IV. "Promise Utility Doctrine"

A. Canadian Law and Courts

Canada has a mixed legal tradition which is reflected on the state of the law today. The first influx of European law came with the French settlers in the 16th century who brought along the civil law tradition.[148] After the victory of the English in the colonial wars in the mid-18th century they started implementing their own legal practices. During the centuries, as Canada was slowly gaining more independence, the judicial and legal links with the English crown were equally being severed.[149] Until 1949 the final appeals court of Canada was an English court — the Judicial Committee of the Privy Council.[150] Nowadays Canada has a fully independent legal system.

The Canadian court system consists of two parts – the main court system and the federal court system. At the top of both systems stands the Supreme Court of Canada. The main court system is territory or province based. The courts in this system can only hear issues arising out of provincial or territorial law.[151] The federal court system adjudicates matters emanating from federal law. The federal courts are therefore in charge of hearing many issues regarding IP.[152] The Patent Act, being a federal act, is subject to the scrutiny of Canadian Federal Courts.

148 Jessi J. Horner, Canadian Law and the Canadian Legal System, 41-3 (2007).
149 *Id, at* 46-7.
150 *Id, at* 47.
151 *Id, at* 242-43.
152 *Id,* at 243-44.

B. Patent Law in Canada

1. Historical Developments

Canadian patent laws are based on the Canadian Patent Act. The right of the Federal government to create such a statute stems from the Constitution Act which vests the power of creating legislation in relation to "[p]atents of inventions and discoveries."[153] The first federal Patent Act was created in 1869,[154] influenced by its two predecessors – the Lower Canada Patent Act of 1823 and the Upper Canada Patent Act of 1826. These acts were in turn significantly influenced by two legal traditions – the English common law legal tradition with the rules coming from the Statute of Monopolies (British patent law was not codified at the time of the two Canadian patent acts) and the United States legal tradition with its codified Patent Act of 1793.[155] The traces of these traditions can be seen in contemporary Canadian patent law. Although codified in the Canadian Patent Act, patent law is still molded by common law traditions.

2. Pharmaceutical Patents in Canada

It is often stated that patent protection is essential for the survival and development of the pharmaceutical industry.[156] Canada is nowadays offering patent protection to pharmaceuticals. However, these rules are of a fairly recent nature. Since the initial Patent Act was enacted in 1869 it has undergone many changes and amendments which included the changes in the temporal length of patent protection,[157] rules addressing chemical and medical inventions,[158] compulsory licensing rules[159] and in particular spe-

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153 Constitution Act, 1867, § 91(22), 30 & 31 Vict. Ch. 3 (U. K.), *as reprinted in* R.S.C., No. 5 (Appendix 1985).

154 Elizabeth F. Judge & Daniel J. Gervais, Intellectual Property: The Law in Canada, 2nd ed., 645 (2011).

155 Stephen J. Perry & T. Andrew Currier, Canadian Patent Law, 2nd ed., 24-5 (2014)

156 Juan Bacalski, Mexico's Pharmaceutical Patent Dilemma and the Lessons of India, 23 Ariz. J. Int'l & Comp. Law, 717, 717 (2006).

157 1883, 1886, 1892, 1935, 1989. Perry & Currier, Supra note 150, at 31-7.

158 1923. *Id,* at 32.

159 1903, 1906, 1923. *Id.*

cific rules regarding compulsory licensing of pharmaceuticals.[160] Compulsory licenses were commonly granted in order to produce medicine which were patent protected and would normally constitute patent infringement.[161] The last rule was introduced as a policy measure to ensure that "Canadian consumers have access to reasonably priced medicines."[162] This sparked the rise of the Canadian generic industry.[163] This provision was unsurprisingly unpopular with the international pharmaceutical companies. Through lobbying efforts, they pushed for a patent law reform which eventually resulted in the Patent Act of 1989, which, with minor amendments from 1996, stands as it is today. In 1993 Canada, preparing the compliance of its laws with the coming of the NAFTA and the TRIPS, abandoned its compulsory licensing scheme.[164]

3. Patent Law Basic Principles

Patents are granted for inventions. According to the Canadian Patent Act an invention "means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter;"[165] In order for the inventor to acquire the rights granted by the Patent Act for its invention, he or she must disclose the details of the invention in full. After the patent protection expires, the patent falls into the public domain and the public is free to use the invention.[166] In order to acquire the patent rights a patent must be granted first. The granting of a patent is done through a registration process. During this process four formal requirements must be met: The invention must be fall under the protectable subject matter, it must be new, inventive and useful.[167]

