The notion of utility as a criterion for patentability

Sara Allameh,

Faculty of Law, McGill University, Montreal

November 2017

A thesis submitted to McGill University in partial fulfilment of the requirements for the degree of Master of Laws

Table of Contents

Abstract

This thesis analyzes why the patent utility requirement has recently become a challenging issue in Canadian law and suggests two solutions to overcome challenges created by recent case law developments. First, this thesis provides a targeted history of the utility requirement as a patentability criterion, noting that it ensures that patents are granted to useful inventions. However, over the past decade, the utility requirement –as applied by Canadian courts– has been criticized by scholars and challenged in practice. This thesis explains that the approaches of Canadian patent jurisprudence to the notion of utility are based on patentee's statements made in the patent specification. If there is a promise made in the specification, based on the promissory approach, the patentee must prove that the patent fulfills that promise, otherwise, the patent is void. This thesis analyzes expert criticisms that have been made of this understanding of the utility requirement. First, the concept of usefulness does not have a statutory definition, which results in vagueness in terms of distinguishing inutility in certain cases. Second, there are ambiguities implicit in the promissory approach that have created challenges to the notion of utility. The Supreme Court eliminated the promissory approach to the utility requirement in its 2017 ruling and held that it is sufficient that a patent has a minimal level of usefulness. This thesis concludes that the Supreme Court's new approach to utility is likely to create more challenges in terms of construing the utility requirement, because patentees are no longer required to fulfill their statements at the filing date. Lastly, this thesis proposes two solutions to overcome these challenges, namely: to adopt a rigorous approach to the patent utility, and suggests a return to the promissory approach, after first solving its obstacles of uncertainty.

Resume

Cette thèse analyse les raisons pour lesquelles l'exigence d'utilité en matière de droit des brevets est récemment devenue une question difficile en droit canadien et suggère deux solutions pour surmonter les défis créés par les récents développements dans la jurisprudence.

Premièrement, cette thèse entreprend un historique ciblé de l'exigence d'utilité en tant que critère de brevetabilité ; notant qu'elle garantit que les brevets sont accordés à des inventions utiles. Toutefois, dans le courant de la dernière décennie, l'exigence d'utilité – telle qu'appliquée par les cours et tribunaux canadiens - a été critiquée dans le milieu académique et contestée dans la pratique. Cette thèse explique que les approches de la jurisprudence canadienne en matière de brevets à l'égard de la notion d'utilité sont fondées sur les déclarations du breveté faites dans le document descriptif du brevet. Si une promesse est faite dans la description, basée sur l'approche de la promesse, le breveté doit prouver que le brevet remplit cette promesse, sous peine de nullité du brevet. Cette thèse analyse les critiques d'experts faites à l'égard de cette compréhension de l'exigence d'utilité. Premièrement, le concept d'utilité n'a pas de définition légale, ce qui entraîne une imprécision en termes de distinction entre brevet utile et inutile dans certains cas. Deuxièmement, il y existe des ambiguïtés implicites dans l'approche de la promesse qui ont soulevé des questions quant à la notion d'utilité. Dans sa décision de 2017, la Cour Suprême du Canada a supprimé la notion de promesse d'utilité et a conclu qu'il suffisait qu'un brevet ait un niveau d'utilité minimal. Cette thèse conclut que la nouvelle approche de la Cour Suprême en matière d'utilité est susceptible de créer davantage de défis en termes d'interprétation de l'exigence d'utilité, parce que les brevetés ne sont plus tenus de remplir leurs déclarations à la date de dépôt du brevet. Finalement, cette thèse propose deux solutions pour surmonter ces défis, à savoir: adopter une approche rigoureuse vis-à-vis de l'utilité du brevet, et proposer un retour à l'approche de la promesse, après avoir solutionné ses problèmes et répondu à son incertitude.

Acknowledgments

I would like to express my thanks to my thesis supervisor, Professor Pierre-Emmanuel Moyse, for his guidance and feedbacks through this research project.

I would also like to thank Prof. Richard Gold, Associate Dean of the Graduate Studies in Law. During this research project, I have been inspired by his articles, interviews, and tweets related to the topic of this research.

Finally, I am thankful to my parents who have genuinely supported me throughout my life and my studies.

Introduction

Over the last decade, the patent utility requirement has become one of the most challenging issues in Canadian patent law. The number of Canadian cases addressing the issue of patent utility has steadily increased since 2005.[1] Further, the Canadian approach to determining patent utility has been criticized as a barrier to innovation. Certain commentators consider that the Canadian approach has also become an issue for foreign investments, especially in the pharmaceutical sector.[2] In 2017, there were two important decisions dealing with the matter of patent utility.[3] In *Eli Lilly v Canada*, the claimant asserted that the invalidation of its patents by Canadian courts, namely Strattera and Zyprexa, was inconsistent with NAFTA. These pharmaceutical patents promised long-term treatment and better clinical treatment for related disorders. The trial and Federal Court of Appeal invalidated the patents on the basis that they failed to prove their promises at the filing date. The tribunal affirmed these decisions on the issue

---

[1] In *Eli Lilly and Company v The Government of Canada*, the claimant provided statistical evidence asserting that since 2005 Canadian courts have undergone a dramatic change in the patent law regarding the rules of utility which led to the invalidation of increased numbers of patents because of lack of utility. See *Eli Lilly and Company v The Government of Canada* (17 March 2017), UNCT/14/2 (International Centre for the Settlement of Investment Disputes), online: <https://www.italaw.com>; Stephen J Perry, T Andrew Currier & Roger T Hughes, *Canadian patent law* (Ontario: LexisNexis Canada, 2014) at 141―42. But according to the empirical evidence provided by Centre for Intellectual Property Policy: "although courts engaged in a utility analysis more frequently after 2005, there is no reason to believe that these affected rates of invalidity" and " the perception that led to Eli Lilly's assertions is due to an increase in the absolute number of patent cases being litigated and the number of cases addressing utility than to any underlying change in patent law." See "Patent Litigation: Putting Assumptions to the Empirical Test", (28 July 2016), online: *Centre for Intellectual Property Policy* <http://www.cippmcgill.ca/news/2016/07/28/patent-litigation-putting-assumptions-to-the-empirical-test/>.

[2] Office of the US Trade Representative, "2017 Special 301 Report", online: *USTR* <https://www.ustr.gov/> at 62.

[3] *Ibid; AstraZeneca Canada Inc. v Apotex Inc.*, 2017 SCC 36.

of utility and accepted the Canadian courts' application of the promissory doctrine. The case of *AstraZeneca Canada v. Apotex* concerned with the pharmaceutical patent esomeprazole (NEXIUM) that promised better treatment of gastrointestinal disorders than other known compounds. In this case, the Supreme Court of Canada overturned the decision of the Federal Court, which had applied the promissory doctrine, and found this patent to be valid. The disparity in rationale between these decisions has created an increasingly complex regulatory environment in which to construe and apply the utility requirement in Canadian patent law.

For patentees, owning a patent means having a term-limited monopoly and exclusivity over use, manufacture, and sale of patented inventions. Traditionally, monopolies are granted where there is adequate disclosure of a novel, non-obvious and useful invention. Since the introduction of the earliest patent statutes, these three requirements have operated as the essential mechanisms for striking a balance between inventors' rights and ensuring public interests in granting a patent.[4] According to Michael Risch, the importance of the usefulness of inventions, often referred to as the "utility" requirement, has been of less academic and judicial interest than the two other criteria noted above: novelty and non-obviousness.[5] In addition, relevant international laws have failed to provide harmonized regulations on patent utility. Because of limited understanding of the notion of patent utility, as well as a lack of unified regulations, the responsibility for interpreting and developing the utility criterion has fallen to domestic courts.

As this thesis will show, the current approaches taken by Canadian courts to determining the utility requirement have most often been developed in cases where the matter at issue was the

[4] *Pfizer Canada Inc v Novopharm Ltd*, 2012 SCC 60, 2012 CarswellNat 4250 at para 32; *Eli Lilly and Company v. The Government of Canada*, *supra* note 3 at para 423.
[5] Michael Risch, "Reinventing Usefulness" (2010) 2010:4 Brigh Young Univ Law Rev 1195 at 1197; Michael Risch, "A Surprisingly Useful Requirement" (2011) 19:1 Geo Mason L Rev 57 at 58.

usefulness of an invention. Further, the notion of patent utility has also been developed in the jurisprudence of other legal systems such as the United States and countries in the European Union. However, to date, the patent utility requirement has mostly been challenged in cases before Canadian courts. This explains the Canadian focus of this research project. In addition, as this research project will indicate, the patent utility requirement is not a new issue in patent law. Rather, it has an extended historical background in Canadian law. However, as indicated above, serious issues of consistency in relation to how courts determine the utility requirement have only arisen in the last decade. This research project will therefore comprehensively analyze the patent utility requirement in Canadian patent law, to determine why the concept of utility has recently become a challenging issue in Canada, and will suggest some potential solutions for addressing these challenges.

It is important to have a thorough understanding of the notion of utility before analyzing how the utility requirement should be interpreted in cases dealing with new technologies. This understanding should then help courts to strike an appropriate balance between supporting new innovations and ensuring that there are public benefits connected to granting a patent. This research project will show that recent controversies surrounding courts' interpretation of patent utility have been raised in cases that concern pharmaceutical and biotechnological patents. Therefore, the important question to address is whether an approach to the issue of patent utility must be contingent on the context of inventions. The development of new technologies has also enabled new patents to be granted, especially in the pharmaceutical and biotechnological industries. Some examples of these new patents include new uses for an already patented compound, and selection patents of a larger class of compounds. Challenges of a lack of utility

have most often been brought against this new generations of patents.[6] Thus, the development of new technologies (and patents of those technologies) contributes to the need for a comprehensive understanding of the utility requirement in patent law, as well as an analysis of proper approaches to determining utility of these patents. Therefore, this research will situate its analysis of approaches to determining patent utility in Canadian law in the context of patents for new technologies in the pharmaceutical sector.

This thesis is divided into three chapters. Chapter I will analyze the notion of utility as a statutory requirement for patentability in national and international patent law. This chapter will first study the historical origins of the notion of utility, and explore how this notion has been applied in patent legal systems over time. Then, it will analyze the two main views of the notion of utility: utility as usefulness and utility as industrial applicability, and will elaborate on the differences and overlaps between these two views. We will see that, although industrial applicability and utility as usefulness are distinct concepts, they both attempt to achieve the same goals in patent law. Chapter I will also address the international approach to patent utility by analyzing relevant international instruments. This chapter will conclude that international law has failed to provide harmonized regulations on patent utility requirement.

Chapter II will analyze relevant Canadian jurisprudence to determine how patent utility has been approached by Canadian legislators and courts over time. This chapter starts from the general position that, in Canadian patent law, there is no necessity for the patentee to disclose the patent utility at the filing date.[7] Accordingly, chapter II analyzes the notion of utility in Canadian jurisprudence under two situations. The first is when the patentee establishes patent utility at the

[6] Jeremy de Beer, "Professors de Beer and Gold represent CIPP at the Supreme Court", (3 February 2017), online: *YouTube* <https://www.youtube.com/>.
[7] *Consolboard Inc v MacMillan Bloedel (Sask) Ltd,* [1981] 1 SCR 504, 1981 CanLII 15 at 526 [*Consolboard*].

filing date. This position is identified as 'demonstrated utility' by applying two main doctrines: patent promise and the mere scintilla of utility.[8] The second situation is that of the 'soundly predicted utility' and the 'sound prediction doctrine'.[9] In this second situation, utility is soundly predicted when the patentee does not establish the utility at the filing date, but the examiner can soundly predict the utility of a patent based on disclosed facts and reasoning. This chapter will then set out the essential role played by the notion of utility in Canadian patent law, and will identify the four main roles of the patent utility in patent system being; ensuring public benefit, preventing double patenting, controlling overreaching claims and ensuring the development of new technologies.

Drawing on the analysis set out in chapter II, the third chapter of this thesis will analyze why and how determining the patent utility requirement under Canadian patent law has recently become more challenging, given significant case law developments. It will then suggest solutions that could address these challenges. This chapter will focus first on issues that arise when Canadian courts interpret usefulness as the main concept of utility. Secondly, the chapter will discuss how issues with interpreting usefulness subsequently affect courts' approaches to determining the utility requirement. Thirdly, this chapter will analyze certain problems that have arisen in terms of how courts approach the utility requirement and will address whether these problems are dependent on the specific field in which they arise: i.e. relevant to the emerging fields of technology and biotechnology. The chapter will then analyze the new approach to the patent utility that was adopted by the Supreme court of Canada in the case of *AstraZeneca*

[8] *Ibid; New Process Screw Corp v PL Robertson Manufacturing Co*, [1961] 39 CPR 31, 1961CarswellNat 40 ; E Richard Gold & Michael Shortt, "The Promise of the Patent in Canada and Around the World" (2014) 30:1 Can Intellect Prop Rev 35; *Aventis Pharma Inc v Apotex Inc*, 2005 FC 1283; Harold G Fox, *The Canadian law and practice relating to letters patent for inventions,* (Toronto: Carswell, 1969) at 152.
[9] *Apotex Inc v Wellcome Foundation Ltd, 2002 SCC 77, [2002] 4 SCR 153*; *Bell Helicopter Textron Canada Limitée v Eurocopter, 2013 FCA 219* [Bell Helicopter].

Canada Inc. v. Apotex Inc on June 30, 2017.[10] In that case, the Supreme Court held that the correct approach to the utility analysis is not the promissory approach, but rather held that a single use related to the nature of the subject-matter of the invention having a scintilla of utility is sufficient to show utility.[11] This ruling can be read as eliminating the requirement for patentees to fulfill the statements and promises they made regarding utility at the filing date. Chapter III will then answer the question of how this new approach to the patent utility requirement is likely to affect the patent protection system in Canada.

This thesis aims to contribute to the current academic literature by providing a clear and comprehensive analysis of utility as a patentability requirement. A deeper, contextualized understanding of the notion of utility is a crucial first step to take before determining any potential solutions for the challenges of patent utility, and before considering any legislative or judicial approaches that support innovation. There are already scholarly commentaries that analyze patent utility. However, few of these analyses provide sufficiently thorough analyses of the notion of utility, its interpretation, the significant role it plays in patent law, and the challenges and solutions facing regulators. Furthermore, the two important patent utility rulings that will be analyzed and interpreted in this thesis were only decided in 2017. Thus, this project will be one of the first to analyze these rulings and predict their impact on Canadian patent law.

[10] *AstraZeneca Canada Inc. v. Apotex Inc.*, *supra* note 3.
[11] *Ibid* at para 55.

Chapter I: The notion of utility as a criterion for patentability

The notion of utility is a foundational requirement for determining the usefulness of patentable inventions. Judicial decisions at the national and international level have interpreted this requirement over time. However, before analyzing the notion of utility as it has been interpreted in case law, we will first look at how this notion is dealt with in legislation. Different legal systems understand the notion of utility differently. The first section of this chapter reviews the historical origins of the notion of utility, analyzing how it has developed over time, with a focus on the historical contexts of Canada, USA, and Europe. The second section of this chapter elaborates on two main conceptions of the notion of utility, namely: utility as usefulness and utility as industrial applicability, and then considers their differences and similarities. This section will also discuss the notion of utility as 'usefulness' as this is understood in the USA and Canada and will also discuss the notion of utility through industrial applicability as this concept has developed in Europe. Finally, the third section of this chapter considers patent utility as this is provided for in international law and presents reasons for the lack of harmonized rules at the international level to determine patent utility.

1. Historical background of the notion of utility

The notion of utility is one of the three main criteria of modern patent law, alongside novelty and non-obviousness. The notion of utility has an extensive historical background going back to the earliest patent statutes: the Venetian Statute (1474) and the English Statute of Monopolies (1623).[12] The 1474 Venetian Statute,[13] often referred to as the first modern written

[12] *Venetian Statute on Industrial Brevets, 1474* (Venice), in Primary Sources on Copyright (1450-1900), eds L. Bently, M. Kretschmer, online: <http://www.copyrighthistory.org/cam/tools/request/showRepresentation>; *Statute of Monopolies, 1623* (UK), 21 Jac.1, c 3, s 6, online: <http://www.legislation.gov.uk> ; Christopher Wadlow, "Utility and

patent law, provides that inventors are "men who have the most clever minds, [who are] capable of inventing all kinds of ingenious contrivances."[14] The Venetian Statute emphasizes that "… the works and contrivances invented by them could not be copied and made by others so that they are deprived of their honour, men of such kind would exert their minds, invent and make things that would be of no small utility and benefit to our State."[15] In addition, the Venetian Statute refers to an inventor of "any new and ingenious device, not previously made within our jurisdiction".[16] The Venetian Statute provides that a patent could be granted to inventions that have the three criteria of novelty, utility or usefulness, and non-obviousness.

The English Statute of Monopolies was passed by Parliament to curtail the granting monopolies granted because of the King's abuses of royal prerogative.[17] However, section IV of this statute included the important exception that allowed for limited monopolies, which formed the basis of modern patent law.[18] Section VI of the Statute of Monopolies provided that patents for new manufacturers would be unobjectionable only if "they be not contrary to the law, nor mischievous to the state, by raising prices of commodities at home, or hurt of trade or generally inconvenient."[19] Christopher Wadlow concluded that the proviso in section VI of the Statute of Monopolies led in due course to the emergence of the doctrine of utility in British and American law.[20] In fact, the Statute did not use the specific term 'utility', and nor did it refer to the

---

Industrial applicability" in Toshiko Takenaka, ed, *Patent law and theory: a handbook of contemporary research* (Cheltenham, UK: Edward Elgar, 2008) at 359—60.

[13] *Ibid* .

[14] *Ibid*.

[15] *Ibid*.

[16] Wadlow, *supra* note 12 at 359.

[17] *Statute of Monopolies*, *supra* note 12, s 6

[18] Perry, Currier & Hughes, *supra* note 1 at 19—22.

[19] Statute of monopolies, *supra* note 12.

[20] Wadlow, *supra* note 12 at 360—61.

necessity of utility for granting patents. However, it referred to one historical and essential element of patentable inventions – as applied in *Darcy v. Allin*[21] –as being the patentable invention "should tend to the furtherance of trade and be for the good of the realm."[22] Harold Fox notes in his 1948 book that the main arguments in *Darcy v. Allin* were based on the view that a valid monopoly is one that contributes to the benefit of the realm.[23] According to Fox, in regards to the sixth section of the Statute of Monopolies, "the grant of a patent of monopoly with respect to a useless manufacture would be not only contrary to the law, but hurtful to trade and certainly generally inconvenient."[24]

According to Donald MacOdrum, the history of patent statutes in Great Britain, the United States, and Canada demonstrates there is a clear and inflexible adherence to the concept of utility.[25] Bound by the Statute of Monopolies, future English patent statutes[26] continued to use the criterion of usefulness as an indispensable element of patentable inventions until 1977.[27] Since *the Patent Act 1977* (Patent Act),[28] the UK has used the concept of 'industrial application'

[21] Darcy v. Allin (1602), Moore K.B. 671, 11 Co. Rep. 84b, cited in Harold Fisher, Russel Sutherland Smart & W J Lynch, *Canadian patent law and practice* (Toronto; Philadelphia: Canada Law Book; Cromarty Law Book, 1914) at 50.
[22] *Ibid*.
[23] Harold G Fox, *The Canadian law and practice relating to letters patent for inventions* (Toronto: Carswell, 1948) at 295—96.
[24] *Ibid* at 296.
[25] Donald H MacOdrum & Harold G Fox, *Fox on the Canadian law of patents* (Toronto: Carswell, 2013) at 6-3.
[26] According to the Patent Act 1949 (UK), 12, 13, & 14 Geo VI, c 87, s 102(1), a patent may, on the petition of any person interested, be revoked by the court if the invention, so far as claimed in any claim of the complete specification, is not useful.
[27] Gold & Shortt, *supra* note 8 at 48 ; Norman Siebrasse, "The False Doctrine of False Promise" (2013) 29:1 Can Intellect Prop Rev 3 1 at 15, 55.
[28] *Patents Act 1977* (UK), c 37, s 1.

because of its obligation to implement European Union laws.[29] According to the *Patent Act,* a patent may be granted only for an invention which is capable of industrial application.[30] In addition, it defines being capable of industrial application as "if it can be made or used in any kind of industry, including agriculture."[31]

The history of patent acts in the United States also shows the important and inflexible status of utility in American patent law. The United States Constitution gives Congress the power "to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."[32] The first US Patent Acts passed into law in 1790 and 1793 repeated the necessity of the usefulness requirement for granting patents. The *Patent Act 1790* provided that a patent may be granted to new and useful inventions, and designated cabinet members must consider the invention sufficiently useful and important.[33] The *Patent Act 1793*[34] reaffirmed the requirement of usefulness of invention but eliminated the "sufficiently useful and important" requirement because its examination and implementation proved difficult.[35] The notion of utility has remained an essential requirement for patentability, as section 101 of the current US Patent Act demonstrates:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent

---

[29] *Convention on the Grant of European Patents*, (5 October 1973), online: *European Patent Office* <https://www.epo.org>. [EPC]
[30] *Patents Act 1977*, *supra* note 28, c 37, s 1(1).
[31] *Ibid*, c 37, s 1(4).
[32] US Const art I, § 8.
[33] *An Act to promote the progress of useful arts*, c 7, §1, 1 Stat 109 (1790).
[34] *Patent Act of 1793*, c 11, § 1, 1 Stat 318 (1793).
[35] Risch, *supra* note 5 at 1235—36.

therefor, subject to the conditions and requirements of this Title.[36]

In Canada, since the first Patent Act of 1823, the utility or usefulness of inventions has been an inflexible requirement for granting patents. The first patent statute of Canada, the *Lower Canada Patent Act 1823,* had the same title as section 8, article 1 of the United States Constitution: *"*an act to promote the progress of useful arts in this province*"* and provided that: "it is expedient for the encouragement of Genius and of Arts in this Province, to secure an exclusive right to the Inventor of any new and useful Art, Machine, Manufacture or Composition of Matter".[37] Likewise, the *Patent Act of Upper Canada* with the long title "An Act to Encourage the Progress of Useful Arts within this Province*"*[38] was passed in 1826 and provided that a patent would be granted for the protection of any new and useful subject matter and any improvement thereof. Furthermore, the Patent Consolidation Act of 1849,[39] which harmonized the patent laws of Lower and Upper Canada, echoed the necessity of being new and useful to be a patentable invention.[40] The first section of this Act provided that any person who invented or discovered any new and useful subject matter could apply for and be granted a patent. [41] The requirement of usefulness or utility was repeated through subsequent versions of the statutes [42] such as the *Patent Act 1923* which emphasized the requirements of novelty and usefulness for inventions to be granted a patent.[43] In the current Canadian *Patent Act 1985*, the notion of utility

[36] *Patent Act,* 35 USC, § 101 (1952).
[37] *An Act to promote the progress of useful arts in this Province*, LC 1824 (5 Geo IV), c. 25.
[38] *An Act to Encourage the Progress of Useful Arts within this Province*, UC 1826 (7 Geo IV), c. 5.
[39] *An Act to consolidate and amend the laws of patents for inventions in this province*, S Prov C 1849 (12 Vict), c 24.
[40] Perry, Currier & Hughes, *supra* note 1 at 24—27.
[41] *Ibid* at 129—30.
[42] *Ibid* at 130.
[43] *Patent Act*, SC 1923 (13-14 Geo V), c 23.

has been clearly reaffirmed by defining "invention" as any new and useful subject matter.[44]

The notion of utility has also been considered to be an essential requirement for patentability in the European legal system. However, in this legal system the notion of utility has been understood as possessing 'industrial application'. It is appropriate to refer to the *Strasbourg Patent Convention*[45] to analyze the background of the industrial applicability requirement in European law. The *Convention on the Unification of Certain Points of Substantive Law on Patents for Invention*, also called the Strasbourg Convention or Strasbourg Patent Convention, was signed in 1963. The Strasbourg Convention was an attempt of member states of the Council of Europe to harmonize European patent laws. Because of the diversity of European countries' patent laws, an Experts' Committee was set up to compare and survey different patent laws and provide a proposal that resulted in the *Strasbourg Convention*.[46] During the surveying of national patent laws, the Committee found marked differences in relation to the *industrial character* of patentable inventions. The variations in how this term was defined were natural consequences of the preceding convention, the *Paris Convention*, [47] that defined "industrial properties" in very broad terms in article 1:

> (1) The countries to which this Convention applies constitute a Union for the protection of industrial property.…
>
> (3) Industrial property shall be understood in the broadest sense and shall apply not only to industry and commerce proper, but likewise to agricultural and extractive industries and to all manufactured or natural products, for example, wines,

---

[44] *Patent Act*, RSC 1985, c P-4, s 2.

