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# The Development of an Expectations Theory of Patent Law by Creating a Nexus with John Locke's Theory of Private Property

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Supervisor: Trosow, Sam, *The University of Western Ontario* : Awad, Bassem, *The University of Western Ontario* A thesis submitted in partial fulfillment of the requirements for the Doctor of Philosophy degree in Law © Jason D. Newman 2023

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#### Abstract

This thesis reviews the Lockean justification of private physical property as an explanation for patent "property," identifies its weaknesses, and modifies it to create a new theory of patent law based on expectations. After describing the characteristics of technical information, that description is applied to three different interpretations of the Lockean condition which demonstrate a strain in defining technical knowledge as property. The technical information paradigm is then applied to an expectations theory, which demonstrates a broad connection to the Lockean conditions, but maintains a fit within a wider patent law interpretation. The expectations theory also creates an avenue for reintroducing utility assessments of patents and setting flexible patent terms. An example of a new medicine is used to test the various forms of the Lockean condition and the expectations model.

The historical development of modern patent law is reviewed then separated into two periods, which are subsequently generalized. While the early period prioritized utility assessments, working requirements and the individualization of patent terms, the later period minimized the importance of utility and working requirements, but prioritized inventiveness. The three different Lockean conditions, along with the expectations theory, are applied to the generalized form of each historical era. While each form of the Lockean condition illustrates a unique relationship to the patent law eras, the expectations model provides an encompassing explanation because of its fitness with the definition of technical information.

The analysis demonstrates that patent law can be categorized as either strong form patent law or weak form patent law, based on what can be expected from it. While the

i

strong form creates an expectation of a societal benefit from a patent beyond simply disclosing it, the weak form does not. The utility assessments of patents in the first era, along with the individualization of patent terms meant that the first era exhibited strong form patent law. The loss of utility assessments, working requirements, and adjustable patent terms during the second era characterize it as weak form. While nonobviousness narrowed the scope of patent to things that were truly innovative in the second era, it was not a sufficient basis for ensuring that a Lockean bargain was achieved.

The modified expectations model is then applied to Canada's pharmaceutical patent law history to demonstrate how Canada's patent law with respect to pharmaceuticals changed from strong form to weak form once it relinquished its compulsory licensing provisions, leaving few expectations from foreign-registered pharmaceutical patents by the early nineties.

The pharmaceutical patent law history of Canada also illustrates the difference in competitors that a modified Lockean theory of patent law creates – close competitors who can act upon each other's patented information and far competitors, where one competitor cannot act upon the other's patented technological information that it patents. The *closest* competitors need not rely on any mechanisms like working requirements or compulsory licenses to achieve the patent bargain because their ability to use the patented information arises in a reciprocal fashion, as suggested by Locke's original enough and as good condition. With far competitors, however, the patent bargain is not as easily attainable because of the inability of the patent grantor to use the patented information to extend the knowledge or employ it after patent expiry. Overall, the close competitor/far competitor distinction reveals the *specificity* of patent "property" (technical knowledge) that makes it

ii

challenging to transfer it to others, in contrast from Locke's general physical property model, which easily transfers interchangeable land from person to person.

The thesis concludes with a practical application of an expectations model to demonstrate its use beyond macro-analysis to the micro-analysis of patents. Employing a Canadian patent case adjudicated at the Federal Court and the Federal Court of Appeal, the analysis demonstrates the use of utility parameters in evaluating patents, creating patent score cards which can eventually be used as a database for evaluating the utility of future patents and setting patent terms accordingly.

#### **Summary for Lay Audience**

This thesis creates a new theory of patent law. It examines John Locke's theory of private property from the 1600's, then uses the characteristics of technical knowledge to demonstrate that Locke's theory does not translate well into a patent law theory. The theory then demonstrates that Locke's enough and as good condition (and its alternate forms) can be generalized into an expectations theory that better describes patent law and allows for the institution of flexible patent terms instead of the current rigid ones.

The thesis reviews the history of patent law development since the 1300's and elucidates two general periods in patent law. Once the periods are characterized and generalized, they are contextualized within a Lockean theory and also within the new expectations theory. From the analysis, two forms of patent law are elucidated: strong form (from the early period) and weak form (from the later period).

Following the historical review, the thesis examines the history of pharmaceutical patent law in Canada and applies the Lockean and expectations theories to it. Besides demonstrating strong form and weak form patent law, the chapter also identifies parties to a patent who have divergent knowledge bases as far competitors, while parties to a patent who have similar knowledge bases are identified as close competitors.

The final chapter demonstrates how an expectations analysis can be used to evaluate patents on an individual basis by examining a specific pharmaceutical patent case from the Federal Court of Canada.

#### Acknowledgements

I would like to acknowledge Doctor Samuel Trosow, Faculty of Law and Faculty of Information and Media Studies, University of Western Ontario, for his encouragement and his constructive criticism during the writing of my thesis. Beyond that, I would like to thank Professor Trosow for expressing his pleasure in reading my works since law school in the early 2000's. Technical matters aside, there is no better motivation to write a thesis than to have such a strong voice of genuine support.

I would like to thank Doctor Bassem Awad, Assistant Professor of Intellectual Property at the Faculty of Law, University of Western Ontario, for his useful comments and suggestions during the writing of this thesis.

I would also like to thank my wife Helen for her unconditional support for my academics, my biggest *personal* rewards in life. Helen is a wife, a mother, and a stand-in father for all of the kids' sports events and school trips missed during the writing of my thesis.

I would also like to thank my parents, Douglas and Lorraine Newman, for establishing a foundation for learning at home, and for teaching me dedication, determination, and organization.

Finally, I would like to thank academia for its eternal open-ended questions.

### **Table of Contents**

Abstracti		i
Sun	nmary for Lay Audience	.iv
Ack	nowledgements	v
Cha	pter One: The Patent Bargain	1
I.	Problem Statement	1
II.	Objectives of the Thesis	2
III.	Justification for the Research	4
А	. Information is non-Rivalrous	4
В	. Further Justification: Reconsidering Fixed Patent Law Terms	7
С	. An International Justification for a New Patent Bargain	9
III.	Thesis Overview	. 10
IV.	Assumptions	. 14
А	. Innovation Policy	. 14
В	. Inventors and Patentholders	. 15
С	. Patent Law's Effects between Societies	. 15
IV.	Background on Ideas and Protecting Innovation	. 16
А	. Ideas: the Genesis for Intellectual Property Protection	. 16
В	. Turning Ideas into Real Things	. 17
С	. Utilitarianism Connects Real Things to their Usefulness	. 18
V.	Modern Technical-Legal Requirements for Patents	. 19
А	. Novelty	. 20
В	. Utility	. 21
С	. Non-Obviousness	. 22
D	Patentable Subject Matter	. 25
E	. Public Examination, Disclosure, and Enablement	. 26
F	Patent Validity	. 28
Cha	pter Two: The Philosophical Bases for Intellectual Property Law	. 30
I.	Introduction	. 30
II.	Patent Law Theories	. 30
А	. Utilitarian-Based Justifications of Intellectual Property	. 30
В	. Personality-Based Justifications of Intellectual Property Protection	. 35
С	. The Insufficiencies of Utilitarian and Personality-Based Law Theories	. 35
D	A Liberal Justification for General Property: Locke	. 37

	1. Locke's Justification for Private Property through God and the State of	
	Nature	38
	2. Property in Locke's Governed Society: Inequality and Surplus	40
	3. The Natural Cycling of Private Property under a Lockean Justification	42
	4. A Theory Based on Locke's Conception of Private Property Requires a	
	Condition	43
E.	. Nozickian Compensation as a Replacement for Enough and As Good	47
F.	. Taking Private Property Requires Compensation: Nozick's Moral Basis	48
III.	Conclusion	48
Cha	pter Three: Modifying the Lockean Property Justification to Patent	<b>F</b> 1
	V	51
l. 		51
II.	The Characteristics of Technical Knowledge	51
A	. Knowledge is not Divisible but Inventors are Finite	52
В	. Knowledge is Prone to Theft	54
С	. Technical Knowledge is Specific and Cumulative	55
D	. Technical Knowledge becomes Obsolete	55
E.	. Wasted Knowledge Does Not Exist in the State of Nature	56
F.	. Defining "Surplus" Knowledge in a Governed Society is Uncertain	57
G	. Summarizing the Nature of Technical Knowledge "Property"	59
III. Justi	Applying the Characteristics of Technical Knowledge to Locke's ification for Private Property	61
Α	. A Necessary Correlation between Patent Grantors and Patentees: A	
Se	ocietal Example	61
В	. The Societal Surplus Approach	61
С	. The Transplanted Enough and As Good Approach	62
D ar	. The Insufficiency of Disclosure-Only in Locke's Surplus and Enough as Good Condition Models	63
E.	. Weak Form versus Strong Form Patent Law	64
F.	. The Nozickian Compensation Approach	64
G	. Nozickian Compensation by Disclosure Only	67
IV. Con	Generalizing Weakness in the Three Interpretations of the Lockean dition in a Patent Law Model	68
A	Enough and as Good is Inflexible but Represents the "Ideal"	68
R	The Surplus Condition is Vague and Lacks Accountability	69
С С	Nozickian Compensation Focuses on Remedving Damage	07 70
C	. 110210Kiun Compensation 1 ocuses on Kenicuying Damage	70

D. A Modified Lockean Justification is Based on Expectations	71
V. Conclusion	
Chapter Four: Patent Law History – A Shifting Emphasis from Utility and the Establishment of a Bargain to Non-Obviousness	
I. Introduction	
II. Pre-Industrial Patent Law: A Focus on Utility and Working Requirements with Customizable Patent Parameters	
III. The Evolution of Nonobviousness, Specification, Disclosure, and the Diminution of Utility after the <i>Statute of Monopolies</i>	84
A. Challenging the Standard of "New Manufacture" – the Lingering Importance of Utility and the Origins of Non-Obviousness	85
1. Broad Definitions of "New Invention" and Inventors	85
2. "New Invention" is not only Broad but Includes Utility	
3. Considerations of Utility and Judiciary Inconsistency	
B. The Development of the New Standard of Invention: Non-obviousness	
C. Developing Clarity in Non-Obviousness	
IV. Working Requirements and the Paris Convention for the Protection of Industrial Property	100
V. Conclusion of Historical Findings from the Development of Patent Law before and after the <i>Statute of Monopolies</i>	103
Chapter Five: A Comparative Analysis of Patent Law <i>before</i> the Development of Non-Obviousness and <i>after</i>	107
I. Introduction	107
A. The Exclusion of Non-Innovative Patents from the Analysis	107
B. The Identification of a Functional Change in Patent Law	108
II. Key Considerations in Applying the modified Lockean Theory to the Historical Time Periods	109
III. An Analysis of Patent Law before the development of Nonobviousness using a Modified Lockean Theory of Patent Law	110
A. Generalizing the Early Period of Patent Law	110
1. The Finiteness of Inventors was Understood	110
2. The Cumulative Nature of Technical Information was Understood	111
3. The Surplus from a Patent was Knowledge for Society	111
4. The Transplanted Enough and as Good Condition in the Early Period Required Intervention	112
5. Disregarding Patented Foreign Inventions was akin to Nozickian Compensation	113

В	An Expectations Analysis of the Pre-nonobviousness Period	114
IV. usin	An Analysis of Patent Law after the development of Nonobviousness ag a Modified Lockean Theory of Patent Law	116
А	. Generalizations about the Later Inventiveness Period	116
	1. The Finiteness of Invention vis-à-vis Inventors was mostly Forgotten	118
	2. The Cumulative Nature of Knowledge in the Nonobviousness Period was dropped as a Concern about Patent Law	118
	3. The Patent Surplus was Static, Satisfied by Disclosure of the Specification Only in the Nonobviousness Period	119
	4. Nozickian Compensation was Uncertain with Nonobviousness	119
В	An Expectations Model of the Late Period	120
V.	Conclusion	120
Cha witl	apter Six: A Consideration of Canada's Recent Patent Law History hin the Context of the Modified Lockean Theory of Patent Law	124
I.	Introduction	124
II.	Canada's Early Patent Law History: An Essential Review	124
А	. Canada's First Statutes: Novelty and Working Requirements	125
В	. The Evolution of the Inventiveness Standard in Canada	127
С	A Low Standard of Utility in Early Canadian Patent Law History	128
III. Pha	Operationalizing Patent Law in Canada toward Specific Goals: rmaceutical Patent Law in Canada	129
A Ir w	The 1923 Amendment to the Canadian <i>Patent Act</i> : the Rising nportance of Pharmaceutical Patents, Compulsory Licensing, and Conflict <i>v</i> ith International Patent Law Treaties	130
В	. The 1950's: Concerns over High Drug Prices from Monopolies	133
С	Revisions to Canadian Patent Legislation in the 1950's	134
D Pi	<ol> <li>Canada's Royal Commissions in the 1950's and 60's Regarding Drug rices and Compulsory Licensing</li> </ol>	136
	1. The Ilslev Commission	137
	2. Commissions after the <i>Ilslev Commission</i>	139
E D	. 1969 <i>Patent Act</i> Revisions: Compulsory Licenses to Import and the Development of the Generic Drug Industry	140
F R	. Market Exclusivity for Innovative Drug Manufacturers in 1987 evisions	141
IV.	Exporting the Protection and Enforcement of Patent Law Globally	143
А	. The North American Free Trade Agreement	145
	1. Equal Treatment of Patents, both Foreign and Domestic	146

2. Extremely Limited Use of Compulsory Licensing	146
3. Canada-United States-Mexico Agreement updates Patent Terms	147
4. Flexibility with Substantive Patent Criteria but no Discrimination	148
B. Agreement on Trade Related Aspects of Intellectual Property Rights	148
V. Conclusions on Canada's Abolition of Compulsory Licensing	149
VI. Doha Declaration and Canada's Access to Medicines Regime (CAMR)	151
VII. COVID-19 Emergency Response Act Overrides Patents	152
VIII An Analysis of Canada's Pharmaceutical Patent Law within a Modified L Theory of Patent Law	.ockean 153
A. Finiteness in Inventing and Inventors was Understood but Relinquished as a Concern	154
B. The Accumulation of Pharmaceutical Knowledge in Canada was Recognized and Important in Earlier Times	155
C. Canada tried to Create a Societal Surplus using Compulsory Licensing for Pharmaceuticals	156
D. A Transplanted Enough and As Good Condition under Canada's Compulsory Licensing Laws Reveals Inadequate Knowledge for Utilizing Pharmaceutical Patents	157
E. Nozickian Compensation through Compulsory Licensing Illustrates Divergent Social Welfare Baselines	158
F. An Expectations Model of Canada's Pharmaceutical Compulsory Licensing Laws	161
IX. Conclusion	162
Chapter Seven: Conclusion	165
I. A Lockean Theory of Patent Law Requires Condition Fulfillment	165
A. <i>Surplus</i> in a Lockean Societal Patent Law Model is Vague and Uncertain	166
B. The Effects of Transplanting Enough and as Good into a Lockean Societal Model: Utility of a Patent is the <i>Utility of the Information</i> to Society	167
C. Nozickian Compensation to a Social Welfare Baseline of Knowledge	168
II. Patent Law History: Two Periods Distinguished by a Functional Change in the Law	170
A. The Modified Lockean Model in the Original Period: Utility and Working Requirements-Based	171
B. The Lockean Model in the Later Historical Period: The Development of Nonobviousness	173
III. Expectations as a General Patent Law Condition: Strong versus Weak Form Patent Law	174

A.	Expectations for Inventors and Patent Grantors and a Just Patent System	175
B.	Close Competitors versus Far and Ideal Patent Law	177
IV. ( under	Conclusions about Canada's Modern Pharmaceutical Patent Law History r a Modified Lockean Theory of Patent Law	180
A.	The Abandonment of Compulsory Licensing and the end of Strong	
For	rm Patent Law in Canada	181
I. I	Introduction	184
A.	Nonobviousness	185
В.	Novelty	185
C.	Utility	185
D.	Disclosure and Enablement	187
II. T	The Case: Pfizer's Norvasc (the Besylate Salt of Amlodipine)	187
A. Me	Background on Amlodipine – an Antihypertensive and Anti Ischemic edicine	187
B.	Case Details: Ratiopharm Inc. v. Pfizer Limited'	191
]	l. Obviousness	191
2	2. Laws Specific to Selection Patents	193
	3. Utility	195
۷	4. Sufficiency in Disclosure and Enablement	196
4	5. Section 53	196
6. (	Case Summary	197
IV. C	Constructing the Patent Expectations Model	198
A.	Defining Expectations	198
1	1. Defining Public Patent Policy	199
2	2. Novelty, Utility, and Nonobviousness as Public Policy Instruments	199
	3. Other Policy Considerations	201
B.	Establishing the Legal-Policy Framework for the Norvasc Case	202
C.	Expectations for an Amlodipine Besylate Salt: The Primary Question	202
1	I. Novelty	203
2	2. Patent Categorization and Description	203
2	3. Nonobviousness	205
۷	4. Knowledge Blockade	207
4	5. Utility	208
6	5. Industrial Capability	210
7	7. Academic Knowledge	211

D.	Summarizing the Amlodipine Besylate Patent	
E.	Scoring the Patent	
G. Bes	Table 1: Patent Expectations Model Categorization of the Amlodipine           sylate Salt	
H.	Table Two: Scoring the Amlodipine Besylate Salt Patent Application	
H.	Chart One: Profile of the Amlodipine Besylate Salt Patent Application	
Bibli	ography	
A.	Journal Articles	
B.	Monographs	222
C.	Government Commissions	225
D.	Government Studies	225
E.	Text Resources	226
F.	Relevant Legislation	226

#### **Chapter One: The Patent Bargain**

#### I. Problem Statement

A liberal justification<sup>1</sup> for private property is a widely accepted doctrine for not only acquiring physical property but creating *intangible property* like patents on new inventions. Though similar to physical property, intangible property requires mental rather than physical "efforts" to be combined with resources to develop new knowledge that can be held and controlled exclusively by the creator if they demonstrate enough innovation.

John Locke's philosophy of private property, a primary school of thought for this justification, creates a natural right in intellectual property when knowledge resources are sufficiently applied to create a new thing. Locke justified his *general* theory of private property by claiming that property taken out of the commons for personal use is eventually returned to the commons for others to use in as good of shape or better than when it was taken, leaving the next person in the same position for using it as the prior. Applying Locke's condition to patent law, this thesis demonstrates that this self-fulfilling

<sup>&</sup>lt;sup>1</sup> See John Locke, *Two Treatises of Government: a critical edition with an introduction and apparatus criticus by ed Peter Laslett.*, (New York: New Am Lib, 1963) for the primary justification for private property discussed in the thesis. A liberal theory is one that perceives the rights of individuals as the basis for establishing laws. Locke's theory of private property encompasses widely held beliefs about why property as private property can be justified. Its publication in the mid sixteen-hundreds was amidst the mass migration of Europeans to the United States, who were seeking economic prosperity. Because of the timing, Locke's theory is commonly attributed to the development of private physical property, but several of his examples reveal that his conception of property was much larger, providing an avenue for the academic development of a justification for intellectual property. See Justin Hughes, "The Philosophy of Intellectual Property" (1988) 77:2 Grgtn LJ 287 for an explanation of the extension of Locke's justification for private property. Besides applying Locke's theory and applies it to the intellectual property variant. The criticisms revolve around consent to private property by society, and the initial unequal distribution of resources among the consenting participants of society, which form a basis for challenging a Lockean theory of intellectual property.

character of acquiring, improving, and bequeathing property does not necessarily create the positive-reinforcing physical property use-cycle described by Locke because *information property is not characteristically like physical property*.

According to classic liberal theory, property rights are a part of personal liberty because *all* rights exhibit characteristics of property.<sup>2</sup> Classical liberals also assert that property is necessary for allowing one's rights to flourish because it necessarily excludes all others but the owner from its use, creating sovereignty in one's personhood.<sup>3</sup> These classic claims have been challenged by revisionist liberal theorists. Among their many arguments, revisionists claim that property rights propagate inequality among people, leading to differing abilities of individuals to exercise their rights. Additional fracturing of liberal theories into libertarianism and liberal social justice have led to an expansive set of what "liberal theories" encompass. While one could examine alternative liberal conceptions of patent law, the basic Lockean conception of combining mental effort with resources provides an uncluttered basis from which a new theory can emerge. Once the basic theory is developed, revised models based on alternative liberal theories could be created and compared.

#### II. Objectives of the Thesis

This thesis will demonstrate how exclusive patent property rights can be created through a modified Lockean technical knowledge "property" theory. The theory retains a Lockean-type condition by incorporating the characteristics of technical knowledge into

<sup>&</sup>lt;sup>2</sup> Gerald F Gaus, "Property, Rights, and Freedom" (1994) 11 Soc Phil & Pol 209 - 40.

<sup>&</sup>lt;sup>3</sup> John S Mill, *Principles of Political Economy* in *Collected Works of John Stuart Mill*, (2) ed by J M Robson, (Toronto: University of Toronto Press, 1963) at 203 – 210.

the model and evaluating them, but the model transforms it into an expectation. The modified theory will be applied to a macro-examination of the historical foundation of patent law in the early Italian city states and England, characterizing patent law as two distinct periods, distinguished by a functional change in the law. It will demonstrate that a Lockean theory modified to incorporate the technological nature of information as property is sufficiently satisfied when utilitarian considerations are taken into account, but only weakly satisfied when they are not. As a corollary to the modified theory, the patent bargain is not always fulfilled if patents are granted without *reasonably foreseeing the application of the patented information* and setting the patent conditions accordingly. Examining patent law history through a Lockean model, using different forms of the Lockean condition, identifies both strong and weak forms of patent law, and close competitors and far competitors, then connects the observations in an expectations model that can explain how technical information can be patented in the granting society.

Canadian pharmaceutical patent law history will be reviewed and analyzed through the same modified Lockean theory. Canada's relaxation of pharmaceutical patent laws and its subsequent re-tightening over the past century support the conclusion that patent law under a modified Lockean model can be characterized as either strong form or weak form. Under the weak form, there is no expectation that a "patent bargain" be met beyond mere disclosure and enablement criteria; under the strong form, stronger expectations for the patent bargain exist. It will also separate patent actors, the parties *to* a patent, as close and far competitors, distinguished by the *effects* of patent law on both of them. Strong form/weak form and close competitor/far competitor concepts will help address weaknesses in the general Lockean model, providing an avenue for redefining a

3

philosophical paradigm of what patent law can be in the future, not by saying that the Lockean condition does not apply, but by *making* it apply through expectations.

Finally, the expectations model is adapted into practical form to exemplify its use regarding a pharmaceutical "invention" that was adjudicated at Canada's Federal Court and Federal Court of Appeal. While the analysis is not meant to be a comprehensive model, this early form provides an insight into how an expectations model might work and how patent evaluation would have to change.

The thesis conclusions, based upon modifying Locke's theory into an expectations model, serve as a platform for future research on pharmaceutical patent law reform. Where a lack of genuine utility considerations in current weak form patent law can describe and explain Canada's patent law today, the theory becomes the basis for future changes to patent law. With a stronger account of utility, patent law transitions toward a stronger form, with more certainty for achieving society's expectations for patents. Specifically, the conclusions in the thesis will provide a basis for creating a detailed patent utility analysis tool in the future for assessing pharmaceutical patents and adjusting patent terms accordingly.

#### III. Justification for the Research

#### A. Information is non-Rivalrous

Because of information's non-rivalrous nature, it's acceptance as indivisible property within liberal schools of thought has been unchallenged, making Locke's theory unconditional - there has been no need to think of technical knowledge as being scarce because one person's uptake of knowledge does not preclude another's. Noted Canadian

4

patent law academic, Harold Fox, was a strong proponent of the patent system, and described the infiniteness of new inventive information succinctly:

The patent monopoly does not, as is commonly and popularly supposed, operate by a process of subtraction. It takes nothing away from the public, but only adds to the common store....Where did this property come from? The state parted with nothing by the patent. The patentee, in effect, received nothing which he did not have without the patent.<sup>5</sup>

Professor Fox's statement that patents take nothing from society for their development is a common presumption that excuses the Lockean condition from making a meaningful contribution to patent law theory, allowing the simple disclosure of patent information to be construed as sufficient for attaining the patent bargain. It is a simple view that is difficult to criticize, reminiscent of how a single, genuinely brilliant, skilled person might arrive at an invention that someone could easily steal, replicate, and use, thereby creating a need to protect it. It does not, however, consider that a Lockean theory of private property ownership must fulfill a more material condition because it cannot be assumed that patented technology is always readily taken up and useable by the patent grantor, or that it matches the grantor's values. Rather, Professor Fox's view suggests that no such condition needs to exist – if a patent adds to the common store of knowledge, what it really adds for society's benefit does not need to be taken into account. This thesis serves to clarify what taking Locke's condition into account does for patent law *theory*, where eliminating it is not the same as satisfying it because the former

<sup>&</sup>lt;sup>5</sup> Harold Fox, *Monopolies and Patents: A study of the History and Future of the Patent Monopoly* (Toronto: University of Toronto Press, 1947, repr 2019) at 202, 203.

becomes a condition-less justification, not a theory.<sup>6</sup> Maintaining the condition is a theory requirement but it needs to be modified because the 'indivisibility of information' remains problematic when trying to generate redress for the issuance of property in information according to an academic theory.

Contemporary patent law grants a term of exclusivity in selling or licensing an invention in exchange for disclosing the workings of the patent and how to construct it, but it guarantees no success that society will be able to apply the information. In many cases, society is left with no benefit.<sup>7</sup> If society wishes to broaden its participation in technical innovation and meet policy-related goals, revamping patent laws is necessary, and the thesis will demonstrate that reconceptualizing the Lockean patent bargain facilitates avenues for making change. By addressing deficiencies inherent in a general liberal theory, other patent law concepts can be revived and used as a basis for patent law reform.<sup>8</sup>

<sup>8</sup> Further research will consider material factors of invention, like *how inventive an invention really is* or how important the invention is to a particular society, but also how likely a patent granted is to be utilized

<sup>&</sup>lt;sup>6</sup> A similar discussion to Locke's as to why property should be granted as-of-right in some cases in society is found in David Hume, Esq, *Enquiry Concerning the Principles of Morals* (Catherine-Street in the Strand, London: A. Millar, 1751) at 41.

<sup>&</sup>lt;sup>7</sup> Patent law remains a key element of innovation, but not the only one. Many factors affect the ability of a nation to innovate, including economic status, the availability of natural resources, educational systems, taxation systems, government incentives, and private investment. Some academicians have argued that the patent system does not hurt anyone. Arnold Plant, "The Economic Theory Concerning Patents for Inventions" (1934) 1:1 Economica 30 at 41 states "If the patented article is something which society without a patent system would not have secured at all-the inventor's monopoly hurts nobody. . . His gains consist in something which no one loses, even while he enjoys them," quoting Professor J.B. Clark, Essentials of Economic Theory (New York: Macmillan, 1927). Because inducing a patent does not divert scarce resources away from some other productive effort, the concern about the reward for patent should be negligible. But David Hume Esq. argues in Enquiry Concerning the Principles of Morals, ibid at page 35, that anything that is in abundance; in other words, having no scarcity among humans, should not be made property. He establishes his claim by exemplifying air and water as abundant commodities that need not be called property. He also differentiates the scarcity of land by comparing large, uncharted areas with fertile land and few inhabitants to the same quality of soil in areas with a lot of inhabitants, requiring property in the second instance but not the first. Under Hume's view, the knowledge imbued in patent could be viewed as abundant and non-rivalrous, so no claim of property would be necessary.

The institution of an applicable Lockean condition is an important component of patent legal theory because it forces a reconsideration of what the law is supposed to return to the society which creates and upholds that law. From an examination of the *characteristics* of technical information, Locke's condition can be generalized as an expectation within the law, meaning that there is some reasonable likelihood that the law will work to assess a societal benefit from the creation of private property. The thesis will also demonstrate that this broad expectation for the betterment of society supports not only legal grounds for the theory but moral or values-based grounds left unconsidered by Fox. The historical examination of patent law using variations in Locke's conditions demonstrate that patent history can be characterized by the use of a general expectations condition instead.<sup>9</sup>

#### B. Further Justification: Reconsidering Fixed Patent Law Terms

Traditionally, patent law has been viewed by academics in a binary sense *in two different ways*. In the first way, the existence of patent law has been academically scrutinized as to whether it should or should not be the law as an either/or question. A

by society *for its knowledge, not just for its immediate utility*. It could consider what *form* the inventor or holder of a patent takes, or how important core academic research was that lead to certain patents. It may also consider how important the environmental impact of any invention is. Consideration of these material factors helps to understand that the disclosure of a patent relates to a reasonable prospect of using the information in the patent embedded within the Lockean theory and facilitates different approaches to patent law, which will be discussed in future writings.

<sup>&</sup>lt;sup>9</sup> Industry is beginning to realize that global innovation cannot solely rely on patent for success. See Richard E. Gold, "Biotechnology, Innovation and Partnerships" (2009) 10 J High Tech L, 1. Professor Gold describes how the shift in the pharmaceutical industry toward the worldwide supply of its products among high, mid-, and low income countries has led to a misfit of patent law with the traditional approach to intellectual property among corporations because the idea of hoarding the intellectual property within a corporation no longer meshes with the broader international community. Professor Gold exemplifies this problem with the actions of the Myriad Genetics corporation, where trying to enforce patents on its diagnostic tests (which essentially was patenting over gene sequences) for ovarian and breast cancer led to extensive global backlash against the company, as well as calls for banning gene patenting altogether. Professor Gold's article serves to reinforce the idea that patents require a bargain, where social gain is an important element of it.

great period of debate emerged in industrial Great Britain in the mid-1800's,<sup>10</sup> where opinions were divided as to whether patents stimulated innovation or restrained trade. Whether patents "should be" or "should not be" is a natural inclination for research because of the *second* binary characteristic of modern-day patent law: patents are either granted according to standard terms or they are not granted at all. Despite the complexities involved in evaluating new technologies for meeting the standard of inventiveness or subject matter criteria, a patent is either granted or not granted, with no gradations of patent status along a spectrum,<sup>11</sup> making the law of patent simple, but creating information blockades from the issuance and observance of patents that do not necessarily reflect the expectations of the society who is granting them.

Examining patent law from binary perspectives has led to little academic encouragement for change in the patent system in modern times, where changes have revolved around technical issues like extending patent term, adding data exclusivity periods, modifying the inventiveness standard, growing or limiting the coverage base of patentable subject matter, and extending patent law protection and enforcement to countries around the world. A primary goal of this research is to remove the notion that

<sup>&</sup>lt;sup>10</sup> Fritz Machlup, Fritz and Edith Penrose, "The Patent Controversy in the Nineteenth Century" (May,1950) 10(1) J Econ Hist 1. The authors of this article recounted the arguments of the major debate about the appropriateness of the patent system during the industrial revolution in Europe and Great Britain. Academic literature in the 1800's, during the rapid growth of industrialization in Great Britain and Europe was flush with articles for and against patenting. The height of this controversy occurred between 1850 and 1875, which forms the focal point of the arguments in this article about patent rights, when patents were attacked on the belief that they were impediments to free trade.

<sup>&</sup>lt;sup>11</sup> In some countries, utility models exist to provide protection for certain technical improvements. While novelty is a key criterion, utility models differ in their standards for nonobviousness, often lower than the threshold required for a full patent. Because the improvements are less significant than a typical patent, the patent reward is set for a shorter time period. The emergence of utility models provides strong evidence for the need for a modified theory of patent law that can encompass the spectrum of technical improvements and how patent protection should be assigned. See World Intellectual Property Organization: https://www.wipo.int/patents/en/topics/utility\_models.html#

<sup>:~:</sup>text=What%20is%20a%20utility%20model,consents%20of%20the%20right%20holders.

the characteristic binary status of granting patents should constrain new patent theories. An expectations model, based on revising the Lockean theory, can move current thinking about patent law outside of binary parameters by reintroducing previously used patent law criteria for assessing innovation in a flexible fashion rather than using the current system of standard rules to provide a theoretical basis for making changes.<sup>12</sup> While patent property rights are granted automatically upon achievement of the standard, a flexible model will allow for the individual determination of rights based on the formation of certain expectations for the rights grantor and the patentee.

C. An International Justification for a New Patent Bargain

Canada signed the *North American Free Trade Agreement*<sup>13</sup> and the *Trade-Related Aspects of Intellectual Property Rights Agreement*<sup>14</sup>over twenty-six years ago and relinquished its compulsory licensing provisions for pharmaceuticals in the process. While Canada's negotiation process has been documented, the change in position has not been analyzed within a philosophical framework. Locke created his theory by observing the actions of migrants to a "new world" who attained private property, and his settling upon that theory was facilitated by the consistency of action of creating that property over time. Canada's actions, however, demonstrate a break in the consistency of patent law,

<sup>&</sup>lt;sup>12</sup> Raymond T Nimmer, "Breaking Barriers: The Relation Between Contract and Intellectual Property Law" (1998) 13(3) Berk Tech Law J 827. On page 830, Professor Nimmer clearly states that "[t]he intellectual property bargain or the delicate balance that allegedly exists in current intellectual property law cannot be referred to as if these were matters merely of a balanced stated in *property* law rules. This clearly misrepresents the circumstances."

<sup>&</sup>lt;sup>13</sup> North American Free Trade Agreement Between the Government of Canada, the Government of Mexico and the Government of the United States, 17 December 1992, Can TS 1994 No 2, (entered into force 1 January 1994); 32 ILM 289 [NAFTA].

<sup>&</sup>lt;sup>14</sup> Marrakesh Agreement Establishing the World Trade Organization, Annex 1C: Trade Related Aspects of Intellectual Property, 15 Apr 1994, 1867 UNTS 154, [TRIPS Agreement or TRIPS]; 33 ILM 1144. TRIPS, contained in Annex 1C, is an amendment to the General Agreement on Tariffs and Trade, 30 Oct 1947, 58 UNTS 187, TS No 27 58 UNTS 187 (entered into force 1 January 1948) [GATT 1947].

creating an opportunity to characterize the law on either side of the change in compulsory licensing.

Canada's change in its pharmaceutical patent laws during this time provides a convenient historical point for characterizing the law according to a modified Lockean theory across two time periods. A broad examination of Canada's legislative changes will reflect what Canada intended to benefit in each time period<sup>15</sup> and matching it to what was achieved could be the subject of future study. Creating a basis for justifying the bargain from patent is overdue and can only serve to benefit Canada when it revisits its patent laws, in light of world patent laws, and will strengthen its participation in reforming international patent agreements.

#### III. Thesis Overview

Creating an expectations model of patent law can begin by describing patent law and the patent bargain through the lens of a liberal justification of private property. In Chapter Two, John Locke is identified as the pre-eminent author of a widely accepted liberal theory of private property. His theory is based upon the actions of an individual, empowering the idea of rights, specifically property rights, which should be assigned to

<sup>&</sup>lt;sup>15</sup> Maryse Robert, *Negotiating NAFTA: Explaining the Outcome in Culture, Textile, Autos, and Pharmaceuticals* (Toronto: U of T Press, 2000). Doctor Robert provides the context for the outcomes of the *NAFTA* negotiations between Canada and the United States and Mexico by recounting the history of the pharmaceutical industry in Canada, then explains government intervention through regulation of pharmaceuticals from a safety standpoint, as well as through patent law. She performs a similar analysis of United States law.

Doctor Robert sets forth provisions of the text for *NAFTA* tabled by Arthur Dunkel and determines which provisions of Canadian patent law were inconsistent with it. She concludes that Canada did not meet its objective of retaining compulsory licensing throughout the negotiations because the Dunkel text required full patent protection of pharmaceuticals, with no discrimination among fields of technology. The negotiations were important because they established nearly identical provisions to be agreed upon in the *TRIPS Agreement* that followed in subsequent years. With Canada relinquishing its compulsory licensing, many other nations no longer viewed the Canadian model as a viable option in establishing world trade agreements on intellectual property, and the ideals that Canada held as a bargain were extinguished.

any person who acts accordingly to gains those rights. Chapter Two reviews Locke's theory of private property in his *Second Treatise of Government* and brief consideration is given to alternate philosophical theories of patent, which are shown to be not inconsistent with Locke's theory, but complementary to it.

The modified Lockean theory is developed in Chapter Three, giving consideration to the nature of technical information as property.<sup>16</sup> Different forms of Locke's proviso are presented and analyzed within the context of patents as property, setting patent disclosure as a minimum condition for achieving the patent bargain. The different forms prove useful as descriptive analysis tools of patent law history and can also be reasoned into one broad "expectation" for facilitating an increase in the *useable* knowledge to society.

Chapter Four reviews patent law from its beginnings as a societal incentive tool for innovation. It describes importance that utility played in assessing early patents, but also revealed a general want by society to restrict the power of the monarchy and only grant special privileges to inventions that were truly remarkable, leading to the English *Statute of Monopolies* and a decline in the importance of utility. It covers English society's struggle to narrow what was valued enough to be awarded patent, defining a

<sup>&</sup>lt;sup>16</sup> An objection to the theory, the idea that consent alone should be sufficient to justify the imposition of patent law, will be considered. Law that is consented to, not for the law itself, but for the sake of achieving something else, can be a form of duress. See Richard E. Gold & Jean Frédéric Morin, "An Integrated Model of Legal Transplantation: the Diffusion of Intellectual Property Law in Developing Countries" (2014) 58 Int'l Stud Quarterly 781. In this paper, the authors demonstrate that decisions by countries to join the World Trade Organization, and concomitantly sign the *TRIPS Agreement*, were not necessarily rooted in rational behaviour, but were reflective of the pressures that nations faced to sign it. The pressures include coercion, emulation, contractualization between states, and regulatory competition. The article is important, because it helps to demonstrate why countries might sign an international agreement, even though it may not be in their best interest. Not only did these forces play a role in expanding intellectual property laws around the world, but they served to destroy compulsory licensing, and all but destroyed the patent bargain, social welfare, or a social contract, related to patent granting and the development of a strong local pharmaceutical industry in Canada.

pathway to "inventiveness" during the Industrial Revolution in England that culminated in the standard of nonobviousness, taking the judiciary centuries to identify and develop. While nonobviousness solidified and expanded in the jurisprudence, other patent law parameters changed too: the scope of patents narrowed through the *Statute of Monopolies*, working requirements tapered off, and utility requirements as mentioned, diminished to a minutia, all restricting patent law's ability to achieve a strong Lockean bargain.

Using the modified Lockean theory from Chapter Three, Chapter Five separates patent law history into two periods and reinforces the *major functional-legal change* between them as the development of an inventiveness standard. This change distinguishes the early period as strong form and the latter as weak form patent law and reveals a difference in the competencies that exist among societies subject to patent law, based on their ability to use the information that they patent. This difference in relationships between patent actors creates a natural separation between *close* competitors, where patent protection is mutually beneficial for both parties, and *far* competitors, where one competitor has no ability to compete with another that has a developed industry, meaning that no mutual benefit for patent protection exists.

The use of compulsory licensing in Canada will be presented in Chapter Six as an historical example of the use of intellectual property rights that leaned toward the fulfillment of established goals for the patent bargain, one of which was the development of a strong domestic pharmaceutical industry in Canada for the benefit of both Canadian consumers and producers of medicine. The history of Canada's use of compulsory licensing in the pharmaceutical industry will highlight the difficulties of accumulating

12

knowledge in the pharmaceutical industry, where easily obtainable licenses for patented medicines for Canadian pharmaceutical companies were no guarantee that successful innovative drug development would ensue. Canada's experience illustrates the idea that far competitors who are *really far* from achieving competitive status with industrialized nations receive no bargain from patent law. The modified Lockean theory of patent law will also reveal that the form of Canada's pharmaceutical patent law changed when it relinquished its compulsory licensing provisions to participate in international trade agreements.<sup>17</sup>

Chapter Seven concludes the thesis by stating that an understanding of patents as "property" is best theorized by modifying Locke's liberal notions of the right to private property into an expectations model. Factors affecting the utilitarian nature of patents are reviewed, plus the necessity of capturing a bargain in the theory for society is reinforced. The strong form/weak form and close competitor/far competitor distinctions are reviewed and serve as a starting point for reinfusing utility as a mechanism for restoring patent law to a stronger form, where such laws ensure the receipt of more certain expectations for those who grant patents as exclusive property to inventors.

The chapter also discusses how reconceptualizing the modified Lockean theory into a strong form expectations model would increase the flexibility of patent law while still protecting liberal notions of inventorship and ownership. It reinvigorates utility by using it as part of the evaluation of any given patent, then *specifying the individual terms* 

<sup>&</sup>lt;sup>17</sup> Canada's commitment to participation in free trade in *NAFTA* and *TRIPS* led to a repeal of its compulsory licensing provisions in the 1990's. See *The Patent Act Amendment Act*, SC 1993, c 2, s 3. The end of compulsory licensing for pharmaceuticals meant that Canada was no longer discriminating on the basis of field of technology, a key provision in its free trade commitments. Not only was discrimination by field of technology barred, but discrimination was not allowed between patents developed in the home country or abroad.

*of that patent to fulfill the Lockean proviso*. The new theory will allow for study of the differential application of patent laws to close and far competitors, the adaptation of standards of non-obviousness, and the decoupling of patents from fixed twenty-year terms in order to satisfy the expanded notion of the patent bargain.

While Chapter Six uses the expectations theory to explain broad changes in pharmaceutical patent law history, Chapter Eight illustrates the expectations model in a microanalysis of a single pharmaceutical patent. It demonstrates the use of nonobviousness, utility, policy, and other parameters for assessing patents, and how they might be scored. Continued development of "patent profiles" could lead to a future database platform for relative valuations of patents that could be used to establish variable patent terms.

#### IV. Assumptions

#### A. Innovation Policy

The thesis presumes that societies have innovation as a governmental policy. It assumes that all nations agree that innovation is good and wish to develop industries locally with a high degree of technological innovation for the purposes of creating selfsufficiency and economic growth. This assumption narrows the motivation of patent law to accept innovation as a fact. It also confronts a potential criticism of the theory that not all societies may want innovation, nor want to apply patent policy in the same way. If a general governmental inclination toward innovation is impractical, then establishing a theory of patent law supported by many societies becomes difficult because it would be trying to capture competing objectives.

#### B. Inventors and Patentholders

Patents can be transferred from the individual who invented something to another individual through the sale or assignment of rights associated with the patent. For simplicity, this thesis assumes that the patentholder is the inventor, and that no sale or assignment of rights has taken place unless expressed otherwise. The words creator, inventor, engineer, patentee, patentholder, and grantee will be used interchangeably.

The assumption is made because the assignment of patent rights can fundamentally change the analysis. If a patent can be purchased, for example, the monetary exchange could be viewed as remuneration for the value of the mental labour of the inventor. The purchaser, however, may intend to profit from the purchase by using the exclusive rights of the patent to generate far greater returns in the marketplace than what was paid to the inventor, creating an issue over the value of inventive labour and the value of markets<sup>18</sup> that deserves its own special treatment in subsequent works.

C. Patent Law's Effects between Societies

The thesis is concerned with the effects of patent laws *between societies*. Where patent was initially used as a tool for drawing innovators from one nation to another to bolster local industries, its impact between societies is relevant because of the lack of concern for patent law's extra-territorial effects. As patent law progressed, international cooperation between nations increased, gearing patent law toward mutual national respect. Therefore, it is the primary relationship that patent law has between societies that is of interest, where a party from one nation is seeking patent protection in another. In a related assumption, an inventor who developed and patented an invention in his

<sup>&</sup>lt;sup>18</sup> Edwin C Hettinger, "Justifying Intellectual Property" (1989) 18(1) Phil & Pub Aff at 38 – 41.

home society has fulfilled the patent bargain because he has used knowledge and resources in his own locale, meaning that his society has the requisite accumulated knowledge to arrive at the invention, and his society achieves the benefits from patent.