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160 1969. *Id,* at 34-5.
161 Adam Falconi, CETA: An Opportunity to Fix Canada's Broken Pharmaceutical Patent Linkage System, 27 I.P.J., 325, 330 (2015).
162 Perry & Currier, Supra note 155, at 25.
163 Falconi, Supra note 161, at 330.
164 *Id at* 330-31.
165 Patent Act, § 2, R.S.C., c. P-4 (Can.).
166 Martin P.J. Kratz, Q.C., Canada's Intellectual Property Law in a Nutshell, 2nd ed., 202 (2010).
167 *Id,* at 223.

a) Protectable Subject Matter

The protectable subject matter is the preliminary requirement for a grant of a patent. A patent can only be granted if the nature of the invention is recognized by the Patent act[168], the matter is not excluded under its statutory requirements and if it avoids the court created exemptions.[169] Without the invention fulfilling this precondition, the analysis of patentability is redundant. The invention might satisfy the rest of the requirements, however if it is by its nature excluded from patenting, the patent will not be granted.

b) Patentability Requirements

Having established that the invention falls under the patentable subject matter, the invention needs to be analyzed under the remaining three patentability requirements – novelty, obviousness and utility.

(1) Novelty

The novelty requirement is derived from section 2 of the Patent act.[170] If the invention is not novel the patent application will be rejected.[171] The Supreme Court of Canada acknowledged that novelty is at the heart of the patent bargain. "If the public has been put into possession of the claimed invention by whatever means, it does not have to pay the price of monopoly to get it again."[172]

(2) Non-Obviousness

Non-Obviousness is a patentability requirement which ensures that the advances made by an invention are not miniscule and that they possess "in-

168 Patent Act, Supra note 165, § 2.
169 Perry & Currier, Supra note 155, at 90.
170 Patent Act, Supra note 165, § 2.
171 *Id.*
172 Perry & Currier, Supra note 155, at 178.

ventive merit." Non-obviousness was not an express statutory category prior to the act of 1989. However, since then its statutory basis is to be found in article 28.3. of the Patent Act. The assessment of non-obviousness is assumed from the perspective of the person skilled in the art and his or hers assessment of the prior art.[173]

(3) Utility

For a patent to be granted the invention must be useful. The way this patentability requirement is defined and what is its scope, is at the core of the *Eli Lilly* case. The utility requirement has been present in statutory Canadian patent law since the early patent statutes.[174] However in comparison with other terms coming from section 2 of the patent Act, utility has received far less judicial elaboration.[175] The term itself had no fixed meaning and it evolved over time. As far as 1841 utility was held by the Canadian courts to be "an apparatus that would answer some beneficial purpose."[176] In 1940 a Canadian court stated: "An invention to be patentable must confer on the public a benefit. Utility as predicated of inventions, means industrial value. No patent can be granted for a worthless art or arrangement."[177] More recently and relevant for the *Eli Lilly* case is the definition the Supreme Court of Canada used in *Consolboard* case. Justice Dickson used the concept of "not useful" in the context of patent law found in Halsbury's Laws of England (3rd ed.) He stated: "It means that the invention will not work, either in the sense it will not operate at all, or more broadly, that it will not do what the specification promises that it will do."[178] This definition created a fork like approach to determining the utility of a patent. Not only is the total absence of utility excluded from satisfying the utility requirement, rather the discord of the stated utility and the established utility will hold the invention not useful. The definition introduced the term "promise" which is the key term in determining the second fork approach. This approach was confirmed in the case of *Eli Lilly v.*

173 Kratz, Supra note 166, at 228-9
174 Perry & Currier, Supra note 155, at 129.
175 *Id,* at 130.
176 *Id,* at 131.
177 *Id*.
178 *Id.*

Novopharm,[179] which is one of the two relevant cases for the investment arbitration. "The general principle is that, as of the relevant date (the date of filing), there must have been either demonstration of utility of the invention or a sound prediction of the utility. Evidence beyond that set out in the specification can, and normally will, be necessary." The court proceeded to elaborate on the relationship of utility and its promise: "Where the specification does not promise a specific result, no particular level of utility is required; a 'mere scintilla' of utility will suffice. However, where the specification sets out an explicit 'promise,' utility will be measured against that promise: *Consolboard; Pfizer Canada Inc. v. Canada (Minister of Health),* [2009] 1 F.C.R. 253, 2008 FCA 108 (*Rambaxy*). The question is whether the invention does what the patent promises it will do."[180]