[45] *Convention on the Unification of Certain Points of Substantive Law on Patents for Invention*, 27 November 1963, online: World Intellectual Property Organization <http://www.wipo.int>.

[46] Wadlow, *supra* note 12 at 367, 368.

[47] *Paris Convention for the Protection of Industrial Property*, (20 March 1883), online: World Intellectual Property Organization <http://www.wipo.int/>

grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers, and flour.[48]

Further, the Paris convention did not require the granting of patents to be in any particular circumstances. Accordingly, member states were not bound to specific circumstances for defining industrial character. Therefore, the Experts' Committee for the *Strasbourg Convention* noted that the industrial characteristic of inventions is a common requirement in all national regulations but that this requirement applied to different terms, such as "capable of industrial application", "arising from any kind of industry", and "of manufacture".[49] The Experts' Committee added that "[t]hough this fundamental requirement and to a large extent, its content do not vary significantly from one country to the other, the same cannot be said of the nature and the bearing of the vary diverse ideas (results, technical effects, utility, etc. …) by which the limits of the industrial invention are defined in the national doctrines or jurisprudence."[50] Therefore, the Committee concluded that it is better not to attempt to "group under general headings the various exclusions laid down by the laws or practices but [rather] to stick to setting out the common features which an examination of the national replies reveals under the diversity of concepts."[51] In 1962, the Experts' Committee approved the draft that formed the present *Strasbourg Convention*, and articles 1 and 3 were adopted into the Convention as signed in 1963 without further amendment.[52] The *Strasbourg Convention* expressly requires all members to enforce three patentability criteria provided in article 1 of the convention: "… patents shall be granted for any inventions which are susceptible of industrial application, which are new and

[48] *Ibid*, art 1.
[49] Council of Europe Committee of Experts on Patents, *Comparative study of substantive law in force in the countries represented on the Committee of Experts on Patents*, 7 November 1953, EXP/BREV (53)18 at 3, online: Council of Europe <http://normalsup.coe.int/>.
[50] *Ibid*.
[51] *Ibid*.
[52] Wadlow, *supra* note 12 at 370—71.

which involve an inventive step."[53] The Convention understands the notion of utility as being susceptible of industrial application, and then clarifies the scope of industrial character in article 3 as being 'made or used in any kind of industry including agriculture'.[54] The *Strasbourg Convention* has had an important influence on the substantive rules of patent, especially the European Patent Convention, which is analyzed in the next section of this chapter.

2. 'Utility as usefulness' and 'Industrial application'

The notion of utility is a patentability criterion which ensures the worthiness of granting a patent. The notion of utility strikes a balance between inventors' rights and public interests by keeping inappropriate inventions out of patent monopolies. For this reason, 'inappropriate' could include the inventions that are useless, based on misinformation or are speculative. In order to ensure the best function of the notion of utility, different legal systems have understood this requirement differently based on their specific legal rules. There are two main understandings of the notion of utility: 'utility as usefulness' and as 'industrial applicability'. Utility as usefulness applies in common-law countries such as the USA, Canada, and in British law until 1977. However, in civil law countries (mostly European countries) industrial applicability is one of the patentability criteria. Therefore, within patent law two major competing systems have developed: novelty, non-obviousness, and utility in Anglo-Canadian-American law;[55] and novelty, inventive step, and industrial applicability, (mostly) in European law.[56]

This section first analyzes utility as usefulness as all Anglo-American jurisdictions including the United States and Canada understand and apply it; then industrial application will

[53] Strasbourg Convention, *supra* note 45, art 1.
[54] *Ibid*, art 4.
[55] In Britain, only until 1977 the utility requirement was the patentability standard.
[56] Gold & Shortt, *supra* note 8 at 57—58; Wadlow, *supra* note 12 at 357.

be analyzed as it applies in Europe. The final section will elaborate on differences and similarities between these two understandings of utility.

2.1. Utility as usefulness

In American and Canadian law, a patentable invention should have demonstrated utility alongside novelty and non-obviousness. Generally, in both the US and Canada's patent laws, the patent utility is referred to as usefulness. The Canadian *Patent Act* defines invention as new and useful subject matter [57] and the US *Patent Law* provides that patents may be granted to whoever invents any new and useful subject.[58] Neither of these Acts gives a clear definition of the term usefulness, and thus the breadth and limitation of the 'usefulness' of an invention has been left to the courts to determine.[59] In general, utility or usefulness is an indispensable part of an invention and, therefore, a patent must be granted for something more than a scientific curiosity or the starter for a research program. Thus, an invention "… cannot be a mere laboratory curiosity whose only possible claim to utility is as a starting material for further research."[60] In other terms, a patent is not a hunting license or a reward for the search, but "compensation for its successful conclusion," therefore, a patent may only be granted when a "specific benefit exists in currently available form."[61] The disclosure must assure the examiner that there is a benefit as the invention currently exists.[62] Despite of the fact that both the US and Canada consider patent utility as usefulness, there are differences between the two approaches to patent utility. Both the

[57] *Patent Act*, *supra* note 44 at s 2.
[58] *U.S. Patent Law, 35 U.S.C.*, *supra* note 36.
[59] Risch, *supra* note 5 at 1200—1201. I return to the concept of 'usefulness' in chapter III to elaborate on the provided interpretations for this term and discuss the current ambiguities on the *useful*ness of the patent in Canadian patent law.
[60] *Re Application of Abitibi Co*, [1982] 62 CPR (2d) 81 (Patent Appeal Board and Commissioner of Patents) at para 32.
[61] *Brenner, Commissioner of patents v. Manson,* 383 U.S. 519 (1966) at 534_536 [*Brenner v. Manson*].
[62] *Ibid* at 534, 535.

US and Canada's laws have different mechanisms that operate to evaluate and ensure the usefulness of an invention.

As mentioned earlier, 'utility' arises from article 101 of the US patent law. The utility requirement is for asking the question: does the invention have a use? [63] or 'whether the patent describes *a* use for its claimed invention.'[64] According to the US jurisprudence on point, the utility requirement must be specific[65] or particular, which in turn means that a patent application must disclose a use "which is not so vague as to be meaningless."[66] In addition, the utility must be "substantial"[67] or practical, that means "an asserted use must show that that claimed invention has a significant and presently available benefit to the public."[68] Moreover, the US approach to the utility requirement has another stage, which is assessing "operability" or "credible utility."[69] The operability standard asks whether the invention can actually accomplish or achieve its alleged utility.[70] In addition, article 112 of the US patent law provides two statutory disclosure requirements, namely enablement and written description:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.[71]

---

[63] Gold & Shortt, *supra* note 8 at 61.
[64] Jacob Sherkow, "Patent Law's Reproducibility Paradox" (2017) 66:4 Duke LJ 845 at 882.
[65] *Brenner v. Manson, supra* note 61 at 534, 535.
[66] *In re Fisher*, [2005] 421 F 3d 1365 (Court of Appeals, Federal Circuit) at 1371 [*Fisher*].
[67] *Brenner v. Manson, supra* note 61 at 534, 535.
[68] *Fisher*, *supra* note 66 at 1371.
[69] Sean B Seymore, "Making Patents Useful" (2014) 98 Minn L Rev 1046 at 1066; See also "Utility Examination Guidelines", (30 January 2001), online: *USPTO* <https://www.uspto.gov>.
[70] Robert P Merges & John Fitzgerald Duffy, *Patent law and policy: cases and materials* (New Providence, NJ: LexisNexis, 2011) at 212.
[71] *U.S. Patent Law, 35 U.S.C.*, *supra* note 36 art 112(a).

The enablement standard ensures that a skilled person can actually make, use or practice what the patentee disclosed at the filing date without undue experimentation.[72] The enablement doctrine tends to prevent patentees from claiming broad and general uses of inventions and limit "*how* broadly patent claims may reach."[73] Furthermore, the enablement doctrine "regulates what degree of speculation is tolerable",[74] especially when the patent applicant cannot prove all aspects of his invention at the filing date and the utility of the invention therefore relies on some degree of prediction.

In the Canadian legal system, the term *useful* invention for the purpose of the *Patent Act* does not imply any value or moral judgments regarding its intended use.[75] In fact, the usefulness of the invention is closely related to the question of whether the claimed invention fulfills its promises, or whether the patent specification includes false suggestion and misrepresentation.[76] The Canadian Intellectual Property Office provides that the utility requirement must be specific, practical and credible, as well as operable, controllable and reproducible.[77] The operability requirement means that the invention works for its intended purpose.[78] Controllability and reproducibility, as elements of the utility requirement,[79] refer to the fact that "the desired result must inevitably follow when the invention is put into practice",[80] and thus inventions that are

---

[72] Seymore, *supra* note 69 at 1083—84; *In re Wright*, 999 F 2d 1557 at 1561 [*Wright*].
[73] Merges & Duffy, *supra* note 70 at 265.
[74] *Ibid*.
[75] Perry, Currier & Hughes, *supra* note 1 at 133.
[76] WIPO Standing Committee on the Law of Patents, "Industrial Applicability and Utility Requirements: Commonalities and Differences" (2003) SCP/9/5 at para 46, online: <http://www.wipo.int/>.
[77] Canadian Intellectual Property Office (CIPO), *Manual of Patent Office practice* (Ottawa: CIPO, 2009) at art 12.08, online: CIPO <https://www.ic.gc.ca/> *[MPOP]*.
[78] *Ibid* at art 12.08.01.
[79] Donald M Cameron, *Canadian patent law benchbook* (Toronto: Carswell, 2014) at 131.
[80] MPOP, *supra* note 77 at art 12.08.02.

arrived at by chance and which cannot be reliably reproduced do not meet the utility requirement.[81]

In addition to these statutory requirements, there are main doctrines for the notion of utility in Canadian law that work as mechanisms for assessing the usefulness of inventions: the patent promise doctrine and the sound prediction doctrine. Chapter II of this thesis will return to these doctrines in order to critically analyze the notion of utility and its importance to the Canadian legal patent system.

2.2. Industrial application

As discussed above, Civil law countries, mostly European countries, understand the notion of utility as industrial application. Industrial applicability as a patent requirement in European law can be studied through the *Convention on the Grant of European Patents*[82] (also known as the *European Patent Convention*, or EPC) and its Guidelines.[83] The EPC expressly identifies industrial application as one of the requirements of granting patents. Article 52 of the EPC, entitled 'patentable inventions', provides that:
"(1) European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application."[84] Furthermore, article 57 of the EPC defines industrial application as being made or used in any kind of industry, including agriculture.[85] According to the EPC, the term industry should be

[81] *Ibid*.
[82] EPC, *supra* note 29.
[83] *Guidelines for Examination in the European Patent Office*, 2016, part G, c 3, online: European Patent Office <http://www.epo.org> [EPO Guidelines].
[84] EPC, *supra* note 29, art 52.
[85] EPC, *supra* note 29, art 57.

understood in its broad sense,[86]and, as stated by the EPO Board of Appeals, should include "all manufacturing, extracting and processing activities of enterprises that are carried out continuously, independently and for financial (commercial) gains."[87] The patent must disclose its "practical application" which means that the invention can be employed for "some profitable use".[88] In fact, the patent must disclose a "practical exploitation in industry", so that the skilled reader could be able to derive from the patent specification the understanding that the invention has an "immediate concrete benefit".[89] If the industrial applicability of the invention is not self-evident, then the inventor must disclose the way in which the invention is industrially applicable in the patent specification. In other terms, if the industrial applicability of the invention is not obvious from its nature or from the patent specification, then the patentee must disclose how the invention is capable of being exploited in the industry.[90] In addition, based on the *EU Biotechnology Directive*,[91] enacted for the protection of biotechnological inventions, "the industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application."[92] The European Patent Organization is not subject to the EU Directive; however, it adopted the rules of this Directive as a regulation under the EPC. According to this Directive, in order to get a patent for a sequence or a partial sequence of a gene, the inventor

[86] EPO Guidelines, *supra* note 83, part G, c 3.
[87] T 0870/04 (BDP1 Phosphatase), (5 November 2005), unpublished at para 3, online: European Patent Office <https://www.epo.org> [BDP1 Phosphatase].
[88] *Ibid*, para 4.
[89] T 0898/05 (hematopoietic receptor), (7 July 2006), unpublished at para 6, online: European Patent Office <http://www.epo.org> [hematopoietic receptor].
[90] EPC, *supra* note 29 at R 27(1)(f) ; EPO Guidelines, *supra* note 88 at part G, c 3(4); *Ibid* at para 6.
[91] "European Union (EU): Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of biotechnological inventions", (6 July 1998), online: World Intellectual Property Organization <http://www.wipo.int>.
[92] *Ibid*, art 5(3).

must disclose the industrial application of invention in the patent application.[93]

2.3. Differences and overlaps

As explained in the two previous sections, industrial applicability and utility are different requirements, and the utility standard differs in substance between the US legal system and the Canadian legal system. In addition to the differences between the systems that are set out above, the WIPO Standing Committee on the Law of Patents recognized another of the differences between the industrial applicability and the utility requirements in 2003, being that: "[C]laimed inventions which could apply solely in the private or personal sphere for one's own needs, or which could be applied solely in association with a particular person, would not meet the industrial applicability requirement, even if the term 'industry' is interpreted in the broadest sense." [94]

Despite the fact that industrial application and utility are different standards for utility, both achieve certain of the same "functional goals",[95] and the same rationales have been provided for each standard.[96] Both the industrial application and utility standards tend to strike a balance between inventor's benefits and the public benefits. These standards play an essential role in balancing the incentive of furthering innovation with the necessity of granting patent monopolies for concrete benefits. Therefore, the notion of utility under European, US, and Canadian patent systems has the same function to ensure granting patents for concrete benefits while avoiding patent monopolies for premature or speculative inventions. The utility requirement has insisted

[93] Martin J Adelman, *Global issues in patent law* (St. Paul, MN: West, 2011) at 76.
[94] WIPO, *supra* note 76 at para 56.
[95] Gold & Shortt, *supra* note 8 at 71.
[96] Norman Siebrasse, "Form and Function in the Law of Utility: A Reply to Gold & Shortt" (2014) 30:2 Can Intellect Prop Rev 1 at 11.

on the avoidance of patenting premature and merely speculative inventions. The US Supreme Court, in the famous case *Brenner v. Manson*,[97] stated that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion," therefore, a patent may only be granted when a specific benefit exists in currently available form.[98] In addition, according to the rulings of the Canadian courts, [99] no one can receive a patent for an unproved and untested hypothesis or mere speculation. By the same token, the decisions of the Board of Appeal of the EPO approve that the same functional goals have been considered for the industrial applicability requirement. In *BDP1 Phosphatase,*[100] the patent claimed a method of identifying chemical compounds capable of mediating biological interactions concerning a protein, BDP1. The applicant described BDP1 as a composition, and identified the protein's significance in several cellular functions, but did not clarify how those cellular functions provided a pharmaceutical effect, namely, the regulation of the growth of cancerous cells.[101] The Board of Appeal stated that the provided disclosure on the subject was "[A] vague and speculative indication of possible objectives that might or might not be achievable by carrying out further research with the tool as described is not sufficient for fulfilment of the requirement of industrial applicability. The purpose of granting a patent is not to reserve an unexplored field of research for an applicant."[102] Furthermore, the Board of Appeal noted that the only practicable use suggested was "to use what is claimed to find out more about the natural functions of what is

[97] *Brenner v. Manson, supra* note 61.
[98] *Ibid* at 534—36.
[99] *Farbwerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning v Commissioner of Patents*, 1966 SCR 604 at 608; *Re Application of Abitibi Co.*, *supra* note 60 at para 32; *Apotex Inc. v Wellcome Foundation Ltd, supra* note 9 at paras 69―84.
[100] BDP1 Phosphatase, *supra* note 87 .
[101] *Ibid* at para 7; Jacob S Sherkow, "Patents, Promises, and Reproducibility", (2017), online: *ATRIP* <http://atrip.org/wp-content/uploads/2017/04/Sherkow-Patents2c-Promises2c-and-Irreproducibility.pdf> at 7—8.
[102] BDP1 Phosphatase, *Supra* note 87 at para 21.

claimed itself. This is not in itself an industrial application, but rather research undertaken either for its own sake or with the mere hope that some useful application will be identified."[103] In addition, in *Hematopoietic receptor,*[104] the Board of Appeal stated that granting a patent to a compound with an unknown function might prevent further research in that area, "and/or give the patentee unjustified control over others who are actively investigating in that area and who might eventually find actual ways to exploit it."[105]

On the other hand, the other function of utility as industrial applicability is to encourage incentives for new innovations, especially in pharmaceutical and biotechnological fields that rely on patent protection to fund research.[106] Both the utility and industrial application standards achieve this goal by different mechanisms based on their location in different legal systems. The utility requirement echoes the same rationales as industrial applicability in EU law through the enablement and written description requirements in US law, and sound prediction doctrine described by the Supreme Court of Canada in *Apotex v. Wellcome Foundation*:[107]

> The doctrine of "sound prediction" balances the public interest in early disclosure of new and useful inventions, even before their utility has been verified by tests (which in the case of pharmaceutical products may take years) and the public interest in avoiding cluttering the public domain with useless patents, and granting monopoly rights in exchange for misinformation.[108]

In addition, a decision of the Board of Appeal of the EPO,[109] and a decision of the UK Supreme

---

[103] *Ibid* at para 22.
[104] Hematopoietic receptor, *supra* note 89.
[105] *Ibid* at para 7.
[106] Norman Siebrasse, "HGS v. Lilly: How Soon Is Too Soon to Patent?" (2011) 24:1 Intellect Prop J Scarb 41 at 48—49.
[107] *Apotex v Wellcome Foundation*, *supra* note 9.
[108] *Ibid* at para 66.
[109] T 0018/09 (Neutrokine/Human Genome Science), (21 October 2009), unpublished, online: European Patent Office <http://www.epo.org> [Neutrokine/Human Genome Science].

Court,[110] both of which lowered the threshold of the disclosure required for industrial application, indicated the same functional goals for the industrial applicability standard. Both decisions dealt with the same patent for "the DNA sequence and amino acid sequence for Neutrokine-α, which was described as being a member of the TNF superfamily of cytokines."[111] Human Genome Science, as the patentee, disclosed no *in vitro* or *in vivo* test results in its patent application. In fact, the description of the activity and uses of Neutrokine-α was a prediction based on the characteristics of other members of the TNF superfamily which were known to play a role in the activity of white blood cells. However, the post-filing evidence proved the correctness of these predictions. The Board of Appeal stated that "post-published evidence on file shows the production of anti-Neutrokine-α antibodies and their possible application for therapy and diagnosis purposes, confirming the plausibility of the disclosure of the patent-in-suit …"[112] The Board noted that the description of the patent renders sufficient technical information to satisfy the requirement of disclosing the nature and purpose of the invention and how it can be used in industrial practice.[113] Indeed, for the Board, it was sufficient that the patent provided a concrete technical basis for a skilled person to recognize a practical exploitation in industry. Thus, the Board held that the industrial applicability requirement was fulfilled.[114]

The reasons of the Board of Appeal were accepted by the UK Supreme Court in dealing with the same patent in *Human Genome Sciences v. Eli Lilly*.[115] According to the principles set out by the Supreme Court, where a patent discloses a new protein and its encoding gene, "the absence of

[110] *Human Genome Sciences Inc. v Eli Lilly and Company [2011] UKSC 51*, 2011 UKSC (2011) [HGS v. Lilly].
[111] *Ibid* at para 71.
[112] Neutrokine/Human Genome Science, *Supra* note 109, at para 33.
[113] *Ibid* at para 27.
[114] *Ibid* at para 34.
[115] *HGS v. Lilly*, *supra* note 110.

any experimental or wet lab evidence of activity of the claimed protein is not fatal" and "a 'plausible' or 'reasonably credible' claimed use, or an 'educated guess', can suffice".[116] Furthermore, the Court held that, where the protein is said to be a family or superfamily member, "if all known members have a 'role in the proliferation, differentiation and/or activation of immune cells' or 'function in controlling physiology, development and differentiation of mammalian cells', assigning a similar role to the protein may suffice", and "If the disclosure is 'important to the pharmaceutical industry', the disclosure of the sequences of the protein and its gene may suffice, even though its role has not been clearly defined."[117] Accordingly, the UK Supreme Court concluded that:

> Just as it would be undesirable to let someone have a monopoly over a particular biological molecule too early, because it risks closing down competition, so it would be wrong to set the hurdle for patentability too high, essentially for the reasons advanced by the BIA [the BioIndustry Association] and discussed in paras 97-100 above. Quite where the line should be drawn in the light of commercial reality and the public interest can no doubt be a matter of different opinions and debate. However, in this case, apart from the fairly general submissions of the parties and of the BIA, we have not had any submissions on such wider policy considerations.[118]

This decision of the UK Supreme Court struck a balance between protecting pharmaceutical and biotechnological inventions and avoiding granting patent monopolies for speculative or useless inventions.