IV. Background on Ideas and Protecting Innovation

The following section explains how ideas get transformed into real things that are special enough to be granted patent status, then reviews legal concepts in modern patent law that will prepare the reader for the remainder of the thesis. Although some of the concepts have changed meaning over time, a familiarity with their modern definitions will facilitate an understanding of the general concepts.

A. Ideas: the Genesis for Intellectual Property Protection

Intellectual property protection stems from the notion that ideas, once developed beyond a description into something tangible, deserve to be protected from emulation by anyone for a specific period of time. Ideas themselves are not protected but are held in the minds of individuals. Many of those ideas become part of the public domain through academic research, commercial research, and personal or collective experience.

Ideas do not have to be apparent to all members of a society. They result from a person's education, work, and general life experiences, which are combined with a mental inclination to retrieve knowledge from a common base and use it. Alternatively, ideas can be viewed as the product of creativity, where ideas are conjured in the mind, as opposed to being drawn from a common pool of ideas. Ideas are then transformed, translated, and communicated, which can be a foundation for other transformations. The idea of a rotating mass, never-before seen or documented, could be sketched, then turned into several real-world incarnations, for example. Ideas are non-rivalrous, in that one

16

person's use of an idea does not preclude another's, meaning that many people can and *will* act upon the same idea.

Ideas and their execution into a physical form are not always readily separated because experimentation often happens simultaneously along the path of execution, so the ideas conjured up are not necessarily ideas catalogued by, or even predicted from common knowledge. The development of a complicated machine could take many turns at any given stage of development, with ingenuity occurring along the way. The amount of research required to create the idea itself can be complicated, where some of the ingenuity happens by trial and error.

#### B. Turning Ideas into Real Things

Using mental "labour," ideas can potentially be translated, transported, and communicated from an ethereal space into something tangible, where society can be given access to it. Regardless of how ideas are retrieved and transformed into an invention for humanity, a person who happens upon a particular idea cannot hold it as exclusive property until it is developed well beyond being an idea, where executing the transformation of that idea requires further thought and labour. The hallmark of modern patent rights is that patent protection will only occur after substantial physical development occurs and the level of ingenuity meets a legal standard.

Once ideas are shaped into something tangible and sufficiently inventive, the knowledge *behind* that more tangible object, or invention, becomes patentable. Patents allow the inventor who formed the invention to enjoy the exclusive right to use, manufacture, distribute, and sell the invention for a fixed period, on the condition that the inventor disclose the invention to the public in such a way that it could be replicated by

17

someone of similar knowledge. By doing so, new ideas are added to the common knowledge base, and society should become better off by having them available for further development when the patent expires.

Ideas generally follow a progression, where one idea leads to subsequent ideas, simple or complex. Knowledge accumulates through ideas, whether patented or not, but patented knowledge delays the onset of the *use* of accumulated knowledge through the patent for the duration of the term for all others except the patentholder. It is unsettled academically as to whether this delay leads to higher social utility.<sup>19</sup>

C. Utilitarianism Connects Real Things to their Usefulness

Where "utility" is a patent term that refers to what an invention is specifically used for, "*utilitarianism*" is a theory of morality that views individuals as decisionmakers who make the best choices for themselves. Collectively, the net consequences of this decision-making results in maximized welfare for society. Beginning in the eighteenth century, it was subject to extensive writings by many authors,<sup>20</sup> becoming a compilation of theories of morality that predicate that the good that emanates from society is because of an inherent drive for individuals to maximize their happiness and well-being, and minimize their pain.

Utilitarianism is an important concept within the thesis because it brings forth the idea that technical knowledge has value to society. Not only is that knowledge important

<sup>&</sup>lt;sup>19</sup> Peter S. Menell, "Intellectual Property: General Theories" (2003) *Encyclopedia of Law and Economics* ch1600 129 at 163.

<sup>&</sup>lt;sup>20</sup> Jeremy Bentham and John Stuart Mill were among the most prominent academicians who developed theories of utilitarianism. While Bentham treated the utility among different choices equally, Mill adapted the theory to value different choices. Both were considered hedonistic, in that individuals would seek to maximize pleasure and minimize pain, and both were consequentialist, where forming choices leads to consequences.

for making a new device that improves the human condition, but the knowledge has value *for the sake of empowering others to use it*, an important distinction within the thesis. Whereas the former refers to a more immediate gratification from the acquisition of a higher technology invention, the latter refers to the longer-term value in gaining knowledge, accumulating knowledge upon existing knowledge, and using all of the cumulative knowledge for further advancements...a process in society that is utilitarian in nature because it leads to higher social welfare.

#### V. Modern Technical-Legal Requirements for Patents<sup>21</sup>

For any invention that meets the requirements outlined in the *Patent Act*,<sup>22</sup> a patent is granted to the inventor by the Canadian Intellectual Property Office. The patent allows the inventor, or the *owner* of the patent, an exclusive time period to manufacture, distribute, and sell the invention. In Canada, this exclusive period is twenty years from the date of filing the patent application.<sup>23</sup> In exchange for the monopoly, the inventor must disclose a description that sufficiently identifies the invention and enables others to recreate it so that it can be a steppingstone to further innovation.

Section 2 of the *Patent Act* defines an invention as 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."<sup>24</sup>

<sup>&</sup>lt;sup>21</sup> For an introduction to patent theory and practice, consult David Vaver's *Intellectual Property Law: Copyright, Patents, Trademarks*, 2<sup>nd</sup> ed (Toronto: Irwin Law, 2011)..

<sup>&</sup>lt;sup>22</sup> Patent Act, RSC, 1985, c p-4.

<sup>&</sup>lt;sup>23</sup> *Ibid* at s 42, 44.

<sup>&</sup>lt;sup>24</sup> Canada Patent Act, supra note 22, at s 2.

From this definition, four key requirements can be set forth for all patents: novelty,

utility, non-obviousness, and patentable subject-matter.

A. Novelty

The first requirement, that the subject matter is new,<sup>25</sup> is met if the invention has

not been disclosed to the public outside of a short grace period before the patent

application is filed.<sup>26</sup> Fulfilling this requirement means that the patent cannot have been

previously disclosed in Canada or elsewhere. An invention that has been deemed to have

been part of the prior art of a particular industry is not novel. Paragraph 28.2(1) states

that

The subject-matter, defined by a claim in an application for patent in Canada (the "pending application") must not have been disclosed

- (a) more than one year before the filing date by the applicant, or by a person who obtained knowledge, directly or indirectly, from the applicant, in such a manner that the subject-matter became available to the public in Canada or elsewhere;
- (b) before the claim date by a person not mentioned in paragraph (a) in such a manner that the subject-matter became available to the public in Canada or elsewhere;
- (c) in an application for a patent that is filed in Canada by a person other than the applicant, and has a filing date that is before the claim date;...<sup>27</sup>

The modern concept of novelty is also referred to as absolute novelty, where

patents are only novel if the inventor is the first to file the patent, and the invention has

not been disclosed to the public by someone, other than the applicant, in any country.<sup>28</sup>

<sup>&</sup>lt;sup>25</sup> *Canada Patent Act, supra* note 22 at s 27(4) states that the subject matter of the patent must be defined explicitly in the claims section of the patent. It is the written claims that make up the patent, not visual descriptions.

<sup>&</sup>lt;sup>26</sup> Canada Patent Act, supra note 22 at s 28.2(1). The subject matter defined in the claims must not have been disclosed more than one year before the filing date.

<sup>&</sup>lt;sup>27</sup> Canada Patent Act, supra note 22 at s 28.2(1)(a)(b)(c).

<sup>&</sup>lt;sup>28</sup> *Ibid* at s 28.2(1)(b).

Early concepts of novelty related to the terms "new manufacture" and "first and true inventor" and held broader meanings than the modern definition.

B. Utility

The second requirement, that the invention be useful, means that the subject matter of the patent must have a benefit to the public, thereby achieving a purpose related to why it was invented. Following *AstraZeneca Canada Inc. v. Apotex Inc.*,<sup>29</sup> the correct approach for the court to determine "whether a patent discloses an invention with sufficient utility is to... [f]irst...identify the subject-matter of the invention as claimed in the patent. Second, courts must ask whether that subject-matter is useful — is it capable of a practical purpose."<sup>30</sup> Therefore, the patent must demonstrate usefulness according *to the claims within the patent application* regarding that particular subject matter, but only one potential use of an invention needs to be realized, despite the presence of additional uses disclosed in the patent specification.<sup>31</sup>

The minute amount of utility of a patented invention stems from much older jurisprudence. At the Supreme Court, Dickson J. affirmed the lack of consideration given to a patented invention's usefulness<sup>32</sup>:

...the Federal Court of Appeal erred also in holding that s. 36(1) requires distinct indication of the real utility of the invention in question. There is a helpful discussion in 29 Hals., 3rd ed., 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

<sup>&</sup>lt;sup>29</sup> 2017 SCC 36, [2017] 1 SCR 943, 147 CPR (4th) 79 (SCC) [AstraZeneca].

 $<sup>^{30}</sup>$  *Ibid* at para 54.

<sup>&</sup>lt;sup>31</sup> Consistent with earlier jurisprudence, the slightest amount of commercial or industrial utility (a mere scintilla of utility) will satisfy the requirement. The first documented use of a mere scintilla of utility was in *Philpott v Hanbury* (UK), RPC 1 (1885) 33 at 37 [*Philpott*]. Grove J. said that "the slightest amount of utility – I will not say an infinitesimal scintilla, but a very slight amount of utility – is sufficient to maintain a patent." Canadian cases that followed supporting this view include *Prentice v Dominion Rubber Co Ltd*, [1928] Ex CR 196 (Ex Ct) at 199; *AstraZeneca Canada Inc. v Apotex, supra* note 29 at para 55.

<sup>&</sup>lt;sup>32</sup> Consolboard Inc. v. MacMillan Bloedel (Sask) Ltd. (1981), 56 CPR (2d) 145 (SCC) [Consolboard].

broadly, that it will not do what the specification promises that it will do". There is no suggestion here that the invention will not give the result promised. The discussion in Halsbury, ibid., continues: ...the practical usefulness of the invention does not matter, nor does its commercial utility, unless the specification promises commercial utility, nor does it matter whether the invention is of any real benefit to the public, or particularly suitable for the purposes suggested. And concludes [at p. 60]: ...it is sufficient utility to support a patent that the invention gives either a new article, or a better article, or a cheaper article, or affords the public a useful choice... Canadian law is to the same effect.<sup>33</sup>

Therefore, the minute amount of utility discussed in *AstraZeneca* is predated by good authority from both Canada and England.

C. Non-Obviousness

The third requirement is that the invention has a non-obvious step, as outlined in Section 28.3 of the *Patent Act*, which states that "[t]he subject-matter must not have been obvious on the claim date to a person skilled in the art or science to which it pertains,...<sup>34</sup> This means that the invention exhibits a level of ingenuity that was not part of the prior art of the particular industrial discipline of the invention. An invention can only be deemed to have an inventive step (it is non-obvious) if a person skilled in the art related to the industry of the invention would not have predicted the solution or mechanism contained within that invention.<sup>35</sup> If "any fool could have done that,"<sup>36</sup> as asserted by Justice Hugessen in *Beloit Canada*, there is no inventive step involved in the invention.

<sup>&</sup>lt;sup>33</sup> *Ibid* at para 160-161.

<sup>&</sup>lt;sup>34</sup> Canada Patent Act, supra note 22 at s 28.3. This is also known as the inventive step requirement, and its interpretation and general form was first confirmed by Canadian jurisprudence in *Burton Parsons v Hewlett Packard (Canada) Ltd.*, [1976] 1 SCR 555.

<sup>&</sup>lt;sup>35</sup> Beecham Canada Ltd v Proctor & Gamble Co, [1982] 61 CPR (2d) 7 [Beecham].

<sup>&</sup>lt;sup>36</sup> Beloit Canada Ltd v Valmet Oy (1986), 8 CPR (3d) 289 at 293 (FCA) [Beloit Canada].

Nonobviousness can be a difficult concept because it involves assessing technical information in scientific fields of study, areas of knowledge in which a judge is not likely an expert. It may be obvious, for example, that changing one component in a doorknob from wood to metal is not sufficiently inventive for a patent because it only involved switching materials, but it is less obvious that changing one subgroup on a complicated molecule could lead to a patent for the new molecule. A chemical process for getting that new subgroup on the molecule would have been used, but that chemical process may be well-known to other chemists who have applied it to other molecules. However, application of that chemical step *in a particularly inventive, technical way* may lead to a compound with a new use, which *could* be sufficient to meet the requirement of obviousness. Because of its complexity, the doctrine of non-obviousness has been developed through jurisprudence to meet a variety of technical challenges, using a non-exhaustive list of questions about the alleged patent.

*Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*<sup>37</sup>provided the detail required for determining whether a person skilled in the art related to the industry of the invention would not have predicted the solution or mechanism contained within a particular invention. Writing for the majority, Justice Rothstein summarized a four-step approach to determine obviousness:

1. (a) Identify the notional "person skilled in the art";

(b) Identify the relevant common general knowledge of that person;2. Identify the inventive concept of the claim in question or, if that cannot readily be done, construe it;

3. Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed;

<sup>&</sup>lt;sup>37</sup> [2008] 3 SCR 265, 2008 SCC 61 at para 67 [Sanofi-Synthelabo].
4. Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?

At paragraph 63, Justice Rothstein warned against using the four-step approach as a rigid test of obviousness, explaining that "in most matters in which a judge or a jury is called upon to make a factual determination, rigid rules are inappropriate unless mandated by statute.," making the concept open to interpretation.

Following the establishment of the parameters of the test, the fourth part of the test in *Sanofi-Synthelabo* poses the primary question about obviousness. In some cases, however, step four requires an expanded test. In *Eli Lilly Canada Inc. et al v. Novopharm Limited*,<sup>38</sup> Justice Layden-Stevenson, for the majority, states that "[an] 'obvious to try' inquiry [in step four] will be appropriate in areas of endeavour where advances are often won by experimentation, such as in the pharmaceutical industry" at paragraph 55. Justice Layden-Stevenson then references *Sanofi-Synthelabo* to identify factors to be taken into account when assessing whether or not something was worth a try:

1. Is it more or less self-evident that what is being tried ought to work? Are there a finite number of identified predictable solutions known to persons skilled in the art?

2. What is the extent, nature and amount of effort required to achieve the invention? Are routine trials carried out or is the experimentation prolonged and arduous, such that trials would not be considered routine?

3. Is there a motive provided in the prior art to find the solution the patent addresses?<sup>39</sup>

<sup>&</sup>lt;sup>38</sup> 2010 FCA 197 at paras 54-64 [*Eli Lilly*].

<sup>&</sup>lt;sup>39</sup> *Ibid* at para 55.

# D. Patentable Subject Matter

Section 27(8) of the *Patent Act* provides that "No patent shall be granted for any mere scientific principle or abstract theorem."<sup>40</sup> In general, what constitutes patentable subject matter is defined by the five categories in the *Patent Act* definition in Section 2: "art, process, machine, manufacture, or composition of matter."<sup>41</sup> "Art" has been defined as "the application of knowledge to effect a desired result."<sup>42</sup> Process is "the application of a method to a material or materials."<sup>43</sup> Machine is defined as "the mechanical embodiment of any function or mode of operation designed to accomplish a particular effect."<sup>44</sup> Manufacture "implies a product made by hand, by machine, industrially, by mass production and so forth, by changing the character or condition of ingredients – a solid, a gas, or fluid – as a chemical union or a physical mixture."<sup>46</sup> This definition has come to include lower life forms, such as cells, enzymes, and genes, but excludes multicellular organisms and higher life forms, such as mice that have been genetically engineered to be predisposed to cancer for research purposes.<sup>47</sup>

<sup>&</sup>lt;sup>40</sup> Canada Patent Act, supra note 22 at s 27(8).

<sup>&</sup>lt;sup>41</sup> Canada Patent Act, supra note 22 at s 2.

<sup>&</sup>lt;sup>42</sup> Shell Oil Co v Commissioner of Patents, [1962] 2 SCR 536.

<sup>&</sup>lt;sup>43</sup> *Commissioner of Patents v Ciba Ltd*, [1959] SCR 278 at 383. A process may be patentable even though the process does not produce a product that is patentable. See Canadian Intellectual Property Office, *Manual of Patent Office Practice* (1998 ed, updated to December 2010), c 12.02.02.

<sup>&</sup>lt;sup>44</sup> Manual of Patent Office Practice, ibid at c 12.02.03.

<sup>&</sup>lt;sup>45</sup> Manual of Patent Office Practice, supra note 43 at c 12.02.04.

<sup>&</sup>lt;sup>46</sup> Vaver, *supra* note 21 at p 294.

<sup>&</sup>lt;sup>47</sup> This has not developed without significant controversy in the jurisprudence and in academia. Patenting, and the distinction between higher life forms and simple life forms has been adjudicated through *Harvard College v Canada (Commissioner of Patents)*, [2002] 4 SCR 45 [*Harvard Mouse*] and *Monsanto Canada Inc v Schmeiser* [2004] 1 SCR 902, 2004 SCC 34 [*Schmeiser*]. In *Harvard Mouse*, at paragraph 155, "manufacture" and "composition of matter" were not considered to encompass higher life forms. This was won by a narrow five to four majority. In *Schmeiser*, a patent for a gene that created a new type of

# E. Public Examination, Disclosure, and Enablement

A patent holder must reveal his patent to the public for examination; doing so has been presumed to fulfill the traditional patent bargain between the inventor and society in the past.<sup>48</sup> Although existing prior to England's *Statute of Monopolies*,<sup>49</sup> public examination, disclosure and enablement became more important afterward because patents would only be granted as *exceptions* under the statute. To be granted an exception meant that society would have to examine the inventor's creation first:

And all monopolies, and all such commissions, grants, licences, charters, letters patents, proclamations, inhibitions, restraints, warrants of assistance, and all other matters and things tending as aforesaid, and the force and validity of them, and every of them, ought to be, and shall be for ever hereafter examined, heard, tried, and determined, by and according to the common laws of this realm, and not otherwise.<sup>50</sup>

As specified in Section Ten of Canada's Patent Act:

(1) Subject to subsections (2) to (6) and section 20, all patents, applications for patents and documents relating to patents or applications for patents that are in the possession of the Patent Office shall be open to public inspection at the Patent Office, under any conditions that may be prescribed.<sup>51</sup>

Disclosure is deemed sufficient for a patent once the patentholder reveals what the

invention is, and how a person skilled in the art or trade would both construct and use or

herbicide-resistant canola was upheld. Whether the genetically-modified canola was the subject of patent was irrelevant because the patent for the gene was incorporated in the make-up of the plant itself. The commercial expression of the gene was found to be at the sole discretion of the patent holder.

<sup>&</sup>lt;sup>48</sup> See *Liardet v Johnson, (1778) Bull. NP 76; 1 WPC 53* for an early English case linking disclosure to the patent bargain.

 $<sup>^{49}</sup>$  Statute of Monopolies (Eng) 1623, 21 Jac 1, c 3.

<sup>&</sup>lt;sup>50</sup> *Ibid* at s 2.

<sup>&</sup>lt;sup>51</sup> Patent Act, supra note 22 at s 10. Underlining added for reconciling disclosure with "examined" and "heard."

work the invention. These requirements are set forth in the patent specification, in

Section Twenty-Seven of the *Patent Act*:

(3) The specification of an invention must

(a) correctly and fully describe the invention and its operation or use as contemplated by the inventor;

(b) set out clearly the various steps in a process, or the method of constructing, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it pertains, or with which it is mostly closely connected, to make, construct, compound or use it;

(c) in the case of a machine, explain the principle of the machine and the best mode in which the inventor has contemplated the application of that principle; and

(d) in the case of a process, explain the necessary sequence, if any, of the various steps, so as to distinguish the invention from other inventions.<sup>52</sup>

An understanding of the purpose of disclosure is found in Teva Canada Ltd. v.

*Pfizer Canada*<sup>53</sup> which reiterates that

[t]he patent system is based on a "bargain", or *quid pro quo*: the inventor is granted exclusive rights in a new and useful invention for a limited period in exchange for disclosure of the invention so that society can benefit from this knowledge. Sufficiency of disclosure lies at the very heart of the patent system, so adequate disclosure in the specification is a precondition for the granting of a patent.<sup>54</sup>

In this pharmaceutical case involving the creation of a new molecule, it was found

that the disclosure provided in the application "would not have enabled the public 'to

make the same successful use of the invention as the inventor could at the time of his

<sup>&</sup>lt;sup>52</sup> Patent Act, supra note 22 at s 27(3).

<sup>&</sup>lt;sup>53</sup> [2012] SCC 60, [2012] 3 SCR 625 [*Teva*].

<sup>&</sup>lt;sup>54</sup> *Ibid* at summary para 1.

application....' [since] further testing would have been required to determine which of those two compounds was actually effective in treating [the medical condition]."<sup>55</sup>

Intertwined with disclosure is enablement in the aforementioned Section 27(3)(b). While disclosure must include instructions for making and using a patented invention, the standard for successfully disclosing it is the enabling of the person ordinarily skilled in the particular art or trade in question to re-create it. The standard developed through the common law, was then enshrined in statute, establishing that the bar for "working" the patent at a level that will not be beyond someone with an ordinary skill set in the particular industry. By satisfying enablement, the expectation that the patent contains information *usable by the public* is met, helping to satisfy the utilitarianism embedded within patent law overall.

Public examination of the patent documents is seen as necessary for upholding the bargain between the public and the inventor for those exclusive rights.<sup>56</sup> Using historical analysis, this thesis refers back to the assumption that a sufficiently disclosed invention, made available to the public, satisfies the bargain that the public has traditionally required for the issuance of a patent and challenges it.

F. Patent Validity

Section 53(1) specifies that

A patent is void if any material allegation in the petition of the applicant in respect of the patent is untrue, or if the specification and drawings contain more or less than is necessary for obtaining the end for which they purport to be made, and the omission or addition is wilfully made for the purpose of misleading.<sup>57</sup>

<sup>&</sup>lt;sup>55</sup> Supra note 53 at summary para 3, Lebel J quoting Dickson J in Consolboard Inc. v MacMillan Bloedel (Sask.) Ltd, [1981] 1 SCR 504 at p 520.

<sup>&</sup>lt;sup>56</sup> Canada Patent Act, supra note 22 at s 10.

<sup>&</sup>lt;sup>57</sup> Canada Patent Act, supra note 22 at s 53(1).

While permitting the striking of excessive content in a patent specification, the remaining portions of the patent specification can still be awarded a patent if the patent applicant's errors were determined to be involuntary.<sup>58</sup>

<sup>&</sup>lt;sup>58</sup> Canada Patent Act, supra note 22 at s 53(2).

### Chapter Two: The Philosophical Bases for Intellectual Property Law

# I. Introduction

Theories of patent law are typically *derivative theories* of traditional physical property theories, where justifications for private tangible property are extended to intangible property like patents. The theories can be grouped into two categories. The first category centers on individualism, where the actions or characteristics of individuals naturally lead to a justification or "right" to property, while the second category focuses on utilitarianism, where a net social gain justifies private property ownership. The former theories are based in liberal thought where individual behaviour is considered paramount, while the latter utilitarian theories focus on the broad social outcomes that result from private property.

This chapter reviews the main categories of patent law theories. It will demonstrate that Locke's liberal justification of private property provides a robust view of why private property is generally justifiable for individuals, and that utilitarian and personality-based theories can be viewed as complementary to the Lockean theory. The creation of any new theory of patents can still prioritize the individual in a liberal theory while giving consideration to the utilitarian and personal aspects of knowledge as property.

## II. Patent Law Theories

# A. Utilitarian-Based Justifications of Intellectual Property

Utilitarian theories of intellectual property are outcome-based, in that the justification for intellectual property rights is based on the premise that such property,

held in the hands of individuals, leads to social outcomes that surpass the outcomes that would result from *not* granting it. This broad social view of patenting reflects the typical objective of modern intellectual property rights-granting institutions in developed societies, where limited intellectual property rights are granted under the premise that they will create incentives for individuals to pursue worthy projects that will benefit mankind. Without that protection, individuals will not be motivated to produce useful tangible goods from their intellectual capital because it would be prone to theft. Instead, those individuals would conduct their affairs in secret, motivated solely for their own benefit.<sup>59</sup> There is no guarantee that providing this protection leads to greater social welfare, but protecting inventors from intellectual theft seems prudent for achieving the objective, even though the costs of that protection are hard to measure.

Utilitarian theories limit monopoly rights in patent law, attempting to balance that exclusivity and the social welfare loss associated with it, where exclusive rights allow for the absence of market competition and exploitation in the form of higher prices. By limiting patents to a fixed term, utilitarians theorize that the innovator will achieve payback of his monetary investment within that term but limits that exclusivity to a set period so that the overall social benefit of the invention will exceed the cost of those private benefits awarded in the long run.

Utilitarian theories of intellectual property protection developed during the fifteenth to eighteenth centuries in Europe and the Americas as colonialism expanded trade and commerce across the world. Adam Smith, often referred to as the father of

<sup>&</sup>lt;sup>59</sup> William Fisher, "Intellectual Property and Innovation: Theoretical, Empirical, and Historical Perspectives," in S Munzer, ed, *New Essays in the Legal and Political Theory of Property* (Cambridge: Cambridge University Press, 2001).

modern economics, saw monopolies as an interference in the general functioning of free markets, with intellectual property being the exception, because innovation required significant up-front investment and risk.<sup>60</sup> Expanding further, utilitarian theorist Jeremy Bentham pinpointed initial fixed costs of investment that needed protection from imitators:

[T]hat which one man has invented, all the world can imitate. Without the assistance of the laws, the inventor would almost always be driven out of the market by his rival, who finding himself, without any expense, in possession of a discovery which has cost the inventor much time and expense, would be able to deprive him of all his deserved advantages, by selling at a lower price.<sup>61</sup>

John Stuart Mill<sup>62</sup> concurred with the high value of monopolies when restricted to new and useful inventions. He saw this restricted form of monopoly as much preferable to general monopolies that had been granted in the past that were simply used to extract higher rents from consumers on everyday items that were made using knowledge already present in society's commons. In essence, new and useful patents could be granted for inventing things that required significant amounts of time, money, and intellect.

Whether patent protection fulfills the tenets of utilitarianism is the subject of much empirical analysis, which has provided little surety in its answers, leaving it less than a complete or functional description of patent law. For one, it is difficult to establish whether or not the granting of a monopoly provides sufficient motivation to spur innovation because motivation is difficult to define, identify and measure. Secondly, studies have demonstrated conflicting results as to whether or not grants of monopoly

<sup>&</sup>lt;sup>60</sup> Adam Smith, *The Wealth of Nations*, ed E Cannan, (Oxford: Clarendon Press, 1776) at 277, 278.

<sup>&</sup>lt;sup>61</sup> Jeremy Bentham, A Manual of Political Economy, (New York: G P Putnam, 1839).

<sup>&</sup>lt;sup>62</sup> John Stuart Mill, *Principles of Political Economy*, 5<sup>th</sup> ed (New York: Appleton, 1862).

over intellectual property actually improve social welfare because studies that measure social welfare benefit are difficult to design, with significant complexities in definitions and measurement.<sup>63</sup>

Some academics have tried to narrow the scope of empirical study in utilitarianbased theories of intellectual property by comparing monopolies granted through intellectual property to the alternatives like trade secrets and restricted markets, which eliminate opportunities for others.<sup>64</sup> Noted twentieth century scholar Fritz Machlup concluded from his study that no scholar could reasonably conclude that the patent system was beneficial or not, but that there are certain values within that entrenched patent system:

If we did not have a patent system, it would be irresponsible, on the basis of our present knowledge of its economic consequences, to recommend instituting one. But since we have had a patent system for a long time, it would be irresponsible on the basis of our present knowledge, to recommend abolishing it.<sup>65</sup>

The social utility gain is not clear, but it is well-established that strong economic growth, and the prosperity associated with it, is largely driven by technological advancement in leading industrialized countries, providing another reason to protect innovation through patent. Robert Solow was among the first economists to demonstrate that most of the annual productivity increases in the United States between 1909 and

<sup>&</sup>lt;sup>63</sup> Mark Lemley, "Faith-Based Intellectual Property" (2015) UCLA Law Rev, 62, pp 1328-1346.

<sup>&</sup>lt;sup>64</sup> Roger Miners and Robert Staaf, "Patents, Copyrights, and Trademarks: Property or Monopoly" (1990) 13 *Harv J Law & Pub Pol* 911; Adam Mossoff, "Saving Locke from Marx: the Labor Theory of value in Intellectual property Theory" (2012) 29(2) *Soc Phil & Pol* 283; Sean O'Connor, "Creators, Innovators, and Appropriation Mechanisms" *George Mason Law Rev* (2015) 22 973.

<sup>&</sup>lt;sup>65</sup> Fritz Machlup, *An Economic Review of the Patent System*, Study of the Subcommittee on Patents, Trademarks, and Copyrights of the Committee on the Judiciary, US Senate Study No 15 (Washington: Gov Print Off, 1958). Fritz Machlup was an Austrian-American economist who achieved his doctorate at the University of Vienna. He held professorships at the University of Buffalo, Johns Hopkins University, Princeton University,

1949, between eighty and ninety per cent, were due to increases in technological advancement.<sup>66</sup>

Robert Merges proposed that utilitarianism accepts both the empirical social costbenefit analysis with patents as well as a moral foundation for their granting.<sup>67</sup> Merges states that the principles of both groups can be accepted by using a midlevel approach that simplifies the language into a common denominator. Academics in both camps share this common technical language from which they will discover an "overlapping consensus,"<sup>68</sup> that will allow them to communicate and create policies within this pluralistic approach.

Utilitarian theories for justifying intellectual property protection need not exist on their own. Rather than providing a foundation for intellectual property protection, utilitarian theories provide a set of observations for the *results* of instituting a regime for protecting innovation. Despite the difficulty in measuring those results, the goals set forth in the utilitarian approach, namely the motivation of inventors to invent, and an overall increase in social welfare from invention, can serve as adjuncts to, and the hopeful end results of a more individualistic theory but they do not provide a foundation for why *any particular individual* would have rights to an invention because they only consider the broad potential outcomes for the society that grants them.

<sup>&</sup>lt;sup>66</sup> Robert M Solow, "Technical Change and the Aggregate Production Function," *Rev of Econ & Stats* (1957) 39 312. Also see Robert Barro & Sala-I Martin, Xavier, "Technological Diffusion, Convergence, and Growth" (1997) 2 *J Econ Grth* 1.

<sup>&</sup>lt;sup>67</sup> Robert P Merges, "Against Utilitarian Fundamentalism" Mar 29, 2017 St. John's Law Rev, 90(3), UC Berkeley Public Law Research Paper, Available at SSRN: https://ssrn.com/abstract=2960712.

<sup>&</sup>lt;sup>68</sup> *Ibid* at p 21, Merges referencing John Rawls, *Political Liberalism* (New York: Columbia Univ Press, 1993).

B. Personality-Based Justifications of Intellectual Property Protection

Based on liberal ideology, personality-based property theorists believe that individuals own their feelings, personality traits, abilities, and experiences. When they combine these features with physical objects or intellectual objects (like existing knowledge), they are able to expand their minds and self-actualize, a process essential for becoming a fulfilled human being.<sup>69</sup> Property rights, as a necessary condition for selfactualization, become a measure of personal freedom. This self-actualization process includes using private property to shield oneself from public scrutiny, and to assist in the pursuit of other activities that lead to further self actualization. Personality can become fused with objects, such as inventions or works of art or literature, leading to moral claims on intangible works where the character traits and experiences of a person have influenced them.<sup>70,71</sup>

# C. The Insufficiencies of Utilitarian and Personality-Based Law Theories

Written verbatim from the United States *Patent Act* of 1793,<sup>72</sup> the first Canadian patent statute stated that patents would be granted "for the encouragement of Genius and of new and useful Art, Machine, Manufacture, or Composition of Matter,"<sup>73</sup> which supports a utilitarian view of the patent system, where exclusive rights are granted to

<sup>&</sup>lt;sup>69</sup> Georg W F Hegel, *Elements of the Philosophy of Right*, ed by Allen Wood (Cambridge: Cambridge University Press, 1991). Hegel's original manuscript was published in 1821.

<sup>&</sup>lt;sup>70</sup> Wilhelm von Humboldt, *The Limits of State Action*, translated by J Coulthard, ed by JW Burrow (Cambridge: Cambridge University Press, 1969) The first release of this publication was 1792.

<sup>&</sup>lt;sup>71</sup> Josef Kohler, *Philosophy of Law*, trans Adalbert Albrecht (New York: AM Kelley, 1969).

<sup>&</sup>lt;sup>72</sup> An Act to Promote the progress of useful Arts in this Province, (UK), 4 Geo IV, c 25 (LC) (1823), s 3. The Canadian statute was borrowed from the *United States Constitution*, US Const art 1, § 8. The Canadian statute uses nearly identical language from Article I.

<sup>&</sup>lt;sup>73</sup> An Act to Promote the progress of useful Arts in this Province, ibid at s 3. The title of the act was nearly identical wording to the of § 8, art 1, cl 8 of the United States Constitution: "[The Congress shall have 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;"

motivate individuals to invent, presumably for the good of all. This passage, very utilitarian in nature, sets the groundwork for what the patent system wants to accomplish, but it does not examine the roots of why personal ownership results in the motivation to invent and create progress. In other words, it is missing the inquiry about *the self* that necessitates the exclusive holding of private property in order to thrive.<sup>74</sup>

While personality-based theories explain the mechanics of why *oneself* would be entitled to personal property, a moral claim over tangible or intangible property because one's personality characteristics have been infused into *some thing* hardly seems sufficient to justify broad-based holding of private property. They may justify moral rights in works of art, where defacing or significantly altering that work could negatively affect the creator's reputation, but their general ability to justify private property ownership is limited because such claims of originality are too broad, many of which may be an extension of one's accumulation of common knowledge, lacking a basis for society to apply any standard for determining why it should be protected. Besides, one's personality and experiences can hardly be owned when they are shared and developed with others as part of a societal existence. Rather than standing alone, personality-based theories reflect the inner workings of how a Lockean theory might operate: once an individual is labouring under the right conditions, that labour from *the self* is fit to be mixed with resources, from whence private property can be created and acquired.

<sup>&</sup>lt;sup>74</sup> While it is the personality-based theory sets an individualistic view of how the "self" might operate to innovate, it is the imposition of the law itself that can put both a utilitarian or personality-based theory in motion. It is the laws that create the justification for patent law, *by being laws of society*, and the utilitarian and personality-based views function as outcomes of this larger picture under the law. While a personality-based theory is grounded in the "self," it also remains unbounded and difficult to verify, making it somewhat incomplete as a theory of law. Utilitarianism, as an outcome, is insufficiently relevant to the "self" to create an individualistic legal framework.

Rather than dismissing them, utilitarian and personality-based theories can be seen as complementary to Locke's justification for private property. Applying outcomesbased utilitarianism, the knowledge behind an invention would create some utility for society that exceeds its costs, where the inventor's visions for the productive capacity of that potential property motivated him to undertake its development in the first place. The inventor's personality would also be infused into the invention's creation, which would then be reflected in the outward manifestation of that property.

D. A Liberal Justification for General Property: Locke

Political philosopher John Locke's justification of private property ownership in Chapter Five of his *Second Treatises of Government*<sup>75</sup> forms the basis of his natural rights argument for the creation of general physical property, where combining labour with resources on the earth justifies the exclusive use of those resources to the person who affected their labour upon them. Locke proposes that all humans possess property in their own 'person,' where

The labour of his body, and the work of his hands, we may say, are properly his. Whatsoever then he removes out of the State that Nature hath provided, and left it in, he hath mixed his labour with and joyned to it something that is his own, and thereby makes it his property. It being by him removed from the common state Nature placed it in, it hath by this labour something annexed to it, that excludes the common right of other men. For this 'labour' being the unquestionable property of the labourer, no man but he can have a right to what that is once joyned to, at least where there is enough, and as good left in common for others.<sup>76</sup>

Locke's theory of property coincided with the migration of large numbers of

Europeans to the western world in the seventeenth century when people were looking for

<sup>&</sup>lt;sup>75</sup> Locke, *supra* note 1.

<sup>&</sup>lt;sup>76</sup> Locke, *supra* note 1, *Second Treatise* at ch V para 27.

opportunities to settle and cultivate new land, so his justification was written with the idea of an original appropriation of physical property as the focal point. A person who mixes their labour with land entitles them to the private use of it, such that activities like clearing, cultivating, and seeding, or building a home on it creates an entitlement to the "new land" upon which those activities took place.

1. Locke's Justification for Private Property through God and the State of Nature

Locke's theory starts with God. Since God shaped the earth and everything on it, including human beings, God has ownership *in them*. Since human beings are created in the image of God, and share with God through worship and servitude, human beings also have the ability to affect and direct the physical environment around them. Locke describes the initial state of nature of the earth created by God as one where goods and resources were granted by God to be held in common. But these resources could not be used in their natural state. Rather, labour had to be applied to them to make them useful to humanity, and once they were worked by a human, they became the property of that human. God ensured there were enough of these resources distributed to allow all people to appropriate the resources they needed to survive without infringing on the resources required by others; when humans were finished with their resources, they left them for other humans.

The abundance of resources in the state of nature and the ability to pass on those resources to others constituted the "enough and as good" condition, where abundance meant that there was no concern about depleting these natural resources. The "enough and as good" condition, when taken to mean that one only takes what one needs for self preservation, allowed individuals to take land exclusively for themselves because there

would be no harm done to others by its appropriation.<sup>77</sup> If there is no harm done in appropriating it, there is no reason to not allow those rights to exist. Locke's theory is set in a world with bountiful resources, reducing the need for consent to be provided for the taking of property for oneself, and he even addresses how that abundance is maintained and passed on to others.

Breaking down enough and as good, "enough" meant that there was still enough property left for all others for their survival even though some had been taken from the commons for private property. "As good" meant that the property that was taken was left in the same way or better for others to use when the original owner was finished with it. This meant that others could also use it productively. Since the owner would have improved the land to make it useful for his survival, the next owner would be as well off as the original owner.

Humans were also subject to the "non-waste"<sup>78</sup> condition, a natural ceiling on the amount of goods required by humans because of their limited natural capacities. Humans took what they needed to survive and nothing more because accumulating excess property would mean that the produce grown on it would be wasted. If humans only took what they could use, there were plenty of resources remaining for others to earn. Locke's discussion of new opportunities in Spain and the Americas<sup>79</sup> during the writing of his

<sup>&</sup>lt;sup>77</sup> Locke, *supra* note 1, *Second Treatise* at ch V para 38. For a concise understanding of Locke's two provisos read as one, see *Gopal* Sreenivasan, *The Limits of Lockean Rights in Property* (New York: Oxford University Press, 1995) at 34: "…in the state of nature, men can – subject to two provisos - legitimately acquire individual property rights in things by labouring on the common. These provisos are, first, that a man appropriate only as much as he can use before it spoils, and, second, that he leave enough and as good for others."

<sup>&</sup>lt;sup>78</sup> Locke *supra* note 1, *Second* Treatise ch V at para 31.

<sup>&</sup>lt;sup>79</sup> He discusses his labour theory of property almost exclusively in terms of improving new land through tilling, planting and harvesting crops. See Locke, *supra* note1, *Second Treatise* at ch V para 32. Locke

treatise were prime examples of his justification for private property, subject to humans not taking more than they could use.

2. Property in Locke's Governed Society: Inequality and Surplus

Locke stated that owners of private property would have no incentive to mix land with labour if the property was constantly appropriated by thieves, which could happen in the state of nature because private land improved by labour made it more valuable than undeveloped land. Therefore, the formation of a governed society, where members abide by an agreed-upon set of laws, which includes provisions for private property, became a necessary evolution of humanity. Though theft of private property was still possible in a governed society, Locke addressed opposition to the theft argument by buttressing his labour justification with a social utility argument, stating that part of the new wealth held by the person who mixed labour with resources gets added back to the common stock of resources available to the benefit of all through barter, quelling the need for theft. A simple example would be selling the surplus produce grown on land in a market, where the land yielded more produce than the owner's needs for survival.

Returning this additional value to the common stock, however, requires the introduction of money to facilitate that transfer because bartering does not always lead to ideal outcomes when the value of traded goods cannot be easily reconciled against each other. Simple bartering can lead to one party holding more of the produce of another vendor than the individual needs, can store, or can keep in edible condition before being able to consume it or trade it away. Spoilage, and therefore wastage, occurs if the amount

references the Americas many times in his chapter on private property. See ch V paras 35-42, 48. Also see Barbara Arneil, "Trade, Plantations, and Property: John Locke and the Economic Defense of Colonialism" (1994) 55(4) J Hist Ideas 591 at p 608.

bartered for cannot be used right away, but money held in exchange is preserved.<sup>80</sup> Producers and traders accumulate economic value by trading with currency and holding it instead of consumables, but it can lead to economic inequality since "Men will [...] be apt to enlarge their *[p]ossessions of [l]and*...<sup>81</sup> if they are holding additional money to purchase it.

Locke states that this enlargement in individual land holdings is accentuated by the differing endowments among humans, manifested as different productivities in their labour, creating inequalities in the amount of money individuals hold. Locke is, however, not concerned with the inequality, because individuals have consented to money as a means of engaging in trade, and they are free to enter into any particular transaction they wish. Locke also suggests that accumulated money would tend to boost the productivity of already-acquired land by giving the surplus to more complex forms of labour that would lead to further innovation and larger surpluses,<sup>82</sup> but this improvement would be impossible in the state of nature.

<sup>&</sup>lt;sup>80</sup> Locke, *supra* note 1, *Second Treatise* at ch V para 50:

<sup>[</sup>I]t is plain, that Men have agreed to disproportionate and unequal Possession of the Earth, they having by a tacit and voluntary consent found out a way, how a man may fairly possess more land than he himself can use the product of, by receiving in exchange for the overplus, Gold and Silver, which may be hoarded up without injury to any one, these metals not spoiling or decaying in the hands of the possessor. This partage of things, in an inequality of private possessions, men have made practicable out of the bounds of society, and without compact, only by putting a value on gold and silver and tacitly agreeing in the use of money.

<sup>&</sup>lt;sup>81</sup> Locke, *supra* note 1, *Second Treatise* at ch V para 48.

<sup>&</sup>lt;sup>82</sup> Locke, *supra* note 1, *Second Treatise* at ch V para 48 and 49. Locke addresses the challenge of bringing "new" land into productive use. He also discusses differences between the relatively modern England and primitive America by pointing to the lack of incentives to use labour to improve the land in England because of its already-improved state. In paragraph 43, Locke discusses several types of value-adding labour that are used as inputs into finished consumption goods.

3. The Natural Cycling of Private Property under a Lockean Justification

Locke's study of Christianity served as the basis for his property philosophy. Spending considerable time studying creation in Genesis One and Two of the Bible, his ideas about God shaping the earth and Man's role within it are embedded within his theory of private property. For one, Locke's non-wastage condition in the state of nature is consistent with an offence against God's laws to take more than one can use. But the operation of the enough and as good and non-wastage conditions as described by Locke occur without the intervention of any Christian moral sentiment of one man for another. Rather, the abundance of property is upheld because of the nature of humans, who are limited by their own ability to produce and consume.

His justification for private property in his societal model also suggests that he viewed humans as selfish, with a propensity to hoard, hardly God-like characteristics. He offset this tendency by stating that an individual who accumulated more property than he needed would distribute the surplus back to others in society who would labour for him and thereby increase their surpluses while simultaneously enlarging his own. The application of an individual's *goodness* does not intercede into the theory of private property; rather, it is self-interest that tends to support it. In addition, the aforementioned issue with consent and the unequal distribution of resources is not adequately remedied as one would expect from Christian beliefs. Rather, inequalities are propagated, and morals are not introduced to solve the problem.

