[24]

11.3.2.2 Data Structures and Databases

Similarly, the Office takes the position that a data structure or a database is a format for organizing and storing a collection of related data items to suit a specific purpose, and in isolation is an abstract idea or plan for organizing data items. As such, data structures and databases *per se,* as well as computer programs or computer-readable media implementing the same, are typically found to be patent ineligible. If a particular data structure or database solves a problem related to computing function, however, which improves performance or resource consumption, then a claim to a method, device or medium implementing a combination of the data structure and function may be patent eligible.[25]

11.3.2.3 Signals

The Office takes the position that electromagnetic and acoustic signals and waveforms *per se* are forms of energy despite requiring a physical medium for transmission, and consequently regard them to be patent ineligible subject matter. Moreover, the Office considers signals to be transitory in nature, and therefore regards claims that define a physical medium storing a signal or a waveform to be indefinite.[26]

24 *MOPOP*, s 22.09.01.
25 *MOPOP*, s 22.09.02, 22.09.03.
26 *MOPOP*, s 22.09.05.

Chapter 12

Living Matter (Life Forms)

12.1 Definition

The *Patent Act* does not provide a definition of lower or higher life forms, nor does it make a distinction between them. However, as will be considered in more detail below, the Patent Appeal Board and the Commissioner of Patents have arbitrarily distinguished between the two, providing patent Applicants with a general idea of what they consider to be patentable in Canada (lower life forms) and what is not (higher life forms).[1]

In the case of *Harvard College v. Canada (Commissioner of Patents)*,[2] the majority of the Supreme Court of Canada supported an arbitrary distinction concerning the patentability of lower and higher life forms, but called for legislative action in this matter:

> Though this Court is not faced with the issue of the patentability of lower life forms, it must nonetheless address the respondent's argument that the line between higher and lower life forms is indefensible. As discussed above, I am of the opinion that the unique concerns and issues raised by the patentability of plants and animals necessitate a parliamentary response. Only Parliament has the institutional competence to extend patent rights or another form of intellectual property protection to plants and animals and to attach appropriate conditions to the right that is granted. In the interim, I see no reason to alter the line drawn by the Patent Office. The distinction between lower and higher life forms, though not explicit in the Act, is nonetheless defensible on the basis of commonsense differences between the two. Perhaps more importantly, there appears to be a consensus that human life is not patentable; yet this distinction is also not explicit in the Act. If the line between lower and higher life forms is indefensible and arbitrary, so too is the line between human beings and other higher life forms.[3]

Almost 20 years later, this legislative action has not yet occurred.

12.2 Lower Life Forms

While there is currently no patent legislation in Canada that expressly sets out what constitutes a lower life form, the case law indicates that such life forms as microscopic algae, fungi, moulds, yeasts, bacteria, protozoa, and viruses

1 The boundary between living matter and non-living matter is explored in section 12.7.
2 *Harvard College v. Canada (Commissioner of Patents)*, 2002 SCC 76 [*Harvard College*].
3 *Harvard College*, at para 199. See also paras 202-206.

are patentable subject matter in Canada. The Patent Office defines "lower life" to include microscopic algae; unicellular fungi (including moulds and yeasts); bacteria; protozoa; viruses; transformed cell lines; hybridomas; and embryonic, pluripotent, and multipotent stem cells.[4] Naturally occurring isolated and purified microorganisms may be claimed, provided that they are distinct from the corresponding non-isolated, non-purified microorganisms found in nature. In this respect, Canadian court decisions are consistent with U.S. patent policy that organisms with markedly different characteristics from those found in nature are patentable subject matter. In addition, a microorganism that is the product of genetic engineering or some other alteration may also be patented, as may a cell line derived from a higher life form or hybridoma. All life form claims must, however, meet the statutory patentability criteria of novelty, inventiveness, and utility.

Diamond v. Chakrabarty[5] appears to have set the stage for the patentability of lower life forms in Canada as well as in the U.S. In this landmark decision, the majority of the U.S. Supreme Court held that genetically modified bacteria met the definition of a "manufacture" or a "composition of matter" set out in the U.S. *Patent Act*.[6] This decision was carefully considered by the Patent Appeal Board and Commissioner of Patents in *Re Application of Abitibi Co.*,[7] which held for the first time that lower life forms are patentable subject matter in Canada.

In *Re Application of Abitibi Co.*, the Board was asked to consider the patentability of claims directed to a microbial culture system consisting of five types of fungi, isolated from domestic sewage after acclimation to sulfite liquor. The culture was useful for digesting spent sulfite liquor from pulp plant effluent. Although the organisms had previously existed in nature, their modification through isolation and purification rendered the culture a patentable invention. This decision paved the way for patenting life forms such as microorganisms, algae, viruses, and cell lines, which are produced en masse and which possess measurable and uniform characteristics.

Single cells derived from higher life forms, such as from isolated cell lines and hybridomas, are also patentable in Canada. Claims to mammalian cell cultures were found allowable following the decision of the Commissioner of Patents in the case of *Re Application for Patent of Connaught Laboratories*.[8] That case

4 See Canadian Intellectual Property Office, *Manual of Patent Office Practice* (*MOPOP*), (Ottawa: Innovation, Science and Economic Development Canada, 2019), s 23.02.01.
5 *Diamond, Commissioner of Patents and Trademarks v. Chakrabarty*, 447 US 303 (1980) [*Diamond*].
6 *United States Code*, Title 35, "Patents".
7 *Re Application of Abitibi Co.* (1982), 62 CPR (2d) 81 (Patent Appeal Board and Commissioner of Patents).
8 *Re Application for Patent of Connaught Laboratories* (1982), 82 CPR (2d) 32 (Patent Appeal Board and Commissioner of Patents); now Patent No. 1,139,691.

dealt with claims to a bovine cell line useful in the production of insulin. After the examiner refused to allow claims to living matter, the Applicant appealed to the Patent Appeal Board. Largely on the basis of the previous decision in *Abitibi*, the Patent Appeal Board allowed claims to the cell line.

In *Re Application for Patent of Merck & Co. Inc.*,[9] the Applicant sought a patent for the use of encapsulated cells from a mouse cell line transformed with recombinant DNA, which secreted bovine growth hormone (BGH). These encapsulated transformed cells could then be implanted into cows to secrete BGH *in vivo*. The examiner rejected the claims as being directed toward a method of medical treatment, which is considered non-patentable subject matter in Canada. However, the Commissioner of Patents found that the use of the encapsulated cells led to a vendible product – specifically, extra milk from the cow – and, when the method claims were reworded to define a use, the claims were allowed.

12.3 Higher Life Forms

Historically, the Canadian Patent Office has refused all patent claims to higher life forms. The Patent Office position on higher life forms was confirmed by a majority decision of the Supreme Court of Canada,[10] reversing the Federal Court of Appeal decision on an oncomouse developed at Harvard.[11] The impact of this majority decision on patent Applicants has been softened by a subsequent Supreme Court majority decision (the *Monsanto v. Schmeiser*[12] decision; see below), which held that claims to chimeric genes and cells containing such chimeric genes were infringed by the grower of a plant comprising such chimeric genes or cells. This means that, in Canada, a patent Applicant may need to amend claims of a patent application to remove claims to higher life forms *per se* and, where possible, replace them with claims to genes, cells, methods of making or using the higher life form, or the like.

In the *Harvard Mouse* decision, both the Commissioner of Patents[13] and the Federal Court Trial Division[14] upheld the Patent Office examiner's position that higher life forms were not patentable. The patent application at issue contained claims to a transgenic non-human mammal, particularly a rodent such as a

9 *Re Application for Patent of Merck & Co. Inc.* (1992), 41 CPR (3d) 52 (Patent Appeal Board and Commissioner of Patents); now Patent No. 1,294,879.
10 *Harvard College.*
11 *President and Fellows of Harvard College v. Canada (Commissioner of Patents)* (2000), 223 FTR 320 (FCA) [*Harvard Mouse*].
12 *Monsanto Canada Inc. v. Schmeiser*, 2004 SCC 34 [*Monsanto*].
13 *Decision 1203* (August 4, 1995), Commissioner of Patents in the Canadian Patent Office, Patent Application No. 484,723; now Patent No. 1,341,442.
14 *President and Fellows of Harvard College v. Canada (Commissioner of Patents)* (1998), 146 FTR 279 (FC).

mouse, modified to contain an activated oncogene sequence. The application also contained claims to a process for producing the transgenic animal, to a transgenic cell culture and a process for producing it, to various plasmids bearing the oncogene, and to the use of the invention to test a material suspected of altering neoplastic development in a mammal. The Commissioner of Patents and the Federal Court Trial Division accepted all the claims except those directed to a non-human mammal. The Federal Court of Appeal[15] found that a non-human mammal is suitable subject matter for a patent and upheld the scope of the claims. This decision was reversed by the Supreme Court of Canada.

In a 5-4 decision, the Supreme Court of Canada held that claims to non-human higher life forms do not encompass patentable subject matter.[16] The Supreme Court looked to the U.S. Supreme Court *Diamond v. Chakrabarty*[17] decision for guidance in this matter. However, the majority of the Supreme Court chose to follow the reasoning of the *minority* of the U.S. Supreme Court in the *Diamond v. Chakrabarty* decision. According to the majority, an oncogenic mouse is not a "composition of matter" within the meaning of section 2 of the *Patent Act*, though the fertilized egg of such an animal is. In the dissent, the minority pointed out that, on this view, subject-matter patentability is lost between two successive stages of a transgenic mouse's genetically pre-programmed growth. In the minority's opinion, such a "disappearing subject-matter exception" finds no support in the statutory language.[18] It is noteworthy that interpretation of the relevant parts of the patent statutes at issue, which are identical in critical respects, is divergent between the U.S. and Canada.

12.4 Claims to Genes and to Cells Containing Such Genes in Higher Life Forms

In the Supreme Court of Canada *Harvard Mouse* decision, the Court held that higher life forms do not comprise patentable subject matter, but commented that the fertilized egg that gave rise to the higher life form was indeed patentable subject matter. This raised the following questions: (1) when does the patentable fertilized egg become an unpatentable higher life form; (2) how are patents containing claims to genes or cells to be construed; and (3) can such claims to genes or cells be enforced against makers, users, or

15 *Harvard Mouse.*
16 *Harvard College.*
17 *Diamond.*
18 Also, by extension, it seems that patentability can reappear when the organism produces fertilized eggs with the patentable attribute. Hence, patentability can appear and disappear in the course of an organism's life cycle without human intervention.

sellers of higher life forms comprising such genes or cells? Answers to the second and third questions appear to have been provided in the *Monsanto v. Schmeiser* Supreme Court decision.[19] In this 5-4 decision, the Court found Monsanto's Canadian Patent No. 1,313,830,[20] claiming chimeric genes[21] and cells[22] containing them (but not the plant containing them), to be valid and to be infringed by the defendant, Schmeiser, when he cultivated plants (canola, a type of oilseed rape) containing such genes and cells. Taken with the earlier Supreme Court *Harvard Mouse* decision, this means that patent Applicants cannot obtain claims to higher life forms, but can enforce claims to genes and cells against users of such genes and cells in higher life forms.

The majority held: "A purposive construction … recognizes that the invention will be practised in plants regenerated from the patented cells, whether the plants are located inside or outside a laboratory."[23]

The majority stated:

> This case is different from *Harvard Mouse*, where the patent refused was for a mammal. The Patent Commissioner, moreover, had allowed other claims, which were not at issue before the Court in that case, notably a plasmid and a somatic cell culture. The claims at issue in this case, for a gene and a cell, are somewhat analogous, suggesting that to find a gene and a cell to be patentable is in fact consistent with both the majority and the minority holdings in *Harvard Mouse*.
>
> Further, all members of the Court in *Harvard Mouse* noted *in obiter* that a fertilized, genetically altered oncomouse egg would be patentable subject matter, regardless of its ultimate anticipated development into a mouse (at paragraph 3, *per* Binnie J. for the minority; at paragraph 162, *per* Bastarache J. for the majority).[24]

19 *Monsanto.*

20 The types of claims in Monsanto's Patent No. 1,313,830 were classified as:
a. the chimeric gene, claims 1-7, that does not exist in nature and is constructed through human intervention of three components;
b. the cloning or expression vector, claims 8-14 (a vector is a DNA molecule into which another DNA segment has been integrated);
c. the plant transformation vector, claims 15-21, 52;
d. the glyphosate-resistant plant cell containing the chimeric gene, claims 22-28 and claims 43-51; and
e. the method for constructing a-d and, in the laboratory, regenerating a plant from the plant cell containing the chimeric gene, claims 29-42.

21 See note 42, below, for Claim 1 of Monsanto's Patent No. 1,313,830.

22 Claim 22 of Monsanto's Patent No. 1,313,830.

23 *Monsanto*, at para 19.

24 *Monsanto*, at paras 22-23.

Notably, the majority then stated:

> Whether or not patent protection for the gene and the cell extends to activities involving the plant is not relevant to the patent's validity. It relates only to the factual circumstances in which infringement will be found to have taken place.[25]

The majority looked at the finding of fact and found that it was clear on the findings of the trial judge that the appellants saved, planted, harvested, and sold the crop from plants containing the gene and plant cell patented by Monsanto. The majority then found that saving and planting seed, then harvesting and selling the resultant plants containing the patented cells and genes, appeared, on a commonsense view, to constitute "utilization" of the patented material for production and advantage, within the meaning of section 42 of the *Patent Act*.

After concluding that Schmeiser did not make or construct the invention (even though the genes and cells would have been reproduced as a result of Schmeiser's activities), the majority decision turned to a discussion of the law on use of an invention and considered whether Schmeiser used the invention. The majority commented:

> As a practical matter, inventors are normally deprived of the fruits of their invention and the full enjoyment of their monopoly when another person, without licence or permission, uses the invention to further a business interest.[26]

The majority further commented: "if there is a commercial benefit to be derived from the invention, a contextual analysis of section 42 indicates that it belongs to the patent holder."[27]

The majority indicated that the appellants did not provide sufficient evidence to rebut the presumption of use, pointing out that

> the appellants in this case actively cultivated canola containing the patented invention as part of their business operations. Mr. Schmeiser complained that the original plants came onto his land without his intervention. However, he did not at all explain why he sprayed Roundup to isolate the Roundup Ready plants he found on his land; why he then harvested the plants and segregated the seeds, saved them, and kept them for seed; why he next planted

25 *Monsanto*, at para 24.
26 *Monsanto*, at para 37.
27 *Monsanto*, at para 38.

> them; and why, through this husbandry, he ended up with 1030 acres of Roundup Ready Canola which would otherwise have cost him $15,000.[28]

The majority added:

> The issue is not the perhaps adventitious arrival of Roundup Ready on Mr. Schmeiser's land in 1998. What is at stake in this case is sowing and cultivation, which necessarily involves deliberate and careful activity on the part of the farmer. The appellants suggest that when a farmer such as Mr. Schmeiser actively cultivates a crop with particular properties through activities such as testing, isolating, treating, and planting the desired seed and tending the crops until harvest, the result is a crop which has merely "grown itself." Such a suggestion denies the realities of modern agriculture.[29]

To assist in determining the nature of "use" for the purpose of determining whether infringement occurred, the Court came up with seven propositions relating to use. These propositions are:

a. "Use" or "exploiter," in their ordinary dictionary meaning, denote utilization with a view to production or advantage.
b. The basic principle in determining whether the defendant has "used" a patented invention is whether the inventor has been deprived, in whole or in part, directly or indirectly, of the full enjoyment of the monopoly conferred by the patent.
c. If there is a commercial benefit to be derived from the invention, it belongs to the patent holder.
d. It is no bar to a finding of infringement that the patented object or process is a part of or composes a broader unpatented structure or process, provided the patented invention is significant or important to the defendant's activities that involve the unpatented structure.
e. Possession of a patented object or an object incorporating a patented feature may constitute "use" of the object's stand-by or insurance utility and thus constitute infringement.
f. Possession, at least in commercial circumstances, raises a rebuttable presumption of "use."

28 *Monsanto*, at para 87.
29 *Monsanto*, at para 92.

g. While intention is generally irrelevant to determining whether there has been "use" and hence infringement, the absence of intention to employ or gain any advantage from the invention may be relevant to rebutting the presumption of use raised by possession.[30]

The majority also rejected the "innocent bystander" argument, stating:

> Invoking the concepts of implied licence and waiver, the appellants argue that this Court should grant an exemption from infringement to "innocent bystanders." The simple answer to this contention is that on the facts found by the trial judge, Mr. Schmeiser was not an innocent bystander; rather, he actively cultivated Roundup Ready Canola.[31]

12.5 Patent Office Practice as Manifested in the Manual of Patent Office Practice

The *Manual of Patent Office Practice (MOPOP)* sets out the current Patent Office practice relating to living matter.[32] The Patent Office indicates that unicellular life forms include microscopic algae, moulds and yeasts, bacteria, protozoa, viruses, cells in culture, transformed cell lines, and hybridomas and may be patentable if new, useful, and inventive. The Patent Office also indicates that higher life forms including animals, plants, seeds, mushrooms, fertilized eggs (see section 12.6), and totipotent stem cells (see section 12.6) are not patentable subject matter. A process for producing such a higher life form may be patentable provided the process requires significant technical intervention by man.

In office actions, examiners now routinely reject claims to tissues and organs as being directed to non-patentable subject matter. For example, the Patent Appeal Board, in Commissioner's Decision 1386, held that a claim to an *in vitro* tissue culture – claim 16 of Canadian Patent Application No. 2,705,008 – was directed to non-patentable subject matter:

> 16. An *in vitro* tissue culture comprising the cell according to any one of claims 1 to 6.

30 *Monsanto*, at para 58.
31 *Monsanto*, at para 95.
32 *MOPOP*, s 23.02.01.

The claim was considered to be directed to a higher life form, for claiming a plant tissue culture. On the other hand, when claiming an organ or tissue based on an inventive artificial scaffold, the patent Applicant likely has ground for argument, especially if the invention resides in the scaffold and its utility.[33]

12.6 The CIPO Notice of June 20, 2006

In this Patent Office Notice, entitled "Office Practice Regarding Fertilized Eggs, Stem Cells, Organs and Tissues," the Patent Office stated:

> The Patent Office takes the position that animals at any stage of development, from fertilized eggs on, are higher life forms and are thus *not* patentable subject matter under section 2 of the *Patent Act*. Totipotent stem cells, which have the same potential as fertilized eggs to develop into an entire animal, are considered to be equivalents of fertilized eggs and are thus higher life forms and are *not* patentable subject matter. [Emphasis added.]

This appears to conflict with the Supreme Court majority decision in the *Harvard Mouse* case on the possible patentability of fertilized eggs (and, by extension, totipotent stem cells). Patent Applicants may wish to consider avoiding drafting claims that encompass such subject matter unless it is of real importance to them and worth the expense of court action.

12.7 Equivalents to Organs or Tissues May Be Patentable

The Patent Office contemplated that some equivalents to organs and tissues may be patentable.[34] The issue of the boundary between organs and tissues and artificial "equivalents" came up in respect of L'Oréal's Patent Application No. 2,306,317.[35] In this case, the applicant claimed an aged dermis equivalent and an epidermis equivalent. The patent application relates to skin equivalents that can be used for the study of phenomena related to skin aging, such as wrinkling and photoaging. The invention avoids the ethical disadvantages of using real skin from natural sources. The Commissioner held that the components are made *in vitro*, and that everything claimed is the result of *in vitro* manipulations in a laboratory performed by scientists or technicians. The Commissioner stated:

33 *MOPOP*, s 23.02.01.

34 In section 23.02.02 of the *Manual of Patent Office Practice*, the Patent Office excludes tissues and organs unless the subject matter is an artificial organ-like or tissue-like structure, generated by technical intervention by combining various cellular and/or inert components.

35 *Decision 1312* (March 31, 2011), Commissioner of Patents in the Canadian Patent Office, Patent Application No. 2,306,317 [*Decision 1312*].

> Although claimed as "equivalents," we do not see that the subject matter should be interpreted to be something that is functionally equivalent to natural skin since none of the subject matter appears to be capable of doing things such as perspiring, secreting sebaceous material, providing for thermal regulation, or responding to environmental stimuli. The claimed subject matter is "equivalent" to natural skin or tissues, but only insofar as it meets the Applicant's very limited requirements.[36]

The Patent Office found that the material was anatomically different from and simpler than skin, stating:

> We find in the Applicant's favour based on the record as it currently stands. The claimed products are compositions of matter because they are made up of ingredients or substances that have been combined or mixed together by a person and because they are anatomically and functionally distinguishable from true tissues or organs.[37]

12.8 Production and Use of Higher Life Forms

Patent Office guidance, as set out in *MOPOP*,[38] is as follows:

> The patentability of a method or process is independent of whether or not the product of the method or process is statutory. Processes to produce higher life forms, organs or tissues are not, therefore, defective on the grounds that they produce non-statutory products.

Accordingly, a process, method, or use claim that involves significant human intervention in order to yield a higher life form may be patent eligible. The *Harvard Mouse* case is an example of this. Harvard's Canadian Patent No. 1,341,442 recites in claim 13:

> A method of producing a transgenic cell culture, comprising:
>
> (a) introducing an activated oncogene sequence into pluripotent cells of a mammalian embryo;
>
> (b) allowing said embryo to develop into an adult animal; and,
>
> (c) culturing somatic cells of said mammal.

Nevertheless, if the production of the higher life form involves (uninventive) traditional or natural techniques (*e.g.*, cross-breeding) then it may be considered

36 *Decision 1312*, at para 28.
37 *Decision 1312*, at para 30.
38 *MOPOP*, s 23.02.03.

by the Patent Office to be directed to patent ineligible subject matter. This was the case in Commissioner's Decision 1404 relating to Monsanto's Canadian Patent Application No. 2,436,203, claim 1 of which recites:

> Use of homozygote black seed coat soybean plants having genotype RRiiTT in separate, alternate rows in the same field as cultivars that have a genetically modified trait and that are not homozygote black seed coat soybean plants to produce a soybean seed mix.

The Board concluded that, despite reciting a use of higher life forms to produce a soybean seed mix, an essential element of the claim requires that different plant types be planted in different rows in close proximity to one another to ensure that the two types cross-pollinate. Since this is the case in traditional plant breeding, the claim was considered to be directed to patent ineligible subject matter. Therefore, the production and use of higher life forms is patentable *per se*, provided the claimed process itself has an inventive step.

12.9 Deposit of Biological Material

A deposit of biological material may be required to provide sufficient disclosure to enable one skilled in the art to practise the claimed invention. A deposit is required for inventions that cannot clearly convey in the written description the steps involved in making or constructing the biological material. However, reference to a deposit in a patent application does not create the presumption that it is *required* for sufficient disclosure.[39]

In *American Cyanamid Co. v. Charles E. Frosst & Co.*,[40] a validity attack was launched on the basis of insufficient disclosure for failure to provide a biological deposit. The patents involved pertained to two patented antibiotics – chlortetracycline and tetracycline – formed by microorganisms. The patents were attacked on the ground that neither disclosed where or how to obtain strains of microorganisms capable of producing the antibiotics. The validity attack failed. There was no evidence that by following the teachings of the patents and by examining the soil as instructed in the specification, one would not obtain an appropriate microorganism. Thus, if the description adequately allows one to obtain a microorganism, a deposit may not be necessary.

39 More information with respect to deposits of biological materials is found in Chapter 3, "Biotechnology-Specific Procedural Requirements", at section 3.2.

40 *American Cyanamid Co. v. Charles E. Frosst & Co.* (1965), 47 CPR 215 (Exchequer Court of Canada).

12.10 Claim Formats

A lower life form or isolated cell of a lower or higher life form can be claimed as a composition of matter by making reference to a deposit, by referring to a characterizing feature such as DNA or a plasmid, by a measurable property, or by a process for preparation. Claim clarity and claim support of this type of subject matter are commonly points of contention in patent prosecution and should be borne in mind in the drafting of patent applications. Process and use claims involving living matter may also be appropriate.

Patentable lower life forms and cells often contain heterologous genetic material or genetic material that is not foreign but that has been rearranged into a novel arrangement, such as modified genetic architecture. Claims to old cells in a new form, such as cells isolated from nature or in dry granules, are also possible.

Claims to methods of producing a higher life form or use of a higher life form may also be achievable (see section 12.8).

The following is a non-exhaustive list of examples of claims that are suitable to cover life forms, their production, and their use:[41]

a. *Composition of matter claim reciting deposit accession number*
   - Cell line A given accession number B at the International Depositary Authority (IDA) of Canada.
   - A microorganism having ATCC accession number 56789.
   - A culture of *E. coli* designated ATCC 45678.
   - A microorganism comprising all identifying characteristics[42] of (genus species) ATCC 12345.
   - Soybeans with a genotype that confers a heritable phenotype of seed stachyose content of less than 30 µmol/g, based on undried seed, said soybeans being non-viable as a result of mechanical processing, wherein said soybeans are obtained from a line comprising the homozygous stc1b mutant gene of LR484 having accession no. ATCC 75325.

     (Claim 1 of Canadian Patent No. 2,121,906 and subject of Commissioner's Decision 1313.)

b. *Composition of matter claim reciting genetic material contained within the cell*
   - A host cell comprising DNA according to SEQ ID NO:1.

41 See also the analysis of the Monsanto claim forms: Monsanto's Patent No. 1,313,830.
42 The identifying characteristics should be detailed in the description and may also be required in the claim.

- An *E. coli* bacterial strain transformed to express a polypeptide of 130,000MW having the immunological properties of the crystal protein of *Bacillus thuringensis*.
- A glyphosate-resistant plant cell comprising a chimeric plant gene of claim 1.[43]

(Claim 22 of Monsanto's Canadian Patent No. 1,313,830.)

c. *Composition of matter claim reciting a modified property or function of a cell*
   - A yeast cell having feature C.

d. *Composition of matter claim defining a cell by a process through which it is prepared*
   - A cell formed according to a process comprising steps D and E.

e. *Process claim for preparation of a cell*
   - A process for forming a cell comprising steps D and E.

f. *Process claim involving a cell*
   - A process for preparation of substance F comprising incubation of a cell according to claim 1 in the presence of substrate G.

g. *Use claim for treatment involving a cell*
   - Use of a cell according to claim 1 for treatment of condition H in a mammal.

h. *Use claim for preparation of a medicament for treatments involving a cell*
   - Use of a cell according to claim 1 for preparation of a medicament for treating condition H in a mammal.

43 Claim 1 of Monsanto's Patent No. 1,313,830 reads:
1. A chimeric plant gene which comprises:
(a) promoter sequence that functions in plant cells;
(b) coding sequence that causes the production of RNA, encoding a chloroplast transit peptide/5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) fusion polypeptide, which chloroplast transit peptide permits the fusion polypeptide to be imported into a chloroplast of a plant cell; and
(c) 3' non-translated region that encodes a polyadenylation signal which functions in plant cells to cause the addition of polyadenylate nucleotides to the 3' end of the RNA;
the promoter being heterologous with respect to the coding sequence and adapted to cause sufficient expression of the fusion polypeptide to enhance the glyphosate resistance of a plant cell transformed with the gene.

Exemplary higher life form claims from Harvard's Canadian Patent No. 1,341,442 and L'Oréal's Canadian Patent Application No. 2,306,317 are provided below.

i. *Process for preparing a cell culture*

- A method of producing a transgenic cell culture, comprising (a) introducing an activated oncogene sequence into pluripotent cells of a mammalian embryo; (b) allowing said embryo to develop into an adult animal; and (c) culturing somatic cells of said mammal.

  (Claim 13 of Harvard's Canadian Patent No. 1,341,442.)

j. *Cell culture*

- A somatic cell culture derived from a transgenic non-human mammal wherein the cells of said cell culture contain an activated oncogene sequence integrated into a chromosome.

  (Claim 19 of Harvard's Canadian Patent No. 1,341,442.)

k. *A method of producing a (higher) life form*

- A method of producing a transgenic mammal having an increased probability of developing neoplasms, said method comprising introducing into a mammal embryo an activated oncogene sequence.

  (Claim 14 of Harvard's Canadian Patent No. 1,341,442.)

l. *Use of a (higher) life form in testing*

- A method of testing a material suspected of being a carcinogen, comprising: exposing a transgenic non-human mammal to said material and detecting neoplasms as an indication of carcinogenicity; said transgenic non-human mammal being a transgenic non-human mammal whose germ cells and somatic cells contain an activated oncogene sequence introduced into said mammal, or an ancestor of said mammal, at an embryonic stage.

  (Claim 1 of Harvard's Canadian Patent No. 1,341,442.)

m. *An "equivalent" of an organ*

- An aged dermis equivalent comprising at least glycated collagen and fibroblasts, characterized by the fact that it presents a level of glycation between 2 and 30, said aged dermis equivalent being produced *in vitro*.

  (Claim 1 of L'Oréal's Canadian Application No. 2,306,317.)

- An epidermis equivalent comprising at least keratinocytes, characterized by the fact that it is obtained by seeding at least keratinocytes on a dermis equivalent as defined in any one of claims 1 to 7, said epidermis equivalent being produced *in vitro*.

  (Claim 8 of L'Oréal's Canadian Application No. 2,306,317.)

PART 3
Regulatory Issues

Chapter 13

Data Protection and the *Patented Medicines (Notice Of Compliance)* Regulations

13.1 Introduction

In Canada, the data protection regime in the *Food and Drug Regulations* (*FDR*) and the regime set out in the *Patented Medicines (Notice of Compliance) Regulations* (*NOC Regulations*) provide benefits to innovators in maintaining market share. The *NOC Regulations* have been amended to provide that proceedings that are commenced pursuant to these regulations are conducted as actions in Federal Court and no longer as applications with limited procedural capabilities. Proceeding in this way ensures that both parties have a right of appeal. The decisions with respect to infringement and validity are now made *in rem*. As a result, the burden on the Courts is reduced, as there is no longer dual litigation for the same patents and the same generic or biosimilar companies. Below is a brief overview of the relevant legislation and jurisprudence. These regimes apply to both small molecule and biologic drugs.

13.2 Data Protection

In Canada, the *FDR* provide data protection to "innovative drugs."[1] Innovative drugs are defined to be those that contain "a medicinal ingredient not previously approved in a drug … and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph.[2]

The Federal Court in *Epicept Corporation v. Minister of Health* found that the medicinal ingredient cannot have been approved previously in *any* drug and is not limited to those drugs that have received marketing authorization.[3] In Canada, marketing authorization is typically granted by way of a Notice of Compliance (NOC), which indicates that a drug is considered to be safe and effective. However, the Court has also found that a drug provided through the Special Access Program (SAP) has not been approved in Canada for the purposes of data protection.[4] The SAP allows Canadians to have emergency access to drugs that are not available for sale in Canada.[5]

When a drug meets the definition of an innovative drug, a subsequent manufacturer cannot file a submission seeking an NOC that makes a direct or indirect comparison to the innovative drug for six years after the day on which the first NOC is granted for the innovative drug. The Minister of Health (Minister) cannot issue an NOC to the subsequent manufacturer for eight years after

1 *Food and Drug Regulations*, SOR/2006-241, s C.08.004.1 [*FDR*]. This amendment was found to be *intra vires* the federal Parliament in *Canadian Generic Pharmaceutical Association et al v Minister of Health et al*, 2009 FC 725, aff'd 2010 FCA 334.

2 *FDR*, s C.08.004.1(1).

3 *Epicept Corporation v. Minister of Health*, 2010 FC 956.

4 *Teva Canada Limited v. Minister of Health et al*, 2011 FC 507.