There is no doubt that the distinctive doctrine of sound prediction is different from the industrial applicability standard. However, as Norman Siebrasse explains, *HGS v. Lilly* indicates that there is a clear, functional parallel between the industrial application and

[116] *Ibid* at paras 107(vii)—(viii).
[117] *Ibid* at paras 107(xi)—(xiii).
[118] *Ibid* at para 130.

utility requirements: sound prediction.[119] Both requirements address the issue of how early the patent may be granted in the research process to strike the appropriate balance between supporting the incentives for innovation and the necessity of avoiding granting patents for mere research. Chapter II will return to the sound prediction doctrine and elaborate further on the importance of this approach in Canadian patent case law.

3. The notion of utility in international law

International agreements and treaties can constitute attempts by countries to harmonize different domestic laws on an issue. Here, although there is no international "explicit substantive rules"[120] on the notion of utility, international intellectual property law has ruled on patentability criteria. This section studies the most important patent-related international regulations in order to examine the notion of utility in international patent law, and analyze why attempts for harmonizing patent utility rules have so far been unsuccessful.

The *Patent Cooperation Treaty* (PCT)[121] was intended to provide unified procedures and regulations for international protection of inventions. The PCT provides a non-binding *International Preliminary Examination* for the purposes of the treaty and, in its related articles, [122] explained patentability requirements:

> (1) The objective of the international preliminary examination is to formulate a preliminary and non-binding opinion on the questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), and to be industrially applicable. …

[119] Siebrasse, *supra* note 106 at 42—44.
[120] Gold & Shortt, *supra* note 8 at 56.
[121] *Patent Cooperation Treaty*, (1970), online: World Intellectual Property Organization <http://www.wipo.int> [PCT].
[122] *Ibid* at arts 33_35.

> (4) For the purposes of the international preliminary examination, a claimed invention shall be considered industrially applicable if, according to its nature, it can be made or used (in the technological sense) in any kind of industry. "Industry" shall be understood in its broadest sense, as in the Paris Convention for the Protection of Industrial Property.[123]

The PCT expressly uses industrial application as a criterion for patentability and avoids mentioning utility. It is surprising that the PCT mentions both alternative concepts of inventive step and non-obviousness; however, no mention is made of utility as an alternative concept to that of industrial application.[124] This approach of the PCT is in contrast with the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS), that expressly refers to both concepts as alternative patentability standards.[125] However, chapter 14 of the PCT *International Search and Preliminary Examination Guidelines* (the PCT Guidelines),[126] in force from July 1 2017, expressly provides that the term industrially applicable "may be deemed by an International Authority to be synonymous with the term 'utility'."[127] In addition to chapter 14 that defines industrial applicability, the appendix to chapter 14 of the PCT Guidelines go on to define utility. According to the PCT Guidelines, a claimed invention is considered industrially applicable "if, according to its nature, it can be made or used (in the technological sense) in any kind of industry,"[128] and a claimed invention is considered industrially applicable if it has a utility that is specific, substantial, and credible.[129] Indeed, the PCT Guidelines consider utility and industrial applicability to be alternative or equivalent concepts and thus the Guidelines

---

[123] *Ibid* at art 33.
[124] Wadlow, *supra* note 12 at 372.
[125] *Agreement on Trade-Related Aspects of Intellectual Property Rights*, 15 April 1994, being Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, 1869 U.N.T.S. 299,33 I.L.M. 1197, art 27.1 [TRIPS].
[126] World Intellectual Property Organization, "Patent Cooperation Treaty International Search and Preliminary Examination Guidelines", (6 June 2017), online: *WIPO* <http://www.wipo.int>.
[127] *Ibid* at art 14.01, A14.01[1].
[128] *Ibid* at art 14.01.
[129] *Ibid* at A14.01[1].

provide alternative regulations for both concepts.

Article 27.1 of the TRIPS clearly requires the notion of utility for patentable inventions, as it provides that "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."[130] In addition, the footnote to article 27.1 clarifies that, for the purpose of this requirement, the term 'capable of industrial application' may be deemed by a member to be synonymous with the term 'useful'. Moreover, the first article of TRIPS clarifies an essential rule for the interpretation of the Agreement, which is that: "Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice."[131]

These articles indicate that the TRIPS agreement did not intend to implement unified regulations on the patentability requirement, specifically the notion of utility. Rather, the TRIPS agreement contemplates two main understandings of the notion of utility, namely industrial application and utility as usefulness, and entitles member states to make the right decision between these standards based on their legal system.[132] In other terms, the TRIPS agreement made member states free to adopt either the industrial application or utility standards, which are clearly

[130] TRIPS, *Supra* note *125 at art 27.1.*
[131] *Ibid* at art 1.1.
[132] The drafting history of the TRIPS agreement indicates that all initial drafts in respect of article 27.1, expressly mentioned both industrial application and utility either in their text or footnote. This can prove the fact that the European and American understandings of the notion of utility have formed the main understandings of this notion, and the TRIPS recognized both. See: Daniel J Gervais, *The TRIPS agreement: drafting history and analysis*, 4th ed (London: Sweet & Maxwell/Thomson Reuters, 2012) at 420_433.

different to the extent that the TRIPS draftsmen could not incorporate them into one clause nor prefer one to the other.[133]

As mentioned at heading 2.1 above, the utility requirement as a patentability criterion, differs in US law from Canadian law. Similarly, the industrial character of industrial application has a broader definition in the *Paris Convention* compared to the EPC.[134] However, because the TRIPS agreement did not define utility nor industrial applicability, referring to these standards as a patentability requirement can cause practical difficulties.

The Patent Law Treaty (PLT)[135] and The Substantive Patent Law Treaty (SPLT)[136] were the attempts of state parties to harmonize international patent regulations. The PLT was adopted in 2000, to harmonize and streamline formal procedures with respect to national and regional patent applications and patents. In contrast with the PLT that only related to patent formalities, the SPLT was an attempt to harmonize substantive patent rules such as novelty, non-obviousness, inventiveness, industrial application and utility.[137] In other words, the SPLT was an attempt to harmonize both law and practice[138] concerning the regulations of patent application and also the "cornerstone requirements of patentability."[139] During the SPLT negotiations, the parties could not reach agreement on the different areas of regulation because of differing views

---

[133] Wadlow, *supra* note 12 at 356.
[134] *Ibid* at 378.
[135] *Patent Law Treaty*, (1 June 2000), online: World Intellectual Property Organization <http://www.wipo.int> [PLT].
[136] World Intellectual Property Organization, Standing Committee on the Law of Patents: Tenth Session, "Draft Substantive Patent Law Treaty (SPLT)", WIPO Doc. SCP/10/2, (30 September 2003), online: *WIPO* < http://www.wipo.int/edocs/mdocs/scp/en/scp_10>.
[137] World Intellectual Property Organization, "Draft Substantive Patent Law Treaty", online: *WIPO* <http://www.wipo.int>.
[138] Jerome H Reichman & Rochelle Cooper Dreyfuss, "Harmonization without consensus: Critical reflections on drafting a substantive patent law treaty" (2007) 57:1 Duke LJ 85 at 90.
[139] *Ibid*.

on patent protection. Therefore, the attempt at harmonization of patent rules by means of the SPLT ended in 2006. The failure of the SPLT negotiations indicates that there remain major disagreements about different aspects of patent law. In fact, as Reichman and Cooper Dreyfus state: "Not only are there discordant views on how high the inventive step should be, there are also disagreements on virtually every substantive topic under discussion in connection with the SPLT: novelty and utility standards, the research exemption, compulsory licenses—along with standards for analyzing infringement and awarding relief."[140] Therefore, there is no international agreement on the notion of utility and neither the PCT nor the TRIPS agreement provide substantive regulations at the international level on the notion of utility as a patentability requirement. The failure of SPLT negotiations, as the sole attempt to provide such regulations, indicates that there are important divergences about patent protection between legal systems.

4. Conclusion to chapter I

This chapter has provided a summary and history of the development utility requirement under national and international patent law. The 'utility requirement' is a patentability criterion designed to ensure public interests are met in granting patent monopolies. Unlike the criterion of novelty, various legal systems understand utility in different ways: notably, utility as usefulness and utility as industrial applicability. These divergent understandings of patent utility are based

[140] *Ibid* at 106.

on specific domestic legal rules; however, overall the two approaches share many of the same goals and outcomes. Both understandings of utility include unique mechanisms designed to ensure patents are granted for concrete benefits, to avoid granting patents for speculative inventions, and to support pharmaceutical and biotechnological innovators that need to conduct numerous experimentations.

This chapter has also discussed the lack of harmonized standards on the patent utility requirement at the international level. One reason for this lack of harmonization is that the current international agreements on intellectual property - such as the TRIPS[141]- did not attempt to harmonize the patent regime. Rather, the TRIPS negotiators preferred to provide greater flexibility for state participants in terms of protecting patents in developing countries. In addition, negotiations for the SPLT - the sole attempt to set unified standards on patentability requirements - failed in 2006. One important reason for this failure of negotiations was the divergent patent standards applicable under various national laws. The fact of emerging technologies and the challenges these present to patent law encouraged national legal systems to adopt different approaches to patent standards, which were then very difficult to harmonize at the international level. Furthermore, developing countries were not optimistic about negotiations for harmonization of patent law after enjoying a degree of regulatory freedom and flexibility under the TRIPS. Indeed, internationally harmonized patent law could impose higher standards of patent protection on developing countries, thereby limiting their innovation and research potential.[142]

In terms of the lack of international standards on patent utility, national patent laws have developed their own approaches to addressing the notion of utility over time. This chapter has

[141] TRIPS, *supra* note 125 at art 65.
[142] Reichman & Dreyfuss, *supra* note 138 at 91—102.

explained that the way Canadian courts interpret patent utility has become a new and challenging issue over the last decade. Chapter II will thoroughly analyze the Canadian approach to the issue of utility requirement by focusing on relevant jurisprudence in this country.

Chapter II: The importance of the notion of utility in the Canadian legal system

Over the last few decades, Canadian courts have developed the notion of utility as a criterion for patentability in patent cases. This chapter focuses on Canadian patent jurisprudence in order to assess how the Canadian legal system addresses the concept of utility. The first section of this chapter discusses the two main concepts of patent utility as it is understood in Canada: demonstrated utility and soundly predicted utility. The study of demonstrated utility focuses on the promise of the patent and the mere scintilla of utility as these concepts have been developed in case law since 1948 to the most recent cases decided in 2017. The second section of this chapter will analyze the essential policies that are served by applying demonstrated utility and soundly predicted utility in Canadian patent law.

1. The concept of utility in Canadian patent jurisprudence

Utility is a concept often approached in the negative rather than in the positive. The general rule is that the notion of utility will only be raised when it has been challenged, in order to answer the question of whether the invention does or does not lack utility.[143] Under Canadian law, the patent applicant is not required to demonstrate the actually achieved utility of the

[143] *In re Oberweger*, [1940] 115 F 2d 826 (Court of Customs and Patent Appeals), cited in "Utility Requirement in the Patent Law" (1964) 53 Geo L J 154 at 156.

invention by the filing date. In other words, applicants are not required to disclose evidence indicating that their inventions are useful. Rather, it is sufficient to prove the utility of an invention when the patent is challenged for invalidity.[144] The Canadian Federal Court of Appeal reaffirmed this rule in *Novopharm v. Pfizer*,[145] stating:

> The appellant's argument that Pfizer was required to include evidence of demonstrated utility in the patent disclosure is without merit. The requirements for demonstrated utility can be provided in evidence during invalidity proceedings as opposed to in the patent itself. So long as the disclosure makes reference to a study demonstrating utility, there do not appear to be any other requirements to fulfil section 2.[146]

Where the applicant, for the purposes of section 27(3) of the Patent Act,[147] establishes the utility of an invention by way of the patent specification (while making no promise of utility) the "mere scintilla" of utility will suffice. It means that the invention must only produce some minimally useful results. However, according to "the promise of the patent", if the patent specification demonstrating utility makes a promise at the filing date, the patent will meet the utility requirement only if it fulfills that promise. In other terms, the patent utility will be measured according to that promise and if the invention achieves some lower levels of usefulness, the patent will not be granted. This approach to the utility requirement was rejected by the recent ruling of the Supreme Court of Canada in *Apotex* which will be discussed in chapter III.

Justice Snider helpfully explained various concepts related to patent utility and provided a list of guiding principles for determining utility in the case of *Laboratoires v. Novopharm*:

Where the specification does not promise a specific result, no particular level of

---

[144] David Vaver, *Intellectual property law: copyright, patents, trade-marks* (Toronto: Irwin Law, 2011) at 341.
[145] *Novopharm Limited v Pfizer Canada Inc.*, 2010 FCA 242.
[146] *Ibid* at para 90.
[147] *Patent Act*, *supra* note 44, s. 27(3).

> utility is required - a "mere scintilla" of utility will suffice (Fox, above at 153). However, as stated in Consolboard, above, where the specification sets out an explicit "promise", utility must be measured against that promise;
>
> Utility does not depend upon marketability [citation omitted]. In other words, in assessing whether an invention has utility, the issue is not whether the invention is sufficiently useful as to be able to support commercialization, unless commercial utility is specifically promised;
>
> The relevant date has been held to be the filing of the Canadian patent application [citation omitted]; and
>
> Where a claim is to a class of compounds, lack of utility of one or more of the compounds will invalidate all of the compounds of that particular claim [citation omitted]
>
> Quite simply stated, the question is whether the invention does what the patent promises that it will do.[148]

These principles accurately convey how the notion of utility in Canadian law has been applied in various patent cases over the years; however, they do not address the concept of 'soundly predicted utility', which is an essential concept in Canadian patent law. This chapter addresses 'sound prediction utility' at heading 1.2 below.

1.1. Demonstrated utility

The patentee must either demonstrate the actually achieved usefulness of an invention or disclose a sound basis for prediction of usefulness by the filing date. In the first situation, the patentee must indicate the usefulness of the invention and prove that the invention does what it claims; for example, by conducting tests. The Supreme Court of Canada has affirmed that there is no requirement to disclose what is demonstrated, and this is in contrast with the disclosure requirement for soundly predicted utility:

> …. Nadon J.A. agreed that there is no requirement that the utility of a patent be demonstrated in the patent disclosure so long as the trier of fact can find that its

[148] *Laboratoires Servier, Adir, Oril Industries, Servier Canada Inc v Apotex Inc*, 2008 FC 825 at paras 270—271 [*Laboratoires Servier*].

> utility has been proven when the patent is challenged. He stated that an inventor must describe the invention so that it can be produced, but is not obliged to describe its effect, advantage or usefulness. In so holding, Nadon J.A. noted that this Court's most recent decision on utility did not mention a requirement to prove utility in the disclosure.[149]

However, in cases where proving utility relies on the context and the nature of the invention, as with pharmaceutical selection patents, the patentee must explicitly assert the utility of the selected compounds to indicate why these particular compounds were selected.[150] In these cases, the applicant must indicate the new and additional utility of the selected compounds that make them eligible to be patented separately from a set of larger compounds. Another example of this situation would be new use claims for already known compounds.

As this section has described, "the promise of the patent" and "mere scintilla of utility" are the two main criteria of demonstrated utility under Canadian law. Where patent utility is demonstrated, it will either be promised by the patentee, or not promised; in which case, the patent must be found to have minimal usefulness. Where the patentee has explicitly demonstrated the utility of a patent, a "mere scintilla of utility" is all that is required to demonstrate usefulness, unless the patentee has made a specific "promise of utility" that the patentee must enforce.

---

[149] *Teva Canada Ltd v Pfizer Canada Inc*, [2012] 3 SCR 625 (SCC) at para 25, Citing *Apotex v Wellcome Foundation*, *supra* note 9.

[150] Perry, Currier & Hughes, *supra* note 1 at 134—35.

1.1.1. The Promise of the patent

1.1.1.1. Introduction and background

"The patent promise doctrine"[151] or "the promise of the patent" is the approach to utility that insists on enforcing the promise made in the patent specification. There is an extensive history of construing and enforcing the promise of the patent in Canadian patent jurisprudence. Multiple cases have been decided on the basis of the promise of the patent: proving the strength of this doctrine in Canadian patent law. This section analyzes these cases.

Consolboard [152] is frequently referred to as the first case to introduce the term 'promise' into Canadian patent jurisprudence.[153] However, *Consolboard* was not the first case where the patent's promise was accepted.[154] In fact, the concept of the patent's promise was accepted in Canadian law more than 30 years before *Consolboard*.[155]

According to Gold & Shortt,[156] the case of *Wandscheer v Sicard*[157] was the first decision in which a majority of the Supreme Court of Canada took a promissory approach to the question of patent utility. The patent in this case concerned a snow blower that could work effectively in

---

[151] Gold & Shortt avoid using "promise doctrine" because they found *"*no support for a court ever referring to it as a doctrine unto itself.*"* Gold & Shortt, *supra* note 8 at 38. In 2014, a Federal Court of Appeal clearly accepted "the promise doctrine" as an exception to the minimum statutory requirements for utility. See *Apotex Inc. v Pfizer Canada Inc.*, 2014 FCA 250.

[152] *Consolboard, supra* note 7.

[153] *Sanofi-Aventis v Apotex Inc.*, 2013 FCA 186 at para 47 [*Plavix Impeachment]* , citing *Consolboard*, *supra* note 7, citing *Halsbury's Laws of England*, 3d ed., vol. 29, at p. 59; Perry, Currier & Hughes, *supra* note 1 at 141.

[154] Various patent cases have been decided on the basis of the promise of the patent. See: *Amfac Foods Inc v Irving Pulp & Paper, Ltd*, [1986] 12 CPR (3d) 193, FCJ 659 (FCA); See also Gold & Shortt, *supra* note 8 at 54—55.

[155] *Wandscheer et al v Sicard Ltd*, [1948] SCR 1, 1947 CanLII 27; *New Process Screw*, *supra* note 8.

[156] Gold & Shortt, *supra* note 8 at 52—53.

[157] *Wandscheer, supra* note 155.

dry, light snow, but heavy, wet snow "seemed to choke the motor down too much."[158] The Supreme Court of Canada held the patent invalid for the lack of utility. Justice Taschereau, writing for two of the three judges in the majority, concluded that *"*… the rotating ejector had no usefulness and was not workable. It could not do what it was intended to do, and could not serve the purposes mentioned in the patent." [159] Therefore, even though the invention was found to have a scintilla of utility because of its usefulness in light snow conditions; the Court held the patent invalid on the basis that it failed to fulfill its promise of working in all winter conditions.

It is worth mentioning that, according to Siebrasse,[160] *Wandscheer v Sicard* is not a promise case but rather a case concerned with "the level of objective utility required to support a patent under the 'actual utility' requirement."[161] Siebrasse refers to the 'scintilla of utility' as the 'actual utility, which is objective utility. He notes that, in the *Wandscheer* case, the main question was not whether the invention failed to fulfill the promise of blowing snow in all winter conditions; rather, the relevant inquiry was whether blowing only light snow was sufficient utility to support a patent, regardless of what the patentee might have promised.[162] However, the promissory approach taken by the Supreme Court in this case cannot be ignored, and the evidence provided in relation to the usefulness of the invention in light snow indicates that the case is not a scintilla of utility case but is really concerned with the patent's failure to fulfil the promise.

New Process Screw Corp v PL Robertson Manufacturing Co[163] was the first case that introduced the phrase "the promise of the patent" into Canadian law. [164] The case concerned

[158] *Ibid* at 24.
[159] *Ibid* at 5.
[160] Siebrasse, *supra* note 96 at 35—41.
[161] *Ibid* at 38.
[162] *Ibid*.
[163] *New Process Screw v. P.L. Robertson Manufacturing*, *supra* note 8.
[164] Gold & Shortt, *supra* note 8 at 53.

improvements made to methods and machines used in making screws. Specifically, the patent promised a process for manufacturing many sizes of screws, which could be varied depending on the "pitch angle" used in the machine: ranging from a No 2 double-threaded screw at 12 degrees to a No 18 double-threaded screw at 22 degrees. However, there was evidence given of experiments that indicated that producing a No 18 screw using a pitch angle of 22 degree generated a rough screw that could not serve as a double-threaded screw. Therefore, although the machine was found to produce workable screws, the patent was void for lack of utility as it was filed for production of the certain types of screws promised.[165]

According to the general rules regarding 'promise', the patentee is bound to the promise made in patent specification. Generally, there is no quantitative requirement for patent utility.[166] However, the promise made about the patent in the specification is a threshold requirement against which usefulness and utility of the invention will be evaluated. Where there is a promise in the patent specification, it is not sufficient for the invention to have a mere scintilla of utility, a lower degree of promised utility, or different utility.

The promissory doctrine has its basis in bargain theory: as the invention must do what the specification promised it would do. The doctrine aims to ensure that the public is provided with the adequate instructions to achieve the utility that is promised in the specification,[167] and so that monopolies would not be granted in exchange for speculative inventions or misinformation.

1.1.1.2. Construction of the promise of the patent

[165] *Ibid* at 53—54.
[166] Harold G Fox, *Digest of Canadian patent law* (Toronto: Carswell, 1957) at 52; Fox, *supra* note 23 at 309.
[167] Freedom-Kai Phillips, "Promise Utility Doctrine and Compatibility under NAFTA: Expropriation and Chapter 11 Considerations" (2016) 40 Can-U S Law J 84 at 102.

The term 'promise' has been defined as: "a representation contained in a patent specification, whether implicit or explicit, that the patented invention will achieve one or more desirable outcomes, or will avoid one or more undesirable outcomes." [168] Various Canadian cases have held that determining the promise of the patent is an aspect of claim construction and is a question of law.[169] The essential elements for the construction of the promise of a patent are set out below.

