APPROPRIATING THE TOOLS OF RESEARCH: PATENT LAW AND BIOTECHNOLOGY

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ABSTRACT

Patent law creates economic incentives for individuals and companies to invest in research and development, as well as to disclose publicly and commercialize new inventions. In creating these incentives, patents also impose costs on society through reduced access to new inventions. Generally, the benefits of the patent system outweigh the costs, but in new and rapidly developing industries the patent system itself can act as a barrier to the development of new technologies. This is of particular concern in the biotechnology industry where a proliferation of patents on basic and fundamental research tools risks hindering further innovation.

This problem was first noted by US academics where patent rights are generally considered absolute. In contrast to the US, there are mechanisms already in place within the Canadian patent system that can be used to balance the public interest in access to technologies with the private interest promoted by patents. Two such mechanisms are studied in depth and compared: experimental use and compulsory licensing. Current conceptions of the experimental use exception to patent infringement are inadequate to deal with abuses found when research tools are patented and an expanded experimental use exception is therefore proposed to address the deficiencies found in the current law. In comparison, existing compulsory licensing provisions within the Competition and Patent Acts are generally sufficient to ensure access to needed research tools. The essential facilities doctrine developed through US antitrust laws provides assistance in determining when such compulsory licences should be granted.

Compulsory licensing has certain advantages over an expanded experimental use exception: it would only be used for tools where there are no reasonable alternatives available to the scientist; and it is more likely to be compliant with Canada's international obligations. Ultimately, however, an expanded experimental use exception is preferred since it more quickly and easily puts the tools required for research into the hands of the scientists.

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LIST OF ABBREVIATIONS

AIDS	Acquired Immune Deficiency Syndrome
ALRC	Australian Law Reform Commission
CPC	Community Patent Convention Council Agreement relating to Community Patents No. 89/695/EEC, 15 December 1989, OJ L 401/01.
DNA	Deoxyribonucleic Acid
DRB	Dispute Resolution Body
DSU	*Understanding on Rules and Procedures Governing the Settlement*, Annex 2 to the *Agreement Establishing the World Trade Organization*, 15 April 1994 available at <www.wto.org/wto/english/docs_e/legal_e/legal_e.htm > (accessed June 12, 2005)
EC	European Community
ECJ	European Court of Justice
EPO	Erythropoietin
FTA	Free Trade Agreement
FTC	Federal Trade Commission
GATT	General Agreement on Tariffs and Trade
HGS	Human Genome Sciences
HIV	Human Immunodeficiency Virus
i.e.	*id est*; in other words
IP	Intellectual Property
MTA	Material Transfer Agreement

NAFTA	*North American Free Trade Agreement Between the Government of Canada, the Government of Mexico and the Government of the United States*, 17 December 1992, 32 I.L.M. 289 (entered into force 1 January 1994).
NIH	National Institute of Health
OECD	Organisation for Economic Co-operation and Development
Paris Convention	*Paris Convention for the Protection of Industrial Property*, 20 March 1883, 828 U.N.T.S. 305 available at <ww.wipo.org/eng/iplex/wo_par0_.htm> (accessed June 12, 2005).
PCR	Polymerase Chain Reaction
R&D	Research and Development
TRIPs Agreement	*Agreement on Trade-Related Aspects of Intellectual Property Rights*, Annex 1C to the *Agreement Establishing the World Trade Organization*, 15 April 1994, 33 I.L.M. 1197 (entered into force 1 January 1996) available at <www.wto.org/wto/english/docs_e/legal_e/legal_e.htm> (accessed June 12, 2005).
UPOV	Union pour la protection des obtentions végétales also known as International Union for the Protection of New Varieties of Plants
US	United States
WTO	World Trade Organization

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If I have seen further, it is by standing on the shoulders of giants.

Sir Isaac Newton (1642-1727)
letter to Robert Hooke, 1676

CHAPTER I
INTRODUCTION

1.0 The Biotechnology Industry

The 21st century has been hailed as the biotech century as a result of the considerable advances that are made almost daily in both our understanding of the genetic resources of this planet, as well as our ability to manipulate them. The Organisation for Economic Co-operation and Development (OECD) defines biotechnology as follows: "The application of Science & Technology to living organisms as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services."[1] The potential of biotechnology is most pronounced in the medical field where medical uses for genes and genetic information include: diagnostic genetic testing; gene therapeutics based upon the introduction of new genes; gene regulators which function by replacing command sequences; protein therapeutics which are medicinal proteins produced in laboratories; pharmacogenetics;[2] and small molecule drugs discovered through the use of

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[1] Organisation for Economic Co-operation and Development, *Scientific, Industrial and Health Applications of Biotechnology – A Statistical Definition* available at <www.oecd.org/document/42/0,2340,en_2649_34537_1933994_1_1_1_1,00.html> [accessed January 20, 2005].