5 *FDR*, ss C.08.010, C.08.011.

the day on which the first NOC is granted to the innovator. This period can be extended a further six months if the results of clinical trials relating to the use of the innovative drug in pediatric populations are provided to the Minister.[6]

This two-year period between when a subsequent manufacturer can file a submission and when it can receive an NOC is said to correspond to the time period required by the subsequent manufacturer to meet its obligations under the *NOC Regulations*, as described below.[7]

The Minister is required to maintain a Register of Innovative Drugs (Register).[8] The Federal Court has held that the Canadian Generic Pharmaceutical Association is not directly affected by a decision of the Minister to include a particular drug on the Register and therefore does not have standing to challenge the Minister's decision.[9]

There are exceptions to this period of data protection, such as if the drug is not being marketed in Canada,[10] or if the innovator consents to the filing of an Abbreviated New Drug Submission (ANDS) or the issuance of an NOC.[11]

It is important to consider, in addition to the data protection provision, the *NOC Regulations*, which tie the marketing approval of a generic or biosimilar product to patent issues, as discussed below.

13.3 *Patented Medicines (Notice of Compliance) Regulations* Generally

In recognition that the regulatory approval process under the *Food and Drugs Act* (*FDA*)[12] and *FDR* takes time, and to facilitate timely entry of generic drugs onto the market upon patent expiry, an "early working" exception to patent infringement is included in the *Patent Act*. The provision states:

> It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product.[13]

6 *FDR*, s C.08.004.1(3).
7 Regulatory Impact Analysis Statement, Regulations Amending the Food and Drug Regulations (Data Protection) (2006) C Gaz II, 1496.
8 *FDR*, s C.08.004(9).
9 *Canadian Generic Pharmaceutical Association v. Minister of Health et al.*, 2010 FC 1211, aff'd 2011 FC 465.
10 *FDR*, s C.08.004.1(5).
11 *FDR*, s C.08.004.1(6), (8).
12 *Food and Drugs Act*, RSC 1985, c F-27 [*FDA*].
13 *Patent Act*, RSC 1985, c P-4, s 55.2(1) [*Patent Act*].

The provision essentially permits a generic drug manufacturer to make, use, or sell a generic version of a patented drug prior to patent expiry, as long as the activities are *solely* related to the development and submission of information required to obtain regulatory approval of the product anywhere in the world.

The Governor in Council is authorized to make regulations to prevent infringement of pharmaceutical patents.[14] Accordingly, the *NOC Regulations* were established, coming into force on March 12, 1993.[15] These are commonly referred to as the "linkage" regulations because they create a link, for practical purposes, between the *Patent Act* and the marketing approval by Health Canada.

The *NOC Regulations* have been amended numerous times since they were implemented. Significant amendments came into force on September 21, 2017.[16]

In order to trigger the protection of the *NOC Regulations*, an innovator must list patents on the Patent Register in respect of their product, as set out below.

13.4 The Link Between Regulatory Approval and the Patent Register

Under the framework governing the approval of medicines, a pharmaceutical or biologic manufacturer must obtain regulatory approval from the Minister, in the form of an NOC, before a drug can be lawfully marketed and sold in Canada. Receiving approval from the Minister in Canada is akin to receiving Food and Drug Administration approval in the U.S.

Before an NOC will be issued, the drug in question must be shown to comply with prescribed regulatory standards pursuant to the *FDA* and the *FDR*.[17] Where a drug has not been marketed in Canada for a period of time sufficient to establish its safety and efficacy, it is considered a "new drug" and its manufacturer must file a New Drug Submission (NDS) as part of the regulatory process.[18] An NDS includes sufficient information to allow the Minister to assess the safety and effectiveness of the new drug, and the requirements are set out in the *FDR*.[19] A Supplementary NDS (SNDS) can also be filed, seeking approval for a change made to an approved drug, such as a change in the formulation or the addition of a new indication.

14 *Patent Act*, s 55.2(4).
15 *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, as amended by SOR/98-166, SOR/99-379, SOR/2006-242, SOR/2008-211, and SOR/2017-166 [*NOC Regulations*].
16 Regulations Amending the Patented (Notice of Compliance) Regulations, 2017 (2017) C Gaz II, 16.; Order Fixing September 21, 2017 as the Day on which the Act Comes into Force, other than Certain Provisions, (2017) C Gaz II, SI./2017-47.
17 *FDA*; *FDR*.
18 *FDR*, s C.08.002.
19 *FDR*, s C.08.002(2)-(3).

Much of the content of an NDS is typically regarded as confidential proprietary information. However, once an NOC has been granted with respect to a particular NDS, a request can be made for some of this information pursuant to the *Access to Information Act*.[20]

The *NOC Regulations* link generic and biosimilar regulatory approval to the clearance of hurdles with respect to certain types of patents. Essentially, in order for the Minister to issue an NOC, the generic or biosimilar filer must obtain a Court finding that they either will not infringe, or that the patent is invalid for certain types of patents.

The *NOC Regulations* set out the rights and obligations of what is termed a "First Person" and a "Second Person." These definitions generally correspond to an innovator and a generic or biosimilar manufacturer, respectively. For the purposes of the *NOC Regulations*, a "First Person" is defined to be the person who files the NDS or SNDS.[21] A "Second Person" is defined to be the person who files a submission that directly or indirectly compares its drug to another drug marketed in Canada.[22] In the context of a submission relating to a small molecule, the Second Person's submission is an ANDS or a Supplemental ANDS (SANDS). Submissions that relate to a biosimilar are typically referred to as a Biosimilar NDS.

13.4.1 Listing Patents with an NDS

The *NOC Regulations* provide a scheme whereby a First Person can submit to the Minister a patent list containing prescribed information about one or more patents relevant to a particular product for which it has filed an NDS or SNDS.[23] Certificates of supplementary protection (CSPs) are also eligible for listing on the Patent Register.[24]

Patents and CSPs meeting the eligibility and timing requirements set forth in the *NOC Regulations* discussed below will be added to a public Patent Register maintained by the Therapeutic Products Directorate under the Minister after an NOC has been issued.[25]

The Minister has discretion to add or delete patents and CSPs from the Patent Register.[26] However, the Minister cannot delete a patent or CSP from the Patent

20 *Access to Information Act*, RSC 1985, c A-1.
21 *NOC Regulations*, ss 2, 4(1).
22 *NOC Regulations*, ss 2, 5(1).
23 *NOC Regulations*, s 4(1).
24 *NOC Regulations*, ss 4(1.1), (3.1).
25 *NOC Regulations*, s 3(2); The Patent Register is found online at: https://pr-rdb.hc-sc.gc.ca/pr-rdb/index-eng.jsp
26 *NOC Regulations*, s 3(2).

Register while an appeal to the Federal Court of Appeal is pending.[27] Where a patent is listed on the Patent Register and the drug identification number (DIN) for the product to which it is related is subsequently cancelled, the Minister is required to remove the patent from the Register within 90 days of cancellation.[28] However, the patent will be re-added to the Patent Register if a new DIN is assigned for the same drug.[29]

The timing and eligibility requirements for listing a patent or CSP in relation to an NDS are set out in section 4 of the *NOC Regulations*.[30] A patent list must be filed at the same time that the NDS is filed.[31] If a relevant patent issues after the NDS is filed, and the patent application was filed before the NDS was filed, a patent list must be filed within 30 days of patent issuance.[32] These deadlines cannot be extended.

A patent can be added to the Patent Register in relation to an NDS if it contains:

a. a claim for the approved medicinal ingredient;
b. a claim for the approved formulation containing the medicinal ingredient;
c. a claim for the approved dosage form; or
d. a claim for the approved use(s) of the medicinal ingredient.[33]

The terms "claim for the dosage form", "claim for the formulation", "claim for the medicinal ingredient", and "claim for the use of the medicinal ingredient" are defined in the *NOC Regulations*.[34] As stated in section 4(2), the subject matter of the patent claim must have been approved through the issuance of a NOC. Thus, the claim must match the commercial product in order to be eligible for listing. In the context of determining whether use claims are eligible for listing, the Court has held that three questions should be considered with respect to a submission: (1) What use does the patent claim? (2) What is the use approved by the existing NOC? and (3) Is the use claimed by the patent approved by the existing NOC?[35]

The Court has determined that a patent that claims a formulation containing only one medicinal ingredient is not relevant for the purposes of listing in respect

27 *NOC Regulations*, s 3(2.1).
28 *NOC Regulations*, ss 3(3)-(4).
29 *NOC Regulations*, s 3(5).
30 *NOC Regulations*, s 4.
31 *NOC Regulations*, s 4(5).
32 *NOC Regulations*, s 4(6).
33 *NOC Regulations*, s 4(2).
34 *NOC Regulations*, s 2.
35 *Abbott Laboratories Limited v. Canada (Attorney General)*, 2008 FC 700 at para 4, aff'd 2008 FCA 354.

of a drug product that contains two medicinal ingredients.[36] Similarly, the Court has found that a dosage form for administering a formulation containing a sole medicinal ingredient is different to a dosage form for administering a formulation containing two medicinal ingredients. Accordingly, a patent containing claims to a dosage form containing one medicinal ingredient is not eligible for listing in respect of a dosage form containing two medicinal ingredients.[37]

Once a patent has been listed with an NDS, a First Person may carry forward the same list with an SNDS but is limited in the new patents that can be added with an SNDS, as set out below.[38] The Patentee is responsible for keeping the information on the Patent Register up to date.[39]

13.4.2 Listing Patents with an SNDS

A new patent list may only be submitted in respect of an SNDS if the SNDS relates to:

a. a change in formulation;
b. a change in dosage form; or
c. a change in use of the medicinal ingredient.[40]

Accordingly, a new patent or CSP cannot be listed with an SNDS for an administrative change, such as an update to a product monograph.[41] Further, it should be noted that patents or CSPs claiming a medicinal ingredient cannot be listed for the first time with an SNDS and must have been previously listed with the NDS.

There is a further requirement that in order for a patent or CSP to be listed on the Patent Register in connection with an SNDS, the patent or CSP must contain a claim relevant to the change for which approval is being sought.[42] In respect of an SNDS for a change in use, the Court has interpreted this to be a requirement that the claims of the patent claim "the very use" that was approved by the issuance of the NOC in response to the SNDS.[43]

36 *Bayer Inc. v. Minister of Health*, 2009 FC 1171 at para 68, aff'd 2010 FCA 161.
37 *Purdue Pharma v. Minister of Health*, 2010 FC 738; aff'd 2011 FCA 132.
38 *NOC Regulations*, s 4.1(2).
39 *NOC Regulations*, s 3(7).
40 *NOC Regulations*, s 4(3).
41 *Solvay Pharma Inc. v. Minister of Health*, 2009 FC 102.
42 *NOC Regulations*, s 4(3).
43 *Searle & Co et al v Minister of Health*, 2009 FCA 35 at para 45.

13.5 Generic and Biosimilar Submissions that Trigger the *NOC Regulations*

Where a generic or biosimilar manufacturer – a "Second Person" – seeks approval to market a version of an approved innovator drug, it must likewise make a submission to the Minister for approval. Where the Second Person can satisfy the Minister that its product is bioequivalent to a Canadian Reference Product for which an NOC has already issued, the Second Person may file an ANDS, comparing its product to the approved Canadian Reference Product and may rely on the safety and efficacy data generated by the First Person to obtain its own approval.[44] Where the Second Person's product is a biosimilar, it must file what is known as a Biosimilar NDS.[45] The company then engages in discussions with Health Canada as to the extent of testing required to show similarity.

The owner of a Canadian Reference Product cannot become involved in Health Canada's consideration of the ANDS or Biosimilar NDS. The Court has repeatedly denied standing to the owner of the Canadian Reference Product on the basis that the issues under the *FDR* do not affect the rights of the First Person provided by the *NOC Regulations*, and the First Person is therefore not directly affected.[46]

The *NOC Regulations* are triggered if a Second Person files a drug submission that "directly or indirectly compares the drug with, or makes reference to, another drug marketed in Canada under a notice of compliance" in respect of which a patent list has been submitted.[47]

Once an ANDS or a Biosimilar NDS has been submitted, a Second Person is not required to address any patents listed on the Patent Register by the First Person after the date the ANDS or Biosimilar NDS was filed.[48] This is commonly referred to as a "patent freeze."

The procedure that is triggered once a Second Person files an ANDS or a Biosimilar NDS is set out below.

44 *FDR*, s C.08.002.1.
45 *FDR*, s C.08.002.1.
46 *Merck Frosst Canada Inc v Canada (Minister of Health and Welfare)* (1998), 146 FTR 249 at paras 10-11 (FCTD), aff'd (1999), 169 FTR 320 (CA); *Reddy-Cheminor Inc v Minister of Health* (2001), 212 FTR 129 at para 46, aff'd 2002 FCA 179; *Aventis Pharma Inc v Minister of Health, 2005 FC 1396.*
47 *NOC Regulations*, s 5(1).
48 *NOC Regulations*, s 5(4).

13.6 Proceedings Under the *NOC Regulations*

13.6.1 Notice of Allegation

When a Second Person files an ANDS or a Biosimilar NDS comparing its proposed product to an approved innovator product in respect of which patents are listed on the Patent Register, the *NOC Regulations* are triggered to ensure that all patents on the Patent Register are addressed before an NOC is issued to the Second Person.

In its submission, a Second Person must address each patent listed on the Patent Register in connection with the approved innovator product. The Second Person may elect to wait until all relevant patents have expired before receiving its NOC or may make one or more allegations in respect of each of the patents, alleging that:

a. certain statements made by the First Person in listing the patent or CSP are false;
b. the patent or CSP is invalid;
c. the patent or CSP is ineligible for inclusion on the Patent Register;
d. no claim of the patent or CSP would be infringed by the Second Person if it received an NOC;
e. the patent or CSP has expired, or
f. in the case of a CSP, it cannot take effect.[49]

The Second Person must also prepare a Notice of Allegation (NOA), including a statement of the factual and legal basis for any allegation of non-infringement and/or invalidity made in respect of the listed patents.[50] The NOA must further contain a description of the medicinal ingredient, dosage form, strength, route of administration and use of the drug.[51]

Additionally, the following documents must accompany the NOA:

- Certificate by the Minister of Health of the date of filing of the ANDS or Biosimilar NDS;
- Address for service;
- Names and contact information for solicitors of record;
- Searchable electronic copy of any portions of the ANDS or Biosimilar NDS that are relevant to determining infringement; and
- Electronic copies of any documents used to allege the patent(s) at issue are invalid.[52]

49 *NOC Regulations*, ss 5(1)-(2).
50 *NOC Regulations*, s 5(3).
51 *NOC Regulations*, s 5(3)(b).
52 *NOC Regulations*, s 5(3)(c).

The Second Person must provide proof of service of these documents and the NOA to the Minister.[53]

The NOA can request the name and contact information for any inventor who might have information relevant to the invalidity allegations. The NOA can also request any laboratory notebooks, research reports or other documents relevant to determine whether a property, advantage or use asserted to be part of the invention by the Second Person to be part of the invention had been established as of the filing date of the patent.[54]

The Second Person must also provide to the First Person, without delay, any portion of the ANDS or Biosimilar NDS that is relevant to determining infringement that changes during the course of the proceeding.[55]

If the First Person is not the Patentee, as is usually the case, they must forward the NOA to the Patentee within five days of being served and notify the Second Person without delay.[56]

13.6.2 Action in the Federal Court

Once served with an NOA, the First Person has the option to do nothing or to commence legal proceedings under the *NOC Regulations*. The First Person must initiate the proceedings within 45 days of being served with an NOA.[57] This deadline cannot be extended. Thus, if a proceeding is not commenced within that time frame, the Minister is not prevented from issuing an NOC to the Second Person. Furthermore, if the First Person does not start a proceeding within that 45-day timeline, they are precluded from bringing an action in relation to that patent or CSP at a later date, unless there was no reasonable basis for bringing an action in response to the NOA.[58]

Once the NOC proceeding is commenced, a statutory stay is triggered that prevents the Minister from issuing an NOC to the Second Person for 24 months, or until the proceeding is withdrawn, dismissed, or concluded in favour of the Second Person, whichever is earlier.[59] In the event that the First Person is successful, an order of prohibition is granted, and the Minister is precluded from issuing an NOC to the Second Person until expiry of the patent.

If commenced, the proceeding is an action in the Federal Court. The First Person issues a Statement of Claim to commence the proceeding. Pleadings then proceed as they do in a typical action.

53 *NOC Regulations*, s 5(3)(e).
54 *NOC Regulations*, s 5(3.1).
55 *NOC Regulations*, s 5(3)(d).
56 *NOC Regulations*, ss 5(3.3)-(3.4).
57 *NOC Regulations*, s 6(1).
58 *NOC Regulations*, s 6.01.
59 *NOC Regulations*, s 7.

If inventor information and/or laboratory notebooks, etc., are requested, they must be served with the Statement of Claim or a reason provided as to why they can only be produced later.[60]

Pleadings set out the cause(s) of action and the relief sought, as well as any defences or counterclaims. The Statement of Claim and Statement of Defence are the main pleadings together with any Counterclaim and Defence to Counterclaim. Parties can file a Reply, but the Reply cannot raise a new cause of action. Pleadings tend to be substantive in nature and must set out all of the material facts upon which a party relies for each allegation. Law does not need to be pled, nor does evidence. The pleadings form the boundaries of both discovery and the issues at trial. Thus, sufficient detail is needed to ensure that a party knows the case they have to meet and can discover other parties in relation to that case.

The First Person cannot join a patent or CSP to the proceeding that was not the subject of the NOA that gave rise to the proceeding. However, the First Person can allege infringement of all claims in the patent or CSP that was listed on the Patent Register, even if not all claims are eligible for listing.

Case management is automatically assigned in an NOC Proceeding, typically within days after such a proceeding is started.[61] The Prothonotary (also known as a Case Management Judge) manages timelines to get to trial and hears most interlocutory motions.

As the stay of generic or biosimilar drug approval is 24 months, the Court has committed to issuing a decision within that period. Shortly after the Statement of Claim issues, the Court will assign a trial date that is two years, less three months and two weeks in the future. This gives two weeks for the trial and three months for the Court to write its decision. This decision decides patent infringement and/or validity *in rem*. Both parties have a right of appeal following the decision.

13.7 Other Considerations

13.7.1 Costs

Actions are subject to the general rules concerning costs.[62] Indeed, the *NOC Regulations* specifically allow a Court to make any order in respect of costs,

60 *NOC Regulations*, s 6.03(1).
61 *NOC Regulations*, s 6.1.
62 *Federal Courts Rules*, SOR/98-106, s 400.

including on a solicitor-and-client basis, and set out factors that can be considered by the Court in the costs award.[63]

The successful party will normally be entitled to recover its costs, although representing only a partial indemnity of actual costs incurred and reasonable disbursements from the unsuccessful party. Costs are typically awarded based on a tariff, although recent case law has occasionally awarded costs in the neighbourhood of 25 to 30% of actual costs incurred. Solicitor-and-client costs more closely approximate the costs associated with the litigation but require a demonstration that a party has engaged in reprehensible, scandalous, or outrageous conduct in order for the Court to make this award.[64]

13.7.2 Section 8 of the *NOC Regulations*

The *NOC Regulations* provide that, if an action is withdrawn or discontinued by the First Person; or is dismissed by the Court hearing the action; or if an order preventing the Minister from issuing an NOC is reversed on appeal, the First Person is liable to the Second Person for any loss suffered after the later of the day on which the NOA was served and the date on which an NOC would have been issued in the absence of the *NOC Regulations*.[65]

The *NOC Regulations* set out a cause of action permitting a Second Person to bring an action seeking compensation from the First Person for the loss.[66] However, the First Person is also permitted to waive the 24-month stay period.[67] This waiver would result in the Minister being permitted to issue a NOC to the Second Person when their submission is otherwise approvable and should also preclude a section 8 action for damages.

The Court has determined that in cases brought pursuant to the *NOC Regulations* that were in force in 1993, damages are available only if the proceeding delayed the issuance of an NOC beyond the expiry of the patent at issue.[68]

The Court has also determined that the Second Person must show on a balance of probabilities that it was prevented from entering the market because of the prohibition application. It must be shown on a balance of probabilities that the chance of making a profit was real.[69]

63 *NOC Regulations*, s 6.12.
64 *Baker v. Canada (Minister of Citizenship & Immigration)*, [1999] 2 SCR 817 at 864.
65 *NOC Regulations*, ss 8(1)-(2).
66 *NOC Regulations*, s 8(1).
67 *NOC Regulations*, s 7(5).
68 *Apotex Inc. v. Syntex Pharmaceuticals International Ltd*, 2009 FC 494, aff'd 2010 FCA 155.
69 *Eli Lilly & Co. v. Apotex Inc.*, 2009 FC 991 at para 762; *Apotex Inc. v Merck & Co. Inc.*, 2010 FC 287 at para 34.

The version of section 8 enacted in 1998 allows a Second Person to claim only damages or its lost profits, but not the profits of the First Person.[70] Further, for cases brought pursuant to the 1998 version of the provision, the Second Person's losses must be shown to have occurred within the period ending on the date of the withdrawal, discontinuance, dismissal or reversal. Claims for continuing loss of market share were not allowed.[71]

As of printing, no cases have been decided under the current version of the provision.

70 *Merck Frosst Canada Ltd. et al. v. Apotex Inc.*, 2009 FCA 187 at para 91 [*Merck Frosst*].
71 *Merck Frosst*, at para 102.

Chapter 14

Patented Medicine Prices Review Board

14.1 Overview

The Patented Medicine Prices Review Board ("the Board") is an independent quasi-judicial body established in 1987 under the *Patent Act*. Its mandate is to ensure that Patentees are not selling patented medicines at excessive prices in any Canadian market.

The Board has broad powers to compel Patentees to disclose pricing and other information.[1] The Board also has broad powers to order Patentees to reduce the prices of medicines, and to make payments to Her Majesty in right of Canada.[2] These orders may be made enforceable in the same manner as an order of the Federal Court.

Notably, the Board has no role with respect to the provincial and territorial reimbursement of the costs of patented medicines through public health insurance programs. Though beyond the scope of this chapter, these regimes warrant further investigation by stakeholders because they can vary significantly among provinces and may have an impact on prices charged for medicines.

New amended regulations are currently scheduled to come into effect on January 1, 2022. These amendments have been delayed several times as of the date of publication of this chapter. The *Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements*) ("Amended *Patented Medicines Regulations*") make a number of important changes to how excessive pricing will be evaluated and the reporting requirements for pharmaceutical patent companies.[3] These Amended *Patented Medicines Regulations* are not without controversy in the industry. Interested parties have launched legal challenges in the Federal Court of Canada and in the Québec Superior Court. These court challenges involve determining if the Amended *Patented Medicines Regulations* are beyond the scope of Cabinet to promulgate through regulations made pursuant to the *Patent Act* or are *ultra vires* the federal jurisdiction granted by section 91 of the *Constitution Act*. In June 2020, the Federal Court found that subsections 4(4) (a) and (b) of the Amended *Patented Medicines Regulations* were invalid and of no force or effect because they were *ultra vires* the *Patent Act*.[4] Similarly, in December 2020, the Québec Superior Court found that these subsections were unconstitutional.[5] Subsections 4(4) (a) and (b) require that a Patentee account for discounts and rebates provided to third parties in their price reporting to the Board. The Court

1 *Patent Act*, RSC 1985, c P-4, s 80 [*Patent Act*].
2 *Patent Act*, s 83.
3 *Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements)*, SOR/2019-298.
4 *Innovative Medicines Canada v. Canada (Attorney General)*, 2020 FC 725.
5 *Merck Canada inc. v. Procureur général du Canada*, 2020 QCCS 4541.

found the other amendments to the Amended *Patented Medicines Regulations* under review to be valid. These decisions are both under appeal as of the date of finalizing this chapter.

The Board is also establishing a *Guideline Monitoring and Evaluation Plan 2021* (GMEP) to analyze trends in the pharmaceutical market before and after the implementation of the new framework.[6] Stakeholders were invited to help shape the development of this plan, such as by commenting on the plan's outline. The GMEP is stated to be intended to assess whether the new framework is in fact working as intended and to identify the need for any future adjustments. The GMEP will focus on four specific areas:

a. the prices of medicines;
b. access to medicines;
c. the pharmaceutical ecosystem; and
d. the Board processes.

14.2 Jurisdiction of the Board

14.2.1 General Principles

In 2011, the Supreme Court of Canada signalled an expansive approach to interpreting the jurisdiction of the Board. In *Celgene Corp. v. Canada (Attorney General)*, the Patentee argued that the Board did not have jurisdiction on the ground that the medicine at issue was not "sold in any market in Canada." The medicine came into Canada through the special access program. Celgene argued that, according to commercial law principles, it was "sold" in New Jersey. In rejecting this argument, the Supreme Court instead adopted a broad interpretation that it held was in keeping with the overriding consumer protection goals of the statute. In so doing, it found that the medicine came within the Board's jurisdiction.[7]

14.2.2 Patents Must Pertain to a Medicine

The *Patent Act* provides that an invention "pertaining to a medicine" falls within the jurisdiction of the Board.[8] Pursuant to section 79(2), for the purposes of the pricing of medicines sections of the *Patent Act*, an invention pertains to a medicine if the invention is "intended or capable of being used for medicine or for the preparation or production of medicine."

6 Patented Medicine Prices Review Board, "Guideline Monitoring & Evaluation Plan 2021" (2021).
7 *Celgene Corp. v. Canada (Attorney General)*, 2011 SCC 1 [*Celgene*].
8 *Patent Act*, ss 80, 83.

"Medicine" is defined in the *Patent Act* as including a drug, as defined, and a medicinal ingredient.[9] "Drug" means a substance or a mixture of substances manufactured, sold or represented for use in (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals; or (b) restoring, correcting or modifying organic functions in human beings or animals.[10]

The Board has published a *Compendium of Policies, Guidelines and Procedures* ("the *Compendium*"), which includes further guidance with respect to the Board's interpretation of its jurisdiction. The *Compendium* remains in effect until the new *Patented Medicine Prices Review Board (PMPRB) Guidelines* take effect, presumably on January 1, 2022, concurrently with the Amended *Patented Medicines Regulations*.[11] These *PMPRB Guidelines* are non-binding and are intended to be reviewed in light of experiences and changing circumstances.[12] The validity of these new *PMPRB Guidelines* is also being challenged in the Federal Court.[13]

The *Compendium* currently provides a similar definition of a "medicine" as "any substance or mixture of substances made by any means — whether produced biologically, chemically, or otherwise — that is applied or administered *in vivo* in humans or in animals to aid in the diagnosis, treatment, mitigation, or prevention of disease, symptoms, disorders, or abnormal physical states, or in modifying organic functions in humans or animals, however administered."[14] The new *PMPRB Guidelines* reflect the updated definition of "medicine" based on the new definition of "drug" in the *Patent Act*:[15]

> "medicine" is defined in the Act as including a drug (*i.e.*, a substance or a mixture of substances manufactured, sold or represented for use in (i) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals; or (ii) restoring, correcting or modifying organic functions in human beings or animals) and a medicinal ingredient.[16]

Prior to the upcoming legislative amendments, the Federal Court of Appeal (FCA) had held that the word "medicine" must be interpreted broadly and in its

9 *Patent Act*, s 79(1).
10 *Patent Act*, s 104.
11 Patented Medicine Prices Review Board, "PMPRB Guidelines" (July 14, 2021), [*PMPRB Guidelines*].
12 *PMPRB Guidelines*, at paras 4-6.
13 *Innovative Medicines Canada et al. v. Canada* (Attorney General) (2020), Court File No. T-1419-20.
14 Patented Medicine Prices Review Board, "Compendium of Policies, Guidelines and Procedures" (February 2017) s B.3.
15 *Patent Act*, s 104.
16 *PMPRB Guidelines*, at para 18.

ordinary sense, and the updated statutory definition could allow this finding to be revisited in the future.[17]

In *ICN Pharmaceuticals*, the FCA set out a three-fold test to determine whether the Board had jurisdiction over patents pertaining to a medicine. This test is as follows:

a. the party must be a Patentee of an invention;
b. the Patentee's invention must pertain to a medicine; and
c. the Patentee must be selling the medicine in any market in Canada.

The FCA held that "[t]here need only be a slender thread of a connection between a patented invention and the medicine sold in Canada in order to satisfy the test for a nexus."[18] The FCA also clarified that (1) there is no requirement that the patent actually be used in the production of the medicine in order for jurisdiction to attach, and (2) the Board's jurisdiction extends not only to patents that contain product claims, but also to patents that contain "process" and "use" claims.[19]

The Board may also have jurisdiction over medicines that are not considered "medicines" pursuant to the *Patented Medicines (Notice of Compliance) Regulations* (*PMNOC Regulations*).[20] In *ICN Pharmaceuticals*, the FCA held that the *PMNOC Regulations* are a different regime, and that an interpretation under the *PMNOC Regulations* is irrelevant for the purposes of establishing the jurisdiction of the Board.[21]

In the same case, the FCA commented on a Patentee's failure to reveal to the Board the existence of a patent based on the Patentee's unilateral determination that it did not pertain to a medicine. The Court underscored the importance for Patentees to meet their reporting obligations by disclosing these patents.[22] The Board's view is that a Patentee should avoid making unilateral decisions on whether a patent pertains to a medicine and that the better practice is to disclose the existence of the patent to the Board on the basis that it does not in fact pertain to a medicine, and thus avoid the possibility of running afoul of the statutory obligations under the *Patent Act*.

17 *ICN Pharmaceuticals Inc. v. Canada (Staff of the Patented Medicine Prices Review Board)* (1996), 119 FTR 70 at para 51 (FCA) [*ICN Pharmaceuticals*].
18 *ICN Pharmaceuticals*, at para 60.
19 *ICN Pharmaceuticals*, at para 57.
20 *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 [as amended].
21 *ICN Pharmaceuticals*, at para 53.
22 *ICN Pharmaceuticals*, at para 78.

More recently, in *Galderma Canada*,[23] the FCA clarified that there is only one legal test of whether a patented invention pertains to a medicine, namely the test set out at subsection 79(2) of the *Patent Act*. Pursuant to section 79(2), an invention pertains to a medicine if the invention is intended or capable of being used for medicine or for the preparation or production of medicine. Whether there is the merest slender thread of a connection is a useful metaphor to express that the connection may be tenuous, but it is not the legal test.[24] Furthermore, the FCA held that the PMPRB must look at the entirety of the patent when considering this question.

14.2.3 Who Is a Patentee?

Section s. 79(1) of the *Patent Act* incudes a definition of "Patentee" which, in respect of an invention pertaining to a medicine, broadly encompasses all persons entitled to the benefit of the patent for that invention and includes any other person who is entitled to exercise any rights in relation to that patent. The Board has held that the definition of "Patentee" at section 79(1) of the *Patent Act* is broad enough to include a licence holder who has an exclusive licence to promote, market, and sell a medicine in Canada.[25] Newly amended section 79(1) also defines a "rights holder" as a Patentee and the person for the time being entitled to the benefit of a certificate of supplementary protection for that invention.[26]

14.2.4 Pending Patent Applications

The Federal Court has held that the Board does not have jurisdiction over pending patent applications.[27] However, once the patent has been granted, the Board has jurisdiction with respect to prices charged dating back to the filing date of the application. If the patent application never issues to grant, the Board will not have jurisdiction.