1.1.1.2.1. Location of the promise of the patent

In order to determine the promise of a patent, several preliminary questions need to be answered. Given that each patent might include various parts, one question should be: in which part or parts of a patent should we find the promise? There are two approaches to determining the location of a promise in a patent. The first approach requires a focus on the claims made by the patentee. This approach was taken in *Fournier Pharma Inc. v. Canada (Health):*

> … The promise of a patent, as that term is used in patent law, is nothing more than the utility the inventor claims for his invention. Where that promise – that claimed utility – is clearly and unequivocally expressed by the inventor in the claims of the patent, then that expression ought to be viewed as the promise of the patent. Any statement found elsewhere should be presumed to be a mere statement of advantage unless the inventor clearly and unequivocally states that it is part of the promised utility. …
> The interpretation should be focused on the claims because an inventor is not obliged to claim a monopoly on everything new, ingenious, and useful disclosed in the specification… [170]

The second approach to determining the location of a promise requires scrutiny of the patent as a whole.[171] Each patent consists of various elements such as claims, disclosure, abstract

---

[168] Gold & Shortt, *supra* note 8 at 38.
[169] *Apotex Inc v ADIR*, 2009 FCA 222 at para 101, where LAYDEN-STEVENSON J.A. cites *Bristol-Myers Squibb Co. v. Apotex Inc.*, 2007 FCA 379 at para 27; *Eli Lilly Canada Inc. v. Novopharm Limited*, 2010 FCA 197 at para 80.
[170] *Fournier Pharma Inc. v Canada (Health)*, 2012 FC 741 at paras 126—127.

and drawings.[172] In *Apotex v ADIR,* the Federal Court of Appeal held that the patent abstract cannot be taken into account in finding the promise of the patent.[173] The reason for this is that the promise of the patent is an aspect of the claim construction, whereas, based on rule 175 of the *Patent Rules*, an abstract provides technical information, so it cannot be considered for the purpose of claim construction:

> Rule 175(1) of the Patent Rules specifically provides that the abstract cannot be taken into account for the purpose of interpreting the scope of protection sought or obtained. See also: Roger T. Hughes and Dino P. Clarizio, Hughes and Woodley on Patents, 2nd ed., looseleaf (Markham: LexisNexis Canada Inc. 2005) at page 302. Rule 175(2) prescribes the contents of the abstract for the purpose of reference, not to aid construction. The promise of a patent, as noted earlier, is an aspect of claims construction. Apotex does not suggest that the abstract is relevant to claims construction. To the contrary, it accepts that it is not (memorandum of fact and law at paragraph 70). The trial judge did not err in refusing to consider the abstract as a factor in determining the promise of the patent. [174]

Tables of data or isolated statistics and drawings contained in the patent specification have also been rejected as considerations to determine the promise of a patent.[175] For example, in *Eurocopter v. Bell Helicopter,* the judge made an explicit distinction between the promise of the patent and the data upon which the promise is made: "The specification of the '787 Patent' promises cumulative advantages. Some advantages naturally flow from the inherent characteristics of the disclosed inventions. Others may only be verified by testing, which may pose the question of sound prediction. A distinction must be made between the promised advantages and the data upon which it is based." [176]

---

[171] Gold & Shortt, *supra* note 8 at 42.
[172] *Ibid* at 41.
[173] *Apotex Inc. v. ADIR*, *supra* note 169 at 104.
[174] *Ibid* at 105.
[175] Gold & Shortt, *supra* note 8 at 43, 44.
[176] *Eurocopter v Bell Helicopter Textron Canada Limitée*, 2012 FC 113 at para 344. [*Eurocopter]*

The most common tendency in construing the promise of the patent is to consider the patent as a whole: namely, the claims made and the disclosure.[177] As the Federal Court held in *Astrazeneca v. Mylan*, when construing the promise of the patent, the Court must look at the whole of the disclosure as well as the specific language of the claims. It should not be benevolent or harsh, and it should prefer a construction which is reasonable and fair to both the patentee and the public.[178] In the recent case of *Mylan Pharmaceuticals v. AstraZeneca,* the Federal Court of Appeal affirmed that taking a microscopic approach to construing the promise of the patent would be misguided. Rather, it endorsed the approach of construing the patent as a whole:

> I do not agree. In my view, this microscopic approach to the construction of the provisions of a patent is misguided. The fact that such an ordinary word as "provide" is used in sentences containing the claims of the patent does not mean that when used in other sentences, it should be construed as connoting a promise of the patent.
>
> I agree with the Judge that an examination of the patent as a whole supports the conclusion that, unlike the express claims of the patent, the object clause contains no more than a forward-looking aim of the invention. In my view, the fact that side effects are not mentioned elsewhere in the patent is telling. [179]

The approach of looking to the patent specification as a whole in order to locate the promise of a patent could result in a decision-maker finding multiple promises. Further, based on the promise of the patent, failure of fulfilling even one of these multiple promises about utility could invalidate an entire patent.

1.1.1.2.2. The distinction between explicit and implicit promise

[177] Gold & Shortt, *supra* note 8 at 42.
[178] *Astrazeneca Canada Inc v Mylan Pharmaceuticals ULC*, 2011 FC 1023 at para 88.
[179] *Mylan Pharmaceuticals ULC v AstraZeneca Canada Inc.*, 2012 FCA 109 at paras 32— 33.

The second important question to be answered when determining promise is: whether the promise of the patent is just an explicit statement that clearly states the purpose and usefulness of the invention, or whether the court can derive the promise from those phrases and adjectives used to describe the patent? In most Canadian case law relating to promise, the promise of the patent will be explicit because it is found in an explicit, unambiguous statement in the disclosure, such as the following: *"*carboxyalkyldipeptides… are useful as inhibitors of angiotensin-converting enzyme and as anti-hypertensive agents…The compounds of this invention have useful pharmacological properties. They are useful in the treatment of high blood pressure.*"*[180] However, some courts have found implicit promises for patents. In some cases, descriptive phrases of quality used in the application were interpreted as the promise of a patent.[181] For example, in the case of *Ratiopharm Inc. v. Pfizer Limited,* the patentee stated in the specification that the besylate salt of amlodipine has a "unique combination" of four properties making it "particularly suitable" and "outstandingly suitable" for preparation of the pharmaceutical formulation of amlodipine.[182] The Federal Court invalidated the patent because of lack of utility, as the invention failed to fulfill the promised utility that was construed by means of certain descriptive phrases of quality: "… As reviewed in the evidence, it is difficult from the face of the patent and unsupportable from the evidence to state that besylate is sufficiently superior to the other salts, for instance tosylate and mesylate so as to make it 'unique' or 'outstanding' or 'particularly suitable'."[183] Another instance of finding an implicit promise is in certain pharmaceutical patent cases where the clinical effectiveness of a drug was construed as being the promise of the patent; which was derived from phrases such as "the medicine of the invention",

[180] *Aventis Pharma*, *supra* note 8 at para 279.
[181] Cameron, *supra* note 79 at 126—127.
[182] *Ratiopharm Inc. v Pfizer Limited*, 2009 FC 711 at paras 112, 125 [*Ratiopharm*].
[183] *Ibid* at 179.

"effective amounts" of the drug, and the specification of daily dosage regimes in the patent.[184] In another instance of implied promise, the invention was a drug for treating a chronic disease such as attention deficit hyperactivity disorder (ADHD)[185] or glaucoma[186], and the court construed long-term treatment as the promise of the patent.

However, in *Sanofi-Aventis v. Apotex*, the Federal Court of Appeal held that it would not look for any implicit promise. Rather, if the court could find no explicit promise in the patent, then a mere scintilla would suffice to meet the utility requirement. The Court stated that: "[i]f the inventor does not make an explicit promise of a specific result, the test for utility is a 'mere scintilla' of utility. If, on the other hand, the inventor makes an explicit promise of a specific result, then utility will be assessed by reference to the terms of the explicit promise."[187]

The nature and context of an invention can also influence the interpretation of explicit or even implicit promises of a patent.[188] One instance would be pharmaceutical patents claiming treatment for chronic diseases such as glaucoma,[189] ADHD,[190] and schizophrenia.[191] In different decisions, these patents have been interpreted by courts as promising chronic treatment, which means long-term effectiveness. In these cases, the chronic nature of these medicines had an influence on the interpretation of the promises of the patent. Selection patents are another example where the nature of the patent could influence the interpretation of the promise of the

[184] *Apotex Inc. v Sanofi-Aventis*, 2011 FC 1486 at paras 114, 116—18 [*Sanofi-Aventis*]
[185] *Eli Lilly and Company v Teva Canada Limited*, 2011 FCA 220 at paras 18—27.
[186] *Apotex Inc v. Pfizer Canada Inc*, 2011 FCA 236 at 24—28.
[187] *Plavix Impeachment*, *supra* note 153 at 49.
[188] Gold & Shortt, *supra* note 8 at 45.
[189] *Apotex Inc. v. Pfizer Canada Inc.*, *supra* note 186 at 24—31.
[190] *Teva Canada*, *supra* note 185 at 18—27.
[191] *Eli Lilly Canada Inc v Novopharm Limited*, 2011 FC 1288 at paras 230, 232.

patent.[192] This is because a selection patent is a specific class of already patented compound that has been selected for protection because it has new and extra utility. Therefore, these patents can be considered as a class of compounds that have substantial and different advantages, in comparison to the larger class of compounds from which they are sourced.[193]

1.1.1.2.3. Distinction between promise and similar concepts

One must draw a distinction between cases where the patent's claim is based on providing a result and cases where the patentee merely points to certain advantages that could accrue from using the claimed invention. In the first instance, the claimed result is the promise of the patent, and failure to fulfill that promise invalidates the patent, as the patent should not be based on false information.[194] However, in the second instance, the failure to merely fulfill identified advantages is not necessarily fatal to the patent. In fact, the promise in these cases is "material" in the sense that the validity of the patent is based on that.[195] Therefore, in construing the promise of the patent, it is important to make a distinction between the stated promise of the patent and terms such as the 'potential use' or 'goal' of the invention. As mentioned above, in *Plavix Impeachment,* the Federal Court of Appeal concluded that the clinical treatment of a drug could not be considered an implicit promise derived from the phrases of the patent specification. This conclusion was based on the distinction made between the promise of the patent and the potential use of the drug in humans. As the inventor explained, the chemical combination had the potential to be used as a medicine in humans, but the invention did not explicitly promise or

[192] Gold & Shortt, *supra* note 8 at 46—47.
[193] *Apotex Inc v Sanofi-Synthelabo Canada Inc,* 2008 SCC 61 at para 10, [2008] 3 SCR 265 [*Plavix* NOC].
[194] Fox, *supra* note 8 at 152—153.
[195] Fox, *supra* note 23 at 310—311.

guarantee that the medical results would be achieved in humans. Although a person skilled in the art could understand that there would be the potential and possibility of using the invention in humans, the inventor did not promise that result.[196] As the Federal Court held: "I accept AstraZeneca's argument that not all statements of advantage in a patent rise to the level of a promise. A goal is not necessarily a promise. The third paragraph of the 420 Patent refers to a forward-looking goal, a hoped-for advantage of the invention. …"[197] The Federal Court of Appeal then made a distinction between the promise of the patent and 'the object clause' of the patent.[198] The Court construed the object clause as a future aspiration rather than a promise that the patent would provide commercial value or advantage.[199]

1.1.1.2.4. Influence of the person skilled in the art on the construction of promise

Finding and determining the promise of the patent is an act of patent construction. Patents are construed through the eyes of a person of ordinary skill in the art (POSITA) or a skilled reader:

> The promise of the patent must be ascertained. Like claims construction, the promise of the patent is a question of law. Generally, it is an exercise that requires the assistance of expert evidence ... This is because the promise should be properly defined, within the context of the patent as a whole, through the eyes of the POSITA, in relation to the science and information available at the time of filing.[200]

A person skilled in the art has technical skills and knowledge that enable him/her to understand and construe the subject matter of the patent. In other words, this test for utility and finding the promise of the patent is conducted by referencing the understanding and

[196] *Plavix Impeachment*, *supra* note 153 at paras 59—67.
[197] *Ibid* at 67, citing *AstraZeneca Canada Inc. v. Mylan Pharmaceuticals ULC*, *supra* note 178 at para 61.
[198] *AstraZeneca Canada Inc. v. Mylan Pharmaceuticals ULC*, *supra* note 178.
[199] Perry, Currier & Hughes, *supra* note 1 at 143.
[200] *Eli Lilly Canada v Novopharm*, *supra* note 169 at para 80.

interpretation of the skilled person. This determination is on available facts, knowledge, experience and the professional identity of the skilled person. The impact of the skilled person for determining the promise of a patent is particularly significant in pharmaceutical patents. Where the skilled reader of a pharmaceutical patent is a practicing physician or psychiatrist, it is more common to find therapeutic and clinical effectiveness as the promise of the patent.[201] This tendency can be explained by the fact that, for practitioners, a drug can be considered useful only when it can treat a claimed disorder or disease. Or, to put it another way, that it has a therapeutically useful effect in humans.[202] A practicing physician or psychiatrist's expectation of a useful medicine is different from a pharmaceutical formulator's expectation of the same medicine, and this difference affects the scope of the promise of a patent.

In the case of *Eli Lilly & Company v. Teva Canada Limited,* the skilled readers were psychiatrists and pediatricians. They interpreted the words "treatment of ADHD" in the patent specification to mean that the promise of the claimed drug would be treatment of the abovementioned disorder in human patients. In this case, the professional background of the skilled persons had a significant impact on their interpretation of the promise of the patent. The court explained the expectation of a medical practitioner from the claimed drug as:

> … this definition of the qualifications of the POSITA relevant to this patent, and especially the inclusion of a psychiatrist and a paediatrician, indicates that he or she would interpret the promise from the perspective of a person involved in the clinical treatment of ADHD. A POSITA would thus understand the promise to mean that atomoxetine will alleviate the symptoms of the disorder in some patients to a clinically meaningful extent. This is not to say that the promise means that clinicians will necessarily prescribe atomoxetine for their patients, because there may be more effective medicines available on the market. The promise does mean, however, that atomoxetine would be regarded by a physician as a realistic option for the treatment of ADHD. [203]

---

[201] Gold & Shortt, *supra* note 8 at 44—45.
[202] *Ibid* at 44.
[203] *Teva Canada*, *supra* note 185 at 23.

However, in *Plavix Impeachment,* the Federal Court of Appeal concluded that the trial judge's decision was incorrect because it had relied on the interpretation of a clinical hematologist, who found therapeutic effectiveness in humans to be the promise of the patent. In this case, other skilled readers were pharmaceutical formulators (chemist, toxicologist and a pharmacologist) who did not find therapeutic effectiveness to be the promise of the patent.[204] Unlike the general trend in the cases, the Court in *Plavix Impeachment* did not accord primacy to the clinical skilled readers; rather it accepted the interpretation of the pharmaceutical formulators. This case indicates that there is an ambiguity in Canadian patent law in cases where there are multiple skilled readers —particularly clinical and pharmacological experts— whose interpretations of the promise of a patent conflict.[205] It is therefore difficult to determine how and why courts should accord primacy to interpretations that differ based on the professional background of skilled readers.

1.1.1.2.5. Patents with multiple promises

Given that finding the promise of a patent is an act of construction by the skilled person, it is possible to find more than one promise in a patent. The multi-promise patent happens when the subject matter covered by a single claim is subject to more than one promise. This situation is referred to as the 'true situation of multi-promise patents'.[206] For example, in the case of *Allergan Inc. c. Canada (Health)*, the Federal Court found seven promises in the pharmaceutical patent:

---

[204] *Plavix Impeachment*, *supra* note 153 at 55—63.
[205] Gold & Shortt, *supra* note 8 at 75—76.
[206] *Ibid* at 74—75.

> … what advantages the formulation is promising to deliver:
> ▪ the combination product in a single dose improves patient compliance
> ▪ it contains brimonidine and timolol
> ▪ which is effective
> ▪ is safe
> ▪ has increased stability
> ▪ requires lower effective concentration of preservative than separate doses of each; and
> ▪ has increased efficacy without increased concentration of brimonidine or timolol.[207]

The true situation of multiple promises must be distinguished from the false situation, in which different promises apply to different claims in the patent and there is no single claim that is subject to the multiple promises. For example, when a patent consists of a process claim and a product claim, the different claims will necessitate different promises.[208]

When multi-promise patents cannot fulfill all of their promises but can fulfill some of the promises, the question arises as to whether they meet the utility requirement or whether they are void because of a lack of utility. There are two different approaches to multi-promise patents in legal systems. According to the first approach, if the patent fulfills some of its promises, it meets the utility requirement and, therefore, the patent could not be invalidated because of its lack of utility. This approach is taken in US law, which does not require the patent to fulfill all of its promises. Rather, the fulfillment of only one of its promises is counted as utility.[209] As a general rule, the invention must have only *a* credible, specific and substantial use to meet the utility requirement of 35 U.S.C. §110.[210] Conversely, based on the traditional British approach, a patent that does not fulfill *all* of its promises is void because of lack of utility.[211] This approach is

---

[207] *Allergan Inc. c Canada (Health)*, 2012 FC 767 at para 114.
[208] Gold & Shortt, *supra* note 8 at 74—75.
[209] *Ibid* at 70,74—75.
[210] John R Thomas, *Pharmaceutical patent law* (Arlington, VA: BNA Books, 2010) at 91—92.
[211] Gold & Shortt, *supra* note 8 at 47.

stricter than the US approach, as it considers patents that fulfill one or more useful results equal to patents that are totally useless. Consequently, under British approach, patents that do not fulfill *all* of their promises are considered void. In Canada, because there is no law limiting patents to single promise, there are cases where the courts have found multiple promises in a single patent.[212] Because there is not yet any precedent in Canadian jurisprudence on the issue of multi-promise patents that cannot fulfill all of its promises, the Canadian approach to this issue is less clear than the US and British approaches.[213] Helpfully, the Canadian Intellectual Property Office has affirmed the traditional British approach: "… Although an invention need only have one use in order to be patentable, where several uses are promised the applicant must be in a position to establish each of them. For example, if a composition is promised to be useful as a drug, the applicant must be in a position to show that it is useful in the therapy of at least one disease. …"[214] Given the lack of judicial authority on this question, however, it seems that one unanswered question in contemporary Canadian patent law is determining the right approach to multi-promise patents that cannot fulfill all of their promises.

1.1.1.3. The current controversy of 'promise' in pharmaceutical patents

The recurring matter of identifying the 'promise' in patent case law since 2008,[215] mostly in pharmaceutical patents, has made this doctrine the most controversial issue in contemporary Canadian patent law.[216] Indeed, over the last ten years, the promissory approach to construing the usefulness of patents has increasingly dominated Canadian patent jurisprudence (notably in

[212] *Ibid*.
[213] *Ibid*.
[214] MPOP, *supra* note 77 at art 12.08.01.
[215] Perry, Currier & Hughes, *supra* note 1 at 141.
[216] Gold & Shortt, *supra* note 8 at 37.

pharmaceutical cases). The prevalence of the promissory approach can be partly explained by the new generation of pharmaceutical patents that are being seen in Canadian cases. Pharmaceutical inventions form an essential part of Canadian innovations and patents. In recent decades, inventors have presented a different, new generation of pharmaceutical and chemical patents. This new patent generation includes inventions such as new uses for known compounds,[217] and selection patents that promise a substantial advantage of a specific selection of compounds over an already patented and larger class of compounds.[218] These patents are attempts of pharmaceutical inventors to extend their monopolies on their patented compounds in the market. In applications for these new patents, applicants are required to specifically describe the usefulness of the invention to indicate that their new invention has a new or extra usefulness that goes above and beyond the already patented compound. This usefulness must be clearly promised in the patent.[219] The rise of these kinds of patents could therefore be interpreted as one reason for the trend in Canadian case law to prefer the promissory approach to pharmaceutical patents.

The result of this trend is the invalidation of various patents because of their failure to obtain the claimed promise. This outcome has led the patent promise doctrine, or the promise of the patent, to be challenged both in theory and in practice.[220] In practice, the doctrine has been attacked before the Supreme Court of Canada and, recently, before a NAFTA tribunal.[221] In the arbitration case of *Eli Lilly v Canada*, the claimant submitted a notice of arbitration asserting that

---

[217] See examples: *Apotex v Wellcome Foundation*, *supra* note 9.; *Allergan Inc. v Minister of Health*, 2011 FC 1316.
[218] See examples: *Plavix NOC*, *supra* note 193; *Plavix Impeachment*, *supra* note 153; *Glaxosmithkline Inc. v Pharmascience Inc.*, 2008 FC 593; *Eli Lilly Canada Inc. v. Novopharm Limited*, *supra* note 191.
[219] Gold & Shortt, *supra* note 8 at 39—40.
[220] *Ibid* at 37.
[221] *Eli Lilly and Company v. The Government of Canada*, *supra* note 1.

the invalidation of its Canadian patents for Strattera and Zyprexa was inconsistent with NAFTA. Canadian courts invalidated these two patents on the ground that they did not meet the utility requirement under Canadian patent law. Strattera is used to treat attention-deficit hyperactivity disorder (ADHD) but the limited and short-term study presented by the patentee was insufficient to predict that Strattera would be an effective long-term treatment for ADHD as a chronic disorder. The antipsychotic drug Zyprexa (olanzapine) is used to treat schizophrenia and related psychotic disorders. The Zyprexa patent applied to a selection patent of specific compounds that had already been patented. The Zyprexa patent promised that olanzapine is substantially more effective in the clinical treatment of schizophrenia than other known antipsychotics, has a better side-effects profile than other drugs, and was highly effective at low doses. However, the Federal Court of Appeal found that the clinical studies done had been insufficient to demonstrate these promises. On this basis, the Supreme Court found that Zyprexa could not meet the promises made at the time of filing the patent.

In this arbitration case, the criticism raised against the promise of the patent included these three arguments:

(i) there is a dramatic change in the Canadian utility requirement that violates the legitimate expectation of investors;[222]

(ii) the promise of the patent is a new utility requirement that is inconsistent with relevant international treaties and practices;[223] and

(iii) the promise doctrine has an arbitrary and discriminatory nature.[224]

However, as discussed above, Canadian patent law has taken a promissory approach to patent utility since such early decisions as *Wandscheer v Sicard* in 1947. Therefore, it would be wrong to assume, from recent pharmaceutical patent cases, that reliance on this promissory doctrine is new, arbitrary and discriminatory to pharmaceuticals. As the NAFTA tribunal recently decided on Eli Lilly's claims about discriminatory nature of the promise of the patent:

> … the Tribunal concludes that Claimant has not proven its allegation that the promise utility doctrine discriminates against pharmaceutical patents. Even if the Tribunal were to accept Claimant's position regarding the legal standards applicable, i.e., that a measure is discriminatory where there is (i) "any differential treatment of a foreign investor. . . based on unreasonable distinctions and demands", and (ii) "facially neutral measures that in practice produce differentially disadvantageous effects on a particular field of technology", Claimant would not succeed in its allegation of discrimination.[225]

Applying the above reasoning more generally, it would seem that continued application of the patent promise doctrine is not a dramatic change in the Canadian approach to patent utility,[226] and that the patent promise doctrine is not arbitrary or discriminatory. In addition, the Tribunal accepted that the Canadian courts' application of the patent promise doctrine was justified by a legitimate public policy interest: as the doctrine helps to ensure the principle of the patent

[222] *Ibid* at para 269.
[223] *Ibid*.
[224] *Ibid* at paras 389— 400.
[225] *Ibid* at para 439.
[226] *Ibid* at paras 308—309.

bargain and to encourage accuracy while discouraging overstatement in patent disclosures. As such, the Tribunal concluded that the patent promise doctrine is rationally connected to legitimate policy goals.[227]

However, on June 30, 2017, the Supreme Court of Canada, in the case *AstraZeneca Canada Inc. v. Apotex Inc.,*[228] decided that the patent promise doctrine "is not a good law"[229] as it is "incongruent with both the words and the scheme of the *Patent Act*."[230] The case concerned AstraZeneca's Canadian Patent No. 2,139,653 (the 653 patent) for esomeprazole (NEXIUM) used to reduce acid reflux in the treatment of gastrointestinal disorders. NEXIUM consisted of one half of the previous drug composition, Prilosec,[231] and the patentee had to prove that NEXIUM is better than the previous compound at treating acid reflux.