Therefore, Locke's statements indicate that it was the human condition that allowed for the cycling of property and resources among individuals, as opposed to sacrosanct reasoning from the Christian doctrine that required individuals to do their best

for humanity. While the development of a modified Lockean theory of patent property need not address any of Locke's discrepancies among the actions of individuals and the imposition of religious moral authority, this natural cycling of property between individuals becomes an important component in the development of a patent law theory, from the perspective of the state of nature *or* a formed society.

4. A Theory Based on Locke's Conception of Private Property Requires a Condition

A justification and a theory are different. A justification creates a basis for believing that some *thing* will generally hold. If acts can be explained by observing what a group of people decided to do, like Locke's witnessing of the migration of Europeans to the Americas to claim land, it is justified by the application of the migrants' actions to some standard, like the natural laws set forth by God and espoused in the Bible about mixing labour and resources. Whether the beliefs held are formed in relation to something one knows is factually true or are based on religious or moral convictions,<sup>83</sup> the acts are justified by relation to one or the other, creating a reasonable basis for the belief. While a religious belief, like the connection between labour, resources, and the entitlement to personal property cannot be examined as being true or false, the holder of that information *may believe* that it is true, creating a link between factual knowledge and belief. This is why either actual knowledge or a belief can be routed in a justification.<sup>84</sup>

<sup>&</sup>lt;sup>83</sup> Rudolph H Weingartner, "Explanations and Their Justifications" 1961 28(3) Phil of Sci at 301.

<sup>&</sup>lt;sup>84</sup> Stewart Cohen "Justification and Truth" (1984) 46(3) Phil Stud: Int'l Jrnl Phil Analyt Trad'n at 279.

If acts can be explained by reasoning based on facts,<sup>85</sup> they are still justified but they can also be a theory because the reasoning provides a sound basis for explaining the action. If Locke believed that some resource can be held by someone with complete exclusion to others for Biblical reasons, then it is justified by recourse to the fact that it was done. When he adds his enough and as good condition, the transference of the property to others transitions the justification to a theory because it predicts that the land will never become scarce if the condition is upheld. Whether it is justified by natural law or by reason, a *modern* theory of law would require that the holding of private property have a connection to some "function" to give it predictive value. Theories are required to have predictive value because they are explanatory by nature.<sup>86</sup>

A consideration of Locke's theory with his two conditions removed illustrates a justification, meaning that it lacks a functional explanation. In bare form, Locke allows labour to be mixed with resources to create property for oneself, which is not a theory because it lacks a line of reasoning from which an expected result would flow, which implies that the results are *known* with one hundred per cent certainty. If the answer is known, there is hardly a reason to postulate what would happen upon operation of the action in question. In Locke's new America, someone who worked a particular piece of ground and turned it into farmland would be entitled to it, simply by the fact that he took the appropriate actions to do so, where justification is based on a belief that God rewards those who work the land by giving it to them for their exclusive use.<sup>87</sup> At best, Locke's

<sup>&</sup>lt;sup>85</sup> Mark E Warren, "What is Political Theory/Philosophy?" (1989) 22(3) Pol Sci & Politics 606. Warren coins reasoning that goes beyond faith-based beliefs to include facts a "meaning-constitutive function." <sup>86</sup> *Ibid* at 607.

<sup>&</sup>lt;sup>87</sup> Samuel Oddi, "Un-Unified Economic Theories of Patents – the Not-Quite-Holy Grail" (1996) 71(2) Notre Dame Law Rev at 274.

justification for private property, stripped of the enough and as good and non-wastage conditions, is justified because of epistemological beliefs.

If a person wished to understand the consequences of individuals taking property for their exclusive use, then one would be seeking an explanation as to *why and how* it should be allowed, regardless of one's religious or moral beliefs. This is the perfect thing for a theory – whether observing laws imposed or the facts recorded in history, an examination as to *why* private property is justified can be hypothesized and researched, upon which conclusions can be drawn and a theory constructed for predicting *future* outcomes of changes in the law. While a philosophy for private property can justify and define taking private property, a theory can explain what results from that taking.

The action of acquiring property for one's exclusive use by infusing it with labour is solely an action, a fact to be described, and justified. There has to be something more from which a theory could develop and dividing Locke's justification for private property into two parts provides an avenue. The first part is that man is entitled to the sole use of property when he mixes his labour with that resource to shape it and improve it, which is based on God's teachings. The second is Locke's conditions, the enough and as good condition and the non-waste condition, which potentially make his justification a theory of private property The two conditions provide the only testable components of Locke's justification for private property, added by Locke's own realization that property needed to be transferred between individuals if it was to be allowed. Although abundant in the Americas during his writings, it is implicit in Locke's conditions that property is finite because his conditions relate to preserving it, not taking more than one needs, and passing it on to others. It is completely plausible, for example, to theorize how and why leaving property to another individual when one is finished with it will legitimize the original proposition that private property should be allowed. Regardless of how difficult it may be to create an experiment to test it, an experiment could be created from this question: if the enough and as good and the non-wastage conditions are satisfied, will members of society consent to the distribution of private property rights, seeing that physical property is not endless in nature? While he did not explicitly state it, Locke's conditions create a prediction that private property can exist because it can cycle among individuals in perpetuity, thereby changing his bare justification into a theory.

Private property rights viewed *only* as the religious entitlement component are an insufficient basis for building a new theory of patent protection. The acquisition of those rights a may be based on a moral or legal philosophy, but any theorization from it has to hinge on something else, and at least one of Locke's conditions could be amended to ensure that it remains a theory.

It is important to ground a new model of patent law on a theory and not a justification because the knowledge in a patent is typically considered to be non-rivalrous, meaning that any person can use it without affecting anyone else's access to it, as stated by Professor Fox. This "infiniteness" has been the reason for dismissing Locke's conditions when using his private property justification for patent law, but it leaves no rationale as to why the mixing of labour with resources should lead to exclusive rights. If a model of patent law rights could simply be based upon the entitlement portion, there would be no postulating as to what the model was trying to achieve – the acquiring of intellectual property would just carry on without question. For example, there would be no reasoning as to why a patent term should last for twenty years.

Without postulating the results of the model, it would be impossible to *build* the theory, as no goals for it would be present to shape it.

E. Nozickian Compensation as a Replacement for Enough and As Good

Robert Nozick's general theory of law in *Anarchy, State and Utopia*<sup>88</sup> stated that Locke's enough and as good condition was insufficient because his claim that private property could be taken without making others worse off was untrue. Despite Locke's description of the abundance of "new land" recently discovered in the Americas, property was still finite. According to Nozick, the taking of any private property diminishes an individual's utility (or social welfare when aggregated across all individuals in society) in two ways. First, the acquisition of private property from the common stock of property means that someone else cannot acquire it for themselves. Second, the person has lost the *common use* of a given property due to the removal of the property from the commons. In either case, Locke's theory simply reflects entitlement to private property, which cannot be adequately buttressed by the enough and as good and non-wastage conditions unless the conditions are modified to overcome the societal losses incurred when property is made private.

Nozick's rejection of the Lockean proviso reflected his belief that the acquisition of private property was simply entitlement. To overcome entitlement, he employed a baseline measurement of social welfare or income,<sup>89</sup> creating a starting point for measuring whether someone is better or worse off when property is taken from the commons for the exclusive use of another. A general application of a baseline for

<sup>&</sup>lt;sup>88</sup> Robert Nozick, Anarchy, State and Utopia (New York: Basic Books, Inc. 1974).

<sup>&</sup>lt;sup>89</sup> *Ibid* at 177.

property is useful, where an individual's social welfare position at baseline could be measured relative to what level of private property exists at the time. As more private property is expropriated from the commons, a person outside of that transaction will be made worse off, creating a reduction from the baseline position.

F. Taking Private Property Requires Compensation: Nozick's Moral Basis

Nozick believed that a check on private property acquisition was necessary because the hoarding of too much property, and the fruits of that property, had the potential to make others worse off, something that Locke's societal surplus model did not address. Nozick proposed that the mechanism for constraining too much ownership was compensating those who could no longer acquire the property for themselves, where the compensation paid would strain the resources of the acquiror enough so as to prohibit him from hoarding the totality of property necessary for life.<sup>90</sup> Whether acquired through an initial distribution of land in the state of nature or purchased with money in a governed society, such hoarding would violate distributive justice, where everyone was presumed to be born equal under God, meaning that resources that were originally distributed equally in the state of nature should always tend to remain that way.

### III. Conclusion

Utilitarian theories of intellectual property law provide a model of incentives and outcomes for patent law, but do not consider how the actions of an individual create an

<sup>&</sup>lt;sup>90</sup> Nozick, *supra* note 88 at 179. Nozick states that

Each owner's title to his holdings includes the historical shadow of the Lockean proviso on appropriation. This excludes his transferring it into an agglomeration that does violate the Lockean proviso and excludes his using it in a way, in coordination with others or independently of them, so as to violate the proviso by making the situation of others worse than their baseline situation.

entitlement to exclusive property in patents. Personality-based theories consider the traits of individuals that lead to creations that reflect their uniqueness as a justification for property in those things, but the theories lack boundaries over what can be pulled from common knowledge to create property. Neither category is inconsistent with Locke's liberal justification for private property because the illustration of the expected outcomes from patents as well as the mechanics of how inventions are created are complementary to it.

Locke's justification of private property in the state of nature only becomes a theory when the right to take property is subject to conditions. For one, the justification of private property hinges on individuals limiting their acquisition of resources to their own productive capacity for shaping them. Second, as long as individuals leave their resources for others to use when they are finished with them, there should be enough and as good for all, and private property can function as part of the natural laws of the land.

Locke stated that a legal system of private property in a formed society would require consent to the use of currency as a store of value, as well as the consent to unequal holdings of property by individuals. Locke recognized that his societal model overstepped his own enough and as good and non-wastage conditions, making way for inequalities in the distribution of property among individuals because of their differing productive abilities. Money and unequal productivity created surpluses, so Locke buttressed his justification by stating that surpluses created by a property owner would be

sent back into the commons by employing others so that they can generate their own surpluses, as well as larger surpluses for the property owner.<sup>91</sup>

While Locke couches his theory in natural law, where individuals act in loving, God-like ways, his explanations of private property in both the state of nature and governed society avoid referencing highly moralistic or charitable ways. Rather, they focus on creating a cycle of property transfer between individuals, where others are always made better off because property was held privately in the state of nature or in governed society. It is Locke's conditions on private property that create the cycle, and they represent the essential component for why a new theory of patent law is actually a theory and not a justification based on the observance of religious beliefs.

Nozick rejects the infiniteness of property inherent in Locke's theory, creating a modified theory that requires individuals in society to be compensated for property that is taken out of the pool of common use. Nozick uses a social welfare baseline to measure how much compensation is required, and states that the compensation acts as a deterrent from individuals acquiring more than what they need, and what was initially fairly distributed by God for all people to use.

<sup>&</sup>lt;sup>91</sup> John F Henry, "John Locke, property rights, and economic theory" (1999) 33(3) Jrl Econ Iss 609. While Locke is generally not regarded as an economist, his claims about redistributing wealth to other forms of labour so that their property holdings could grow bear similarities with neoclassical economics. While Locke's right to property developed with an original appropriation of land, artisans, tradesmen, and servants came after that appropriation, when populations were increasing and causing crowding on the land. As labourers in a formed society, they have given up their right to equal property in exchange for wages, which they earned from property owners who do not need the surpluses that they can generate on their land...they are morally obligated to return them to society.

While neoclassical economics sees *individuals* as wealth maximizers, there is no moral obligation among them to keep the economy going. Rather, it is their self-interest that keeps generating supply and demand, perpetuating the cyclical nature of the economy. While Locke claims that a moral obligation exists to return surpluses to others, he does not rely on it. Instead, he states that a man with more than what he needs would have hopes of trading with other parts of the world, suggesting redistributing that surplus into the economy, which would make others better off, as well as himself. See Locke, *supra* note 1 at 317.

## **Chapter Three: Modifying the Lockean Property Justification to Patent Law**

### I. Introduction

Chapter Three projects the main components of Locke's theory of private property onto technical information to create a model of patent law that considers the differences between physical property, like land, and technical knowledge "property." The differences in the new theory demonstrate that patent property is not adequately explained by normal interpretations of Locke's conditions, making a broader condition appropriate. Once patent law history is reviewed in Chapter Four, the modified theory will be applied to elucidate fundamental differences in patent law history that lead to the identification of two forms of patent law – weak form and strong form, plus two types of competitors – close competitors and far. The analysis will then be carried over to a characterization of Canada's patent law history, with an emphasis on pharmaceutical patent law in Chapter Six.

# II. The Characteristics of Technical Knowledge

When Locke described man's entitlement to private property in the state of nature as the mixing of labour with resources to create *some thing*, he was primarily discussing the acquisition of land by large numbers of immigrants to the Americas who worked the land during that time period.<sup>92</sup> While land was abundant for the taking in the New World, Locke still realized some *finiteness* in it, so he buttressed the taking of property

<sup>&</sup>lt;sup>92</sup> Locke did suggest that the justification for property was more general than just physical property. See Locke, *supra* note 1, *Second Treatise* at ch V para 27: "Whatsoever then he removes out of the state of nature hath provided, and left it in, he hath mixed his labour with, and joined to it something that is his own, and thereby makes it his property...."

with the enough and as good condition, implying that no one would be worse off with individuals acquiring private property, even though it would diminish the amount of land remaining for others - private property's exclusivity was deemed to be okay because it would eventually be returned to the commons for others to use. This, plus the natural abundance of "new" land in the Americas, constituted the reasoning for the issuance of these private rights.

While physical land *is* finite, technical knowledge has been presumed to be infinite and indivisible, where technological progress in modern times takes nothing away from others, as expressed by Professor Fox.<sup>93</sup> With intellectual property in inventions, the natural law embedded in Locke's theory could flow further than physical property because information lacks scarcity. Rather, intellectual property *creates* property that had not existed previously, enlarging the scope of private property. By its limitless nature, intellectual property does not need to fit into the standard "enough and as good" condition in Locke's primitive state, thereby making it appear unimportant. However, an understanding of the characteristics of technical knowledge will justify why the taking of "knowledge property" should still be subject to a Lockean-type condition, and scarcity in another form will be developed by taking into account the nature of technical knowledge.

A. Knowledge is not Divisible but Inventors are Finite

Knowledge is not divisible, in that one individual's use of it does not preclude another's, making Locke's conditions less pertinent – the enough and as good condition is easily fulfilled because the knowledge in patents is added to the commons as part of the patent bargain *for all to see and examine* while the patent term is running, making it

<sup>&</sup>lt;sup>93</sup> Fox, *supra* note 5.

difficult to assert that one man's patent property diminishes the ability of another man to acquire property – the property created was additive to the whole of knowledge and took nothing from the commons.

This premise is straightforward if one presumes that *technical information* comprises the entirety of the patent. But the individuals who generate patents, those with inventive capacity, are limited in number, where not all members of society are capable or desirous of creating inventions, making intellectual property in patents bounded at any given time by those who can create it. The limited number of inventors decide *what* knowledge is taken from the commons for innovation, shaping technology and the future of humanity. If knowledge is not limited but inventive capacity *is* limited by the number of inventors, an inventor, as a resource, who is committed to one project leaves all other potential innovation un-researched and unworked. Therefore, a patent granted reflects the opportunity cost to society of everything else that was not invented, including things with higher priority for society.

Criticisms of the non-rivalrous nature of information as property typically focus on the *effect* of creating property from non-rivalrous information, as opposed to criticizing the non-rivalrous nature of the information itself. Gordon, for example, recognizes the interdependence of a patent holder and the patent granting society, where a new invention changes society which necessitates the need for further change. By blocking society's use of the inventive information in the patent, society is not able to use

it to affect further change for some time, despite the fact that it may need the freedom to use it before patent expiry.<sup>94</sup>

Whether interpreting the finiteness condition as an opportunity cost or by focusing on the consequences of granting the property, those concepts become strained in comparison to Locke's original reference to land, where its physical nature easily precludes its use by others when it is taken out of the commons for the exclusive use of an individual, making it completely *rivalrous* - an opportunity cost does not reflect the same type of scarcity as diminishing physical property does. And a discussion of the consequences of granting patents, like Gordon's, for society is a larger issue than the nonrivalrous nature of knowledge itself. However, it is not necessarily the infiniteness of knowledge that presents the *entire* opportunity for establishing a condition for patent law within a Lockean theory of private property.

B. Knowledge is Prone to Theft

Physical property can be stolen, which is a reason for society to agree upon rules to protect each other's property. An invention that is disclosed to the public without patent protection is susceptible to copy (a form of theft) by others. At the cost of disclosing the technical specification of the invention to the public, the inventor becomes entitled to legal protection for that vulnerability. While the consequences of the theft of one's land could lead to an inability to survive, the consequences from the theft of technical knowledge potentially makes individuals less prone to invent because they cannot attain the rewards for their efforts.

<sup>&</sup>lt;sup>94</sup> Wendy J Gordon, "A Property Right in Self-Expression: Equality and Individualism in the Natural Law of Intellectual Property" (1993) 102(7) Yale LJ at 1765 to 1770.

#### C. Technical Knowledge is Specific and Cumulative

Knowledge is expansive by nature. New technical knowledge begets the development of other knowledge creating the potential for inventions to follow. Because new knowledge generally follows from pre-existing knowledge, the use of new knowledge requires an understanding of the relevant knowledge that preceded it. Therefore, new knowledge, as property, only has value to others who have accrued sufficient prior knowledge.

#### D. Technical Knowledge becomes Obsolete

Locke's non-wastage condition requires that no person would accumulate more property than he needs to sustain himself because he would have no choice but to ignore it and let it go to waste. Locke states that a person cannot take more than he can manage for himself in the state of nature.

There are similarities between the wastage of physical property and the obsolescence of knowledge property. Where fruits and vegetables perish from degradation over time, the information contained in patents might not perish, but the ability to *use* the information can perish. As knowledge accumulates, for example, multiple solutions to technical challenges can develop, creating improvements that work around existing technology, making it obsolete. Many factors influence the ability to use the knowledge in patents, and some knowledge will remain unused or become obsolete.

Operationally, acquiring a patent is indistinguishable from the acquisition of new land in a new world – if the invention has not been thought of and patented by someone else, it is free for the inventor to patent and use exclusively because it will not be infringing upon another person simply because it is available. However, the nature of

patents as property imparts some differences from real property that demonstrate the potential inhibition on other information. Knowledge plucked from the commons for use in a new invention is non-rivalrous, in that others are free to use it. Once the knowledge has been used to create a patented invention, knowledge has leapt ahead. That knowledge is also returned to the commons for others to examine and research, but the patent restricts others from using it commercially until patent expiry. If an examiner of such information looks back to the commons from which the patent originated, he may find that the common knowledge is now obsolete, or functionally unusable, given that the patent may *hypothetically* be the only narrow window of development feasible from it, thereby impeding others who may have been working toward a similar invention.

Although a similar "race to property" could be analogized with physical property, the physical property case assumes that there is other land available for the taking for those who work for it, while technical knowledge "property" excludes others in a highly specific way once it is patented. Therefore, patent "property" *may or may not* leave enough and as good "knowledge" for others because the exclusion of very specific property to others leaves no identical substitute property for them – patents are one-of-a-kind, and the more unique they are, the less likely substitutes will be available.

E. Wasted Knowledge Does Not Exist in the State of Nature

Knowledge, as property, dictates an additional interpretation of wastage due to the difficulty of perceiving how patents could exist in the state of nature. A consideration of the advancements in society through knowledge accumulation reveals that patents belong within the realm of the modern state as a matter of what the state defines itself as being – an organized group of individuals consenting to rules and regulations for their own

benefit, where such societies that consent to the protection of knowledge inherently understand that the knowledge is prone to theft. Logically, the non-wastage condition is telling of why patents do not belong in the state of nature – if an individual is only concerned about survival and only takes what he needs, it is difficult to see why he would create protected ideas that he would ignore and let go to waste. If he creates something that has no direct use to him, he is setting himself further back in the management of his own survival, making it illogical to do. If a man creates an invention that helps him sustain himself, it should be irrelevant to him if someone copies the invention because it would make no difference to his own survival in an abundant world. Regardless of the invention, the inventor would only use it to harvest enough food for himself in the state of nature or he would be wasting his time and effort. Therefore, technical knowledge and its spoilage (through obsolescence) are situated squarely within governed society.

F. Defining "Surplus" Knowledge in a Governed Society is Uncertain

If patents naturally occur outside Locke's state of nature, then the patent bargain needs to be redefined as property within a formed society. When an individual specializes his labour to invent things to earn a living, protecting that knowledge from theft through patents can be assumed to be necessary. Patents have the potential to create a surplus because the patented invention, protected by a monopoly position in the marketplace, may have so much utility that its sale to members of society leads to more wealth for the inventor than he needs for his own survival. Under a Lockean societal model, surpluses generated could be viewed as wasteful but they can also result in the

inequality to which society consents when the inventor transforms the surplus value into a durable and valuable commodity like money and hoards it.<sup>95</sup>

While "surplus" denotes what an individual earns that exceeds what is needed for his survival in Locke's theory, partitioning surplus from patents into what is necessary and what is excessive does not provide a meaningful definition of what the surplus is. By dissecting the surplus into components, however, a modified understanding of how knowledge *might* satisfy the surplus arises. The surplus is generated by the sale of the invention to individuals in society's market, who also grant the inventor a patent for his invention. The money given to the inventor can be partitioned into its research costs, production costs, a general level of profit, plus a premium.<sup>96</sup> The general profit is the profit that any person would earn from selling any item in society for his survival, and might redeploy among other labourers with the intent of generating an even larger surplus.<sup>97</sup> The second surplus, the premium, is the debt that society pays for the invention by giving the inventor a monopoly on its sale but hopes to recoup from the knowledge revealed in the patent. The knowledge gained from the patent is in the public domain, free for others to use for expanding knowledge even further, creating more innovation and more surplus, and for being copied and reused after patent expiry. The *utility* of the knowledge will be at least based upon society's previously accumulated

<sup>&</sup>lt;sup>95</sup> Locke, *supra* note 1 at ch V paras 45-51.

<sup>&</sup>lt;sup>96</sup> Consent in a civilized society requires money for the sake of facilitating bargaining. Currency facilitates the holding of surpluses in a non-spoilable way when individuals sell the fruits of their private land in the market. Similarly, patented inventions have the potential to create a monetary surplus value through selling the *product* of the invention or selling the knowledge from the invention in a marketplace, rather than bartering. Presuming that an inventor sells the patented invention far and wide, the surplus generated from the patent would have to be converted into currency so that the inventor can exchange it for reasonable amounts of the things that he needs to survive and to continue making the invention.

<sup>&</sup>lt;sup>97</sup> Locke, *supra* note 1 at ch V para 48.

knowledge in the trade associated with the patent. Where the general nature of land allows it to be transferred between individuals, the ability to use specific patent property requires a working knowledge of what preceded it in order to capture the surplus from it.

To clarify, the surplus from patents is not the *general* surplus associated with selling the invention in the marketplace. The traditional understanding of Locke's surplus means that the surplus "produce" from land is sold, then returned back into production, employing others to create an even larger *general* surplus. The surplus for patents is isolated to the premium paid to society *in exchange for the information* and the opportunity to use it productively. Thinking of knowledge as a surplus is only meaningful when that surplus is tied to the return bargain it brings, but it is difficult to conceive of the surplus as being unnecessary or excessive. Rather, the ability to use the information provided is akin to the fundamental bargain for the patent, making it the "surplus *from* the knowledge in the patent."

G. Summarizing the Nature of Technical Knowledge "Property"

The preceding section described the nature of technical information in both Locke's state of nature and governed society. It considered the specific and cumulative nature of knowledge, where technical information results from developing and deriving new information from existing information. If an individual is to be able to use new knowledge, he must be well-versed with the knowledge that preceded it.

Secondly, technical information is generally considered to be non-rivalrous and therefore infinitely available to members of society. Considering technical knowledge as finite is weakly accomplished when it is linked to the *finiteness of inventors*, where the generation of technical knowledge is constrained by the number of inventors in society.
What an inventor chooses to invent means that other inventions that society values are potentially pushed further back, forming an opportunity cost of that choice, which is fundamentally different than the idea that existing knowledge is simply indivisible. Considering the consequences of *protecting* knowledge through patent is also fundamentally different than an infinite characterization of knowledge property.

Knowledge can become obsolete when new knowledge is added to the commons, making knowledge a highly specific, unique type of property. Because knowledge property can become obsolete, it does not have the substitutability that land generally does, as it may never become a useful part of information returned to the commons, despite society's grant of patent.

The use of patents in the governed state creates the potential to generate surpluses. "Surplus knowledge" does not make sense in everyday language, but gains meaning when one considers the term "surplus *from* knowledge." Where a general surplus arises from selling anything, a knowledge surplus can be linked to the premium price associated with products that are sold vis-à-vis a patent monopoly. The inventor recycles the general surplus through the labour of other individuals who will grow the surplus even larger, but the use of money means that inventors may tend to hoard some of it. While the inventor keeps the funds from the second surplus for his efforts, the knowledge surplus is given back to the patent granting society as the ability to practically employ the patent in workings and research in exchange for the premium paid for the patent.

III. Applying the Characteristics of Technical Knowledge to Locke's Justification forPrivate Property

A. A Necessary Correlation between Patent Grantors and Patentees: A Societal Example

Consider an inventor who patents a new medicine that treats a previously incurable disease in a foreign jurisdiction that does not have the research capacity to use the information in the patent. In other words, that society has an insufficient amount of accumulated knowledge to make use of the specific disclosed patented information (a key characteristic of technical knowledge) even though it needs the invention itself to overcome the disease. The inventor is under no obligation to do anything but disclose the patent for all to see and society is made no worse off than before the new medicine arose, giving the inventor a free pass from all obligations beyond disclosure. The addition of knowledge led to no diminishment of existing technical information because it is nonrivalrous.

B. The Societal Surplus Approach

Using the previous breakdown of the surplus highlights why satisfying the patent bargain with only disclosure is problematic. When the inventor sells the new medicine to the foreign society, he receives the general surplus and the premium surplus in exchange for the patent. The general surplus satisfies society's utility for the invention, which can be used by the patentee to generate new medicines and even larger surpluses. The premium surplus (derived by selling it over a competitive market value) that the patentee receives is offset by the inventor's obligation to disclose the patent to the public for its own benefit. This premium surplus should result in a surplus from knowledge for the

patent grantor. Since society cannot use the knowledge, there is no utility in the surplus knowledge held by the patent grantor. Without any utility in the knowledge, there is no rationing of part of the surplus to the granting society.

## C. The Transplanted Enough and As Good Approach

Locke's enough and as good condition need not survive a theory of intellectual property law if patents do not exist in the state of nature; as Locke stated, the enough and as good condition would not apply to a governed society due to the inequality engendered through differences in abilities and the use of money as a medium of exchange. If the condition *is* transposed into the governed state, it facilitates the examination of a naturally cyclical, recurring benefit from a patent property owner to society without relying on the goodhearted nature of the inventor to return surpluses to the commons – the benefit of the patent should simply occur through the performance of granting the patent in the first place.

If the enough and as good condition was satisfied only by the disclosure of the patent in the new medicine example, then technical knowledge would simply pass through the condition without any assessment of its value made by the granters of property. Patent law would then exist unbridled from the burdens of a theory, having no expectations from patent property awarded or its potential transference from the inventor to society. The enough and as good condition would easily cycle because enough and as good had no meaning left. But patent property that is "as good" for the patent grantor means that the property should show the equivalent utility with the patentor, meaning that they can both conduct research from it and employ it productively. This requires the patenting society to have the same level of *specific* accumulated knowledge as the

inventor. There is "enough" information when the patent is disclosed, but it is only "as good" when the patent granting society can use it in the same way as the inventor.

D. The Insufficiency of Disclosure-Only in Locke's Surplus and Enough and as Good Condition Models

Under the simple disclosure legal model, above, both the knowledge surplus and the enough and as good condition are satisfied when the patent is revealed to society, even though the preceding analysis demonstrated that it is not necessarily the case when the full meaning of the patent bargain is considered. Even though the patent granting society is unable to use the patented information to benefit itself and initiate its own research and development projects from it (due to a lack of accumulated knowledge), the inventor has still fulfilled the enough and as good obligation by disclosing it. Therefore, a lifesaving benefit like this new medicine, with personal property embodied within it, creates a moral dilemma around balancing the inventor's rights to his invention and society's need for making progress in the development of its own medicines, whilst still meeting the tenets of the Lockean property justification through the surplus or the enough and as good interpretation of the model. In essence, the disclosure-only model of patent law has no additional legal obligation to satisfy but only a moral obligation on the part of the patentee to continue to support the ongoing innovation needs of the non-inventing jurisdiction...an obligation that it can abandon at any time, despite the interdependence between the two societies for improving social welfare. Hence, the patent granting society needs to receive more than disclosure to achieve the patent bargain if it wishes to reduce its dependence on the inventing society. This inter-relatedness of the patent grantor and the patentee represents a major difference between general property like land,

and specific property like patents, but is only elucidated once technical knowledge is made subject to the enough and as good condition or Locke's surplus condition.

E. Weak Form versus Strong Form Patent Law

The granting of a patent for an invention whose knowledge could never be used in society generates a weak form of patent law under the traditional interpretation of Locke's enough and as good condition, where the condition is satisfied by patent specification disclosure and does not have to be worked to any degree to justify the granting of property. The weak model, however, leaves questions about the merits of the enough and as good condition because its traditional operation in Locke's state of nature is automatic, where one man's need for land led to improvements upon it which will benefit the next individual who acquires it as a guarantee. This pass-through type of validation of information will not allow the enough and as good condition to necessarily rise up to the improvements that it is supposed to create, but a stronger form of the theory would make the condition hold *with meaning*. Rhetorically, how could disclosure of a patent to an unsophisticated society be "as good" as what the inventor holds with it, given the vast differences in their information sets? If disclosure is the only requirement for satisfying the Lockean societal surplus argument, it also results in the same weak form of patent law because the there is no *utility in the knowledge* for the patent granting society, receiving nothing for the premium that it paid to the inventor.

F. The Nozickian Compensation Approach

In governed society, Locke's justification hinged on consent, not just to an initial distribution of property when leaving the state of nature, but to the *potentially unequal* distribution of private property in society over time. Nozick stated that private property

needed to be capped as a matter of equality under God and the achievement of social justice. By making individuals to compensate society for property taken out of the commons, the amount of private property would be minimized and would tend to be equally held by all. Applied to information contained in patents, consent to the unequal distribution of intellectual property is hard to imagine, seeing that the information is free for all to examine and use, where one individual's use does not preclude another's. But consent to patent property laws can lead to the *differing rates of utilization* of the information in the patents between the inventor's home and a patent granting foreign society, meaning that the accumulation of specific technical knowledge among the consenting parties varies, and there is no necessary tendency toward minimizing patent holdings in private hands because society has not capped the property given to inventors in the form of patents.

The thesis has already established that the creation of inventions and the carving out of patents as property ignores the real potential of the parties to use the knowledge in weak form patent law, where the inventor has the advantage of being learned and knowledgeable in that information, giving him the ability to conduct further research with it or commercialize it. The other party has access to the information but does *not necessarily* have the ability to experiment with it or exploit it for the duration of the patent or after it. Nozick's social justice condition, however, would have the patentee compensate the patent grantor to minimize the differential in their ability to use the information.

Nozick's employment of a baseline social welfare condition can be translated into a knowledge property model as a *knowledge social welfare baseline*. As the inventing

society's social welfare knowledge baseline increases with the addition of patent knowledge, the granting society's knowledge baseline could either increase or stay the same. Using Nozick's social justice argument, if the knowledge cannot be used, the differential in knowledge between the two societies increases, making compensation to the granting society necessary. If the information does not make their knowledge baselines diverge, no compensation is necessary.

Under a Nozickian compensation model for patent law, therefore, the accumulated knowledge of an inventor who embodies it in an invention and exchanges it with society for exclusive patent rights is required to compensate society for a divergence between the two relative information social welfare baselines. This would be justified by any potential restrictions that the patent might create on existing knowledge – it might impede similar current research in the patent granting jurisdiction or it may create obsolescence in its knowledge base that is not convenient or desirable. If the granting society thinks that they would have achieved the same invention over a longer period of time, it would make the *current* taking of that knowledge potentially diminishing to society's future learning and knowledge base.

Despite being a flexible model, knowledge property becomes a difficult concept to reason within a Nozickian compensation mechanism in patent law. With the new lifesaving drug example, the inventor does not make others worse off when he patents it: if he had not stumbled upon it, no one would have had access to the cure and no one would have access to his research, so his actions have no negative side effects. Over time, however, a society that has some level of drug development knowledge among its researchers could eventually develop the same drug, which provides a reason to limit the original acquiror's claim to exclusive patent rights, because his continued holding of the patent may impede the research and development uses that are already under way. Either relinquishing the monopoly or paying a higher level of compensation remedies the problem, but the argument focuses on the negative effects of the patent on the knowledge baseline and the knowledge differential between the two societies.

An awareness of the difference in knowledge social welfare baselines between the patentee and patentor societies created by a patent leads to the potential for compensation to the patentor. However, the justifications for compensation for new knowledge are strained because they have to relate to what the patent grantor has lost in the process when it is considering acquiring and protecting new technical knowledge. The *negative effects of the knowledge* on the granting society of the patent become the key drivers for compensation, leaving the patentee's overall positive contribution outside of the assessment.

## G. Nozickian Compensation by Disclosure Only

When basic disclosure is deemed to be a sufficient bargain in patent law, giving no consideration to the real effects of specific knowledge accumulation, weak form patent law results. This weak form conflicts with a Nozickian knowledge social welfare baseline model because compensation would be fixed *at the value of disclosure* and not allowed to fluctuate according to how the patent property would affect society - the social welfare baseline has to be re-evaluated with each patent application, making the *real effects* of patent relevant. A disclosure-only legal model makes compensation static and removes all of the flexibility that was key to the Nozickian model, supporting only a weak form of patent law. IV. Generalizing Weakness in the Three Interpretations of the Lockean Condition in a Patent Law Model

The three interpretations of Locke's justificatory condition are uniquely reflective of patent law, but each has weaknesses as a model. There are some facts about technical knowledge property that are clear, though. Patents are markers for knowledge accumulation, representing the culmination of research knowledge into a physical form that can be commercialized and sold to others for improving humanity. The fact that patent knowledge is disclosed for others to examine does not make it useable to all, where the specificity of the knowledge and the accumulated knowledge base, knowledge obsolescence, knowledge theft, and the opportunity costs of not inventing other things are material aspects that affect the value of any given patent to society. As the number of patents held by an inventor increases, the *material knowledge base* of that patentee increases, while the effect on the knowledge base of the other party is variable, depending on its existing knowledge base at the time. Overall, the knowledge bases of both the inventing and the granting societies have to be correlated to a high degree in order for the granting society to be able to utilize the patents it grants.

A. Enough and as Good is Inflexible but Represents the "Ideal"

Locke's enough and as good condition in the state of nature is rigid, in that it does not leave any latitude to depart in meaning between the patentee and the patentor – if something is enough and as good for the patentee, it must be *enough and as good in the same way for the patentor*. When disclosure is defined as satisfying "enough and as good," a weak model of patent law arises because there is no guarantee that the property is "as good" for others in society to use. Simply, disclosure is enough and as good for

the patentee and the patentor when there is no accounting for the differences in the utility of the knowledge between the parties. "Enough" could mean that there is enough information disclosed to be shared to enable the patent (reconstruct it), given the patentor's current state of accumulated knowledge, which highlights the potential problem with the gap in knowledge bases between the societies. Or it could mean that there is always enough information available because it is non-rivalrous. "As good" implies that society can use the information in as good a way as the inventor, which is also highly dependant on the patentor's level of technological advancement.

The rigidity of the enough and as good condition, however, is useful in representing the ideal condition for satisfying the patent bargain. Where two competing and trading societies are at equal technological levels, both are motivated to provide reciprocal patent protection because they serve to benefit similarly. Not only do they receive protection for their technical information in each other's societies, they serve to benefit from the new patented information shared by their competitor because they have the ability to act upon it. When this is the case, enough and as good operates automatically as something that is just observed and does not need special conditions or enforcement through the law. This ideal form, when the expectations from patents are always met, operates without need for adjustment.

# B. The Surplus Condition is Vague and Lacks Accountability

Since patent property is usually the subject of governed society, Locke's surplus argument is befitting, but fulfilling the bargain through society's acquisition of "surplus knowledge" is constrained by definition. Being difficult to ascribe meaning to what "surplus knowledge" is, it finds meaning once it is interpreted as "surplus *from* 

knowledge" as established previously, so the surplus can be measured as the price premium above fair market value paid by society given in exchange for the use of the knowledge.

A surplus argument can also lead to a dispute over value by redrawing the lines as to what each part of the surplus is supposed to account for, complicating its use in theory. This vagueness with what the surplus means, and whether it is to be "given" to society to use or is to remain in the hands of the inventor (who recycles the surplus into other forms of labour) is unclear, leaving Locke's surplus argument with an accountability problem and concern over the voluntariness of the use of surpluses. In essence, it separates itself from an *individualistic* model that the theory is trying to be because it is no longer considering the knowledge in isolation as a *specific component of surplus*.

The surplus model also leads to weak form patent law when simple disclosure defaults to being the only sure thing to result from patent. Simple disclosure guarantees no such useability of the surplus, yet a premium is still paid by the patentor to the inventor, creating a mismatch between what is paid and what society gets.

C. Nozickian Compensation Focuses on Remedying Damage

Under the Nozickian model, the social welfare loss associated with new inventions can be measured and used as a guide to compensate society. This makes it a much more flexible mechanism than the enough and as good condition because it allows for adjustments to compensation based on society's assessments of a patent's social cost. It also overcomes any voluntariness needed among inventors to return a surplus to the commons by making it a precondition to their grant.

But examining what is potentially lost in this model is difficult to justify and it ignores the inventor's utility contribution to society. Society considers what existing knowledge it may make obsolete, where it fits in its accumulated knowledge base, and how other relevant information is going to be impacted. It is focused on negative effects, trying to remedy the social welfare knowledge gap as a matter of social justice, not prioritizing the patentee's inventive contribution.

# D. A Modified Lockean Justification is Based on Expectations

Both the Lockean enough and as good condition and societal surplus model freeze the ability of the patent grantor to adjust the terms of the patent. The actions of the patentee drive what *should* be available to the patentor but leave no opportunity for the patentor to adjust the parameters to create a higher likelihood that it actually takes place. By focussing on the remedy for patent property with Nozickian compensation, the actions of the patentor become the primary driver of the patent granting system. A condition more akin to an assessment of loss, there is less accounting for the utility of the information that the patentee had created with Nozickian compensation. Therefore, all three conditions, though useful for understanding the patent bargain, demonstrate weaknesses as legal models. By employing an assessment of the utility of the knowledge embodied in patents (an evaluation of the use and uptake of the information by society), the application of an expectations proviso can create the natural cycle that Locke described among property holders and others who will eventually need it, while imparting a high degree of flexibility in patents by aligning expectations from the patent with the terms of their grant.

While the enough and as good condition works ideally when the abilities of the patent grantor and the patentee are the same, a divergence in their abilities means that each party expects different things from any given patent grant. For the inventor, enough and as good means *exactly* the utility in knowledge that the patentee accrued through his efforts as a tautology because he defines it in his disclosed patent. For any given patentor, the information can have varying degrees of utility, based upon his ability to apply the information. To compensate for differences in what an inventor and a patent granting society consider enough and as good for any particular patent, an expectations model employs an assessment of patent utility within its own scope of use, and assigns patent terms accordingly, relative to the "ideal" enough and as good condition created with extremely close competitors who can use shared patented information equally well.

Locke's societal surplus condition *hypothesizes* what should happen when patent surpluses are generated, but the vagueness in the theory as to how surpluses are defined, how surpluses lead to other surpluses, and how much surplus is returned indicates a lack of accounting of the patentor's expectations, making the patentee's expectations the only consideration. He also admits to man's natural tendency to increase his holdings of property beyond what he needs, conflicting with the idea of returning surpluses to others. Once again, expectations set according to the utility of the information that society sees would more specifically stipulate what the patentor was to receive as a surplus from the patent bargain.

While a Nozickian social welfare knowledge baseline adds flexibility to the model by adjusting compensation, it minimizes the assessment of utility and focuses on what society could lose with a patent grant. Nozick can justify the need to compensate society

when new technology arrives by only employing social justice arguments as to what society *should* be given access to, but the compensatory model gives no consideration to the positive utilitarian side of that technology. The moral argument for moving the knowledge social welfare baselines of society toward one another through compensation tries to move knowledge bases toward equality, but it is lacking a key component that an expectations model can provide. While an expectations model can insist upon compensation because that compensation can move the patent granting society's knowledge baseline toward the patentee's in the same way Nozickian compensation can, it rationally considers a robust assessment of the utility in the knowledge, which adds a practical element de-emphasized in Nozick's negative assessment model.

When evaluating a patent application through the lens of an expectation, it can be evaluated using the characteristics of technical knowledge to see how it fits – whether there is a fit with societal need, whether society will be able to employ the technology, and what society's long-range capabilities and goals are for that particular industry. Such evaluations would not be easy, requiring many judgments, and spanning various time frames but they represent a new way of examining technological information protected as property. This model focuses on many factors that affect the potential usefulness of new technological information, giving less consideration to any potential detriment to the existing and future knowledge property base of the common knowledge of society.

In an expectations model of patent law, property is granted for sufficiently inventive, new technical information that takes into account the expectations of the patentee and the patentor, brought together by an assessment of the utility of the knowledge in the patent. In this model, the expectations of both the patent grantor and

the patentee for any given patent are congruent when they have identical technical knowledge bases and industrial know-how. When their knowledge bases start to diverge, the expectations of the patentee and the patentor can be realigned by the examination of the information's utility and the adjustment of patent terms accordingly.

Developing an expectations model begins with creating a nexus of expectations between patent grantors and patentees. The party requesting rights expects a commercial monopoly on selling the product of its patent in exchange for disclosing its patent, and retains all of the utility in the information, since it developed it. The party granting the property right expects to grant the commercial monopoly but also expects the patent to be disclosed *so that there will be an opportunity for others to utilize it*, making only one of the two components *common* between them. In order to make the bargain hold, the patent must impart something valuable to society beyond disclosure, making the patent more than just something that is observed. There is an expectation that the disclosed patent will become useful for society *at some point in time* and *to some degree*. Once it is assessed, it is used to set specific patent terms to satisfy its bargain. Over time, accumulated data on patents granted will assist inventors and patent grantors in creating expectations regarding their own patent applications.

Depending on society's expectations from granting a patent, the terms of the patent would vary to meet it. In simplest form, a society that expects to never benefit from the disclosure of a patent, will never benefit from providing exclusive rights in it. If it could never "work" the invention, there is no benefit to the would-be patent holder

because the invention is safe.<sup>98</sup> The inventor could receive *discounted patent terms*, measured as a decline from the ideal terms, that reflected the simple utility of the invention itself, or he could be required to provide and explain more basic knowledge that would allow the granting society an opportunity to accumulate *other* useful information.

At the other extreme, an inventor may seek a patent from another party whom forecasts significant benefits from doing so because it has a high expectation of using the intellectual property rights. When expectations are high, the party is therefore eager to enter into the agreement. Similarly, the inventor is eager for an agreement because it sees that the party is a closer competitor, and more likely to displace its technology by adding to it or working around it. For both, the accumulation of knowledge from the parties through the disclosure of the patent has a higher expectancy of relevance and usefulness, and the close competition between them serves to heighten what they can each achieve through disclosure. And the disparities in accumulated knowledge between the two close competitors are smaller than those with uneven knowledge bases. Setting patent terms between them will be easy, seeing that their expectations are highly aligned.