(a) Demonstrated Utility

The demonstrated utility does not relate to any valuation of its intended use or any attributed value to it. The only referential point according to the Canadian Patent Act is that the patent will do what has been described and claimed in the patent.[181] Moreover there is no requirement for the patentee to establish utility in the patent. Utility is then assumed from the wording of the patent. Nevertheless, when certain improvements are directly prescribed in the patent, it is expected that these improvements materialize upon the patent's deployment or construction. If they do not materialize the patent can be found invalid.[182] An example stated by professors Perry and Currier in their book nicely illustrates this difference. A mechanical invention patent that plainly instructs how to build the invention without any prescribed promises is found useful if a person skilled in the art follows the instruction and builds the invention. However, in a pharmaceutical selection patent the invention is found in the choice of a compound from a group of compounds. A direct promise is necessary in such cases, as the promise lies in the explanation (description) of the choice of that

179 *Eli Lilly v. Novopharm*, Supra note 96.
180 Perry & Currier, Supra note 155, at 131.
181 *Id,* at 133.
182 *Id,* at 134.

particular compound.[183] Different types of patents, even though *de jure* subject to the exact same requirement of utility, in practice apply the requirement differently. A one-size-fits-all approach is not applicable here. However, utility must be demonstrated at the moment of patent application. If not demonstrated the utility can be soundly predicted.[184]

(b) Sound Prediction Doctrine

As opposed to the demonstration of utility at the moment of patent filing, Canadian patent law allows another possibility for the patentee to satisfy the utility requirement. When the patentee is unable to demonstrate utility at the appropriate date a patent may be granted on the basis of a sound prediction of utility.[185] The principal reason behind this doctrine was stated in the *Apotex v. Wellcome*[186] case. "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 is 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."[187] The *Apotex v. Wellcome* case is not only relevant for formulating the justification of the sound prediction doctrine but also for the creation of the three-element test by the Canadian courts. In order to determine if there are grounds for a sound prediction of utility the court must determine "1) [a] factual basis for the prediction; 2) the inventor's articulable and 'sound' line of reasoning, at the date of the patent application, from which the desired result can be inferred from the factual basis; and 3) proper disclosure." As such the sound prediction is a matter of fact.[188]

183 *Id,* at 134.
184 Judge & Gervais, Supra note 154, at 728.
185 *Id,* at 727-28.
186 Apotex Inc. v. Wellcome Foundation Ltd., [2002] 4 SCR 153, 2002 SCC 77 (Can.) [herein after: Apotex v. Wellcome].
187 *Id*, at 155.
188 Judge & Gervais, Supra note 154. at 728.

(3) Promise of a Patent

Another constituent part of the utility requirement which is closely related to the sound prediction is the patent promise. The promise of a patent means that the invention in the patent will achieve what has been written in the claims and description. The court is the one responsible for interpreting and ascertaining what the promise of a patent actually is. However, there is no obligation for the inventor to disclose the promise of utility, except "where a promised utility is at the core of the novelty of the invention." This rule is particularly important for pharmaceutical patents as sometimes the utility of the pharmaceutical patent cannot be clearly determined at the moment of patenting.[189]

The sound prediction doctrine and the promise of the patent doctrine joined together are what in the *Eli Lilly v. Canada* case is called the "promise utility doctrine." In essence this doctrine posits that when it is not possible for the utility of the patent to be demonstrated at the moment of the filing, the patent applicant can "promise" such utility. However, he or she must provide ample evidence that indicate the possibility that the utility will be proved in the future.

C. Compliance of Doctrine with International Intellectual Property Standards

The approach taken by Lilly to establish violations of NAFTA articles 1110 and 1105 heavily relies on the claim that the "promise utility doctrine" is inconsistent with international IP norms. So, is the promise utility doctrine really inconsistent with international IP standards?