14.2.5 The Effect of Dedicating Patents to the Public

In the past, Patentees have attempted to circumvent the jurisdiction of the Board by dedicating their patents to the public.[28] Patentees argued that because they no longer receive exclusivity under a patent, they no longer

23 *Canada (Attorney General) v. Galderma Canada Inc.*, 2019 FCA 196 [*Galderma*].
24 *Galderma*, at paras 63-67.
25 *Patented Medicine Prices Review Board v. Ratiopharm Inc. (Re: ratio-Salbutamol HFA)* (2011), PMPRB-08-D3-ratio-Salbutamol HFA-Merits; See also *Hoechst Marion Roussel Canada Inc. v. Canada (Attorney General)*, 2005 FC 1552 [*Hoechst*].
26 *Patent Act*, s 79(1) [as amended].
27 *Hoechst*.
28 *Genentech Canada, Re* (1992), 44 CPR (3d) 316 (Canada Patent Medicine Prices Review Board); see also *ICN Pharmaceuticals*, at para 29.

fall within the jurisdiction of the Board. However, the *Patent Act* contains no express provisions for dedicating a patent to the public. A patent that is dedicated to the public remains in force until it becomes abandoned or lapses for the statutory reasons set out in the *Patent Act*. The Board has therefore held that it has jurisdiction where the patent is in force, regardless of whether it has been dedicated to the public.

14.3 Powers and Functions of the Board

The Board has two major mandates, namely investigation and reporting.

14.3.1 Investigative Functions and Research and Development

In determining excessive pricing under the *Patent Act*, the Board has the power to investigate sales and expense activities in Canada. It can order the Patentee or a former Patentee to furnish the Board with information and documents respecting the following:

a. identity of the medicine;
b. the price at which the medicine is being or has been sold in any market in Canada or elsewhere;
c. the costs of making and marketing the medicine, if that information is available to the rights holder or is within the knowledge or control of the rights holder;
d. the factors referred to in section 85 of the *Patent Act*; and
e. any other related matters.[29]

The *Patented Medicines Regulations* provide details about how prices must be calculated and reported.[30]

The factors that may be considered under section 85 of the *Patent Act* in determining whether prices are excessive include:

a. the prices at which the medicine has been sold in the relevant market;
b. the prices at which other medicines in the same therapeutic class have been sold in the relevant market;
c. the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada;
d. changes to the Consumer Price Index; and
e. any other factors that may be specified in any regulations made for the purposes of section 85.

29 *Patent Act*, s 80.
30 *Patented Medicines Regulations*, SOR/94-688, s 4 [*Patented Medicines Regulations*].

Following the coming into force of the Amended *Patented Medicines Regulations* on January 1, 2022, additional factors will also be considered. For medicines assigned their drug identification number (DIN) on or after August 21, 2019, a revised framework will incorporate three additional pricing factors to determine whether the patented medicine is being sold in Canada at an excessive price.[31]

The first new factor is the medicine's pharmacoeconomic value, which is its cost per quality-adjusted life year. If a cost-utility analysis prepared by a publicly funded Canadian organization shows that the cost of the medicine, when pro-rated for use over a 12-month period, is greater than or equal to 50 percent of the gross domestic product (GDP) per capita in Canada at the time the analysis is published, Patentees will be required to provide that analysis to the Board. This requirement applies to an analysis in which the outcomes are expressed as the cost per quality-adjusted life year for each indication that is the subject of the analysis. Furthermore, if any information is redacted from the public version of the analysis, the Patentee is required to provide that redacted information to the Board. This information will be due 30 days after the day the medicine is first offered for sale in Canada, or 30 days after it is first published, if publication is after the date of the first sale.[32]

The second new factor is the size of the Canadian market for the medicine.[33] The Patentee will be required to provide to the Board the estimated maximum use of the medicine in Canada as measured by the total quantity of the medicine expected to be sold in final dosage form and the period of time used for this estimate. This will be required within 30 days of the date the medicine is first offered for sale in Canada. Updates to this estimate will be required within 30 days of any Notice of Compliance (NOC) approving a new or modified therapeutic use of the medicine.

The third new factor is the annual per-patient cost in relation to the GDP per capita in Canada. There are additional criteria set out in the Amended *Patented Medicines Regulations* explaining this factor. The Patentee will not need to report on this information, as it can be obtained from Statistics Canada.

In considering the factor related to prices in other countries, historically the Board considered as comparators prices in Germany, France, Italy, Sweden, Switzerland, the United Kingdom, and the United States. As of January 1, 2022, the basket of comparator countries will be amended.

31 *Patented Medicines Regulations*, s 4.4 [as amended, SOR/2019-298, s 4].
32 *Patented Medicines Regulations*, s 4.1 [as amended, SOR/2019-298, s 4].
33 *Patented Medicines Regulations*, s 4.2 [as amended, SOR/2019-298, s 4].

The United States and Switzerland will be removed, while Australia, Belgium, Japan, Netherlands, Norway, and Spain will be added. France, Germany, Italy, Sweden, and the United Kingdom remain in the basket.[34] Notably, the price used for comparison from these countries is still the ex-factory price. It is expected that this change will generally result in a lower comparator price.

In addition, for all medicines, the calculations of "average price" and "net revenue" that require reporting have changed.[35] For both calculations, the Patentee is now required to report the actual price or revenue obtained, taking into account any adjustments, reimbursements, or reductions including as a result of free goods or free services, gifts, or other benefits of a like nature. According to the Regulatory Impact Analysis Statement (RIAS), this information will be considered privileged under section 87 of the *Patent Act*. As mentioned above, this new requirement was struck down by both the Federal and Québec Provincial Courts. However, as of the date of writing, these decisions are under appeal.

Reporting requirements will be reduced for patented veterinary medicines, generic medicines, and over the counter (OTC) medicines (with the exception of drugs found in Schedule D to the *Food and Drugs Act*). These Patentees will only be required to report price, sales, identity information, and information on the new regulatory factors when requested by the Board. This has expanded the reduced requirements for OTC medicines to include controlled substances and radiopharmaceuticals; however, biologics listed on Schedule D will still be required to report.

If the Board is unable to determine whether the medicine is being, or has been, sold at an excessive price, it may also consider the cost of making and marketing the medicine and any other factors that it considers relevant. Research costs that may be considered by the Board are the Canadian portions only of the cost related to the research that led to the invention or to the development and commercialization of the invention.[36]

The Patentee or former Patentee is required to comply with any order made by the Board. In other words, the Board maintains jurisdiction to institute proceedings for excessive pricing following the expiration (or where the former Patentee ceases to be entitled to the benefit) of the patent in order to issue a binding order. However, the Board's order does not apply to a former Patentee where the Board instituted proceedings more than three years after the

34 Patented Medicines Regulations, schedule to s 4(1)(f)(iii) [as amended, SOR/2019-298, s 6].
35 *Patented Medicines Regulations*, s 4(4)(a), 4(4)(b) [as amended, SOR/2019-298, s 3(4)].
36 *Patent Act*, ss 85(2), (3).

Patentee ceased being entitled to the benefit of the patent or ceased being able to exercise any rights in relation to the patent.[37]

Where the Board finds that a patented medicine is sold in Canada at a price that is excessive, it may order the Patentee to sell the medicine at a reduced price. The Board may also order the Patentee to do any one or more of the following to offset the amount of excess revenue estimated by the Board to have been derived by the Patentee from the excessive price:

a. reduce the price at which the Patentee sells the medicine in any market in Canada to such an extent and for such a period as set out by the Board;
b. reduce the price at which the Patentee sells one other medicine to which a patented invention of the Patentee pertains in any market in Canada to such an extent and for such a period as set out by the Board; or
c. pay an amount specified by the Board to the government.[38]

The Board may also direct the Patentee to meet any one or more of the above requirements, which will, in the Board's opinion, offset not more than twice the amount of the excess revenues estimated by it to have been derived by the Patentee or former Patentee from the sale of the medicine at the excessive price.

Before the Board makes an order, the Patentee or former Patentee has a right to a hearing. A panel of the Board acts as decision maker and the Board staff assume the role of prosecutor. The Board may accept voluntary compliance undertakings from any company under investigation, which must be consistent with the Board's statutory mandate, guidelines, and policies, and be in the public interest.[39]

14.3.2 Reporting Functions

In order to fulfill its mandate, the Board monitors prices of patented medicines in Canada and tracks overall research and development expenditures relative to the sales of pharmaceutical companies. The Board produces an annual report on activities by Patentees in Canada, including research and development related to medicines as well as overall revenues from sales of medicines.[40]

37 *Patent Act*, s 83(7).
38 *Patent Act*, s 83.
39 Ciba-Geigy Canada Ltd., Re (1994), 58 CPR (3d) 542 at 547, 549-552 (*PMPRB*).
40 *Patent Act*, s 89.

The purpose of the annual report, which is tabled to Parliament, is to disclose relevant information in order to establish new policies reflecting the economic reality of the Canadian drug industry. In order to meet this reporting obligation, the Board can require a Patentee to provide it with relevant information and documents including the following:

a. the identity of licensees in Canada;
b. the revenue of the Patentee, and details of the source of the revenue (whether direct or indirect) from sales of medicine in Canada; and
c. the expenditures made by the Patentee in Canada on research and development relating to medicine.[41]

The Board may also order other persons to provide information, if the Board believes they have relevant information on the sales of medicines in Canada or expenditures made by a Patentee in Canada on research and development relating to a medicine. On the basis of the information collected, the Board prepares an estimate of the proportion of the expenditures spent by each Patentee in Canada in the preceding year on research and development relating to the medicine to the revenues earned by the Patentee from sales of the medicine in the same year in Canada.

The Board makes these submissions in such a way that it is not possible to identify the people who have submitted the information requested by the Board. The report does, however, identify the Patentees in respect of whom the estimates of various percentages are given, and may also identify Patentees who have failed to comply with orders requesting submissions to the Board. In addition to a summary of pricing trends in the pharmaceutical industry, the report also contains the name of each Patentee in respect of whom an order was made during the year as well as a statement as to the status of the matter in which an order was made.[42]

14.4 Judicial Review

As discussed above, pursuant to its investigative functions, the Board practices a dual role. To ensure that patented medicine prices are not excessive, it takes on a prosecutor's role. However, if a manufacturer does not accept a voluntary compliance order, it may hear the case and issue orders. Like every administrative tribunal, the Board's decisions are subject to review, in this case, by the Federal Court. The Federal Court's decision may be appealed to the FCA, and a leave to appeal to the Supreme Court of Canada (SCC) may be sought from the FCA's decision.

41 *Patent Act*, s 88.
42 *Patent Act*, s 100.

In *Celgene*, the SCC clarified that the applicable standard of review of a Board decision is "reasonableness" (and not correctness). Therefore, only an unreasonable Board decision will be set aside. An unreasonable decision is one that falls outside "a range of possible, acceptable outcomes which are defensible in respect of the facts and law."[43]

In 2019, the SCC released a seminal decision concerning the substantive review of administrative decisions, *Canada (Minister of Citizenship and Immigration) v. Vavilov*.[44] *Vavilov* did not substantially change the jurisprudence in the Federal Court concerning the unreasonableness of outcomes reached by administrators, but the SCC's decision did change the law substantially by requiring that reviewing courts be able to discern a reasoned explanation for an administrative tribunal's decision.[45]

In *Galderma*,[46] the FCA confirmed that when the Board was working within the framework of sections 79-103 of the *Patent Act*, which set out its mandate and its powers, the Board was applying its home statute. Consequently, the Board's decision in that respect is presumptively reviewed on the reasonableness standard, unless the presumption of reasonableness is rebutted. The Court further confirmed that questions of mixed fact and law are also to be reviewed on the standard of reasonableness. The Board's position was that it was limited to examining the face of the patent which involved a matter of methods and techniques of analysis, and that is not a question of statutory interpretation since the *Patent Act* does not deal with this issue. On that basis, that portion of the Board's reasons were reviewed on the reasonableness standard.

In *Alexion Pharmaceuticals*,[47] the FCA confirmed that when reviewing a decision of the Board, the jurisprudence requires the Court to ask if there is a sufficient reasoned explanation in support of the Board's decision. If there is not a sufficient reasoned support, the decision will be considered unreasonable and must be quashed. In *Alexion Pharmaceuticals*, the FCA held that the Board's decision fell significantly short of the mark. The FCA considered that terms used by the Board suggested that it went beyond its permissible statutory mandate by regulating the reasonableness of pricing, rather than preventing abusive pricing, namely excessive pricing made possible by abusing the monopoly power granted by a patent.[48]

43 *Celgene*, at para 34.
44 *Canada (Minister of Citizenship and Immigration) v. Vavilov*, 2019 SCC 65.
45 *Alexion Pharmaceuticals Inc. v. Canada (Attorney General)*, 2021 FCA 157 at para 7 [*Alexion*].
46 *Galderma*, at paras 29-31.
47 *Alexion*, at para 10.
48 *Alexion*, at para 11.

Chapter 15

Certificates of Supplementary Protection

15.1 Introduction

Patent term restoration is available in Canada. Such restoration is known as a Certificate of Supplementary Protection (CSP). This supplement to the 20-year patent term is meant to restore part of that term that was lost as a result of the time spent doing research and obtaining marketing authorization from Health Canada. This restoration is achieved through the interaction of certain provisions of the *Patent Act* together with the *Certificate of Supplementary Protection Regulations*.[1]

Through this chapter, we will link the provisions of the *CSP Regulations* to the *Patent Act* and provide an overview of the eligibility requirements for and benefits of a CSP.

15.2 Requirements for Obtaining a CSP

In order to obtain a CSP, one needs three things:

a) An eligible authorization for sale;
b) An eligible medicinal ingredient; and
c) An eligible patent.

Eligible Authorizations for Sale

The authorization for sale required by the *CSP Regulations* is a Notice of Compliance (NOC) issued pursuant to section C.08.004 or C.08.004.01 of the *Food and Drug Regulations* (*FDR*).[2],[3]

It must be the first NOC issued in Canada for that medicinal ingredient or combination of medicinal ingredients.[4] The NOC must have been issued on or after September 21, 2017.[5]

If Canada is not the first country for which an application for marketing approval for that medicinal ingredient or combination has been submitted, the application for the NOC in Canada must have been filed within 12 months of the earliest foreign application for marketing approval in:

- The European Union or any country that is a member of the EU;
- The United Kingdom;
- The United States of America;
- Australia;
- Switzerland; or
- Japan[6]

1 *Certificate of Supplementary Protection Regulations*, SOR/2017-165 [*CSP Regulations*].
2 *Food and Drug Regulations*, CRC c 870, s C.08.004 or C.08.004.01.
3 *CSP Regulations*, s 4.
4 *Patent Act*, RSC 1985, c P-4, s 106(1)(d) [*Patent Act*].
5 *Patent Act*, s 106(1)(c).
6 *Patent Act*, s 106(1)(f); *CSP Regulations*, ss 6(1)(a), 6(1)(b)(ii).

Eligible Medicinal Ingredients

As mentioned above, the NOC for the medicinal ingredient must be the first NOC issued in Canada for that medicinal ingredient. The *Patent Act* indicates that "prescribed variations" of a medicinal ingredient will be considered to be the same medicinal ingredient for the purposes of determining whether such a medicinal ingredient is eligible for a CSP.[7]

The *CSP Regulations* set out what "prescribed variations" of medicinal ingredients will be considered to be the same medicinal ingredient:

- Esters, salts, complexes, chelates, clathrates, or other non-covalent derivatives;
- Enantiomers or mixtures of enantiomers;
- Solvates or polymorphs;
- *In vivo* or *in vitro* post-translational modifications; and

Any combination of the above variations.[8]

However, a medicinal ingredient or combination will not be considered the same if they are approved for human and for veterinary uses.[9]

There can have been no other CSP issued for the medicinal ingredient.[10]

Eligible Patents

For a patent to be eligible to receive a CSP, it must meet the following requirements:

a) It must be in force (not expired or void);[11]

b) It must have been filed after October 1, 1989;[12]

c) It must pertain to a medicinal ingredient or combination of medicinal ingredients in a drug for which the NOC was issued, and contain a claim for:

   a. The medicinal ingredient or combination,

   b. The medicinal ingredient or combination as obtained by a specified process, or

   c. The use of the medicinal ingredient or combination.[13]

7 *Patent Act*, s 105(3).
8 *CSP Regulations*, s 2.
9 *Patent Act*, s 105(2).
10 *Patent Act*, s 106(1)(e).
11 *Patent Act*, s 106(1)(a); *CSP Regulations*, s 3(1).
12 *Patent Act*, s 106(1)(b).
13 *Patent Act*, s 106(1)(c); *CSP Regulations*, s 3(2).

15.3 How to Apply

Health Canada has posted a CSP Application Form on its website.[14] If the criteria with respect to medicinal ingredient and patent eligibility are met, then one can apply for a CSP.[15]

One must apply within 120 days of the day on which the NOC is issued, if the patent is granted before that day, or within 120 days of the day on which the patent is granted, if the patent is granted after the NOC is issued.[16]

The prescribed fee was C$9011 until April 1, 2018. Beginning on that date, the fee will increase annually by 2% of the previous year's fee, rounded up to the nearest dollar.[17] The current fee is listed on Health Canada's website.

Each application can only set out one patent.[18] The application must contain:

a) The number of the patent;
b) The medicinal ingredient or combination of medicinal ingredients;
c) The number of the authorization for sale (the New Drug Submission number);
d) The Applicant's name and contact information in Canada, including their complete address;
e) The filing date, issue date, and expiry date of the patent;
f) An attestation that either the Applicant is the patentee recorded as patent owner in the Patent Office, or that they are the manufacturer who is authorized to file the application.
g) In order to be authorized to file the application, the manufacturer must hold the NOC.
h) An attestation that when the application for an NOC was filed either:
    a. no authorization for sale with respect to the medicinal ingredient or combination had been submitted in any of the prescribed countries; or
    b. that if an authorization for sale had been submitted in one or more of those countries, the application for the NOC was filed within a year of the filing of the application for marketing authorization in one of those countries.
i) A description of the method of payment used to pay the fee.[19]

14 Health Canada, "Certificate of Supplementary Protection (CSP) Application Form".
15 *Patent Act*, s 113.
16 *Patent Act*, s 106(3); *CSP Regulations*, s 6(2).
17 *CSP Regulations*, s 9(1).
18 *Patent Act*, s 106(6).
19 *Patent Act*, s 106(5); *CSP Regulations* s 6(3).

15.4 The Certificate

The Minister of Health will issue a CSP if the criteria are met and the period for applying for a CSP has expired and no other application has been filed.[20] (If other applications have been filed, there are a series of priority provisions for determining who has priority to the CSP.[21])

The Certificate will contain:

a) the number, as recorded in the Patent Office, of the patent set out in the application;

b) the medicinal ingredient or combination of medicinal ingredients set out in the application;

c) a statement as to whether the certificate relates to use in humans or to veterinary use;

d) the number of the authorization for sale set out in the application; and

e) the day on which the certificate's term begins and the day on which the term ends.[22]

The Minister maintains an electronic register of Applications for CSPs and CSPs.[23] This Register lists both the medicinal ingredient and the date on which the term of the patent expires/date upon which the CSP will take effect and whether the medicinal ingredient is for human or veterinary use. The CSP register also lists the date upon which the term ends, the patent number, the number of the New Drug Submission and, in the case of a CSP, its number.[24]

15.5 Rights of a CSP Holder

The holder of the CSP has the same rights and privileges as a patentee with respect to making, constructing, using, and selling any drug referenced in the CSP.[25] Thus, the holder of a CSP can sue for patent infringement. The *NOC Regulations*, discussed in Chapter 17, will also apply to any CSP of a listed patent.

20 *Patent Act*, s 113.
21 *Patent Act*, ss 108,109.
22 *Patent Act*, s 114.
23 Health Canada, "Register of Certificates of Supplementary Protection and Applications" (the Register).
24 *CSP Regulations*, s 13.
25 *Patent Act*, s 115(1).

However, it will not be considered an infringement of the CSP if the medicinal ingredient or combination is made, constructed, used or sold for export.[26]

The CSP will take effect upon expiry of the patent and be valid for a period of not more than two years. It 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 NOC set out in the certificate is issued, but in any event is for a maximum of two years.[27] This period can be reduced if the Minister is of the opinion that that the holder's failure to act resulted in a period of unjustified delay in the process of obtaining the NOC.[28]

26 *Patent Act*, s 115(2).
27 *Patent Act*, s116(3).
28 *Patent Act*, s 116(4).

Chapter 16

Advertising for Therapeutic Products

16.1 Overview

The *Food and Drugs Act* (*FDA*) and its regulations set out a number of rules governing the advertising of drugs and medical devices ("therapeutic products"), including specific rules governing advertisements directed to the general public and specific rules governing advertisements directed to health care professionals. Any person who promotes the sale of a specific therapeutic product is subject to such rules, including without limitation, product manufacturers and health care professionals, regardless of the means used to promote the therapeutic product, whether traditional media (*e.g.*, print, broadcast, point-of-sale, direct mail) or digital media (*e.g.*, websites, email, social media platforms).

16.2 What is Advertising?

The *FDA* defines the term "advertisement" as including any representation by any means whatever for the purposes of promoting directly or indirectly the sale or disposal of any therapeutic product.[1] The definition is deliberately broad.

Health Canada has issued guidance that explains how it distinguishes between information and advertising.[2] Among other factors, Health Canada will consider the context in which the given message is disseminated, where and how it is delivered, its intended audience, its content, the frequency of the message delivery, the influence of the manufacturer on the message content, as well as the presence and method of sponsorship of the message. Messages that are on their face promotional can be considered informational, depending on content and context. This could include press releases, patient information booklets, patient support group literature, consumer brochures, clinical trial recruitment, international conferences, and journal supplements, to name but a few.

To the extent a message is considered to be advertising, the advertiser must ensure that the message complies with the applicable restrictions imposed by the *FDA* and its regulations, as well as the applicable regulatory guidance.

16.3 Advertising of Therapeutic Products

According to the *Food and Drug Regulations* (*FDR*), only therapeutic products that have been authorized for sale by Health Canada can be advertised in Canada. This means that the advertising of new therapeutic products is generally

1 *Food and Drug Act*, RSC 1985, c F-27, s 2 [*FDA*].
2 Health Canada, "The Distinction Between Advertising and Other Activities" (12 January 1996).

prohibited until the products have been authorized for sale.[3] Moreover, the advertising must not exceed the terms of the therapeutic product authorization issued by Health Canada,[4] which is based on the information and materials submitted by the manufacturer to establish the safety and efficacy of its therapeutic product.

There exists one basic prohibition applicable to all advertising of therapeutic products, which is intended to guide advertisers. That is, no person may advertise a therapeutic product in a manner that is false, misleading, or deceptive, or that is likely to create an erroneous impression regarding its character, value, quantity, composition, merit, or safety.[5] Such prohibition is the basis for most, if not all, advertising restrictions imposed by the *FDA* and its regulations.

16.4 Advertising Directed to Consumers

The *FDA* and its regulations restrict the types of advertisements that can be directed to the general public, and we have set out in this section some of the most important of these restrictions.

First, the advertising of therapeutic products to consumers is prohibited where the advertisement includes a claim to the effect that the drug or medical device treats, prevents, or cures any of the serious diseases, disorders, or abnormal physical conditions listed in Schedule A.1 of the *FDA* (*e.g.*, alcoholism, asthma, cancer, congestive heart failure, dementia, diabetes, obesity, STDs, etc.),[6] other than certain limited prevention claims made concerning non-prescription drugs.[7]

Second, the type of permitted consumer-directed prescription drug advertisements is limited. Prescription drugs cannot be advertised to the general public in relation to a specific disease or condition. Notably, the *FDA* prohibits the advertising of prescription drugs directed to consumers, which offer more than the drug's brand name, proper name, common name, price, and quantity.[8] This means that, when a prescription drug is advertised by name to consumers, there can be no reference to its therapeutic use or benefits. Health Canada generally permits two types of consumer-directed prescription

3 *Food and Drug Regulations*, CRC, c 810, s C.08.002 [*FDR*].
4 Terms of Market Authorization (TMA) are issued for drugs and Class II, III and IV medical devices. Class I devices are not issued a Medical Device Licence and therefore, do not have a TMA. Products should not be advertised if the TMA has been withdrawn by Health Canada, or if products have been voluntarily withdrawn or discontinued by the manufacturer.
5 *FDA*, ss 9(1), 20(1).
6 *FDA*, s 3(1).
7 *FDR*, s A.01.067; Health Canada, "Guidance Document: Schedule A and Section 3 to the Food and Drugs Act [Health Canada, 2010]" (February 2003), (Schedule A.1 previously referred to as Schedule A).
8 *FDR*, s C.01.044.

drug advertisements. The first are reminder advertisements, which identify a drug by name, but make no reference whatsoever to a disease (such as the well-known advertisements for Viagra®). The second are help-seeking messages, which identify a disease, but make no reference whatsoever to a specific prescription drug. The latter are permitted as they are considered informational, and thus not *per se* advertising.

Third, the *FDA* also prohibits the advertising of narcotic and controlled drugs to consumers.

Fourth, the *Medical Devices Regulations* (*MDR*) set out a number of advertising restrictions applicable to medical devices generally and to specific types of medical devices (such as condoms and contraceptive devices). Among other restrictions, the *MDR* state that no person may advertise a Class II, III, and IV medical device unless (a) the device manufacturer holds a medical device licence or an amended medical device licence, or (b) the advertisement is placed only in a catalogue that includes a clear and visible warning that the devices advertised in the catalogue may not have been licensed in accordance with Canadian law, where applicable.[9]

In order to assist advertisers in understanding the advertising provisions of the *FDA* and its regulations, including the restrictions applicable to the consumer-directed advertising mentioned above, Health Canada has made available guidance documents to advertisers. This includes guidance issued by Health Canada as well as guidance issued by Ad Standards Canada (Ad Standards), one of the agencies mandated to preclear consumer-directed drug and medical device advertising.[10] The guiding principles set out in such guidance are: (a) that all therapeutic products should be promoted in a responsible manner with consumer health and safety paramount, and (b) that advertisements should clearly communicate the intended use of the therapeutic product in a manner that is consistent with its Terms of Market Authorization (TMA). The guidance documents provide practical advice to advertisers on how to make and substantiate claims made in respect of product performance (*e.g.*, absence of side effects, strength, prevention), composition (*e.g.*, natural, organic), product comparisons and safety (*e.g.*, side effects), as well as claims of opinion and authorization (*e.g.*, testimonials, endorsements).

9 *Medical Devices Regulations*, SOR/98-282, s 27 [*MDR*].

10 Ad Standards Canada, "Guidelines for Consumer Advertising of Health Products for Nonprescription Drugs, Natural Health Products, Vaccines and Medical Devices" [*Guidelines for Consumer Advertising of Health Products*] (2018).

16.4.1 What About Comparative Advertisements?

As stated above, Health Canada has issued various guidance documents and policies to assist advertisers in complying with the basic prohibition on false, misleading, and deceptive advertising. This also includes a policy on and guidance for comparative claims related to the therapeutic and non-therapeutic attributes of therapeutic products.[11] Health Canada guidance takes into consideration a similar prohibition on false, misleading, and deceptive advertising found in the *Competition Act*[12] and guidance issued by the Competition Bureau.[13]

For ease of reference, a therapeutic comparative claim is "a statement that compares an identified therapeutic attribute of one health product or ingredient to that of another health product or ingredient in terms of comparability or superiority." [14] Whereas, a non-therapeutic comparative claim is a statement that compares an identified non-therapeutic attribute of a health product with that of another health product, or with that of other product categories for human use (*e.g.*, "moisturizes better", "best-selling", "#1 recommended.")[15]

Pursuant to Health Canada's statements, therapeutic comparative claims must comply with the following principles:

(a) The comparisons must be based on drugs that have an authorized indication for use in common, and they must be drawn between drugs under the same conditions of use in a similar patient population.

(b) The comparative claims must not conflict with any of the terms of the market authorizations issued for any of the compared drugs, and they must also be of clinical relevance to humans and rely on evidence that is conclusive, complete, and scientifically accurate.[16]

(c) At a minimum, the comparative drug advertisement must identify the compared drugs and the medicinal use related to the claims made in the advertisement (where not readily apparent), they must use language

11 Health Canada, "Policy: Principles for Claims Relating to Comparison of Non-therapeutic Aspects of Non-prescription Drug Products" (November 9 1998), [*Policy: Principles for Claims Relating to Comparison of Non-therapeutic Aspects of Non-prescription Drug Products*]; Health Canada, "Therapeutic Comparative Advertising: Directive and Guidance Document" (April 6 2001), [*Therapeutic Comparative Advertising*].; Guidelines for Consumer Advertising of Health Products, ch 4.

12 *Competition Act*, RSC 1985, c C-34, ss 52, 74.01(1).

13 Guidance issued by the Competition Bureau on "Performance representations not based on adequate and proper tests" and s 74.01(1) requires that performance or efficacy claims be based on "adequate and proper" tests, and that these tests must be "concluded before the representation is made", that "the results must not only be significant but must be meaningful", and that "the reliability of the data resulting from a test is conditional upon achievement of similar results from a repetition of the test."

14 Therapeutic Comparative Advertising, Part II

15 Therapeutic Comparative Advertising, Part II

16 The data requirements to support comparative therapeutic claims in consumer-directed advertising for non-prescription drugs are generally less strict than those for prescription drugs.

and graphics that can be understood by their intended audience, and they must not obscure the therapeutic use or attack the compared drug in an unreasonable manner.[17]

The principles set out in Health Canada guidance on non-therapeutic comparative are similar to those set out in its guidance on therapeutic claims for non-prescription drugs. Comparisons between drugs in terms of comparability or superiority with respect to non-therapeutic attributes can be made under the following conditions:

(a) the advertised product is primarily represented as a drug;

(b) the compared drug or drugs have an authorized indication for use in common with the advertised drug;

(c) the information provided in the advertisement may have some benefit to consumers; for instance, enabling consumers to select a drug;

(d) the comparative claim is supported by adequate, up to date, unbiased, and statistically valid data;

(e) the comparative claim does not obscure information on the authorized indication(s) or intended medicinal use(s) of the advertised drug;

(f) any comparison of non-therapeutic attributes should also include a reference to therapeutic attributes; and

(g) the advertisement should include a statement to the effect that superiority does not mean better compliance and/or better therapeutic attributes, unless such a claim can be substantiated by scientific data.[18]

Although the aforementioned guidance on comparative claims issued by Health Canada addresses the comparison of drugs, the principles outlined therein should also generally be applied by advertisers making comparative claims concerning medical devices.

16.5 Advertising Directed to Health Care Professionals

Advertising of therapeutic products to health care professionals is, to some extent, not as restrictive as consumer-directed advertising. However, the basic prohibition still applies: a drug or medical device cannot be advertised in a manner that is false, misleading, deceptive, or that is likely to create an erroneous impression regarding its character, value, quantity, composition, merit, or safety.[19] Such prohibition is further expanded upon in several

17 *Therapeutic Comparative Advertising*, Part I.
18 *Policy: Principles for Claims Relating to Comparison of Non-therapeutic Aspects of Non-prescription Drug Products*, s 5.
19 *FDA*, s 9(1).

provisions of the *FDR*, which provides, among other things, that a drug manufacturer who makes certain representations in its advertisements must conduct necessary investigations, using acceptable methods, prior to making such representations.[20]

Whether or not drug advertising directed to health care professionals is appropriate falls under the purview of the Pharmaceutical Advertising Advisory Board (PAAB). This is due to the fact that Health Canada has delegated such supervision to the PAAB.

The PAAB has set out general requirements concerning the information that can be disclosed in drug advertisements directed to health care professionals.[21] Such advertisements must be designed to promote credibility and must be accurate, complete, and clear. They must be presented in a way that accurately interprets research findings, while at the same time reflecting an attitude of caution regarding drug use and emphasizing rational drug therapy. An advertisement should not state or imply in absolute terms that a drug is safe, has guaranteed efficacy or entirely predictable effects. A general guideline to follow is that drug advertisements must provide the health care professional with sufficient information to allow them to properly assess the risks and benefits of use for their patients. The above principles can also be generally applied to medical device advertisements.