In applying the patent promise doctrine, the Federal Court of Appeal held that the NEXIUM patent was invalid because the invention could not fulfill its promises at the filing date.[232] The Court identified two promises in the NEXIUM patent specification: (1) the use of esomeprazole as a proton pump inhibitor, and (2) an improved therapeutic profile based on enhanced pharmacokinetic and metabolic properties over Prilosec.[233] The Federal Court of Appeal accepted that it was soundly predicted by the filing date that the optically pure salts of the enantiomer of omeprazole would be useful as a proton pump inhibitor to reduce production

---

[227] *Ibid* at para 423.
[228] *AstraZeneca Canada Inc. v. Apotex Inc.*, *supra* note 3.
[229] *Ibid* at para 51.
[230] *Ibid* at para 36.
[231] Richard Gold, "Supreme Court harms Canada's innovation policy stand ahead of NAFTA negotiations", (2 July 2017), online: *Globe Mail* <https://www.theglobeandmail.com/report-on-business/rob-commentary/supreme-court-harms-canadas-innovation-policy-stand-ahead-of-nafta-negotiations/article35532093/>.
[232] *Astrazeneca Canada Inc v Apotex Inc*, 2015 FCA 158.
[233] *Ibid* at paras 7—8.

of gastric acid;[234] however, the Federal Court ultimately found that the patent failed for lack of utility because the improved therapeutic profile of the NEXIUM over Prilosec was not demonstrated or soundly predicted at the filing date.

The Supreme Court of Canada overturned the decision of the Federal Court of Appeal and found the patent to be valid. According to the Supreme Court's decision, the promise doctrine "is not a good law"[235] because the doctrine inappropriately imports the disclosure requirement under section 27(3) of the *Patent Act* into the utility requirement under section 2 by requiring that any disclosed use be demonstrated or soundly predicted at the time of filing.[236] According to the Supreme Court, the promise doctrine conflates the utility requirement which is a "condition precedent to an invention" and the disclosure requirement.[237] In addition, the promise doctrine improperly requires that every promised use of an invention must be demonstrated or soundly predicted at the filing date, otherwise the entire patent would be invalidated. The Supreme Court reasoned that holding that the entire patent would be invalidated if any one of the promises in the patent was not fulfilled would have the effect of discouraging patentees from fully disclosing the utility of an invention. On this basis, the Court held that the promise doctrine is inconsistent with patent bargain theory and the purpose of section 27(3).[238]

The correct approach to the utility analysis, as set out by the Supreme Court, is to identify the subject matter of the invention as claimed in the patent, and then ask whether that subject matter is useful or capable of a practical purpose.[239] The analysis of the Supreme Court is

---

[234] *AstraZeneca Canada Inc. v. Apotex Inc.*, *supra* note 3 at 62.
[235] *Ibid* at para 51.
[236] *Ibid* at para 44.
[237] *Ibid* at para 43.
[238] *Ibid* at para 51.
[239] *Ibid* at para 54.

focused on the legislative origin of the utility requirement under section 2 of the *Patent Act* [240] and the relation of this section with other sections of the Act; specifically section 27(3). By reasoning that the *Patent Act* does not prescribe the degree or quantum of usefulness required, the Supreme Court concluded that "a single use related to the nature of the subject-matter"[241] of the invention having a scintilla of utility is sufficient to demonstrate utility.

In the period from March 17 to June 30, 2017, two important court decisions were handed down that addressed the promise doctrine. In fact, the Supreme Court of Canada and the arbitration tribunal reached completely contrary conclusions, although both referred to the patent bargain theory and disclosure requirement as the reasoning that underpinned their decisions. Furthermore, according to Prof. Richard Gold, the Supreme Court's ruling would increase confusion and introduce more challenges for interpretation and application of the patent utility standard,[242] given that, based on the ruling, there is now a wide gap between the Court's new approach to the patent utility and the promissory approach. According to this ruling, patentees would not be bound by their statements at the filing date, which would make it relatively straightforward to obtain monopolies. The flexibility apparent in the new approach to patent utility taken in Canada is contrasted to the strict doctrines or rules equivalent to the promise of the patent in countries such as the USA, that bind patentees to their statements made in the patent specification. Indeed, as Richard Gold argues, on the basis of the Supreme Court's new ruling, there could be inventions that are void in the US because of the lack of utility, but which are still

[240] "Canada's Supreme Court Abolishes Controversial 'Promise Doctrine'", (30 June 2017), *PCK,* online: *PCK* <http://www.pckip.com/patent/promise-doctrine-abolished-one-use-mere-scintilla-utility-will-satisfy-utility-requirement>.
[241] *AstraZeneca Canada Inc. v. Apotex Inc.*, *supra* note 3 at para 55.
[242] Cristin Schmitz, "Updated: SCC revamps patent utility standard by scrapping 'promise doctrine'", (30 June 2017), online: *The Lawyers Daily* <https://www.thelawyersdaily.ca>.

patentable in Canada.[243] Chapter III will elaborate on the current challenges of the utility requirement, the reasons for these challenges, and suggest practical solutions for resolving them.

1.1.2. A mere scintilla of utility

The other element of demonstrated utility is "a mere scintilla of utility". The term "scintilla" was first used in the phrase "scintilla of invention", which referred to the minimum quantum of the inventiveness or non-obviousness of a patent.[244] The term "mere scintilla of utility" has appeared in Canadian case laws, since *Aventis Pharma v. Apotex,* citing Harold G Fox *Canadian Law and Practice Relating to Letters Patent for Inventions*, 4th edition. [245] According to Fox, who seems to be the first to commentator use the term "scintilla of utility", there is a distinction between patent specifications that promise a result and specifications that contain no promise of results. Where the patent contains no promise of a result, a mere scintilla of utility is sufficient for validity of the patent. That is, in this situation, no particular quantum of utility is required.[246] This criterion could also be interpreted as requiring that the invention produces some minimally useful result.[247] In other words, the patent would be issued only for useful inventions that demonstrated "a mere scintilla" of usefulness. However, if the patent promises a specific result, the invention would not be considered useful, even if it has a minimal level of usefulness, unless it fulfills this promised result.

As mentioned above at heading 1.1.1.2.2, the Federal Court of Appeal in the *Plavix Impeachment* case avoided recognizing implicit promises. Rather, it affirmed that, where a patent

---

[243] Josh Wingrove, "'Bombshell' Canadian Patent Ruling Seen Favoring Foreign Companies", *Bloomberg* (30 June 2017), online: <https://www.bloomberg.com>.

[244] AstraZeneca Canada Inc., et al. v. Apotex Inc., et al., 2016 SCC 36654 (Factum of The Intervener Centre For Intellectual Property Policy at para 25), online: <https://www.mcgill.ca/law/files/law/2016-richard-gold-36654-cipp-factum.pdf>.

[245] *Aventis Pharma*, *supra* note 8, citing Fox, *supra* note 8 at 153.

[246] Fox, *supra* note 8 at 153.

[247] Gold & Shortt, *supra* note 8 at 52.

contains no explicit promise, "a mere scintilla" of utility would suffice to meet the utility requirement: "… if a person skilled in the art would understand it to contain an explicit promise that the invention will achieve a specific result. If so, the inventor will be held to that promise. If there is no explicit promise of a specific result, then a mere scintilla of utility will do."[248]

The issue that the term "scintilla of utility" raises is about the quantum of the usefulness of a patentable invention. However, the term "the promise of the patent" investigates what usefulness an invention must have, rather than quantum of usefulness. This difference between how the two concepts measure usefulness indicates that mere "scintilla of utility" and "the promise of the patent" should not be conflated.[249]

In recent years, most patent utility law decisions have been based on the patent promise doctrine, and the scintilla of utility standard has been avoided.[250] In addition, the CIPO Manual of Patent Office Practice does not speak about a scintilla of utility standard. Rather, it speaks about the promise of the patent and self-evident utility.[251] Given this trend, it is unclear whether the scintilla of utility has continued relevance in patent law. The status of the scintilla of utility standard is more unclear in pharmaceutical and chemical patents, as the utility of these compounds are not self-evident, which means that inventors must disclose the utility in specification. In this situation, courts tend to interpret the disclosure as the promise of the patent, and thus expect the compound to fulfill the promise.[252]

1.2. Soundly predicted utility

[248] *Plavix Impeachment*, *supra* note 153 at para 50.
[249] AstraZeneca Canada v. Apotex, *Supra* note 244 at para 26.
[250] Gold & Shortt, *supra* note 8 at 74.
[251] MPOP, *supra* note 77 at 12.08.01.
[252] Gold & Shortt, *supra* note 8 at 74.

1.2.1. Introduction and background

As discussed at heading 1.1, in Canadian patent law, applicants are not required to establish the utility of inventions in the patent specification. If the inventor is not able to demonstrate the utility of an invention at the time of their patent application, the utility must be soundly predictable by a person skilled in the art. Therefore, "the doctrine of sound prediction allows the inventor to meet the utility requirement at the time of filing date which is the date of demonstrated utility."[253]

In some cases, it is difficult for inventors to establish the utility of the invention at the filing date, especially when the invention needs to go through more tests and experiments. This situation frequently arises in pharmaceutical and chemical compounds patent applications.[254] For example, a pharmaceutical invention might claim classes of compounds, but at the filing date, the inventor has not tested all compounds for their properties because of considerations of expense and time.[255] In the case of *Apotex v. Wellcome Foundation Ltd,* [256] the validity of a pharmaceutical patent covering the new use of the known drug AZT to treat HIV/AIDS[257] was soundly predicted based on the evidence provided. In Canada, the sound prediction doctrine is not limited to pharmaceutical patents. In 2013, the doctrine was applied to mechanical patents in the case of *Eurocopter v. Bell Helicopter Textron Canada Limitée* [258] where no calculations supporting a sound line of reasoning were made available.[259]

---

[253] Elizabeth F Judge & Daniel J Gervais, *Intellectual property: the law in Canada* (Toronto: Carswell, 2011) at 727.
[254] Cameron, *supra* note 79 at 146.
[255] Perry, Currier & Hughes, *supra* note 1 at 135.
[256] *Apotex v Wellcome Foundation, supra* note 9.
[257] Cameron, *supra* note 79 at 146.
[258] *Bell Helicopter*, *supra* note 9 at paras 152—155.
[259] Perry, Currier & Hughes, *supra* note 1 at 135.

The sound prediction doctrine has its roots in the "fairly basis" doctrine in British patent law. The historical roots of the "fairly basis" doctrine can be found in the comment of Lord MacDermott in the case *May & Baker Ltd. V. Boots Pure Drug Co. (1950).*[260] *Monsanto Co. v. Canada (Commissioner of patents)*, decided in 1979, was the first case where the doctrine of sound prediction was explicitly received into the Canadian legal system. [261]

The doctrine of sound prediction aims to strike a balance between public benefits and inventor's rights. Based on this doctrine, inventions that provide convincing evidence for prediction of utility will be granted a patent, despite the fact that they need more tests. In *Apotex v. Wellcome*, the Supreme Court of Canada considered patent bargain to be the fundamental basis of the doctrine:[262]

> A patent, as has been said many times, is not intended as an accolade or civic award for ingenuity. It is a method by which inventive solutions to practical problems are coaxed into the public domain by the promise of a limited monopoly for a limited time. Disclosure is the quid pro quo for valuable proprietary rights to exclusivity which are entirely the statutory creature of the Patent Act. Monopolies are associated in the public mind with higher prices. The public should not be expected to pay an elevated price in exchange for speculation, or for the statement of "any mere scientific principle or abstract theorem" (s. 27(3)), or for the "discovery" of things that already exist, or are obvious. The patent monopoly should be purchased with the hard coinage of new, ingenious, useful and unobvious disclosures. … [263]

The sound prediction doctrine has two fundamental parts: prediction and soundness. As stated in *Monsanto Co. v. Canada,* [264] and then recently repeated by Justice Snider in *Laboratoires Servier Canada Inc. v. Apotex Inc.,* [265] for soundly predicted utility, the prediction does not need to amount to certainty. As it is a prediction, there is always the risk of proving that

---

[260] *Apotex v Wellcome Foundation*, *supra* note 9 at 59.
[261] *Ibid at para 61*.
[262] Perry, Currier & Hughes, *supra* note 1 at 137.
[263] *Apotex v Wellcome Foundation*, *supra* note 9 at 33.
[264] Perry, Currier & Hughes, *supra* note 1 at 137.
[265] *Laboratoires Servier*, *supra* note 148 at 348.

the claimed invention lacks utility. In other words if, after the grant of the patent, it is shown that the prediction was unsound or the prediction was sound at filing date but later shown to be incorrect, the granted patent will be invalid because of lack of utility.[266] Mere speculation is not sufficient to be considered a "sound" prediction.[267] The question of whether the prediction is sound or not is a question of fact or a mixed question of fact and law.[268] Therefore, the evaluation depends on evidence and the characteristics of each case. The doctrine of sound prediction consists of a three-part test to ensure that the granting of monopolies is not in exchange for mere speculation or misinformation.

1.2.2. The three-part test

In *Apotex v. Wellcome*, the Supreme Court devised a three-part test to evaluate the validity of soundly predicted utility: "The doctrine of sound prediction has three components. Firstly, as here, there must be a factual basis for the prediction. … Secondly, the inventor must have at the date of the patent application an articulable and "sound" line of reasoning from which the desired result can be inferred from the factual basis. … Thirdly, there must be proper disclosure. ..."[269]

1.2.2.1. A factual basis for prediction

The inventor must provide, through the patent specification, the logical basis for sound prediction of utility. The factual basis will be different in each case – depending on the nature

[266] Barry B Sookman, Steven Mason & Daniel Glover, *Intellectual property law in Canada: cases and commmentary* (Toronto: Carswell, 2013) at 378.
[267] Perry, Currier & Hughes, *supra* note 1 at 138.
[268] Cameron, *supra* note 79 at 148.
[269] *Apotex v Wellcome Foundation*, *supra* note 9 at 70.

and features of the invention – and there is not an exhaustive list of features to take into account. According to the Canadian Intellectual Property Office, the evaluation of factual basis for sound prediction must be conducted on a case-by-case basis and could rely on such factors as:

> (i) the scope of the claims;
> (ii) the state of the art;
> (iii) the nature of the invention and its predictability; and
> (iv) the extent to which the applicant has explored the area claimed, for example by conducting experiments which provide factual support for the utility asserted. [270]

In order to predict the utility of pharmaceutical and chemical inventions' utility, the skilled person might also expect the relevant factual bases to vary from case to case, depending on consideration of the CIPO factors (above) and other factors, such as *in vivo* and *in vitro* tests. In the case of *Apotex Inc. v. Wellcome* case, [271] the Court concluded that, for predicting the utility of pharmaceutical inventions, there is no need to disclose proof in the form of human trials to show the claimed drug is non-toxic in humans. [272] The Court explained its conclusion by noting the sound prediction doctrine requires that, as a prerequisite, the inventor needs to do further work and tests.

1.2.2.2. A sound line of reasoning

Generally, an inventor is expected to disclose how an invention works in the patent specification, but s/he does not need to explain how it is useful and why it works. However, the doctrine of sound prediction is an exception to this general rule.[273] The sound prediction doctrine requires the articulation of a sound line of reasoning in order to be satisfied. As the Court stated in *Apotex v. Wellcome*: "… It is generally not necessary for an inventor to provide a theory of

[270] MPOP, *supra* note 77 at 12.08.04a.
[271] *Apotex v Wellcome Foundation*, *supra* note 9 at 77.
[272] Perry, Currier & Hughes, *supra* note 1 at 139.
[273] Judge & Gervais, *supra* note 253 at 724.

why the invention works. Practical readers merely want to know that it does work and how to work it. In this sort of case, however, the sound prediction is to some extent the quid pro quo the applicant offers in exchange for the patent monopoly. …" [274]

The types of sound lines of reasoning vary depending on the nature of inventions, which means there cannot be exhaustive guidance on the types of "sound" reasoning.[275] For instance, in the *Monsanto* case, the "architecture of chemical compounds"[276] was considered as the sound line of reasoning from which to derive the utility of untested chemical compounds from the three tested chemical compounds. [277] In *Apotex v. Wellcome*, the invention was the new use and efficacy of AZT as a known compound, in the treatment of HIV/AIDS. The "chain terminator effect" of AZT, relying on *in vitro* tests and mouse tests of AZT, convinced the person skilled in the art to soundly predict the efficacy of AZT against HIV:

> On March 1, 1985, Glaxo/Wellcome received from the NIH the key results of the in vitro test of AZT against the HIV in a human cell line. This, taken together with Glaxo/Wellcome's own data on AZT, including the mouse tests, provided a factual foundation. **Glaxo/Wellcome's knowledge of the mechanism by which a retrovirus reproduces, and the "chain terminator effect" of AZT, as disclosed in the patent, was found by the trial judge to provide a line of reasoning** by which utility could be established as of the date of the U.K. patent application, March 16, 1985, which is also the priority date by which the invention must be evaluated for purposes of the Canadian patent. Although "sound prediction" was not the precise approach followed by the trial judge, his reasoning as well as his ultimate ruling is entirely consistent with its application. [emphasis added] [278]

As the cases above suggest, a person skilled in the art would assess the soundness of the line of reasoning. As stated in *Bell Helicopter*: "… The soundness of a line of reasoning can also be effectively assessed by asking whether the skilled person would accept the logic presented in

---

[274] *Apotex v Wellcome Foundation*, *supra* note 9 at 70.
[275] MPOP, *supra* note 77 at 12.08.04b.
[276] *Apotex v Wellcome Foundation*, *supra* note 9 at 70.
[277] *Ibid* at 61.
[278] *Ibid* at 72.

the specification and derive from the sound prediction as a whole an expectation that the invention will provide the promised utility."[279] However, in practice, the successful inventor is one who has convinced the skilled person to accept the logic presented in the patent specification.

1.2.2.3. Proper disclosure

The last requirement of the sound prediction doctrine is the proper disclosure of two other requirements, namely factual basis and the line of reasoning that runs through the specification at the filing date. In the sound prediction doctrine, the proper disclosure is a disclosure that has the following features:

- It is present at the patent filing date;
- The disclosure is made through the patent specification, as the Canadian Intellectual Property Office indicates: "…The requirement for proper disclosure means that the person skilled in the art has to, through the specification alone, be provided with sufficient information to understand the basis of the sound prediction and to practice the entire scope of the claimed invention. …". [280]
- It enables the person skilled in the art to understand the factual basis and derive the soundly predicted utility from that basis, and to practice the claimed invention as it has been disclosed, as noted in *Apotex Inc. v Wellcome*: "… Normally, it is sufficient if the specification provides a full, clear and exact description of the nature of the invention and the manner in which it can be practised: H. G. Fox, The Canadian Law and Practice Relating to Letters Patent for Inventions (4th ed. 1969), at p. 167. …" [281]

[279] *Bell Helicopter*, *supra* note 9 at 154.
[280] MPOP, *supra* note 77 at 12.08.04c.
[281] *Apotex v Wellcome Foundation*, *supra* note 9 at 70.

Through making a proper disclosure, the inventor can fulfill his side of the patent bargain with the public, and obtain a monopoly upon a patent that he has disclosed. [282]

There is an exception to the requirement of proper disclosure in the form of the sound prediction doctrine. When the factual basis or sound line of reasoning forms part of common general knowledge – for example, scientifically accepted facts, laws or principles – these facts are not required to be disclosed.[283] The reason is that the assessment of the factual basis, the line of reasoning and the level of the disclosure, all rely on knowledge that the skilled person would have to soundly predict the utility.[284] On this basis, the proper disclosure will be assessed with reference to the relevant knowledge of the skilled person. To put it another way: the elements that are self-evident to a person skilled in the art in the light of common general knowledge, are not required to be disclosed.[285]As stated in *Eurocopter v. Bell Helicopter:*

> Where the factual basis can be found in scientifically accepted laws or principles or in information forming part of the common general knowledge of the skilled person, then no disclosure of such factual basis may be required in the specification. On the other hand, where the factual basis is reliant on data which does not form part of the common general knowledge, then disclosure in the specification may indeed be required to support a sound prediction. [286]

In the case of *Eli Lilly v. Apotex*, the court concluded that, where a particular study is the factual basis for sound prediction of utility, that study must be disclosed in the patent specification at filing date:

> … the appellant at the hearing accepted for purposes of the appeal the conclusion reached by the Federal Court Judge at paragraphs 155 and 156 of his reasons that the Hong Kong study was required in order to turn the prediction on which the '356 Patent was predicated into a sound one. According to the Federal Court Judge, the

[282] *Ibid* at 3.
[283] MPOP, *supra* note 77 at 12.08.04c.
[284] *Bell Helicopter*, *supra* note 9 at 152.
[285] *Ibid* at 154.
[286] *Ibid* at 153.

> Hong Kong abstract of the study conducted by the appellant on 251 post-menopausal women which concluded that "raloxifene show[ed] promise as a skeletal anti-resorptive" would have been a sufficient factual basis upon which a sound prediction of utility for raloxifene could have been made as of the filing date. However, this study was not disclosed in the '356 Patent with the result that the underlying factual basis for the prediction and the sound line of reasoning that grounded the inventors' prediction were not disclosed.[287]

Recently, arguments have been made that the sound prediction doctrine is inconsistent with patent international and regional rules,[288] as it places an additional burden on patent applicants to disclose the factual basis and a line of reasoning for the invention at the filing date.[289] In addition, Siebrasse argues that the requirement that the evidence supporting utility – namely the factual basis for a sound prediction of utility – must be disclosed, is unsound in terms of both law and policy, and can discourage innovation in the pharmaceutical industry. [290] However, the requirement to disclose an invention is not specific to the sound prediction doctrine. In Canada, the sufficient disclosure of patent is an essential requirement under Section 27(3) of the *Patent Act*. This section requires the applicant to disclose the invention in the patent specification. The disclosure should describe the invention in such detail and clear terms so as to enable a skilled person to practice the invention and achieve the desired utility.[291] In addition, various patent laws aim to address the important public interest to prevent speculative patents. Different patent laws all have diverse methods to achieve the same policy: whereas Canada uses the promise of the patent and sound prediction doctrine, the United States use enablement, and written description

---

[287] *Eli Lilly Canada Inc. v Apotex Inc,2009 FCA 97* at para 12, *78 CPR (4th) 388*.
[288] *Ibid*.
[289] Jay A Erstling, Amy M Salmela & Justin N Woo, "Usefulness Varies by Country: The Utility Requirement of Patent Law in the United States, Europe and Canada" (2012) 3 Cybaris Intellect Prop Law Rev 1 at 18.
[290] Norman Siebrasse, "Must the Factual Basis for Sound Prediction Be Disclosed in the Patent?" (2012) 28:1 CIPR 1.
[291] Phillips, *supra* note 167 at 93.

doctrines as disclosure requirements, as set out in chapter I of this thesis. However, all of these different methods and doctrines are designed to achieve the same result: preventing the regulation of speculative patents.[292]

2. Essential policies served by applying the approaches of Canadian law to patent utility

One purpose of granting patent monopolies is to reward inventors; however, there are other, arguably more important goals for granting patent exclusivity. These goals include enforcing policies such as ensuring public benefit, preventing double patenting, controlling overreaching claims and ensuring innovation and the development of new technologies. The notion of utility, as one of the main criteria for patentability, aims to ensure the achievement of these goals and policies. This section analyzes the expected roles of the notion of utility and judicial approaches to this notion that help to achieve and maintain these essential policies in the Canadian patent system.