#### V. Conclusion

The preceding chapter modified three versions of the Lockean condition for application to patent law, all of which were individually inadequate theoretical justifications for why technical information should sometimes be patented: the traditional enough and as good condition, the societal surplus condition, and Nozickian

<sup>&</sup>lt;sup>98</sup> This analysis assumes that other individuals from outside the two societies in question are not free to enter such a granting society and take advantage of the fact that there is no patent on the information, which could be a motivation for inventors wanting patent protection. See Chapter One at 15.

compensation all demonstrated weaknesses. It demonstrated that both of Locke's conditions, the enough and as good condition in the state of nature and the surplus condition in governed society, lead to weak form patent law when the conditions do not have to be satisfied beyond disclosure. The Nozickian model was neutralized inside the disclosure-only model, seeing that no flexibility for creating just compensation remained.

When the bargain for patent *does* have to be satisfied beyond disclosure, patent law takes on a stronger form. Strong form patent law requires a would-be patentee to satisfy the expectations of the patentor for any given patent. It does not mean that the patentor has to derive the same utility from the patent as the patentee, but it has to set its expectations for the patent according to its own knowledge base and vision for the future.

When ideal conditions exist, Locke's enough and as good condition for property demonstrates that the cycling of patent property between patentees and granting societies is perfect, where the information disclosed is fully utilized by society in the same manner and to the same extent as the patentee. This ideal situation occurs between closely competitive societies, where their knowledge bases and productive capabilities are equal and therefore highly correlated. The ideal patent situation serves to demonstrate why patent terms need to adjust when the competitiveness between societies diverges, serving as a future "ideal standard" for assessing the utility of patents.

An expectations model of patent law can take into account the differences in knowledge bases between societies and set patent terms based upon an assessment of the utility of the information in any given patent. Not only can it consider differences in levels of competitiveness, it can also consider a range of factors, such as how useful society will find the patented information, and how it might impact existing knowledge.

It can then vary patent terms based on these factors. While Nozickian compensation is also flexible, its focus on what patents would remove from a societal common, as opposed to what it would add, make it an incomplete model for patent law. The expectations model is broad and provides a motivation for challenging existing patent law and changing it by incorporating utility in a meaningful way.

# Chapter Four: Patent Law History – A Shifting Emphasis from Utility and the Establishment of a Bargain to Non-Obviousness

## I. Introduction

Examining the historical development of patent law provides a perspective of how patent law initially emphasized utility and working requirements for bolstering societal know-how, then diminished as the importance of an assessment of inventiveness grew. While utility and working requirements contribute to the bargain society receives from patent, nonobvious does not directly do so because its purpose is to narrow the scope of things that are innovative enough to be granted patent. This makes the reformation of the law away from utility highly substantive when viewed through the lens of Lockean justification. This chapter covers the beginnings of patent law and elucidates this substantive change, forming an historical context for characterizing patent law according to the three Lockean conditions and the expectations model described in Chapter Three.

Patent law history can be categorized into two major eras: pre-industrial patent law of the Italian city states and England up to the *Statute of Monopolies* with its emphasis on utility and working requirements for creating a competitive advantage over others, followed by a migration of patent law away from assessment of patents as objects for increasing social welfare toward those based on achieving a new bar of inventiveness. The early period historicizes patent law in mercantilist Europe (from the 1400's to the middle of the 1600's), and the second era canvasses patent law in an age of rapid technological, industrial and colonial expansion (from the middle 1600's to the turn of the twentieth century). The history of patent law tracks changes in the primary influences of the patent bargain: working requirements, utility, novelty, non-obviousness, and disclosure, all of which are cornerstones to a corollary of the thesis that states that strong form patent law requires more than simple disclosure if there is a reasonable expectation for society to develop and utilize the technology in any given patent. After establishing the general conclusion that patent law was tailored with respect to working requirements and patent duration in early years, then moved toward unfettered rights with few conditions attached, the analysis in Chapter Five will demonstrate that, although the two periods are legally different, the new philosophical paradigm of patent law described in Chapter Three can explain them both, given that the generalization of Locke's conditions into an expectations model is predicated on an understanding of how technical information operates as property.

# II. Pre-Industrial Patent Law: A Focus on Utility and Working Requirements with Customizable Patent Parameters

Patent law in the early Italian renaissance city states developed as customary law that protected and motivated inventors yet achieved a bargain for society with respect to the uptake of new technical knowledge. There was a broad base of patentable subject matter and patent terms were variable, dependant upon the perceived utility of the subject of the patent.<sup>99</sup> Inherent in patents of the time was the need to work them locally, which

 $<sup>^{99}</sup>$  Giulio Mandich, "Venetian Patents (1450 – 1550)" (1948) 30(3) J Pat Off Soc'y 166 at 171. Patents could be granted for teaching members of a guild a particular craft, for example. Patents were also granted for extracting minerals from the earth and were restricted to set time periods and delineated to specific geographical areas.

was outlined in the grant. The law was also very regional in nature, designed to create advantages for particular geographical areas.

The first city state to pass patent legislation was Venice, whose statute reflected the prior customary law, still giving great latitude to what was considered "new" and who was considered an inventor.<sup>100</sup> The additional transparency of patent law created by the statute led to a need for extensive disclosure with stronger examinations of novelty and utility to verify old patents and assess new patent applications. Despite the fixed patent duration in the statute to ten years, government officials rarely followed the rule, often extending patent duration based on the perceived utility of what any given invention might have for Venice.<sup>101</sup>

In England, patents issued by royal charter existed as a customary means for the monarchy to organize commerce through guilds as early as the fourteenth century. The reigns of Elizabeth I and James I in the sixteenth and seventeenth centuries made the practice of granting patents much more extensive across England, with a broad base of overlapping subject matter, creating public discontent. While still serving the interests of trade guilds, patents were granted for a wide variety of home-grown and "imported" inventions with the goal of uplifting English standards of manufactured goods to equivalencies found in other European countries that imported their goods to England.<sup>102</sup>

<sup>&</sup>lt;sup>100</sup> The statute was passed in 1474. Craig A Nard & Andrew P Morriss, "Constitutionalizing Patents: From Venice to Philadelphia" (2006) 2:2 Rev Law & Econ at 237. Also see F D Praeger, "The Early Growth and Influence of Intellectual Property," (1952) 34 Jr Pat Off Soc'y at 123-128.

<sup>&</sup>lt;sup>101</sup> Mandich, *supra* note 99 at 192.

<sup>&</sup>lt;sup>102</sup> Robert Merges, Peter Menell & Mark Lemley, *Intellectual Property In The New Technological Age* 2nd ed (New York: Aspen Law & Business, 2000). Inventors from other European nations often brought their inventions to England, seeking a patent in exchange for working the invention in England, despite the invention no longer being novel. Also see Frederick Abbott et al (eds), *The Making of the International Intellectual Property System* (The Hague: Kluwer Publications, 1999) at 228.

But patents were also granted for the production and sale of everyday wares, the management and oversight of industries, and for getting around general prohibitions on exports, imports and other commercial laws.

The monarchy often tailored patents to meet specific goals, granting terms befitting of what the monarchy expected society to gain from them. Accordingly, patents were granted on a case-by-case basis, where the king or queen would try to estimate the value of the invention to society overall then set the patent terms according to that benefit. This often involved providing a monopoly to manufacture, distribute, and sell the invention in exchange for promises from the patentee to disclose the invention to the public and work it within the set jurisdiction using local labour. The technology would lead to improvements in goods and services, increased levels of employment, the transfer of technical knowledge to others, and the employment of local labour, all prime considerations when deciding to grant a patent. Additional benefits were often provided such as land and housing, for developing the technology. The involvement of the monarchy was a major factor in assessing the utility of the invention more so than ensuring that any patented invention had a truly inventive quality within it or establishing an inventor as the actual originator of an invention. The main goal was to have those various aspects of the invention operating within the nation itself: the specificity of the knowledge, the application of it on English soil, and the access to the information byoperating the invention on the ground created a certain utility among all of the pieces of a patent, despite concerns about the unchecked power of the monarchy.

Whether the grants involved the self-interest of the monarchy is subject to further research, but the general opinion of the public was that restrictions on the manufacture,

distribution, and sale of general commodities were an affront to how people wanted to carry on their day to day lives. The actions within the common law to restrict the power of the monarchy *generally*, and to restrict monopolies to genuinely innovative machines reflected the narrow tolerance that the public held for privilege, and the *Statute of Monopolies* verified it and began the process of filtering out extraneous patents, making patent granting restrictive and more systematic. There was no *present* reward to the public if they had to pay the price for special privileges in all manners of their daily life, nor a *foreseeable* one.

Passed by Parliament in 1624, the *Statute of Monopolies* restricted the prerogative of the Crown to grant monopolies for *non obstante* patents, meaning that all restrictive instruments, like grants, charters, licenses and monopolies issued for the purchase, sale, manufacture, and use of any "thing" were declared to be void and unusable.<sup>103</sup> It included an exception in the form of exclusive rights for new manufactures, setting forth the basis of modern patent law *in statute*:

Provided also, that any declaration before mentioned shall not extend to any letters patents and grants of privilege for the term of fourteen years or under, hereafter to be made, of the sole working or making of any manner of new manufactures within this realm to the true and first inventor and inventors of such manufactures, which others at the time of making such letters patents and grants shall not use, so as also 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; the same fourteen years to be accounted from the date of the first letters patents or grant of such privilege hereafter to be made, but that the

<sup>&</sup>lt;sup>103</sup> Though the *Statute of Monopolies* is often considered the origin of modern patent law, the common law that preceded it aided in the codification of limitations upon monopolies. The *Statute of Monopolies* was a declaration and a crystallization of that common law which maintained broad interpretations about what a novel invention was and who a true inventor was. But it was also an over-reach by Parliament to curb the power of the monarchy, leading to a narrowing of patent law to not just the *scope* of patentable subject matter (to innovative things), but to the inability to assess the utility of any given patent because the statute left no room for establishing a mechanism for assessing for doing so, a task previously undertaken by the monarchy.

same shall be of such force as they should be if this act had never been made, and of none other.  $^{104}\,$ 

The *Statute of Monopolies* contained no proviso that a patent must be useful, and the jurisprudence that followed initiated a course of requiring minimal utility.<sup>105</sup> By restricting any consideration of utility by the monarchy, the way patents were perceived and granted was fundamentally changing.

The granting of patent by royal prerogative was still permitted by the terms of the *Restoration of the Stuart Monarchy* to the throne of England, but that discretion was bounded by the *Statute of Monopolies* in terms of subject matter, novelty, and patent duration. An inventor could still receive a patent for importing a previously discovered invention under the statute, maintaining patent law as an incentive for inventors to migrate to England meaning that novelty still meant *new to England*, keeping the "first and true inventor" definition broad, <sup>106</sup> but limitations on "new" meant that ordinary wares could not longer be the subject of a patent. Flexible working requirements remained as an artifact of English customary patent law. Overall, the limiting of patent terms and the disabling of the monarchy's power to adjust them after the *Statute of* 

<sup>&</sup>lt;sup>104</sup> *Supra* note 49 at s 6. The *Statute of Monopolies* made all letters patent invalid, other than new manufactures.

<sup>&</sup>lt;sup>105</sup> James Ridout, *Treatise on the Patent Law of the Dominion of Canada*, (Toronto: Roswell & Hutchison, 1894) at 47, citing *Neilson v Harford*, 1841 151 ER 1266, 1Web PC 202. Also citing *Pilpott v Hanbury*, 1885, RPC, vol 2 at 37. Only the slightest amount of utility is necessary to support a patent.

<sup>&</sup>lt;sup>106</sup> Cases preceding and proceeding the *Statute of Monopolies* demonstrate no difference in adjudication where an invention was brought from another nation. Following the *Statute of Monopolies, Edgebury v Stephens* (1691) Holt 475; (1693) 1 WPC 35 continued to support imported inventions. Cases consistently arose that upheld the imported invention principle well into the 1800's. From *Plimpton v Malcolmson* (1876) 3 Ch D, learning about new inventions abroad, then replicating them at home was commonplace. See Fox, *supra* note 5 at p 230. Also see W. Edward Hulme, *The History of the Patent System under the Prerogative and at Common Law: A Sequel* (1900) 16 LQR 44 at 45 (as published in *Select Essays in Anglo-American Legal History*, ed J Bryce & F Maitland (Boston: Little, Brown, and Co, 1909) vol 3 at 139-41; Sir William Holdsworth, *History of English Law Volume 3: Book III – Medieaval Common Law* (London: Sweet & Maxwell, 1922) at 354.

*Monopolies* restricted the potential of patent law to adjust grants to the variable nature of inventions.

The funneling of patents strictly to those inventions with significant innovation over what society already had establishes a major demarcation for the thesis, where patents outside of this scope are outside the domain of a new theory of patents. Any new theory of patent is constrained to patentable subject matter that is absolutely novel and demonstrates significant innovation, reflective of a natural tendency to respect the manifestation of an individual's knowledge when it exceeds "average" thought, harkening to a naturalness in this limit. The struggle between the Crown and Parliament manifested itself in the development of this limitation, created by the problems with the execution of the earlier patent regime by the Crown.<sup>107</sup> Where restricting the monarchy was legitimately about the restriction on patentable subject matter (to things that were novel), the research conducted herein on patent law history does not reveal that it was about the monarch's utility assessments of inventions, making the flattening of the utility parameter an unintended consequence of the general restrictions placed on the Crown.

III. The Evolution of Nonobviousness, Specification, Disclosure, and the Diminution of Utility after the *Statute of Monopolies* 

The general restrictions on monopolies in the *Statute of Monopolies* set in motion a functional change in patent law because the monarchy was no longer instrumental in determining what constituted a new invention. Through evolution in the jurisprudence

<sup>&</sup>lt;sup>107</sup> Fox claimed that supervisory patents and other general patents could have been effective, but the manner by which that supervision was carried out was often corrupt, defeating the well-intentioned purposes. Therefore, Fox concluded that the monopolies themselves were not the culprit, *but it was the abuse of that monopoly power that brought them into disrepute*. Fox, *supra* note 5 at 189, concurring with John H Wigmore, "The Public Interest in a Sound Patent System" (1943) 195(15082) J Comm 24.

following the statute, the standard of inventiveness eventually became a question of whether a particular invention would *not* be considered obvious to a person skilled in the particular trade in question. This section of the history chapter will track the development of "new manufacture" and the inventive standard of nonobviousness, the erosion of utility and working requirements, and the increasing importance of disclosure.<sup>108</sup>

A. Challenging the Standard of "New Manufacture" – the Lingering Importance of Utility and the Origins of Non-Obviousness

1. Broad Definitions of "New Invention" and Inventors

Broad definitions of what an invention was and who was considered an inventor persisted beyond the *Statute of Monopolies* because the statute made no effort to change their meaning from their customary interpretation. In his *Essay on the Law of Patents*,<sup>109</sup> John Dyer Collier surveyed patent law in industrial England from the 1600's until his time of writing during the Industrial Revolution in the early 1800's when the Industrial Revolution was at its height, and monopoly power in commerce was under scrutiny. He addressed terms within the *Statute of Monopolies*, including "new manufacture" and "first inventor," and outlined what type of patents would be contrary to the law. Collier used the terms "inventor" and "discoverer" interchangeably, demonstrating the persistence of the lack of distinction between truly inventing something and taking someone else's invention from another jurisdiction from pre-*Statute of Monopoly* times.

<sup>&</sup>lt;sup>108</sup> Satisfying the Lockean condition after these developments leads to the weak form of the new expectations model, discussed in Chapter Six.

<sup>&</sup>lt;sup>109</sup> John D Collier, *Essay on the Law of Patents*, 2<sup>nd</sup> ed (London: Longman & Matthey Rees, 1803), ch 9. Collier was an influential English journalist during the late 1700's and early 1800's.

Similarly, he implied no difference between the words "manufacture" and "invention" - whether a device had never been seen before anywhere, or was witnessed elsewhere and newly manufactured in England, it was supposedly tied to the social benefit of the people, making a distinction unimportant. He did not elaborate on the *sufficiency* of an invention's ingenuity for the grant of a patent, being radically different from modern-day patent law's emphasis on having an inventive step. Rather, Collier's discussion focused on the *effects* of a patent, and whether those effects would be beneficial to the public.

Collier quoted Buller J. from *Rex v. Arkwright* for establishing a broad definition of "new" to support a patent: "...if there be any thing material and new, which is an improvement of the trade, that will be sufficient to support a patent."<sup>110</sup> Buller J.'s quotation suggested where the law was heading, but he did not define "material and new." Where "new" could be established by examining prior patents (prior art), what was "material" was undefined, indicating that the law was still searching for a standard by which inventiveness could be measured. With patent clearly resting on benefits to manufacture and trade, that evaluation was akin to a utility analysis inherent in the patent's grant, but not according to a standard of inventiveness.

Collier's recognition of "material and new" may have been easy to define because of the nature of inventions at the time, where most could be inspected with the eye, having less technical sophistication than what is observed in today's industries, making them easier to distinguish from things seen previously. This suggests that the ability to evaluate what constitutes a patent is contextual with respect to the level of advancement

<sup>&</sup>lt;sup>110</sup> Ibid, quoting Rex v Arkwright (1785) 1 WPC 64 at 71.

of industry and is perhaps why it was easier to identify something as a patent in the time before many industries rapidly accelerated and became much more complicated.

2. "New Invention" is not only Broad but Includes Utility

Despite no discussion in the Collier essay, the issue of *how inventive* a new manufacture needed to be to achieve patent had already been in play well before *Rex v. Arkwright*. More than two-hundred years prior, the case of *Matthey's Patent*<sup>111</sup> involved a challenge to the inventiveness of a patented process for attaching a bone knife handle to the knife blade. There was no use of the term non-obviousness offered by the defence, but it alleged that the contribution of the handle-attaching device was not significant enough to call the invention a new manufacture.<sup>112</sup> Although no further explanation was given, it did provide a clue as to how the issue of patents would be assessed as manufacturing competition heightened across industries during the industrial revolution.<sup>113</sup>

Applying *Matthey's Patent*, Popham C.J. stated in his judgment in *Darcy v*. *Allin*<sup>114</sup> thirty years later that one of the conditions of patent is that "the subject matter must be such as the result leads to a new trade or manufacture."<sup>115</sup> An *improvement* did not necessarily result in a new trade or manufacture because it might harm existing

<sup>&</sup>lt;sup>111</sup> Matthey's Patent (1571), Noy 283; 1 WPC 6.

<sup>&</sup>lt;sup>112</sup> (UK) 78 Eng Rep 147 (KB). *The Cloth Workers of Ipswich* case contains a specific reference to importers being regarded as legitimate grantees of patent as well.

<sup>&</sup>lt;sup>113</sup> Despite the inference that the invention was not inventive enough, the case was decided on other grounds, where the Cutler Company stated that the new technology imported by Matthey, albeit an improvement in the knife-making industry, would ruin their family business and their apprenticeship program. The court agreed, stating that it was not in the business of closing businesses, demonstrating the difference in philosophical thought about patents and their purpose before the development of modern-day parameters on inventiveness.

<sup>&</sup>lt;sup>114</sup>(1602) Moore KB 671; 11 Co Rep 84b; Noy 173; 1 WPC 1 [Darcy v. Allin].

<sup>&</sup>lt;sup>115</sup> Fox, supra note 5 at 233, quoting Webster's commentary on Darcy v Allin in 1 WPC 7.

businesses, demonstrating that the overarching government policy of issuing patents included a measure of assessing "unique usefulness" that could potentially establish *new manufacturing or commerce*. It was *not* an assessment of the inventiveness of a particular patent. Despite the fact that *Darcy v*. *Allin* stands as the primary case for enforcing the general restriction on monopolies, the definition of a patent was still much broader than a technical assessment of an improvement in the early seventeenth century.

3. Considerations of Utility and Judiciary Inconsistency

In *Losh v. Hague*,<sup>116</sup> two-and-a-half centuries after *Matthey's Patent*, the issue of inventiveness was touched upon again when Lord Abinger J. stated that one of the pleas to the defense of infringement was that the nature of the invention was rather insignificant. Though decided on other grounds, the issue raised by Lord Abinger was worthy because the prevailing purpose of using patents to bolster domestic industries meant that minute improvements to an invention were not seen as serving that purpose and were therefore not befitting of patents. The persistence of utility-like assessments as to how patents would benefit society or hurt it persisted.<sup>117</sup>

This negative view of minute improvements was contradicted by Tindal C.J.'s decision in *Crane v. Price*<sup>118</sup> four years later, where the plaintiff inventor had taken a *known* method of smelting iron ore with anthracite coal in a hot blast furnace and substituted bituminous coal to make the process more efficient. While the defendant

<sup>&</sup>lt;sup>116</sup> (1838) 1 WPC 200 at 204 [Losh].

<sup>&</sup>lt;sup>117</sup> Fox, *supra* note 5 at 233, quoting Lord Abinger. Also see E Wyndham Hulme, *On the Consideration of the Patent Grant, Past and Present* (1897) 13 LQR at 313-14.

<sup>&</sup>lt;sup>118</sup> Crane v Price et al (1842) 1 WPC 377 at 410 [Crane].

charged that substituting one form of coal for another did not constitute a patent, Tindal C.J. disagreed, stating in his charge to the jury:

There are numerous instances of patents which have been granted, where the invention consisted in no more than in the use of things already known, and acting with them in a manner already known, and producing effects already known, but producing those effects so as to be more economically or beneficially enjoyed by the public. It will be sufficient to refer to a few instances, some of which patents have failed on other grounds, but none on the ground that the invention itself was not the subject of a patent.<sup>119</sup>

Reinforcing *Rex v. Arkwright*, *Crane* examined an improvement in a process undertaken with virtually no change in the existing technology where the input material in the furnace was simply switched to another form. It was an easy demonstration of lack of inventiveness by today's patent standards; at that time, however, the increased efficiency led to higher utility which made it patentable. Therefore, the judgment expressed the idea that a small improvement in *utility* should be patentable and reflected the overall difficulty in assessing what a truly inventive thing should be in order to achieve patent.

Despite the discussion in the judgment that alluded to an inventiveness standard about what was "already known," *Crane* followed the utilitarian view, where Tindal C.J. charged the jury that an invention that was "good for the realm" was patentable. Where the issue in the case was whether the inventiveness was sufficient, the arguments had not yet evolved into a standard. Subsequent cases did latch on to the charge to the jury in this case, paving the new way for defeating the patent by stating that something could only be good for the realm if it was truly inventive.

<sup>&</sup>lt;sup>119</sup> *Ibid* at 409.

B. The Development of the New Standard of Invention: Non-obviousness

*Crane v. Price* was instrumental in developing a more objective method for defeating patents that lacked ingenuity. Despite the broad charge to the jury that inventions could be patented if they were good for the realm, the judgment changed the argument from one of "industrial-territorial" boundary to one of "technical" boundary, where the scope of invention shifted toward a microscopic examination and away from broad policy. But the development of the standard had some hiccups, with confusion in the law for years following the case.

By rejoinder of "the first and true inventor," "new manufacture," and "new and material" from the developing jurisprudence with the general prohibition on monopolies in the *Statute of Monopolies*, what inventions had in common was being distilled as a level of ingenuity that made them worthy of patent, more so than macroscopic arguments about novelty or the preservation of established business. Closely following *Crane v. Price*, Lord Brougham stated in the *Soames' Patent*<sup>120</sup> case:

It is very fit their lordships should guard against the inference being drawn, from the small amount of any step made in improvement, that they are disposed to undervalue that in importance; if a new process is invented, if new machinery is invented, if a new principle is found out and applied so as to become the subject of a patent right, embodied in a manufacture, then, however small it may be in advance of the state of science or of art previous to the period of that step being made, that is no reason whatever for undervaluing the merits of the person who makes a discovery in science or an invention in art, because the whole history of science, from the greatest discoveries down to the most unimportant—from the discovery of the system of gravitation itself, and the fractional calculus itself, down to the most trifling step that has ever been made - is one continued illustration of the slow progress by which the human mind makes its advance in discovery; it is hardly perceptible, so little has been made by any one step in advance of the

<sup>&</sup>lt;sup>120</sup> Soames' v Tindal (1843) 1 WPC 729 [Soames' Patent].

former state of things, because generally you find that just before there was something very nearly the same thing discovered or invented.<sup>121</sup>

A tide of change with how inventions were viewed followed the case; decisions were being framed within a context of slow and incremental progress in science and technology, meaning that nearly imperceptible improvements were potentially worthy of patent. Although not applying a *standard* to the level of ingenuity, it was clear that the court was still assessing inventiveness on an overall impression, examining the new manufacture and comparing its technical merits to what existed before it.

Applying the principle in *Crane v. Price*, Willes J. extended the ingenuity doctrine to a combination of pieces of prior art in *Horton v Mabon*,<sup>122</sup> finding that "[n]o doubt a new combination of old machinery or instruments, whereby a new and useful result is attained, may be the subject of a patent; but there must be some invention."<sup>123</sup> This established concerns about a bottom limit on inventiveness, where compiling known inventions together had to involve taking something beyond what was known in a trade to be considered patentable.

Malins V.C. deviated from the same principle in *Crane* in *White v. Toms*, <sup>124</sup> five years later. Although the plaintiff had been granted a patent for a new way of folding a hat, the infringer claimed that the technique for making the folds was previously known but not used on the hat style in question. Malins V.C. stated that "There is no invention

<sup>&</sup>lt;sup>121</sup> *Ibid* at 735.

<sup>&</sup>lt;sup>122</sup> (1862-3) 12 CBNS 437; 16 CBNS 141; 31 LJCP 255 [Horton].

<sup>&</sup>lt;sup>123</sup> *Ibid*.

 $<sup>^{124}</sup>$  (1867) 37 LJ Ch 204 [*White*]. The plaintiff had created an improved version of a mourning hat, where folds were placed on the underside of the hat to match those on the top, in case the hat was folded, or blowing upward in the wind. He wanted to stop others from copying the design.

in it. However meritorious as an improvement...it is not the subject of a new patent."<sup>125</sup> Malins further stated "that where there is merely an improvement in the mode of manufacture and no invention, that is not a proper subject for a patent."<sup>126</sup> Despite making a ruling consistent with modern day patent law around applying an old technique to a new object, Malins did not apply a standard of measuring the inventiveness to determine if thing created required the inventor to mentally go beyond what was already known.

Twelve years later, patents were still being evaluated according to subject matter, novelty, and utility, with no elaboration of an inventiveness criteria. In *Hayward v*. *Hamilton*,<sup>127</sup> Brett L.J. stated:

There was a point raised and discussed which for a time did seem to me to present a difficulty, namely, whether although this was new and useful, it could be said to be an invention. Now the difficulty that that proposition presented to me was this: that I did not recollect of myself any case in which, where a thing had been pronounced to be new and useful, the question of whether it was an invention had been ever discussed, or even left to a jury, for instance. It seemed to me in all previous cases it had been taken for granted that if the thing were new and useful there must have been an invention in order to arrive at a thing that can be so described, and I should say that in nine hundred and ninety-nine cases out of a thousand that must be so. I say if the thing is new and useful it is impossible to suppose there is not sufficient to make an invention, but I do not think as a matter of law that could be predicated as an absolute rule of law, because I think it is possible, although a thing were new and useful, it might be, under certain circumstances, that there was no invention in it.<sup>128</sup>

<sup>125</sup> *Ibid*.

<sup>&</sup>lt;sup>126</sup> White, supra note 124.

<sup>&</sup>lt;sup>127</sup> (1879-81) Griff PC 115 [Hayward].

<sup>&</sup>lt;sup>128</sup> *Ibid* at 121.

From Brett L.J.'s comments, satisfying novelty and utility would nearly always mean that a thing was the proper subject matter of a patent, but they were not necessarily sufficient conditions for achieving patentable status. Brett L.J. was clearly pushing "sufficiency of ingenuity" as being a condition for the proper *subject matter* of a patent, because utility was satisfied with the slightest amount of usefulness, and novelty could be satisfied with an accurate examination of the prior art. The law was groping at something else and Brett L.J. felt that mysterious concept would act as a check for the legal system as to whether or not the thing was an invention. His perspective, however, was that this check on the system would almost always be satisfied, highly under-representing its current use in patent law.

Trying to move patent law back to its traditional roots, Lord Esher M.R., in *Edison Bell Phonograph Co. v. Smith & Young*<sup>129</sup> demonstrated the rigidity of the traditional idea of patents as things to be left undisturbed; simply stated, a grant given to someone for the purposes of carrying out a certain function should not become the subject of a serious challenge. A patent was a grant, and it was not meant to be dethroned by someone who had set their designs on making the patent useless:

Now, whenever I hear the objection taken to a patent which has been used, which has been bought and sold, which has been therefore treated by men of business, as a useful thing, that it is wanting in subject matter, I look upon it, I confess, with an amused contempt. What is the meaning of want of subject matter? It is not the same thing as want of invention, or rather I should say want of novelty; it is not the same thing as want of utility, but, where you cannot maintain either of these propositions which would be sufficient to destroy the patent, it is something else which someone or other at some time has invented as an idea for destroying patents. And what is it? It really comes to this, that, although the invention is new - that is, that nobody has thought of it

<sup>&</sup>lt;sup>129</sup> Fox, *supra* note 5 at 237, quoting Lord Esher in *Edison Bell Phonograph Co. v Smith & Young* (1894) 11 RPC 389 [*Edison Bell*].

before - although it is useful, yet when you consider it you come to the conclusion that it is so easy, so palpable that everybody who thought for a moment would come to the same conclusion; or, in more homely language, hardly judicial, but rather business-like, it comes to this, it is so easy that any fool could do it. Well, I look, as I say, upon that objection, when all others have failed, generally with amused contempt. It can be made out, but hardly ever, when you find that which I have stated, it is hard to think that people would be buying and selling a thing - and that has been sometimes the whole thing - and yet the objection should be taken that it is wanting in subject matter.<sup>130</sup>

Esher M.R. was attacking the "any fool could have done it" criticism which could be used to quash a patent when novelty and utility were satisfied, yet the patent was judged invalid due to some technical detail that looks simple in hindsight. His opinion was that patents were not meant to be attacked in this manner because the person making the claim had not previously constructed the invention and had no meritorious grounds for stating that he could accomplish the same thing. If the patent was being used in trade and commerce successfully, there was no reason to attack the patent for lack of inventiveness as it was deemed sufficient, evidenced by its use. He did not like the evolving law, nor did he like judges *making law* instead of *interpreting law* in the customary sense. He also felt that patents could easily fit within the definition from the *Statute of Monopolies* as "any manner of new manufacture"<sup>131</sup> without micro-analyzing what "new" meant because the matter would be dealt with through a patent examination at the Patent Office. In his disdain for the approach, however, his judgment demarcated the thing that was being sought as being different from the criteria of subject matter,

<sup>&</sup>lt;sup>130</sup> *Ibid* at 398.

<sup>&</sup>lt;sup>131</sup> Statute of Monopolies, supra note 49 at s 6: "Invention means any manner of new manufacture the subject of letters patent and grant of privilege." The same definition was given in the new *Patents and Designs Act*, 1907 (Edw VII, C 29, s 93).

novelty, and utility, setting forth progress toward the new independent patent criteria of nonobviousness.

Despite Esher M.R.'s ruling in *Edison Bell*, the law kept moving toward an inventiveness criteria and was changing the way patents were granted, creating a technical approach to patent grant instead of an economic or utilitarian one.<sup>132</sup> Where holders of patents in earlier times could rely on the argument that patents were granted for substantial investments made, often making judges refrain from allowing new competitors to intrude upon it, assessing inventiveness meant that financial investment was irrelevant. Adjudicating something deeper, creators of new technology were scrutinized according to the inventiveness of their technology rather than being assessed on broad factors, like the scope of industrial coverage of a patent or the amount of benefit to the public.<sup>133</sup>

<sup>&</sup>lt;sup>132</sup> Many judges' and scholars' views on the definition of invention were also temporally fixed with this older macroscopic view of the law, where inventiveness was only one of several factors to be considered for the issuance of a patent. Where inventions from the 1600's or 1700's could be considered new through written descriptions and illustrations that outlined their usefulness, it was not critical to distinguish them when the actual work of the patents benefitted society. It was also implausible to think that a judge at the time to expect a judge to evaluate technical details across a spectrum of technologies when his expertise was the law and not science or engineering. See Fox, supra note 5 at 291. Fox states that a patent could simply be recognized as a "guise" where anything in that same guise, or form, would not be novel. If the guise was different, it must therefore be indicative of a novel invention, and be a new manufacture, meaning that a consideration of inventiveness, as a test of the worthiness of the subject matter of a patent, was not necessary. This approach rejected the idea that the subject matter of a patent needed be evaluated through the lens of non-obviousness and collapsed patent back to its traditional parameters of novelty and utility. Adjudicature by such a rule would not be able to differentiate between two inventions that operate via the same mechanism but appear different, or are used in different circumstances, but the authority of the state to grant patents, which it had done for centuries, would override any overlapping of inventions by assessing the utility of the patent before its grant.

<sup>&</sup>lt;sup>133</sup>Academically, the change would have been a positive step toward further participation in industry, because it invited more "new manufactures" to participate in any given field, leading to a network of technology-based businesses that examined the state of various technologies and set forth to improve upon them. New technology could supersede old technology much more easily, foraging a path toward progress.
# C. Developing Clarity in Non-Obviousness

An understanding of the functional change in the approach to evaluating patents requires recognizing the rapid acceleration of industrial growth in Britain in the late eighteenth and early nineteenth centuries. With huge strides in electrical and chemical engineering, radio communication, and many other industries, the spectacular nature of the inventions meant that the old undefined benchmark of "new manufactures" in the *Statute of Monopolies* was not practical. Not only were many amazing advances being made, but their complexity also meant that simply stating that "something like that already exists and is covered by a patent" was an impediment to the natural progress embodied in the minds of scientists and engineers when an old patent holder complained about a new invention in their space.<sup>134</sup>

The complexity of chemical compounds in *Sharpe & Dohme Inc. v. Boots Pure Drug Co. Ltd.*<sup>135</sup> was an example of the need to codify and clarify the doctrine of nonobviousness within the context of using a known chemical process to create a new molecular entity. Sir Stafford Cripps, counsel for the appellant Sharpe & Dohme Inc., famously stated:

Was it obvious to any skilled chemist, in the state of chemical knowledge existing at the date of the Patent, that he could manufacture

<sup>&</sup>lt;sup>134</sup> Manufacturing was also changed in the industrial revolution with the rise of assembly line processes. With the segmentation of jobs on assembly lines, factories grew into large complexes with multitudes of different machinery that could be adapted from a general use or be designed from the ground up for a specific task. As machine manufacturing grew to support assembly lines, their machines, along with their inventiveness, could serve a wide range of industrial customers. The days of having one operation that produced one succinct thing by one process were declining, and a patent system that recognized "new manufactures" needed an assessment of inventiveness to identify and protect such inventions that could be used across a multitude of industries.

<sup>&</sup>lt;sup>135</sup> (1928), 45 RPC 153 [*Boots*]. In this case, the plaintiffs sued for infringement of their higher alkyl resorcinol compounds that were to be used as intestinal antiseptics. The development of the compounds relied upon the application of the processes of condensation and reduction, both of which had been previously presented in academic literature. The defendants claimed that the compounds were not patentable, because the compounds' development was due to the application of the revealed processes.

valuable therapeutic agents by making the higher alkyl resorcinols by the use of condensation and reduction processes described? If the answer is "No" the Patent is valid as regards subject-matter; if "Yes" the patent is not valid.<sup>136</sup>

Cripps' wording was adopted in the decision by Lord Hanworth M.R., setting wide precedent in the cases that followed and superseding the *foolhardy test* first mentioned in *Edison Bell*. Cripps did not delineate the specific abilities of the chemist who would serve as the marker for non-obviousness. Rather, Cripps' question set the level of skill very high, where the chemist would have pervasive knowledge of *all chemistry* at that date and time, evidenced by the use of "any" by Cripps to describe the chemist within the suggested standard. But the decision avoided applying the standard by stating that the patent lacked "intrinsic characteristics which are the invention of the inventor."<sup>137</sup>

As judge-made law on non-obviousness continued along the same lines, legislation in England encapsulated it in 1932, where patent revocation for a lack of inventiveness was incorporated into the law, representing the first statutory use of the term "obvious." An act of Parliament in 1883 allowed for the revocation by patent according to a list of fifteen grounds, or *scire facias*, and the 1932 amendment added a sixteenth ground where an "invention [was] obvious and does not involve any inventive step having regard to what was known or used prior to the date of the patent."<sup>138</sup> What

<sup>&</sup>lt;sup>136</sup> *Ibid* at 162-163.

<sup>&</sup>lt;sup>137</sup> *Boots*, *supra* note 135 at 175.

<sup>&</sup>lt;sup>138</sup> Patent and Designs Act 1932 (UK), 22 & 23 Geo V, c 32, s 3, adding sixteen express revocation grounds to the Patents and Designs Act 1907 (UK), 7 Edw VII, c 29, s 25.

courts had been applying, albeit inconsistently, for a century was finally set forth in statute but it once again avoided delving into *whom* would find the invention obvious.

The wording of the new obviousness challenge in the statute reflected the evolution of the common law and required the patent claims to be evaluated by it; if no inventive step could be identified, the patent would not be granted. The newness of the law meant that there were few cases in the jurisprudence to draw upon for determining "inventiveness" and the rapid pace of technological expansion meant that the cases available were not usually relevant for technological comparison. With new legal territory in play and no hard standard of inventiveness to apply, each case was evaluated on its own merits, based upon the opinion of the judge, who did not carry the expertise of someone immersed in any particular scientific field.<sup>139</sup>

There was opposition to the change, where members of the British Departmental Committee on the *Patents and Designs Acts*<sup>140</sup> suggested that a non-obviousness clause was not necessary, and that the issue of inventiveness could be resolved by accumulating the common law jurisprudence and extracting and codifying what an invention or "new manufacture" was instead of using the Cripp's question. In considering the change to the definition of "new manufacture" in the 1932 amendment, the Committee decided to retain the original simplistic definition of invention from the *Statute of Monopolies* as "any manner of new manufacture." Being concerned that a change in the definition would not

<sup>&</sup>lt;sup>139</sup> Several similar comments were being made in cases at the time. See, for example, *Pirrie v York Street Flax Spinning Co*, (1894) 11 RPC at 454.

<sup>&</sup>lt;sup>140</sup> UK, *Report of the British Departmental Committee on the Patents and Designs Acts*, (Gr Br, HM Stationery Office, 1931) at 68, 69 and 308-310. The British Committee on the *Patents and Designs Acts* was established by the British Science Guild in 1927 to evaluate the reforms being made in the new patent legislation.

align with the principles of patent arrived at through the common law at any given point in time, which could create stagnation in the law, the committee stated:

Not only would any attempt to embody the result of these decisions in a statute prove very difficult and be likely to fail, but the result might be to stereotype the law at the date of the statute, and to deprive the Courts in the future of any elasticity of power of adaptation to changing circumstances such as they have enjoyed in the past. This would, we think, be a retrograde step. Further we have not found that there is any general criticism of the present position in this respect, or any general demand for any such codification as suggested.<sup>141</sup>

The committee recognized the importance of the judiciary in the evolution of

patent law, and that harnessing it with static definitions could leave the law inflexible, and unable to adapt to the tide of technological progress. The negative formulation of what an invention "*is not*," through an assessment of non-obviousness, was more flexible than trying to establish what "*it is*."

While the *Patent Acts* was revised again in 1949,<sup>142</sup> the grounds for revocation by non-obviousness was not amended to include the common law standard. It was not until the 1977 revision that the person having *ordinary* skill standard<sup>143</sup> was implemented into the Cripp's question which persists in this general form: "An invention shall be taken to

<sup>&</sup>lt;sup>141</sup> *Ibid* at paras 279-80, 62.

<sup>&</sup>lt;sup>142</sup> 1949 (UK), 12, 13 & 14 Geo 6, C 87.

<sup>&</sup>lt;sup>143</sup> The American case of *Hotchkiss v. Greenwood* 52 US 248 (1850) [*Hotchkiss*] has often been credited with establishing the person having **ordinary** skill in the art: "unless more ingenuity and skill in applying the old method of fastening the shank and the knob were required in the application of it to the clay or porcelain knob than were possessed by an ordinary mechanic acquainted with the business...." at 237. *Boots* had set the precise standard as "skilled..in the state of...knowledge." that was applied in English and Canadian statutes. Also see John F Duffy, "Inventing Invention: A Case Study of Legal Innovation" (2007) 86(1), Tex LR 1 at 1.

involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms part of the state of the art....<sup>144</sup>

IV. Working Requirements and the Paris Convention for the Protection of Industrial Property<sup>145</sup>

The *Paris Convention* emerged as a cooperative treaty among western European nations during a high period of international debate on patent law in the 1800's. On one side of the international debate, patents were expected to enhance production and bring new innovation to domestic industry whilst offsetting the technological advantages of foreign competitors. On the other side, many industrialized nations believed that nationalistic policies designed to give advantages to domestic residents by denying foreigners patents needed to be changed in order to continue to motivate inventors, regardless of their citizenship.

The notion that patent law was a source of international cooperation in trade and commerce was a marked change in the philosophy behind patent law, which had previously stood for creating comparative advantages against other nations. As stated by German lace manufacturer, author, and publicist, Friedrich Georg Wieck on the state of patent law in England in 1839, "England justifiably views its patent law as a guarantee that no invention...will be lost for the country, but instead it must contribute – and with

<sup>&</sup>lt;sup>144</sup> *Patents Act* 1977 (UK), c 37, s 3. Prior to the statute, *Hotchkiss v. Greenwood* created a great deal of controversy over the standard, which distinguished mechanical skill from invention. From *Cuno Engineering Corporation v. The Automatic Devices Corporation* (1941) 51 USPTQ 272, the invention must demonstrate a flash of genius to be entitled to patent, creating further dispute in the standard, and a long time period for the standard to be codified in law.

<sup>145 20</sup> March 1883, 21 UST 1629, 828 UNTS 305 [Paris Convention].

all potential of which it is able – to the welfare and progress of the domestic industry."<sup>146</sup> The debate was *precisely* about the bargain and whether society should press some exactness upon it as a reward for its grant at the expense of a foreign inventor, or relent upon it to uphold the inventor in reverence of his creation.

The *Paris Convention for the Protection of Industrial Property*<sup>147</sup> covered patents, trademarks, and industrial design, where member states afforded the same intellectual property protection to foreign nationals as they did for their own citizens. Individual countries still had latitude to grant or not grant patents, based on their own assessment of what was of novel and useful in their domestic laws.

The original *Paris Convention* of 1883 stated that national laws could stipulate residency requirements of the inventor and also require a patent to be worked locally, but it specifically disallowed forfeiture *just because* an invention was imported to a new country by the original inventor. Addressing both issues simultaneously,

(1) The introduction by the patentee into the country where the patent has been granted of objects manufactured in any of the States of the Union shall not entail forfeiture.

(2) Nevertheless, the patentee shall remain bound to work his patent in conformity with the laws of the country into which he introduces the patented objects.<sup>148</sup>

<sup>&</sup>lt;sup>146</sup> Friedrich Georg Wieck, "Grundsätze des Patentwesens" (1839) 6 (Germany: Chemnitz: Expedition d. Gewerbeblattes für Sachsen, 1839). The framers of the United States Constitution held similar views when constructing Art I, § 8 for the promotion of art and innovation. See Camilla A Hardy, "State Patent Laws in the Age of Laissez-Faire" (2013) 28 Berk Tech LJ 45, 98.