The PAAB has also issued guidance concerning comparative advertisements directed to health care professionals,[22] which are based on the basic prohibition on false, misleading, and deceptive advertising and which reflect the principles set out in Health Canada's guidance. Broadly, comparative claims made in such advertisements must be fair, accurate and based on relevant and sound scientific evidence, just like consumer-directed advertisements.

16.6 Administration and Enforcement

Health Canada, with the assistance of advertising preclearance agencies, administers and enforces the advertising provisions of the *FDA* and its regulations. Health Canada has delegated to such preclearance agencies certain roles related to health product advertising.[23]

20 *FDR*, s C.01.012.

21 Pharmaceutical Advertising Advisory Board, *PAAB Code of Advertising Acceptable*, Pickering: PAAB, 2018, *Administrative Guidelines, Key Principles and Code Standards* [PAAB Code].

22 *PAAB Code*, Code Standards, s 5 "Making Comparisons".

23 Health Canada, "Guidance Document - Health Canada and Advertising Preclearance Agencies' Roles Related to Health Product Advertising" (November 3 2010).

Advertising preclearance agencies will review and preclear advertising material to help advertisers ensure compliance with applicable laws and regulations, as well as the various Health Canada guidance documents and voluntary codes of advertising applicable to them. Moreover, when Health Canada receives a complaint arising from an advertisement for a health product, it can treat the complaint itself or delegate it to one of its authorized preclearance agencies, as appropriate.

As of the date of publication, Health Canada has recognized three independent and non-for-profit organizations to provide preclearance services for the advertising of therapeutic products. These preclearance agencies ensure that therapeutic product advertising meets regulatory, scientific, therapeutic, and ethical standards. First, the PAAB provides preclearance services for direct-to-consumer prescription drug advertising and advertising directed at health care professionals. Second, Ad Standards provides preclearance services for medical device advertising, non-prescription drug advertising, and direct-to-consumer prescription drug advertising. Third, Extreme Reach Toronto provides preclearance services for medical device advertising and non-prescription drug advertising.

The legal consequences of non-compliance with the advertising provisions of the *FDA* and its regulations are assessed based on the health risk level of an advertisement. When a complaint is made, Health Canada conducts an assessment to determine the level of risk to human health associated with the exposure to the advertising. After the assessment is made, appropriate risk management actions are taken. These actions include the issuance of a warning letter, the request for the immediate withdrawal of the advertisement, the suspension or cancellation of the market authorization issued for the therapeutic product featured in the advertisement in question, and/or the imposition of penalties pursuant to the *FDA*.

PART 4
Disputes

Chapter 17

Infringement and Validity Determinations in Court

17.1 Overview

Once a patent issues, the owner or Patentee has the right to exclude all others from making, using and/or selling that which is claimed until the expiry of the patent. In the event that the Patentee believes that others are encroaching on its rights, an infringement action can be commenced. However, challenges to the validity of the patent can also be made. These issues can be determined either through the Patent Office, as discussed in a previous chapter, or the federal or provincial courts, which will be discussed in this chapter.

There are a number of ways that the issues of infringement/non-infringement and validity/invalidity of a patent can end up before a Court to be determined. A Patentee can bring an action for infringement, or any person that has reasonable cause to believe that any process used or proposed to be used, or any article made, used, sold, or proposed to be, might be alleged by any Patentee to constitute infringement may bring an action in Federal Court against the Patentee for a declaration that the process or article does not or would not constitute an infringement.[1] A third party may defend and/or counterclaim asserting invalidity of the patent in response to a Patentee alleging infringement. An interested person can also start an action in the Federal Court seeking a declaration of invalidity of a patent or any claim of the patent.[2] The plaintiff who commences such an action is obliged to deposit the security for costs with the Court in such sum as the Federal Court may direct, unless the plaintiff is a plaintiff by counterclaim in an action for infringement.[3]

Notwithstanding the manner in which the action comes before the Court, the general questions to be answered by the Court are the same and will be discussed below.

17.2 Cease and Desist Letters

Often before commencing legal action, a Patentee will send a demand (also called a cease and desist) letter to the alleged infringer to inform them of the existence of an issued patent(s), and to advise them that legal action may be taken if the alleged infringer does not cease its allegedly infringing activity, in order to try to resolve the situation without the need for legal action.

Canada enacted section 76.2 of the *Patent Act* in 2018, which permits the government to enact regulations stipulating the requirements for written demand

1 *Patent Act*, RSC 1985, c P-4, s 60(2) [*Patent Act*].
2 *Patent Act*, s 60(1).
3 *Patent Act*, s 60(3).

letters.[4] All demand letters must comply with the prescribed requirements, but as of the writing of this chapter, no regulations have been published and/or enacted.

Pursuant to this section, any person in Canada who receives a written demand letter regarding an invention that is patented in Canada or elsewhere that does not comply with the forthcoming requirements, and any person who is aggrieved as a result of the receipt by another person of the written demand, may bring a proceeding before the Federal Court seeking damages, punitive damages, an injunction, a declaration, or an award of costs.[5]

If a demand letter that is not compliant with the prescribed requirements is sent on behalf of a corporation, and the corporation is notified of any defects in the demand letter and does not remedy the defects, then the corporation's officers, directors, agents, or mandataries are jointly and severally, or solidarily, liable with the corporation if they directed, authorized, assented to, acquiesced in, or participated in the sending of the demand.[6] However, a due diligence defence may be available.[7]

Patentees who send demand letters should therefore be diligent in watching for the publication of the regulations to section 76.2, including whether there will be any retroactive effect on existing demand letters and litigation.

17.3 Infringement and Validity Proceedings in Court

The *Federal Courts Act* gives the Federal Court concurrent jurisdiction with provincial courts over patent disputes, and exclusive jurisdiction where a party seeks to impeach or annul a patent.[8] The majority of patent cases are thus brought in the Federal Court. The Federal Court has authored a number of guidances to the profession to address the litigation process.[9]

As a starting point, in any proceeding in which validity is raised, the *Patent Act* contains a presumption that, in the absence of any evidence to the contrary, an issued patent is valid.[10]

Generally speaking, the burden is on the patent challenger to demonstrate, on a balance of probabilities, that a patent is invalid,[11] while the burden is on the Patentee to demonstrate, to the same standard, that a patent is infringed.

4 *Patent Act*, s 76.2.
5 *Patent Act*, ss 76.2(2)-(3).
6 *Patent Act*, s 76.2(4).
7 *Patent Act*, s 76.2(5).
8 *Federal Courts Act*, RSC 1985, c F-7, s 20.
9 See for example, Federal Court, "Notice to the Parties and the Profession Trial Management Guidelines" (April 2017).
10 *Patent Act*, s 43(2).
11 *Whirlpool v Camco*, 2000 SCC 67 at para 75 [*Whirlpool*].

17.4 Claims Construction

Whether the matter in issue is one of infringement or validity, the first step in any patent suit is to construe the claims.

Canadian law with respect to claims construction and infringement was reviewed and restated by the Supreme Court of Canada (SCC) in two cases: *Free World*[12] and *Whirlpool*.[13] Each case emphasizes that the language of the claims, purposively construed, defines the legal boundary of the claims. Once the Court has construed the claims in accordance with construction principles, it can then consider the issues of infringement and validity.

17.4.1 The Person of Ordinary Skill in the Art

The Court must construe the claims in accordance with the way in which a person of ordinary skill in the art (POSITA) would understand them on the date of publication of the patent application. The notion of the POSITA is one that is essential to construction, infringement, and validity. It follows that defining the POSITA is a critical element in every case.

A POSITA is one who possesses ordinary skill and knowledge of the particular art to which the invention relates and a mind willing to understand the patent specification. The POSITA is sufficiently versed in the art to which the patent relates to enable them to appreciate, on a technical level, the nature and description of the invention.[14] Their knowledge is the knowledge of a competent, ordinary worker,[15] though "ordinariness" varies according to the subject matter of the patent — rocket science patents may, in fact, be comprehensible only to rocket scientists.[16] Knowledge of purpose is one of the important attributes a POSITA brings to the exercise of claims construction. They look for success, rather than difficulty or failure.[17] For example, POSITAs would not read a claim to a family of chemical compounds to be used on a person's skin as including a chemical that they know to be toxic to humans, irritating to skin, or likely to discolour the skin, even if the claims language clearly encompasses such chemicals.[18]

A POSITA is understood to be acquainted with the surrounding circumstances concerning the state of the art and the manufacture at the time of the publication

12 *Free World Trust v Électro Santé Inc*, 2000 SCC 66 [*Free World*].
13 *Whirlpool*.
14 *Whirlpool* at para 53.
15 *Free World*, at para 44.
16 *Whirlpool*, at para 71.
17 *Free World*, at para 44.
18 *Whirlpool*, at para 53; *Burton Parsons Chemicals Inc v Hewlett-Packard (Canada) Ltd*, [1976] 1 SCR 555 [*Burton Parsons*].

of the invention, and understands any particular word or words used in a patent to have the same technical meaning as the words have within the art or manufacture, unless the specification says otherwise.[19]

A POSITA has been defined as:

> a hypothetical person possessing the ordinary skill and knowledge of the particular art to which the invention relates, and a mind willing to understand a specification that is addressed to him. This hypothetical person has sometimes been equated with the "reasonable man" used as a standard in negligence cases. He is assumed to be a man who is going to try to achieve success and not one who is looking for difficulties or seeking failure.[20]

Thus, the POSITA must be able to work the patent addressed to them without inventive skill.

The burden to prove invalidity, on a balance of probabilities, is on the person attacking the validity of the patent.[21] The patent and its claims will be either upheld or struck down, in whole or in part, but a finding of invalidity of some claims will not affect the validity of the remaining claims.[22] The Court will not redraft the claims in order to save the patent.[23]

17.4.2 Principles of Claim Construction

The rules of claim construction are not defined in the *Patent Act* but have been established in Canadian jurisprudence. The SCC has held that: It has always been a fundamental rule of claims construction that the claims receive one and the same interpretation for all purposes.[24]

In construing a patent, and to give effect to the true invention, the "patent specification should be given a purposive construction rather than a purely literal one derived from applying to it the kind of meticulous verbal analysis in which lawyers are too often tempted by their training to indulge."[25] The language of the claims, purposively construed, defines the legal boundary of the claims. A patent is also an enactment within the definition of "regulation" under

19 *Whirlpool*, at para 53.
20 *Free World*, at para 44, citing H.G. Fox, *The Canadian Patent Law and Practice Relating to Letters Patent for Inventions*, 4th ed (Toronto: Carswell, 1969) at 184 [Fox, *Letters Patent for Invention*].
21 *Whirlpool*, at para 75.
22 *Patent Act*, s 58.
23 *Eli Lilly & Co v O'Hara Manufacturing Ltd* (1989), 26 CPR (3d) 1 at 7 (FCA).
24 *Whirlpool*, at para 49(b).
25 *Whirlpool*, at para 44, citing *Catnic Components Ltd v Hill & Smith Ltd* (1982) RPC 183 at 243 (HL).

the *Interpretation Act* and must accordingly be given an interpretation as best ensures the attainment of its objects.[26]

The key to purposive construction is the identification of the essential elements of the invention. Construction of a patent is a question of law for the Court. However, it should be undertaken with the knowledge of a POSITA to the extent that such knowledge is revealed by expert evidence at trial.[27]

In adopting a purposive method of construction, the Court has eschewed a two-step process of determining literal and then substantial infringement in favour of a single test that distinguishes between essential elements, non-essential elements, and permissible variants. Non-essential elements may be substituted or omitted without having a material effect on the structure or operation of the invention as described in the claim, while essential elements must be present in order for the device to work as contemplated and claimed by the inventor.[28]

The wording of the claims must be read in context, and it is unsafe in many instances to conclude that a term is plain and unambiguous without a careful review of the specification. One must be careful not to interpret the claims in a way that does not accord with the specification as a whole.[29] Where possible, different claims are to be given distinct meanings. This is referred to as "claim differentiation". "Claim differentiation simply requires that limitations of one claim not be read into a general claim. … Where some claims are broad and others narrow, the narrow claim limitations cannot be read into the broad."[30] It follows that "independent claims must be construed in a manner consistent with their dependent claims."[31] In *Eli Lilly & Co v Apotex Inc*,[32] Justice Gauthier adopted the following commentary with respect to claim differentiation:

> Each part of the specification must be effectively construed and, if it is at all possible, each claim must be construed independently of the others and be given an effective and distinct meaning. The court will not be inclined to construe two claims in a specification as identical, for if one claim bears the same meaning as another it does not bear an effective meaning.[33]

26 *Whirlpool*, at para 49(e), citing *Interpretation Act*, RSC 1985, c I-21, s 2(1).
27 *Whirlpool*, at para 45; *Free World*, at para 52; *Beecham Canada Ltd et al v Procter & Gamble Co* (1982), 61 CPR (2d) 1 at 9 (FCA).
28 *Free World*, at para 52.
29 *Nekoosa Packaging Corp et al v United Dominion Industries Ltd et al* (1994), 85 FTR 160, at para 37 (FCA).
30 *Halford v Seed Hawk Inc*, 2004 FC 88 [*Halford FC*] at para 93, var'd by *Halford v Seed Hawk*, 2006 FCA 275, aff'd with respect to claim construction at para. 28.
31 *Halford v Seed Hawk Inc, 2004 FC 88 [Halford FC]* at para 95.
32 *Eli Lilly & Co v Apotex Inc*, 2009 FC 991 [*Eli Lilly cefaclor*], aff'd 2010 FCA 240.
33 *Eli Lilly cefaclor*, at para 90 [emphasis in original].

Claim differentiation is a rebuttable presumption.[34] "However, the starting assumption must be that claims are not redundant, and only if a purposive analysis shows that claims are in effect duplicated can this construction be adopted."[35]

To reject purposive construction would imply embracing a purposeless approach that ignores the context and use to which the words are being put.[36] Purposive construction does not go outside the four corners of the specification:

> it [is] perfectly permissible for the trial judge to look at the rest of the specification, including the drawing, to understand what was meant by [a particular word] in the claims, but not to enlarge or contract the scope of the claim as written and thus understood.[37]

The construction of a patent must be neither benevolent nor harsh, but rather should be reasonable and fair to both the public and the Patentee. A patent must be read by a mind willing to understand, not a mind desirous of misunderstanding. This necessarily means that close attention must be paid to the purpose and intent of the author. The Court should not apply an overly technical or astute approach, and should endeavour to give effect to the construction that will give the inventor protection for that which they have in good faith invented.[38]

Historically, it had been held that claims construction should not be allowed to become a result-oriented interpretation. One should not have an eye on the allegedly infringing device, nor should one be looking at the prior art with respect to validity. However, the Court has allowed that claims construction can be performed with an eye to where the dispute lies between the parties.[39]

A dictionary approach is not to be used in construing claims. This approach would be using evidence from outside the four corners of the specification. Furthermore, looking at the claims of the patent using a dictionary approach is equivalent to looking at the words through the eyes of a grammarian or etymologist rather than through the eyes of and with the knowledge of a POSITA.[40] In addition, the Court has also commented on claim differentiation, holding:

Each part of the specification must be effectively construed and, *if it is at all possible, each claim must be construed independently of the others and*

34 *Halford v Seed Hawk Inc, 2004 FC 88 [Halford FC]*, at para 94.
35 *Abbott Laboratories v Canada (Minister of Health)*, 2007 FCA 153 at para 33; Cited with approval in *Bridgeview Manufacturing Inc v 931409 Alberta Ltd*, 2010 FCA 188 at para 33.
36 *Whirlpool*, at para 49(d).
37 *Whirlpool*, at para 52.
38 *Whirlpool*, at para 49(g); *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.*, [1981] 1 SCR 504 at 157 [*Consolboard*].
39 *Shire Biochem Inc v Canada (Minister of Health)*, 2008 FC 538 at para 21; *Eli Lilly cefaclor* at para 88.
40 *Whirlpool*, at para 53.

be given an effective and distinct meaning. The court will not be inclined to construe two claims in a specification as identical, for if one claim bears the same meaning as another it does not bear an effective meaning.[41]

Purposive construction is not to be confused with the "spirit of the invention" school of construction.[42] A purposive construction is not necessarily a substantive one, nor is it intended to divine some monopoly not described by the language of the claims themselves. The language of the claims remains paramount. The task of the Court is simply to determine what that language means in the context of a patent as a whole and, having done so, to determine which elements of the claim so described are essential and which are non-essential.

17.4.3 Essential Versus Non-Essential Elements

Part of claim construction is to determine the essential versus non-essential elements. The SCC has set out that the distinction between essential and non-essential elements of the claim is made having regard to five factors:

i. What is essential or non-essential is determined having regard to the words chosen by the inventor, in light of the patent specification as a whole, in a way that is sympathetic to accomplishing the inventor's purpose as expressed in the claims, and through the eyes of a worker skilled in the art to which the patent relates.[43]

ii. Whether an element is essential or not is determined in light of the knowledge of the art as of the date of publication of the patent specification. The issue here is whether persons with practical knowledge and experience in the art would understand that strict compliance with a particular descriptive word or phrase appearing in a claim was intended by the Patentee to be an essential requirement of the invention, so that any variant would fall outside the monopoly claimed, even though it would have no material effect on the way in which the invention worked. If so, the element is essential.[44]

iii. For an element to be classified as non-essential, either of two conditions must be satisfied. First, it must be shown that, on a purposive construction of the words of the claim, the inventor clearly did not intend the element to be essential. Alternatively, it must

41 *Eli Lilly cefaclor*, at para 90 [emphasis in original], citing Fox, *Letters Patent for Invention* at 219; see also *Hoffmann-Laroche Ltd v Mayne Pharma (Canada) Inc,* 2005 FC 814 at para 43.
42 *Free World*, at paras 45-50.
43 *Free World*, at para 51.
44 *Free World*, at para 51.

be shown that as of the date of publication of the patent a skilled addressee would have appreciated that the element in question could be substituted without affecting the working of the invention — that is, that the variant would have performed substantially the same function in substantially the same way in order to obtain substantially the same result.[45]

iv. The construction of the patent is based on the specification itself, without resort to extrinsic evidence. The doctrine of file wrapper estoppel, so central to claim construction in the United States, has less application in Canada. The use of the file wrapper to define the scope of the grant of the monopoly was rejected as inconsistent with the doctrine of purposive construction.[46] However, it should be noted that in 2018, a provision was added to the *Patent Act* that allows that in any action respecting a patent a written communication may be admitted into evidence to rebut any representation made by the Patentee as to the construction of a claim if certain conditions are met.[47]

v. The onus is on the Patentee to establish known and obvious substitutability as of the date of publication of the patent. If the Patentee fails to discharge that onus, the descriptive word or expression in the claim is to be considered essential unless the context of the claim's language otherwise dictates.[48]

Purposive construction has a direct and significant effect on the infringement test that can be employed. Where a purposive construction is adopted, by definition one cannot apply an infringement test that seeks to determine whether there is literal infringement and, if not, whether there is substantive infringement. The purposive construction does away with all of that. It asks, simply, what is essential and what is non-essential?

17.5 Infringement/Non-Infringement Overview

The *Patent Act* does not provide a definition of what constitutes infringement. Section 42 states that the grant of a patent affords the Patentee the exclusive right of "making, constructing and using the invention and selling it to others to be used." The principles as developed in the case law generally provide that any act that interferes with the exercise of the Patentee's monopoly constitutes infringement. Infringement proceedings are governed by sections 54 to 57 of

45 *Free World*, at para 52.
46 *Free World*, at paras 66-67.
47 *Patent Act*, s 53.1.
48 *Free World*, at para 57.

the *Patent Act*.

The limitation period for infringement is six years.[49] The burden to prove the infringement is on the plaintiff, except in an action for infringement of a patent granted for a process for obtaining a new product.[50] In that case, any product that is the same as the new product is, in the absence of proof to the contrary, considered to have been produced by the patented process.

17.5.1 Liability and Remedies

The ability to make a claim for patent infringement extends not only to the Patentee, but to all persons claiming under the Patentee.[51] The definition of a person claiming under the Patentee extends to Licensees. Furthermore, there is no requirement for the licence to be express; it can be implied.[52] When considering the facts as to whether an implied licence exists, the Court has held that a corporate affiliation is not enough to give a company standing.[53] Something more, giving the entity rights to use the patent, must exist.[54]

Liability extends to all damages sustained after the grant of the patent by reason of the infringement.[55] It is also possible, in some circumstances, to claim the equitable remedy of an accounting of the infringer's profits in lieu of damages. The Court has held that the trial judge has complete discretion in deciding whether to grant this remedy.[56] The Federal Court of Appeal (FCA) upheld a decision of the trial judge refusing to award an accounting of profits because of the slow pace of the litigation and the failure of the Patentee to compete with the generic company's price in the market.[57]

Also to be factored into remedies is the concept of a non-infringing alternative or NIA. This concept requires that a defendant could have and would have made use of a NIA in a but-for world.[58]

A defendant can only be held liable for infringement of valid issued claims as of the issue date. Such claims often differ in scope from the published claims. If the issued claims are of similar scope to the published claims, then the defendant can be held liable for "reasonable compensation", which generally

49 *Patent Act*, s 55.01.
50 *Patent Act*, s 55.1.
51 *Patent Act*, s 55(1).
52 *Laboratoires Servier v Apotex Inc*, 2008 FC 825 at para 77 [*Servier*], aff'd on other grounds (without comment on this point) 2009 FCA 222.
53 *Servier* at para 82.
54 *Servier* at para 82.
55 *Patent Act*, s 55.
56 *Apotex Inc v Merck & Co*, 2006 FCA 323 at para 127 [*Apotex v Merck & Co*].
57 *Apotex v Merck & Co* at paras 128-133.
58 *Apotex Inc v Merck & Co, Inc*, 2015 FCA 171.

amounts to a reasonable royalty rate, calculated as of the publication date for conduct that would have constituted infringement, back to the date that the patent application is open to public inspection, as if the patent had been issued on that day.[59] This seems to be understood to mean a reasonable royalty rate.[60]

Punitive damages, intended to punish the infringer, have been awarded in patent cases.[61]

17.5.2 Test for Infringement

The question to be asked by the Court in determining infringement is:

> did the defendant, by his acts or conduct, deprive the inventor, in whole or in part, indirectly or directly of the patented invention?[62]

In particular, where a defendant's impugned activities furthered its own commercial interests, the Court should be particularly alert to the possibility that the defendant has committed an infringing act.[63]

At the infringement analysis stage, the accused device or process is to be examined and its constituent elements identified using the same kind of purposive analysis as is applied to the patent. Whether a defendant's product or process falls within the scope of the monopoly identified is decided on the basis of the following criteria:

a. Where the defendant's product or process does not have all the essential elements of the claim, it does not infringe and the inquiry ends.
b. If the defendant's product or process has all the essential elements, then does it incorporate the non-essential elements claimed? If so, there is infringement, unless the non-essential elements consist of a variation that has a material effect on the way in which the invention works. If that is so, there is no infringement.
c. If the non-essential element consists of a variant which has no material effect on the way in which the invention works, then was that fact obvious as of the date of publication of the patent to a reader skilled in the art? If not, there is no infringement.
d. If the POSITA would nevertheless have understood from the language of the claim that the Patentee intended that strict compliance with the primary meaning was an essential requirement of the invention, then the variant is outside the claim and there is no infringement.[64]

59 *Patent Act*, s 55(2).
60 *Jay-Lor International v Penta Farm Systems Ltd*, 2007 FC 358 at 123.
61 *Bell Helicopter Textron Canada Limitée v Eurocopter* 2013 FCA 219; *Airbus Helicopters SAS v Bell Helicopter Textron Canada Limitée*, 2019 FCA 29.
62 *Monsanto Canada Inc v Schmeiser*, 2004 SCC 34 at para 44 [*Monsanto*].
63 *Monsanto* at para 37.
64 *Free World*, at para 55, citing *Improver Corp v Remington Consumer Products Ltd*, [1990] FSR 181 at 182.

17.5.3 Inducement

A person who induces or procures another to infringe a patent is responsible for the infringement. Inducement requires three conditions to be met:

(1) that the act of infringement was completed by the direct infringer;

(2) the completed act of infringement was influenced by the seller, to the point where without said influence, infringement by the buyer would not have otherwise take place; and

(3) the influence must knowingly be exercised by the seller, such that the seller knows that his influence will result in the completion of the act of infringement.[65]

The FCA has held that each of these criteria is a question of fact as to whether inducement is proved.[66]

The classic case of inducement in Canada occurred when a manufacturer sold the components of a sailboard that, when assembled, infringed the patent. The FCA held that the manufacturer was not simply selling parts — those parts were for the purpose of making a sailboard.[67] The FCA then drew inferences that the manufacturer knew of the existence of the patent and induced purchasers of its sailboard kits to infringe the patent and was thus guilty of infringement.[68]

17.5.4 Exceptions to Infringement

The *Patent Act* contains an early working exception that permits a person to make, construct, use, or sell a patented invention solely for uses reasonably related to the development and submission of information required to comply with a regulatory regime in respect of the manufacture, construction, or sale of that product.[69] This exception is relied on heavily in the generic pharmaceutical industry, as it applies to otherwise infringing products required for any regulatory regime around the world.

Changes to the *Patent Act* in 2018 resulted in statutory exceptions to infringement. For example, section 55.11 provides for third-party rights.[70] Section 56 exempts prior use under certain conditions.[71]

65 *AB Hassle v Canada (Minister of National Health & Welfare)*, 2002 FCA 421 at para 17; see also *Bauer Hockey Corp. v. Easton Sports Canada Inc.*, 2010 FC 361 at paras 181-182, aff'd on other grounds (without comment on this point) 2011 FCA 83.
66 *Dableh v Ontario Hydro* 1996 CanLII 4068 (FCA), [1996 3 FC 751.
67 *Windsurfing International Inc v Trilantic Corporation* (1985), 8 CPR (3d) 241 at 265 (FCA) [*Windsurfing*].
68 *Windsurfing* at 268.
69 *Patent Act*, s 55.2.
70 *Patent Act*, s 55.11.
71 *Patent Act*, s 56.

At common law, the Courts established a separate experimental-use exception to infringement for *bona fide* experimental use. The leading case is *Micro Chemicals*, where making the patented substance for the purpose of establishing that a quality product could be manufactured was held to be experimental and, thus, non-infringing.[72] In 2018, the *Patent Act* was amended to include a provision that states that an act committed for the purpose of experimentation relating to the subject matter of a patent is not an infringement of the patent.[73]

17.6 Validity

A party can try to cancel an issued Canadian patent pursuant to the *Patent Act*. If a party is sued for patent infringement, they can defend the suit with allegations of invalidity,[74] and/or start a counterclaim to impeach the patent pursuant to section 60(1) of the *Patent Act*.[75]

In order to start an impeachment proceeding, the proposed plaintiff must establish that it has standing as an interested person to attack the patent, but it need not be actually making, using, or selling the invention in Canada. The meaning of "interested person" has been described as broad.[76] Standing will generally be established if the challenger can show that the patent detrimentally affects its business interests, or that the challenger intends to sell a product in competition with the Patentee.[77] As in a non-infringement action, the plaintiff must post a bond for security of the Patentee's costs of the action.[78]

An impeachment proceeding is conducted by way of action, originating by way of a statement of claim or by way of counterclaim and defence to an infringement action.

There are a number of grounds on which the validity of a patent can be contested, and most mirror the grounds on which a patent is granted. We discuss here some of the more common grounds — anticipation, obviousness, sufficiency, utility, sound prediction, double patenting, ambiguity, overbreadth,

72 *Micro Chemicals Ltd v Smith Kline & French Inter-American Corp* (1971), [1972] SCR 506.
73 *Patent Act*, s 55.3.
74 *Patent Act*, s 59.
75 *Patent Act*, s 60(1).
76 *Purcell Systems Inc v Argus Technologies Ltd*, 2008 FC 1210.
77 *Wakefield Properties Corp v Teknion Furniture Systems Inc* (1992), 56 FTR 228, 44 CPR (3d) 474 (FCTD).
78 *Patent Act*, s 60(3).

and methods of medical treatment. The courts have held that patent law is entirely statutory:

> It is well established that Canadian patent law is entirely statutory in nature. It is derived from the Act and the regulations enacted under it. … the Act and Regulations are described by this Court as a "complete code."[79]

17.6.1 Anticipation/Novelty

Pursuant to the *Patent Act* (applicable to applications filed after October 1, 1989), the subject matter of a patent must not be previously disclosed.[80] The *Patent Act* then defines four different ways in which such previous disclosure could occur:

i. more than one year before the filing date by the Applicant (or a person who obtained knowledge from the Applicant) in such a manner that the subject matter became available to the public;
ii. before the claim date by someone other than the Applicant, or a person who obtained the knowledge from the applicant, in such a manner that the subject matter became available to the public;
iii. in a patent application filed in Canada by a person other than the Applicant, with a filing date before the claim date; or
iv. in certain circumstances, in a patent application filed in Canada by a person other than the Applicant which has a filing date on or after the claim date.[81]

The SCC has set out a two-part test for determining whether a piece of prior art is anticipatory; it must both disclose and enable the invention in the patent at issue.[82]

The disclosure element is met if the prior art discloses "subject matter which, if performed, would necessarily result in infringement of that patent."[83] All of the essential elements of the invention must be present in a single document. No trial and error is permitted at this stage.[84] In the context of a genus patent being alleged to anticipate a selection patent, the Court held that the prior disclosure must also disclose the special advantages of the selection patent.[85]

79 *Weatherford Canada Ltd v Corlac Inc*, 2011 FCA 228 at para 141 [citations omitted] [*Weatherford*];see also *Sanofi-Synthelabo Canada Inc v Apotex Inc*, 2008 SCC 61, [Sanofi].
80 *Patent Act*, s 28.2.
81 *Patent Act*, s 28.2.
82 *Sanofi* at para 49.
83 *Sanofi* at para 25.
84 *Sanofi* at para 32.
85 *Sanofi* at para 32.

When considering enablement, some amount of experimentation is permitted; however, "the skilled person must still be able to perform or make the invention of the second patent without undue burden."[86] If that trial and error goes so far as to be an inventive step, then the prior disclosure is not enabling.[87]

The following factors were set out for consideration:

1. Enablement is to be assessed having regard to the prior patent as a whole, including the specification and the claims. There is no reason to limit what the skilled person may consider in the prior patent in order to discover how to perform or make the invention of the subsequent patent. The entire prior patent constitutes prior art.
2. The skilled person may use their common general knowledge to supplement information contained in the prior patent. Common general knowledge means knowledge generally known by persons skilled in the relevant art at the relevant time.
3. The prior patent must provide enough information to allow the subsequently claimed invention to be performed without undue burden. When considering whether there is undue burden, the nature of the invention must be taken into account. For example, if the invention takes place in a field of technology in which trials and experiments are generally carried out, the threshold for undue burden will tend to be higher than in circumstances in which less effort is normal. If inventive steps are required, the prior art will not be considered as enabling. However, routine trials are acceptable and would not be considered undue burden. But experiments or trials and errors are not to be prolonged even in fields of technology in which trials and experiments are generally carried out. No time limits on exercises of energy can be laid down; however, prolonged or arduous trial and error would not be considered routine.
4. Obvious errors or omissions in the prior patent will not prevent enablement if reasonable skill and knowledge in the art could readily correct the error or find what was omitted.[88]

Thus, the challenger must show that the prior publication meets the tests for both disclosure and enablement. Since this is a two-step test, if there is no disclosure, the Court does not even have to consider whether there has been enablement.[89]

86 *Sanofi* at para 33.
87 *Sanofi* at para 33.
88 *Sanofi* at para 37.
89 *Sanofi* at para 42.