2.1. The notion of utility as a mechanism to ensure public benefit

One of the first goals for granting a patent and its monopolies is ensuring there is a public benefit. Granting patent has an important connection with public benefit because issuing a patent means granting twenty-year monopolies and exclusivities to the patentee. In some cases, particularly pharmaceutical patents, granting patent exclusivities and monopolies could block further valuable research by other innovators on the patented subject matter.[293] Further, granting a patent prematurely could impede subsequent researchers and innovators from developing the patented speculation to "the point where it delivers a real benefit to the public."[294] Therefore, it is

[292] *Ibid* at 103—104.
[293] *Brenner v. Manson, supra* note 61 at 534─35.
[294] Siebrasse, *supra* note 106 at 37.

crucial to ensure that there would be a useful result in exchange for patent monopolies. The notion of utility is the patentability criterion that works as a mechanism to ensure public benefit. The notion of utility ensures public benefit by application of the criteria and doctrines in the Canadian system that have been discussed in this chapter. First, the utility requirement ensures that no patent will be granted unless the invention has minimum usefulness. This requirement ensures public benefit through the doctrine of a mere scintilla of utility that requires all applied inventions to have at least minimal usefulness. Second, the notion of utility, through the promise of the patent, ensures that the public is provided with a specific and presently available benefit in exchange for twenty-year monopolies of a patent. The utility requirement, particularly the promise of the patent, discourages the granting of patents for mere ideas, speculative inventions, or misinformation by requiring the fulfillment of the promise that was made in the specification.[295]

2.2. The notion of utility as a mechanism to prevent double patenting

As mentioned at heading 1.1.1.3 above, the recent decades have seen a new generation of patents developed, such as selection patents and a new use for already-patented inventions. These patents can be seen as attempts by patentees, mostly pharmaceutical companies, to extend their monopolies over twenty years. In some cases, these attempts are "double patenting" which is considered as an artificial extension of the patent exclusivity. This phenomenon occurs when "the patent claims an invention which was previously in an earlier patent by the same applicant."[296] Double patenting is interpreted as an abuse of patent because it contravenes the

[295] Gold & Shortt, *supra* note 8 at 39—40

[296] Adrian Zahl, *International pharmaceutical law and practice* (New Providence, N.J.: LexisNexis, 2013) at 4-18 to 4-19.

principle that only a single patent can be granted on an invention.[297] In addition, pharmaceutical firms have a common practice to "evergreen" their inventions, in order to preserve exclusivity over the duration of one patent. Evergreening occurs when the patentee applies for a secondary patent application to extend the exclusivity period, without identifying any significant advantage or benefit.

Selection patents, as a selected class of compounds, must promise a substantial advantage over the larger class of compounds to be of sufficient merit for a patent. Therefore, the notion of utility through the promise of the patent, works as a mechanism to prevent the abuse of selection patents to evergreen an invention.[298] Indeed, the promise of the patent requires the invention to enforce its promise and, in the case of selection patents, the promise will be enforced only when all the members of the selected compound possess the substantial advantage. To summarize: the notion of utility ensures that the selected compound provides appropriate usefulness for patent exclusivity.

2.3. The notion of utility as a mechanism to control overreaching claims

Patent exclusivity tempts patentees and new applicants to try for an extension of their monopolies either in terms of the duration of exclusivity or the breadth of claims. As mentioned above, double patenting, or evergreening for pharmaceuticals, is an attempt to extend the duration of patent exclusivity. This occurs when the patentee applies for a new patent which does not claim any novel or sufficient benefit. In other cases, the patentee will raise claims that are overly-broad and this is really an attempt to extend patent exclusivity. When this occurs, these claims will go beyond the demonstrated or soundly predicted results, and the possible patent

[297] *Ibid*.
[298] Gold & Shortt, *supra* note 8 at 39—40.

could be based on misinformation because the patent application claims results that have not been demonstrated or soundly predicted at the filing date.

The notion of utility also works as a mechanism to avoid granting a patent on the basis of overreaching claims. This safeguarding occurs through the promise of the patent and sound prediction doctrine. The promise of the patent scrutinizes the specification to verify operability of implicit or explicit promises at the filing date, and thereby avoids overpromising. In addition, the sound prediction doctrine, through its disclosure requirement, requires patentees to provide sufficient evidence to ensure the validity of claimed results. Accordingly, the notion of utility avoids phenomena such as "the patent thicket phenomenon" that occurs "when a technology or a product is covered by multiple patents that are often held by numerous patentees."[299] This patent thicket makes a "dense web of overlapping"[300] patents on a technology, which in turn creates complexities for future innovation and technological progress.

2.4. The notion of utility as a mechanism to develop new innovations

The notion of utility can ensure more innovation and the development of new technologies through the doctrine of sound prediction. Specifically, the doctrine of sound prediction, especially the three-part test, plays a crucial role in improving technological inventions. The doctrine provides the opportunity to grant patents to inventions where the utility can be soundly predicted, even though inventor needs to do further work. Further, the doctrine, through the elements of the necessity of proper disclosure of the basis and reasoning for prediction, helps the examiner to distinguish between patentable inventions and mere speculation

[299] Ian Ayres & Gideon Parchomovsky, "Tradable Patent Rights" (2007) 60 Stanford Law Rev 863 at 869—870

[300] Stu Woolman, Elliot Fishman & Michael Fisher, "Evidence of Patent Thickets in Complex Biopharmaceutical Technologies" (2013) 53:1 IDEA Intellect Prop Law Rev 1 at 7.

or lucky guesses. In fact, the three-part test can be interpreted as a method to remove the complexity and ambiguity of utility, especially for pharmaceutical and biotechnological inventions.[301]

These goals and policies cannot be achieved in some situations because of the ambiguities that exist in related rules. Chapter III will explore theses ambiguities and elaborate on specific solutions.

3. Conclusion to chapter 2

This chapter has provided a thorough analysis of how Canadian patent jurisprudence has approached the patent utility requirement. Additionally, this chapter studied the how the patent utility requirement is dealt with in patent disputes, and concluded that the issue of utility will be raised when the usefulness of a patent is challenged. In order to meet the utility requirement, as required by the Canadian *Patent Act*, no particular quantity of utility must be demonstrated. Rather, the claimed invention must produce some minimally useful result by the filing date. However, where a patent specification includes a promise of a result, the invention will meet the utility requirement only when it demonstrates the fulfillment of the promise as made at the filing date. This is known as the patent promissory doctrine, which has an extensive background in Canadian patent law. The purpose of the promissory doctrine is to ensure that patent monopolies are not granted for misinformation or mere research ideas, but rather that the claimed invention can actually do what it promises to do. In most cases, Canadian courts consider specification as a

[301] Sivaramjani Thambisetty, "Legal Transplants in Patent Law: Why 'Utility' Is the New 'Industrial Applicability'" (2009) 49:2 Jurimetr J Law Sci Technol 155 at 175.

whole in construing the promise of a patent: which will include claims and disclosures made. Promises are mostly explicit, and are recognizable as a clear statement in the patent specification. However, there are decisions that conflict with the above principle in Canadian case law. These cases have accepted implicit promises which are descriptive phrases of quality in the patent application.

A person skilled in the art has an essential role in finding and construing the promise of a patent. The professional background of a skilled persons will influence their expectation of the usefulness of patent, and their interpretation of the promise of a patent. Canadian courts might find it difficult to decide a case where multiple skilled readers with different expectations have conflicting interpretations of the promise of a patent.

The patent promise doctrine has increasingly dominated Canadian pharmaceutical patent case law. This is due to the rise of a new generation of pharmaceutical and chemical patents that include a new use or a specific class of already-patented inventions. The patentees of these inventions must clearly promise through the patent specification that their claimed invention has a new or extra usefulness that goes beyond that of the already patented compound. When these inventions fail to fulfill their promise, a court will invalidate whole the patent. To date, Canadian courts have invalidated various pharmaceutical patents due to a lack of utility. This approach of Canadian courts has been challenged nationally and internationally; although so far, these challenges have been unsuccessful. However, in 2017 the Supreme Court of Canada held that the promissory approach to patent utility is not the correct approach. This decision has generated a significant degree of confusion regarding the best approach to patent utility, specifically in the case of pharmaceutical patents.

Another doctrine for interpreting patent utility is the sound prediction doctrine developed by Canadian case law. This doctrine might apply where a patentee is not able to demonstrate the utility of an invention by the filing date because the invention must go through further testing before utility can be assured. The sound prediction doctrine supports innovators of these inventions when they can disclose a factual basis and a line of reasoning for the claimed result by the filing date. This doctrine aims to strike a balance between the public interest in new inventions and the need to avoid granting speculative patents.

Chapter III will elaborate further on current challenges to the concept of patent utility in Canadian patent law and set out reasons for these challenges. Chapter III also suggests some practical solutions for solving certain ambiguities that exist in patent law in terms of the utility requirement, as well as current challenges in terms of the promissory approach to utility.

Chapter III: Current challenges of the notion of utility; reasons and solutions

As outlined in chapter II, Canadian patent law takes three main approaches to the notion of utility: all of which are based on how applicants demonstrate or predict patent utility at the

filing date. In recent years, criticisms of these approaches have focused mainly on the promissory approach to the utility requirement, also known as the promise of the patent. Chapter II explained these three approaches to the notion of utility and responded to certain criticisms that have been raised against the promissory doctrine. Chapter III now analyzes current challenges to the patent utility requirement by setting out the reasons for these challenges and posing some potential solutions to them. This chapter also discusses ambiguities that exist in terms of applying the main concept of the utility requirement as set out in the *Patent Act*; and suggests that drawbacks of approaches taken by Canadian patent law to the notion of utility could explain some of the current challenges facing applicants and courts today.

The focus of the first section of this chapter is on ambiguities that exist in the Canadian *Patent Act* in terms of the definition and interpretation of the main concept related to the patent utility requirement; "usefulness" and also the negative aspect of utility; "inutility". The second section of this chapter analyzes those different interpretations that arise when considering the 'promissory' and 'new' approaches taken by Canadian courts to the utility requirement. For the purposes of this section, the *new* approach refers to the approach taken by the Supreme Court in *AstraZeneca v. Apotex*.[302] This section first identifies those unanswered questions that arise out of the 'promissory approach' to patent utility. As discussed above in chapter II, the patents that have been challenged because of a lack of utility are often pharmaceutical and biotechnological patents. This section therefore analyzes whether the approach taken to the notion of utility under Canadian patent law is contingent on the context of inventions or, to put it another way, whether Canadian patent law has taken a specific approach to chemical, pharmaceutical, and biotechnological patents. This section then analyzes the recent ruling of the Supreme Court of

[302] *AstraZeneca Canada Inc. v. Apotex Inc.*, *supra* note 3.

Canada in *Apotex* that introduced a new approach to the notion of utility by eliminating the promissory doctrine. It concludes with a discussion of the prospective results and impacts of the elimination of the promissory approach to innovation and future patent law cases. Finally, chapter III sets out some potential solutions to these current challenges that arise in terms of the notion of utility.

1. Ambiguities that arise in determining the main concept of the utility requirement

The statutory basis of the utility requirement is section 2 of the *Patent Act* that defines "invention" as any new and useful subject matter. The word "useful" in section 2 of the *Patent Act* is the main statutory interpretation of the utility requirement, and accordingly, this Act requires usefulness as one of the patentability criteria. However, the *Patent Act* does not give any definition of usefulness and this creates uncertainties in the application of patent law. In addition, based on the statutory definition of an invention, if a process or product is not useful it is not an invention within the meaning of the Act.[303] Thus, 'not usefulness' or inutility as the negative aspect of the utility requirement has been crucial in patent utility cases. A review of patent utility cases in Canada indicates that they are often based on an allegation of lack of utility. For this reason, it is important to have a clear understanding of inutility and to look at examples where inutility of an invention has been central to a determination.

The first part of this section elaborates on the various definitions of usefulness as provided by courts and legal scholarship both in Canada and the United States. Then, this section discusses how courts interpret the 'usefulness' of an invention, and argues that this interpretation influences how courts approach the utility requirement. This section focuses on the recent case of

[303] *Apotex v Wellcome Foundation*, *supra* note 9 at para 51.

AstraZeneca v. Apotex[304] where the Supreme Court rejected the promissory interpretation of usefulness, emphasized the *de minimis* interpretation of usefulness, and held that the scintilla of utility is the correct approach to take when determining utility.

The second part of this section analyzes the concept of inutility in Canadian patent law by focusing on inutility cases. This section explains how Canadian courts interpret inutility to date. As this section demonstrates, courts have come to different rulings in inutility cases where the patent covered a claim to a class that included an embodiment that was not useful. This section analyzes this category of cases, their difference from other utility cases, and explains how issuing different rulings on inutility causes uncertainty in determining patent cases where utility is at issue.

1.1. Ambiguities in statutory definitions and Court interpretations of the concept of "usefulness"

The Patent Acts of the United States and Canada refer to the patent utility requirement as the "usefulness" of inventions.[305] However, these Acts do not provide a definition of the concept of usefulness,[306] nor determine from what perspective "usefulness" is to be defined.[307]

A review of various Canadian and American sources on patent law and the utility requirement[308] indicates that the concept of usefulness of inventions has been defined and

---

[304] *AstraZeneca Canada Inc. v. Apotex Inc.*, *supra* note 3.
[305] *U.S. Patent Law, 35 U.S.C.*, *supra* note 36, § 101; *Patent Act*, *supra* note 44, s. 2.
[306] AstraZeneca Canada v. Apotex, *Supra* note 244 at para 12.
[307] Seymore, *supra* note 69 at 1047.
[308] Samuel Dillon Hirschl, *Patent law.* (Chicago: publisher not identified, 1914) at 119—121; V Alexander Scher, *Patenting the invention: application, prosecution, interference proceedings, with rules and forms.* (Albany: M. Bender, 1948) at 13—14; John Barker Waite, *Patent law* (Princeton, N.J.: Princeton University Press, 1920) at 107—117; A John Michel & Kurt Kelman, *Dictionary of intellectual property* (1954) at 336—37; Seymore, *supra* note 69 at 1051—52; *Bedford v Hunt et al*, 3 F. Cas. 37, 37 (Story, Circuit Justice, C.C.D. Mass. 1817); *Lowell v Lewis*, 15 F. Cas. 1018 (C.C. Mass. 1817).

interpreted by courts and scholarship since the introduction of early patent laws. According to these sources, usefulness can be reduced to three essential interpretations. First, an invention must provide *some* beneficial use to the public.[309] This *de minimis* interpretation of usefulness forms a basis for the mere scintilla of utility approach taken in Canada, as it requires a low threshold of utility for patentable inventions. Second, the invention should not be frivolous or injurious to the morals, the health, or the good order of society.[310] The origin of this negative definition of utility, or the moral concept of utility, is decisions of the United States' courts in the nineteenth century.[311] However, this concept of utility has not been commonly applied in the US in recent decisions,[312] and it has no place in Canadian patent law.[313] Third, an invention must work as described in the patent specification, and be able to serve the purpose as mentioned in the patent. This interpretation of usefulness has come to be known as *operability* in the United States.[314] In Canadian cases, according to the 'promise of the patent', an invention is useful when it does what it alleges to do in the patent specification.[315]

The issue of how to define the usefulness of an invention is a basic issue to determine in patent utility cases; however, the lack of a statutory definition of usefulness creates uncertainty in terms of the interpretation and enforcement of the utility requirement. This is one of the

---

[309] David Vaver refers to this definition of usefulness as "technical usefulness". See Vaver, *supra* note 144 at 339—41.

[310] David Vaver refers to this definition of usefulness as "social usefulness". See *Ibid* at 338—39.

[311] *Bedford v. Hunt et al.*, *supra* note 308, The negative interpretation of usefulness also can be traced to the English Statute of Monopolies of 1623 See Seymore, *supra* note 69 at 1051.

[312] Craig Allen Nard, *The Law of Patents* (Wolters Kluwer Law & Business, 2014) at 242—43 ;Vaver, *supra* note 144 at 339 ; Thambisetty, *supra* note 301 at 160—170; *Juicy Whip, Inc. v Orange Bang, Inc.*, 185 F. 3d 1364 (Fed. Cir. 1999) at 1366—68 , citing *Webber v. Virginia*, 103 US 344 at 347—48 (1880) ("Congress never intended that the patent laws should displace the police powers of the States...")

[313] According to Vaver the moral aspect of usefulness "may have no place in Canadian law since the repeal in 1994 of the ban on inventions with an 'illicit object in view'." See Vaver, *supra* note 144 at 339.

[314] Seymore, *supra* note 69 at 1052 citing *Mitchell v Tilghman*, 86 US (19 Wall) 287 at 396 (1873); Risch, *supra* note 5 at 1201.

[315] Fox, *supra* note 23 at 298—99; AstraZeneca Canada v. Apotex, *Supra* note 244 at paras 2, 12—19.

reasons for current challenges to the notion of utility in Canadian patent law. For example, in the recent case of *AstraZeneca v. Apotex*[316] where the promissory approach to determining patent utility was challenged, the argument about the correct statutory meaning of patent utility was based the parties' different definitions of usefulness to meet the utility requirement under section 2 of the *Patent Act*. The Federal Court clearly emphasized the promissory interpretation of usefulness, and held that requiring "a patent [to] be useful begs the question: 'useful for what?' The answer to that question is the promise of the patent."[317] However, the Supreme Court of Canada affirmed the definition of utility by focusing on the *de minimis* interpretation of usefulness and thus emphasized that the mere scintilla of utility is the correct approach to determining patent utility.[318] The Supreme Court rejected the promise of the patent approach, on the basis that it denied the importance of the operable and promissory usefulness of an invention.[319] One outcome of defining the usefulness of inventions according to the mere scintilla of utility approach is that each product or process with a use, no matter how unimportant, can meet the utility requirement. Therefore, the mere existence of the claimed subject matter renders it useful, and the usefulness requirement in the *Patent Act* would be left without a substantive, practical element to its definition.[320]

1.2. The definition of "inutility" as the negative aspect of utility requirement

According to section 2 of the *Patent Act*, when something is not useful, it does not meet the utility requirement. Given this, the definition of 'inutility' could be important for determining

[316] *AstraZeneca Canada Inc. v. Apotex Inc.*, *supra* note 3.
[317] *AstraZeneca Canada Inc. v Apotex Inc.*, 2014 FC 638 at para 86, citing *Pfizer Canada Inc v Mylan Pharmaceuticals ULC*, 2011 FC 547 at paras 210—11 [Mylan Aricept].
[318] *AstraZeneca Canada Inc. v. Apotex Inc.*, *supra* note 3 at para 55.
[319] *Ibid* at paras 52—55; The section 2 of chapter III elaborates on the results of this ruling on Canadian patent law.
[320] AstraZeneca Canada v. Apotex, *Supra* note 244 at para 29.

the appropriate scope of the definition of usefulness, and to limit ambiguity in the definition and examples of inutility could limit ambiguity in the utility requirement. In fact, patent utility cases are mostly based on an assertion of a lack of utility or inutility of the issued patent. Thus, as there is no statutory definition or guideline to scope inutility, courts have defined this aspect of utility in a case specific way: that is, based on the specific and different facts of cases. The Supreme Court of Canada affirmed a two-aspect definition of the concept of "inutility". According to this definition, "There is a helpful discussion in Halsbury's Laws of England, (3rd ed.), vol. 29, at p. 59, on the meaning of 'not useful' in patent law. It means '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'."[321] On the basis of this definition, inutility can be found in one of these two circumstances: first, where the invention does not work at all, and second, when the invention works for certain purposes but does not fulfill the promise of utility made in the patent.[322]

In *Wellcome v. Apotex,*[323] the court distinguished between inutility — when an invention lacks utility — and inoperability — when an invention fails to yield the promised utility:

> If the patent claims a process that does not in fact work the claim is too broad because its promise fails. If a patent claims a process that does work but has no reasonable prospect of commercial or industrial application it fails not because it is inoperable but because it lacks utility and in that sense the claim may be said to be too broad, for the process lacks substance; it is not an invention, since it is not useful, a requirement of an "invention" under section 2 of the Patent Act.[324]

[321] *Consolboard*, *supra* note 7 at 525.
[322] Cameron, *supra* note 79 at 129–130.
[323] *Wellcome Foundation Ltd v Apotex Inc*, [1991] 39 CPR (3d) 289, 1991 CarswellNat 213.
[324] *Ibid* at para 126.

For certain types of patents, it will be evident from the nature of the claimed subject matter that the invention is entirely useless [325] and will not operate at all, such as patents for a perpetual motion device[326] or for a 'death ray.'[327]

In certain patent cases, the decision on inutility depends on whether courts interpret the omitted elements of patents as essential or non-essential. This is the claim to a product or process that, according to the court's construction, omits an essential element is invalid.[328] In *Feherguard Products Ltd. v. Rocky's of B.C. Leisure Ltd.,*[329] the patent related to a telescoping roller for a pool cover that had at least two tubes that telescoped and locked together, upon rotation of one tube with respect to the other. The claim in issue specified that the tubes had mating longitudinal ribs and "the said ribs of said first tubular section engaging upon the said ribs of said second member when the said ribs of each section are aligned radially, thereby securing said tubular sections relative to each other."[330] The court held that claim 1 promised that, once the ribs of a tubular section were engaged, both telescoped sections would be secured; however, it could not be so secured without the use of screws or the bolts. Therefore, without the inclusion of screws or bolts, the roller is useless, and as claim 1 is silent about screws and bolts, the patent was void.[331]

However, the omission of elements from a claim that, according to courts are non-essential or immaterial, would not result in invalidity.[332] Thus, in *Metalliflex Ltd. v. Rodi &*

---

[325] Cameron, *supra* note 79 at 130–131.
[326] *Otta v Canada (Patent Commissioner)*, [1979] 51 CPR (2d) 134, 1979 CarswellNat 793.
[327] *X v Canada (Patent Commissioner)*, [1981] 59 CPR (2d) 7, 1981 CarswellNat 740.
[328] MacOdrum & Fox, *supra* note 25 at 6-52.3.
[329] *Feherguard Products Ltd v Rocky's of BC Leisure Ltd*, [1994] 53 CPR (3d) 417, 1994 CarswellNat 1857.
[330] *Ibid* at para 9.
[331] *Ibid* at para 24.
[332] MacOdrum & Fox, *supra* note 25 at 6-52.3 to 6-53; Cameron, *supra* note 79 at 134.