<sup>&</sup>lt;sup>147</sup> The original states that signed the *Paris Convention* were: France, Italy, the United Kingdom, Spain, Portugal, Belgium, Brazil, the Netherlands, Norway, Switzerland, Sweden, the Dominican Republic, Trinidad and Tobago, and Tunisia. Canada became a party to the Convention at *The Hague Conference* in June, 1925.

<sup>&</sup>lt;sup>148</sup> Paris Convention, supra note 145 at art 5A.

The *Paris Convention's* disallowance of patent forfeiture for importation and its requirement for local working requirements provides strong evidence that the patent bargain went beyond specification and disclosure – it had to include concrete national requirements for the application of the invention in the granting state so that society could benefit from it. <sup>149,150</sup>

In the 1900 Brussels Revision to the *Paris Convention*,<sup>151</sup> the signatory countries agreed to soften working requirements, such that forfeiture for not working a patent could *not* occur before three years from the filing of a patent application and could *only* occur if a patent owner could not justify the nonworking of it. Patent revocation was not allowed *at any time* if the patent holder could justify his inaction with respect to working requirements. At the Washington Conference in 1911, opposition over the limits imposed in the 1900 amendments arose from several countries, including England and Germany, but the three-year grace provision was upheld.<sup>152</sup> Strengthening the idea of equal patent protection among signatory nations, the 1911 *Paris Convention* revision

<sup>&</sup>lt;sup>149</sup> As early as 1331, King Edward of England was granting the privilege of a patent for those willing to settle in England and teach their skills and arts to the locals, and the practice continued throughout the renaissance, where patents granted in England in the late sixteenth century would be invalidated if not practiced. A patent granted in 1639 specifically required the patent to worked within three years of the date of grant, or else it would be invalidated. Stephen Van Dulken, *British Patents of Invention, 1617–1977: A Guide for Researchers*, (The British Library, 1999) at 41. Early examples of working requirements can also be seen in Frank I Schechter, "Would Compulsory Licensing of Patents Be Unconstitutional?" (1936) 22 Va L Rev at 287, 299–304; Nicholas A Vonneuman, "Conditionally Exclusive Patent Rights and the Patent Clause of the Constitution" (1956) 5(3) Am J Comp L at 391.

<sup>&</sup>lt;sup>150</sup> As discussed, the *Venetian Patent Act* of 1474 required the invention to be worked locally in order to be granted the patent. Michael Halewood, "Regulating Patent Holders: Local Working Requirements and Compulsory Licences at International Law" (1997), 35(2) Osgd Hall LJ 243 at 251, 252. See also Giulio Mandich, "Venetian Patents (1450-1550)" *supra* note 99 at 176-177.

<sup>&</sup>lt;sup>151</sup> See *Paris Convention, supra* note 145, *Paris Convention*, as revised at Brussels, Dec 14, 1900, (Geneva: United International Bureaux for the Protection of Intellectual Property (BIRPI), 1968) [*Paris Convention*, *Brussels Act*].

<sup>&</sup>lt;sup>152</sup>*Paris Convention*, as revised at Washington, June 2, 1911, (Geneva: United International Bureaux for the Protection of Intellectual Property (BIRPI), 1968) [*Paris Convention*, *Washington Act*].

removed residency requirements for foreign patent holders and facilitated easier patent filings across member states.<sup>153</sup> To compensate for the diminishment of working requirements, the 1925 Hague revision included an allowance for compulsory licenses on patents when the patented product itself was unavailable, or the patent holder did not provide for licensing of the patent.<sup>154</sup>

V. Conclusion of Historical Findings from the Development of Patent Law before and after the *Statute of Monopolies* 

Many patents granted before the *Statute of Monopolies* had a wide berth of subject matter, encompassing not just inventive machines, but trade worker guilds, management contracts, and patents on everyday products that people could often make themselves for their own use. Naturally, some people served to benefit from patent, while others did not, leading to a demand for change by the public because the monarchy was using too much latitude in picking the things that it felt were viable for improving the economic future of England.

Upon contemplation of the benefit to society overall, and a negotiation of terms with an inventor to "work" a patent in England, the patent would be granted if the monarchy felt there was going to be long term benefits of the patent beyond patent expiry. The patentholder was usually required to employ local workers to operate the invention, yielding additional benefits to society through employment and experiential learning. However, the subject matter of the grants often overlapped with other

<sup>&</sup>lt;sup>153</sup> *Ibid, Paris Convention, Washington Act.* Besides removing the residency requirement, the 1911 amendment allowed a national of one country who filed for patent protection in one country one year to file the patents in any of the other member countries, where the date of filing from the first country would apply.

<sup>&</sup>lt;sup>154</sup> *Paris Convention*, as revised at the Hague, Nov 6, 1925, (Geneva: United International Bureaux for the Protection of Intellectual Property (BIRPI), 1968) at art 5(3), [*Paris Convention, the Hague Act*].

monopoly rights granted to organizations who controlled a particular trade, or another patent that granted control over an entire industry. Patents also covered the manufacture, sale and distribution of ordinary items, causing outrage among the citizenry, who felt that patents were being attached to many facets of economic life.

Monarchial patents were not necessarily intended to be a way for the Crown to siphon money for the public; they have been characterized by some academics as the result of honest efforts to promote industry in England, but their practical operation was problematic – the scope of patents was too wide, encompassing management monopolies over ordinary industries; even patented "inventions" covered too large of scope to permit others to either be inventive themselves, or carry on with normal daily practices in life, like making their own clothes.

The restriction of monopoly to merit-based "inventions," where only those who met the requisite bar for ingenuity could be granted the patent lessened the perceived favoritism in society. This was a process set in motion with the passing of the *Statute of Monopolies* by parliament, motivated by the English citizenry and its parliamentarians who wished to restrict the power of the monarchy generally. The patent system (and the monarch's grant of letters patent for centuries) was a strong symbol of that power, which was curbed as part of the Restoration of the Stuart Monarchy.

Even though the *Statute of Monopolies* was enacted, the change in the evaluation of patents took time to develop. The statutory definitions of "new manufacture" and "true and first inventor" had been taken from the customary law that had developed around patents, meaning that inventions still did not have to be absolutely novel, but just new to England, reinforcing the territorial nature of patent law at the time. Patent laws

were still outcome-based for a couple of centuries following the *Statute of Monopolies*, where patents were granted after considering the material aspects of what a patent might do for English society.

Broad definitions of "new manufacture" and "inventor" meant that the common law often adjudicated cases of infringement by examining novelty and utility in a macroscopic view – if a patent had been granted for something, improvements in technology were not adjudicated as novel enough to be granted a patent or overturn an existing one, often seeing patent challenges as an incursion into stable industries as opposed to giving them consideration as something sufficiently ingenious. Where a previous patent had already established its utility, there was little reason for judicial interference in government or monarchy-issued patents. While there was some grasping for a standard of inventiveness as early as 1571 (*Matthey's Patent*), the rapid growth of technological change in the late 1700's and 1800's led to more frequent challenges against longstanding patents, accelerating the development of the standard.

While the inventiveness standard developed inconsistently, with many judicial retreats to patents as territorial rights or business fortresses, the law was clarified with the institution of the Cripp's question in *Boots*, which was eventually codified in statute. It took additional time to develop the measure of what a "person having ordinary skill in the art" would be able to accomplish given what was known about that particular art at the time<sup>155</sup> within the Cripp's question. Once that standard developed, nonobviousness

<sup>&</sup>lt;sup>155</sup> Steps in the evaluation of non-obviousness have developed to deal with what the person having ordinary skill in the art might find obvious-to-try, or may have discovered by teaching, suggestion, or motivation from the prior art, infusing significant flexibility in patent adjudication in infringement cases where the level of ingenuity is at issue. See Chapter One.

became a tool that allowed the relevant science and scientists to become the marker for assessing ingenuity, transforming the adjudication of patents into a microscopic evaluation of fitment within patent criteria. While nonobviousness became the metric for invention, the attachment of patent rights to working requirements had gradually tapered,<sup>156</sup> encouraged by loosening restrictions for inventors holding patents in foreign countries signatory to the *Paris Convention*. Therefore, the functional change in patent law after the *Statute of Monopolies*, was not simply the general prohibition on monopolies, but the development of the nonobviousness standard of inventiveness as a substitute for the diminished importance of utility and working requirements once the monarchy was prohibited from setting patent terms.

<sup>&</sup>lt;sup>156</sup> While *the Paris* Convention influenced the tapering off of working requirements, compulsory licensing was permitted under the Convention, and it remained in England and Canada for most of the twentieth century, which will be discussed in Chapter Six.

# Chapter Five: A Comparative Analysis of Patent Law *before* the Development of Non-Obviousness and *after*

#### I. Introduction

Using the modified Lockean theory of patent law developed in Chapter Three, this chapter will analyze and characterize the two historical periods in Chapter Four against the main tenets of the new theory. The comparison will demonstrate that the early period can be characterized as strong form while the latter period, once nonobviousness had fully evolved in the law, can be characterized as weak form patent law. Overall, the characterization of the two periods will reveal that the strong form of patent law will fulfill an expectation that disclosed patents will have utility within the granting society, where that utility is defined as the ability to use and build upon the patented knowledge. The weak form exhibits a low expectation for disclosed patents, where disclosure does not necessarily lead to the ability to use and build upon the patent.

#### A. The Exclusion of Non-Innovative Patents from the Analysis

The foregoing analysis will exclude patents related to trade guilds, management contracts, and patents on everyday use items that were common in the Italian states and pre-Victorian and Victorian England. The intent of the analysis is to examine patents as to how they relate to manners of new invention that represent progress beyond existing technology. While the analysis excludes patents that are extraneous to a legal system that only protects innovation, it retains a broad concept of novelty, encompassing absolute novelty and "borrowed novelty" for inventions observed in foreign nations but patented by a national of the home country. Consequently, the analysis also covers a broad definition of who is considered an inventor.

#### B. The Identification of a Functional Change in Patent Law

The distinction drawn between pre- and post- *Statute of Monopolies* centers on the development of nonobviousness as the inventive standard after the *Statute of Monopolies* was passed. Although the *Statute of Monopolies* has often been cited as the reason for the change in the law, it was the development of an inventive standard as a replacement for monarchial decision making that represents the functional change in patent law in the latter period. While the *Statute of Monopolies* was a method curtailing the prerogative of the monarchy to grant patents and narrowing the granting of patents to new inventions, it did not spell out the standard of invention, only stating that the exception for patents would be "new manufactures" by a "true and first inventor." As discussed, the standard developed over the course of three centuries following the statute.

Before nonobviousness, patent law was discretionary, where grants were made according to the monarch's thoughts about the usefulness of any given patent, customized to fit the circumstances. Once the monarchy's authority was neutralized, patent granting that was once a matter of assessing the societal outcomes evolved into a microscopic examination of the specific level of ingenuity in any given patent. Early importance on utility shifted to inventiveness, and eventually to the nonobviousness form, while utility diminished to a level where an invention had to *only be at least* useful, without any specification of *how* it would be useful. The assessment of nonobviousness became a job for the courts, then later, patent examination boards, with jurisprudence interpreting the law throughout its course of development. This change from authoritative direction based on an assessment of utility to a system based primarily on inventiveness (nonobviousness) represented a functional change in the law, because it purported to

allow accumulated knowledge, transferred to invention, to set its own course for the establishment of what was considered patentable. Recognizing this functional change in the law is crucial to understanding and characterizing the differences in the two time periods, where it is the *culmination* of the second period in modern times that will be generalized for the analysis.

II. Key Considerations in Applying the modified Lockean Theory to the HistoricalTime Periods

The pre- and post- *Statute of Monopolies* periods will be evaluated through the lens of the modified Lockean theory of patent law developed in Chapter Three. Applying the new theory means taking into consideration the characteristics of technical knowledge as property. The finiteness of inventors (instead of inventions themselves), the specific and cumulative nature of technical information, knowledge obsolescence, and the proneness of knowledge to theft are factors in the development of the new theory and will be given weight in the historical analysis.

The analysis will examine each historical period according to the three Lockean conditions previously discussed: the surplus condition in a governed state, the enough and as good condition (transplanted from the state of nature *to* governed society), and a Nozickian compensation condition. Each condition will be weighed against patent disclosure, which serves as the minimum for fulfilling the Lockean conditions in a modified patent model. Using the three Lockean conditions as descriptors will facilitate a characterization of patents as property using the expectations approach. The expectations model will then be applied to elucidate the concepts of strong form and weak form patent law developed in the theory.

III. An Analysis of Patent Law before the development of Nonobviousness using a Modified Lockean Theory of Patent Law

A. Generalizing the Early Period of Patent Law

Before the *Statute of Monopolies* and the development of nonobviousness, patents were granted upon an assessment of utility (how good the invention was for the realm) and the establishment of working requirements that firmly situated the benefit of the patent within the local economy. Working requirements meant that the patent was only given in exchange for building or operating, distributing, or selling the patent using local labour. These requirements were strictly set and enforced by the Crown to ensure that the conditions were met; when the conditions were in default, the patent could be transferred by the Crown to another party.

1. The Finiteness of Inventors was Understood

Regardless of the time period, inventing is carried out by inventors, binding invention to those who had the ability to do it. An understanding of this finiteness is what motivated the English monarchs to offer patents to inventors from the Italian city states who relocated to England. Seeing that industries were falling behind in the efficiency and quality of their products, patents were a way to drive innovation toward the higher standards set elsewhere, making themselves competitive and reducing outflows of money to foreign competitors by bolstering sales in the home market. There was recognition that inventors were rare and needed to be "imported" in order to have the benefit of their knowledge.

#### 2. The Cumulative Nature of Technical Information was Understood

The languishing of innovation in England in the sixteenth and seventeenth centuries meant that knowledge base was relatively obsolete compared to its technically superior trading partners. The inability to match the quality of imported goods was evidence of England's insufficient accumulation of knowledge in industry to achieve the same levels of technology as its competitors, making the importation of invention a way of accumulating that knowledge and possibly exceeding it. By taking a utilitarian approach to examining patents, the monarchy could individualize patent terms to help society accede the new knowledge and utilize it. One means of accomplishing this was instituting specific working requirements that ensured society was immersed with a working knowledge of the invention. Another was to grant a wide scope of protection for an invention, sometimes covering an entire industry, rather than just the invention.

#### 3. The Surplus from a Patent was Knowledge for Society

Since patents naturally fit within an organized society, beyond the state of nature, they are apt to generate a Lockean surplus. Patent law in the early period would therefore require societal consent which could naturally lead to knowledge inequality among society's members, providing monopolies for those who were able minded enough to create patentable inventions. But a Lockean theory of patents requires that the surpluses they generate be given back to society, offsetting part of that inequality by giving the "surplus knowledge" back. While difficult to define "surplus knowledge," defining it as "surplus from knowledge," meant that society would be able to actively use the information contained within patents beyond the mere use of the invention itself. In the early period, the monarchy tried to ensure that this surplus was actually given to society

by instituting special patent terms and working requirements to work the patent locally with local labour in all facets of the development and operation of the patent. These working requirements brought a level of certainty to what the patent was expected to bring to society.

Consent within the Lockean system was not always present since patents were often granted for inventions that were not original but brought from other countries. The monarchy rejected the need for consent from the true inventors, helping to frame patent law as something that was not originally universally consensual; rather, it was law designed to reduce information disparity and economic disadvantage between trading members. Overall, the influence of the monarchy in trying to establish a bargain from patent demonstrates a divergence from the self-fulfilling nature of a Lockean cycle of generating surpluses and returning them. Technical knowledge, being prone to theft, facilitated this policy.

4. The Transplanted Enough and as Good Condition in the Early Period Required Intervention

Where Locke's *enough and as good* condition is easily satisfied within the context of physical land being taken from the commons, there is understandably less of it available to all. Such diminution does not apply to non-rivalrous information like patents because new ideas are thought to beget more ideas, *expanding* the available intellectual property and removing none of it. In the early period, however, active participation by the monarchy in England in setting patent terms ensured that "enough" information was present and that the information would leave them "as good" at using it as the patent holder. In other words, society would be versed with it in the same way that the inventor

was at the time. While the outcomes from the patent grants did not always work out, the setting of specified terms heightened the potential for achieving them and facilitating a cyclical transference of information between inventors and society. Although the time period could be described by the enough and as good condition, the active intervention by the monarchy suggested that "enough and as good" was not cycling on its own as it could ideally do.

5. Disregarding Patented Foreign Inventions was akin to Nozickian Compensation

When Nozick's requirement for compensation is applied, the diminution in intellectual property in the commons occurs when a patent is granted because it potentially creates a discrepancy in the knowledge social welfare baselines between the patent holder and the granting society. From one perspective, a divergence in the knowledge baselines between the inventor (and his home country) and the granting society needs to be reduced because of the inventor's moral obligation to be a part of improving society overall. One can argue that society would be no better off if the inventor had not created the new invention, so that they have no entitlement to it, but it begets the question of why the inventor went to the trouble of inventing if he had no intention of benefitting society, where such an adornment of advancement upon society would have to be tied to a reward, but the reward would need to be bound with conditions as society's reassurance for the grant of privilege. The good graces of the inventor were not assurance enough, and variable but firm terms were instituted so that society would ultimately benefit.

Nozickian compensation, a means of maintaining a knowledge social welfare baseline for society, is precisely the point of the monarchial-driven patents, where

technical progress during the patent-filled Tudor, Elizabethan and Stuart reigns can be viewed as an elevation of the knowledge social welfare baseline of society because the terms of patents required sufficient working in order for society to become comfortable with them (and apply the knowledge so as to remove the discrepancy in the social welfare information baselines). The broad definitions of "invention" and "inventor" were also reflective of this, citing the need for England to keep up with the progress of other nations (and be more self-sufficient) as fulfilling its own moral obligation to society. Comparing the progress of more advanced European nations to their own was evidence of widening knowledge social welfare baselines, and an increasingly larger gap in the ability to compete in trade.

#### B. An Expectations Analysis of the Pre-nonobviousness Period

While the societal surplus model does not adequately facilitate the type of active intervention the governments of the early Italian city states or the monarchy in England practiced, the Nozickian compensation approach tends to explain it based on an ethical responsibility to prevent knowledge social welfare baselines between societies from diverging too much. The Nozickian approach is flexible, consistent with the setting of flexible patent terms in the early period, but its focus on the difference between knowledge social welfare baselines lacks a consideration of the merits of the invention an activity undertaken by the early societies, and the consideration of the utility that patents might bring is missing.

The transplanted enough and as good condition partially fits the characterization of the early period because adjusting patent terms could make "enough" mean "enough information to re-create and use patents," and "as good" mean "society has the ability to

use the information in as good a way as the original inventor." While the adjustable patent terms and working requirements of the early patents were geared to making the enough and as good condition work, the circular nature of transferring property from one individual to another implies a high level of certainty of condition fulfillment, more reflective of the *ideal* patent model that requires no intervention from Chapter Three. But technical information as property is highly specific, and Locke's model referenced land, where the substitutability of one piece with another was high. The high specificity and cumulative nature of technical knowledge property leaves no guarantee of similar substitutability with anything else, making "as good" become much more dependent upon the granting society's ability to use that knowledge than would be expected from land.

England and the early Venetian states' active intervention in establishing patent terms was evidence that the enough and as good condition was not cycling naturally. Because the early governments often speculated on the value of a patent to society, an expectations model is a better fit for the early period because it can encompass what the outcomes of the patent might be, with patent terms and working requirements set according to that forecast.

Disclosure was not as heavily emphasized in the early period, as the value of patents lay in their specific application by the people in the granting society. Applying disclosure as the base level of patent fulfillment, however, demonstrates that the expectations model in the early period went beyond expecting disclosure for its patents and governments and monarchs set goals that were expected to be met. Because the expectations were established beyond disclosure, patent law in the early period is characterized as a strong form of the expectations model. By examining any given

patent, that information was used to develop expectations and patent terms were set to meet them.

IV. An Analysis of Patent Law after the development of Nonobviousness using a Modified Lockean Theory of Patent Law

#### A. Generalizations about the Later Inventiveness Period

While patent law in the later period was a transformation over three centuries, the analysis will generalize its character to what it became in modern times. As the inventiveness standard developed from the seventeenth to the twentieth centuries, utility not only became less important in the adjudication of patent disputes, it formed the basis of several judicial decisions that indicated that the utility of a patent was often in conflict with its inventiveness for assessing patentability. There was no requirement for utility in the *Statute of Monopolies* either,<sup>157</sup> and there was little deviation from the standard fourteen-year duration of a patent. With no substantial statutory changes taking place until the twentieth century, the judiciary often continued to support the bargain that grants of patent were supposed to create through working requirements, and by the simple fact that a patent had been granted in the first place.

Disclosure of an invention's specification was required more frequently during Queen Anne's reign in the early 1700's,<sup>158</sup> and working requirements simply carried on as was customary, both addressed within the specifics of a patent grant.<sup>159</sup> Although

<sup>&</sup>lt;sup>157</sup> *Statute of Monopolies, supra* note 49 at 6(b). At best, utility could be implied from 6(b), which stated that patents could only be granted for new manufactures. If an individual invented something new and planned on manufacturing it, it could be presumed that such an invention contained utility, seeing that the inventor had contributed himself and his resources to its development.

<sup>&</sup>lt;sup>158</sup> The requirement for disclosure was written directly into the grant.

<sup>&</sup>lt;sup>159</sup> Supra note 149. Examples can be found in Stephen Van Dulken supra note 149 at 41, Frank I Schechter, supra note 149 at 299–304 and Nicholas A Vonneuman, supra note 149 at 397–98, 401.

patents temporarily restricted knowledge in the commons, the expectation was that the disclosure of the patent would lead to further accumulation of knowledge and future invention.

The *Paris Convention for the Protection of Industrial Property* granted equal national treatment among the member states, meaning that a patent granted in one state should not be invalidated in another simply because the inventor was not from the granting country. Despite becoming parties to the Convention, many nations, including England, retained an interest in having foreign patents worked locally for the upholding of the monopoly. While the *Paris Convention* initially supported working requirements<sup>160</sup> in individual countries like England, later conferences curtailed the requirements and they eventually languished, along with compulsory licensing of unworked patents which had followed-on from them.

As working requirements were diminishing, nonobviousness was gradually developing, which meant that inventions were being compared to the prior art to establish novelty, and the claimed technical advancement was then measured for its ingenuity to

<sup>&</sup>lt;sup>160</sup> Paris Convention, supra note 145 at 5(1), where the importation of patented inventions did not lead to forfeiture. 5(2) stated that the patent holder must abide by individual country patent laws in the exploitation of that patent. The Paris Convention, Brussels revision, 1900 diminished working requirements in Section 5(2) by prohibited member states from forfeiting patents within the first three years of patent protection, despite any nonworking of the patent locally. In addition, patent revocation was not allowed *at any time* if the patent holder could justify his inaction with respect to working requirements. At the Washington conference in 1911, the Paris Convention lessened working requirements even more by clarifying the nature of what inaction on patent was, stating that the patent shall not be forfeited unless the patentholder could not justify his inaction. See Paris Convention, Washington Act, 1911 revisions to 5(2), supra note 152. To compensate for the diminishment of working requirements, the 1925 Hague revision added 5(3) for an allowance for compulsory licenses on patents when the patented product itself was unavailable, or the patent holder did not provide for licensing of the patent. See Rajeev Dhavan et al, "Conquest by Patent: the Paris Convention Revisited" (1990) 32(2) J Ind Law Inst at 131-178. Also see Thomas Cottier et al, "Use it or Lose it: Assessing the Compatibility of the Paris Convention & TRIPS Agreement with Respect to Local Working Requirements" (2014) 17(2) J Int Econ Law at 437- 471.

see if it went beyond what a person having ordinary skills in that particular industry could do.

By focusing on the inventive standard, absolute novelty, and the equal treatment of foreign and domestic patents among the signatory nations, the scope of a "new manufacturer" finally excluded imported patents and a first and true inventor could only be the *actual* person who filed the patent first among signatory countries, characterizing the culmination of the second period by an emphasis on absolute novelty, nonobviousness and disclosure, with minimal importance given to utility and working requirements.

1. The Finiteness of Invention vis-à-vis Inventors was mostly Forgotten

Modern patent law, the later historical period characterized by the predominance of nonobviousness, gives little credence to the finiteness of invention. Overall, the eventual relinquishing of a meaningful assessment of utility and working requirements meant that there was no attempt to direct the activities of the limited numbers of inventors by the state. Rather, invention itself, and the ideas brought forth that represent a leap from current technology, began driving what was patentable.

2. The Cumulative Nature of Knowledge in the Nonobviousness Period was dropped as a Concern about Patent Law

Like finiteness, there was little concern over how the specific and cumulative nature of technical knowledge got integrated into society's knowledge base in the late period because patents were granted upon the basis of their ingenuity over existing technology. With the flattening of utility and the erosion of working requirements, nonobviousness became the primary factor in determining patentability, removing the

ability to link society's knowledge and capabilities to the specific knowledge in the patent.

3. The Patent Surplus was Static, Satisfied by Disclosure of the Specification Only in the Nonobviousness Period

Though the surpluses generated by patents in a formed society are difficult to define, the theory defines them as the ability of society to use and apply the patented information, coined as "surplus from knowledge." Nonobviousness became the sufficiency standard for inventiveness, but the lack of a utility assessment or working requirements (to control the parameters of the patent) meant that there was no certain "surplus" from the patent. Rather, standard terms were granted for the patent regardless of what the patent may or may not achieve for society which represent the over- or undervaluing of the knowledge. With no certainty as to whether the information would be a useful part of the cumulative technical knowledge base of society, the cycling of surplus knowledge into the system has no expected value. Patents can continue to accentuate inequalities in knowledge between the inventor's society and the granting society.

4. Nozickian Compensation was Uncertain with Nonobviousness

With a Nozickian compensation model, a legal system primarily based on nonobviousness provides for no *certain* compensation because the compensation mechanism cannot adjust. An invention that is granted a patent may or may not be added to the social welfare knowledge base because the lack of patent adjustment through working requirements or other special terms means that there is no way of making compensation commensurate with what society feels it is giving up for the patent.

Whether compensation is due to a moral obligation to or due to society's perception of how any patent might hamper its own use of accumulated knowledge, the mechanism is frozen, meaning that disclosure of the patent becomes the only *necessary* compensation for society.

## B. An Expectations Model of the Late Period

A society with a patent law system that prioritizes nonobviousness and holds working requirements and utility fixed at extremely low levels can only expect to achieve patent disclosure with certainty. With no working requirements to help equalize knowledge social welfare baselines, an inventor can claim that society would be no better off without his invention, so he owes them little in return. While the inventor's reward is certain, the benefit for society is uncertain, meaning that there is no expectation of a bargain from patents granted beyond disclosure. When there is no expectation by society to uptake and utilize the information contained in the patents it grants, the weak form of patent law ensues, which is the primary characterization of the late period.

# V. Conclusion

While Professor Fox believed that a patent "takes nothing away from the public, but only adds to the common store...."<sup>161</sup> his argument presumed exactly what this thesis chooses to uphold: the addition of patents to the common good for new and useful amenities enriching the public domain must mean that the patents themselves enrich the knowledge of society, or the patented information serves no benefit to a "social welfare baseline of information" in society. Professor Fox's comments fall short by describing

<sup>&</sup>lt;sup>161</sup> Fox, *supra* note 5 at 202, 203.

only the additions of *new and inventive goods* to society as being beneficial, excluding *the common store of knowledge* they impart and any expectations about being able to use it. While disclosure has often been cited by academicians and the judiciary as the patent bargain or the Lockean condition, instituting individualized patent terms and working requirements versus simply disclosing the patent are clearly incongruent methods of fulfilling a Lockean-type bargain in patent law. This separates the two historical periods.

The rules of the utility-driven early period prioritized the importance of inventors for driving invention, and patents were used as an incentive tool, recognizing that inventing is only as finite as the number of inventive minds in society. Specific patent terms and benefits, and the institution of working requirements were employed to allow society to accumulate sufficient working knowledge from patents.

The societal surplus model reflects little about the early period. When the societal surplus is defined as "knowledge from surplus," it is hoped that inventors would return knowledge willingly to society, but the active intervention of governments and the monarchy to achieve something from patent refutes the natural circularity of the societal model yet reinforces the idea that unequal holdings of knowledge can result from patents.

The transplanted enough and as good condition does reflect the early period, where patent requirements meant that society was trying make enough and as good mean the same thing to them as the inventor, but the active intervention of the government meant that the knowledge from patents was not naturally cycling as would be expected under the Lockean model due to discrepancies in accumulated technical knowledge among countries.

The Nozickian compensation model in the early period reflects the Crown's desire to reduce trade deficits with its superior trading partners by moving its knowledge social welfare baseline closer to that of its competitors. However, the compensation model's focus on what might be lost from patent does not encompass the entirety of the *expected benefit* that was being considered by these early governments and monarchs.

Through the lens of an expectations model, the early period can be characterized as strong form patent law, where society's expectations for patents were met by adjusting the parameters of patent, often going beyond simple disclosure. The monarchs and early governments took into account what society was losing when new technologies emerged, and they also considered the utility of the advancements that were being made, and an expectations model encompasses both, given its broad range of considerations.

The later period's focus on nonobviousness, with the eventual freezing of working requirements, patent duration, and other terms in the grant meant that the finite number of inventors could no longer be persuaded by the law to work on certain inventions in certain locales. It also meant that there were no mechanisms for ensuring that the knowledge of any given patent would accumulate upon relevant existing knowledge, creating uncertainty as to whether there was any utility in it.

The three conditions applied to the later period were incomplete descriptions. The transplanted enough and as good would not necessarily have the same meaning to the inventor and the granting society, and the rigidity of patent terms meant that society could not adjust them to bring the meaning of both parties closer together. Similarly, there was no certain surplus in the formed society, meaning there was no mechanism to offset the inequality that might result from differing levels of knowledge surplus between the

inventor (and his society) and the granting society. Nor does Nozickian compensation work, seeing that no working requirements could be used to compensate society when knowledge social welfare baselines diverged. All three conditions could only be weakly satisfied by this period, which merely requires disclosure for achieving patent.

In the late period, where nonobviousness becomes the sole criteria for patenting, there was no expectation that society would achieve a bargain from patents beyond disclosure, characterizing this period as having weak form patent law. While the expectations model leads to the same descriptive result about the lack of a certain patent bargain as the others, its generality facilitates a motivation for incorporating changes to patent legal requirements in the future.

# Chapter Six: A Consideration of Canada's Recent Patent Law History within the Context of the Modified Lockean Theory of Patent Law

### I. Introduction

The purpose of this chapter is to characterize the history of Canada's pharmaceutical patent law using the three modified Lockean conditions, followed by a contextual expression of the expectations model. With the rapid growth of the pharmaceutical industry during the late nineteenth century and evidence of Canada's desire to expand it at home, the relinquishing of compulsory licensing provisions in exchange for participation in world trade agreements in the late twentieth century provides evidence as to how Canadian policymakers shifted pharmaceutical patent law from strong form to weak form.

The chapter begins by aligning Canada's patent law history with that of England after the functional change to an inventiveness standard, having the same patent criteria, the same evolved standard of inventiveness, and similar patent working requirements. This shared path of evolving patent systems facilitates a convincing description of Canada's pharmaceutical patent law within the modified theory which will draw from the characterizations developed in Chapter Five.

# II. Canada's Early Patent Law History: An Essential Review

Patent legislation was incorporated into Canadian law in the late 1800's, written nearly verbatim from early American patent statutes. The essential features of modern Canadian patent law are the same as England and the United States, which include setting patent duration, limiting patents to new, previously undisclosed inventions to the public, integrating an inventiveness criterion (toward the latter part of the nineteenth century and the early twentieth century), disclosing and enabling inventions in the applications, and establishing the patent granting process as an examination system.

A. Canada's First Statutes: Novelty and Working Requirements

As a unified country, Canada's first patent act was promulgated in 1869, two

years following confederation. Legislative authority for the act was founded in Section

91(22) to the British North America Act of 1867.<sup>162</sup> Entitled An Act Respecting Patents

of Invention and Discovery,<sup>163</sup> the act granted exclusive legislative authority to the

Parliament of Canada for all matters relating to patents.<sup>164</sup> Modelled on the Patent Act of

1836 of the United States, the legislation maintained the hallmarks of the previous

statutes of Upper and Lower Canada for patent criteria:

Any person having been a resident of Canada for at least one year next before his application, and having invented or discovered any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvement on any art, machine, manufacture or composition of matter, not known or used by others before his invention or discovery thereof, or not being at the time of his application for a patent in public use or on sale in any of the Provinces of the Dominion with the consent or allowance of the inventor or discoverer thereof, may, on a petition to that effect presented to the Commissioner and on compliance with the other requirements of this Act, obtain a Patent granting to such person an exclusive property therein; and the said Patent shall be...good and avail to the grantee...for the period mentioned in such Patent ; but no Patent shall

<sup>&</sup>lt;sup>162</sup> Constitution Act (UK), SC (1867), 30 & 31 Vict, c 3 (1867).

<sup>&</sup>lt;sup>163</sup> (UK), 32 & 33 Vict, c 11, s 14, RSC 1869, ch 6, s 6. Despite the inclusion of "discovery" in the section title, any discoveries of scientific principles were not covered by patent.

<sup>&</sup>lt;sup>164</sup> Patent term was fifteen years (s 22) and it applied to all four original provinces of Canada: Ontario, Quebec, New Brunswick, and Nova Scotia. Further modelling off the United States *Patent Act* of 1836 meant that a patent office was established for the examination of patents and the administration of patent records, and the courts were given the role of enforcing patent rights. All patents required a full specification, a description with drawings, and a scale model. The Patent Office, the Commissioner of Patents, specification and disclosure, and the deference to the court for patent disputes, as established in this new act, are elements of patent law that persist in Canada's laws today, creating an examination-based patent granting system with matters of enforcement left up to the courts.

issue for an invention or discovery having an illicit object in view, nor for any mere scientific principle or abstract theorem.<sup>165</sup>

This new act required absolute novelty prior to the date of the invention and disallowed the importation of inventions seen or "discovered" while travelling abroad without consent of the inventor.<sup>166</sup> It carried over the working requirements provision from the earlier statutes, whereby the invention was required to be constructed or manufactured in Canada within three years of the patent grant date or else the patent would become null and void,<sup>167</sup> reinforcing society's requirement that the public become familiar with the invention.

In 1872, the 1869 act was superseded by a new one, removing the words "discovered" from Section Six.<sup>168</sup> While the word "discovery" typically applied to principles learned through science, the section still retained separate wording for the exclusion of scientific principles or theorems from patent. Removing "discovered" further clarified that inventions read about or witnessed in another country could not be granted a patent in Canada by someone other than the original inventor.<sup>169</sup> As of 1872, any form patent importation was clearly disallowed, its removal likely motivated by the avoidance of potential conflicts with Great Britain or the United States. Consistent with the ban on patent importation, the act allowed for inventors from other nations to be

<sup>&</sup>lt;sup>165</sup> *Supra* note 163.

<sup>&</sup>lt;sup>166</sup> Ridout, *supra* note 105 at 11, 12. Affirmed with *Woodruff v Mosely*, (1875) 17 CJ 306, SC (Que), 19 LCJ (Que), 169 QB.

<sup>&</sup>lt;sup>167</sup> *Supra* note 164 at s 28.

<sup>&</sup>lt;sup>168</sup> An Act Respecting Patents of Invention, 1872 (UK), 35 Vict, c 26, reprinted in RSC 1872, ch 26, s 6. (Ottawa: Brown Chamberlin, Law Printer to the Queen).

<sup>&</sup>lt;sup>169</sup> Gaylen A Duncan, "Business and Economic Implications of Programme Patent Protection in Canada" (1978) 1 Comptr LJ at 105.

granted patents for their own inventions in Canada without having a residency requirement.<sup>170</sup>

#### B. The Evolution of the Inventiveness Standard in Canada

By 1870, English jurisprudence like *Horton v. Mabon*<sup>171</sup> and *White v. Toms*<sup>172</sup> for assessing inventions by their ingeniousness were working their way into the Canadian cases. The first was *Waterous v. Bishop*,<sup>173</sup> which separated the definition of "invention" from a physical embodiment in "manufacture" by linking "invention" to the mental act of making something with enough ingenuity to conclude that it went beyond the prior art. The doctrine gained strength when it was adopted by the Supreme Court of Canada in 1887 in *Ball v. Crompton*,<sup>174</sup> further espousing the mental quality behind the word invention in the statute by declaring that something that could be described as ingenious was not necessarily sufficient for patentability.<sup>175</sup> However, the case did not offer any standard for the level of ingenuity that would rise to patentability. While the judiciary could have applied some of the English cases that rejected the new doctrine, like *Hayward v. Hamilton*,<sup>176</sup> it followed the course of developing consensus, meaning England and Canada were moving toward a *general* alignment of an inventiveness standard for assessing patents.

<sup>&</sup>lt;sup>170</sup> Margaret Coleman. "The Canadian Patent Office from Its Beginnings to 1900" (1976) 8(3) Bulletin – Assoc for Pres Tech at 56–63.

<sup>&</sup>lt;sup>171</sup> Supra note 122 (1862). Willes J. stated that "[n]o doubt a new combination of old machinery or instruments, whereby a new and useful result is attained, may be the subject of a patent, but there must be some invention."

<sup>&</sup>lt;sup>172</sup> Supra note 124 (1867) 37 LJ, Ch 204. Malins V.C. stated that "[t]here is no invention in it. However meritorious as an improvement...it is not the subject of an improvement."

<sup>&</sup>lt;sup>173</sup> (1870) 20 UCCP 29 [*Waterous*].

<sup>&</sup>lt;sup>174</sup> (1887) 13 SCR 469 [*Ball*].

<sup>&</sup>lt;sup>175</sup> Ibid.

<sup>&</sup>lt;sup>176</sup> *Supra* note 127.

The "person having ordinary skill in the art" standard was first recognized by the judiciary in Canada in 1966 in *Burns & Russell of Canada Ltd. v. Day & Campbell Limited*<sup>177</sup> then finally adopted in 1979 in *Hoechst v. Halocarbon (Ontario) Ltd. et al.*<sup>178</sup> The Cripp's standard for non-obviousness finally became part of the Canadian statute in 1993,<sup>179</sup> where its form remains essentially the same today: "The subject-matter defined by a claim in an application for a patent in Canada must be subject-matter that would not have been obvious on the claim date to a person skilled in the art or science to which it pertains...."<sup>180</sup> In this form, the common law of non-obviousness has been the primary source of adjudication for interpreting the newly incorporated statutory provision, expanding to include the four-part test from *Sanofi-Synthelabo* and the three-part obvious-to-try test from *Eli Lilly*, described in Chapter One.

C. A Low Standard of Utility in Early Canadian Patent Law History

Despite the express proviso that a patent be useful in the Canadian patent statute, there was no elaboration of what constituted usefulness, and no quantum of usefulness, consistent with English and American jurisprudence. Borrowing jurisprudence from England, only the slightest amount of commercial or industrial utility was necessary to support a patent.<sup>181</sup> While the patents granted by the English monarchy undoubtedly

<sup>&</sup>lt;sup>177</sup> [1966] Ex Cr 673 at 681-82 [Burns].

<sup>&</sup>lt;sup>178</sup> [1979] 2 SCR 929 at 945 [*Halocarbon*].

<sup>&</sup>lt;sup>179</sup> (1993) c 15 at s 1.

<sup>&</sup>lt;sup>180</sup> *Ibid* at s 28.3.

<sup>&</sup>lt;sup>181</sup> *Philpott v Hanbury* (UK), RPC 1 (1885) 33 at 37 [*Philpott*]. Grove J. said that "the slightest amount of utility – I will not say an infinitesimal scintilla, but a very slight amount of utility – is sufficient to maintain a patent." Canadian cases that followed supporting this view include *Prentice v Dominion Rubber Co Ltd*, [1928] Ex CR 196 (Ex Ct) at 199; *AstraZeneca Canada Inc. v Apotex Inc*, 2017 SCC 36, [2017] 1 SCR 943, 147 CPR (4th) 79 (SCC) at para. 55.

considered utility, it had diminished to a *mere scintilla*<sup>182</sup> by the end of the nineteenth century.

Utility still remains easily satisfied in Canadian patent law. Once the court construes the subject matter of the invention from the patent claims, it then asks if the subject matter is useful. If it is "capable of a practical purpose"<sup>183</sup> or can achieve "an actual result,"<sup>184</sup> utility is achieved. This general standard, combined with significant jurisprudence, means that a *mere scintilla* of utility is all that is required to satisfy the criterion.

III. Operationalizing Patent Law in Canada toward Specific Goals: PharmaceuticalPatent Law in Canada

Following the establishment of the general hallmarks of Canadian patent law in the late 1800's and early 1900's, the Canadian government went beyond simple patent approval processes and began operationalizing patent law policy. This policy was ingrained with the historical importance of working requirements for patents, which supported the idea that patents were a tool for fostering innovation at home. The following section tracks the changes in Canada's pharmaceutical patent laws in the twentieth century with an emphasis on working requirements that were designed to foster innovation in the sector.

<sup>&</sup>lt;sup>182</sup> Ibid, Philpott.

<sup>&</sup>lt;sup>183</sup> AstraZeneca, supra note 29 at para 55.

A. The 1923 Amendment to the Canadian *Patent Act*: the Rising Importance of
Pharmaceutical Patents, Compulsory Licensing, and Conflict with International Patent
Law Treaties

Working requirements for patents were a contentious issue in international patent law negotiations in the early 1900's.<sup>185</sup> At this time, many countries were relaxing working requirements in accordance with the Brussels Revision to the *Paris Treaty*, but England was increasing them in response to the virtual monopolization of the entire chemical industry in the United Kingdom by German chemical companies, leaving England uncompetitive. Not only was Germany dominating the industry, but the use of pharmaceuticals in general was increasing sharply, making the acceleration of the domestic industry a priority. In 1902, feeling the economic pinch from German domination, England amended its *Patents and Designs Act* to allow for the revocation of a nonworking patent if "the patent was not being worked in the United Kingdom," as well as "if…the patent [was] worked…exclusively or *mainly*, outside the United Kingdom."<sup>187</sup>

Beginning in 1903, forfeiture of non-worked patents in Canadian legislation followed England's lead.<sup>188</sup> There was no three-year grace period for the patent holder, nor was there an opportunity for the patent holder to make submissions as to why the patent was not being worked. An entity could petition the Commissioner of Patents for a license to make, construct, use and sell a patented invention, where the Commissioner

<sup>&</sup>lt;sup>185</sup> Marketa Trimble, "Patent Working Requirements: Historical and Comparative Perspectives" (2016) 6 UC Irvine L Rev 483 at 487.

<sup>&</sup>lt;sup>187</sup> Patents, Designs and Trade Marks Act 1902 (UK) 2 Edw VII, c 34 art 3 (amending art §22(5) of the *Patents, Designs, and Trade Marks Act 1883* (UK), 46 &47 Vict c 57. England furthered this domestic push to protect the chemical industry by amending the *Patents and Designs Act* again in 1907 by simplifying the procedure for revoking a non-worked patent. See *Patents and Designs Act 1907* (UK), 7 Edw VII, c 29, s 38A(1).

<sup>&</sup>lt;sup>188</sup> An Act to Amend the Patent Act, SC 1903, 3 Edw VII, s 7.

was satisfied that "the reasonable requirements of the public in reference to the invention have not been satisfied by reason of the neglect or refusal of the patentee."<sup>189</sup> Upon such judgment, the Commissioner could grant the applicant a license on reasonable terms. Such terms kept Canada from becoming a signatory to the *Paris Convention*, which required a three-year grace period for all foreign patents and full respect for foreign patents that were unworked but justified by the inventor, according to the changes in the Brussels revision.