The concepts of "novelty", "inventive step" or "non-obviousness" and "industrial application" or "utility" have been for a long time a matter of debate in domestic legal systems and they have been put under the test of litigation many times.[190] And even though there seems to be a level of proximity of all of the concepts, their interpretation still remains different

189 Perry & Currier, Supra note 155, at 141-43.

190 Kathleen Liddell & Michael Waibel, Fair and Equitable Treatment and Judicial Patent Decisions, 19 J. Int'l Econ. L., 145, 150 (2016).

across jurisdictions.[191] However patent law has historically been diverse.[192] From an international perspective the situation is quite the opposite. The TRIPS is an agreement that leaves a number of concepts undefined or defined broadly[193] and states have been using this opportunity to curtail the laws according to their domestic policy goals. Such laws often find opposition. The common argument is that they do not comply with the obligations set out in the TRIPS. Perhaps the most well-known case is the *Novartis* case and the section 3(d) of the Indian Patent Act.[194] The section limits the patentability of new forms of already known substances. Novartis lost one of its pharmaceutical patents according to the provision. Consequently, it brought the case before the Indian courts, where one of the claims was that the particular provision is inconsistent with the TRIPS. The Indian court declined jurisdiction over the claim. The question of consistency of the particular provision was never brought before the WTO dispute settlement mechanism. Therefore, the consistency of the norm with the TRIPS is implied and all considerations remain in the realm of academic debate.[195] As such the provision still stands today. This does not however mean that the provision is still present in law because it was not challenged despite its perceived illegality. There are arguments that point to its possible compliance with the TRIPS. WTO allows a level of differentiation for specific areas, whose subject matter are in themselves specific.[196] Therefore this provision can be justified as falling under the allowed

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191 Even authors who argue for uniformity of the concepts recognize that they are not identical in different jurisdictions – "remarkably similar". See, Jay Erstling, Amy M. Samela & Justin N. Woo, *Usefulness Varies by Country: The Utility Requirement of Patent Law in the United States, Europe and Canada*, Faculty Scholarship Paper 3(1) Cybaris, 1, 12 (2012).

192 *The U.S. Expansion of Patentable Subject Matter: Creating a Competitive Advantage for Foreign Multinational Companies*?, 18 B.U. Int'l L.J., 111, 112 (2000)

193 Liddell & Waibel, Supra note 190, at 150.

194 The Patents (Amendment) Act, § 3(d), No. 15 of 2005, India Code (2005) [herein after: Indian Patent Act].

195 Henning Grosse Ruse-Khan & Roberto Romandini, Patentability of Pharmaceutical Inventions under TRIPS, Domestic Court Practice as a Test for International Policy Space, (Max Planck Institute for Innovation and Competition Research Paper Ser., Paper No. 16-02, 2016), 1, 30 http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2736224 (Visited last on Mar. 6, 2018).

196 Cynthia M. Ho, Should All Drugs Be Patentable?: A Comparative Perspective, 17 Vand. J. Ent. & Tech. L., 295, 340 (2015).

differentiation and not under forbidden discrimination. However, until decided by the competent adjudicatory body, the provision's consistency should be presumed.

A similar approach can be applied to the "promise utility doctrine". The interpretation of the NAFTA is in the jurisdiction of the NAFTA state to state dispute settlement[197] under the Institutional Arrangements and Dispute Settlement Procedures Chapter or the FTC. The doctrine has been in existence for some time and the NAFTA parties have had the chance to challenge the existence and the use of the doctrine, as incompatible with NAFTA IP Chapter rules. However, until now no challenge of the sort had been logged. This reason for this can be that other NAFTA member states have similar doctrines in their own patent laws.[198]

The fact that both dispute resolution options under the TRIPS and the NAFTA are left to challenge at the discretion of the states, private parties must seek recourse in other fora. A worldwide corporate law firm, Jones Day, has in an open publication advised pharmaceutical patent holders to challenge such measure in investment arbitration. A way to do that is to adapt their claims so that the measures taken by the state can be qualified as violations of the FET standard and legitimate expectations.[199]

197 One of the most common proceedings of state to state arbitration is to obtain an interpretation of the treaty. See, Nathalie Bernasconi-Osterwalder, State-State Dispute Settlement in Investment Treaties, (IISD Best Practice Ser. 2014), 1, 8. https://www.iisd.org/sites/default/files/publications/best-practices-state-state-dispute-settlement-investment-treaties.pdf (Visited last on Mar. 6, 2018).

198 Norman Siebrasse, HGS v. Lilly: How Soon Is Too Soon to Patent*?*, 24 I. P. J., 41, 45 (2011).

199 *Treaty Protection for Global Patents: A Response to a Growing Problem for Multinational Pharmaceutical Companies*, Jones Day Publications (2012) available at: http://www.jonesday.com/treaty_protection/ (Visited last on Mar. 6, 2018).