Wienenberger AG,[333] the court rejected the contention that a claim to a watch band or bracelet having three components lacked utility for failing to recite the means to hold the parts together. The Court emphasized that "[i]t is beyond question that the parts have to be held together, but the means to attain that purpose and hold together the combination, which is the invention claimed in 1 and 2, is not material." [334] Hence, deciding on the inutility or usefulness of inventions relies on how courts distinguish essential or immaterial elements of patents in each case.

Although the interpretation of inutility was a difficult issue in the abovementioned cases, other rulings by Canadian courts on the question of inutility indicate that distinguishing inutility could be even more confusing and rigorous when certain circumstances are present. For example, where a claim to a class includes within its scope an embodiment that is not useful or inoperative, it may be invalidated because of inutility.[335] However, various facts may affect a decision on inutility and subsequent invalidation of a patent. In *Minerals Separation North American Corp. v. Noranda Mines Ltd,*[336] one of the claims of the patent was a process for improving the concentration of minerals by subjecting the mineral to the flotation operation "in the presence of a xanthate".[337] This patent in that case was invalidated because one class of xanthate, the cellulose xanthate, did not work. The court rejected the argument that "for various practical reasons no persons skilled in the art would ever attempt to use these xanthates for froth

[333] *Metalliflex Ltd v Rodi & Wienenberger AG*, [1961] SCR 117, 35 CPR 49.
[334] *Ibid* at 122; See also *Appliance Service Co v Sarco Canada Ltd*, [1974] 14 CPR (2d) 59, 1974 CarswellNat 562. (Similarly, the court decided on steam traps for high pressure steam systems.) See also *Mobil Oil Corp v Hercules Canada Inc.*, [1994] 57 CPR (3d) 488. (Based on the court's construction a slip agent was not an essential feature and its omission from the claim did not preclude utility)
[335] Cameron, *supra* note 79 at 138—139.
[336] *Minerals Separation North American Corp v Noranda Mines Ltd*, [1952] 15 CPR 133, 1952 CarswellNet 2.
[337] *Ibid* at para 16.

flotation and therefore they could be disregarded."[338] According to this decision, if a claim contains a process or product that will not work, the claim cannot be saved by indicating that no skilled person would ever try to use that method or material.[339] Similarly, in 2016, in the case of *Meda AB v. Canada (Health),*[340] the claims for a pharmaceutical composition included one component of a bioadhesion and/or mucoadhesion promoting agent. The claims were attacked for inutility because the list of bio/mucoadhesive ingredients in the description included microcrystalline cellulose, which was not in fact a bio/mucoadhesive. The court rejected the allegation of inutility and concluded that a person skilled in the art "would on a purposive construction and with a mind willing to understand, given the common general knowledge at the relevant time, know to disregard this one ingredient."[341]

The same argument was raised in *Burton Parsons Chemicals, Inc. v. Hewlett-Packard (Canada) Ltd*,[342] where the Federal Court invalidated a claim to an electrocardiogram cream based on inutility because there was a contention made that the claims could possibly have substances or compositions made of chemicals that were toxic or otherwise incompatible with the skin. [343] However, the Supreme Court of Canada rejected the contention that the claim lacked utility:

> In my view, the rights of patentees should not be defeated by such technicalities. While the construction of a patent is for the Court, like that of any other legal document, it is however to be done on the basis that the addressee is a man skilled in the art and the knowledge such a man is expected to possess is to be taken into consideration. To such a man it must be obvious that a cream for use with skin contact electrodes is not to be made up with ingredients that are toxic or irritating, or are apt to stain or discolour the skin. The man skilled in the art will just as well appreciate this necessity if the cream to be made is

[338] *Ibid* at para 21.
[339] MacOdrum & Fox, *supra* note 25 at 6-49.
[340] *Meda AB v Canada (Health)*, 2016 FC 1362.
[341] *Ibid* at para 181.
[342] *Burton Parsons Chemicals, Inc v Hewlett-Packard (Canada) Ltd*, [1974] 1 SCR 555.
[343] MacOdrum & Fox, *supra* note 25 at 6-51; Cameron, *supra* note 79 at 138.

> described as "compatible with normal skin" as if it is described as containing only ingredients compatible with normal skin.[344]

In this case, the Supreme Court sought to distinguish the facts and circumstances from those in the *Minerals Separation v. Noranda Mines,* concluding that: "the task of avoiding unsuitable materials in the making of the mixture, a task which any man skilled in the art ought to be able to perform without having to be told because any unsuitability depends on well-known properties. No unexpected or generally unknown unsuitability was proved or even suggested, which makes this case quite unlike *Minerals Separation* or *Rhône-Poulenc*."[345] In terms of the reasons given by the Supreme Court for distinguishing *Burton Parsons* form *Minerals Separation,* Donald Cameron asserts that it is not entirely clear that these cases can be distinguished for the reasons given in *Burton Parsons*.[346] According to Cameron, "in *Minerals Separation,* the Privy Council noted that cellulose xanthates were unsuitable for use, as they formed a colloidal solution and that it was known for a considerable time that colloids should always be avoided in froth flotation."[347] Furthermore, the Privy Council dealt specifically with the argument that a skilled person would have known to avoid cellulose xanthate: finally rejecting this argument.[348] Cameron argued that a better basis to distinguish these cases might be that, in *Burton Parsons*,

---

[344] *Burton Parsons v. Hewlett-Packard (Canada)*, *supra* note 341 at 563; See also *Farbwerke Hoechst AG Vormals Meister Lucius & Bruning v Halocarbon (Ontario) Ltd*, [1979] 42 CPR (2d) 145, 1979 CarswellNat 636F (a claim to a process that did not specify the proportions of the ingredients was held to be valid because a skilled person would know to avoid useless proportions.); *Bayer AG v Apotex Inc*, [1998] 82 CPR (3d) 526, 1998 CarswellNat 3777 (the patent that included allegedly inoperable glycols and toxic lower alcohols held valid because the skilled reader would know in what proportions to use the compounds.); *Mahurkar v Vas-Cath of Canada Ltd*, [1988] 18 CPR (3d) 417, 1988 CarswellNat 204. (the patent on a catheter was held valid because the skilled person would use his own knowledge to avoid constructions which would be dangerous for patients.)

[345] *Burton Parsons v. Hewlett-Packard (Canada)*, *supra* note 341 at 565—566.

[346] Cameron, *supra* note 79 at 140.

[347] *Ibid*.

[348] *Minerals Separation North American Corp. v. Noranda Mines*, *supra* note 336 at 21; See also *Union Carbide Canada Ltd v Trans-Canada Feeds Ltd*, [1966] 49 CPR 29, 1966 CarswellNet 5 at para 44. (similarly, the court rejected the argument that a skilled person would know not to use nitro-cellulose, as an inoperative embodiment, for making flattened thermoplastic tubing.)

there was nothing in the claim which positively pointed to the use of an electrocardiogram cream that was incompatible with the skin. However, in *Minerals Separation*, there was a finding made that the cellulose xanthates which were unsuitable for use were the only xanthates that were widely known.[349]

These cases indicate that, in practice, distinguishing inutility from immaterial claims might be not as simple as the two-aspect definition of inutility affirmed by the Supreme Court in *Consolboard.* In fact, the courts in all of the abovementioned inutility cases defined and found inutility based on the fact that a skilled reader, as the addressee of the patent specification, could not expect the invention to be useful as described and promised. In some of the abovementioned cases, the court concluded that the skilled reader could expect the invention to work as described and promised by disregarding the embodiment that does not work or is useless. However, in other cases, the court invalidated the patent that covered a claim with a useless embodiment. Thus, the issuance of different rulings based on the varied reasoning in inutility cases creates complexity and uncertainty in terms of applying the utility requirement.

2. The notion of utility after the new approach of the Supreme Court taken in *Apotex*

This section analyzes the drawbacks and ambiguities that result from the different approaches of Canadian courts to the utility requirement in patent law. The analysis of this section is first focused on the ambiguities that exist in the promissory approach to utility requirement. This section presents the ambiguities and drawbacks of this approach to the utility requirement as possible reasons for recent challenges to the notion of utility. Secondly, this section elaborates on ambiguities that arise out of the 'new' approach to the utility requirement

[349] Cameron, *supra* note 79 at 140.

taken by the Supreme Court in 2017, and prospective outcomes that will follow the elimination of the promissory doctrine in Canadian patent law.

2.1. The challenges of reliance on the promissory approach to the notion of utility

As reviewed above in chapter II, the notion of utility has been mainly challenged patents issued on pharmaceutical or chemical inventions, and this has led to criticism that Canadian patent law takes a discriminatory approach to these fields of technology. This section focuses first on this argument about the discriminatory nature of the promise of the patent when applied against pharmaceutical and chemical fields of technology, and analyzes the accuracy and validity of this assertion. Secondly, this section identifies and analyzes the current drawbacks and uncertainties that arise when applying the promissory approach.

2.1.1. The approach to the notion of utility; neutral or contingent on the context of inventions

Challenges to the Canadian approach to the notion of utility have mostly been raised in pharmaceutical and biotechnological patent cases and most recently in patents related to engineering. The prevalence of challenging the promissory approach to the notion of utility in pharmaceutical and biotechnological patents can raise the question of whether the approach to the patent utility requirement is contingent on the context of the invention. In other words, does Canadian patent law take an industry-specific approach to the utility requirement, and is this approach discriminatory?

The applicable standard for assessing the two other patentability requirements – novelty and non-obviousness – [350] are objective, which means that they are the same in each invention. In fact, the standards for the assessment of novelty and non-obviousness require a court to assess whether the claimed invention is respectively new and not obvious (on the claim date) to a person skilled in the art. These objective standards do not vary in accordance with particular inventions or on the basis of patentees' statements made in the specification. However, in Canadian patent law, the approach to assessing the utility requirement depends on the patentees' statements in the patent specification. As was explained in chapter II, generally a patent must live up to the use promised by the applicant in the patent specification and, if the applicant says nothing about the use in the specification, then a mere scintilla of utility would be sufficient in order to meet the utility requirement. The mere scintilla of utility, as a *de minimis* approach, is an objective standard for the assessment of utility because it applies regardless of anything said in a particular patent.[351]

However, in contrast to these objective standards, the argument has been made that the promissory approach to the utility requirement is a subjective standard, because the promise of the patent measures the utility of invention according to the promised utility in the specification.[352] Siebrasse explains the subjective nature of the promise of the patent by giving the example of pharmaceutical patents where: "[d]epending on the wording of the disclosure, a pharmaceutical compound might be held to a high standard of clinical efficacy in humans, or it might be held to a lower standard such as being a member of class of physiologically active

[350] Siebrasse, *supra* note 96 at 13; Siebrasse, *supra* note 27 at 47—48.
[351] Siebrasse, *supra* note 96 at 14—15.
[352] *Ibid* at 35.

compounds."[353] According to Siebrasse, the standard for assessment of utility varies in accordance with the wording of the patent specification. This argument has been invoked to strengthen the assertion that the promise of a patent requires a heightened utility standard for pharmaceutical and chemical patents.[354] For example, one of the main claims of Eli Lilly, in the arbitration case against Canada, was that the utility requirement under Canadian patent law, specifically the promise of the patent, has an arbitrary and discriminatory nature. Eli Lilly alleged that: "the subjective process of construing the promise of a patent is 'inherently arbitrary' in that it allows courts to ignore the distinction between the claims and the disclosure."[355] Eli Lilly made this subjectivity claim to strengthen his argument that the promissory approach to interpreting the utility requirement is arbitrary and discriminatory, especially against the pharmaceutical and chemical fields.[356]

A similar argument is made about the operability requirement in United States patent law. According to Seymore, chemical and pharmaceutical inventions are referred to as "unpredictable", because a person skilled in the art often cannot "predict outcomes or extrapolate results with a reasonable expectation of success."[357] Seymore argues that, because of the prevalence of chemical and pharmaceutical inventions[358] deemed to be unpredictable in comparison to mechanical devices, courts found that the *de minimis* standard of utility was

---

[353] *Ibid* at 13.

[354] *Eli Lilly and Company v. The Government of Canada*, *supra* note 1; See also Tim Wilsdon & Adam Mitchell Heggs, "The impact of IP and the promise doctrine on pharmaceutical R&D activity in Canada", (12 October 2016), online: *Charles River Associates* <http://www.crai.com/publication/impact-ip-and-promise-doctrine-pharmaceutical-rd-activity-canada>. (This report asserts that "the subjective nature of the promise doctrine's interpretation by Canadian courts contributes a significant level of uncertainty to the national pharmaceutical IP system.")

[355] *Eli Lilly and Company v. The Government of Canada*, *supra* note 1 at para 391.

[356] *Ibid* at paras 397—400.

[357] Seymore, *supra* note 69 at 1053.

[358] *Ibid* at 1054. (Seymore asserts that by the end of World War II, the invention landscape had transformed from mechanical to predominantly pharmaceutical inventions.)

insufficient and therefore added the operability requirement to the modern utility standard.[359] Based on the current definition of the operability requirement, an invention must achieve its intended result or serve the purpose mentioned in the patent in order to be useful. As Seymore argues, operability is a heightened utility standard for assessing the usefulness of pharmaceuticals and chemicals as these are targeted inventions that initially seemed to be unpredictable or even impossible.[360] In addition, he concludes that operability has made the utility requirement a "technology-specific standard"[361] for chemical, pharmaceutical, and biotechnological inventions and thus, the utility standard is a subjective and arbitrary value-based assessment in these fields of technology.[362]

However, contrary to the above arguments, the subjective nature of the promise of the patent cannot stand as proof that the promissory approach is technology-specific. The technology-specific approach requires a heightened level of utility for patents of the pharmaceutical and chemical fields of technology. The promissory approach assesses the usefulness of inventions based on a skilled person's understanding of a patent's purpose or promise as clarified by applicants, and this assessment does not impose a heightened level of utility.[363] Rather, skilled readers' understanding and courts' patent construction are essential and inseparable determinants for assessing the utility requirement in all types of patents. This conclusion was supported by the arbitration tribunal, which rejected the assertion that "… the promise utility doctrine has 'differentially disadvantageous effects' on the pharmaceutical

[359] *Ibid* at 1051—54.
[360] *Ibid* at 1056.
[361] *Ibid* at 1060—66.
[362] *Ibid* at 1066, 1080.
[363] AstraZeneca Canada v. Apotex, *Supra* note 244 at para 12.

sector."[364] The tribunal concluded the allegation that the promise utility doctrine discriminates against pharmaceutical patents is not proven by an authentic factual analysis. [365] In addition, as was argued in chapter II, a thorough study of patent utility cases in Canada reveals that the promissory approach to the utility requirement has not been specifically applied to pharmaceutical and chemical patents.

2.1.2. Ambiguities that arise when applying the promissory approach to the notion of utility

The promissory approach to the notion of utility has received criticism in theory and practice but, as analyzed in chapter II, it plays an essential role in Canadian patent law by requiring patentees to prove that their inventions actually work as promised. Furthermore, most of the current criticism of this approach are not accurate and are not based on a factual premise.[366] However, there are substantive reasons for critiques of the promissory approach, and this section presents and analyzes these reasons as creating challenges for the application of the promissory approach to the utility requirement.

As was explained in chapter II, most Canadian courts consider the entire patent (including claims and disclosure) in construing the promise.[367] By considering both claims and disclosure as part of the whole patent, courts make possible a greater number of promises because the disclosure will include implicit promises.[368] According to Gold & Shortt, the decision of *Plavix impeachment*[369] "appears to repudiate any reliance on 'implicit' promises"; thus, they argue, it has led to uncertainty in the law of promise because it does not clarify how

[364] *Eli Lilly and Company v. The Government of Canada*, *supra* note 1 at para 432.
[365] *Ibid* at paras 439, 442.
[366] *Ibid* at para 442.
[367] Gold & Shortt, *supra* note 8 at 42.
[368] *Ibid* at 43.
[369] *Plavix Impeachment*, *supra* note 153 at para 49.

courts can differentiate between implicit and explicit promises.[370] According to the promissory approach, if a patent cannot fulfill even *one* of its promises made at the filing date, then it would be void in its *entirety* although it has successfully achieved the other promises that it made. In addition, the fact that courts also look at the disclosure to construe the promise of a patent may result in applicants preferring to disclose less about their inventions and make fewer promises. According to Sherkow, patent applicants can make smaller promises, and "disclose concomitantly less in their applications, to circumvent the promissory doctrine's force."[371] Applicants disclosing less information is contradictory to the objective of the promissory approach, which is to encourage patentees to sufficiently disclose how their invention may benefit the public.

As this thesis has shown, the promissory approach effectively holds patentees to statements made in the patent at the filing date and strikes a balance between the goal of supporting new innovations and ensuring benefits of patent protection for the public. Regardless, the promissory approach has some drawbacks and causes complexity and confusion in determining utility. In order to solve the current challenges that relate to the notion of utility, it is therefore necessary to address some of drawbacks of the promissory approach. The last section of this chapter discusses potential solutions to address these drawbacks.

2.2. Ambiguities and challenges of the Supreme Court's new approach to the notion of utility

As set out in chapter II, the Supreme Court of Canada's ruling in *Apotex*,[372] can be interpreted as ending reliance on the promissory approach to the notion of utility. In this ruling,

[370] Gold & Shortt, *supra* note 8 at 76.
[371] Sherkow, *supra* note 101 at 6.
[372] *AstraZeneca Canada Inc. v. Apotex Inc.*, *supra* note 3.

the Supreme Court concluded that the promise of the patent is not the "correct"[373] approach to the patent utility requirement. The Court provided three main reasons for the elimination of the promissory approach to the utility requirement. First, in analyzing novelty and non-obviousness, the focus would be only on the claims made, and "claim construction precedes all considerations of validity."[374] In other words, patent disclosure will not be considered except where there are ambiguities in the claims.[375] However, the patent promise doctrine directs courts to identify the promises of the patent through consideration of the *entire* specification which includes both the claims and the disclosure.[376] Second, where there are multiple expressed promises of utility, the promise of the patent requires that all promises be fulfilled for a patent to be valid.[377] That is, even one of the promises of the patent is not fulfilled, the patent *entirely* is invalid. Third, the promise of the patent conflates the requirement in section 2 of the *Patent Act* that an invention be "useful" and the requirement to disclose an invention's "operation or use" under section 27(3). According to the Supreme Court, the usefulness requirement for inventions set out in section 2 is a "condition precedent to an invention" and the requirement under section 27(3) is a "disclosure requirement, independent of the first."[378] Accordingly, the rejection or elimination of the promise of the patent forms the essential part of the new approach to the notion of utility. In addition, the Supreme Court reaffirmed the validity of the sound prediction doctrine as a test to determine that the disclosure of the patent adequately ensures the usefulness of the invention.[379] Finally, the Supreme Court affirmed and emphasized the validity of the 'mere scintilla of utility' approach in

[373] *Ibid* at paras 2, 24.
[374] *Ibid* at para 31.
[375] *Ibid*.
[376] *Ibid*.
[377] *Ibid* at paras 37, 47.
[378] *Ibid* at para 43.
[379] *Ibid* at paras 55—56, 62.

meeting the utility requirement: "a single use related to the nature of the subject-matter is sufficient."[380] As a result of focusing on a mere scintilla of utility, the invention must not be devoid of utility, and this is sufficient for meeting the utility requirement.

The new ruling of the Supreme Court will have effects on Canadian patent law as well as innovators.[381] First, the new approach to patent utility requirement reverses over sixty years of Canadian patent case law which has defined the usefulness of inventions based on rules requiring inventions to do what the patentees stated that they would do. [382] As a result, this new ruling could create confusion about how to construe and apply the patent utility requirement in the future. Second, the elimination of the promise of the patent means that patentees are no longer required to fulfill their statements at the filing date. In the new situation, Canadian patent law would become the less restrictive patent protection system because, as explained in chapter I, both the US and European patent laws have mechanisms to ensure that the invention does what the patentee says it does. The patent law of the United States has rigorous mechanisms, namely operability and enablement standards, that determine and ensure the usefulness of inventions by referring to the patentee's alleged or promised utility.[383] The operability standard ensures whether the invention can actually accomplish its alleged utility,[384] and the enablement requirement ensures that the examiner can actually practice what the patentee disclosed at the

[380] *Ibid* at para 55.

[381] According to Richard Gold, the new ruling of the Supreme Court has also negative effects on Canadian innovation policies: "In its decision, the Supreme Court weakened Canada's hand in advancing an innovation policy that helps Canadian firms and creates Canadian jobs." See Gold, *supra* note 231.

[382] E Richard Gold, "Eli Lilly's odyssey to use a fake rule and fake news to protect bad patents", (16 August 2017), online: *STAT* <https://www.statnews.com/2017/08/16/eli-lilly-canada-patents-zyprexa-strattera/>.

[383] Gold & Shortt, *supra* note 8 at 69; *Ibid* at 377.

[384] Merges & Duffy, *supra* note 70 at 212.

filing date without undue experimentation.[385] In addition, the elimination of the promise of the patent, as a restrictive patentability test, makes receiving and holding Canadian patents very easy for both domestic and foreign patentees. However, according to Richard Gold, this would tend to favor foreign patentees and therefore be to the detriment of the Canadian innovators: "each foreign patent is a roadblock for a Canadian firm hoping to develop its own product or service. Getting around that roadblock requires money and leverage – two things that smaller companies often lack."[386] Thus, as Gold predicts, the new approach to patent utility makes it more difficult for Canadian innovators, particularly small domestic firms, to come up with invention and develop them.[387] Third, by eliminating the promise of the patent and emphasizing the low threshold of utility, the ruling allows inventions with any use, no matter how insignificant, to be patented.[388] Consequently, the number of issued patents will be raised while the quality of the patents is likely to be reduced.

3. Solutions

The recent ruling of the Supreme Court in *Apotex* – that minimized the level of usefulness of inventions for meeting the utility requirement – has resulted in Canadian patent law becoming less restrictive than other countries in granting patents. As argued in the section above, although the Canadian promissory approach to the patent utility has received criticism, other patent law frameworks have mechanisms to ensure the same objectives as the promissory doctrine are met. For instance, under the United States' approach to patent utility, patents will be

[385] Seymore, *supra* note 69 at 1083—1084; *Wright*, *supra* note 75 at 1561.
[386] Gold, *supra* note 230.
[387] Wingrove, *supra* note 243.
[388] E Richard Gold, "NAFTA 2.0 and Beyond; Levelling the patent playing field", (15 August 2017), online: *Centre for International Governance Innovation* <https://www.cigionline.org/articles/nafta-20-and-beyond>.

granted only for inventions that have specific, substantial, and credible utility as well as being required to meet the enablement requirement. Based on United States law, a patent will be issued where there are significant and available benefits to the public, and when an invention can fulfill its alleged utility. This means that, under the new Canadian approach to the utility requirement, there could be many inventions that are patentable in Canada which will not be patented under United States' patent law. One solution to overcome this issue could be to adopt the United States approach to the utility standard: requiring inventions to have a specific, substantial and credible utility.[389] In fact, an argument could be made that adopting the US approach to the utility requirement would provide Canadian patent law with a restrictive mechanism, similar to the eliminated promise of the patent, for keeping patentees to their promises as well as reducing the disadvantages of the mere scintilla of utility standard.