As described above, there is a one-year grace period for disclosure by the Applicant.[90]

There is no restriction as to the geographical location of a disclosure to the public. Section 28.2 of the *Patent Act* applies to public disclosures made in Canada or elsewhere. Any single disclosure of information about the invention made to another party without a confidentiality restriction may constitute public disclosure. The disclosure may be, for example, in writing, by selling a product, by using a product, or by performing a method.

Subject matter that has not been disclosed to the public but is disclosed in a co-pending patent application previously filed in Canada is citable against a patent application for determining novelty.[91] If a Canadian application claims the same subject matter as disclosed and claimed in a co-pending Canadian application, the patent application having the earliest claim date will be entitled to claims to the subject matter over any application having a later claim date.

The FCA has held that whether a piece of prior art discloses, the second invention will be determined by how a POSITA would understand the document.[92] If disclosure is found to exist, then enablement is addressed. "The prior art must provide the POSITA, using his or her common knowledge, with enough information to allow the subsequently claimed invention to be performed without undue burden."[93] Routine experimentation is acceptable in a field of technology where trials and experiments are generally carried out.[94]

Whether the alleged anticipatory disclosure is to the public can be the subject of debate and will be dependent on the specific facts surrounding the disclosure. However, the Court has held that it is the unconditional sale that makes a product available to the public.[95] Furthermore, a general industry practice of confidentiality has been held to render a sale confidential.[96]

Although the sale of a product may constitute public disclosure, Canada does not enforce an on-sale bar. In some cases, the sale of a product that falls within a claim may not constitute public disclosure of the subject matter of the claim.

90 *Patent Act*, s 28.2(1)(a).
91 *Patent Act*, ss 28.2(1)(a), (c); s 28.2(1)(d) of the *Patent Act* is an analogous provision for other Canadian applications filed after the filing date of the application but with a priority claim earlier than the filing date.
92 *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2010 FCA 197 at para 44 [*Eli Lilly v Novopharm olanzapine FCA*].
93 *Eli Lilly v Novopharm olanzapine FCA* at para 45.
94 *Eli Lilly v Novopharm olanzapine FCA* at para 45.
95 *Weatherford* at para 45.
96 *Weatherford* at para 63.

This applies in cases where the invention cannot be determined or reverse-engineered from the product. If the sale of the product does not make the invention available to the public, then the sale of the product is not anticipation.[97]

17.6.2 Obviousness/Inventiveness

The *Patent Act* also states that the subject matter defined by a claim in an application for a patent must be subject matter that would not have been obvious on the claim date to a POSITA to which it pertains (applicable to applications filed after October 1, 1989).[98] The POSITA can consider information disclosed more than one year before the Canadian filing date by the Applicant or a person obtaining knowledge through them and information disclosed before the claim date, in the case of other persons.[99] In both cases, the information must become available to the public.

Thus, the same one-year grace period for disclosure exists for the Applicant. When alleging obviousness, multiple pieces of prior art can be used. Also, similar to the novelty provisions, section 28.3 applies to public disclosures made in Canada or elsewhere; there is no restriction on the geographical location of the publication. In contrast to the novelty provisions, undisclosed Canadian applications with a filing date or claim date prior to the filing date of the Canadian application are not citable against a claim under section 28.3.

The SCC has restated the test for obviousness as follows:

(1) (a) Identify the notional "person skilled in the art";

(1) (b) Identify the relevant common general knowledge of that person;

(2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;

(3) Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed;

(4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?[100]

Then, at this fourth stage of the test, the Court can consider the issue of whether the claimed invention is "obvious to try", This has been held to be

97 *Baker Petrolite Corp v Canwell Enviro-Industries Ltd*, 2002 FCA 158.
98 *Patent Act*, s 28.3.
99 *Patent Act*, ss 28.3(a) and (b), respectively.
100 *Sanofi* at para 67.

appropriate in areas where advancement is won by experimentation.[101] The factors in an analysis of whether a claimed invention was obvious to try are:

1. Is it more or less self-evident that what is being tried ought to work? Are there a finite number of identified predictable solutions known to persons skilled in the art?
2. What is the extent, nature, and amount of effort required to achieve the invention? Are routine trials carried out or is the experimentation prolonged and arduous, such that the trials would not be considered routine?
3. Is there a motive provided in the prior art to find the solution the patent addresses?[102]

The FCA has held that "worth a try" is not synonymous with "obvious to try".[103] The "mere possibility that something might turn up is not enough."[104]

Canadian courts caution themselves repeatedly against the dangers of hindsight because, after the event, nothing is easier than to say that the thing was obvious and involved no invention:[105]

> Every invention is obvious after it has been made, and to no one more so than an expert in the field. Where the expert has been hired for the purpose of testifying, his infallible hindsight is even more suspect. It is so easy, once the teaching of a patent is known, to say, "I could have done that"; before the assertion can be given any weight, one must have a satisfactory answer to the question, "Why didn't you?"[106]

17.6.3 Sufficiency

Section 27(3)(b) of the *Patent Act* requires that a Patentee set out clearly in the specification the method of making or using the invention in such full, clear, concise, and exact terms as to enable a POSITA to make or use it.[107] The description of the invention is the *quid pro quo* for which the inventor is given a monopoly for a limited term of years.[108]

101 *Sanofi* at para 68.
102 *Sanofi* at para 69.
103 *Pfizer Ltd v Ratiopharm Inc*, 2010 FCA 204 at para 15.
104 *Sanofi* at para 66.
105 *Reading & Bates Construction Co v Baker Energy Resources Corp* (1987), 14 FTR 81 at 188, citing *Non-Drip Measure Co Ltd v Stranger's Ltd* (1943), 60 RPC 135 at 142 (HL).
106 *Beloit Canada Ltd v Valmet Oy* (1986), 8 CPR (3d) 289 at 295 (FCA).
107 *Patent Act*, s 27(3)(b).
108 *Consolboard* at 154.

Historically, the SCC has held:

> The Applicant must disclose everything that is essential for the invention to function properly. To be complete, it must meet two conditions: it must describe the invention and define the way it is produced or built. The Applicant must define the nature of the invention and describe how it is put into operation. A failure to meet the first condition would invalidate the application for ambiguity, while a failure to meet the second invalidates it for insufficiency. The description must be such as to enable a person skilled in the art or the field of the invention to produce it using only the instructions contained in the disclosure and once the monopoly period is over, to use the invention as successfully as the inventor could at the time of his application.[109]

The SCC has also held that, in order for the patent specification to be sufficient pursuant to the *Patent Act*, it must answer two questions: What is your invention? How does it work?[110]

In a subsequent decision, the SCC reiterated that *Consolboard* requires that the specification, which includes the claims and the disclosure, defines the precise and exact extent of the privilege being claimed so as to ensure that the public can, having only the specification, make the same use of the invention as the inventor.[111]

17.6.4 Utility and Sound Prediction

Utility is an essential part of the definition of an invention.[112] To establish a lack of utility, the alleged infringer must demonstrate "that the invention will not work, either in the sense that it will not operate at all or, more broadly, that it will not do what the specification promises that it will do."[113]

Generally speaking, patent claims that include inoperable embodiments are invalid.[114] However, if a POSITA would know that a particular compound or combination falling within the claims would be inoperable, then it falls outside the claim, and the claim itself is valid.[115]

109 *Pioneer Hi-Bred Ltd v Canada (Commissioner of Patents)*, [1989] 1 SCR 1623 at 268 [citations omitted].
110 *Consolboard* at 157.
111 *Teva Canada Ltd v Pfizer Canada Inc*, 2012 SCC 60 at para 70 [*Teva v Pfizer sildenafil*].
112 *Patent Act*, s 2.
113 *Consolboard* at 160, citing *Halsbury's Laws of England*, 3d ed, vol. 29 (London: Butterworths, 1980) at 59.
114 *Noranda Mines v. Minerals Separation Corp.*, [1950] SCR 36.
115 *Omark Industries (1960) Ltd v Gouger Saw Chain Co*, [1965] 1 Ex CR 457; *Appliance Service Co v Sarco Canada Ltd* (1974), 14 CPR (2d) 59 (FCTD); Burton Parsons.

Where not demonstrated in fact, utility must be premised on a sound prediction. If a patent supported on the basis of sound prediction is subsequently challenged, the challenge will succeed if the prediction at the date of the application was not sound or, irrespective of the soundness of the prediction, there is evidence of lack of utility in respect of some area covered.[116] However, "the doctrine of sound prediction presupposes that further work remains to be done."[117]

The SCC held that the doctrine of sound prediction has three components. First, there must be a factual basis for the prediction. Second, at the date of the patent application, the inventor must have an articulable and sound line of reasoning from which the desired result can be inferred from the factual basis. Third, there must be proper disclosure, meaning that the specification needs to provide a full, clear, and exact description of the nature of the invention and the manner in which it can be practised.[118] A line of reasoning grounded in known "architecture of chemical compounds" is acceptable.[119] There is a line of cases that have held that the factual basis and the sound line of reasoning must be properly described in the patent disclosure.[120]

Recently, the FCA has considered issues of utility on a number of occasions. Each of these cases appears to turn on the particular facts of the case and the construction of the promise of the patent. The Court has held that whether a particular compound within the claim can be made is not an element of sound prediction, but rather of sufficiency.[121] The FCA has held that "testing is not an absolute requirement for a patent based on sound prediction."[122] The Court has also held that "evidence with respect to utility will generally go well beyond the patent's content."[123] However, in other cases, the testing performed by the Patentee was not considered to be sufficient to demonstrate utility, and the tests were not adequately described in the patent to support a finding of sound prediction.[124]

The SCC has written repeatedly that utility is not a disclosure requirement. There is no requirement in section 27(3) to disclose the utility of the invention.[125]

116 *Apotex v Wellcome Foundation Ltd*, 2002 SCC 77 at para 56 [*Wellcome*].
117 *Eli Lilly v Novopharm olanzapine FCA* at para 82.
118 *Wellcome.*
119 *Wellcome* at para 70, citing *Burton Parsons* and *Monsanto Co v Canada (Commissioner of Patents)*, [1979] 2 SCR 1108.
120 *Eli Lilly Canada Inc v Apotex Inc*, 2009 FCA 97 [*Eli Lilly v Apotex raloxifene FCA*]; *Eli Lilly & Co v Teva Canada Ltd*, 2011 FCA 220 [*Eli Lilly v. Teva atomoxetine*].
121 *Apotex Inc v Laboratoires Servier*, 2009 FCA 222 at para 115 [*Apotex v Servier*].
122 *Pfizer Canada Inc v Apotex Inc*, 2007 FCA 209 at para 152.
123 *Eli Lilly v Novopharm olanzapine FCA* at para 92.
124 *Eli Lilly v Teva atomoxetine*; *Eli Lilly v Apotex raloxifene FCA.*
125 *Teva v Pfizer sildenafil* at para 40; *AstraZeneca Canada Inc v Apotex Inc*, 2017 SCC 36 at para 42-43 [*AstraZeneca*].

The SCC provided the analysis to be performed by courts: first, identify the subject matter of the invention as claimed in the patent; second, ask whether that subject matter is useful – is it capable of a practice purpose?[126] The SCC noted that the *Patent Act* does not prescribe the quantum of usefulness required, or that every potential use be realized – a scintilla of utility will do.[127]

17.6.5 Double Patenting

Section 27 of the *Patent Act* provides that the Commissioner shall grant *a patent* for an invention.[128] This provision has been the basis for a series of decisions defining the judge-made concept of double patenting and the prohibition on having two patents covering the same invention. Unlike U.S. law, Canadian patent law does not allow for terminal disclaimers.

The SCC has held that there are two branches to the prohibition on double patenting.[129] The first branch is termed "same invention" double patenting, and the question to be determined by the judge is whether the two patents contain claims that are identical or coterminous.[130] The second branch is termed "obviousness" double patenting. It is "a more flexible and less literal test that prohibits the issuance of a second patent with claims that are not 'patentably distinct' from those of the earlier patent."[131]

The classical case is one in which a Patentee obtains a patent for a medicine in diluted form where it already has a patent on the medicine. In that event, the claims are neither identical nor coterminous. They are, however, invalid on the basis that the diluted and undiluted substances are but two aspects of exactly the same invention.[132]

Divisional applications may be especially susceptible to an attack based on double patenting. Divisional applications are either voluntary or forced. If the Commissioner of Patents issues a unity objection during prosecution of the patent, and a divisional patent is filed as a result, it is a forced divisional.[133] However, if no such objection is made, and a divisional is filed, it will be considered to be voluntary.

In relation to "forced" divisionals, the SCC determined in 1981 that "if patents are granted on divisional applications directed by the Patent Office, none of

126 *AstraZeneca* at para 54.
127 *AstraZeneca* at para 55.
128 *Patent Act*, s 27.
129 *Whirlpool*.
130 *Whirlpool*, at para 65.
131 *Whirlpool*, at para 66.
132 *Commissioner of Patents v Farbwerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning* (1963), [1964] SCR 49.
133 *Patent Act*, s 36(2.1).

them should be deemed invalid or open to attack, by reason only of the grant of the original patent."[134] Thus, the Court has held thus far that a divisional application required to be filed by the Commissioner cannot be invalidated by reason of double patenting.

However, voluntary divisionals are in danger. The Federal Court has held a patent resulting from a voluntary divisional invalid for "obviousness-type" double patenting over the parent patent, even though both expired on the same date.[135] The courts have found that a Patentee receives a benefit by having two patents for an invention, even if both expire on the same day.[136]

In view of this case law, a Patentee should be extremely reluctant to file a divisional application in cases where the Patent Office has not required that the claims be limited. When enforcing the resulting divisional patent, the Patentee may run into double-patenting issues.

17.6.6 Ambiguity

Section 27(4) of the *Patent Act* requires that patent claims must define "distinctly and in explicit terms" the subject matter for which exclusivity is claimed. Thus, the inventor must describe in language, free from ambiguity, the nature of their invention, including the manner in which it is to be performed.[137] If the inventor uses language that, read fairly, is avoidably obscure or ambiguous, the patent is invalid. Mere difficulty in construing the meaning of a term is not, however, invalidating.[138]

A claim that is unclear as to its boundaries is invalid. If the POSITA, in attempting to put a claim to use or in trying to determine the boundaries outside of which another method would not infringe, is given insufficient or obscure direction, then the claim is invalid.[139] Put otherwise, a patent must make clear what is within and what is not within a given claim.[140] Where a claim can be interpreted in more than one way, it may be found invalid for ambiguity.[141] In such a case, it would be impossible for the POSITA to know, at least in advance, when a manufacture, use, or sale of a product is within the claim.

Notwithstanding the foregoing, courts are reluctant to invalidate a claim for ambiguity. A phrase that can be properly interpreted using grammatical rules

134 *Consolboard* at 169.
135 GlaxoSmithKline Inc et al v Apotex Inc et al., 2003 FCT 687 ; (2003), 234 FTR 251, (FCTD) [*GlaxoSmithKline*].
136 *GlaxoSmithKline*.
137 *French's Complex Ore Reduction Co of Canada v Electrolytic Zinc Process Co*, [1930] SCR 462 at 470.
138 *Natural Colour Kinematography Co v Bioschemes Ltd* (1915), 32 RPC 256 (HL).
139 *Xerox of Canada Ltd v IBM Canada Ltd* (1977), 33 CPR (2d) 24 at 82 (FCTD).
140 *Smith Incubator Co v Seiling*, [1937] SCR 251 at 255.
141 *Apotex Inc v Hoffmann-La Roche Ltd* (1989), 27 FTR 240 at 299 (FCA).

and common sense is not ambiguous. Conflicts among experts' interpretations of a phrase can sometimes be solved with a common-sense grammatical reading of the phrase.[142] The Court has reviewed many of the relevant authorities, including *Mobil Oil*, and held that, "[i]n short, ambiguity is truly a last resort, rarely, if ever, to be used."[143]

17.6.7 Overbreadth

An allegation of overbreadth can take two forms – the claims of a patent are broader than the invention disclosed in the specification, a legal issue, or broader than the invention made, a factual issue.[144]

Overbreadth is said to arise as a result of the requirement in section 27(4) of the *Patent Act* that requires a claim or claims to define distinctly and in explicit terms the subject matter of the invention for which an exclusive privilege or property is claimed.[145]

One example of an allegation of overbreadth is that a claim is overbroad if an essential element of the invention is omitted from the claim.[146]

17.6.8 Method of Medical Treatment

An allegation may be made that the applicable claims are invalid on the basis of being unpatentable methods of medical treatment. The allegation is that these types of claims do not constitute a process within the definition of invention in section 2 of the *Patent Act.*[147]

For example, claims to a dosage regimen have been challenged on the basis that a physician may be prevented, by a patent, from exercising skill and judgment in using a known compound. It appears that the question to be answered by the Court in the face of such an allegation is whether the claim is directed to the skill of a medical professional, as opposed to a vendible product.[148]

17.6.9 Selection Patents

Selection patents commonly arise in the context of chemical patents. Often, the first patent claims a "genus" or a group of products or processes from which a particular result can be predicted. If one or more members of the genus have a particular property or quality, that group may be considered a separate

142 *Mobil Oil Corp v Hercules Canada Inc* (1995), 63 CPR (3d) 473 at 484 (FCA) [*Mobil Oil*].
143 *Pfizer Canada Inc v Canada (Minister of Health)*, 2005 FC 1725 at para 53.
144 *AFD Petroleum Ltd v Frac Shak Inc*, 2018 FCA 140 at para 49.
145 *Seedlings Life Sciences Ventures, LLC v Pfizer Canada ULC*, 2020 FC 1 [Seedlings v Pfizer]; *Patent Act*, s 27(4).
146 *Seedlings v Pfizer* at para 173.
147 *Tennessee Eastman Co et al v Commissioner of Patents*, [1974] SCR 111.
148 *Novartis Pharma Canada Inc v Cobalt Pharma Co*, 2013 FC 985 at paras 91-92.

invention. That invention could give rise to a selection patent. The *Patent Act* provides for this eventuality, allowing a person to obtain a patent for an improvement.[149]

The SCC upheld the concept of selection patents in general and adopted the criteria that must be satisfied for a valid selection patent as set out in 1930 by Maugham J. in *In re I.G. Farbenindustrie A.G.'s Patents*:

1. There must be a substantial advantage to be secured or disadvantage to be avoided by the use of the selected members.
2. The whole of the selected members (subject to "a few exceptions here and there") possess the advantage in question.
3. The selection must be in respect of a quality of a special character peculiar to the selected group. If further research revealed a small number of unselected compounds possessing the same advantage, that would not invalidate the selection patent. However, if research showed that a larger number of unselected compounds possessed the same advantage, the quality of the compound claimed in the selection patent would not be of a special character.[150]

The SCC also held that a selection patent should not be treated differently from any other patent.[151]

Following *Sanofi*, the FCA held that:

> a challenge directed to a determination that the conditions for a selection patent have not been met does not constitute an independent basis upon which to attack the validity of a patent. Rather, the conditions for a valid selection patent serve to characterize the patent and accordingly inform the analysis for the grounds of validity set out in the Act — novelty, obviousness, sufficiency and utility. In short, a selection patent is vulnerable to attack on any of the grounds set out in the Act.[152]

17.7 Other Procedural Challenges to Patents

In addition to the traditional validity challenges described above, a number of other patent challenges can be brought pursuant to the *Patent Act*. Some of these are set out below.

149 *Patent Act*, s 32.
150 *Sanofi* at para 10, citing *IG Farbenindustrie AG's Patents, In re* (1930), 47 RPC 289 (Ch D).
151 *Sanofi* at paras 9, 108.
152 *Eli Lilly v Novopharm olanzapine FCA* at para 27.

The allegation of improper disclaimer was addressed in a previous chapter and will not be discussed here.

17.7.1 Section 53 - Material Misstatement/Fraud

Section 53 of the *Patent Act* states that a patent is void if a material allegation in the petition is untrue or if the specification contains more or less than is necessary for obtaining the patent and the omission or addition is wilfully made for the purpose of misleading.[153] The Court has held that allegations under section 53 are akin to allegations of fraud.[154] The Court has also held that pleadings under section 53 must be pleaded with particularity so that the party has enough opportunity to know what is alleged and prepare its defences.[155]

17.7.2 Section 73 - Abandonment

Section 73 of the *Patent Act* provides that an application for a patent will be deemed to be abandoned if the Applicant does not reply in good faith to a requisition made by an examiner in connection with an examination within six months after the requisition is made.[156]

Section 73 has been relied upon as a basis alleged to invalidate an issued patent. However, the FCA in an infringement action held:

> In my view, subsection 53(1) of the Act speaks to misrepresentations in relation to patents, that is, issued patents. Paragraph 73(1)(a) speaks to good faith in the prosecution of the patent application. The provisions are mutually exclusive. This interpretation is consistent with the plain meaning of the provision, its context within the Act and Canadian jurisprudence. There is no indication that Parliament intended to alter the existing law that establishes a dichotomy between an application for a patent and a patent.
>
> To be clear, the concept of abandonment in paragraph 73(1)(a) operates during the prosecution of the application for a patent. Its operation is extinguished once the patent issues. Post-issuance, the provisions of subsection 53(1) must be utilized with respect to allegations of misrepresentation. To conclude otherwise would result in absurdity. An issued patent would be subject to retroactive scrutiny by the courts in relation to the submissions made by

153 *Patent Act*, s 53(1).
154 *Eli Lilly Canada Inc v Apotex Inc,* 2008 FC 142 at paras 62-63 [*Eli Lilly v. Apotex raloxifene FC*], aff'd on other grounds (without comment on this point) *Eli Lilly v Apotex raloxifene FCA.*
155 *Ratiopharm Inc v Pfizer Ltd*, 2009 FC 711 at para 199, aff'd 2010 FCA 204 [*Ratiopharm*].
156 *Patent Act*, s 73.

> an applicant to the Patent Office during prosecution (generally many years prior), judged against unknown criteria. It is for the Commissioner to determine whether an applicant's response to a requisition from an Examiner is made in good faith, not for the courts. The courts do not issue patents.[157]

The FCA has noted that a patent infringement action is not a judicial review – the matter is not decided on the basis of what was before the Commissioner.[158]

17.7.3 *Competition Act* Allegations

Allegations pursuant to the *Competition Act*[159] have been raised as defences to patent infringement actions.

In a case involving Servier, Adir, and Apotex, Apotex alleged that Adir contravened section 45 of the *Competition Act* by entering into a settlement agreement with Schering and Hoechst.[160] The settlement agreement in question related to a dispute over who was entitled to patent claims that had been placed into conflict pursuant to section 43 of the pre-1989 *Patent Act*. The parties settled the court case and divided the claims at issue between them. Apotex asserted that this agreement ensured that each party obtained patents covering ACE inhibitors, and that this was anti-competitive.[161] The FCA upheld the trial judge's determination that, at every step of the process, the parties were exercising their rights under the *Patent Act* and *Federal Court Rules*.[162] Because there was "nothing more" than mere assertion of patent rights, there was no contravention of section 45 of the *Competition Act*.[163] In addition, the claim was found to be time-barred by the trial judge; but, this was not considered by the FCA.[164] Apotex had also pursued this allegation in an infringement action involving Schering and Aventis (formerly Hoechst) relating to another ACE inhibitor; however, it was dropped before trial.[165]

In a case involving Eli Lilly, Apotex, and Shionogi, Apotex alleged that Eli Lilly and Shionogi conspired to allow Eli Lilly to acquire patent rights granted to Shionogi for the purpose of preventing or impeding other manufacturers from making the antibiotic cefaclor, thus preventing competition in the Canadian market for cefaclor, contrary to section 45 of the *Competition Act*.[166]

157 *Weatherford* at paras 149-150.
158 *Apotex Inc v Pfizer Inc*, 2017 FCA 201 at para 71.
159 *Competition Act*, RSC 1985, c C-34, ss 36, 45.
160 *Apotex v Servier*.
161 *Apotex v Servier* at para 130.
162 *Apotex v Servier* at para 131.
163 *Apotex v Servier* at para 135.
164 *Apotex v Servier* at paras 131, 137.
165 *Sanofi-Aventis Canada Inc v Apotex Inc*, 2009 FC 1138 at para 12.
166 *Eli Lilly cefaclor* at para 683, aff'd on other grounds (without comment on this point) 2010 FCA 240.

The Court held that the claim was time-barred, because the assignment of the patents occurred more than two years prior to the claim.[167] The effects of the assignment "may be examined for the purposes of determining whether or not this agreement was likely to unduly lessen competition, but it does not extend the period during which such conduct occurred."[168] The Court also held that in order to make out its claim, Apotex must first prove that it suffered loss or damage as a result of the alleged anti-competitive conduct.[169] In this case, Apotex did not suffer any damages as a result of the assignment.[170] The Court did not comment on whether there was a violation of section 45 of the *Competition Act*.[171]

In another case, the plaintiff alleged that purchasing agreements which the defendant made with other companies were anti-competitive. However, the Court dismissed these claims on summary judgment due to the application of the limitation period.[172]

167 *Eli Lilly cefaclor* at para 750.
168 *Eli Lilly cefaclor* at para 743.
169 *Eli Lilly cefaclor* at paras 726, 769.
170 *Eli Lilly cefaclor* at paras 842, 850.
171 *Eli Lilly cefaclor* at para 881.
172 *Garford Pty Ltd v Dywidag Systems International*, 2010 FC 996, aff'd 2012 FCA 48.

Chapter 18

Product Liability Litigation: Drugs, Devices, and Emerging Health Technologies

18.1 Introduction

Drugs and medical devices are subject to heavy regulatory oversight in Canada.[1] The regulatory framework creates the tapestry for the advancement of product liability claims as against drug and device manufacturers and distributors. Many product liability claims are founded in negligence rather than in contract. The quintessential types of products claims advanced include claims for alleged negligent design, research, development, testing, licensing, manufacture, labelling, marketing, distribution, sale, monitoring, and representation. In this chapter, we summarize general principles related to product liability claims in relation to drugs and devices, as well as discuss developments in the liability associated with emerging technologies such as connected devices and 3D/4D printing devices and organs.

18.2 Product Litigation: Drugs and Devices

18.2.1 Overview: Manufacturers Principal Obligation

Manufacturers of drugs and devices represent the most common class of defendants in product liability suits. Generally, a manufacturer will be named either as a defendant in a lawsuit or will be added to the lawsuit as a third party by one of the named defendants. There usually is no direct contract between a manufacturer and the purchaser of a product, so a plaintiff will have to establish that the manufacturer was negligent in either the design or the manufacture of the product at issue or that it failed to warn of a danger associated with the product.

Certainly, in order to succeed in any such negligent claims against a drug and device manufacturer, a plaintiff must prove – on a balance of probabilities – that the defendant was negligent. To establish negligence, the plaintiff must prove: a) the defendant owes the plaintiff a duty of care; b) the defendant's behaviour breached the standard of care; c) the plaintiff suffered compensable damages; d) the damages were caused by the defendants' breach; and e) the damages are not too remote in law.[2]

1 See *Food and Drugs Act*, RSC 1985 c F-27; *Canadian Food Inspection Agency Act*, SC 1997 c 6; *Consumer Packaging and Labelling Act*, RSC 1985 c C-38; *Natural Health Products Regulations*, SOR/2003-196; *Cosmetic Regulations*, CRC, c 869; and *Medical Devices Regulations*, SOR/98-282.

2 *Kuiper v. Cook (Canada) Inc.*, 2018 ONSC 6487 at para 109 [*Kuiper*].

In the context of product liability claims, the jurisprudence has established categories in relation to the duty of care of manufacturers. We have outlined below three established categories:

1. Duty of care to manufacture products free of defects in the ordinary course of use of the product;[3]
2. Duty of care to warn of dangers inherent in the use of the product that the manufacturer knows or ought to know;[4] and
3. Duty of care to design the product to avoid safety risks and to make the product reasonably safe for its intended purpose.[5]

In the context of drug and device litigation, plaintiffs who have sustained injury in relation to the intended use of a device or drug will often not face difficulty in establishing that there exists at law a duty of care on the manufacturer to take care not to cause harm.

18.2.2 Product Liability Claims Deconstructed

The law does not impose strict liability on manufacturers such that they are liable for all harm caused without proof of negligence.[6] While the law does not require manufacturers to produce drugs and medical devices that are accident proof, a plaintiff must still prove all the necessary elements of the cause of action asserted as against a manufacturer to establish liability. In this section, we distill the necessary elements of claims dealing with negligent manufacture, negligent design, and failure to warn.

18.2.3 Negligence in Manufacturing

A plaintiff alleging that a drug or device was negligently manufactured must prove that a) the product in question was defective (*e.g.*, the product was not manufactured in accordance with the specifications that the manufacturer intended); b) the defect arose as a result of the manufacturer's failure to take reasonable care; and c) the plaintiff sustained harm that was caused by the defective condition of the product.[7]

3 *Kuiper* at para 110, citing *Donoghue v Stevenson*, [1932] AC 562 (HL).
4 *Hollis v. Dow Corning Corp.*, [1995] 4 SCR 634 at para 20 [*Hollis*]; *Lambert v. Lastoplex Chemicals Co.*, [1972] SCR 569 at 574 [*Lastoplex*]; see also *Bow Valley Husky (Bermuda) Ltd. v. Saint John Shipbuilding Ltd.*, [1997] 3 SCR 1210 [*Bow Valley*].
5 *Ragoonanan v. Imperial Tobacco Canada Ltd.*, 51 OR (3d) 603 (Ont Sup Ct) [*Ragoonanan*]; *Rentway Canada Ltd. v Laidlaw Transport Ltd.*, [1989] OJ No 786 (High Ct J), aff'd [1994] OJ No 50 (CA) [*Rentway*].
6 *Phillips v. Ford Motor Co.*, [1971] 2 OR 637 at 653–55.
7 *Meisel v. Tolko Industries*, [1991] BCJ No. 105 (SC).

Proof of a defect in a product is a threshold issue: unless a defect is established, it is unnecessary to consider the other elements of negligence.[8] Thus, the plaintiff must retain an expert to examine the product and provide expert evidence that establishes the presence of a defect. Without such proof, a plaintiff's claim should fail.[9]

However, in circumstances where it is impossible to physically produce the proof, courts may still infer the presence of a defect where there is sufficient circumstantial evidence to prove, on a balance of probabilities, that a manufacturing defect was present in the product.[10]

To satisfy this test, a plaintiff will generally have to establish the absence of any other reasonable explanation for what happened. The courts have found that a trier of fact can draw an inference of proof of defect where the cause of the defect is unknown.[11]

For all intents and purposes, where the product in question has been shown to be defective, the manufacturer bears an evidentiary burden to prove the defect was not the result of its failure to take reasonable care. Courts have imposed liability on manufacturers for having faulty assembly, faulty fabrication and/or failing to have in place proper systems of inspection, quality assurance and quality control. Even where near-perfect systems have been devised, the possibility of human error remains.

Accordingly, in defending a negligently manufactured product case, a manufacturer will have to show that it had proper procedures and protocols in respect of employee training, inspection, and quality control.

18.2.4 Negligence in design

The liability theory in a negligence design claim is that a manufacturer has a duty of care not to design a product negligently because the manufacturer ought to be held liable for the decisions it makes to address the safety of the product.[12] The negligent design liability theory rests on the allegation that something went wrong with the design of the device or drug so as to affect its safety.[13]

8 See *Rowe (Guardian ad litem of) v. Sears Canada*, 2005 NLCA 65 at para 19 [*Rowe v Sears*]; *Hans v. Volvo Trucks North America Inc.*, 2016 BCSC 1155 at para 334, aff'd 2018 BCCA 410 [*Hans v. Volvo*].
9 See for example, *McDougall v. Black & Decker Canada Inc.*, 2016 ABQB 253.
10 *Farro v. Nutone Electrical Ltd.* (1990)72 OR (2d) 637 at paras 16-18 (CA); *Rowe v. Sears* at para 19.
11 *Marcil v. Eastview Chevrolet Pontiac Buick GMC Ltd.*, 2016 ONSC 3594, at para 40.
12 *Kuiper* at para 112.
13 Kuiper at para 112; *Rowe v. Sears*, at para 20.