Two significant amendments to the Canadian *Patent Act* <sup>190</sup> were made in 1923 to support the development of the pharmaceutical industry in Canada. The first one prohibited the grant of patents on pharmaceutical molecules but not the processes to derive them, protecting only the chemical techniques that were considered state of the art.<sup>191</sup> With a multitude of techniques for deriving new medicines, the impetus for the change was to encourage work-around processes for developing the same product.

The second restriction provided for very liberal grants of compulsory licenses on patents for food and medicine. It loosened working requirements so that inventions could be imported into Canada and obtain patent protection but allowed for applications for compulsory licenses on food and medicine patents if an applicant could demonstrate that the patented process described in the patent was not being worked sufficiently in

<sup>&</sup>lt;sup>189</sup> *Ibid* at s 7.

<sup>&</sup>lt;sup>190</sup> Patent Act, SC 1923, 13 & 14 Geo V, c 23, s 17(2), [Patent Act (1923)]. United Kingdom amendments to the Patents and Designs Act of 1907, supra note 187, in 1919 were the basis for the Canadian amendments (9 & 10 Geo V, c 8).

<sup>&</sup>lt;sup>191</sup> This was subject to the presumption that in an action for infringement, any substance of the same chemical composition should be deemed to be produced by the same chemical process, unless the infringer could establish that it was not. This proviso ensured that the burden of proof was on the alleged infringer for establishing that the product was not made by infringing on the same patented process held by the patentee.
Canada.<sup>192</sup> In practice, an entity could apply for a compulsory license for an invention used in the production and preparation of food or medicines so long as the active ingredient for the pharmaceutical was manufactured in Canada.<sup>193</sup> The compulsory license was subject to a royalty to be paid to the patent holder, fixed by Canada's Patent Office.<sup>194</sup> There was no grace period, and no need to prove that an abuse of patent rights was taking place.

In 1925, the *Paris Convention* amendment in The Hague established the granting of compulsory licenses as a preliminary condition prior to patent forfeiture for failure to work an invention in the patenting country, thereby giving patent holders *something* in return for unworked patents: "These measures shall not provide for forfeiture of the patent unless the grant of compulsory licenses is insufficient to prevent such abuses."<sup>195</sup> This change in wording lessened the effect of the term "patent abuse," attempting to shift the non-working of a patent outside of what abuse was considered to be and maintain compulsory licenses instead of giving up all rights to a patented invention. The three-year waiting period remained in place. In that same year, Canada became a signatory to the *Paris Convention*, where its allowances for compulsory licensing system were deemed satisfactory for membership, despite its lack of a three-year grace period.

<sup>&</sup>lt;sup>192</sup> Added as an amendment to the 1923 *Patent Act* in 1927. *Supra* note 190, *Patent Act*, SC 1923, c 23, s 17.

<sup>&</sup>lt;sup>193</sup> See Margaret Smith, *Patent Protection for Pharmaceutical Products*, (Ottawa: Library of Parliament, Research Branch, 1993).

<sup>&</sup>lt;sup>194</sup> Milan Chromecek, "The Amended Canadian Patent Act: General Amendments and Pharmaceutical Patents. Compulsory Licensing Provisions," (1987) 11(3) Ford Int LJ 504 at 527-528. The Patent Office affixed a royalty rate of four per cent to the patentee from the compulsory license holder.

<sup>&</sup>lt;sup>195</sup> Paris Convention, supra note 154, art 5A, 1925, [Paris Convention, The Hague Act].

## B. The 1950's: Concerns over High Drug Prices from Monopolies

The 1923 *Patent Act* amendment that allowed for a compulsory license to be granted for a patented chemical process but not the end product was made while the Canadian drug industry was immature, lacking enough sophistication to experiment with and use many known chemical processes. Therefore, the availability of compulsory licensing from the 1920's and onward in Canada did not mean that the provisions were used frequently because creating the medicinal ingredient remained outside of the general levels of competency of the Canadian industry. Of the forty-nine applications for compulsory licenses made between 1935 and 1969, only twenty-two were granted,<sup>196</sup> where most of the others were abandoned due to the difficulty in formulating them.

Between the two World Wars, the development of insulin and penicillin<sup>197</sup> led to a surge in growth in the pharmaceutical industry, changing the way the industry operated. Until this point, the industry was localized, borne out of small pharmacies that developed medicines and supplied them in small quantities. The post-World War Two explosion in pharmaceutical manufacturing led to partnerships and amalgamations that created large scale manufacturing facilities to serve international markets that had common, high-frequency medical problems. Broad spectrum antibiotics, hormones, antihistamines,

<sup>&</sup>lt;sup>196</sup> Maryse Robert, *supra* note 15 at 222, at 222, citing Canada, *Report of the Royal Commission of Inquiry on the Pharmaceutical Industry* (Ottawa: Minister of Supply and Services, 1985) at 14-15 [*Eastman Commission*]. Of the forty-nine applications, twenty-three were withdrawn and four were refused. Also see Donald G McFetridge, "Intellectual Property, Technology, Diffusion, and Growth in the Canadian Economy" in R Anderson and G Gallini eds, *Competition Policy and Intellectual Property Rights in the Knowledge Economy* (Calgary: U of Clgry Press, 1998) 79 at 81.

<sup>&</sup>lt;sup>197</sup> The first large scale development project arose from Frederick Banting's isolation and purification of insulin for treating diabetes at the University of Western Ontario. The second was Alexander Fleming's initial discovery of penicillin moulds and the antibiotic properties within them that led to an international collaboration of several drug companies to make penicillin.

chemotherapy agents, and oral contraceptives rapidly made their way from core research to clinical trials, regulatory approval, production, and distribution during this time.

Questions emerged about the prices consumers were paying for pharmaceuticals as part of a larger ethical concern regarding profits in healthcare, a question contemplated previously but heightened by the rapid expansion of the industry.<sup>198</sup> By the 1950's, social institutions flourished across Europe and North America, focusing on stimulating pharmaceutical research and development in local markets, developing government drug reimbursement programs for citizens, and heightening consumer safety by deepening the regulatory approval process. As such, pharmaceutical firms were perceived as part of this domestic health infrastructure, partly due to their economic imprint on the nation, and partly due to their focus on improving health. Canada wanted to be part of this developing industry.

## C. Revisions to Canadian Patent Legislation in the 1950's

In the 1952 revision of the *Patent Act*,<sup>199</sup> patent laws established in the 1923 reform remained essentially the same. There were still no compulsory licenses granted for end products made by chemical processes, limiting pharmaceutical patents to processes only, meaning that the active ingredient in any pharmaceutical still had to be

<sup>&</sup>lt;sup>198</sup> George Merck, the president of Merck and Company, addressed this question directly in 1950, proclaiming that: "We try never to forget that medicine is for the people. It is not for the profits. The profits follow, and if we have remembered that, they have never failed to appear. The better we remember it, the larger they have been." See James C Collins & Jerry I Porras, *Built to Last* (New York: Harper Business, 1994) at 48. Merck was speaking to the Medical College of Virginia in Richmond, Virginia on December 1, 1950.

<sup>&</sup>lt;sup>199</sup> RSC 1952, c 203 s 41.

manufactured in Canada.<sup>200,201</sup> The allowance for compulsory licensing on

pharmaceuticals still had no minimum initial term for the patent to run. It did, however,

add a provision that allowed the Commissioner of Patents to refuse a compulsory license,

but it was very difficult to meet:

In the case of any patent for an invention intended for or capable of being used for the preparation or production of food or medicine, the Commissioner shall, unless he sees good reason to the contrary, grant to any person applying for the same, a licence limited to the use of the invention for the purposes of the preparation or production of food or medicine but not otherwise; and, in settling the terms of such licence and fixing the amount of royalty or other consideration payable the Commissioner shall have regard to the desirability of making the food or medicine available to the public at the lowest possible price consistent with giving to the inventor due reward for the research leading to the invention.<sup>202,203</sup>

What constituted a "good reason to the contrary" was up to the discretion of the

Commissioner of Patents. Generally, the license would be granted if:

- 1) The applicant has a reasonably permanent organization
- 2) If he is qualified to work the patent
- 3) The Canadian market is not oversupplied with the product, and

 $<sup>^{200}</sup>$  *Ibid* at s 41(1). In the case of inventions relating to substances prepared or produced by chemical processes and intended for food or medicine, the specification shall not include claims for the substance itself, except when prepared or produced by the methods or processes of manufacture particularly described and claimed or by their obvious chemical equivalents.

 $<sup>^{201}</sup>$  The assumption of infringement on a patented process, unless otherwise proven, also remained intact. *Supra* note 199 at s 41(2). In an action for infringement of a patent where the invention relates to the production of a new substance, any substance of the same chemical composition and constitution shall, in the absence of proof to the contrary, be deemed to have been produced by the patented process.

 $<sup>^{202}</sup>$  Supra note 199 at s 41(3). An application for a compulsory license was answered with a statement from the patent holder and the Commissioner of Patents could decide if a hearing would be held to examine the matter.

<sup>&</sup>lt;sup>203</sup> Until 1967, the Commissioner generally granted a royalty of ten to fifteen per cent of the net price of the bulk raw material before it was made into a final dosage form. See Immanuel Goldsmith, "Drugs in Canadian Patent Law" (1967) 13:2 McGill LJ 232 at 241. There was some suggestion in the patent cases that originated during this time that patent holders who pay no royalties to the actual inventor (an assignee is paid instead should not be eligible to receive royalties at all through compulsory licensing. See Goldsmith, above, citing *Parke, Davis & Co v Fine Chemicals of Canada Ltd* [1959] SCR 219; *Hoffman-La Roche v Delmar Chemicals Ltd* [1965] SCR 575, *Hoffmann-La Roche Ltd. v Bell-Craig* (1966) SCR 313.

## 4) The public interest will benefit, or at least not suffer $^{204}$

The provision made it very difficult to stop the grant of a compulsory licence. Opposition by patent-holding drug companies to compulsory license applications revolved around accusing the Canadian compulsory license applicants of being smaller companies without the ability to maintain the strict quality control of the larger importing innovators. These arguments were rejected by the courts, who referred the matter of quality control to the Food and Drugs Directorate of Health Canada. "Good reason to the contrary" was a difficult burden for complainants to meet, establishing a high threshold for restricting the grant of compulsory licenses and furthering the regular issuance of compulsory licenses.

D. Canada's Royal Commissions in the 1950's and 60's Regarding Drug Prices and Compulsory Licensing

Ongoing concerns about innovation, monopoly profits, and altruism's role in healthcare led to several studies in Canada in the 1950's and 1960's that examined the nation's pharmaceutical industry. Comparing drug prices in Canada to other nations, most of the studies concluded that domestic prices were higher.<sup>205</sup> While observing higher than average pricing, investigations about working requirements and compulsory licensing emerged as a main theme of the inquiry into the bargain behind patented medicines.

 <sup>&</sup>lt;sup>204</sup> Frank W Horner Ltd v Sharp & Dohme (Canada) Ltd, (1952) 15 CPR 68, [1951] Carswell Nat 282.
 <sup>205</sup> Canada, Report of the Commission of Inquiry on the Pharmaceutical Industry, (Ottawa: Supply and Services Canada, 1985) at 222 (Chair: Harry C Eastman) [Eastman Commission].

#### 1. The Ilsley Commission

In 1960, the *Ilsley Commission*<sup>206</sup> observed that nearly all Canadian pharmaceutical patents were foreign-owned: ninety per cent in the 1930's and ninety-two to ninety-five per cent in the 1950's.<sup>207</sup> The *Ilsley Commission* recommended that enforcing further working requirements would not be beneficial to Canada since there would be no guarantee that they would be practical enough to be accepted by the patentholders because they did not necessarily fit with the scale of manufacturing required to make medicinal products profitable.<sup>208</sup>

To deal with the high prices of pharmaceuticals, the *Ilsley Commission* made two significant recommendations. It first recommended re-instituting patents over pharmaceutical products themselves<sup>209</sup> and lifting patents on processes to greatly expand pharmaceutical patentability. One chemical process often yielded several compounds that could be separated from one another, researched, and potentially developed for their medicinal properties, creating several avenues for additional research. A process patent could easily stop similar pharmaceutical research pathways by blocking other molecules created by that process if no alternative pathway was found, so removing the patent on the process was expected to generate multiple opportunities. Patenting the end product,

<sup>&</sup>lt;sup>206</sup> Royal Commission on Patents, Copyright and Industrial Designs, Report on Patents of Invention (Ottawa: Queen's Printer, 1960) (Chair: James L Ilsley) [Ilsley Commission]. This commission sat between 1954 and 1960.

<sup>&</sup>lt;sup>207</sup> *Ibid* at 13, citing Edith Penrose, *The Economics of the International Patent System* (Baltimore: Johns Hopkins Press, 1951) at 111 (footnote).

<sup>&</sup>lt;sup>208</sup> "We see no merit in attempting a bias in our legislation to direct investment by the working of new inventions. Rather we believe that the public interest will best be served if investment finds its way into the most productive fields available rather than being artificially diverted into exploitation of new inventions when the value of the enterprise to the economy is doubtful." Statement of Mr. George Laidlaw, *Ilsley Commission* member, in APLA Bulletin, 1971 at 68.

<sup>&</sup>lt;sup>209</sup> Recall, as of the revised 1952 *Patent Act*, that patents existed for chemical processes that derived pharmaceuticals, but not the products themselves. This was reversed in 1987. See *Patent Act*, RSC 1970, c P-4, as amended by Bill C-22 (1987) RSC 1985 c33; 33d Parl 2d sess 35 & 36 Eliz II.

however, meant that multiple molecules could still be derived and patented from that same process. If the patent holder was not using those compounds, then a "wall" or "patent thicket" was essentially being placed around those compounds, with no ability to research, manufacture, and commercialize them. Despite instituting this change to patenting compounds and not processes, any interested party could still apply for a compulsory license for any of the substances produced through that process, reducing the problem with over-patenting end products.

The recommended change from patenting processes to final products was augmented by the second recommendation, which was to retain compulsory licensing provisions and make them more accessible by modifying Section 41(3) of the *Patent Act*. Seeing that the Commissioner of Patents would grant a compulsory license "...unless it appears there are good reasons for refusing the application,"<sup>210,211</sup> the recommendation was to negate spurious reasons about quality provided by the patent holders to not issue the compulsory license. Applying the *Ilsley Commission* recommendation, a compulsory license could only be withheld if proof of misuse of the patent existed. This reduced the strength of patent protection, as it was much harder to establish actual "misuse" by a compulsory license holder and not just *potential* misuse. These recommendations would afford the Commissioner of Patents less discretion to refuse a compulsory license.

<sup>210</sup> Canada, House of Commons, *Special Committee on Drug Costs and Prices, Second Report of the Special Committee of the House of Commons on Drug Costs and Prices* (Ottawa: Queen's Printer, 1967) at 65 (Chair: Harley Cruickshank) [Harley Committee]. The *Ilsley Commission* recommendation for lessening restrictions on compulsory licensing was adopted by the Harley Committee.

<sup>&</sup>lt;sup>211</sup> This has been the position in England since 1949; see *Patents Act 1949* (UK), 12, 13 & 14 Geo VI, c 87), s 41.

#### 2. Commissions after the Ilsley Commission

Other commissions followed that supported the continued use of compulsory licenses to bolster the pharmaceutical industry in Canada and reduce drug costs to consumers. The *Restrictive Trade Practices* Commission<sup>212</sup>of 1963 reported that compulsory licensing was underutilized because ninety-five per cent of the drug patents were owned by foreign multinational corporations<sup>213</sup> which had production subsidiaries supplying Canada's generic market, making their pricing not reflective of the true cost savings and employment opportunities that could be achieved through a domestic generic pharmaceutical industry. The *Restrictive Trade Practices Commission* took a strong position of recommending the complete abolition of pharmaceutical patents because the payment of licensing fees associated with compulsory licenses would not go far enough in decreasing drug prices.

The *Hall Report*<sup>214</sup> was a federal health commission with a wide mandate for examining the comprehensive health care needs of Canadians and the resources for achieving those needs. As one of several components, the *Hall Report* addressed high drug costs by confirming the *Restrictive Trade Practices Commission's* conclusion that only a small number of Canadian pharmaceutical patents were actually held by Canadian firms and recommended expanding compulsory licensing to include drugs that required

<sup>&</sup>lt;sup>212</sup> Canada, Department of Justice, Restrictive Trade Practices Commission, *Report Concerning the Manufacture, Distribution, and Sale of Drugs* (Ottawa: Queen's Printer, 1963) at 516-524.

<sup>&</sup>lt;sup>213</sup> Canada, House of Commons, Standing Committee on Health, "A Brief History of Drug Patenting" by Ronald Lang (21 Oct 2003) at 2.

<sup>&</sup>lt;sup>214</sup> Canada, Royal Commission on Health Services, *Report of the Royal Commission on Health Services* (Ottawa: Queen's Printer, 1964) vol 1 at 701 – 709 (Chair: Robert Hall) [Hall Report]. The Commission's period of operation was from 1961 to 1964.

the active ingredient to be imported, a practical consideration of the state of the Canadian industry and its ability to actually manufacture raw active ingredients.<sup>215</sup>

The *Harley Committee*<sup>216</sup> was an interdepartmental committee tasked with examining patents, justice, and health and welfare. It concluded that drug prices in Canada were seventy-five per cent higher than other developed nations because most of the active ingredients had to be imported. Supporting the *Hall Report*, the *Harley Committee* recommended compulsory licensing for drugs where the active ingredient was imported.

E. 1969 *Patent Act* Revisions: Compulsory Licenses to Import and the Development of the Generic Drug Industry

Following the conclusions of the *Hall Report* and the *Harley Committee*, Bill C-102 in 1969 amended Section 41 of the *Patent Act* to widen compulsory licenses to cover medicines with imported active ingredients. The law's purpose was to create a generic drug industry that would increase competition in the marketplace and lower drug prices while stimulating investment and employment in Canada.<sup>217</sup> This was a marked change – before the passage of the bill, compulsory licenses were only allowed if the active ingredient was manufactured in Canada, which was too restrictive to allow the drug industry to develop. Over the following decade, the relaxed restrictions led to an

<sup>&</sup>lt;sup>215</sup> The *Hall Report* also recommended streamlining compulsory licensing procedures and standard royalties to facilitate more compulsory licensing applications and implement a sense of fairness for all patent holders. *Ibid*, Recommendation 69 at 43.

<sup>&</sup>lt;sup>216</sup> Harley Committee, supra note 210.

<sup>&</sup>lt;sup>217</sup> The new statute required the Commissioner of Patents to issue compulsory licenses when requested unless very significant reasons to not do so existed. The royalty rate payable to the patent holder was fixed at four per cent of the net selling price of the drug.

explosion of new generic pharmaceuticals in Canada,<sup>218</sup> fostering the development of a Canadian-owned and based generic drug industry and the growth of affordable provincial drug assistance programs for seniors and disadvantaged members of society.

Weighing concerns about the still-languishing innovative sector of the Canadian pharmaceutical industry against a rapidly accelerating generic industry, the 1984 *Eastman Commission*<sup>219</sup> recommended giving completely Canadian-developed drugs (with absolute novelty, not generic copies of other drugs) *full* patent protection, meaning they would have market exclusivity for the full patent term with monopoly pricing. The *Eastman Commission* also recommended a four-year market exclusivity period for new, innovative medicines imported to Canada from out-of-country manufacturers and an increase in the royalty rate payment from four to fourteen per cent for compulsory licenses for Canadian-made pharmaceuticals with imported medicinal ingredients.<sup>220</sup>

## F. Market Exclusivity for Innovative Drug Manufacturers in 1987 Revisions

In 1987, the Canadian government passed Bill C-22 in an attempt to address the national economic and social aspects of the pharmaceutical industry, while strengthening intellectual property laws to bring them closer to conformity with international practices. The goal was to transform Canada's pharmaceutical industry into a world-class *innovative* industry, with an unprecedented increase in investment and jobs while

<sup>&</sup>lt;sup>218</sup> Between 1969 and 1992, 1030 applications for compulsory licenses with imported active ingredients were made and six-hundred and thirteen were granted. See McFetridge, *supra* note 196.

<sup>&</sup>lt;sup>219</sup> Report of the Commission of Inquiry on the Pharmaceutical Industry [*Eastman Commission*], *supra* note 205.

<sup>&</sup>lt;sup>220</sup> *Eastman Commission, supra* note 205 at 63. The *Eastman Commission* also recommended the creation of a pharmaceutical royalty fund to be funded "by payments made by firms holding compulsory licences, the payments to be determined by the value licensee's sales of compulsory licensed products in Canada multiplied by the pharmaceutical industry's world-wide ratio of research and development to sales…plus 4 per cent." The pharmaceutical royalty fund recommendation was never implemented.

preserving the growth in the generic sector of the pharmaceutical industry. The bill also intended to ensure that fair prices on drugs remained by creating a quasi-governmental body that would oversee drug prices.

To accomplish these goals, the bill took the *Eastman Commission's* recommendations further by extending market exclusivity for an innovative out-ofcountry drug to ten years before a compulsory license could be granted for a generic Canadian copy with an imported medicinal ingredient (as opposed to the four years recommended by the commission).<sup>221</sup> The exclusive period was reduced to seven years before compulsory licensing if the medicinal ingredient for the generic copy was developed in Canada. In an attempt to foster the development of active ingredients in Canada, the deeper, core-science that drives the development of new drugs, a full twenty years of patent protection, with no issuing of compulsory licenses, would be granted to those drugs fully researched and produced in Canada. Three tiers to patent protection were created, where full intellectual property protection was only given to innovative pharmaceuticals completely developed within Canada.

In return for the increased patent protection, the *Pharmaceutical Manufacturers Association of Canada* pledged to increase its spending on research and development in Canada to ten per cent of its total sales. The *Patented Medicines Prices Review Board*, established in Bill C-22, was charged to monitor and review the promised level of spending.<sup>222</sup> The *Patented Medicines Prices Review Board* was also charged with

<sup>&</sup>lt;sup>221</sup> This was partly due to lobbying by the Pharmaceutical Manufacturers Association of Canada, an association of innovative drug companies, either multinational or from individual countries, whose goal is to promote the interests of brand name drug manufacturers in Canada.

<sup>&</sup>lt;sup>222</sup> The Pharmaceutical Manufacturers Association of Canada has met or exceeded the promised spending goals in the past but updated work on the value of that spending needs to be completed. See Maryse Robert, *supra* note 15 at 224.

regulating and monitoring the price of drugs, making Canada the first nation to regulate its drug prices through its patent legislation.<sup>223</sup>

IV. Exporting the Protection and Enforcement of Patent Law Globally

The changes in Bill C-22 reflected an initial move toward harmonizing Canada's intellectual property laws with its major trading partners; doing so would allow Canada to complete free trade agreements with its major trading partner, the United States, as well as other nations. The free trade agreement between Canada and the United States,<sup>224</sup> the first free trade agreement signed by Canada, did not include any provisions on intellectual property, so the provisions in Bill C-22, although imposing a market exclusivity period, still provided for compulsory licensing that was much broader than the narrow emergency compulsory licensing provisions in place in the United States.

By 1990, Canada was negotiating a more extensive free trade agreement with the United States and Mexico. Simultaneously, Canada was negotiating for membership in the World Trade Organization, which required agreeing to new international standards of trade protection like significant levels of patent protection and equal patent treatment for all of the signatory nations. Canada's compulsory licensing rules were inconsistent with membership in both of the agreements, where most of the signatories already had or were developing much more stringent patent protection. By 1991, for example, Mexico had fully modernized its intellectual property laws, providing patent protection for a full

<sup>&</sup>lt;sup>223</sup> The establishment and functions of the Patented Medicines Prices Review Board is set forth in Canada's *Patent Act, supra* note 22 at s 79–103.

<sup>&</sup>lt;sup>224</sup> Free Trade Agreement between Canada and the United States of America, 2 Jan 1988 (entered into force 1 Jan 1989) [Canada-United States Free Trade Agreement]. Implemented in Canada in Canada-United States Free Trade Agreement Implementation Act, SC 1988, c 65. Foreign Affairs, Trade & Development Canada.

twenty years from patent filing, as well as further protection for products going through the regulatory processes.<sup>225</sup>

Canada's *1991 Pharmaceutical Review*<sup>226</sup> concluded that its 1987 Bill C-22 was strengthening patent protection for pharmaceuticals but was not sufficiently attracting additional investment in the industry:

Competing economies (U.S., France, Italy and Japan) have implemented or are actively considering the implementation of legislation to provide increased periods of market exclusivity for drug products in response to concerns about the erosion of effective patent protection due to lengthy R&D and regulatory approval periods.<sup>227</sup>

Countries were using *more stringent* patent regimes to attract investment to their jurisdictions to conduct pharmaceutical research and development instead of reducing patent protection and trying to grow the industry organically like Canada. The Review concluded that competitive patent protection would be a necessary condition for further foreign direct investment in the innovative pharmaceutical sector, but it would not necessarily guarantee that such investment would take place.

The concern of the United States with its large, advanced pharmaceutical industry over Canada's compulsory licensing provisions extended beyond Canada's position in isolation. Developing countries viewed Canada's model as a reason to justify implementation of similar licensing provisions into their own laws for developing

<sup>&</sup>lt;sup>225</sup> This is known as pipeline protection. In 1991, President Gerald Mossinghoff of the Pharmaceutical Manufacturers Association of Canada used Mexico as an example to show how Canada's compulsory licensing regime weakened its intellectual property laws far below the standard of a developed nation. He also pointed to Korea and Eastern European countries as examples of stricter patent protection. See Maryse Robert, *supra* note 15 at 237-8.

<sup>&</sup>lt;sup>226</sup> Intellectual Property Research Branch, Department of Consumer and Corporate Affairs, Interdepartmental Working Group, by Ross Duncan & Dave Blaker, *Trends in the Pharmaceutical Industry in Canada in the Post-1987 Environment* (Ottawa: Queen's Printer, 1991).

<sup>&</sup>lt;sup>227</sup> *Ibid* at 52.

industries and controlling prices,<sup>228</sup> so quashing Canada's compulsory licensing would have a significant influence on other nations. Quoting the same reasons, the *1991* 

*Pharmaceutical Review* stated that:

The pressure in the GATT and *NAFTA* negotiations to remove the compulsory licensing provisions from our *Patent Act* is coming from many countries. The demand is based on both economics and politics. These countries see Canada's current intellectual property regime as a threat to their economic prosperity in that many developing countries are considering Canada's system for themselves. Obviously, this would provide a lower cap on the revenues of pharmaceutical companies than would be the case if compulsory licensing were completely eliminated.<sup>229</sup>

Therefore, Canada's position was viewed by the nations with developed drug

industries<sup>230</sup> as precarious, either leading to larger, worldwide preservation of patent

rights or the depletion of them.

# A. The North American Free Trade Agreement<sup>231</sup>

Despite initially maintaining compulsory licensing provisions for

pharmaceuticals,<sup>232</sup> Canada relinquished them during the North American Free Trade

<sup>&</sup>lt;sup>228</sup> Maryse Robert, *supra* note 15 at 238.

<sup>&</sup>lt;sup>229</sup> Supra note 226 at 60.

<sup>&</sup>lt;sup>230</sup> The countries with concerns over Canada's compulsory licensing provisions included the United States and Germany. See Maryse Robert, *supra* note 15.

<sup>&</sup>lt;sup>231</sup> NAFTA, supra note 13. North American Free Trade Agreement Between the Government of Canada, the Government of Mexico and the Government of the United States, 17 December 1992, Can TS 1994 No 2 (entered into force 1 January 1994); 32 ILM 289 [NAFTA]. Updated intellectual property provisions are contained in Chapter 20 of the new Canada–United States–Mexico Canada, United States and Mexico Agreement, 30 Nov 2018, Can TS 2020 No 5(revised 10 December 2019, entered into force 1 July 2020) [CUSMA].

<sup>&</sup>lt;sup>232</sup> Maryse Robert, *supra* note 15 at 208.

Agreement negotiations and endorsed full patent protection<sup>233</sup> in suit with patent laws in place in the United States and Mexico.

1. Equal Treatment of Patents, both Foreign and Domestic

Through Article 1701, all *NAFTA* parties were required to adhere to the substantive provisions of *the Paris Convention* of 1967,<sup>234</sup> which set the general language for the remaining *NAFTA* provisions. Equal national treatment of patents had to be afforded to all parties, meaning that patent protection had to be the same, whether inventions were created in foreign jurisdictions or the home country,<sup>235</sup> providing guarantees for corporations and their investors.<sup>236</sup> And enforcement provisions were in place as well, where parties could obtain compensation for infringed rights under the intellectual property chapter.<sup>237</sup>

2. Extremely Limited Use of Compulsory Licensing

Because the United States still had a limited form of compulsory licensing, where the government could absolve an entity from patent infringement so long as that entity sells the product to the government or lets the government use it, a compulsory licensing provision remained in the *NAFTA* text. A compulsory license could only be granted in

<sup>&</sup>lt;sup>233</sup> Arthur Dunkel was the Director General of the General Agreement on Tariffs and Trade [*GATT*]. He drafted a text for full patent protection that was used in *NAFTA* and the *Trade-Related Aspects of Intellectual Property Agreement (TRIPS Agreement)*, as part of the Uruguay Round of the General agreement on Tariffs and Trade.

 <sup>&</sup>lt;sup>234</sup> Paris Convention for the Protection of Industrial Property of March 20, 1883, as revised at Stockholm,
 July 14, 1967, (Geneva: United International Bureaux for the Protection of Intellectual Property (BIRPI),
 1968) [Paris Convention, Stockholm Act].

<sup>&</sup>lt;sup>235</sup> Equal treatment across parties also meant that a priority system for filing patents had to be established for assessing novelty. Priority was based on the first application received in any of countries, and subsequently applied to applications in other member states.

<sup>&</sup>lt;sup>236</sup> *NAFTA*, *supra* note 13 art 1703. Article 1703 specified that "Nationals of another party will not be discriminated against with respect to protection and enforcement of all the intellectual property rights that a party accords to its own nationals."

<sup>&</sup>lt;sup>237</sup> NAFTA, supra note 13 at art 1714-1718.

limited circumstances where a failure to work an invention in any party's jurisdiction had taken place during a rare instance of national emergency.<sup>238</sup>

#### 3. Canada-United States-Mexico Agreement updates Patent Terms

The new *Canada-United States-Mexico Agreement* replaced the *North American Free Trade Agreement* in July 2020. A notable addition was an adjustment to patent term for unreasonable delays in granting a patent, where greater than five years from the date of filing or three years from the date for a request for examination constitutes an unreasonable delay.<sup>239</sup>

When copying innovative drugs after patent expiry, generic companies rely on the safety and efficacy data of the original manufacturer for their own abbreviated submissions for approval. Section 20.48 creates a data exclusivity period for any new pharmaceutical product of five years following marketing approval. By denying the use of safety and efficacy data for five years following marketing approval, innovative pharmaceutical companies are guaranteed a minimum monopoly marketing period

<sup>&</sup>lt;sup>238</sup> *NAFTA*, *supra* note 13 at 241. Article 1709(6) stated that only "limited exceptions to the exclusive rights conferred by patents provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of other persons." Article 1709(10) expanded upon the conditions where compulsory licensing, as an "exception to the exclusive rights conferred by patents," can be issued. They could not be arranged as a blanket provision, such that a compulsory license could be granted by an established, routine process. Rather, it could only take place on a case-by-case basis, where an applicant cannot obtain reasonable commercial terms with the rights holder to exploit the patent in the country of origin of the patent. Even so, the compulsory license granted can only be used for domestic production, providing reasonable compensation to the rights holder. Since Section 1709(10) allowed for compulsory licensing in cases of national emergency or extreme urgency, the rights only exist insofar as the conditions exist for their operation. If conditions requiring the compulsory license change, and the rights holder chooses to execute their rights in the party country, then the compulsory license no longer needs to be in place, and such conditions for the compulsory license would need to be reviewed by an appropriate legal authority.

<sup>&</sup>lt;sup>239</sup> Canada, United States and Mexico Agreement, 30 Nov 2018, Can TS 2020 No 5(revised 10 December 2019, entered into force 1 July 2020) art 20.44 [CUSMA].

because generic companies will have to wait to obtain data for filing their own abbreviated new drug submissions.

4. Flexibility with Substantive Patent Criteria but no Discrimination

The *Paris Convention* allowed individual signatory countries to have latitude to grant patents based on the development of their own substantive patent criteria (novelty, inventiveness, and utility), providing only broad guidelines for their interpretation. Extending beyond the *Paris Convention*, *NAFTA* Article 1709(7) specified that "... patents shall be available and patent rights enjoyable without discrimination as to the field of technology, the territory of the Party where the invention was made and whether products are imported or locally produced."<sup>240</sup> Patents had to be available, regardless of the industry in question, with the only exclusions being for the maintenance of public order or morality. The non-discrimination clause in Article 1709(7) did not explicitly say that there could not be any compulsory licensing, but it specified that it must not be industry specific. In other words, it could not be geared toward pharmaceuticals.<sup>241</sup>

#### B. Agreement on Trade Related Aspects of Intellectual Property Rights

The Agreement on Trade-Related Aspects of Intellectual Property Rights<sup>242</sup> is a comprehensive multilateral intellectual property rights agreement which requires domestic laws of signatory countries to meet minimum standards related to all aspects of

<sup>&</sup>lt;sup>240</sup> *NAFTA*, *supra* note 13 at art 1709(7).

<sup>&</sup>lt;sup>241</sup> Patents also had to be available to protect both products and processes, where Canada's patent laws were already compliant.

<sup>&</sup>lt;sup>242</sup> Marrakesh Agreement Establishing the World Trade Organization, 15 Apr 1994, 1867 UNTS 154; 33 ILM 1144 [Marrakesh Agreement]. The Marrakesh Agreement was the final round of negotiations of *GATT 1947*, which established the World Trade Organization (WTO) as the international forum for negotiating agreements, reducing trade obstacles, and settling trade disputes. Recall that the *TRIPS Agreement* was negotiated as part of the Uruguay Round of the World Trade Organization's General Agreement on Tariffs and Trade, which took place between 1986 and 1994. *TRIPS* is contained in Annex 1C, *supra* note 14.

intellectual property.<sup>243</sup> Canada signed the *TRIPS Agreement* in 1994 and implemented it at the beginning of 1995. Ratification of *TRIPS* was a prerequisite to World Trade Organization membership,<sup>244</sup> meaning that all one-hundred and fifty-three World Trade Organization member states have ratified the agreement.<sup>245</sup>

The text compiled during the Uruguay Round of the *GATT Agreement* became the draft agreement for both *TRIPS* and *NAFTA*, where the main provisions were for full patent term protection (not just pharmaceuticals, but all inventions), non-discrimination by member states based on field of technology or location of the original invention, and allowances for data exclusivity.<sup>246</sup> The text of both documents with respect to patents is essentially the same.

# V. Conclusions on Canada's Abolition of Compulsory Licensing

Canada's eagerness to participate in free trade across its major trading partners led to a relinquishment of its compulsory licensing provisions in the 1990's, which were its last vestiges of working requirements. The trade off for this concession was the hope that it would lead to an improved investment climate and increased research and development of pharmaceuticals in Canada.

New provisions that reflected Canada's commitments to both *NAFTA* and *TRIPS* were made to the *Patent Act* in 1993 through Bill C-91. The compulsory licensing provisions were mostly dropped, retaining rare exceptions for situations where reasonable

<sup>243</sup> *TRIPS, supra* note 14, Part I & II. This included patents, trademarks, copyright, industrial design, geographical indicators, plant variety protection, integrated circuit protection, trade secrets, and test data.
 <sup>244</sup> *TRIPS, supra* note 14, art XXXIV. This article states that the annexes to *GATT 1947* are an integral part of the agreement. As discussed, *TRIPS* is contained in Annex 1C of GATT.

<sup>&</sup>lt;sup>245</sup> TRIPS continues to be administered by the World Trade Organization.

<sup>&</sup>lt;sup>246</sup> As discussed, the emerging international consensus for these provisions had already led to the abolition of compulsory licensing in Canadian patent legislation as part of its *NAFTA* commitments.

commercial terms for a patent could not be negotiated, and the patent remained unworked in emergency situations. Such exceptions could only be made on a case-by-case basis, and any such grant could only be used for domestic manufacture and use. The full length of a patent term was to be otherwise respected, set at twenty years from the date of filing, or seventeen years from the date of grant of the patent.

Killing compulsory licensing also meant that Canada was no longer discriminating on the basis of field of technology, a key concept in its free trade commitments. Not only was discrimination by field of technology barred, but discrimination was not allowed between patents developed in the home country, or patents developed abroad and imported. With the removal of compulsory licenses, the longstanding policy for controlling drug prices for Canadians meant shifting additional oversight to the *Patented Medicines Prices Review Board*.<sup>247,248</sup>

Participating in international free trade agreements was the dominating policy concern for the federal government in the early 1990's, but it was reluctant to relinquish

<sup>&</sup>lt;sup>247</sup> The Board was given the power to decrease drug prices and institute fines for noncompliance. Price control was undertaken with two instruments. Introductory prices were assessed to ensure that they were not too high by looking at their therapeutic value. Drugs that were characterized as breakthrough treatments were allowed the highest prices. "Me too" drugs, or drugs that were similar to the breakthrough drug, and only added incremental benefit to the breakthrough drug, were priced lower. Drugs that were simply reformulations of existing drugs, with new therapeutic uses, were allowed the lowest introductory prices. Prices were also examined according to the Board's previous criteria, which included comparing the price in Canada to the prices in other developed countries, the cost of making and marketing the medicine, predicting the quantity of sales expected in Canada, comparing the price of alternative medicines available in Canada, and scrutinizing the amount of research and development funds spent by the patent holder in Canada to bring the drug to market. The second instrument was monitoring the price of innovative drugs after their introduction into the Canadian market, in six-month intervals, and compare any price increases to the consumer price index, which essentially capped price increases on innovative drugs to an inflation-adjusted index. Despite the lack of compulsory licensing brought on by NAFTA, Canada was still finding a way to indirectly modify patent protection to control drug prices for consumers. <sup>248</sup> Following the passage of Bill C-91, the Pharmaceutical Manufacturers Association of Canada increased its investment commitments in Canada. It promised a ten per cent ratio of research and development to

its investment commitments in Canada. It promised a ten per cent ratio of research and development to sales, with new investments of over four hundred million dollars by the end of 1996. It also made promises to broaden the reach of its clinical research across Canada.

its compulsory licensing provisions when it entered negotiations.<sup>249</sup> With significant global restructuring and rationalization in manufacturing and research in the pharmaceutical industry, Canada wanted to attract foreign investment in the pharmaceutical industry, but its broad use of compulsory licensing created discrimination in the pharmaceutical field in relation to other fields of technology, which countries with advanced pharmaceutical industries were dead-set against. Stripping away routine compulsory licensing, the key change for this period, hinged on the hopes that strengthening patent protection would lead to further research and development in the pharmaceutical industry in Canada, despite the warning in the *1991 Pharmaceutical Review* that it was not a guarantee.

#### VI. Doha Declaration and Canada's Access to Medicines Regime (CAMR)

The Doha *Declaration on the TRIPS Agreement and Public Health*<sup>250</sup> was adopted by the World Trade Organization Ministerial Conference in Doha on November 14, 2001 to address public health problems afflicting member countries. Article 31 of the *TRIPS Agreement* permitted compulsory licenses for use in domestic markets in cases where reasonable commercial terms of the patent holder could not be reached or in cases of extreme emergency. But countries with insufficient manufacturing capabilities in the pharmaceutical sector could face difficulties making effective use of Article 31. The new Article 31bis from the *Doha Declaration* creates an exception for pharmaceuticals, permitting the use of compulsory licensing provisions for producing and exporting low-

<sup>&</sup>lt;sup>249</sup> Milton Freudenheim, "Canadians See Rise in Drug Costs," *New York Times*, 16 Nov 1992 D1.
<sup>250</sup> World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 ILM 746 (2002) [*Doha Declaration*].

cost generic medicines to countries in need that cannot manufacture those products themselves. Twenty-three member nations registered for participating with Article 31bis provisions and are permitted to import generic copies of patent protected medicines from other member nations in order to fulfill the medicinal needs of their populations only (and not for export).

Canada's *Patent Act* was amended in 2005 with the *CAMR* provisions,<sup>251</sup> facilitating the issuance of compulsory licenses to Canadian pharmaceutical companies for the manufacture and distribution of generic copies of patented medicines to the twenty-three World Trade Organization member nations as well as other nations for humanitarian purposes. The generic medicines are still subject to the usual regulatory approval process for medicines in Canada.

#### VII. COVID-19 Emergency Response Act Overrides Patents

In 2020, the *Patent Act* was amended in response to the COVID-19 pandemic. Section 19.4 permitted the authorization of the "Government of Canada and any person specified in the application to make, construct, use and sell a patented invention to the extent necessary to respond to the public health emergency described in the application."<sup>252</sup> Licenses would be granted for only one year, with remuneration given to the patent holder. While one year is a short time frame for developing and bringing a vaccine, antiviral, or other pharmaceutical to market,<sup>253</sup> the provision does recognize that

<sup>&</sup>lt;sup>251</sup> Canada Patent Act, supra note 22 at 21.01 to 21.2.

<sup>&</sup>lt;sup>252</sup> Canada Patent Act, supra note 22 at 19.4.

<sup>&</sup>lt;sup>253</sup> Jeremy de Beer and Richard E. Gold, "International Trade, Intellectual Property, and Innovation Policy: Lessons from a Pandemic" in Colleen Flood et al, eds, *Vulnerable: The Law, Policy and Ethics of COVID-19* (Ottawa: U Ottawa Press, 2020) 579.

the extremely high utility of some innovations means that the patent system has to be overridden to bring the technology to society as soon as possible.

VIII. An Analysis of Canada's Pharmaceutical Patent Law within a Modified Lockean Theory of Patent Law

In Chapter Five, the analysis of pre- and post-*Statute of Monopolies* patent law within a modified Lockean theory revealed a distinction between patent law forms, where the former was linked to a strong form of patent law gained from more certain expectations and the latter was a weak form with no expectations regarding the outcome from any given patent. The distinction in the law was not only brought about by the general restrictions on monopolies in the *Statute of Monopolies* but by patent law jurisprudence that gave little consideration to utility, the individualization of patent terms, or working requirements. It did not have to give much consideration to utility or the fulfillment of promises associated with a patent because they were not part of the statute, the monarchy's power to impose such conditions had been relinquished, and international pressure was curtailing customary patent working requirements.

Canada's modern pharmaceutical patent law history is characterized by the decline of working requirements, the development of the non-obviousness standard of inventiveness, a constant low bar for utility, and the institution and extinguishment of compulsory licensing, which will be considered within the same theoretical context as the analysis in Chapter Five. The finiteness of inventors and invention, the accumulation of knowledge, patent surpluses, a transplanted enough and as good condition, Nozickian compensation, and an expectations model will be applied to pharmaceutical patent law during this period.

A. Finiteness in Inventing and Inventors was Understood but Relinquished as a Concern

Canada's early patent laws maintained statutory working requirements during the late nineteenth century for non-residents wishing to patent an invention in Canada, ensuring that a Lockean bargain was met. If patents were not worked locally, they were not enforced. This early on-the-ground requirement reflected the finiteness of inventors, where the development of technology was limited to those who could develop and employ it, suggesting that the employment of the inventor alongside the technology becomes essential for its transference to others; without them, the rights cease to exist so that others might be enticed to develop the invention locally. As a new nation, Canada was paying less heed to rights of inventors in order to make technological gains, and therefore utility gains, for its citizens in a less populated, primarily agrarian society.