Another solution could be that Canadian patent law returns to the approaches that it has been using, including the promissory approach, by resolving the ambiguities and drawbacks of this approach that have been set out in this chapter. As noted above, where the situation arises of patents that make multiple promises, the Canadian position is similar to the British position, in that all promises must be fulfilled; otherwise, the entire patent would be void because of lack of utility.[390] This position could be more effectively balanced to avoid negative results in patent cases and limit criticism of the current position. Further, the issuance of conflicting rulings on implicit promises created uncertainty in the law about how to differentiate between implicit and explicit promises. This situation could also be resolved by relying on the skilled person's understanding of the patent and the purposive construction to determine the promises made by patentees.

[389] *Ibid*; Gold, *supra* note 231.
[390] Gold & Shortt, *supra* note 8 at 74—75.

Conclusion

This thesis analyzed the reasons why the patent utility requirement has recently become one of the most challenging issues in Canadian patent law; and suggested possible solutions to overcome these challenges. The historical and comparative analysis of chapter I indicated that the utility requirement as a criterion for granting patents is not limited to Canadian patent law. Rather, this requirement has been an inseparable criterion of patentability since the earliest patent statutes. Other common law and civil law countries impose equivalent mechanisms to ensure that patent monopolies are granted to inventions that benefit the public. As international law has failed to provide unified substantial regulations on the utility requirement, each national legal system prefers its own definition of the notion of utility. However, in the past decade, the utility requirement imposed by Canadian patent law has received substantial criticisms from scholarship and has been challenged in practice.

Chapter II elaborated on the notion of utility as interpreted by Canadian patent jurisprudence that has addressed the notion of utility based on patentee's statements in the patent specification. This chapter noted that patent applicants are not required to establish the utility of an invention at the filing date, and thus the mere scintilla of utility would suffice to demonstrate utility. However, if there is a promise in the specification, then the patentee must prove that the patent actually fulfills that promise, otherwise, the patent would be void. In some cases when the patentee cannot demonstrate the usefulness of invention at the filing date but s/he can disclose a sufficient factual basis and reasoning for achieving the aimed result, courts could soundly predict the utility, and so the patent would be valid.

As Chapter II explained, there are essential policies that are served by applying these approaches in Canadian patent law; however, the patent utility requirement as imposed by

Canadian courts has recently been challenged: specifically the promissory approach to the notion of utility. Chapter III explored the reasons for current challenges made to the notion of utility, and focused on current uncertainties in Canadian patent law and the approaches of Canadian courts to the utility requirement. The analysis of this chapter indicated that the concepts of usefulness and inutility do not have a clear statutory definition and there is therefore the issue of vagueness in terms of distinguishing inutility in certain cases. This uncertainty could cause the issuance of conflicting rulings by courts and uncertainty in the patent law.

Chapter III also made the case that, although the promissory approach plays an important role in Canadian patent law by holding patentees to their statements, there are some ambiguities and drawbacks implicit in this approach. First, courts emphasize that both claims and disclosure are relevant for patent construction; second, that conflicting rulings issued on implicit promises create uncertainty about the nature of these promises; third, that based on the promissory approach the entire patent is void even if one of the promises is not fulfilled at the filing date; and finally, that the emphasis of courts on disclosure can make patentees disclose less about their invention than they otherwise would, and make smaller promises which would be contrary to the objectives of the promise of the patent.

Chapter III then provided an overview of the Supreme Court's elimination of the promissory approach to the utility requirement in its 2017 ruling, where the Court held that the mere scintilla of utility was the correct approach to take to patent utility. This new approach could generate more uncertainty and risk negative results in patent law because it reverses over sixty years of Canadian patent case law, which defined the usefulness of inventions with reference to the promissory approach. Thus, chapter III concluded that this new ruling could create confusion in the manner of construing the patent utility requirement in the future. Because

patentees are no longer required to fulfill their statements at the filing date, Canadian patent law would become the less restrictive patent protection system, comparably to US and European patent frameworks that have mechanisms to ensure that the invention does what the patentee says it does. By comparison, the new approach in Canada makes receiving and holding Canadian patents easier for foreign patentees while making it more difficult for Canadian small firms to come up with their inventions and develop them.

Further, by emphasizing the low threshold of utility, namely a mere scintilla of utility, the new Supreme Court ruling allows inventions with any use, no matter how insignificant, to be patented, and this would increase the number of low-quality patents in Canadian law. Accordingly, this paper considered the ambiguities and drawbacks of the new approach. Two solutions were proposed: (1) to adopt a rigorous approach to the patent utility, such as the US approach, requiring inventions to have a specific, substantial and credible utility; and (2) a judicial return to the promissory approach, made possibly by solving its ambiguities. The ramifications of the new approach to the utility requirement for Canadian law and for Canadian innovators will need to be evaluated over time.

Bibliography

LEGISLATION

Canada

Patent Act, R.S.C., c. P-4 (1985)

An Act to promote the progress of useful arts in this Province, 4 Geo IV, c.25 (1824).

An Act to Encourage the Progress of Useful Arts within this Province, 7 Geo. IV, c. 5 (1826).

An Act to consolidate and amend the laws of patents for inventions in this province, 12 Vic., c. 24 (1849).

Patent Act, S.C. 1923, c. 23, s 17.

The United States

US*, An Act to promote the progress of useful Arts*, c. 7, 1 Stat. 109-112 (1790).

US*, Patent Act*, c. 11, 1 Stat. 318-323 (1793).

US*, Patent Law, 35 U.S.C.*, 2007.

Europe

UK*, Patents Act 1977*, c.37.

Statute of Monopolies, 1623, 21 Jac. 1, c.3 online: <http://www.legislation.gov.uk/aep/Ja1/21/3/section/VI>.

Venetian Statute on Industrial Brevets, 1474, online: <http://www.copyrighthistory.org/cam/tools/request/showRepresentation>.

International law

Agreement on Trade-Related Aspects of Intellectual Property Rights, (15 April 1994), online: <https://www.wto.org/english>.

Convention on the Grant of European Patents, (5 October 1973), online: *European Patent Office* <https://www.epo.org/law-practice/legal-texts >.

Convention on the Unification of Certain Points of Substantive Law on Patents for Invention, (27 November 1963), online: *World Intellect Prop Organ* <http://www.wipo.int/wipolex/en >.

Paris Convention for the Protection of Industrial Property, (20 March 1883), online: *WIPO* <http://www.wipo.int/>.

Patent Cooperation Treaty, (1970), online: *World Intellect Prop Organ* <http:// www.wipo.int >.

Patent Cooperation Treaty International Search and Preliminary Examination Guidelines, (6 June 2017), online: *WIPO* <http://www.wipo.int >.

Patent Law Treaty, (1 June 2000), online: *WIPO* <http://www.wipo.int/wipolex/en/treaties/ >.

JURISPRUDANCE

Canada

Allergan Inc c Canada (Health), 2012 FC 767.

Allergan Inc v Minister of Health, 2011 FC 1316.

Amfac Foods Inc v Irving Pulp & Paper, Ltd, [1986] (3d) 12 CPR (3d) 193, FCJ 659 (FCA).

Apotex Inc v ADIR, 2009 FCA 222.

Apotex Inc v Pfizer Canada Inc, 2011 FCA 236.

Apotex Inc v Pfizer Canada Inc, 2014 FCA 250.

Apotex Inc v Sanofi-Aventis, 2011 FC 1486 Sanofi-Aventis.

Apotex Inc v Sanofi-Synthelabo Canada Inc, 2008 SCC 61, [2008] 3 SCR 265 (SCC).

Apotex Inc v Wellcome Foundation Ltd, 2002 SCC 77, [2002] 4 SCR 153 [Apotex] (SCC).

Apotex Inc v Wellcome Foundation Ltd, 2002 SCC 77, [2002] 4 SCR 153.

Appliance Service Co v Sarco Canada Ltd, [1974] 14 CPR (2d) 59.

AstraZeneca Canada Inc v Apotex inc, 2014 FC 638.

Astrazeneca Canada Inc v Apotex Inc, 2015 FCA 158.

AstraZeneca Canada Inc v Apotex Inc, 2017 SCC 36.

Astrazeneca Canada Inc v Mylan Pharmaceuticals ULC, 2011 FC 1023.

Aventis Pharma Inc v Apotex Inc, 2005 FC 1283.

Bayer AG v Apotex Inc, [1998] 82 CPR (3d) 526.

Bell Helicopter Textron Canada Limitée v Eurocopter, 2013 FCA 219, 2013 FCA 219 Bell Helicopter.

Burton Parsons Chemicals, Inc v Hewlett-Packard (Canada) Ltd, [1974] 1 SCR 555 (C).

Consolboard Inc v MacMillan Bloedel (Sask) Ltd, [1981] 1 SCR 504.

Eli Lilly and Company v Teva Canada Limited, 2011 FCA 220.

Eli Lilly Canada Inc v Novopharm Limited, 2010 FCA 197.

Eli Lilly Canada Inc v Apotex Inc,2009 FCA 97, *78 CPR (4th) 388*.

Eli Lilly Canada Inc v Novopharm Limited, 2011 FC 1288.

Eurocopter v Bell Helicopter Textron Canada Limitée, 2012 FC 113.

Farbwerke Hoechst AG Vormals Meister Lucius & Bruning v Halocarbon (Ontario) Ltd, [1979] 42 CPR (2d) 145.

Farbwerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning v Commissioner of Patents, 1966 SCR 604.

Feherguard Products Ltd v Rocky's of BC Leisure Ltd, [1994] 53 CPR (3d) 417.

Fournier Pharma Inc v Canada (Health), 2012 FC 741.

Glaxosmithkline Inc v Pharmascience Inc, [2008] 72 CPR (4th) 295 593 (FC).

Laboratoires Servier, Adir, Oril Industries, Servier Canada Inc v Apotex Inc, 2008 FC 825 Laboratoires Servier.

Mahurkar v Vas-Cath of Canada Ltd, [1988] 18 CPR (3d) 417.

Metalliflex Ltd v Rodi & Wienenberger AG, [1960] 35 CPR 49.

Meda AB v Canada (Health), 2016 FC 1362.

Minerals Separation North American Corp v Noranda Mines Ltd, [1952] 15 CPR 133.

Mobil Oil Corp v Hercules Canada Inc, [1994] 57 CPR (3d) 488.

Mylan Pharmaceuticals ULC v AstraZeneca Canada Inc, 2012 FCA 109.

Novopharm Limited v Pfizer Canada inc, 2010 FCA 242.

Otta v Canada (Patent Commissioner), [1979] 51 CPR (2d) 134.

Ratiopharm Inc v Pfizer Limited, 2009 FC 711 Ratiopharm.

Re Application of Abitibi Co, [1982] 62 CPR (2d) 81 (Patent Appeal Board and Commissioner of Patents).

Sanofi-Aventis v Apotex Inc, 2013 FCA 186 Plavix Impeachment.

Teva Canada Ltd v Pfizer Canada Inc, [2012] 3 SCR 625 (SCC).

Union Carbide Canada Ltd v Trans-Canada Feeds Ltd, [1966] 49 CPR 29.

Wandscheer et al v Sicard Ltd, [1947] [1948] SCR 1 (SCR), 1947 CanLII 27.

Wellcome Foundation Ltd v Apotex Inc, [1991] 39 CPR (3d) 289.

X v Canada (Patent Commissioner), [1981] 59 CPR (2d) 7.

The United States

Bedford v Hunt et al, [1817] 3 F. Cas. 37 (CCD Mass).

Brenner v Manson, 383 US 519 (1966); 86 S. Ct. 1033; 16 L. Ed. 2d 69; 1966 U.S. LEXIS 2907; 148 U.S.P.Q. (BNA) 689.

In re Fisher, [2005] 421 F.3d 1365 (Fed. Cir.).

In re Oberweger, [1940] 115 F 2d 826 (CCPA).

In re Wright, [1993] 999 F.2d 1557; 1993 US App. LEXIS 18347.

Juicy Whip, Inc v Orange Bang, Inc, [1999] 185 F.3d 1364 (Fed. Cir.).

Lowell v Lewis, [1817] 15 F. Cas. 1018 (CCD Mass).

Mitchell v Tilghman, [1873] 86 US 287; 19 Wall. 287.

Webber v Virginia, [1880] 103 US 344 13 Otto 344.

Europe

Human Genome Sciences Inc v Eli Lilly and Company [2011] UKSC 51, 2011 UKSC (2011) (available on http://www.bailii.org/uk/cases/UKSC/2011/51.html).

Case T 0870/04 (BDP1 Phosphatase), (5 November 2005), online: *European Patent Office* <https://www.epo.org/law-practice/case-law-appeals/recent/t040870eu1.html>.

Case T 0898/05 (Hematopoietic receptor), (7 July 2006), online: *European Patent Office* <http://www.epo.org/law-practice/case-law-appeals/recent/t050898eu1.html>.

Case T 0018/09 (Neutrokine/Human Genome Sciences), (21 October 2009), online: *European Patent Office* <http://www.epo.org/law-practice/case-law-appeals/recent/t090018eu1.html>.

International

Eli Lilly and Company v The Government of Canada, (2017) UNCT/14/2 (International Centre for the Settlement of Investment Disputes (ICSID)) (available on https://www.italaw.com/sites/default/files/case-documents/italaw8546.pdf).

SECONDARY MATERIAL: MONOGRAPHS

Adelman, Martin J. *Global issues in patent law* (St. Paul, MN: West, 2011).

Cameron, Donald M. *Canadian patent law benchbook* (Toronto: Carswell, 2014).

Fisher, Harold, Russel Sutherland Smart & W J Lynch. *Canadian patent law and practice* (Toronto; Philadelphia: Canada Law Book Co. ; Cromarty Law Book Co., 1914).

Fox, Harold G. *Digest of Canadian patent law* (Toronto: Carswell Co., 1957).

Fox, Harold G & Canada. *The Canadian law and practice relating to letters patent for inventions* (Toronto: Carswell Co., 1948).

———. *The Canadian law and practice relating to letters patent for inventions,* (Toronto: Carswell Co., 1969).

Gervais, Daniel J. *The TRIPS agreement: drafting history and analysis*, 4th ed (London: Sweet & Maxwell/Thomson Reuters, 2012).

Hirschl, Samuel Dillon. *Patent law.* (Chicago: publisher not identified, 1914).

Judge, Elizabeth F & Daniel J Gervais. *Intellectual property: the law in Canada* (Toronto: Carswell, 2011).

MacOdrum, Donald H & Harold G Fox. *Fox on the Canadian law of patents* (Toronto: Carswell, 2013).

Merges, Robert P & John Fitzgerald Duffy. *Patent law and policy: cases and materials* (New Providence, NJ: LexisNexis, 2011).

Michel, A John & Kurt Kelman. *Dictionary of intellectual property* (1954).

Nard, Craig Allen. *The Law of Patents* (Wolters Kluwer Law & Business, 2014).

Perry, Stephen J, T Andrew Currier & Roger T Hughes. *Canadian patent law* (Ontario: LexisNexis Canada Inc., 2014).

Scher, V Alexander. *Patenting the invention: application, prosecution, interference proceedings, with rules and forms.* (Albany: M. Bender, 1948).

Sookman, Barry B, Steven Mason & Daniel Glover. *Intellectual property law in Canada: cases and commmentary* (Toronto: Carswell, 2013).

Takenaka, Toshiko. *Patent law and theory: a handbook of contemporary research* (Cheltenham, UK: Edward Elgar, 2008).

Thomas, John R. *Pharmaceutical patent law* (Arlington, VA: BNA Books, 2010).

Vaver, D. *Intellectual property law: copyright, patents, trade-marks* (Toronto: Irwin Law, 2011).

Waite, John Barker. *Patent law* (Princeton, N.J.: Princeton University Press, 1920).

Zahl, Adrian. *International pharmaceutical law and practice* (New Providence, N.J.: LexisNexis, 2013).

SECONDARY MATERIAL: ARTICLES

Ayres, Ian & Gideon Parchomovsky. "Tradable Patent Rights" (2007) 60 Stanford Law Rev 863.

Erstling, Jay A, Amy M Salmela & Justin N Woo. "Usefulness Varies by Country: The Utility Requirement of Patent Law in the United States, Europe and Canada" (2012) 3 Cybaris Intellect Prop Law Rev 1.

Gold, E Richard & Michael Shortt. "The Promise of the Patent in Canada and Around the World" (2014) 30:1 Can Intellect Prop Rev 35.

Phillips, Freedom-Kai. "Promise Utility Doctrine and Compatibility under NAFTA: Expropriation and Chapter 11 Considerations" (2016) 40 Can-U S Law J 84.

Reichman, Jerome H & Rochelle Cooper Dreyfuss. "Harmonization without consensus: Critical reflections on drafting a substantive patent law treaty" (2007) 57:1 Duke Law J 85.

Risch, Michael. "Reinventing Usefulness" (2010) 2010:4 Brigh Young Univ Law Rev 1195.

———. "A Surprisingly Useful Requirement" (2011) 19:1 George Mason Law Rev 57.

Seymore, Sean B. "Making Patents Useful" (2013) 98 Minn Law Rev 1046.

Sherkow, Jacob. "Patent Law's Reproducibility Paradox" (2017) 66:4 Duke Law J 845.

Siebrasse, Norman. "HGS v. Lilly: How Soon Is Too Soon to Patent?" (2011) 24:1 Intellect Prop J Scarb 41.

———. "Must the Factual Basis for Sound Prediction Be Disclosed in the Patent?" (2012) 28:1 Can Intellect Prop Rev 1.

———. "The False Doctrine of False Promise" (2013) 29:1 Can Intellect Prop Rev 3 1.

———. "Form and Function in the Law of Utility: A Reply to Gold & Shortt" (2014) 30:2 Can Intellect Prop Rev 1.

Thambisetty, Sivaramjani. “Legal Transplants in Patent Law: Why ‘Utility’ Is the New ‘Industrial Applicability’” (2009) 49:2 Jurimetr J Law Sci Technol 155.

Wingrove, Josh. “‘Bombshell’ Canadian Patent Ruling Seen Favoring Foreign Companies”, *Bloomberg.com* (30 June 2017), online: <https://www.bloomberg.com/news/articles/2017-06-30/canada-bombshell-patent-ruling-seen-favoring-foreign-companies>.

Woolman, Stu, Elliot Fishman & Michael Fisher. “Evidence of Patent Thickets in Complex Biopharmaceutical Technologies” (2013) 53:1 IDEA Intellect Prop Law Rev 1.

“Utility Requirement in the Patent Law, The Note” (1964) 53 Georgetown Law J 154.

SECONDARY MATERIAL: OTHERS

Centre for Intellectual Property Policy. “Patent Litigation: Putting Assumptions to the Empirical Test”, (28 July 2016), online: *CIPP* <http://www.cippmcgill.ca/news/2016/07/28/patent-litigation-putting-assumptions-to-the-empirical-test/>.

Centre For Intellectual Property Policy (Factum of The Intervener). *AstraZeneca Canada Inc., et al. v. Apotex Inc., et al., 2016 SCC 36654*, online: <https://www.mcgill.ca/law/files/law/2016-richard-gold-36654-cipp-factum.pdf>.

Council of Europe Committee of Experts on Patents. “Comparative study of substantive law in force in the countries represented on the Committee of Experts on Patents, presented by the Secretariat - General”, (7 November 1953), online: *Counc Eur* <http://normalsup.coe.int/>.

“European Union (EU): Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of biotechnological inventions”, (6 July 1998), online: *World Intellect Prop Organ* <http://www.wipo.int/wipolex/en>.

European Patent Office. “Guidelines for Examination in the European Patent Office”, (2016), online: *EPO* <http://www.epo.org/law-practice/legal-texts/html/guidelines/e/index.htm>.

Gold, E Richard. “Supreme Court harms Canada’s innovation policy stand ahead of NAFTA negotiations”, (2 July 2017), online: *Globe Mail* <https://www.theglobeandmail.com/report-on-business/rob-commentary/supreme-court-harms-canadas-innovation-policy-stand-ahead-of-nafta-negotiations>.

———. “NAFTA 2.0 and Beyond; Levelling the patent playing field”, (15 August 2017), online: *Cent Int Gov Innov* <https://www.cigionline.org/articles/nafta-20-and-beyond>.

———. “Eli Lilly’s odyssey to use a fake rule and fake news to protect bad patents”, (16 August 2017), online: *STAT* <https://www.statnews.com/2017/08/16/eli-lilly-canada-patents-zyprexa-strattera/>.

Jeremy de Beer. “Professors de Beer and Gold represent CIPP at the Supreme Court”, (3 February 2017), online: *YouTube* <https://www.youtube.com/watch>.

PCKIP. “Canada’s Supreme Court Abolishes Controversial ‘Promise Doctrine’”, (30 June 2017), online: *PCK* <http://www.pckip.com/patent/promise-doctrine-abolished-one-use-mere-scintilla-utility-will-satisfy-utility-requirement>.

Schmitz, Cristin. “Updated: SCC revamps patent utility standard by scrapping ‘promise doctrine’”, (30 June 2017), online: *Lawyers Dly* <https://www.thelawyersdaily.ca/articles/4111/updated-scc-revamps-patent-utility-standard-by-scrapping-promise-doctrine>.

Sherkow, Jacob S. “Patents, Promises, and Reproducibility”, (2017), online: *ATRIP* <http://atrip.org/wp-content/uploads/2017/04/Sherkow-Patents2c-Promises2c-and-Irreproducibility.pdf>.

Wilsdon, Tim & Adam Mitchell Heggs. “The impact of IP and the promise doctrine on pharmaceutical R&D activity in Canada”, (12 October 2016), online: *Charles River Assoc* <http://www.crai.com/publication/impact-ip-and-promise-doctrine-pharmaceutical-rd-activity-canada>.

WIPO Standing Committee on the Law of Patents. “Industrial Applicability and Utility Requirements: Commonalities and Differences”, online: <http://www.wipo.int/ >.

———. “Draft Substantive Patent Law Treaty”, online: *WIPO* <http://www.wipo.int/patent-law/en/draft_splt.htm>.

SECONDARY MATERIAL: GOVERNMENT DOCUMENTS

Canada

Canadian Intellectual Property Office. "Manual of Patent Office practice" (Ottawa: CIPO, 2009).

The United States

US, Patent and Trademark Office. “Utility Examination Guidelines”, (30 January 2001), online: *USPTO* <https://www.uspto.gov>.

US, Office of the US Trade Representative. “2017 Special 301 Report”, (2017), online: *Off USTR* <https://ustr.gov/sites/default/files/301/2017>.