In order to succeed in a negligent design case, the plaintiff must: a) identify the design defect; b) establish that the defect created a substantial likelihood of harm; and c) establish that there exists a safer and more economical feasible way to manufacture the product.[14]

In assessing whether a design is negligent due to an underlying safety defect, the Court may undertake a "risk-utility analysis" where the Court considers the risks of the product measured against its utility and costs.[15] Some of the utility and costs factors include: utility of the product to the consumer, likelihood that the product will cause injury, availability of a safer design, degree of awareness of the product's potential danger, and the manufacturer's ability to spread out any costs related to improving the safety of the design.[16]

A manufacturer can only be held liable of the alleged design defect on the basis of foreseeable risks that the manufacturer either knew *or ought to have known* about at the time the product was manufactured, or which came to its attention afterwards, and that it failed to address such risks.[17] Certainly, in determining what was known and what ought to have been known, the Court will consider the state of the knowledge and technology at the time the product was manufactured so as not to fall into the faulty logic of judging the standard of care with the benefit of hindsight.[18] Generally, the fact that a manufacturer took remedial measures following the plaintiff's injury to address an issue is not itself indicative of negligence.[19]

In assessing liability for negligent design, the Court will also consider whether the design complied with any applicable statutory, regulatory, or industry standards.[20] While regulatory compliance will not necessarily absolve a manufacturer from liability, such evidence, however, will assist the manufacturer in showing that the design was reasonable.[21] In cases of competing international industry standards, the Canadian-specific standards should be followed.[22] As well, the Court will also consider the ability of the plaintiff to have avoided the injury by careful use of the product.[23] If the manufacturer is able to

14 *Kuiper* at para 116; *Martin v. Astrazeneca Pharmaceuticals PLC*, 2012 ONSC 2744 at paras 135-37, aff'g 2013 ONSC 1169 (Div Ct); *Kreutner v. Waterloo Oxford Co-operative Inc.* (2000), 50 OR (3d) 140 at para 8 (CA); *Rentway*; *Cantlie v. Canadian Heating Products Inc.*, 2017 BCSC 286 at para 197.
15 *Ragoonanan*; *Rentway*.
16 *Rentway* at para 55.
17 *St Isidore Co-Op Limited v. AG Growth International Inc.*, 2019 ABQB 763 at para 42 [*St Isidore*].
18 *St Isidore* at para 42; *Brunski v. Dominion Stores Ltd.*, 1981 CarswellOnt 591 at para 32 (Ont High Ct).
19 *Hans v. Volvo* at para 334.
20 See *St Isidore at 38*; *Baker v. Suzuki Motor Co.*, [1993] AJ No 605 at para 129 (QB) [*Baker v Suzuki*]; *Tabrizi v. Whallon Machine Inc.*, [1996] BCJ No 1212 at para 37 (SC) [*Tabrizi v Whallon*].
21 See *St Isidore* at 38; *Baker v. Suzuki* at para 129; *Tabrizi v. Whallon* at para 37.
22 *Gendron v. Thomson Fuels*, 2017 ONSC 4009.
23 *Boulanger v. Johnson & Johnson Corp.*, [2007] OJ No 179 at para 37 (SC)

point to the plaintiff's misuse of its product to establish that its design was not defective, it can use this evidence to establish contributory negligence on the part of the plaintiff.

18.2.5 Failure to Warn

Manufacturers have a duty of care to warn consumers of dangers inherent in the use of the product of which the manufacturer has knowledge or ought to have knowledge.[24] The jurisprudence establishes that the warning must be reasonably communicated and provide the consumer sufficient detail as to the dangers associated with the ordinary use of the product.[25] The warnings must relate not just to dangers from proper use but also improper use.[26]

In the case of drugs and devices, manufacturers face a high standard of care, particularly given the substantial risks of improper use, to provide clear, complete, and current information concerning the dangers inherent in the ordinary use of its products.[27] The nature and scope of any given warning depends on what is reasonable having regard to all the facts and circumstances relevant to the product at issue.[28] The higher the danger associated with the use of a medical product, the higher the onus is on the manufacturer to provide very specific indication of each of the specific dangers arising from the use of the product.[29]

Specifically in relation to medical products, where the consumer will not receive information directly from the manufacturer without the intervention of a learned intermediary, the manufacturer's duty of care is discharged if the manufacturer provides the learned intermediary with an adequate warning of the potential dangers associated with the use of the particular product.[30] In the context of manufacturers of drugs and medical devices, the learned intermediary is the physician that prescribes the drug or the use of the medical device.

18.3 Causation

As noted above, the burden falls on the plaintiff to establish on a balance of probabilities that the negligent conduct of the defendant caused or contributed to the damages of the plaintiff.

24 *Kuiper* at para 118; see also *Bow Valley*; *Hollis* at para 20; *Lastoplex* at 574.
25 *Kuiper* at para 118; Hollis at paras 20-21; *Lastoplex* at 574–75.
26 *Kuiper* at para 118; *Lastoplex*.
27 *Kuiper* at para 120; *Hollis* at para 23.
28 *Kuiper* at para 121; *Buchan v. Ortho Pharmaceutical (Can) Ltd.*, 54 OR (2d) 92 at para 18(CA) [*Buchan*].
29 *Hollis* at para 22.
30 *Kuiper* at paras 122–23; *Hollis* at paras 28-29; *Buchan* at paras 23-59.

The default rule for causation is the "but for" test: but for the defendant breaching the standard of care, the plaintiff would not have suffered the loss.[31] An alternative test of material contribution to the plaintiff's injuries may be applied, but is generally to be confined to circumstances in which there are multiple potential tortfeasors and it is not possible to determine causation by any one of them on the "but for" analysis.[32] Under the material contribution test, it is not necessary to prove that the defendant's conduct was the sole cause of the injury.[33] Rather, a plaintiff need only prove that the defendant's breach materially contributed to their loss or damage.[34] Therefore, if a defendant is part of the cause of the injury or loss, even if the defendant's action alone could not create the injury or loss, the defendant is liable.[35] However, the defendant is not liable for all injuries flowing from their negligence, rather, only the losses or injuries that were foreseeable. Any loss that was not foreseeable to the defendant as a result of their conduct is considered to be too remote by the courts.

Where the conduct of two or more independent tortfeasors combines to bring about an indivisible harm, the court will determine whether each defendant's conduct was a contributory factor in bringing about the plaintiff's injury. If so, each negligent defendant then becomes jointly and severally liable to the plaintiff for 100 percent of the plaintiff's loss, but each may seek reimbursement from the other negligent parties according to their respective degrees of fault.[36]

Proof of causation with scientific certainty is often difficult, but the Supreme Court of Canada (SCC) has indicated that this level of precision is typically not required.[37] Accordingly, the courts will often infer causation from circumstantial evidence where it is proved that the defendant's negligence could have caused the harm complained of, and where there is no cogent evidence of any other explanation for how the harm could have been caused.[38] However, merely recognizing an association between products and the alleged events will not satisfy a court that causation can be inferred.

Experts play a very important role in the courtroom in product liability cases, and the selection of experienced and well-qualified experts is crucial to a litigant's success. The SCC has identified four prerequisites for the admission of

31 *Clements v. Clements*, 2012 SCC 32 at para 46 [*Clements*]; *Resurfice Corp. v. Hanke*, 2007 SCC 7 at para 21 [*Resurfice*]; *Athey v. Leonati*, [1996] 3 SCR 458 at paras 13–14 [*Athey*].
32 *Clements* at para 46; *Resurfice Corp* at paras 24–25; *Athey* at para 15.
33 *Athey* at para 17.
34 *Clements* at para 46.
35 *Athey* at para 17.
36 *Clements* at para 12.
37 *Athey* at para 16; *Clements* at para 46.
38 *Clements* at para 38; *Snell v. Farrell*, [1990] 2 SCR 311.

expert evidence: 1) necessity in assisting the court; 2) relevance; 3) absence of any exclusionary rule; and 4) the requirement that the expert is properly qualified to give their opinion.[39]

Expert evidence is necessary when it provides information that is beyond the experience and knowledge of a judge or jury.[40] In order to be relevant, the evidence must be related to the issues before the court.[41] Expertise is achieved when the expert possesses special knowledge and experience.[42] In general, the expert must have sufficient background in the area of expertise, whether from experience or from formal training and study.[43] Courts will often exclude witnesses who do not satisfy this threshold, although some courts will admit the evidence, provided the witness is generally qualified. However, such evidence is not given as much weight as that from a more qualified expert.

Expert witnesses are not allowed to usurp the function and duties of the trier-of-fact by determining the facts of a case or stating conclusions of law.[44] The evidence given by expert witnesses must be only within the scope of their expertise.[45] If the expert goes beyond their expertise, that evidence will be excluded or given little or no weight by the court.[46]

Experts are also subject to the common law duties of independence and impartiality. An expert is required to be neutral, objective, and unbiased.[47] An expert will not be properly qualified to provide an opinion where they are not independent and impartial.[48]

The trier-of-fact does not have to accept the evidence of an expert, even if unchallenged, but does have a duty to monitor the scope of an expert's evidence throughout a trial.[49] However, courts state that expert evidence that is not contradicted should be seriously considered.[50] When two or more experts testify, the trier-of-fact must decide which testimony to accept. Where competing experts are equally qualified and credible, the trier-of-fact must adopt the theory that best coincides with all other evidence accepted in the case. While rarely done, the court may also appoint its own expert to help in resolving technical issues.[51]

39 *R. v. Mohan*, [1994] 2 SCR 9 at 20 [*Mohan*]; *Jones v. Zimmer GMBH*, 2013 BCCA 21 at para 48.
40 *R. v. Abbey*, [1982] 2 SCR 24 at 42; *Mohan* at 23.
41 *Mohan* at 20–21.
42 *R. v. Beland*, [1987] 2 SCR 398 at 415.
43 *Mohan* at 25.
44 *Mohan* at 24.
45 *R. v. Marquard*, [1993] 4 SCR 223 at 244 [*Marquard*].
46 *Marquard* at 244; *Rowe v. Sears* at para 5.
47 *White Burgess Langille Inman v. Abbott and Haliburton Co.*, 2015 SCC 23 at para 32; *Wise v. Abbott Laboratories Ltd.*, 2016 ONSC 7275 at para 66.
48 *Deemar v. College of Veterinarians of Ontario*, 2008 ONCA 600 at para 21.
49 *R. v. Abbey*, 2009 ONCA 624 at para 63.
50 See for example, *R. v. Vallentgoed*, 2016 ABCA 358 at paras 80–81.
51 *Rules of Civil Procedure*, RRO 1190, Reg 194, s 52.03.

18.4 Class Actions

Class actions remain a continued area of risk for medical device and drug manufacturers. In fact, it is often said that product liability cases are ideal for class treatment.[52] Unlike a regular action, a proposed class action must be certified before it may proceed. In Ontario, a suit is filed with a view to having it certified as a class action.[53] In Québec, an application for authorization is filed and, if authorized (a.k.a certified), the plaintiff files a class action lawsuit.[54]

18.4.1 Overview

At a certification motion, a judge determines whether a proposed class action is suitable to be certified as a class proceeding. The defendant is given an opportunity to attack the suitability of the action as a proposed class action before it is certified. Accordingly, the lawyer and client must work together closely early in the class action process to develop a strategy, share information about the nature of the product, deal with all technical issues, retain experts, identify any design issues, assemble relevant documents, interview witnesses, and conduct other research. In July of 2020, Ontario's Legislative Assembly passed Bill 161, the *Smarter and Stronger Justice Act*, 2020, which entered into force on October 1, 2020. The Act, which gained Royal Assent the next day, amended a number of statutes, including the *Class Proceedings Act*, 1992 (CPA).

For instance, the new section 4.1 of the amended CPA reads as follows:

> **Early resolution of issues**
>
> **4.1** If, before the hearing of the motion for certification, a motion is made under the rules of court that may dispose of the proceeding in whole or in part, or narrow the issues to be determined or the evidence to be adduced in the proceeding, that motion shall be heard and disposed of before the motion for certification, unless the court orders that the two motions be heard together. 2020, c. 11, Sched. 4, s. 6.

This appears designed to facilitate a greater number of pre-certification motions. Plaintiffs in proposed class proceedings, who generally want the certification motion to be the first order of business, tend to resist such motions. While class proceedings judges already have the discretion to permit pre-certification motions in limited circumstances, section 4.1 expressly requires that a pre-certification

52 *Richardson v. Samsung*, 2018 ONSC 6130 at para 2.
53 See *Class Proceedings Act*, 1992, SO 1992, c 6, s 2 [*Class Proceedings Act*].
54 See Art 574 CCP.

motion that "may dispose of the proceeding in whole or in part, or narrow the issues to be determined or the evidence to be adduced" be heard before certification, subject to the discretion of the class proceedings judge to order that the proposed motion be heard at the same time as the certification motion. It is very likely that section 4.1 will embolden defendants in proposed class proceedings to bring a greater number of pre-certification motions, attempting to narrow the scope of proposed class proceedings pending against them.[55]

Notably, the multi-jurisdictional amendments to the CPA explicitly call on Ontario courts to have regard to competing class actions in other Canadian jurisdictions involving the same or similar subject matter. When a motion for certification is brought in Ontario in a multi-jurisdictional class proceeding, the representative plaintiff is now required to give notice of the motion to a proposed representative plaintiff in a competing multi-jurisdictional proceeding, who will be entitled to make submissions at certification. In determining whether the class action is the "preferable procedure," amendments to the CPA now mandate a determination by the Ontario court as to "whether it would be preferable for some or all of the claims of some or all of the class members, or some or all of the common issues raised by those claims, to be resolved in the proceeding commenced in the other jurisdiction instead of in the proceeding under [the CPA]."

In Québec, the criteria for authorization are set out in section 575 of the *Code of Civil Procedure*. Some differences with the common law provinces include that there is no preferability rule, and that there is no requirement to produce a workable plan. Québec courts will grant authorization to institute a class action in cases in which the court is of the opinion that: 1) the claims of the members of the class raise identical, similar, or related issues of law or fact; 2) the facts alleged appear to justify the conclusions sought; 3) the composition of the class makes it difficult or impracticable to apply the rules for mandates to take part in judicial proceedings on behalf of others or for consolidation of proceedings; and 4) the class member appointed as representative plaintiff is in a position to properly represent the class members.[56] If an application for authorization is granted by the Québec court, the certified claim for the class action must be filed within three months.[57]

55 *Dufault v. Toronto Dominion Bank* 2021 ONSC 6233 – first Ontario decision to consider s. 4.1 as granting defendants a "presumptive right to have certain motions heard and decided before the plaintiff's motion for certification". However, plaintiffs can "displace this presumption by persuading the court that there is nonetheless an overarching and good reason for the two motions to be heard together".

56 Art 525 CCP.

57 Art 583 CCP.

Mandatory language is used in Canadian class proceedings legislation to indicate that a court shall grant certification in the event that all five branches of the test are satisfied.[58] The test for certification is to be applied in a purposive and generous manner, to give effect to the important goals of class actions – providing access to justice for litigants; promoting the efficient use of judicial resources; and sanctioning wrongdoers to encourage behaviour modification.[59]

18.4.2 Test for Certification

Canadian courts in the common law provinces generally apply a five-branch test for certification:

a. the pleadings must disclose a cause of action;
b. there must be an identifiable class of two or more persons;
c. the claims of the class members must raise common issues;
d. the class proceeding must be the preferable procedure for the resolution of the common issues; and
e. there must be a representative plaintiff who would fairly and adequately represent the interests of the class and who has produced a plan for the proceeding that sets out a workable method of advancing the proceeding on behalf of the class.[60] This representative plaintiff must notify class members of the proceeding[61] and must not have a conflicting interest with the interests of other class members regarding the common issues for the class.[62]

In the section that follows, we examine each of the five certification criteria.

1) **Cause of Action Criterion**

The first certification criterion is that the plaintiffs' pleading discloses a cause of action. The court is not to make findings of fact for the purposes of determining the merits of the action.[63] In determining whether the pleadings disclose a cause of action, the courts consider whether it is "plain and obvious" that the facts alleged in the statement of claim, if proved, would not give rise to a tenable cause of action.[64] In determining the first criterion, the pleadings are interpreted liberally and the material facts are accepted as true.[65]

58 See for example, *Class Proceedings Act*, s 5.
59 *Kuiper* at para 97; *Hollick v. Toronto (City)*, 2001 SCC 68 at paras 15–16 [*Hollick*].
60 *Kuiper* at para 96; *O'Brien v. Bard Canada Inc.*, 2015 ONSC 2470 at para 145 [*O'Brien v Bard*].
61 *Class Proceedings Act*, s 17.
62 *Kuiper* at paras 96, 208.
63 *O'Brien v. Bard* at para 147; *Hollick* at para 16.
64 *Hunt v. Carey Canada*, [1990] 2 SCR 959.
65 *Kuiper* at para 108; *Hollick* at para 25.

2) **Identifiable Class Criterion**

Typically, the representative plaintiffs' counsel will attempt to define the broadest possible class to maximize the case value as a larger aggregation of claims yields substantial fees. However, a large and heterogeneous or overbroad class is also a basis on which to defeat certification as issues may not be common, and the litigation may become unmanageable.[66] Depending on the case, defendants may prefer a larger or smaller class. A larger class may increase a defendant's exposure, but also allows the defendant to defend and potentially settle a larger number of claims at one time, allowing for greater efficiency and certainty.

3) **Common Issues Criterion**

The claims of the class must raise common issues. The inquiry is focused on a two-part test: a) whether there is "some basis in fact" that the asserted issue actually exists, and that 2) the issue is common to the entire class.[67] Individual issues in product liability class actions can overwhelm the common issues, particularly issues of causation and/or reliance, thereby defeating the purpose of class proceedings legislation – efficiency.[68] In order to satisfy the commonality requirement, the plaintiff only needs to adduce evidence sufficient to establish some basis in fact, *i.e.*, some evidence that there are issues that can be answered in common across the entire class.[69] Accordingly, the defendant must carefully consider whether a class action will be the effective procedural vehicle to handle mass tort claims based on allegedly defective drugs and/or devices where the plaintiffs have been exposed to the product (or different products) at various points in time. Québec courts view this issue more liberally and often certify cases of exposure over time (*e.g.*, cigarettes, medication) and only require that one substantive issue exists (*e.g.*, whether or not the product was defective).[70]

4) **Preferable Procedure Criterion**

Canadian courts outside Québec apply both an absolute and a relative test to determine whether there is a preferable alternative to a class action. A class proceeding must be a fair, efficient, and manageable method of advancing the claim as a whole.[71] This determination is made on a

66 *Kuiper* at para 147; *O'Brien v. Bard* at para 168; *Hollick* at para 21.
67 *Kuiper* at para 165.
68 *Hollick* at paras 14–15.
69 *Kuiper* at para 165.
70 See for example, *Imperial Tobacco Canada ltée c. Conseil québécois sur le tabac et la santé*, 2019 QCCA 358.
71 *Kuiper* at para 193; *O'Brien v. Bard*, at para 146.

comparative basis.[72] Assuming that a class proceeding is a fair, efficient, and manageable method of advancing the claim, it must also be preferable to other methods of advancing the claim, such as joinder of actions, test cases, and consolidation of actions.[73] In considering relative preferability, courts consider other means of resolution, including settlement proposals made by defendants prior to certification.[74]

A strong argument against certification can be made in recall cases based on a preferable procedure already being in place: a voluntary or government mandated recall.[75] It is important for a manufacturer to consider whether its "recall letter" is probative of a defect or an unreasonable danger that could expose it to liability.

Alternatively, some defendants have chosen to offer unilateral remedies to their customers, pre-certification, in exchange for a release of their claims, which would otherwise be pursued in the course of a class action.

The CPA's certification-related amendments added new gloss on the long-standing certification requirement in section 5(1)(d) of the CPA, which corresponds to this preferable procedure criterion of the five-branch test for certification.

The amendments provide that, in order for a class action to be the preferable procedure, it must "at a minimum" be "superior to all reasonably available means" of addressing class members' claims, and the proposed common issues to be addressed by the class action must "predominate over any questions affecting only individual class members." These new predominance and superiority requirements will reduce the number of proposed class actions that satisfy the "preferable procedure" criterion for certification in Ontario.

5) **Representative Plaintiff Criterion**

The adequacy of representative plaintiffs is not routinely questioned and challenged by the courts in Canada.

When assessing the adequacy of a proposed representative plaintiff, the courts consider the motivation of the representative plaintiff, the competence of the representative plaintiff's counsel, and the capacity of the representative plaintiff to advance the action and provide instructions to class counsel that best serve the overall interests of the class.[76] A representative plaintiff must also have at

72 *Berg et al. v. Canadian Hockey League et al.*, 2019 ONSC 2106 at para 25.
73 *Kuiper* at para 192; *O'Brien v. Bard*, at para 210.
74 *Kuiper* at paras 192–93; *O'Brien v. Bard*, at paras 210, 212.
75 See *Richardson v. Samsung*, 2018 ONSC 6130 at paras 73–74.
76 *Kuiper* at para 210; *O'Brien v. Bard*, at para 237.

least a basic understanding of the case to be advanced and their role in the proceeding.[77]

The courts have been taking a harder look at whether a representative plaintiff has a conflict of interest with other class members.[78] The test for conflict of interest may arise under other branches of the test for certification, such as when it is argued that the existence of common issues and the interests of persons falling within the class definition diverge to such an extent that certification would be inappropriate.[79]

Ontario courts have held that for any given defendant there must be at least one representative plaintiff who has a reasonable cause of action.[80] In Québec, the representative plaintiff is not required to have a personal cause of action against each defendant.[81] This requirement may form the basis of an attack on the plaintiff's pleading in a product liability case involving both retailers and manufacturers as co-defendants. Courts in most common law provinces have also held that a plaintiff may be able to sue defendants in the same industry without having a cause of action against each of them.[82]

18.5 Conclusion

Notwithstanding the mechanisms by which plaintiffs choose to advance claims related to losses sustained as a result of the use of a medical product, product liability remains a risk that drug and device manufacturers face and must mitigate against.

18.5.1 The New Product Liability Frontier: Digital Health Products and 3D/4D Printed Organs and Devices

In this section of this chapter, we will delve into the product liability risks associated with digital health technologies and 3D/4D printed devices and organs. As will be discussed in more detail below, this emerging frontier of product liability presents new opportunities and challenges for manufacturers and distributors. In what follows, we provide a summary of the regulatory and litigation concerns related to this new frontier of products.

77 *Sullivan v Golden Intercapital (GIC) Investments Corp.*, 2014 ABQB 212 at paras 55–57.
78 See for example, *Pearson v. Inco Ltd.*, [2002] OJ No 2764; TL v Alberta (Child, Youth and Family Enhancement Act, Director), 2008 ABQB 114; *Asp v. Boughton Law Corporation*, 2014 BCSC 1124 [*Aspen v Boughton Law*].
79 See for example, *Asp v. Boughton Law.*
80 *Ragoonanan* at para 50; *Hughes v. Sunbeam Corp. (Canada) Ltd.*, 219 DLR (4th) 467 at para 18.
81 *Marcotte v. Bank of Montreal*, 2014 SCC 55.
82 See for example, *Campbell v. Flexwatt Corp.* (1997), [1998] 6 WWR 275 (BCCA).; *MacKinnon v. National Money Mart Co.*, 2004 BCSC 140, aff'd 2004 BCCA 472; *Condominium Plan No 0020701 v. Investplan Properties Inc.*, 2006 ABQB 224.

18.5.1.1 New Frontier: Digital Health Products

Digital health technologies are diverse. These devices range from standalone software applications to integrated hardware systems which can utilize external platforms such as computers and smart phones. While digital health technologies promise to positively transform the health care delivery model for patients, health care systems, and industry, these technologies also present significant liability and regulatory concerns. These concerns are heightened depending on the level of connectivity and the data collected, stored, and used by such technologies. These concerns should be on the radar of not just the manufacturers, distributors, and importers of such products, but also for health care institution adopters and health practitioners that may be recommending the use of such products to their patients.

Health Canada has recognized the complexities of regulating such technologies and is looking to implement both pre-market and post-market methods of regulation to provide additional oversight. The impetus for such changes appears to be the regulator's recognition of the increased complexities of such technologies and their data collection abilities, increasing alignment with other regulators, and the development of policies that support the integration of such technologies while maintaining patient safety.

On April 10, 2018, Health Canada announced expected changes to the regulator's approach to digital health technologies. The regulator announced the launching of the new Digital Health Review Division, which is poised to assist with improving access to innovative digital health technologies with a special focus on cybersecurity, artificial intelligence, mobile medical apps, telemedicine, software as a medical device, medical device interoperability, and wireless medical devices.[83]

This focus on digital health technologies is not, however, expected to displace the manufacturer's statutory obligation to "take reasonable measures to" address the risks inherent with the medical device (regardless of its class categorization), as stipulated under section 10 of the *Medical Devices Regulations*[84] (the *MDR*):

> *A medical device shall be designed and manufactured to be safe, and to this end the manufacturer shall, in particular, take reasonable measures to:*
>
> *(a) identify the risks inherent in the device;*
>
> *(b) if the risks can be eliminated, eliminate them;*
>
> *(c) if the risks cannot be eliminated,*
>
> *(i) reduce the risks to the extent possible,*

83 Health Canada, "Notice: Health Canada's Approach to Digital Health Technologies" (10 April, 2018).
84 *Medical Devices Regulations*, SOR/98-282.

(ii) provide for protection appropriate to those risks, including the provision of alarms, and

(iii) provide, with the device, information relative to the risks that remain; and

(d) minimize the hazard from potential failures during the projected useful life of the device.

Within the context of connected medical devices and a manufacturer's obligations under section 10 of the *MDR*, it is arguable that cybersecurity risks and unauthorized intrusions on the data integrity of such products that cannot be eliminated would require the manufacturer to devise protective measures and inform consumers and learned intermediaries of said risks. On December 7, 2018, Health Canada confirmed that manufacturers should consider cybersecurity vulnerabilities at the pre-market stage in its draft guidance document on *Pre-Market Requirements for Medical Device Cybersecurity*.[85] Pending finalization of this guidance document following stakeholder comments, Health Canada is expected to call on manufacturers to: 1) incorporate cybersecurity into the risk management process for every device; 2) develop and maintain a framework for managing cybersecurity risks throughout their organizations; and 3) verify and validate cybersecurity risk measures in the design requirements and/or specifications.[86] As the language used in the draft guidance document is permissive, it is not clear what aspects, if not all, may be set as mandatory by Health Canada.

In addition to regulatory oversight by Health Canada, digital health technology stakeholders may be subjected to additional oversight by provincial and federal regulators with respect to the manner in which the data is stored, collected, and used by these devices. Depending upon the province and the data at issue, a breach may also require a mandatory notification to the provincial and federal privacy regulators. For example, in Ontario, the provincial regulator now requires a health information custodian to notify an affected individual at the first reasonable opportunity if "personal health information" in its custody or control is stolen, lost, used, or disclosed without authority or following a significant breach event.[87] The following are some factors that can be considered in determining if a breach is "significant": whether the compromised personal health information is sensitive, involved a large volume of information and

85 Health Canada, "Draft Guidance Document – Pre-Market Requirements for Medical Device Cybersecurity" (7 December 2018).
86 Health Canada, "Draft Guidance Document – Pre-Market Requirements for Medical Device Cybersecurity" (7 December 2018).
87 O Reg 329/04 (in force as of October 2017).

individuals, and whether more than one health information custodian or agent was responsible for the unauthorized disclosure.[88] Under the Ontario personal health information legislation, a custodian includes health care practitioners such as doctors and nurses, but also organizations, such as public or private hospitals or care homes.[89] A similar mandatory breach notification requirement where a "real risk of significant harm to an individual" exists is also reflected in the federal privacy legislation.[90] Further, organizations subject to the *Personal Information Protection and Electronic Documents Act* (PIPEDA) will be required to notify the individuals affected, the federal privacy commissioner, and possibly other organizations and government entities for the purposes of mitigating the impact of the breach. Under the federal legislation, "significant harm" includes "bodily harm, humiliation, damage to reputation or relationships, loss of employment, business or professional opportunities, financial loss, identity theft, negative effects on the record and damage to or loss of property."[91]

Finally, an often less talked about regulatory compliance issue is the additional licensing and certification approvals that may be required under the *Radiocommunication Act*[92] and related regulations. Depending on the nature of wireless connectivity inherent within the digital health technology, this set of regulatory requirements may be an additional source of regulatory concern for manufacturers, distributors, importers, and retailers of such technologies. Depending on the technology, these considerations may also apply at the research and development stage.

18.5.1.2 Litigation Risks: Beyond Traditional Product Liability

Digital health technologies can present litigation risks. In addition to inherent product liability risks associated with design, manufacturing, marketing, labelling, or promotion of the product, the cyber breach and data security vulnerabilities represent a significant source of liability depending on the connectivity and data capabilities of these types of technologies.

While there have not been any reported product liability decisions involving connected medical devices in Canada, the developing Internet of Things (IoT) litigation in other common law jurisdictions highlights the litigation concerns

88 Ontario's *Personal Health Information Protection Act, 2004*, SO 2004, c 3, Sched A [*PHIPA*], which governs how identifying identifiable information about an individual interacting with a healthcare custodian ought to be protected defines "personal health information" as "information that identifies an individual or for which it is reasonably foreseeable in the circumstances that it could be utilized, either alone or with other information, to identify an individual".
89 *PHIPA*, s 3.
90 *Personal Information Protection and Electronic Documents Act*, SC 2000, c 5, s 10.1 [*PIPEDA*].
91 *PIPEDA*, s 10.1.
92 *Radiocommunication Act*, RSC 1985, c R-2.

associated with connected technologies. As an illustration, in the California case of *Ross v. St Jude Medical Inc.* (Ross), the connected medical device manufacturer resisted a proposed class action related to alleged cybersecurity failures within the defendant's connected cardiac devices.[93] These devices came equipped with a wireless monitoring technology, allowing remote observations. While there was no evidence that the representative plaintiff was harmed by the alleged product vulnerability, the claims for damages were advanced on the basis of the possibility that a loss may occur due to the purported failures. While the action was ultimately dismissed, the July 5, 2018, decision in *Flynn v. FCA*,[94] involving similar claims, but a different type of technology (connected vehicles), described the product litigation risks associated with alleged cybersecurity vulnerabilities, even when there is no evidence that the plaintiffs were harmed by the alleged flaws in certain vehicles' infotainment system. In that case, the defendants prevailed against the plaintiffs by successfully dismissing on summary judgment their claims for unjust enrichment and part of their fraud claims. However, the plaintiffs' remaining claims of fraud and warranty claims survived and the class action was partially certified. Despite a further appeal to the U.S. Supreme Court, the defendants were unsuccessful in defeating the partial certification of claims surviving the summary judgment motion. It remains to be seen if the evolution of the *Flynn* case may inspire more class actions involving connected products.

While the foregoing discussion focusses on the inherent product-specific vulnerability risks, undoubtedly the increase in usage of other connected devices to IoT platforms and their related interconnections may pose extraneous risks to the integrity of product-specific digital health technologies. The fast-paced developments and adoption rates of digital health technologies have already called for an update to the current Canadian medical device regulatory framework. It remains to be seen, however, how Courts will consider the liability theories associated with product liability claims of IoT technology failures. Regardless of the industry, it is likely that we all stand to witness an incredible evolution in the product liability landscape.

93 *Ross v. St Jude Medical Inc,* No 2:16- cv- 06465 (CD Cal 2016).
94 *Flynn v. FCA US LLC*, 3:15-cv-00855 (SD Ill 2015), see page of the July 2018 decision of Justice Reagan.