As working requirements diminished through the changes in the *Paris Convention*, Canada's desire to commit to the Convention meant relinquishing those requirements. Canada tried to remain committed to a patent bargain by reshaping working requirements into compulsory licensing for pharmaceutical patents – unworked pharmaceutical patents in Canada were not enforced because the inventor was not present to make use of the information for Canadians, reinforcing the notion that technological information is not infinite in its application and uptake by society, but is bounded by what society's pre-existing knowledge set can apply through a limited number of inventors.

Compulsory licensing represented a shift in the opportunity cost to the inventor, raising the stakes for any inventor who chose not to work the patent in Canada. It simultaneously created an opportunity cost for Canadian inventors as well since the terms

for pharmaceutical patents through compulsory licensing made choosing pharmaceutical research a more favorable option over other industries. Canada extended compulsory licensing for pharmaceuticals specifically – an area it wished to develop internally for the sake of its own residents' welfare. Compulsory licensing recognized the finiteness in invention by creating this special privilege in one industry, trying to direct inventive resources toward its highest priorities.

Canada's Access to Medicines Regime recognizes the same finiteness of inventors and the practical issues of research and production capability that come with that limitation. The regime extends Canada's know-how to other nations by overstepping patent laws, thereby creating an opportunity to achieve a *partial* bargain. Although it provides *access* to medicines, it still does not achieve the full Lockean bargain, which involves accruing the know-how involved with researching, developing, and producing medicines. But the *Doha Declaration* and *CAMR* both exist as exceptions to the laws around patent rather than being embedded *within a patent theory*. The new expectations theory recognizes the limitations of other parties to patent agreements directly, and the bargain adjusts accordingly, meaning that a theory that allows for adjustments to patent terms is more applicable to modern times.

B. The Accumulation of Pharmaceutical Knowledge in Canada was Recognized and Important in Earlier Times

Canada's use of compulsory licensing aligned with its desire to grow a sophisticated domestic pharmaceutical industry but was indicative of its lack of knowledge for being able to do so. With insufficient accumulated knowledge for developing innovative pharmaceuticals, compulsory licensing would allow Canadian

researchers to examine the patent specification and try to work backward to attain a working knowledge of the technology. Despite the opportunity, Canada was still unable to replicate many new pharmaceutical innovations in the early years, given its lack of industrial knowledge, as evidenced by its very infrequent use of the provisions before the law changed in 1969 to include pharmaceuticals with imported active ingredients.

C. Canada tried to Create a Societal Surplus using Compulsory Licensing for Pharmaceuticals

As working requirements lessened in the twentieth century, the expectation of getting something back from pharmaceutical patents beyond disclosure was growing thin. Canada's institution of compulsory licensing was indicative of an insufficient Lockean surplus of "pharmaceutical knowledge" in Canada, and therefore insufficient reinvestment of that knowledge back into society. At best, Canada tried to create a "societal surplus from pharmaceutical knowledge" by adding and amending its compulsory licensing laws, where true pharmaceutical inventors who did not willingly give Canada a surplus by working their pharmaceutical patents locally could have their patented information utilized by others in exchange for a royalty.<sup>254</sup> How much of that surplus Canada demanded was expressed in varying terms; initially, compulsory licenses were only granted to an inventor who completely copied and developed a patented medicine within Canada, but the provision became variable through Bill C-22, which took into account the amount of the working of the patent in Canada and the extent of the development of any given medicine in Canada. More innovation within Canada deserved

<sup>&</sup>lt;sup>254</sup> Refer to Canada's changes in compulsory licensing laws and its various commissions in this chapter for an understanding of how they shaped a general national policy for trying to grow the pharmaceutical industry in Canada.

more protection because the surplus value *to* Canada was expected to be larger, as expressed in Bill C-22. Bill C-22 represented a *decided purpose* for pharmaceutical patents in Canada that extended beyond the pure protection of an inventor's right to his invention; rather, it shifted the balance between that right and society's need to be rewarded. Through its commissions and its legislation (including the variable measures in Bill C-22), Canada deliberately decided to become a world leader in pharmaceutical innovation, creating higher intellectual-capital jobs while simultaneously lowering drug costs to Canadians using the surplus embedded in patent to capture it. Therefore, Canada's actions to achieve patent surplus were indicative that patent holders were insufficiently *voluntarily* contributing surpluses, and intervention was necessary to propagate the surplus knowledge cycle. Even contemporary times indicate a lack of surplus transfer to less wealthy nations, where Canada is stepping in with *CAMR* to try to establish a bargain for those nations with insufficient resources for capitalizing on pharmaceutical patents.

D. A Transplanted Enough and As Good Condition under Canada's Compulsory Licensing Laws Reveals Inadequate Knowledge for Utilizing Pharmaceutical Patents

Transplanting the enough and as good condition into formed society facilitates an examination of what "enough" and "as good" meant in the context of Canada's pharmaceutical compulsory licensing laws. Where the enough and as good condition meant that "enough" pharmaceutical knowledge property was provided to the society for using the information in research and development and that the knowledges is in "as good" of hands as the inventor when it is transferred to society, Canada's early pharmaceutical patents granted to foreigners did not meet either aspect of the condition.

Where very few active medicinal ingredients could be copied and manufactured domestically, there was not enough information present in the patents to do so, meaning that sufficient *previous* knowledge had not accumulated in society "enough." With insufficient information present, there was no way for the information in these foreign patents to be as good or as useful to Canadian society as they were for their foreign inventors. Since compulsory licensing only allowed copying drugs if the active ingredients were Canadian-made before 1969, the provisions were used so infrequently that it is remiss to think that the relaxation in patent laws was sufficient to create "enough and as good." After Bill C-102 in 1969, the loosening of the medicinal ingredient requirement spurred the generic industry, but was still insufficient for stimulating growth in *innovative* pharmaceuticals, meaning that foreign pharmaceutical patents were still not "enough and as good" for Canadians.

# E. Nozickian Compensation through Compulsory Licensing Illustrates Divergent Social Welfare Baselines

Canada's actions were more Nozickian in the approach to the patent condition than a societal surplus model, because the Lockean societal formulation would *accept* the inequalities of information that patents created and *rely* on the patent holders to give their surplus value back to Canada. Canada's compulsory licensing provisions did not rely upon the good nature of foreign pharmaceutical patent holders to return their surplus to Canada in the form of additional knowledge and skills for Canadian society but created a compensation mechanism to return a "surplus from knowledge." The current compulsory licensing provisions in *CAMR* are intended to return a surplus by creating additional access to medicines themselves, but not by returning the surplus in the form of

technological know-how to the countries which need the medicines, re-emphasizing the distinction between the utility of the medicine and the utility of the knowledge in the patent.

Nozick's compensation model poses an objective question: did Canada obtain compensation for pharmaceutical patents by instituting compulsory licensing laws? The answer involves measuring a baseline of pharmaceutical knowledge when compulsory licensing policy was in place, then comparing that baseline knowledge after the compulsory licensing laws changed. Conveniently, the question can be addressed by examining the changes in pharmaceutical development capabilities before and after 1969. Until Bill C-102 in 1969 allowed for the importation of active ingredients, the compulsory licensing provisions were hardly used. After the bill, the provisions' use dramatically increased, demonstrating how increasing the Nozickian compensation level to the patent granting society could affect innovation. But the change in policy also revealed the inadequacies in Canada's innovative pharmaceutical sector, where an insufficient accumulated knowledge base in the industry meant that the creation of active pharmaceutical ingredients stagnated, failing to implement patented knowledge into actual pharmaceutical products. Even the changes following Bill C-102 in 1969 indicated that Canada was incapable of copying active ingredients, let alone developing its own innovative ones.<sup>255</sup> Canada's inability to capitalize upon the knowledge contained in pharmaceutical patents reflected its own substandard information baseline of pharmaceutical knowledge compared to its competitors who were patenting innovative

<sup>&</sup>lt;sup>255</sup> After Bill C-102 was passed, the generic drug industry in Canada saw extensive growth but the innovative sector continued to languish. Joel Lexchin, "After Compulsory Licensing: Coming Issues in Canadian Pharmaceutical Policy and Politics" (1997) 40 Hlth Pol 69. Also see Maryse Robert, *supra* note 15 at 222.

drugs in Canada, meaning that information added to its baseline knowledge through patent was inadequate compensation for the granting of pharmaceutical patents.

Canada's inability to close the gap in its baseline knowledge with that of nations with highly innovative pharmaceutical industries reveals the important distinction among nations who cooperate on terms for granting patents – some are close competitors, whose information in patents can be readily taken up by society for commercial use and for the extension of their own research, while others are far competitors who cannot uptake the information for the same commercial and research-based benefits. Canada's use of compulsory licenses led to a rapid expansion of the generic industry that overshadowed minimal growth in the innovative industry, demonstrating that Canada was a *really far* competitor from those countries leading the innovative sector, meaning that its patent compensation mechanism could not overcome that difference, despite relaxing the requirements. It does reveal, however, that the remnants of simple patent disclosure and enablement following the disappearance of working requirements do not provide adequate compensation for a patent when competitive nations are too far apart, begging the question of why the patents are upheld when the knowledge has no purpose for society.

When Canada desired to participate in international trade treaties in the 1990's, it relinquished its use of compulsory licensing, and gave up its rights to augment compensation to its social welfare baseline of information through an active legal system. The full term for pharmaceutical patents was mandatory, with few legal requirements for ensuring that the knowledge from those patents was applied in Canada in a way that would lead to an accumulation of pharmaceutical knowledge for the development of

innovative pharmaceuticals. Compensation only remained in the form of disclosure, plus the additional oversight mechanism of the Patented Medicines Prices Review Board.<sup>256</sup> Only recently has Canada revisited the desire for a Lockean bargain by instituting *CAMR*, which focuses on the benefits to Canada, in furtherance of other nations' access to lifesaving medicines. The new aims are less self-centric than Canada's compulsory licensing regimes of the past.

F. An Expectations Model of Canada's Pharmaceutical Compulsory Licensing Laws

The history of Canada's compulsory licensing provisions demonstrate that their implementation was part of a desire to expand the domestic pharmaceutical research and manufacturing. Through its early use of working requirements for foreign patents, it expected to attain more than simple disclosure from them. Working requirements curtailed, but the attitudes toward what patents were meant to do for society continued, meaning that Canada still expected more from its *pharmaceutical* patents through compulsory licensing because the industry had high governmental priority for development. While early compulsory licensing requirements were not stringent, only requiring active medicinal ingredient development in Canada, they were still inadequate for meeting societal expectations regarding the use of pharmaceutical patents, as demonstrated by their general lack of use. When the requirements were lessened by Bill C-102 in 1969 to allow for the importation of active ingredients for domestic manufacturers, the provisions escalated in their use dramatically. However, the generic

<sup>&</sup>lt;sup>256</sup> Its approach to managing compensation was two-fold. First, it observed utility gains from pharmaceutical patents by ensuring that research funding promises made by pharmaceutical firms was performed. Secondly, it matched the utility of some patents to the prices that drug companies were able to charge for them in Canada. Setting prices may be equating the price to the utility the consumer has for a given pharmaceutical, but it does not provide for the utility that the invention would bring to Canada's existing pharmaceutical knowledge base.

pharmaceutical industry flourished instead of an innovative one *because the Canadian* government changed its expectations of what patents would return to the domestic pharmaceutical industry and set the licensing provisions according to what the industry could accomplish. The expectation was set to develop the generic industry because of the difficulty of synthesizing active medicinal ingredients, and patent laws were adjusted to meet this expectation by allowing the importation of active ingredients.

The use of the information from the various governmental commissions established policies indicative of Canada's desire to maintain strong form pharmaceutical patent laws, where the expectations for pharmaceutical patents extended beyond mere disclosure. After relinquishing its compulsory licensing laws in the early 1990's, Canada's pharmaceutical patent laws required nothing beyond absolute novelty, nonobviousness, minimal utility, suitable patentable subject matter, disclosure and enablement, setting an expectation of low societal benefit, defined only by *patent disclosure*, and therefore weak form patent law.

## IX. Conclusion

Canada's early use of working requirements was evidence of its desire to achieve a bargain for society for patents in general. While reverence was given to foreign inventors and their inventions, working requirements with a three-year grace period were initially maintained, but were curtailed as the *Paris Convention* set stricter standards for the member states.

Canada, however, instituted compulsory licensing *for pharmaceuticals* in the early 1900's as working requirements became less stringent and German chemical companies started outpacing the technological levels of England and its colonies. With

the desire to participate in international trade treaties, Canada relinquished its compulsory licensing in the early 1990's, eliminating any form of working requirements left for Canada. New international trade objectives required equal national treatment for foreign investors and the removal of any discrimination by industrial sector, meaning Canada had little choice but to remove the provisions. With the removal of compulsory licensing, Canada's patent law for pharmaceuticals became weak form patent law, with no built-in expectation for the use of patented information beyond disclosure. Canada traded its pharmaceutical patent laws for the hope that it would receive increased levels of foreign investment in pharmaceuticals.

While working requirements diminished and compulsory licensing came into being in the early 1900's, the inventiveness standard of nonobviousness was maturing. Its development was indicative of a need for assessing what a truly novel and inventive invention was, but the concurrent use of working requirements and compulsory licensing revealed that nonobviousness, though instrumental in narrowing patent law, was not part of the patent bargain, nor could it replace the missing elements to turn weak form patent law into strong form. The patent bargain required another element of patent law to institute the cycling of useable knowledge through society.

The analysis of Canada's modern pharmaceutical patent law history demonstrates a shift from an initial strong form of patent law to weak form over the course of the twentieth century. While Canada attempted to maintain a strong form of patent law for pharmaceuticals through compulsory licensing, the policy did not work for turning Canada into a leader in *innovative* pharmaceutical research and manufacturing, but it did turn it into a world leader in the generic pharmaceutical industry. Although many factors

were at play, Canada's relinquishing of compulsory licensing as a form of international cooperation with the nations who led pharmaceutical innovation facilitated the change of Canada's law to the weak form. The weak form meant that Canada's patent bargain would be a disclosure-only model, but patent law theory can now begin to question how viewing the law as an expectations model can developed the law into its stronger form. Such an analysis can justify reforms in patent law, where the tension developed in any reforms can ask *to what extent* can patents be used to satisfy a societal knowledge benefit and *how much* protection can be justified for any invention. While the expectations theory requires an understanding of the knowledge base of the patent grantor, the history of Canada's compulsory licensing reveals that setting expectations within patent law aids in accomplishing an intended purpose, but setting expectations *accordingly* is the start.

#### **Chapter Seven: Conclusion**

#### I. A Lockean Theory of Patent Law Requires Condition Fulfillment

The Lockean theory of physical property in the state of nature states that property is earned by those who combine their labour with resources. So long as there is enough and as good property left over for others to use for survival, private property should be allowed – a basic model that pre-conditions property's taking with an acknowledgement of its scarcity and an understanding that humans only take what they need to survive. Property that is left in the same or better condition for others to use once the prior owner is finished with it creates a cycle of property transference among members of society that leaves no one worse off for its taking.

Applied to a patent law property model, Locke's scarcity condition has been considered irrelevant because patents, as technical information, represent *new* information disclosed to society, making it expansive and not diminutive. Since patents do not create scarcity in the same way that physical property does, it is tempting to conclude that one who creates a patented invention is simply entitled to it because society was no better off than before the inventor created it. But this proposition leaves no reasoning beyond the absence of the benefits of the invention before it existed; it simply allows for the keeping of intellectual property for oneself precisely *because* there has been nothing taken from the common pool of knowledge by doing so. Therefore, the use of the information does not *necessarily* cycle back to fulfill the needs of others as it would under Locke's enough and as good condition because there is no premise for making it happen. The withholding of technical knowledge, and the provision of patents in exchange for unusable knowledge presents a moral problem for society.

Therefore, reasoning that the theory holds by waiving this condition is different than *meeting* the condition. Without recognizing patents as diminishing available knowledge "property," their dissimilarity with physical property makes the extension of the basic physical-based theory challenging, but Locke's theory is premised on the enough and as good condition, making it unreasonable to extend it to patent law without fitting it in, regardless of the nature of information as property. Disregarding the condition is easy, but it leaves the granting of intellectual property incomplete by not promising return benefits for others, creating a *non-theoretical* justification.

A. Surplus in a Lockean Societal Patent Law Model is Vague and Uncertain

The challenge of meeting the Lockean condition is not any easier when considering Locke's societal consent model. When the acquisition of physical property takes place within a formed society, Locke states that its members have consented to rules regarding the division of physical property. With the use of currency as a store of value, property is no longer strictly held by individuals in just the right amount to maintain their own survival, making the enough and as good condition obsolete. Because individuals differ in their abilities, it can lead to unequal holdings of property under Locke's societal model because different abilities infer different levels of productivity. Like Locke's physical property justification in society, individuals who consent to rules regarding the granting of intellectual property consent to the creation of the disparity in patent property holdings (knowledge holdings) because their propensity to invent differs as well. Individuals who generate a surplus from patent "property" would return it to labourers in society who would use it to generate their own surpluses and generate larger

surpluses for the inventor, implying a high level of voluntariness by the patent holder, and reliance by society on it.

But creating a definition of "surplus knowledge" is vague, possibly meaning "surplus from knowledge," bearing a relationship to the information in any given patent and its potential use by society. The voluntariness of the inventor's donation of surplus is also suspect because Locke states that surpluses lead to inequality, which indicates that the two conditions are somewhat contradictory. If the surplus is donated back, why is there inequality? If man generally hoards, why would he donate back to society at all?

B. The Effects of Transplanting Enough and as Good into a Lockean Societal Model:Utility of a Patent is the *Utility of the Information* to Society

The voluntary return of surplus knowledge to society by the inventor holds little value in a legal theory of patent law because it is impractical to conceive of what surplus technological information is, making the normal societal condition problematic under a Lockean notion of patent property. If Locke's societal surplus model was exchanged for the basic enough and as good condition inside a formed society, holding this condition strictly holds implications for a new model. It could mean that patent information as property would be deemed finite, which can be accomplished by viewing inventing as a task undertaken by a finite number of inventors at any given time who could direct their inventive skill in any number of directions. By focusing on one type of invention, the remaining universe of things to be invented remains untouched by any specific inventor, leaving things un-invented that have differing amounts of utility (in the end product and in the information) for others. Plucking one new invention out of the "pool of inventiveness" is one way of fulfilling the creation of a finite enough and as good
condition and how it might be satisfied using Locke's model but it is a significantly different interpretation than finiteness within the context of physical land.

One does not need to rely solely on the finiteness of property for establishing the enough and as good condition into the model, however. Instituting the enough and as good condition requires the original holder of the patent to pass the information on to the next holder in such a way that it leaves him as well off as the patent holder *by definition*. In order to do so, "enough" would mean enough information is disclosed to replicate the invention and "as good" means that society can utilize the information in the same way as the inventor, which is conditional upon the relative difference between the patent holder's knowledge and the patent grantor's knowledge. If the grantor is to be at least as well off as the patent holder, then he must be able to work the patent and be able to perform research with it, just as the patent holder could, leaving the patent grantor in "as good" of a position as the patent holder. The enough and as good condition would therefore insist that patents extend beyond the utility of any given invention in individuals' daily lives to create their own productive purposes.

C. Nozickian Compensation to a Social Welfare Baseline of Knowledge

The transplanted enough and as good condition requires no active effort for information property to be transferred between individuals – the good that property does is propagated from one holder of it to another, meaning that inventors in two different societies can invent independently from one another, yet still satisfy the Lockean condition when their knowledge levels are highly correlated, creating mutual benefit from patents granted in either society. However, the societal surplus model relies on the creator of that surplus to return it to the commons, yet still accepts the inequalities in

surplus holdings that could develop. In the Nozickian model of compensation, this societal reliance is turned into the patentee's legal requirement to pay those who have had their property diminished by the granting of a patent.

Although there is nothing in the commons that is taken if a simple infinite characterization of technical information is made, examining the taking from the perspective of its impact on pre-existing knowledge in the commons is one avenue of legitimizing compensation. However, the Nozickian model's focus on compensation for what new knowledge "takes" leaves no room for assessing the positive side of patents, namely utility assessments of new patent information. But one can sidestep the issue of what patents may have taken from the commons by examining patents as a more idealistic "taking" of information under the Nozickian compensation model, which is a measurement of the discrepancy between the baseline knowledge of the patent holder and the baseline knowledge of the granting society, which morally requires redress by the *patent holder*, unlike the Lockean societal surplus model that accepts that inequality. Compensation to the baseline knowledge of society is made when society gets to *work* the patent – in production and in research for further accumulation of knowledge because it reduces the disparity in the parties' knowledge bases. Therefore, compensation should be set accordingly.

The Nozickian model differs from Locke's societal consent model in the formalizing of the return of surpluses to the commons as mandatory. What defines an adequate return of surplus to the commons is a broad question, but an observance of the historical development of patent law and its categorization into two distinct historical periods demonstrated if and how compensation was generally sought.

II. Patent Law History: Two Periods Distinguished by a Functional Change in theLaw

By generalizing patent law history according to key patent criteria, two major periods can be distinguished. The early period, encompassing renaissance Italy and England, extending to the mid-seventeenth century, utility, enablement, and working requirements were emphasized, with novelty and inventiveness of lesser importance. The second period, following England's *Statute of Monopolies* in 1624 and carrying on to modern times, minimized utility and evolved a standard of inventiveness for evaluating patentability, making the mental component of the invention the core of a patent. It raised the importance of novelty, enablement, and disclosure because of more frequent challenges to what was truly inventive, requiring a narrower definition of what was novel and better descriptions of what had been patented beforehand.

The historical record indicates that the main problem with patents before the *Statute of Monopolies* was the *breadth* of patentable subject matter, not the tailoring of patents based upon the monarchy's assessment of their utility, yet the freezing of the monarchy's customary role in doing so led to utility's eventual diminishment to a very low standard.

The long period of development of the inventiveness standard in England can be attributed to judicial disagreement over what that standard was, and whether inventiveness was even a part of the law. Seeing that patents had historically been granted under the authority of the monarch or state, many judges believed that there was no matter of dispute to be had over what had been rightfully granted, regardless of overlapping patents or the level of ingenuity. The continued grant of patents by the

monarchy in the 1700's and 1800's was additional evidence that functionally changing patent from a system based on utility to one based on inventiveness was not necessarily an intuitive nor objective legal concept for the judiciary to wrestle. It was also evidence that the monarchy saw patents as a necessary tool for developing industry. Where utility, enablement, and working requirements framed the patent bargain in the early period, inventiveness did not, but it became a tool for *narrowing* what was considered patentable subject matter in the later period.

A. The Modified Lockean Model in the Original Period: Utility and Working Requirements-Based

The early utility-based period of patent law, existing in the Italian city states and pre-industrial England, featured patents that were individually tailored. The patent term, the breadth of coverage of the patent, and the inclusion of additional resources were all considered in relation to the utility the government or monarchy felt that the invention would create. Working requirements, usually in the form of operating the invention with local labour were almost always present. Perceived utility was not always achieved, but the patent parameters were set with enough specificity to set a reasonable expectation for achieving significant integration of the knowledge into society. Because of the establishment of expectations, there was generally less concern over disclosure because society's involvement was beyond mere disclosure, being immersed in *working* the patents.

Patents during this period in England, however, were either inconsistent or unpredictable in their grant, often overlapping with patents granted to others with different inventions for doing the same thing; such overly broad patenting by the monarch

reflected his assessment of the utility of different patents for the country. But monarchial patents often begat other patents for addressing the dissatisfaction that resulted within the system and caused more unrest with the public. This, plus the patenting of objects of everyday use created inconsistency with what the public expected to be patentable through the laws at the time. Encapsulating this period within a general Lockean theory of patent law, society was prepared to grant exclusive rights of property for inventions if it was clear that it would eventually have a grasp of the technology being introduced...its demands naturally whisked away the patents on everyday items or other machines where society was already familiarized with the information contained within them, leaving no benefit in their granting. This strictly situated the knowledge of inventive things as "knowledge property" because new knowledge was worth protecting since a return to society could be expected from it. Therefore, patent law historically did exhibit a fit within a Lockean model because there was a societal benefit attached to having new information available for things that were highly innovative, as evidenced by the rebellion against those patents that were not.

Simply applying intellectual resources was insufficient to create property in invention at this time, where the establishment of strict promises written directly into a patent grant reflected a need to meet a Lockean condition. Rather than relying on a selffulfilling enough and as good condition or a donation of "surplus knowledge" to the commons, the imposition of individualized patent terms and working requirements were akin to Nozickian compensation because the inventor was required to familiarize society with the new technology by hiring its members, which would give them the ability to

build upon it, thereby re-establishing closer positions of the social welfare knowledge baselines of the granting society with the home society of the inventor.

Ideally, the strict requirements meant that the patent *would* leave enough and as good knowledge or *would* leave "surplus knowledge" for society to use, or *would* lead to an increase in the baseline knowledge of society. If these historical requirements could be viewed as operating under ideal conditions, then enough and as good, a donated surplus, and a contribution to the baseline knowledge level of compensation create the same satisfaction of the Lockean condition. The establishment and fulfillment of something tangible in order to receive a patent creates a theoretical *solitary fulfillment condition* for the modified Lockean theory, regardless of its various forms – the fulfillment of the condition, accurately established by assessing the utility of the information behind an invention and its demonstrable effects on existing knowledge is an expectation for the use of disclosed patent information in society.

B. The Lockean Model in the Later Historical Period: The Development of Nonobviousness

The functional change in the law to an inventiveness standard eventually led to the granting of patents based upon on the mental quality of what constituted a sufficient advancement in knowledge. It had to go beyond what was obvious to persons skilled in the art, industry, or science in question. While the development of nonobviousness took nearly three centuries to crystallize, examining patents according to what was absolutely novel and inventive narrowed the scope of the law to inventions that society would generally welcome as property, which made a natural fit for a *potential* Lockean bargain for society. The idea that patents were still required to give something back to society in

this period was initially upheld in England, where governments demanded working requirements consistently long after the removal of the monarchy from the process. Working requirements for patents existed through customary law in England and eventually statute (as well as in Canada), and early international agreement through the *Paris Convention* meant that nations *could* insist upon the working requirements, once again, fulfilling the Lockean requirement that something concrete be expected by society from the patent holder. Nonobviousness simply narrowed patents to those things that had the *potential* to fulfill the bargain but it did not satisfy the bargain on its own.

III. Expectations as a General Patent Law Condition: Strong versus Weak Form Patent Law

By generalizing the Lockean condition into an expectation for patent law, strong form and weak form patent law are distinguished, yet fall under one theory. When societies legislate reciprocal patent laws, both can expect to benefit from utilizing the knowledge in each other's patents, making the promises underlying those expectations hold, leading to not just enforcement of those laws, but the upholding of them for their mutual benefit. In this case, the theory is complete because the Lockean condition for the granting of private property is fulfilled *between* them, creating the strong form of patent law. With the condition intact, theoretical strong form patent law states that the action of mixing intellectual labour with resources leads to property *because one expects that the creation of that property will lead to additional accumulation of knowledge and more knowledge property for others*.

Under the weak form of patent law, the Lockean bargain is still fulfilled, even though the granting of private property in patents may or may not lead to a benefit for

society. Disclosure becomes a minimal but sufficient condition for satisfying the bargain, but the attainment of a *material* bargain (the use and application of the patent knowledge) is inconsequential to its fulfillment. Without any expectation from the patent beyond disclosure, there is nothing that society can use for justifying its protection of private property *beyond a mere expression of what the thing is* that they are protecting. Under the weak form, patentholders are shielded from a moral obligation to ensure their patents are useful to another society because predicting and measuring the use of the patent is not part of the legislation or jurisprudence, and no one in the administration or examination of patents considers its final utility or outcomes for society.

A. Expectations for Inventors and Patent Grantors and a Just Patent System

In its weak form, however, patent law theory is not devoid of expectations, where the functional change to a nonobviousness standard creates *expectations for the inventor*. Under current law, an inventor can expect to receive monopoly rights for a specified term, provided that the invention is new, has at least a minute amount of utility, and meets the standard for inventiveness. While the standard of inventiveness has been problematic in its application due to the technical nature of any given field of study for the judiciary, including pinpointing *who* exactly is the person having ordinary skill in the particular art in question,<sup>257</sup> patent law under this guise provides a fairly consistent mechanism for recognizing what innovations are worthy of the award of patent property by asking the same basic question about each invention.

<sup>&</sup>lt;sup>257</sup> Matthew Herder, "Demythologizing PHOSITA — Applying the NonObviousness Requirement under Canadian Patent Law to Keep Knowledge in the Public Domain and Foster Innovation" (Winter 2009) 47:4 Osgd Hall L Rev 695.

The lack of consideration of the utility of patentable inventions (despite the inherent difficulty in measuring utility) leaves unanswered questions about the expectations from patents *for the patent grantor*. While such questions about utility would require forecasting, which would inevitably lead to *forecasting errors*, eliminating a consideration of the worth of any invention from the patent granting process stagnates the development of modern patent law. If patents have differing levels of utility for society, yet fixed patent terms are granted, the patent award has lessened its relevance in law to society.

Therefore, forecasting the utility of new inventions is relevant to a just patent grant in the expectations model. While incorrect forecasts of patent utility could be adjusted by extending patent terms or shortening them accordingly, omitting utility assessments means that society has handcuffed itself in deciding how much protection it wishes to give to certain inventions. Flexibility gained by introducing a utility analysis can also reduce information asymmetry in the patent bargain by relating the knowledge, and hence, the terms of a patent, to a baseline of societal knowledge. Although the current form of patent law, with its lack of a meaningful utility standard, can yield expected results, it is due to the *uniformity of patent criteria* that allow an inventor to gauge his own success in achieving a fixed result. A just system takes into account inventiveness to narrow the scope of patentable inventions, creating a *potential* bargain, but must also take into account utility for setting society's expectations so that there is a higher likelihood of *achieving* the patent bargain.

#### B. Close Competitors versus Far and Ideal Patent Law

Uniform patent laws across an array of societies with varying levels of technical knowledge create divergent effects, leading to the primary conclusion that standard patent laws (with no adjustments to the patent grant) create two forms within the expectations model, either strong form patent law or weak form patent law, depending upon the baseline knowledge of the granting society. Actors who absorb strong form patent law have can expect to utilize the patents they grant; actors who absorb weak form patent law have a lesser or absent expectation for utilizing the patents granted. Generally, the closer two societies are in their underlying knowledge bases, the closer the competitors they are, and the more likely they are to absorb strong form patent laws between them.

The removal of the Lockean condition, the enough and as good form, leaves the theory in a less than theoretical state, where intellectual resources that are applied in a sufficiently innovative manner (they are novel and inventive, with a minimal amount of utility) are granted patent property rights with no obligation beyond simple disclosure and enablement of the invention. Close competitors will find patent law in its bare state more acceptable because they *expect* to receive reciprocal patent protection and patent benefits from their close competitors – in other words, the law no longer is really bare; rather, a Lockean-type condition naturally arises in the enough and as good form. The reciprocal treatment of the law makes sense for both, regardless of the size and quality of the bargain one promises to another because close competitors already have a high expectation for taking up and utilizing the information contained in the patents that they have issued - a new patent is always enough and as good for the patent grantor when it is disclosed. Linking this back to the strong form/weak form distinction, the *ideal* form

requires no active intervention of the law to make it work, given the high level of reciprocity. Therefore, Professor Fox's assertion about society not giving anything up when patents are created *only holds when the Lockean condition operates among identical (close) competitors, not because the enough and as good condition disappears, but because it operates in its strongest form.* It is unclear if this ultimate form of patent law between patent actors exists but it serves as an ideal for proposing and evaluating changes to domestic and international patent law.

Far competitors, competitors who have vastly different levels of patented information (and therefore accumulated technical knowledge), do not share this reciprocity. At the extreme, a highest-level knowledge competitor acquires patents from its furthest (lowest level knowledge) competitor, leaving no chance that the far competitor can use the information contained within it. Therefore, the far competitor has issued the higher-level competitor a patent, yet has attained nothing in return for its grant. Nor is there any reciprocity in patent granting because the weaker competitor has no patent knowledge to offer the sharper competitor. Without any requirement to satisfy the Lockean condition, there is no offsetting bargains, and the granting of the patent by the far competitor becomes meaningless in law because its citizenry is incapable of capitalizing on the information.

At these two extremes, close competitors and far competitors, the disparity in viewing patent law as fulfilling the enough and as good condition in both cases becomes difficult. While fulfillment based on Nozickian compensation could bridge the gap between far competitors, its use is not necessary between close competitors, making a Nozickian theory insufficiently robust. A justification based on what the patent actors

*expect* from the patent bargain becomes more reasonable for explaining both close and far competitors. When the expectations from patent law diverge too much, the expectations model naturally asks, "Why should we grant this patent, what patent terms should we set, and what should we expect from it if we do?"

Comparing patent law *before* and *after* the functional change to a system of inventiveness in patent law's history, patents prior to the change were used to *reduce* information baseline asymmetry between trading partners by establishing rigid patent bargains, taking into account the utility of the knowledge in any given patent. Patents granted in later times were no longer able to be granted according to any such considerations. Therefore, the expectations were much stronger before the change to an inventiveness standard. It is not so much that the latter patents *could not* improve a social welfare knowledge baseline; there was just no legal mechanism for ensuring it, making the expectations from patent law much weaker.

Historical evidence of the narrowing of patents to things that are new and truly innovative, using an inventiveness standard that can be applied across all of the different realms of technology, is easily construed as a natural development within the law for achieving a just and moral system of patent property, but it does not guarantee that a societal bargain will be achieved. And fixing utility to a minimum standard has frozen utility's value as a tool for assessing patents and adjusting patent conditions. While patent law history demonstrated a desire to limit the *breadth* of patenting, the restraint on monarchial power also eliminated the ability to assess the quality of patents meaningfully. If one was to reintroduce utility as a measure for evaluating patents and adjusting patent terms then patent disclosure would take on a different meaning, where

the patent terms were adjusted so that disclosure led to some set expectations of societal uptake of the information in the patent. While nonobviousness reduces patents to those things with the potential to create a societal bargain, utility assessments become the tool for achieving it.

Chapter Two discussed a general utilitarian model of patent law, where patent law was designed to motivate individuals to invent and improve the lot of mankind, but the theory was macroscopic, too broad to be incorporated into an individualistic theory like Locke's property theory. Rather, it was considered complementary to Locke's theory by being a hopeful outcome to it, similar to the donation of surpluses under Locke's societal surplus condition. By reintroducing *specific* assessments of utility into the new expectations model, the motivation of *any* individual to invent can be tied to the utilitarian aspects of what they invented, marrying the individual inventor to the *exact thing* that he created, instead of leaving utilitarianism as a broad outcome to an otherwise liberal theory.

IV. Conclusions about Canada's Modern Pharmaceutical Patent Law History under a Modified Lockean Theory of Patent Law

While Canada's early patent laws already assessed patent applications primarily by their inventiveness, Canada employed working requirements for patents to ensure that the Lockean bargain was met. As working requirements lessened among signatory countries to the *Paris Convention* in the twentieth century, Canada maintained a commitment to them *for pharmaceuticals* in the form of compulsory licensing, where patent holders were only compensated with royalties while the use of their patented information could be granted to others before patent term expiration. Canada's efforts to

improve the patent bargain within the pharmaceutical industry was intensified in the late sixties by removing the requirement for active medicinal ingredients to be developed in Canada in order for a compulsory license to be granted.

Canada's actions were more Nozickian in their approach to the patent condition than purely Lockean, because a consenting societal Lockean formulation would accept the informational inequalities that patents created and *rely* on the patent holders to give their surplus value back to Canada. Applying a transplanted enough and as good condition, Canada would not have needed to implement compulsory licensing to benefit from the pharmaceutical patents it was granting to foreign pharmaceutical inventors if it felt that the patent bargain was automatically reciprocally satisfied. Canada, however, imposed mandatory conditions for pharmaceutical patent protection, not relying upon the good nature of foreign inventors to return their "surplus knowledge" to Canada in the form of additional pharmaceutical knowledge and skills for Canadian society. During this period of Canadian pharmaceutical patent law history, Canada exhibited strong form intellectual property laws, asserting the need for pharmaceutical patents to compensate the social welfare baseline of knowledge in Canada and move it closer to the position of its competitors. Canada wanted to catch up to the baseline knowledge of nations with highly innovative pharmaceutical industries.

A. The Abandonment of Compulsory Licensing and the end of Strong Form Patent Law in Canada

Once Canada removed its pharmaceutical compulsory licensing provisions in the early nineties as a concession for joining international trade treaties, Canada was left with weak form pharmaceutical patent law. Honoring the full term for foreign pharmaceutical

patents was mandatory due to equal national treatment and non-discrimination provisions in *TRIPS* and *NAFTA*. Other than patent disclosure and enablement, no patent requirements existed to help Canadian society take up the knowledge in pharmaceutical patents and build upon them except for trivial concessions earned from international pharmaceutical firms operating in the Canadian drug industry. Therefore, property granted in pharmaceutical patents was done so without any *necessary exchange* of useable knowledge for Canada to accumulate and without any *necessary* satisfaction of a Lockean condition. While Canada's investigatory commissions in the 1950's and 1960's demonstrated that "enough and as good" was not being fulfilled and that "surpluses from knowledge" were not being returned to Canada, the removal of compulsory licenses as compensation meant that there would be no expected contribution to Canada's baseline pharmaceutical knowledge. At most, the corporate funds pledged at the time could be viewed as a pressured donation of Lockean surplus to Canadian society.

Foreign pharmaceutical patent holders were no longer materially obliged to directly use Canadian labour or Canadian scientists to research and develop its patented medicines to achieve full term patent status. Without any fulfillment of the Lockean condition beyond disclosure by foreign patent holders, Canada's early patent law and its subsequent condition-less patent law after dropping compulsory licensing provide evidence of an expectations model bifurcated into the strong and weak forms. In its strong form, like the early utility-based patent law formats of the Italian city states and pre-industrial and renaissance England, specific expectations for patents in Canada were set to increase the likelihood of what society intended to achieve from them. Under weak form patent law, the expectation that society had for the uptake and use of that

information internally were drastically reduced and could be satisfied with *no expected use and only disclosure* of the patented information to society.

Canada's pharmaceutical patent history, overall, describes a society which had some elements of knowledge for drug development, but needed additional knowledge to augment its baseline levels to reach the innovative levels of more technically advanced societies who were patenting in Canada. Canada, therefore, primarily acted like a far competitor to more knowledge-wealthy nations that housed the pharmaceutical industry but it tried to make itself a close competitor by reducing the information asymmetry that existed between them by restricting their patent rights. Although it relented, Canada's actions were consistent with the notion that societies do see patents as taking something from the commons that needs to be given back, as opposed to believing that simply creating property out of technical information has no negative effect upon the common pool of information and only enhances it.

Canada's expectations from its compulsory licensing program were optimistic but it could not make much use of the provisions initially due to a lack of specific accumulated pharmaceutical research and development knowledge. By adjusting its expectations, Canada allowed for the importation of active medicinal ingredients to develop its generic pharmaceutical industry, an industry characterized by sophistication, but lacking sufficient technical knowledge for innovative drug development. This historical fact does not weaken the importance of expectations within the model but shows that expectations for patent usage must be set reasonably if the bargain for a particular patent is to be achieved, thereby establishing a basis for a discussion about how utility assessments and working requirements can be used to establish the patent bargain.

### **Chapter Eight: An Expectations Analysis of a Single Pharmaceutical Patent**

## I. Introduction

While the expectations model of patent law was employed in the thesis to derive broad historical characterizations of the history of patent law and Canada's pharmaceutical patent law, the conclusion that an expectations model would justify implementing variable patent terms provides the motivation to illustrate its operation with respect to a single pharmaceutical invention. The theory will therefore be modified into a practical set of investigations that are applied to a pharmaceutical patent case in Canadian law. The practical expectations model will not supplant the pillars of patent law but will support novelty, nonobviousness, and utility, because they can be used as analysis tools for measuring the quality of the patent, helping to develop benchmarks for innovation. As this is the first application of the expectations model, no benchmarks exist for scoring the patent, but iterative applications of the model would develop not just one benchmark, but a cross-section of benchmarks that can be used to evaluate *new* patents relative to previous patents. After presenting the case, questions will be asked in furtherance of "measuring" the patent and developing a patent characteristic profile. Rather than using the expectations model to adjudicate the case, the expectations model will be applied as a legal mechanism for issuing the patent, where the patent "profile" justifies the patent award.

### A. Nonobviousness

The four-part test developed for nonobviousness in *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*,<sup>258</sup> along with the three-part obvious-to-try sub-component from *Eli Lilly v. Novopharm*<sup>259</sup> will prove useful in establishing the inventiveness of the patent. Rather than asking *if* the invention in question was obvious, however, the obviousness analysis characterizes *how* obvious the invention is, taking into account the potential patentee's submissions and other pertinent information collected by the evaluator and scoring it.

B. Novelty

The analysis will use a static definition of novelty congruent with Section Two of the *Patent Act*. In other words, the invention was not disclosed to the public any more than one year before the filing date,<sup>260</sup> nor was the invention part of the prior art. Though static, future revisions to patent law could consider dynamic models of novelty, where absolute novelty is not necessarily required. This could be the case, for example, when parallel industries in different nations have been working *independently* towards the same invention, and patenting would serve to derail one of the competitors. While eliminating absolute novelty could introduce significant conflict in patent law, maintaining an open mind toward absolute novelty may prove useful in very specific circumstances.

C. Utility

The patent profile that arises from the expectations analysis is the result of benchmarking across a number of key considerations when evaluating the utility of a

<sup>&</sup>lt;sup>258</sup> Sanofi-Synthelabo, supra note 37.

<sup>&</sup>lt;sup>259</sup> Eli Lilly, supra note 38.

<sup>&</sup>lt;sup>260</sup> Patent Act, supra note 22 at s 28.3.

patent. As a patent criterion, utility has maintained a low bar since the passing of the *Statute of Monopolies* and the development of nonobviousness. Section Two of the *Patent Act* states that a patented invention should be "new and useful,"<sup>261</sup> but usefulness has maintained a fairly benign existence in patent law, where the current standard from *AstraZeneca* requires a patent to only be capable of *a* [single] practical purpose.<sup>262</sup>

The expectations analysis steps beyond miniscule utility and reintroduces the "use" into utility, making 'one potential use of an invention' from *AstraZeneca* no longer a valid threshold for full patent terms. The reintroduction of utility requires consideration of several aspects of the invention, categorized as industry-specific and perhaps sub-industry specific.

The issue of disclosing the use of any potential patented invention requires statutory change to include the provisions. While expressing the use could be mandated, such a use would need to coincide with the patent claims and with the patent description so that the use could be validated during the application process. Patent policy could dictate whether a single use of the invention would be supplied by the applicant or construed from the patent claims.<sup>263</sup>

Beyond the use of the invention, utility will include the *utility of the information*, taking into account the ability of society to use the information, and how much use it will be to them in furtherance of research or other related industrial goals.

<sup>&</sup>lt;sup>261</sup> *Patent Act, supra* note 22 at s 2.

<sup>&</sup>lt;sup>262</sup> AstraZeneca, supra note 29.

<sup>&</sup>lt;sup>263</sup> AstraZeneca, supra note 29.

### D. Disclosure and Enablement

As cornerstones for society's participation in utilizing patents, disclosure and enablement remain intact in the new sample model, following statutory requirements in Section 27(3)(a) and (b) of the *Patent Act*. The goal for this society, however, is to ensure that the utility of the knowledge in patents extends beyond disclosure and enablement to *actual use*.

# II. The Case: Pfizer's Norvasc (the Besylate Salt of Amlodipine)

Patent litigation between the innovative pharmaceutical company Pfizer and generic pharmaceutical manufacturer Ratiopharm provides an insight as to how utility and nonobviousness can be evaluated in an expectations analysis of a single patent application. Because this case focuses on both issues, it presents an opportunity for a robust evaluation of the patent in question. The case was litigated through a patent invalidity proceeding at the Federal Court vis-à-vis the *Patent Act*, then appealed to the Federal Court of Appeal, providing a sufficient information set for illuminating the utility and nonobviousness issues, including the judges' insights and the acceptance of certain evidence in their rulings. The current analysis will focus on the Federal Court's adjudication of the patent invalidity proceeding.