18.5.1.3 New Frontier: 3D/4D Printed Organs and Devices

Although 3D printing has been around since the 1980s, economies of scale and cost considerations have led to a proliferation of the technology in recent years.[95] The industry is currently worth an estimated 15 billion dollars and is expected to grow to 35 billion by 2022.[96] In a state of greater infancy, 4D printing technology is also positioned to have an impact in the very near future. The fourth dimension that 4D printers add to their end product is the ability to react when subjected to a stimuli (*e.g.*, exposure to heat, ultraviolet light, or others).[97] At this stage, academic institutions, non-profit organizations, and for-profit corporations are racing to improve clinical outcomes through the use of 3D and 4D printed medical devices and organs. For these two technologies, Canada's regulator, Health Canada, has issued guidance to manufacturers and distributors of 3D printed medical devices and organs. In this section, we explore these regulatory developments, along with emerging liability concerns for 3D printing manufacturers and distributors.

18.5.1.4 What are 3D Printed Medical Devices and Organs?

3D printers are considered an additive manufacturing device because successive layers of raw material are printed and piled until a solid 3D object is formed. This process can produce nearly limitless iterations. For this reason, early use of the technology in the medical context has been geared to creating customized medical devices.

3D printed organs are made using the same underlying technology and process of layering. Unlike medical devices, the "ink" used to produce 3D printed organs is made of human tissue. This printing method is referred to as "bioprinting". An example is the 3D printed heart, which was developed in Tel Aviv and engineered from cells, blood vessels, ventricles, and chambers.[98]

While essentially the same technology is responsible for the creation of both types of products, it is important to keep in mind that their distinct features impact the way in which each of these products is regulated.

95 Jeff Mason, Sarah Visintini, & Teo Quay, "An Overview of Clinical Applications of 3-D Printing and Bioprinting" (2019) 175 CADTH Issues in Emerging Health Technologies at 3.
96 TJ McCue "Significant 3D Printing Forecast Surges To $35.6 Billion", *Forbes* (27 March 2019.
97 Shida Miao et al "4D printing of polymeric materials for tissue and organ regeneration" (2017) 20:10 Materials Today at 577.
98 "'First' 3D print of heart with human tissue, vessels unveiled", *CTV News*, (16 April 2019).

18.5.1.5 Regulatory Aspects of 3D Printed Medical Devices and Organs

Health Canada has had its eyes on 3D printing technology for years, culminating with an initial guidance document to the industry in April 2019. The history of the regulator's focus on 3D printing has its origins in the work of the Canadian Senate. Particularly, beginning in 2016, the Canadian Senate focused its attention on 3D printed medical devices by adopting an Order of Reference authorizing the Standing Committee on Social Affairs, Science and Technology to examine and report on innovative technologies in healthcare (including artificial intelligence and 3D printing).[99] From February to May of 2017, the Senate Committee met with a number of expert witnesses in the field to hear their opinions. As part of this process, and perhaps most importantly, the Senate Committee engaged Health Canada in this space.

The Senate Committee asked Health Canada a number of questions about how 3D printed products would fit into the existing regulatory regime.[100] As part of its response, Health Canada announced that it was actively monitoring the introduction of innovative technologies such as 3D printing in the medical context. On this same note, it was suggested that printed medical devices would likely be considered a Class III device (out of the four existing classes of the risk-based framework of categorizing medical devices).[101]

Medical devices produced using 3D printing are subject to the *Medical Device Regulations*, which the regulator views as sufficiently flexible and adaptive to accommodate for innovative technologies. In October 2018, the regulator released a draft guidance document for manufacturers wishing to obtain licenses for implantable 3D printed medical devices. Following feedback by relevant stakeholders, the regulator issued a final draft of its guidance document entitled *Supporting Evidence for Implantable Medical Devices Manufactured by 3D Printing*.[102] Guidance documents are an administrative tool by which the regulator provides assistance to the industry on complying with the governing medical device laws. Health Canada had made it clear that this document represents "the first phase" in the evolving 3D printing technology policy in Canada.

99 Standing Senate Committee on Social Affairs, Science and Technology, *Challenge Ahead: Integrating Robotics, Artificial Intelligence and 3D Printing Technologies into Canada's Healthcare Systems* by the Honourable Kelvin Kenneth Ogilvie, Chair & the Honourable Art Eggleton, PC, deputy chair (Ottawa: Senate of Canada, October 2017).

100 Senate Standing Committee on Social Affairs, Science and Technology, *Study on Robotics, Artificial Intelligence and 3d Printing:* Health Canada Response (2017).

101 The system of classification is based on the risk level associated with each medical device class. For example, implantable devices like prosthetics are considered to be class IV versus thermometers, which are classified as class I.

102 Health Canada, "Guidance Document: Supporting Evidence for Implantable Medical Devices Manufactured by 3D Printing" (30 April 2019).

This initial guidance document is helpful for manufacturers and distributors of 3D printed medical devices (including hospitals) seeking to obtain a license to produce implantable 3D class III and IV medical devices. The guidance document also makes it clear that healthcare facilities that manufacture 3D printed implantable medical devices under their own name and distribute them outside their organization would be considered a manufacturer and must therefore abide by all regulatory requirements under the regulations. However, the document does not provide guidance for standalone software, custom-made devices, and anatomical models incorporating viable living cells. Perhaps most notable are the sections of the document relating to the additional information that manufacturers will need to provide for the purpose of obtaining a license to sell and/or distribute 3D printed class III and IV implantable medical devices in Canada.

To provide some context, a manufacturer must obtain a licence to sell or import products that fall within the *Medical Device Regulations*. In order to do so, an application must be made to the federal Minister of Health to demonstrate the safety and effectiveness of the product, such as evidence of safety and effectiveness, biocompatibility testing, and software validation. In addition to all of the information that would be required under an ordinary Class III or IV licencing application for non-3D printed devices, Health Canada stated in its guidance document that applications pertaining to 3D medical devices must also provide detail with respect to the following aspects:

1. Device description (including reference to starting material and any additives) and the description of the 3D printing method (*e.g.*, laser sintering, metal laser sintering and power bed fusion) and any post-processing steps;
2. A description of the "design philosophy" which "may" include an explanation of the choice to use 3D printing as a manufacturing process;
3. Justification for why modifications may exist from a previously approved device produced using other methods (*e.g.*, changes in material, post-processing steps, material-printer combination, software-related changes affecting the finished device, etc.)
4. A description of the marketing history of the 3D printed device or relevant previously approved comparable device or components;
5. A declaration of conformity with design and manufacturing standards, but the regulator has made it clear that the "use of standards" is not compulsory as the manufacturer may demonstrate safety and effectiveness independent of any standard;

6. Pre-clinical performance testing summary for all pre-clinical testing performed, but specific test requirements vary depending on the device type and other indicia, such as whether the device is patient-matched or manufactured to pre-determined sizes;
7. For devices with a novel design, material, or intended use, the regulator may require clinical studies and animal studies to support safety and effectiveness; and
8. Considerations on the specific labelling of patient matched devices, along with a warning that the patient should be assessed for potential anatomical changes prior to any procedure involving the custom-made device.[103]

While 3D printed medical devices are subject to the *Medical Device Regulations*, the regulatory umbrella for 3D printed organs is less clear. When asked about how 3D printed organs should be regulated, Health Canada's response was more nuanced than it was for 3D printed medical devices. First, Health Canada affirmed that because this process involves the use of human tissue and cells, it would generally be regulated under the *Food and Drug Regulations*, and not the *Medical Device Regulations* (as is the case for 3D printed medical devices). Second, the regulator stated that in a situation where a combination of biologic and inert materials are used, the entire product may be regulated under either the *Food and Drug Regulations* and/or the *Medical Device Regulations*. This suggests that a re-evaluation of the current regulatory framework may be required to address the appropriate regulatory pillars for evaluating the safe use and effectiveness of 3D printed organs.

18.5.1.6 Emerging Liability Concerns for 3D Printing Manufacturers

In addition to how regulators plan to govern the production, distribution, and use of these technologies, manufacturers will also be concerned about how these new technologies may fit into the existing product liability legal framework.

A fundamental aspect of Canadian law regarding product liability is the manufacturer's duty to warn consumers of the potential risks associated with their products. This does not exclude the duty of care that others in the supply chain may have vis-a-vis the end user. An important exception to this rule that is often relevant in the medical context is the learned intermediary rule.

103 Health Canada, "Guidance Document: Supporting Evidence for Implantable Medical Devices Manufactured by 3D Printing" (30 April 2019).

We would not expect any deviations on the manufacturer's ability to rely on the learned intermediary doctrine as a defence in product suits in the context of 3D printed medical products. That said, the liability pendulum may shift further to the learned intermediary if the healthcare professional and/or the healthcare facility is equipped with a 3D printer capable of producing 3D medical products on demand. In this context, a physician and/or hospital may well be considered a manufacturer of the final product and the manufacturer of the 3D printer itself may then be subject to somewhat limited liability.

Another doctrine that becomes increasingly relevant in the wake of 3D and 4D printing for manufacturers of the printers is the defence of lack of knowledge of danger. Generally, a manufacturer will not be liable for its failure to warn of a risk related to its product that it neither new or ought to have known of. This is not an unlikely predicament in the case of 3D printers, which may well be used to produce a limitless array of finished products. In this context, proper labelling and marketing materials may assist manufacturers to defend against such future claims.

18.6 Concluding Remarks

There truly is a great deal to be excited about in emerging technologies in life sciences. However, manufacturers and distributors should carefully monitor the evolving statutory and regulatory regime to mitigate against regulatory and litigation risks following the deployment and adoption of these emerging technologies. Most importantly for manufacturers looking to sell their products across jurisdictional borders, care should be taken to review jurisdictional differences in the regulation of emerging technologies so as to inform internal processes and procedures. For some manufacturers, the calculus of this method often results in abiding by the highest regulatory standard across the different applicable jurisdictions.

PART 5
Other Forms of Protection

Chapter 19

Trademarks: Another Valuable Asset for Life Sciences Companies

19.1 What is a Trademark?

In addition to patent protection, trademarks are an important form of intellectual property protection. Trademarks cover branding, as well as corporate image and reputation, and can be a valuable commercial asset for companies.

A trademark can take on a number of different forms. In its essence, a trademark is any "sign" or combination of "signs" that are used to distinguish the products and services of one company or organization from those of another. A "sign" is defined in the *Trademarks Act* as including:[1]

> *a word, a personal name, a design, a letter, a numeral, a colour, a figurative element, a three-dimensional shape, a hologram, a moving image, a mode of packaging goods, a sound, a scent, a taste, a texture and the positioning of a sign;*

Canada's *Trademarks Act* is, to some extent, consumer protection legislation, as it is intended to protect consumers from confusion between competing trademarks. The registration of a trademark under Canada's *Trademarks Act* provides a monopoly of sorts to the mark owner – granting them with the exclusive right to the use of the trademark across Canada in respect of specified goods and services.

Canadian courts have long recognized that trademarks are an anomaly in intellectual property law. Unlike patent or copyright right protection, trademarks do not require that a novel benefit be provided to the public in exchange for a monopoly. Instead, the monopoly conveyed to a trademark owner is seen as a trade-off between fair competition and the protection of the public from deception. Trademark legislation serves to protect the public interest by assuring consumers they are buying from a particular source and receiving a product or service of a particular quality standard that is associated with that trademark.[2] Accordingly, trademark law provides brand owners with protection, while at the same time aiming to prevent consumer confusion and deception.

19.2 From a Legal Perspective, What Should be Considered When Choosing a Trademark?

Prior to marketing a product or service in association with a new trademark, it is important to consider whether the trademark of interest is available for use and registration in Canada, as well as in any other jurisdiction of interest. Engaging trademark counsel early on in this trademark selection and adoption process

1 *Trademarks Act*, RSC 1985, c T-13, s 2 [*Trademarks Act*].
2 *Mattel, Inc. v. 3894207 Canada Inc.*, 2006 SCC 22.

can help avoid spending time and money on a trademark that may not be registrable, or that may infringe on another trademark, if and when it is used.

As a best practice, it is important to have trademark counsel conduct a "clearance search" prior to using or applying to register a trademark. A "clearance search" will identify potential risks in adopting a particular trademark and will alert the mark owner to any issues which could form the basis of an objection, either to the registration or to the use of the trademark of interest. Typically, it is recommended that clearance searches be completed in any jurisdictions where the sale or marketing of products or services under the new mark is contemplated. Canadian trademark counsel can assist in providing strategic filing advice and coordinating clearance searches in various jurisdictions.

19.3 Does a Trademark Need to be Registered?

Although trademarks do not need to be registered in Canada, and certain common law rights can be acquired through the commercial use of a trademark, trademark registration affords numerous benefits above and beyond those associated with unregistered trademarks. Some of the benefits of trademark registration include:

(1) providing public notice to others of trademark rights, through the publication of applications and registrations on a public register maintained by the Canadian Intellectual Property Office;

(2) providing the exclusive right to the use of the trademark for the registered goods and/or services across all of Canada (common law rights are limited to the geographical location in which a reputation associated with the mark can be shown);

(3) providing trademark owners with the ability to sue third parties for statutory trademark infringement (which cannot be done without a registration);

(4) providing additional grounds to oppose the registration of a third party's application for a confusingly similar trademark;

(5) allowing brand owners to take advantage of the Canadian border enforcement regime against counterfeit products;

(6) a registration may be of some assistance in delineating rights in a licensing regime;

(7) there may be a perceived benefit of a registered mark over an unregistered one in the valuation of a trademark;

(8) a pending or registered trademark will prevent the registration of a confusingly similar trademark at the Canadian Intellectual Property Office.

(9) A registered trademark entitles a non-Canadian to hold a .ca domain name.

(10) A pending or registered mark can form the basis for international trademark filings under the Madrid trademark registration system.

(11) A registered trademark may qualify as an exception to translate a brand under Québec's language laws.

Given the wide range of benefits of a trademark registration, trademark protection is something that brand owners should consider *before* bringing a product or service to market. In Canada, unlike the United States, there is no requirement to 'use' a mark in order to obtain a trademark registration.

Once a trademark is registered, an owner has three years to commence use of the mark in Canada. At that point, the registration becomes vulnerable to a challenge for non-use by third parties. Considering that it currently takes at least three years or more to make it through the trademark registration process in Canada, brand owners can wait six years or more (depending on the circumstances) before they actually need to commence using the mark in Canada, and before a corresponding registration becomes vulnerable to cancellation for non-use.

19.4 What is the Process to Register a Trademark in Canada?

The process of trademark registration can be a complex task — particularly if the Trademarks Office issues an objection or a third party opposes the registration of the trademark application. Careful consideration should be given, beginning with the preparation of a trademark application, to the specific legal requirements in Canada and other jurisdictions where the trademark application is filed. Important considerations include ensuring that correct and relevant information is provided to the Trademarks Office without unduly restricting or jeopardizing the trademark owner's rights.

A brief summary of the trademark registration process is outlined below:

19.4.1 Preparing and Filing a Trademark Application

In Canada, new trademark applications should include:

(1) A clear depiction of the trademark;

(2) The full legal name and business address of the trademark owner;

(3) A statement of the goods and services associated with the trademark. Canada now adheres to the Nice Agreement, and requires each good and service to be grouped into "classes" designated by the international Nice Classification system;

(4) Any additional relevant claims and information, including priority claims flowing from foreign trademark applications, color claims, etc.;

(5) An official filing fee (for one class of goods or services) and additional class fees (for each additional class of goods or services covered by the application); and

(6) Identification of the Canadian agent (if using an agent, often your Canadian trademark counsel).

19.4.2 Examination of a Trademark Application

Once a trademark application is filed, a formal receipt is issued, providing a serial number and an official filing date. The application then waits (a part of the process that is currently taking well in excess of one year) until it is formally examined. This stage is generally referred to as the "examination" stage. There are technical and substantive objections that may be raised during the examination stage.

The Examiner will require that the wording of the goods or services be in 'ordinary commercial terms'. CIPO maintains a list of acceptable terms, and by using goods or services from that list, an application will be examined faster than an application not using that list.

An Examiner at the Trademarks Office will also review the application to ensure that the application is registrable.

For example:

- The trademark cannot be a word that is primarily merely the name or the surname of an individual who is living or has died within the preceding thirty years.
- It cannot clearly describe a feature or quality of the goods or services.
- It cannot be the name in any language of any of the goods or services.
- The trademark must be inherently distinctive.

The Examiner will also assess whether the applied-for trademark is confusing with a trademark for which another party has previously applied or registered. Confusion is determined from the perspective of the relevant consumer in light of the surrounding circumstances, which include:

(1) the inherent distinctiveness of the trademarks or trade names and the extent to which they have become known;

(2) the length of time the trademarks or trade names have been in use;
(3) the nature of the goods, services, or business;
(4) the nature of the trade; and
(5) the degree of resemblance between the trademarks or trade names, including in appearance or sound or in the ideas suggested by them.

If the Examiner considers the applied-for trademark to be confusing with a trademark that is the subject of another party's previously-filed application or a registration, or has any other objections to raise, an examiner's report will issue setting out all of the examiner's objections to the registration application. The Applicant will then have an opportunity to submit written submissions in reply, in an attempt to convince the Examiner that the trademark is registrable.

19.4.3 Advertisement and Opposition

Once a trademark application successfully passes the examination stage, it is advertised in the *Trademarks Journal*. Advertisement provides official notice to the public of the imminent registration of an Applicant's application and provides an opportunity for third parties to oppose the registration of the advertised application. The advertisement (or "opposition") period extends for two months from the date of advertisement.

When a third party wishes to prevent the registration of a mark, the process is referred to as a trademark opposition. A trademark opposition is an administrative proceeding held before an administrative tribunal known as the Trademarks Opposition Board. A trademark opposition proceeding concerns the rights of the Applicant to the registration of its trademark application. An opposition does not affect the applicant's right to 'use' the particular trademark. The right and ability of a party to 'use' a trademark in the marketplace must be challenged through a separate legal proceeding before a court of law. These include actions claiming trademark infringement, passing off and depreciation of the value of the goodwill attaching to a trademark.

A third party that has initiated a trademark opposition proceeding may base its opposition on a number of grounds of opposition, including prior use or registration of a confusing trademark, the lack of distinctiveness of the Applicant's trademark, and other grounds. If a trademark application is successfully opposed, and the decision not appealed, the application will be refused.

While trademark Applicants are sometimes faced with defending their trademark rights at opposition, brand owners must also actively monitor the *Trademark Journal* to prevent any third-party Applicants from registering marks that could cause confusion. Canadian trademark counsel can set up a watch service that

notifies a business of the advertisement of any trademark applications in the *Trademarks Journal* that may pose a threat or warrant initiating an opposition.

19.4.4 Registration

Once a trademark application successfully passes the two-month publication period without being opposed (or the opposition is withdrawn, or ends favourably for the Applicant), the registration of the trademark will be granted and the Trademarks Office will issue a certificate of registration.

19.5 Special Considerations for Pharmaceutical and Medical Device Companies

19.5.1 Trademark Registration vs. Drug Name Approval

In selecting a brand name for a new drug, pharmaceutical companies should be aware that although a brand name may be registered as a trademark, it will *not* necessarily be approved by Health Canada as the brand name for a prescription pharmaceutical and vice versa. Obtaining a trademark registration for a brand name and obtaining Health Canada approval to sell a pharmaceutical under a particular brand name are separate processes that involve different considerations.

Under Canada's *Food and Drug Regulations*, sponsors are required to provide a brand name assessment as part of the drug safety and effectiveness evaluation for a drug submission.[3] The purpose of a brand name assessment is to prevent errors resulting from confusion between drugs with similar names. If Health Canada considers that the proposed brand name is likely to be confusing with the names of other medications (because it looks like another drug name or sounds like another drug name), Health Canada may refuse to issue a Notice of Compliance.

The Brand Name Assessment Process requires an applicant, referred to in this process as a sponsor, to conduct (1) an initial brand name review according to enumerated safety criteria; and (2) a Look-alike Sound-alike (LASA) brand name assessment to assess the likelihood of confusion between the proposed brand name and product names already authorized in Canada.

The assessment of confusion under the LASA brand name assessment is different in nature than the assessment of confusion from a trademark perspective. Under LASA, the assessment involves a variety of considerations, which may include having reference to the Drug Product Database, medication-use process simulations, and the Phonetic Orthographic Computer Analysis (POCA).

3 *Food and Drug Regulations*, CRC c 870.

As the Health Canada approval process can take several years, a trademark registration could be obtained prior to brand name drug approval.

Recent changes to Canadian Trademark law now make it possible to obtain a trademark registration without ever having used the trademark in Canada. Although a registration is vulnerable to non-use cancellation three years from its registration date, a registration will be maintained where there are "special circumstances" justifying non-use.[4] It is possible under these circumstances that the pending Health Canada Approval of a drug name *could* be a "special circumstance" justifying non-use of a trademark.

19.5.2 Challenges in Protecting Non-Traditional Trademarks

In addition to product brand names, trademarks can take on many unique forms, including colour, a mode of packaging, a three-dimensional shape, etc. When applying to register non-traditional trademarks in Canada, Applicants must file evidence that, as of the filing date of its application, the trademark had a reputation and was distinctive throughout Canada. Although this is a new requirement (that came into force in 2019 with Canada's new *Trademark Act*), historical case law in Canada suggests that pharmaceutical and medical device companies will likely face challenges in obtaining registered trademark protection for non-traditional trademarks, such as the color and shape of medical devices or prescription pharmaceuticals. The threshold of the extent of evidence required to prove distinctiveness tends to be fairly high, as demonstrated in the following cases:

In *Canadian Generic Pharmaceutical Association v. Boehringer Ingelheim*,[5] the Trademark Opposition Board considered the opposition of two trademark applications for the designs of inhalers for therapeutic purposes. Citing previous Federal Court and Federal Court of Appeal decisions, the Trademark Opposition Board held that substantial and impressive sales figures alone do not satisfy the burden on an Applicant to prove its trademark is distinctive. The Board stated that shape or color of a product must be distinctive to a "significant degree" of a single source of manufacture, not just to the end consumer of the product, but also to physicians and pharmacists. Accordingly, the evidentiary burden on Applicants seeking to register the shape of a medical device as a trademark is extremely high.

4 *Trademarks Act*, s 45(3).
5 *Canadian Generic Pharmaceutical Association v. Boehringer Ingelheim Pharma GmbH & Co KG*, 2017 TMOB 47.

Similarly, in *Canadian Generic Pharmaceutical Association v. Pfizer*,[6] the Trademarks Opposition Board held that Pfizer's trademark application for its blue Viagra tablet was not registrable as it was not distinctive in view of the large number of other blue tablets in the marketplace. The Board found that the blue Viagra tablet was distinctive amongst patients, as the evidence suggested at least some patients referred to the tablet as a "little blue pill". However, the Board was not convinced that the blue Viagra tablet was distinctive to physicians and pharmacists and refused to register the application. On appeal, the Federal Court ultimately agreed with the Board's decision to refuse the registration of the application, but disagreed with the Board that the blue Viagra tablet was distinctive to patients. The Federal Court held that "evidence is required that patients connect appearance with source to a significant degree".[7] The Court also noted that the advertising and promotional material provided by Pfizer highlighted the beneficial effects of Viagra but did not "draw attention to the appearance of the pill as an indicator of source". The Court noted that there were other source identifiers associated with the blue tablet (for example, the trademark "Pfizer" appeared on the blue tablet). The Federal Court held that Pfizer had not established that the blue Viagra tablet on its own, without the word "Pfizer", was distinctive to patients, physicians, and pharmacists.

6 *Canadian Generic Pharmaceutical Association v. Pfizer Products Inc.*, 2013 TMOB 27.
7 *Pfizer Products Inc. v. Canadian Generic Pharmaceutical Association*, 2015 FC 493.

Chapter 20

Evaluating Trade Secrets and Patent Protection

20.1 Overview

When a company is investing in research and development (R&D), or is involved with ongoing work to develop and commercialize a product or service, various legal approaches are available in Canada to protect the intellectual property and confidential business information that is generated. For example, patent laws provide a mechanism to protect work associated with inventions.

Another method of protecting R&D or development efforts is through trade secret protection. In contrast with patent protection, if a company wants to maintain a trade secret, there is currently no statutory protection in Canada. However, Canadian common law and contract law principles can help protect the value of information that is considered a trade secret, and can help protect sensitive, confidential business information and work product by dissuading parties receiving such information from making unauthorized disclosures.

Each method of protecting intellectual property has advantages and disadvantages, which makes the selection of the method of protection a strategic choice. Which method of protection is more appropriate for a given circumstance? As described below, the scope of patent protection and trade secret protection varies. With these differences in mind, a business can determine whether a particular development, information, or work product is best protected by a patent or by attempting to keep the information as a trade secret, taking into consideration a number of factors as described below.

20.2 Patents – Scope of Protection

The patent regime is discussed in detail in other chapters of this book. However, for comparative purposes, a brief summary follows. Patents can be granted by the Canadian Intellectual Property Office (CIPO) if the following criteria are met. What is claimed in the patent needs to be:

(1) new and not previously publicly known or published,

(2) useful in some way, and

(3) inventive or, in other words, not obvious.

A Canadian patent will give the owner the right to prevent others from using the invention in Canada for a period of 20 years from the date the patent application was filed.[1] In addition, the specification of the patent must correctly and fully describe the invention and its operation or use as contemplated by the inventor.[2] With complicated inventions in the technology and life sciences fields,

1 *Patent Act*, RSC 1985, c P-4, s [*Patent Act*].

2 *Patent Act*, s 27(3).

it can sometimes take a number of years for a patent application to get through the iterative prosecution process and issue as a final patent, and potentially with a more limited scope than originally sought.

A patent is meant to be a bargain between the patent holder and the state (for the benefit of the public). The bargain for the patent holder is that, if a patent is granted, then the patent holder obtains a period of exclusivity during which the patent holder can prevent others from making, using, or selling what is included in the patent's claims. The bargain for the public is that the patent publicly discloses new information in a field of knowledge that is information that may not have otherwise been made public until much later, if ever, but for the incentive of the exclusive period granted to the patent holder. For this bargain to work effectively, when a patent application is filed, the Applicant is required to fully disclose the details of the invention, and this must be done in a way that would enable someone reading the patent application to be able to practice the invention; in other words, to use the invention.

The scope of protection is the right to exclude others from making, using, or selling what is claimed (and to pursue infringers), but the cost of doing so is that the invention is publicly disclosed, so after the exclusive period anyone can freely use the invention.

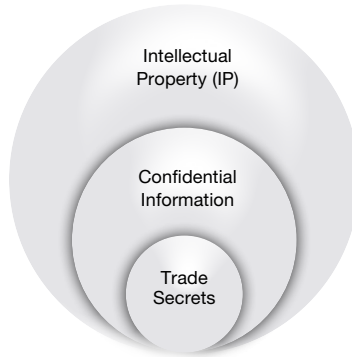
20.3 Trade Secrets – Scope of Protection

Trade secrets are a form of intellectual property, but are not registrable like patents, trademarks, industrial designs, or copyrights. Trade secrets have value because they are secret.

In most provinces in Canada, trade secrets can be protected by the courts by virtue of a combination of common law, contract law, and equity principles. There are some trade secret provisions in the province of Québec's *Civil Code.*[3]

Uniform definitions of trade secrets and confidential information have not been adopted by Canadian courts, which have taken a flexible approach to enforcement in this area. The common law tort of breach of confidence can be used to award damages for the improper or unlawful use of confidential information.[4] Remedies are available to ensure that the owner of a misappropriated trade secret can be compensated, at least in theory, for the full extent of their loss.[5]

3 *Civil Code of Québec* (SQ, 1991, c 64) Articles 1472 (disclosure of trade secret can be justified for reasons of public health or safety) and 1612 (loss sustained by the holder of a trade secret).
4 *Cadbury Schweppes Inc. v. FBI Foods Ltd.*, [1999] 1 SCR 142 at para 20-26 [*Cadbury v FBI Foods*].
5 *Cadbury v. FBI Foods* at para 54.



Courts have used a number of criteria or characteristics to determine whether information can be considered a trade secret.[6] If information is a secret formula, process, or know-how, which has not been patented but is kept confidential, this will tend to indicate it is a trade secret. If information has been treated in a way where it has only been shared with certain individuals or groups within a company, namely only those to whom disclosure is necessary, this will also indicate the information is in the nature of a trade secret. As a result, for information to be legally recognized as a trade secret, and to be able to access remedies in law related to the protection of a trade secret, the way in which the information has been kept secret and the measures to prevent disclosure are crucial.

A trade secret also needs to have some commercial value. Trade secrets are generally understood to be used to create some article of trade having a commercial value. A trade secret gives an advantage to a business over competitors who do not have the same information. Information properly maintained as a trade secret can also add value to the business, because it can be used, licenced, and transacted as an asset.

There must be some difference between a trade secret and something which is merely confidential, such as proposal documents supplied to a government institution to bid on a government contract. A trade secret is something, often of a technical nature, which is closely guarded and is of such peculiar value to the owner of the trade secret that harm to the owner would be presumed by its mere disclosure.[7] As such, a bid to obtain a contract for translation services was not found to constitute a trade secret.

In *AstraZeneca*,[8] the Federal Court reviewed a decision to release records related to a new drug submission (NDS). The Federal Court held that Parliament's intention was to protect genuine trade secrets based on the common law definition of the term and noted that the question was whether

6 *Merck Frosst Canada Ltd. v. Canada (Health)*, 2012 SCC 3 at paras 107-110 [*Merck Frosst*].
7 *Merck Frosst* at para 108; *Société Gamma Inc. v. Canada (Department of the Secretary of State)* (1994), 56 CPR (3d) 58 (FCTD) at 62-63.
8 *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, 2005 FC 189 [*AstraZeneca v Canada*], aff'd 2006 FCA 241 and cited with approval in *Merck Frosst* at paras 110-111.

the records fell within the legal definition of "trade secret".[9] The Court referred with apparent approval to a Federal Government guideline document produced by Health Canada entitled *Access to Information Act — Third Party Information — Operational Guidelines.* This *Access to Information Act* guideline, as well as other similar federal government guidelines, set out four main criteria that need to be met for information to be a trade secret:

1. the information must be secret in an absolute or relative sense (*i.e.*, the information must be known only by a relatively small number of persons);
2. the person possessing the information must demonstrate that they have acted with the intention to treat the information as secret;
3. the information must be capable of industrial or commercial application; and
4. the possessor must have an economic interest worthy of legal protection.

Consequently, a trade secret can be a plan, process, tool, mechanism, or compound. The type of information which could potentially be considered a trade secret also includes the chemical composition of a pharmaceutical product and the manufacturing processes used. However, not every process or test will fall into this class, particularly where the process or test is common in a particular industry.[10]

The new trade agreement between the U.S., Mexico, and Canada explicitly sets out provisions for the identification and enforcement of trade secrets.[11] Under the *Canada-United States-Mexico Agreement* (*CUSMA*), a "trade secret" is specifically defined. This definition is similar to the criteria the courts have used in the same context. A trade secret means information that:[12]

1. is not generally known among, or readily accessible to, persons within the circles that normally deal with that kind of information, either as a body or in the precise configuration and assembly of its components;
2. has actual or potential commercial value because it is secret; and
3. reasonable steps have been taken to keep it secret by the person lawfully in control of the information.

9 *AstraZeneca v. Canada* at para 64.
10 *AstraZeneca v. Canada* at para 65.
11 *Canada-United States-Mexico Agreement (CUSMA)*, 30 November 2018, Section I: Trade Secrets, Articles 20.70-20.78.
12 *CUSMA*, Article 20.73: Definitions.