A. Background on Amlodipine – an Antihypertensive and Anti Ischemic Medicine<sup>264</sup>

Researchers discovered amlodipine in the early 1980's, as part of a class of drugs called dihydropyridine calcium channel blockers. It was found to be exceptionally

<sup>&</sup>lt;sup>264</sup> Thomas Eschenhagen, *Treatment of Ischemic Heart Disease*, in *Goodman and Gilman's: The Pharmacological Basis of Therapeutics*, ed by Laurence Brunton et al (New York: McGraw Hill, 2013) ch 27, 28.

effective at treating hypertension and ischemia, both common ailments in aging populations in western societies. Hypertension, also known as high blood pressure, is a condition where the filling pressure and ejection pressure in the heart are too high, which stretches and deforms the heart muscle over time, leading to premature heart wear and shortened life expectancy. Ischemia is a condition where blood vessels lose their elasticity due to an excessive accumulation of calcium inside the blood vessel wall. With a loss of elasticity, insufficient vascular dilation occurs when the body is undergoing physical stress, resulting in decreased stamina. Often, the loss of elasticity of the vessels occurs within the heart, meaning that insufficient blood flow to the heart results when the body is under a load. The lack of blood flow means that there is an insufficient amount of oxygen being distributed to the heart itself, resulting in pain known as angina.

As a pharmacological antagonist, amlodipine blocks calcium channels on blood vessels, preventing the influx of calcium into the vessels. By preventing the influx of calcium, the blood vessels dilate, meaning that the volume inside the vessels increases. For a given volume of blood, the larger blood vessel diameter means that the pressure on the vessel will be reduced, translating into less stress on the heart. For ischemia, amlodipine still works by blocking the inflow of calcium into blood vessels but the resulting reduction in calcium inside the vessels means that less calcium gets deposited into ischemic areas, helping to prevent further narrowing. Because of its beneficial effects, amlodipine is one of the top prescribed medicines in Canada for treating hypertension, ischemia, and angina.

Amlodipine, as one compound of several dihydropyridine molecules, was granted patent status in Canada in 1989 and was scheduled to expire in 2006 based on Pfizer

filing the patent in 1983.<sup>265</sup> But Pfizer developed a "salt" of amlodipine, amlodipine *besylate*, and was granted a separate patent for this salt in 1993,<sup>266</sup> with an expiry date of August, 2010. After completing the regulatory testing phase, the medicine was granted a Notice of Compliance in August, 1997, making *amlodipine <u>besylate</u>* available for Canadians, extending Pfizer's patent protection (therefore, market protection) by four years. By developing basic amlodipine into a salt and achieving patent protection for that particular salt, generic drug companies would have to yield to the patent term before marketing the generic product because all of the data in the generic company's abbreviated new drug submission to Health Canada is based on matching the same technical specifications as the branded product (Pfizer's brand of amlodipine besylate is called Norvasc). This process is called interchangeability.

1. What is the Salt of a  $Drug?^{267}$ 

Many drug compounds in their basic form do not have the physical characteristics to make them optimally bioavailable in the human body, nor are they necessarily amenable to good outcomes during the drug manufacturing process. By forming a salt of a base drug, its physical properties are modified to address the pertinent development issues. The main physical properties that are modified are the solubility of the drug compound (including its rate of dissolution in the gastrointestinal tract), processability during manufacturing, stability of the final drug form, and hygroscopicity. Since drugs have to be dissolved by the stomach's acidic solution in order to be absorbed from the

<sup>&</sup>lt;sup>265</sup> See Government of Canada, Canada Patent Database Patent 1253865. https://www.ic.gc.ca/opic-cipo/cpd/eng/introduction.html.

<sup>&</sup>lt;sup>266</sup> Canadian Patent Number 1,321,393 [the '393 Patent].

<sup>&</sup>lt;sup>267</sup> Steven Neau & Nikhil Loka, *Pharmaceutical Salts*, in *Water-Insoluble Drug Forumlation*, ed by Ron Liu, 3<sup>rd</sup> ed (Boca Raton: CRC Press, 2017) ch 15.

gastrointestinal system, their solubility in stomach acid and the rate at which they dissolve is critical. Drugs also have to be able to survive the manufacturing process some drugs adhere to the manufacturing equipment to such an extent that it becomes very difficult to produce consistent lots. In addition, the final product has to be stable, with a shelf life of two to three years, where the effectiveness of the active ingredient is maintained at one-hundred per cent, making the product consumer-reliable over a reasonable period of time. Drugs also have to resist the formation of water on their surface (they must demonstrate acceptable levels of hygroscopicity). In other words, the drug product has to resist combining with moisture in the air which then settles on the surface of the dosage form. Although this moisture does not necessarily reduce the effectiveness of the drug product, it can affect the appearance and structural integrity of it. Finding and forming the right salt of the drug can often address all of these potential issues.

Depending on the acidity or basicity of a drug, the compound is paired with an opposite to make a salt; in other words, an acidic compound would be paired with a base or a basic compound would be paired with an acid. In either case, a salt is formed while maintaining the molecular structure of the drug so that its intrinsic medicinal effects are retained. But the peculiar physical characteristics of any particular salt cannot be predicted so empirical testing is carried out on a number of different salts to verify their characteristics and compare them. There are many salt options available, but the usual screening process is to start with five or six known salts that have demonstrated broad effectiveness and have been deemed safe by Health Canada or the United States Food and

Drug Administration or other regulatory bodies.<sup>268</sup> If no suitable salts are found, a broader trial of salts is conducted. Although the chemist will try a few known options, there is no prescribed method for finding a salt that possesses the desired characteristics.

# B. Case Details: Ratiopharm Inc. v. Pfizer Limited<sup>269,270</sup>

The plaintiff Ratiopharm Inc., a Canadian generic drug manufacturer, sought to declare Pfizer's '393 Patent (Canadian Patent Number 1,321,393) invalid so that neither it nor the originating patent (Canadian Patent Number 1253865), which expired in 2006, would be in force, allowing Ratiopharm to proceed with the manufacture, distribution, and sale of its generic copy of Norvasc. Ratiopharm alleged the invalidity of the '393 Patent primarily on the grounds of lack of utility and obviousness. The parties agreed that the deficiencies were found in claim eleven of the patent: the claim to the *besylate salt* of amlodipine.

### 1. Obviousness

Pfizer claimed that it was motivated to create a salt of amlodipine to improve the stability of the drug, thereby giving it a longer shelf life, and also reducing the stickiness of amlodipine in the tablet-making process. Several formulations were tried during the salt screening process, revealing salts with varying dissolution rates, solubility, stability, hygroscopicity, and stickiness. Of the disclosed salts in the case, the besylate salt was shown to have several good characteristics. Creating a besylate salt, however, had been

<sup>&</sup>lt;sup>268</sup> A good starting point is usually with the list of commercially available salts found in Stephen M Berge et al, "Pharmaceutical Salts" (1977) 66:1 J Pharm. Sci. 1-19.

<sup>&</sup>lt;sup>269</sup> (2009) FC 711 [Pfizer] and Pfizer Limited v. Ratiopharm Inc. (2010) FCA 204 [Pfizer FCA].

<sup>&</sup>lt;sup>270</sup> The Federal Court case was affirmed at the Federal Court of Appeal: *Pfizer Limited v. Ratiopharm Inc.* (2010) FCA 204.

previously disclosed in unrelated drug formulation work in the industry, and was part of the well-known salt screening process.

Answering whether the salt screening technique made the besylate salt obvious, Hughes J. applied the four-part test in *Sanofi-Synthelabo*, along with the three-part obvious to try test that clarifies part four of the main test when repeated trials are undertaken. In identifying the notional person skilled in the art, there was little disagreement among the parties about the credentials and knowledge base outlined in parts 1(a) and (b) of the test:

The patent is addressed to salt selection for use in pharmaceutical formulations. The person skilled in the art would be a pharmaceutical development team comprising chemists (synthetic and analytical) and formulation scientists. Leaders within such a team may have a doctorate and many of the team members would have at least a Bachelors degree in chemistry or pharmacy or at least five years of practical experience in synthetic, or analytical chemistry or pharmaceutical formulation.<sup>271</sup>

Hughes J. identified the inventive concept as the formation of a besylate salt of amlodipine and identified salt screening as part of the state of the art known by drug formulation scientists. He then concluded that screening for a besylate salt was not any different than screening for other salts. Using the three-part obvious to try doctrine, he concluded that the process for finding a suitable salt for amlodipine was routine for a pharmaceutical development team, and the fact that they found the besylate salt in the first round of screening attested to the ease with which the process was conducted. The four-part test and the three-part obvious to try doctrine allowed Hughes J. to find that little difference between the inventive concept and the existing general knowledge of the

<sup>&</sup>lt;sup>271</sup> *Supra* note 269 at para 29.

art of pharmaceutical formulating, making the formation of the salt obvious. The salt screening process, unless amounting to something beyond routine empirical trials, was essentially a process of verifying the characteristics of each particular salt for their suitability in the formulation.<sup>272</sup>

# 2. Laws Specific to Selection Patents

Even though Hughes J.'s decision regarding the obviousness of the amlodipine besylate salt meant that no further adjudication of the remaining issues was necessary, he commented on the remaining arguments made by the parties in the case. With regard to the '393 Patent (besylate salt patent), its status as a selection patent meant that it was subject to a separate and unique obviousness analysis. Hughes J. articulated the obviousness question of selection patents as "if a class of compounds has been discovered, is it obvious that a particular member or group within that class will have the same or different properties, and, if different, how different?"<sup>273</sup>

While the *Sanofi-Synthelabo* nonobviousness test still applies to selection patents, the inventive concept to be identified in step two is the specific molecular compound of the selection patent. Whether or not this inventive step is different from the knowledge already in the prior art is identified, then compared to what the person having ordinary

<sup>&</sup>lt;sup>272</sup> Hughes J. came to the same conclusions on nonobviousness as the Federal Circuit did in *Pfizer v. Apotex Inc.* (2006) 480 F3d 1348 at page ten:

However, on the particularized facts of this case, consideration of the routine testing performed by Pfizer is appropriate because the prior art provided not only the means of creating acid addition salts but also predicted the results, which Pfizer merely had to verify through routine testing.... The evidence shows that, upon making a new acid addition salt, it was routine in the art to verify the expected physicochemical characteristics of each salt, including solubility, pH, stability, hygroscopicity, and stickiness, and Pfizer's scientists used standard techniques to do so. These types of experiments used by Pfizer's scientists to verify the physicochemical characteristics of each salt are not equivalent to the trial and error procedures often employed to discover a new compound where the prior art gave no motivation or suggestion to make the new compound nor a reasonable expectation of success.

<sup>&</sup>lt;sup>273</sup> *Supra* note 269 at para 175.

skill in the art could accomplish. The Supreme Court had already addressed the issue of selection patents in *Sanofi-Synthelabo*, where selection patents must demonstrate a special quality and character compared to the other members of the genus patent in order to be inventive:

9. The locus classicus describing selection patents is the decision of Maugham J. in In re I.G. Farbenindustrie A.G.'s Patents (1930), 47 R.P.C. 289 (Ch. D.). At p. 321, he explained that in the field of chemical patents (which would of course include pharmaceutical compounds), there are often two "sharply divided classes." The first class of patents, which he called originating patents, are based on an originating invention, namely, the discovery of a new reaction or a new compound. The second class comprises patents based on a selection of compounds from those described in general terms and claimed in the originating patent. Maugham J. cautioned that the selected compounds cannot have been made before, or the selection patent "would fail for want of novelty." But if the selected compound is "novel" and "possess[es] a special property of an unexpected character," the required "inventive" step would be satisfied (p. 321). At p. 322, Maugham J. stated that a selection patent "does not in its nature differ from any other patent."

10. While not exhaustively defining a selection patent, he set out (at pp. 322-23) three conditions that must be satisfied for a selection patent to be valid.

1. There must be a substantial advantage to be secured or disadvantage to be avoided by the use of the selected members.

2. The whole of the selected members (subject to "a few exceptions here and there") possess the advantage in question.

3. The selection must be in respect of a quality of a special character peculiar to the selected group. If further research revealed a small number of unselected compounds possessing the same advantage, that would not invalidate the selection patent. However, if research showed that a larger number of unselected compounds possessed the same advantage, the quality of the compound claimed in the selection patent would not be of a special character.

11. Although much has been written about selection patents since I.G. Farbenindustrie, Maugham J.'s analysis is consistently referred to and is

well accepted. I find it is a useful starting point for the analysis to be conducted in this case.<sup>274</sup>

In reviewing the results of the salt screening, Hughes J. determined that there was nothing particularly outstanding about the besylate salt over the others. Despite Pfizer's claims that the besylate salt demonstrated "a unique combination of good solubility, good stability, non-hygroscopicity and good processability which makes it outstandingly suitable for the preparation of pharmaceutical formulations of amlodipine,"<sup>275</sup> Hughes J. determined, on the basis of all of the evidence supplied, that it was not sufficiently better than the other salts to make it unique, seeing that other salts had characteristics that would have made them suitable candidates as well.

### 3. Utility

Citing "useful" from Section Two of the *Patent Act*, Hughes J. compared the besylate salt of amlodipine to the other salts that were made during the salt screening process. Concluding that the besylate salt was not "sufficiently superior to the other salts,"<sup>276</sup> like the tosylate or the mesylate salt, Hughes J. stated that the lack of uniqueness, relative to the others, invalidated the besylate salt as a selection patent, on the basis of utility *because it offered no additional utility beyond any of the other salts already under consideration*. Also noting that the maleate salt that was registered with the originating patent and made commercially available further supported the conclusion that the besylate salt was not unique.<sup>277</sup>

<sup>&</sup>lt;sup>274</sup> Hughes J. *supra* note 269 at para 176, quoting *Sanofi-Synthelabo*, *supra* note 37, quoting Maugham J. in *Re IG Farbenindustrie AG's Patents*, 1930, 47 RPC 289 (Ch D).

<sup>&</sup>lt;sup>275</sup> *Pfizer*, *supra* note 269 at para 145.

<sup>&</sup>lt;sup>276</sup> *Pfizer, supra* note 269 at para 179.

<sup>&</sup>lt;sup>277</sup> *Pfizer, supra* note 269 at para 183.

4. Sufficiency in Disclosure and Enablement

Hughes J. referenced Section 27(3)(a) and (b), the Patent Act provisions that

outline disclosure and enablement, where sufficient information must be disclosed "so as

to enable a person skilled in the art to make use of the invention."<sup>278</sup> Reciting Sections

27(3)(a) and (b):

(3) The specification of an invention must

(a) correctly and fully describe the invention and its operation or use as contemplated by the inventor;

(b) set out clearly the various steps in a process, or the method of constructing, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it pertains, or with which it is mostly closely connected, to make, construct, compound or use it;<sup>279</sup>

Focussing on "as contemplated by the inventor," Hughes J. concluded that an

examination of the data for all of the various salts that were screened revealed that some

of the salts were included in the patent application and some were omitted from it,

indicating that the patent application itself did not coincide with what the inventors had

contemplated, invalidating the patent on the insufficiency of the application.

5. Section 53

Section 53 of the *Patent Act* requires the patent application to be truthful and not to be overly broad or narrow with the information in the specification and drawings. It also permits the granting of patents *on part* of the application, if appropriate, that is outside any extraneous or omitted information:

<sup>&</sup>lt;sup>278</sup> *Pfizer, supra* note 269 at para 188.

<sup>&</sup>lt;sup>279</sup> *Patent Act, supra* note 22 at s 27(3).

(1) A patent is void if any material allegation in the petition of the applicant in respect of the patent is untrue, or if the specification and drawings contain more or less than is necessary for obtaining the end for which they purport to be made, and the omission or addition is wilfully made for the purpose of misleading.

Exception:

(2) Where it appears to a court that the omission or addition referred to in subsection (1) was an involuntary error and it is proved that the patentee is entitled to the remainder of his patent, the court shall render a judgment in accordance with the facts, and shall determine the costs, and the patent shall be held valid for that part of the invention described to which the patentee is so found to be entitled.

Hughes J. found that misstatements made in the pleadings that "enhanced the alleged uniqueness and outstanding characteristics of the besylate salt" over the other salts, which he found to be misleading, and that there was intent to make those statements misleading.

### 6. Case Summary

Hughes J. found Pfizer's '393 Patent from Claim 11 of the patent application to be invalid on all of the grounds argued at trial. The invention was found to be obvious to a chemist skilled in the art of pharmaceutical formulation because it was essentially discovered through a verification process that was part of the state of the art, and it was also found through an obviousness examination to not be a proper selection patent because it lacked sufficient uniqueness from the other salts. Overlapping with obviousness, the besylate salt also lacked utility because of insufficient uniqueness from the other salts. The patent application was deemed insufficient because the disclosed specification did not contain all of the information contemplated about the various salts that led to the formulation of the besylate salt. Finally, the '393 Patent was found invalid because many of the statements plead by Pfizer were extraordinary and misleading.<sup>280</sup>

## IV. Constructing the Patent Expectations Model

## A. Defining Expectations

Expectations in patent law is defined in the thesis as matching the patent monopoly grant to the perceived societal benefit of the patent, including the utility of the knowledge within the patent. The usefulness of the knowledge in the patent can be forecasted by using several types of analyses. These analyses include defining government's patent policy and industrialization goals, categorizing and subcategorizing the nation's industries and measuring their capabilities, comparing industrial capability to industrialization goals, and examining academic and private research that steers and contributes to that industrialization. The expectations model employs nonobviousness at the application processing stage to assess the inventiveness of any particular application. It also includes a utility analysis, a novelty analysis, a sufficiency analysis, and a knowledge "blockade" analysis that examines a patent's effects on existing technical knowledge.

<sup>&</sup>lt;sup>280</sup> Pfizer appealed the decision to the Federal Court of Appeal. See *Pfizer Limited v Ratiopharm Inc.* (2010) FCA 204. One of Pfizer's arguments to the Federal Court of Appeal was based on a legal error, alleging that Hughes J. erred when he focussed on the process for creating the besylate salt and not the *result* of the process, that being the amlodipine besylate salt itself. Pfizer claimed that the salt screening was more than Hughes J.'s perception that it was mere verification of the results. Pfizer contended that the invention would only be obvious if the resulting product was obvious. Layden-Stevenson J. concluded, however, that the trial judge's use of the obvious to try doctrine portion of the obviousness test in *Sanofi-Synthelabo* was not necessarily process-focussed. Rather, sulphonic acid salts (of which the besylate salt is a class member) had previously demonstrated their advantages in stability as salts over others, meaning that the result obtained could have easily been predicted. Pfizer's appeal was dismissed.

1. Defining Public Patent Policy

Patent policy establishes society's goals for patents. Policy recognizes industrial and technological areas of strength and weakness and can set patent law to encourage areas of innovation by extending patent terms accordingly. Patent policy can include envisioning what future industrial and technological sectors look like and defining innovation pathways to achieve them. It may involve making value judgments about the "worth" of certain patents for society, and it may involve taking into account major streams of academic and private research. Patent policy can set a standard bar or floor on patent terms or allow them to float on a scale. All of these policy objectives operate through a consideration of what society *expects* from granting patents.

2. Novelty, Utility, and Nonobviousness as Public Policy Instruments

The three pillars of traditional patent law reflect policy choices that society has made. Early in patent law, novelty often meant "new to a particular region" as opposed to "absolutely novel everywhere in the world," which developed in the twentieth century. Utility was central in early patents too, where would-be patents were assessed according to how they might benefit society but has now diminished to "a use." And an inventiveness standard was initially not considered as an independent criterion but developed as patent challenges arose following the *Statute of Monopolies*. Despite the development of these standards through custom, the common law, and legislation, they are still value judgments that are subject to continuing evolution of public policy.

Utility, for example, only considers being capable of a single use, as disclosed in the patent claims, but the *actual* use does not have to be disclosed in contemporary patent law. Policy *could* dictate that the final use of any given patent be disclosed for an

assessment of its utility *to society* as well as the *utility of the knowledge* for society. In patent law's current state, without the indication of a final use, successful patents are awarded standard terms, bearing no relation to society's value of the knowledge. Public policy that chooses to measure utility can set patent terms accordingly, in-line with an expectations model of patent law. Public policy can also determine how to evaluate patents with open-ended uses, where the invention is novel and nonobvious, but has no practical application specified. Society may choose to construe a final use, or it may classify the use as general and specify patent terms according to prescribed rules.

While "novel" implies "something completely new anywhere in the world," patent policy could facilitate that "new" only has to mean "new to our society." In other words, it may choose to not grant patents to a foreign inventor if there will be no local working of the patent. Instead, it may decide to grant a patent to someone who could copy the invention and work it locally in exchange for paying the original inventor a royalty. It may also recognize competing streams of industrial development and permit patenting for both, reducing the importance of being the first to file.

Nonobviousness is set according to a bar, where inventions either clear the bar and achieve patent or do not. Patent policy may choose to adjust patent terms according to *how much* inventiveness is embedded in any invention, meaning that there is flexibility to exceed standard terms for highly ingenious inventions, or to set lower standards for patents that are not as ingenious, where these assessments would require a deepening and a broadening of the nonobviousness criteria. Stretching nonobviousness across a larger spectrum of inventiveness may incur more overlap with existing technologies and other new inventions, creating excessive patenting and confusion over what is protected by

patent. As with any policy, society has to determine how it chooses to deal with the consequences, becoming an expression of how it values them.

#### 3. Other Policy Considerations

Society may choose to institute other policies into its patent-making decisions. It may choose, for example, to evaluate patents on their propensity to stifle the innovation efforts of others. As in the Norvasc case, and notable in the pharmaceutical industry in general, patents are often a way for innovative manufacturers to block the efforts of generic drug manufacturers to copy expired pharmaceutical patents. Examining the inventiveness of pharmaceutical patents, in light of the facts surrounding the *intent* for patenting those innovations, could be a way of preventing spurious patents that are costly for society. While patent evaluation in contemporary times has been fairly "bright line" or "black and white" law, examining the intent of would-be patentees represents a departure from that type of law, requiring different modes of legal analysis, more akin to the flexible approach of the expectations theory. Examining the selfishness in patenting imbues concerns about honesty in the system and how it impacts the *utility of the knowledge* gleaned from patents because the patent sets the use of the information into the future.

Society may also choose to examine the academic content behind any patent. While academic research can and often does lead to patents, other research is not patentable because it is merely scientific or because it has been disclosed in publications, but it brings others *closer* to potentially patentable innovations. The value of these more basic research contributions to patents could lead to the assignment of royalties from patents granted or other adjustments to the patent grant to reward the basic research.

Patent policy may choose to prioritize public goals like environmentalism. An application for a new cellular telephone component may demonstrate significant inventiveness and utility for the end user. If the existing technology is recyclable, but the new technology would make it obsolete, society may choose to limit or disallow any patent if it has no recyclability for the sake of protecting the environment.

B. Establishing the Legal-Policy Framework for the Norvasc Case

An established set of policy considerations would create a unique legal environment for the evaluation of patents, taking into account a multiplicity of factors that help society achieve a bargain from patent. The aforementioned analysis is only a brief overview of some of the considerations. Despite the difficulties in trying to achieve it to date, international cooperation on patent policies, including fundamental patent terms, would greatly expand the adaptability of patent granting and how "society" (and how society might be defined) might benefit.

C. Expectations for an Amlodipine Besylate Salt: The Primary Question

The pertinent question for the evaluators of the Norvasc patent application under an expectations analysis would be "can we expect that the knowledge gained from a patent on the besylate salt of amlodipine salt will benefit society and to what degree if it does?" Assuming a policy-derived endpoint for pharmaceutical patents in general, Canadian society expects that patents granted for pharmaceuticals should be able to be taken up and exploited at patent expiration, or within a reasonable time frame following the termination of the patent based on industrial capability and projections of future capability. This period is set at ten years following patent expiration, based on an analysis of Canada's sophisticated generic drug industry, which is able to adapt quickly

to new technology. A reasonable expectation is that the patent knowledge *could* be used for forming new drug salts in the future.

The evaluation that follows presents the information that will be used to answer the primary question and set the patent terms accordingly. For the Norvasc case, a simple national approach is specified. The national approach does not involve cooperating on *all* patent terms according to international patent treaties; rather, it gives priority to national concerns.

### 1. Novelty

National policy determined that novelty is established as absolute novelty worldwide, in concert with current *Patent Cooperation Treaty* patent filing requirements. The application evaluators will therefore assess the patent for absolute novelty. In the besylate salt case, absolute novelty of the besylate salt of amlodipine is assumed because it was not addressed as a litigation issue in the case.

# 2. Patent Categorization and Description

The application evaluators then undertake a patent categorization exercise so that the nature of the invention can be compared to other *similar* inventions in the remaining parts of the analysis. This exercise also aids in establishing the relevant standard in determining the "person having ordinary skill in the art" because the various categories employ specialized personnel with specific credentials that can be correlated with industries and tabulated.

Using the International Patent Classification System (IPC) developed by the World International Property Organization, the formulation of a besylate salt of amlodipine falls under A61 P9 (10) and (12): (A) human necessities, (61) medical or
veterinary science; hygiene, (P) specific therapeutic activity of chemical compounds or medicinal preparations, (9) disorders of the cardiovascular system, (10) treating ischemic diseases, and (12) treating hypertension.

While the above classification defines the therapeutic class of the drug and aids in assessing end-use utility, categorization by level of improvement over existing technology could also be undertaken. In this case, categorizing the level of therapeutic improvement in hypertension and ischemia of amlodipine besylate over the amlodipine base could be performed and used in the utility analysis using pertinent therapeutic data and disease progression markers in health sciences.<sup>281</sup> This analysis would start, though, with benchmarking the initial amlodipine base patent's therapeutic effects.<sup>282</sup> While the patent granting stage precedes the collection of data from clinical trials, efficacy data would need to be submitted for the final determination of patent terms. A preliminary patent could be granted but final terms would be determined once the data was submitted, altering the patent granting process.

Classification can also be undertaken from an industrial or developmental perspective, where the main category is pharmaceutical formulations, subcategorized as pharmaceutical molecular chemistry, then sub-subcategorized as salt formations of pharmaceutical molecular bases. The patent can be secondarily categorized as a selection

<sup>&</sup>lt;sup>281</sup> This is a technique used by Canada's Patented Medicines Prices Review Board (PMPRB), an independent quasi-governmental organization that ensures that prices on patented medicines is not set at exorbitant levels. The PMPRB's activities can be viewed as establishing a bargain for patents, or, at the least, establishing a ceiling on the patent award to ensure that a patent bargain is attainable. The activities of the PMPRB are evidence as to why an expectations model of patents needs to exist, encompassing both patents and pricing regulation under one theory.

<sup>&</sup>lt;sup>282</sup> Different countries use different patent classification systems. The United States has recently begun cooperating with Europe to establish a common patent classification system, the Cooperative Patent Classification System. The Canadian patent database contains Canadian patents only and uses the International Patent Classification System. Patents are often cross-classified across different systems.

patent. These categorizations facilitate an examination of the scientifically closest innovations in the patent database for establishing the level of innovation at the nonobviousness stage, as well as for assessing the overall utility *of the invention as well as the utility of the information* in the patent application for industry.

Finally, the besylate salt patent can be classified as a *derivative patent* because of the presence of the original base patent that contained the majority of the benefit of the invention. Derivative patents are viewed in the analysis as having a fraction of the utility of the originating patent because the *material ingenuity* in that originating patent has already been disclosed, yet it is highly correlated with the derivative patent.

## 3. Nonobviousness

The expectations model evaluates nonobviousness in the same manner that has developed through the common law but employs it at the patent application stage. Patent protection fluctuates according to the level of inventiveness, but the same patent "standard" is applied to determine if the application meets it or falls below it, providing a benchmark for establishing patent terms. The *Sanofi-Synthelabo* four-part test and threepart subtest are still employed for making that determination.

Hughes J.'s adjudication of the nonobviousness test in the case will be used as a proxy for an evaluation of all of the evidence pertaining to the inventiveness of the besylate salt for expedience. As additional data accumulates in the patent database, more information would be available for determining the extent of inventiveness and who the relevant person having ordinary skill in the art would be, given who it has been in the past. Applying Hughes J.'s judgment, the amlodipine besylate salt patent was obvious because salt screening was a routine part of drug formulation, with specific references to established protocol. Therefore, marrying the besylate salt to the base amlodipine molecule was not seen as being something that someone having ordinary skill in the art could not achieve. The state of the art demonstrated that attaching salts to base drug molecules was well-established. The obvious-to-try doctrine was also applicable since the formation of the salt was subject to routine trial-and-error experimentation. Given that such routine salt screening took place and was often successful, it was self-evident that *some salts* would prove suitable.

The categorization of amlodipine besylate as a selection patent facilitates further evaluation of the inventiveness of the patent. Employing the patent selection test reiterated in *Sanofi-Synthelabo*<sup>283</sup> requires comparing the selected amlodipine besylate against the other salts to determine if the salt possesses any characteristics of that particular selection over the others. Seeing that the solubility, stability, and stickiness of the besylate salt were not particularly advantageous to the besylate salt over the tosylate, maleate, or other salts, Hughes J. determined that the besylate salt was obvious.

Therefore, the two streams of obvious analysis, facilitated by the categorization of the science behind the besylate salt, demonstrated that the besylate salt fell below the common law threshold for patenting which can be used in scoring the inventiveness of the besylate salt.

<sup>&</sup>lt;sup>283</sup> Supra note 37, quoting the test originally employed in *Re IG Farbenindustrie AG's Patents*, 1930, 47 RPC 289 (Ch D) at p 322.

### 4. Knowledge Blockade

The national patent policy includes a provision to evaluate whether patent applications were intended to solely extend patent life and block competitors from using a patent following expiry. While establishing the intent to block competition could be akin to establishing intent in criminal matters, doing so would require a different type of investigation and a different process, adding significant complexity to the process.<sup>284</sup> The tests involved in establishing nonobviousness provide indications of a lack of inventiveness and a possible knowledge blockade if the invention falls below the standard, but it may not always be the case. There could be cases where inventions are inventive enough to pass the obviousness test yet lack sufficient utility to be worthwhile blocking the entrance of competition into the marketplace, like the formation of a neverdiscovered-before salt that did not offer any utility beyond other salts already employed. If it can be demonstrated that its purpose was to block competition, then it can be a factor considered when evaluating the patent. If its utility is rather insignificant, the patent may be disallowed.

There is some evidence presented that the development of the besylate salt of amlodipine was a deliberate attempt to block the use of the knowledge in the original amlodipine compound because of the omitted data on alternate salts. But its characterization as a derivative patent, where the majority of the drug's benefit was attained in the originating patent, already provides an avenue for assessing the knowledge blockade, minimizing the importance of the besylate salt formulation knowledge in

<sup>&</sup>lt;sup>284</sup> Section 53 of the *Patent Act* requires patent applications to be truthful and accurate, helping to reduce the effect of patents that have been sensationalized, but it does not specifically examine whether there is intention to block knowledge pathways.

comparison to the benefit of getting generic amlodipine besylate approved, manufactured, and distributed to society.

### 5. Utility

A simple end-use utility analysis is employed by comparing the previous related amlodipine base patent to the current besylate salt application. This becomes an evaluation of if- and how a new patent affects current knowledge pathways so that the societal costs and benefits of a patent can be measured. Identifying the previous patent (the prior art), comparing it to the current application, and examining the distinguishing features would facilitate this evaluation. While similar to the four-part nonobviousness test in *Sanofi-Synthelabo*, the analysis transitions to a question of utility, asking *how much utility of the new invention is garnered over the previous invention*. The final *uses* of the new salt and the base are also identified and compared, and the list of any benefits arising from the comparator can be identified and quantified. Using the therapeutic categories previously discussed, and measuring the therapeutic differences between the reference standard and the new standard would be an essential part of the test.

In the besylate salt case, the analysis proceeds by identifying the previous amlodipine base molecule from the original genus patent as the baseline reference. The amlodipine besylate salt becomes the comparator. The final use of both is identified as reducing hypertension and ischemia. Considering how they work inside the human body (the pharmacology behind amlodipine) would indicate that they do so in exactly the same fashion.<sup>285</sup> Data presented over the therapeutic differences of the base molecule and the

<sup>&</sup>lt;sup>285</sup> Thomas Eschenhagen, *Treatment of Ischemic Heart Disease*, in *Goodman and Gilman's: The Pharmacological Basis of Therapeutics*, ed by Laurence Brunton et al (New York: McGraw Hill, 2013) ch

salt would demonstrate that there is no difference in the reduction in hypertension and no difference in the reduction of angina attack rates of ischemic patients.

The other useful aspects of the salt would then be considered. Showing better stability, solubility, and stickiness than the base molecule would be recorded and referenced with the evidence. In this case, multiple salts showed the same enhanced characteristics, failing to distinguish the besylate salt.

Although benefits over the reference patent are recognized, they are tempered against the lack of distinction from other salts of amlodipine in the second utility analysis, which compares the characteristics of the various salts, like the tosylate and maleate salts. The lack of distinction reduces the overall utility of the besylate salt from a societal use perspective because alternative salts existed.

Because the pharmacology of the base molecule is nearly identical to that of the besylate salt, society questions whether the utility of the salt form is worth a patent because it will hold up generic production of the drug until the patent lapses, keeping drug prices higher for the ensuing four years. The base molecule patent could be deemed to be the primary patent and the salt deemed a derivative innovation not worthy of much or any protection at all. Once again, the reference patent and the comparator patent application create a relative comparison for evaluating the potential utility of the proposed salt. A standard for measuring the effect of the improvement would be required, perhaps established through expert clinicians or academics.

<sup>27</sup> at 8-14 and Thomas Eschenhagen, *Treatment of Ischemic Heart Disease*, in *Goodman and Gilman's: The Pharmacological Basis of Therapeutics*, ed by Laurence Brunton et al (New York: McGraw Hill, 2013) ch 28 at 17, 18.

Beyond this comparative "utility test" is a consideration of the *utility of the knowledge* of the comparator patent over the reference patent. Given Hughes J.'s conclusion that the besylate salt represented a routine process that could be carried out by a person having ordinary skill in the art, the utility gained by patenting *the knowledge itself* for society is low because it already has a working knowledge of it. With a strong emphasis on pharmaceutical patents, society does not need to be held up for such a small knowledge benefit.

## 6. Industrial Capability

The current model considers the industrial capability and goals of the pharmaceutical industry. Using the categorization established earlier, the patent evaluation process examines the general pharmaceutical category and all of the subcategories listed to determine if the industry is capable of applying the patent knowledge now or when, in the future, it might be able to do so. This would involve using governmental, nongovernmental, and academic studies of the industry, as well as corporate self-reporting activities. In the current case, however, Hughes J.'s acceptance of Ratiopharm's evidence that the capability to formulate a besylate salt already exists in Canada is sufficient for this analysis to conclude that the additional utility from a besylate salt patent would be low, given that the information and know-how is already present. Since the technology is already in use, there is no need to evaluate projections of the Canadian pharmaceutical industry. While the focus would be *pharmaceutical industrial capability*, the *breadth* of that capability also needs to be considered, where a picture of how many firms might be capable of carrying out a salt formation in medicinal chemistry is an important consideration in how new knowledge can be utilized. Assuming a policy

goal of maintaining and growing a strong generic drug industry, patent expectations on innovative medicines could be set high, where little tolerance exists for minute improvements, like *derivative* salt patents of base drugs.

## 7. Academic Knowledge

The current example does not account for assigning credit for patented inventions to academic research. While it is clear that academic references exist to teach other medicinal chemists how to salt screen, it is already a factor in establishing whether the new besylate salt was obvious.

### D. Summarizing the Amlodipine Besylate Patent

Summarizing the besylate salt analysis aids in determining the primary question of what the expected benefit of a patent on the molecule yields. Society expected the besylate salt of amlodipine to be absolutely novel and it was. The evaluators then categorized the patent according to its scientific characteristics to facilitate further analysis of the invention's obviousness and utility, then situated it within the current and future industrial capability of Canada. The evaluators concluded that there was a low level of inventiveness in the besylate salt because its development was performed using routine techniques. Secondarily, the besylate salt, as a selection patent, did not have physical properties that were *special enough* to distinguish it from other amlodipine salts, also reducing its inventiveness below the common law standard of nonobviousness.

Amlodipine besylate's utility, from an application point of view, was low when compared to the base amlodipine reference standard because both held the same pharmacological traits, verified with clinical evidence. The utility of the besylate salt, compared to other amlodipine salts, was very low because other salts demonstrated

211

similar usability. Third, the utility of the knowledge itself was also low because the knowledge was already within the domain of the person having ordinary skill in the art of medicinal pharmaceutical chemistry. The lack of additional utility, compared to base amlodipine and compared to other salts of amlodipine, warrants a short patent term, or no patent at all, given that additional monopoly protection on the molecule is a societal cost that cannot be overcome through the revelation of additional protected knowledge.

Assessing industry capability, the Canadian pharmaceutical industry already possesses the ability to make a multiplicity of pharmaceutical salts using standard screening techniques, contributing to the low utility associated with protecting the information.<sup>286</sup> Therefore, society's expectations from a patent of the besylate salt of amlodipine are low, meaning that the grant of any terms should be correspondingly low or absent, consistent with the Federal Court's ruling.

# E. Scoring the Patent

The expectations analysis can be scored to create a patent application summary profile. Using the analytical categories, historical patent profiles can be used comparatively to evaluate new patents and set patent terms and expectations. Scoring requires defined parameters for achieving consistency across the various criteria. They can be highly detailed with many criteria, or they can be more general. Scoring may be difficult to normalize from industry to industry but the point of *this* exercise is to not establish a precise score, but to demonstrate how a patent *could* be scored.

<sup>&</sup>lt;sup>286</sup> Note that the industrial size-up is related to the "person having ordinary skill in the art." While the person having ordinary skill in the art does not have regional boundaries, the industrial capability analysis is bounded, meaning that the person having ordinary skill in the art may or may not be present in the patenting region.

The patent criteria measured in the analysis above will be scored on a scale of one to ten. More detailed questioning could break up each criterion into subunits, depending on the level of analysis required. Using five as a reference standard, scores of five to eight will be graded as moderate, while scores of nine to ten will be graded as high. Scores of three to four will be graded as low and scores of zero to two will be graded as extremely low. By applying this generalized grading scheme, less emphasis is applied to the actual numbers, but a general "character" of the patent is created. As more patents are scored, that category becomes a reference standard, more clearly defined but dynamic, evolving with technology and changing government patent policy.

In building a scoring system for patents, scores could eventually be determined relative to other patents already in the database. But initial patents entered into the system would have to be assigned numbers based on objective criteria established by the evaluators. It may be beneficial to take clear cases of obviousness or lack of utility (as in the case of Pfizer's Norvasc), where score assignments at the extreme ends of the scoring spectrum are more apparent and subject to higher levels of consensus among the evaluators.

The amlodipine besylate salt patent application will be fractioned into the same categories presented in the application analysis. While industry capability assesses current capabilities and future capabilities, industry desirability which accounts for subjective policy choices about the importance of various industries to national interests could also be considered. Such subjectivity is included to demonstrate that national goals to bolster certain industries could influence the assignment of patent.

213

## F. Conclusion

The development of an expectations model for the amlodipine besylate patent provided an opportunity to examine how a flexible patent law regime might evaluate the new salt. Creating the regime meant reconsidering already-defined patent terms and redefining them, then formulating patent policies that would shape the determination of the patent grant. Patent classification across industrial and therapeutic systems facilitated comparisons with similar therapeutic agents, creating benchmarks for utility scoring. Comparison with the related amlodipine base formulation also provided an avenue for assessment.

The exercise highlighted the difficulty in creating the system, and one can predict that its administration would be complex. While Machlup stated that eliminating the patent system would be highly irresponsible, redefining how patents are granted would also be highly disruptive to the legal system. But incorporating a system of patent scoring based upon an examination of utility and inventiveness would prove useful to the legal system once a database of the information was created and populated with significant data, helping patent administrators situate any given patent among the prior art. Once a level of fluidity develops with the system, its eventual employment in setting patent terms could start. G. Table 1: Patent Expectations Model Categorization of the Amlodipine Besylate

Salt

Patent Application: Amlodipine Besylate (a salt of amlodipine)

International Patent Classification System (therapeutic classification)	A61P9(10) and (12). Human necessities, medical or veterinary science; hygiene (61), P (specific therapeutic activity of chemical compounds or medicinal preparations, 9 (disorders of the cardiovascular system), 10 (treating ischemic diseases), and 12 (treating hypertension).		
Industrial Classification Sub-industry Sub-sub-industry	Pharmaceutical sciences Pharmaceutical medicinal chemistry Salt formation of a base medicinal drug molecule		
Improvement Classification	Improvement of besylate salt of amlodipine over amlodipine base		
Original or Derivative Classification	Amlodipine besylate is a derivative of original amlodipine base		

Category	Criteria	Criteria Description	Scoring Method	Rank	Categorical Ranking
Novelty	Novelty	Absolute novelty worldwide	Rank as 0 (no absolute novelty) or 10 (achieved absolute novelty)	10	High (absolute novelty achieved)
Nonobviousness	Is the amlodipine besylate salt obvious to a medicinal chemist involved in drug formulation?	Sanofi-Synthelabo four-part test and three-part subtest	Rank from 0 (lowest amount of inventiveness) to 10 (highest)	1	Very low
Nonobviousness	Is the amlodipine besylate salt, as a selection patent, obvious to a medicinal chemist involved in drug formulation?	Sanofi-Synthelabo selection patent test, originating in <i>Re IG</i> <i>Farbenindustrie</i> <i>AG's Patents</i> , 1930, 47 RPC 289 (Ch D).	Rank from 0 to 10	1	Very Low
Utility	Is the patent an attempt to create a blockade of knowledge derived from previous patents?	Use the amlodipine base patent as the reference standard and compare the besylate salt patent application to it; is the comparator patent being sensationalized? The comparator patent is already a derivative of the reference patent.	Rank from 0 to 10 (10 is highest blockade of knowledge)	7	Moderately high

H. Table Two: Scoring the Amlodipine Besylate Salt Patent Application

Category	Criteria	Criteria Description	Scoring Method	Rank	Categorical Ranking
Utility	How much utility <i>in the</i> <i>application of</i> <i>the patent</i> is gained beyond that attained in the reference patent (amlodipine base)?	Utility Test Comparing the pharmacological properties of amlodipine base to amlodipine besylate salt	Rank 0 to 10 (10 is highest utility)	4	Moderately low
Utility	How much utility is present <i>in the</i> <i>knowledge</i> <i>within the</i> <i>patent itself</i> that goes beyond the reference patent (amlodipine base)?	Examining the salt screening and formation of amlodipine besylate, the salt which differs from the amlodipine base; applying the obviousness test, but examining the usefulness of the improvement from the base to the besylate form	Rank 0 to 10 (10 is high utility)	3	Moderately low
Industrial Capability	How does the innovation of the patent fit with current industrial capability in Canada?	Applying the industrial categorization to locate and evaluate whether Canada is already using the technology	Rank 0 (not using at all) to 10 (using or could use regularly). Rank 5 (not using but capability exists)	5	
Industrial Capability	How does the innovation of the patent fit with <i>future</i> industrial capability in Canada?	Using the industrial categorization and evaluating the potential to use the technology in the future	Rank 0 (no future potential for the patent) to 10 (excellent potential for using the patent in the future)	0	Very low

H. Chart One: Profile of the Amlodipine Besylate Salt Patent Application



Assessment Criteria Rank from 0 to 10

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