In addition to the provision of protection for trade secrets, which Canada had at common law, the *CUSMA* also required criminal procedures and penalties for any authorized and willful misappropriation of trade secrets.[13] To comply with these international obligations, Canada enacted provisions in the *Criminal Code*.[14] The definition of a trade secret in that provision reasonably tracks with the *CUSMA* provisions:

391(5) For the purpose of this section, *trade secret* means any information that

(a) is not generally known in the trade or business that uses or may use that information;

(b) has economic value from not being generally known; and

(c) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

The scope of protection is that others (including competitors) do not get the benefit of applying the trade secret to their business because it is not known. The risk of this form of protection is that if a trade secret is disclosed (innocently or not), is independently created by a third party, or is reverse engineered by a competitor, then the protection (and associated value of being a secret) is no longer available.

20.4 Factors When Considering Patent Protection or Trade Secret Protection

Across a business's portfolio of information and technology, it is common to use both patent protection and trade secrets to protect different elements of information and technology to maximize the scope of protection offered by each form of intellectual property.

For a trade secret that meets the requirements necessary to be a patentable invention, how does a business decide which form of intellectual property is more appropriate?

In view of the differences between protecting information or technology through the patent regime or relying on trade secret law, a number of different factors should be analyzed and considered. Additionally, the forms of protection are not always mutually exclusive for a particular technology, as some aspects of the technology could be protected by a patent while other aspects might be kept as a trade secret. This means a nuanced analysis may be required.

13 *CUSMA*, Article 20.72: Criminal Enforcement.
14 *Criminal Code*, RSC 1985, c C-46, s 391.

In addition to the differences in scope of protection, a company can also consider company and information-specific factors, such as the risk of competition if the information is disclosed, the technology field (which may determine the likelihood that the information can be kept secret), the value of the information, the business appeal of developing or having a patent portfolio, the desire to license the technology, the company's ability to enforce its rights, and the sensitivity of the information. Additionally, there may be constraints on which form of protection is available, depending on whether the information has already been publicly disclosed in some way.

Some key considerations and factors are described in more detail below. While the importance of a particular factor will vary by the technology and by the company (such as its risk tolerance, position in the market, and intellectual property budget), arguably the most important thing is for a company to be deliberate about its approach to considering the applicable factors.

20.4.1 Differences in Scope of Protection

As mentioned, unlike a trade secret, which can theoretically be kept secret forever, the term of a patent is limited. After the end of the 20-year patent term, anyone is free to then use the invention.

These differences in the scope of protection are a key factor to consider. While a trade secret can be protected for a very long time with the right safeguards in place, it is vulnerable to disclosure, independent development, or reverse engineering. By contrast, once a patent is granted, it is not vulnerable to these risks, but the information included in a patent application will eventually become public after a limited confidentiality period expires. Also, there is a risk that no valid patent will ever issue (or that a granted patent will be impeached), in which case what might otherwise have been protected as a trade secret is compromised.[15]

As a starting point, with this scope in mind, a business should consider (a) the likelihood of a patent being granted; (b) the likelihood of reverse engineering or the independent development of a trade secret; (c) the desired term of protection (if 20 years of protection is long enough, a longer period is desired, or a shorter period is fine); and (d) the risks of disclosure of a trade secret when considering the number of parties who have to know about the trade secret, the safeguards that can be implemented, and how obvious a trade secret is in the final product.

15 *Patent Act*, ss 10(2)-(3): the confidentiality period is 18 months from priority date, thus can be limited to only 6 months from filing date.

For example, if the invention field is evolving quickly, the time period between the filing of a patent application and the issuance of the patent can be crucial. As a result, in areas where the useful life of an invention or advance in technology is very short, the benefit from obtaining a patent may not outweigh the costs and the information may be best protected as a trade secret for the short period required.

20.4.2 Availability of Protection – Public Disclosures

One of the first considerations is whether an invention or trade secret has already been disclosed to the public in some way.

If the technology a company is working on is not new, then it cannot be the subject of a patent in Canada. Consequently, if the subject matter of a patent application has already been disclosed to the public, such as through a press release, conference call accessible with investors, or scientific paper, then no one will be entitled to obtain a patent for that invention. However, the detailed knowledge of how a company is using the technology can still be a trade secret, despite a more general disclosure that does not disclose such specific details.

With a trade secret, there is an ongoing risk that the trade secret will be disclosed to others, including through theft or inadvertence. Public disclosure will essentially eliminate a trade secret's business value, and if it was previously disclosed, then it will not meet the criteria described above to be considered a trade secret.

20.4.3 Danger of Others Patenting First

Canada is a first-to-file patent jurisdiction, like many other jurisdictions around the world. That means that for a patentable invention, the first person to apply for a patent on the new invention is entitled to obtain a patent. Because of this, the decision to maintain technology as a trade secret and not apply for a patent for the technology means there is a danger that someone else may apply for a patent for the same invention.

If a company attempts to keep a trade secret, and the information is not otherwise made public or published, there is still a risk that a third party will independently be working on the same technology and will apply for and receive patents that cover or overlap with the company's trade secret. The trade secret will become public (so it will lose its commercial value to the company trying to maintain the trade secret), and if a valid patent issues in such circumstances, the patent holder will then be in a position to prevent others from infringing their patent rights.

In such a case, the company that was attempting to maintain the trade secret may have some limited rights as a prior user of the technology before it was patented. Recent changes to Canadian patent law have enhanced protections for prior users, and revised section 56 protects from infringement acts "that would otherwise constitute an infringement" if the act had been completed before the claim date."[16] However, the exact scope of these enhanced prior user rights has yet to be clarified, so it weighs against a trade secret strategy when the trade secret is likely to be independently developed, and then patented, by others.

20.4.4 Enforcement

If someone is infringing a patent holder's rights by making, using, or selling a product which incorporates their invention, it is the patent holder who must enforce their rights under the patent by bringing an action for patent infringement and claiming associated damages, typically in the Federal Court of Canada. And while a patent gives a patent holder the ability to enforce rights and obtain damages from the infringer, there can be significant costs and effort in so doing. There is an upfront cost to litigation, including counsel fees, disbursements to attend motions and hearings, and fees to engage experts in the field. Often, damages for patent infringement, if awarded, are awarded many years later, as full patent actions can take years to resolve. In the Federal Court of Canada, unlike some other foreign jurisdictions, a successful party is entitled to be reimbursed for their costs to pursue the litigation, but under the applicable tariff, only a portion of costs would actually be recoverable, typically between 25% and 35%.

Conversely, claims for misappropriation of trade secrets, breach of confidence, unlawful interference with contractual relations, and unjust enrichment are made in the provincial courts. In such an action, the plaintiff will have to prove that the technology was in fact a trade secret, and that the information had been treated as such by the plaintiff. The plaintiff will also have to prove that the defendant appropriated or made improper use of the information, as well as its quantum of damages directly related to the loss of the trade secret.[17] In terms of injunctions, plaintiffs may be more likely to be able to obtain an interlocutory injunction in a trade secret case than in a patent infringement action in the Federal Court. Litigation costs in provincial courts can sometimes be recovered to a greater degree than the Federal Court, if a plaintiff is ultimately successful.

16 *Patent Act*, s 56.
17 *Cadbury v. FBI Foods* at para 54, 94-99.

These differences in enforcement approaches, timelines, potential recovery, and complexity will often guide a company's preference between patent and trade secret protection.

20.4.5 Costs

There are typically out-of-pocket costs required to prepare a patent application, as well as government fees associated with filing the application, having an application issue to patent, and ongoing yearly patent maintenance fees to keep the patent in good standing. Conversely, to maintain something as a trade secret, there are no such direct costs. However, costs to maintain trade secrets could involve implementing appropriate organizational, administrative, technical, and physical measures to protect and maintain the information as a trade secret.

20.5 Protecting Trade Secrets

A business must establish and maintain appropriate measures to protect and ensure the continued secrecy of its trade secrets.

For instance, it is important to ensure that measures are in place to specifically limit who will obtain knowledge of, or access to, a company's trade secrets. Wide access to information will make it more difficult, both practically and legally, to maintain the information as a trade secret. Physical measures are advisable, such as the use of locked cabinets and limiting access by key-card or codes to specific rooms, buildings, or floors. Similarly, technical safeguards such as limiting access to network resources, databases, and other electronic records containing trade secrets can be accomplished by the use of passwords, electronic permissions, roles-based access controls (RBAC), and firewalls, and by limiting the ability to save or transfer electronic data to portable media or external cloud memory systems.

Administrative safeguards, such as policies on maintaining trade secrets, employee training, and contracts protecting trade secrets are also often necessary. The obligation for employees to protect a company's trade secrets can arise in a number of ways. The employment relationship can create an implied duty of good faith which exists during the term of employment. Key individuals in companies, such as directors and officers, and sometimes others who hold a particular position of power within a company, have additional fiduciary obligations that would include preventing the improper disclosure or misuse of the company's trade secrets. However, employers should also take additional measures to outline in detail an employee's obligations by drafting appropriate employment contracts.

Employment contracts should ensure that employees who have access to their employer's confidential information (for instance, its software, related manuals/documentation, information contained in electronic and paper records, data, and other business documents) acknowledge that this information is confidential and that it may constitute valuable know-how or trade secrets. Sometimes confidential information held by the employer is that of a client or other third party. Employment contracts should clearly set out how the employee is expected to treat all such confidential information and should require as a minimum the following provisions:

1. all confidential information must be held in confidence until it is no longer confidential;
2. all confidential information is only accessed and shared on a "need-to-know" basis;
3. employees only copy or reproduce confidential information only as needed to perform their work;
4. employees return all confidential information in their possession upon demand and upon termination; and
5. employees do not disclose or discuss confidential information, or make it available to any other party, without the prior written consent of the owner of the confidential information.

Courts have found that copying large amounts of data onto a memory device shortly before the end of employment is considered strong *prima facie* evidence of a breach of the employee's contractual duty of confidentiality, where the confidentiality clause in the employment agreement required that the employee only copy or reproduce confidential information as needed to perform their work.[18] Despite this, clear agreements setting out expectations on the handling of confidential information (including trade secrets) are strongly recommended.

Similarly, when entering into business relationships with other legal entities, consultants, or partners, contractual obligations related to the proper and careful treatment of trade secrets and confidential information are strongly recommended. This typically is addressed in a Non-Disclosure Agreement (NDA) or through specific confidentiality provisions, which stipulate what is considered confidential information and how this information is to be treated, both during the business relationship and after its termination.

18 *Questor Technology Inc. v. Stagg*, 2020 ABQB 3.

20.6 Licensing Trade Secrets

Despite not being registrable, trade secrets can be a valuable type of intellectual property. In some cases, trade secrets and associated technologies can be licensed to others in a similar way to other forms of intellectual property. However, licensing terms need to be very carefully considered because omitting key elements can ultimately result in the loss of the trade secret and its value as an asset.

A trade secret license should describe the trade secrets that are the subject of the license to some limited degree. But because of the nature of trade secrets, this needs to be done judiciously without disclosing the trade secret itself. In licensing trade secrets, the licensor is typically licensing the right of the licensee to receive the trade secret, rather than licensing the ongoing use of the trade secret, as is the case with a patent license.

Trade secret license terms can also be incorporated in a larger, hybrid licensing agreement. Often when licensing patent rights, that company's know-how and trade secrets are also required to form part of the technology license in order for the licensee to be able to effectively make use of the licensed patent rights.

Trade secret licenses have some other unique elements that should be carefully considered, as BLG has written about separately.[19]

19 Please see Borden Ladner Gervais LLP, "Unique Trade Secret License Agreement Features" (March 2017), online: https://www.blg.com/en/insights/2017/03/unique-trade-secret-license-agreement-features and "Some Key Elements of a Trade Secret License" (March 2017), online: https://www.blg.com/en/insights/2017/03/some-key-elements-of-a-trade-secret-license.

Chapter 21

Plant Breeders' Rights

21.1 Overview

Canada does not allow the patenting of higher life forms, such as plants.[1] However, new plant varieties, whether propagated by seed or vegetatively, can be protected under the *Plant Breeders' Rights Act (PBRA)*.[2] New genetically modified varieties produced through biotechnology can also be protected, though the system is primarily focused on morphological distinctness.

Plant Breeders' Rights (PBR) are granted by the Plant Breeders' Rights Office (PBRO), which is administered through the Canadian Food Inspection Agency (CFIA). The *PBRA* provides protection in Canada in a manner similar to the protection provided by the *Plant Patent Act* and the *Plant Variety Protection Act*[3] in the United States. The Canadian system provides protection for propagating material in Canada for a term of at least 20 years. All plant species, except algae, bacteria, and fungi, are eligible for protection.[4] A certificate of PBR is awarded to the Applicant for a new, distinct, uniform, and stable variety following examination of these criteria.

Canada is signatory to the International Union for the Protection of New Varieties of Plants (UPOV), meaning that an application for PBR in Canada may claim priority from an earlier application for right to the same variety in a UPOV country (and vice versa), provided that the Canadian application is filed within one year of the earlier filing.[5] Likewise, an application filed in Canada may serve as a basis for a priority claim in an application filed in another country that is signatory to the UPOV.

21.2 Rights Conferred to Holder of a Plant Breeders' Right

21.2.1 Exclusive Rights

The holder of a PBR has the exclusive right in Canada:

(a) to produce and reproduce propagating material of the variety;

(b) to condition propagating material of the variety for the purposes of propagating the variety;

(c) to sell propagating material of the variety;

(d) to export or import propagating material of the variety;

(e) to make repeated use of propagating material of the variety to produce commercially another plant variety if the repetition is necessary for that purpose;

1 See Chapter 12, Living Matter (Life Forms) for more on this topic.
2 *Plant Breeders' Rights Act*, SC 1990, c 20 [*PBRA*].
3 *Plant Variety Protection Act*, 7 USC 2321 and *Plant Patent Act*, 35 USC 15
4 *PBRA*, s 4(1). See also *Plant Breeders' Rights Regulations*, SOR/91-594, s 3, Sched 1 [*PBRR*].
5 *PBRA*, s 11(1).

(f) in the case of a variety to which ornamental plants belong, if those plants are normally marketed for purposes other than propagation, to use any such plants or parts of those plants as propagating material for the production of ornamental plants or cut flowers;

(g) to stock propagating material of the variety for the purpose of doing any of (a) to (f); and

(h) to authorize, conditionally or unconditionally, the doing of any of (a) to (g).[6]

21.2.2 Term and Maintenance of Rights

PBRs are granted for a term of 25 years for trees and vines, and for 20 years for any other plant variety.[7] The term begins on the date of issue of the certificate. An annual maintenance fee must be paid to maintain the rights.

21.2.3 Provisional Protection

The *PBRA* provides for provisional protection during the period between the filing date of an application and its date of grant. This interim protection allows a breeder to seek remuneration from any person who carries out acts that, if the PBR were granted, would require the PBR holder's authorization.[8]

21.2.4 Limitation of Rights

Rights extend only to propagating material of a given variety. This may include seeds, cuttings, bulbs, tubers, or any other plant part that can be used to propagate the variety vegetatively. The rights do not extend to non-propagating material. For example, once seed is sold to a commercial producer, the producer is free to grow the seed into a plant and sell the plant or plant parts in any non-propagating form (for example, for food or feed, but not for further propagation).

PBR rights also do not extend to acts carried out privately and for non-commercial purposes, for experimental purposes, or for the purpose of breeding other plant varieties.[9]

The *PBRA* also includes a "farmer's privilege" provision, indicating that rights do not prevent farmers from stocking harvested material grown on the farmer's holdings for the sole purpose of the propagation of the plant variety on those holdings.[10]

6 *PBRA*, s 5(1).
7 *PBRA*, s 6(1).
8 *PBRA*, s 19(1).
9 *PBRA*, s 5.3(1).
10 *PBRA*, s 5.3(2).

21.3 Eligibility Requirements

For a new variety to be granted a certificate, it must be new, distinct, uniform, and stable, collectively termed "DUS" by the PBRO.[11] Evaluation of these criteria falls to examiners employed by the PBRO. Examination is based on field trials arranged by the Applicant, and on a technical report and comparative photographs that must be submitted to the PBRO within six months of a site visit by an examiner.

21.3.1 Novelty

Unlike patents, "novelty" in the context of PBR is determined exclusivity by prior sale – more specifically, by the *lack* of sale prior to a designated grace period.

To qualify as novel, a candidate variety must not have been sold *in* Canada more than one year prior to the effective filing date of the application. In addition to this, the variety must not have been sold *outside* of Canada more than six years prior to the filing date if the variety is a tree or vine, or more than four years prior to the filing date for all other plants.[12]

The effective filing date for this assessment is the date an application was filed in Canada, or, if priority is claimed from an earlier application in a UPOV country, the date that the earlier application was filed in that country.[13]

21.3.2 Distinctness

To be considered distinct, a new variety must be clearly distinguishable, by one or more characteristics, from all varieties known to exist within common knowledge at the filing date of an application.[14] Varieties of common knowledge include those cultivated or exploited for commercial purposes and those disclosed in publications accessible to the public.[15]

A candidate variety must ultimately be compared, in field trials, to the most similar reference variety or varieties currently grown in Canada. A new variety will be accepted as distinct if the differences with the reference variety are shown in at least one testing place in Canada and if the differences are clear and consistent.[16] The minimum testing required is two years for seed-propagated varieties and one year for vegetatively-propagated varieties.[17] Specific parameters

11 *PBRA*, s 4(2).
12 *PBRA*, s 4(3).
13 *PBRA*, ss 10(1), 11(1).
14 *PBRA*, s 4(2)(b).
15 *PBRR*, ss 5(a)-(b).
16 *PBRA*, ss 4(2)(a)-(b).
17 Canadian Food Inspection Agency, "Guidelines for Conducting Plant Breeders' Rights Comparative Tests and Trials" (22 April 2020), [*Conducting Plant Breeders' Rights Comparative Test and Trials*].

to be measured for a candidate variety in field trials are detailed in a document termed a Test Guideline (TG). The PBRO has established TGs for different categories of plants and will provide them to applicants upon request. A completed TG is *not* required for filing a PBR application, but one must be completed and submitted to conclude examination following field trials.

21.3.3 Uniformity

A candidate variety must be sufficiently homogeneous.[18] Any variation upon reproduction or propagation must be predictable, describable, and commercially acceptable.[19]

21.3.4 Stability

A candidate variety must be adequately stable in the essential characteristic(s) used to describe the variety. A new variety is considered stable when it remains true to this description after repeated reproduction or propagation.[20] The stability of a variety may be tested by growing a further generation of new seed stock or by successive rounds of vegetative propagation.

21.4 Who May Apply

The Applicant may be the breeder or a legal representative of the breeder. The Applicant must also be a citizen of, a resident of, or have a registered office in Canada or in a UPOV member country.[21] All applications require a Canadian address to which correspondence from the PBRO may be sent. Applicants resident outside Canada are required to appoint an agent who is resident in Canada to submit an application on their behalf.[22]

21.5 Filing Requirements

The PBRO describes the application for a PBR as a three-part process: filing of the application, examination of the application, and grant of rights.[23] To obtain a plant breeder's rights certificate for a new variety, a complete PBR application form must be filed, along with the required supporting documents, and the official fee. Filing requirement are described in detail on the PBRO web site.[24]

18 *PBRA*, s 4(2)(d).
19 *PBRA*, s 4(4).
20 *PBRA*, s 4(2)(c).
21 *PBRA*, s 7(1).
22 *PBRA*, s 9(2).
23 Canadian Food Inspection Agency, "Applying for Plant Breeders' Rights: 3 Part Process" (26 February 2021).
24 Canadian Food Inspection Agency, "Instructions for Filing a Plant Breeders' Rights Application" (22 April 2020), [*Instructions for Filing a Plant Breeders' Application*].

21.5.1 Application Form and Content

The application form is available on the PBRO web site.[25] The form requires information concerning the name and address of the breeder and the Applicant. It requires the Applicant to indicate if the candidate variety has been sold in Canada or elsewhere. The application must also indicate whether or not priority is being claimed to an earlier application filed in a UPOV member country. If a priority claim is being made, the country, filing date, and application number for the earlier filing must be provided. An additional fee is required.

Completed application packages may be mailed, faxed, or emailed to the PBRO.

21.5.2 Proposed Denomination

The completed application form must also include a proposed name ("denomination") for the candidate variety, which must comply with several criteria: For example, the denomination:

- must be a minimum of two characters,
- should be unique,
- must not include punctuation marks or typographical symbols,
- should not include spaces or mixes of uppercase and lowercase letters,
- must not be a trademark,
- must not include a botanical name,
- should avoid superlatives and comparatives, such as "better", "best", "superior", "sweeter", etc.,
- must not be confusing, *e.g.*, a single letter difference as compared to another registered denomination is not permitted,
- must not be misleading, *e.g.*, as to a particular characteristic, derivation, or origin that the variety does not possess, and
- must not be offensive.

The PBRO has published detailed guidelines for naming new varieties.[26]

21.5.3 Description of Origin and Breeding History

The application package must include a written description of the origin and breeding history of a candidate variety, including information regarding:

- parental varieties or lines used for breeding,
- breeding techniques,

25 Canadian Food Inspection Agency, "Privacy Notice Statement applicable to form CFIA/ACIA 5087 – Plant Breeders' Rights – Application for filing Purposes" (1 September 2020).
26 Canadian Food Inspection Agency, "Variety Naming Guidelines" (12 February 2020).

- selection methods and criteria,
- propagation methods employed during breeding, and
- an indication of when and where initial and final crosses and selections were conducted.[27]

21.5.4 Statement of Uniformity and Stability

The application package must include a statement indicating that the candidate variety has been observed to be stable and uniform over successive rounds of propagation.[28] This statement must indicate the period of time and number of rounds of propagation over which stability and uniformity have been observed to date. There are no minimum requirements specified by the PBRO.

A candidate variety is permitted to be variable and to produce what are termed "off-types, variants, and mutations" provided that such variation is predictable, describable, and commercially acceptable. The Statement of Uniformity and Stability should describe any such observed variation, and the frequency and/or conditions under which it occurs.

21.5.5 Distinctness Statement

The application package must include a Distinctness Statement providing a summary of the major distinguishing characteristics that distinguish the candidate variety from the closest variety or varieties of common knowledge.[29] A new variety should be described by as many characteristics as possible to ensure its proper identification during examination and in later infringement proceedings.

The Distinctness Statement will set the stage for later field trials and site examination, and should therefore be written bearing in mind that an Applicant will be required to grow the candidate and reference varieties together in controlled conditions and demonstrate distinctness to an examiner during a site visit and in a subsequent report. Applicants may therefore wish to consider the TG document for the relevant category of plant – specifically the mandatory measurements and observations required by the TG – prior to drafting the Distinctness Statement.

The Statement of Distinctness should identify at least one reference variety for comparison. The reference variety should be selected from varieties of common knowledge and should be of the same species as the candidate variety. It should be the most similar, morphologically, to the candidate variety in most, if not all,

27 *Instructions for Filing a Plant Breeders' Application.*
28 *Instructions for Filing a Plant Breeders' Application.*
29 *Instructions for Filing a Plant Breeders' Application.*

of the characteristics for which the latter has been selected by the breeder. The reference variety should be cultivated in Canada, though foreign varieties may be used for comparison. Importantly, an Applicant will need to have access to the reference variety for field trials. The PBRO has published detailed guidelines for the selection of reference varieties, which are accessible on its web site.[30]

21.5.6 Description of How and Where the Variety will be Maintained

The application package must include a description of how the variety will be maintained and the address at which it will be maintained. The former should describe basic cultivation and propagation conditions.[31]

21.5.7 Sample of Propagating Material (if required)

For candidate varieties that are seed-propagated, a sample of seeds must be submitted at filing. The weight requirements for seed samples vary between plant categories.[32] Vegetatively-propagated crops are exempt from the seed sample filing requirement.

21.5.8 Evidence Establishing the Applicant to be a Legal Representative (if required)

If the Applicant is not the breeder, the application must include a "Legal Representative Statement". This establishes the Applicant as the legal representative for the PBR application. Contact information is required about the assignor, assignee, and information about the variety. The form must be witnessed. The PBRO has published a sample form on its web site.[33]

21.5.9 Authorization of Agent (if required)

When an Applicant authorizes an agent to represent them before the PBRO, the application must include an "Authorization of Agent". The PBRO has published a sample form on its web site.[34]

30 *Guidelines for Conducting Plant Breeders' Rights Comparative Tests and Trials.*
31 *Instructions for Filing a Plant Breeders' Application*.
32 Canadian Food Inspection Agency, "Seed sample requirements for Plant Breeders' Rights application" (5 May 2021).
33 Canadian Food Inspection Agency, "Legal Representative Statement – Assignment before the issue of Plant Breeders' Rights" (7 November 2014).
34 Canadian Food Inspection Agency, "Plant Breeders' Rights authorization of agent" (7 November 2014).

21.6 Publication

The PBRO publishes the *Plant Varieties Journal*, which includes details of new applications, applications under examination, and new grants of PBR. The Journal is published online quarterly and provides an opportunity for interested parties to review the particulars of the published applications.[35]

21.7 Examination

21.7.1 Field Trials

Field examination in Canada is different from that of many other countries in which the responsible government authority grows and tests the submitted propagating material. In Canada, it is the Applicant who must grow (or arrange for a third party to grow) the candidate variety. A site visit by an examiner must also be arranged prior to the relevant growing season. A written report must be submitted to the PBRO, with comparative photographs, within six months of the site visit. This requires a degree of planning and coordination.

The TG established by the PBRO for the relevant plant category will set out the requirements for field trials, including the minimum number of plants and the parameters to be assessed or measured. Statistical data may be required. Distinctiveness is determined primarily based on morphological features, though molecular data may be submitted as supplementary data. Molecular data is a requirement for some varieties. For example, THC content of flowers must be reported routinely according to the current TG for *Cannabis sativa*.

Some Applicants engage third-party service providers to conduct field trials. The PBRO can often assist Applicants in identifying qualified third-party growers.

21.7.2 Purchasing Foreign Test Results in Lieu of Tests and Trials in Canada

Under certain circumstances, the PBRO allows the purchase of foreign test results from a UPOV member country to demonstrate that a new variety is distinct, uniform, and stable. For vegetatively-propagated varieties, these can be submitted in lieu of field testing in Canada. For seed-propagated varieties requiring two growing cycles of trials, the purchased test results may replace observations for one of the two growing cycles.

35 Canadian Food Inspection Agency, "Plant varieties journal" (30 April 2021).

In brief, the following criteria must be met for foreign test results to be submitted:

1. The candidate variety must be a variety that is considered to be ornamental or horticultural, with the exception it must not be a potato of species *Solanum tuberosum*.
2. The candidate variety must have been applied for and have been tested (or is being tested) in a UPOV country, and must have been grown and examined following official test guidelines and testing procedures.
3. Canadian varieties of common knowledge should have been considered as reference varieties in the trial.
4. There must be sufficient data and descriptive information available from the foreign DUS test results to publish the variety description in an acceptable format in the PBRO's *Plant Varieties Journal*.
5. A photograph demonstrating the distinguishing characteristic(s) of the variety must be submitted in an acceptable format for publication in the *Plant Varieties Journal*.
6. Only official test results obtained from the national PBR authority in a UPOV country will be considered for purchase.

In cases where the testing of a variety has not yet been completed in the UPOV country at the time a request to purchase the test results is made, the PBRO cautions that unfavourable foreign test results, leading to refusal, will result in the same refusal in Canada. It will not be possible to circumvent this refusal with further trials.[36]

21.7.3 Site Examination and Timeline

Examination of the application commences after a Request for Site Examination form is completed and submitted with the examination fee.[37] The examination must generally be completed within four years of the filing date of an application in order to avoid abandonment. However, the PBRO will inform the Applicant of the deadline when receipt of a new application is formally acknowledged. Discretional extensions may be granted.

36 Canadian Food Inspection Agency, "Purchasing foreign distinctness, uniformity and stability (DUS) test results in lieu of conducting comparative tests and trials in Canada" (30 November 2020).
37 *Instructions for Filing a Plant Breeders' Application.*

The completed Request for Site Examination form is available online and includes details of the proposed site and approximate date for site examination, and also identifies reference varieties or varieties with justification for the selection(s).[38]

The PBRO conducts independent site examinations during the growing season between June 1st and September 30th of each year to verify results of field trials. A Request for Site Examination must be submitted by May 1st prior to the relevant growing cycle during which a site examination is desired. For varieties requiring trials spanning two growing cycles, the request must be made prior to the second growing cycle.

The PRBO currently sends reminder notices of the annual May 1st cut-off date for requesting examination in the ensuing growing season. However, the effective "final deadline" for submitting a Request for Site Examination for an application will be the May 1st preceding the growing season preceding the deadline for completion of examination.

21.7.4 Completing Examination

Within six months of the site examination conducted by the PBR examiner, the Applicant must submit the following:

- A completed TG document. This provides a thorough description and measurements of the candidate variety and reference variety, which may also be used in the event that the PBR is challenged.
- A description of the trials. This is important so that the trial can be duplicated, if required.
- Comparative photographs with the reference variety or varieties.[39]

A third-party grower, if experienced, can be of great help in preparing these materials.

21.7.5 Objections to a Plant Breeders' Rights Application

Any person who considers that an application under examination should be refused a grant of rights may file an objection.[40] The objection may be made for any incompatibility with the *PBRA* or Regulations. For example, someone who feels that the new proposed variety is not distinct from a known variety may file an objection. Such objections must be filed with the PBRO within six months of publication of the application in the *Plant Varieties Journal*.[41]

38 Canadian Food Inspection Agency, "Privacy Notice Statement applicable to form CFIA/ACIA 5618 – Plant Breeders' Rights – Request for Site Examination" (1 September 2020).
39 *Instructions for Filing a Plant Breeders' Application.*
40 *PBRA*, s 22(1).
41 *PBRR*, s 8.

21.8 Grant of Rights

If, after the examination, the Commissioner of PBR finds that the variety described in the application is new, distinctive, uniform, and stable, a PBR certificate will be issued to the Applicant upon payment of an issue fee.[42] The PBR holder is required to maintain the propagating material of the variety, and is required to furnish the Commissioner of PBR with the propagating material upon request.[43] An annual fee must also be paid to keep the PBR certificate in force.[44]

21.9 Licensing

To exercise any rights granted under a PBR, a person who is not the PBR holder must first obtain permission from the PBR holder. Such permission is usually in the form of a licence. For example, a grower who wishes to propagate a protected variety for the purpose of selling it must obtain a licence from the holder of the PBR. The grower could be held liable if they propagate and sell a protected variety without prior permission. A grower should not assume that they will be protected from a charge of infringement simply because they propose to pay a royalty to the rights holder afterward, because the rights holder is under no obligation to grant a licence, other than when a compulsory licence is granted (see below).

Licensing (except for compulsory licensing) does not fall under the PBR legislation. A licence is an implied or written agreement between two or more parties granting rights. In licences relating to PBRs, the terms most frequently included are (1) payment terms (for example, royalties or lump-sum payments); (2) length of term (for example, for all or part of the term of the certificate); and (3) geographical restrictions (for example, worldwide or only in Canada).

A compulsory licence may be granted to anyone who can demonstrate that the holder of the right has unreasonably refused to license it.[45] However, the PBRO will not grant a compulsory licence until any party that would be adversely affected by the granting of the compulsory licence (that is, the rights holder and any other licensees) is permitted the opportunity to present their case. A request for exemption from compulsory licensing can be made at the time of application for PBR; however, such a request is granted only if the Applicant requires time to multiply and distribute the propagating material.

42 *PBRA*, s 27(1).
43 *PBRA*, s 30(1)(a).
44 *PBRA*, s 6(2).
45 *PBRA*, ss 32-33.

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