[2] Pharmacogenetics is an exciting new field where examination of a patient's gene may someday allow health care providers to tailor the treatment to meet that patient's specific needs with fewer side-effects and costs: M. Malinowski & M. O'Rourke, "A False Start? The Impact of Federal Policy on the Genotechnology Industry" (1996) 13 Yale Journal On Regulation 162 at 177; Industry Canada, *The Biopharmaceutical Industry: Overview, Prospects and Competitiveness Challenges* (2001) at 32 available at <strategis.ic.gc.ca/epic/internet/inbio-pha.nsf/en/h_df00004e.html> (accessed January 25, 2005) [hereinafter Industry Canada Report].

biotechnology techniques and disease targets.[3] Although biotechnology also has the potential to affect agriculture, forestry and the fisheries, this thesis will focus on the medical applications of biotechnology.

In 1982, the first drug produced by genetic engineering, human insulin, was placed on the market. By 2001, biopharmaceuticals accounted for 6 of the top 50 selling drugs.[4] Such growth could not have occurred were it not for patents: patents are widely acknowledged as providing the basis for the significant growth in biotechnology industry over the last two decades[5] and this is reflected in the number of patent applications filed. For example, in 1985, 2000 biotechnology patents were issued in the US whereas by 2000, this number had grown by more than 650%.[6] In Canada, there are more than 2,500 applications every year for patents related to biotechnology.[7]

Of the 30,000 genes in the human genome, an estimated 10% are thought to correspond to potential drug targets for diseases of socio-economic importance.[8] However, gene sequence data by itself does not provide much information about a gene's particular relationship to disease. Instead, the focus of research activities is on the function of the gene, recognizing that most diseases result from protein imbalances or

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[3] L.L. Hill, "The Race to Patent the Genome: Free Riders, Hold Ups, and the Future of Medical Breakthroughs" (2003) 11 Texas Intellectual Property Law Journal 221 at 223; Malinowski *ibid.* at 176.

[4] Industry Canada Report *supra* note 2 at 4.

[5] J.P. Walsh, A. Arora & W.M. Cohen, "Effects of Research Tool Patents and Licensing on Biomedical Innovation" in W.M. Cohen & S.A. Merill, eds., *Patents in the Knowledge-Based Economy* (Washington: National Academy of Sciences, 2003) 285 at 287.

[6] Walsh *ibid.* at 293.

[7] BIOTECanada, *Mighty Maples from Little Saplings Grow: A Working Paper for a Strategic Partnership with Canadian Biotechnology* (2004) available at <www.biotech.ca/EN/publications.html> (accessed Dec. 15, 2004) [hereinafter BIOTECanada Report].

[8] Hill *supra* note 3 at 229.

aberrations in protein-protein interactions.[9] All current pharmaceuticals are active against approximately 500 proteins implicated in diseases, though genomics is expected to lead to the discovery of up to 10,000 new protein targets implicated in disease.[10]

Now that the human genome has been sequenced, the new phase of research and development (R&D) has been referred to as the post-genomic era.[11] This era can be categorized into the following four main research areas:

1. structural genomics and proteomics: the assignment of gene sequences to particular proteins and the characterization of those proteins;
2. functional genomics and transcriptomics: the elucidation of which genes are turned on or off at particular stages of the human life cycle and the detection of variation between individuals;
3. targeted drug discovery and pharmacogenomics;
4. enabling technology: continually evolving enabling technologies that allows the previous three research categories to proceed.[12]

Basic research, also called fundamental or upstream research, generally relates to activities that fall within areas 1 and 2 and can be defined as research that focuses on the formulation of conceptual schemes, their development and their testing. Basic research is relatively theoretical in nature and a significant period of time may elapse before any practical applications can be realized. Research may even be considered to be basic

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[9] Industry Canada Report *supra* note 2 at 31.
[10] Industry Canada Report *ibid.* at 31: most diseases are due to protein imbalances or aberrations in protein-protein interactions.
[11] D. Nicol & J. Nielson, "The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development" (2001) 23 Sydney Law Review 347 at 351.
[12] Nicol *ibid.* at 351-352.

when it suggests a number of practical applications to the extent that a significant time period is still needed before the practical uses can be realized.[13] Applied or downstream research is more focused on developing an end-product, medicine or therapy and tends to fall within research areas 2 and 3. New research tools and techniques from category 4 are instrumental to the development of all the areas of biotechnology and significantly contribute to the productivity of biomedical research.[14]

Direct government support has been instrumental to the development of the biotechnology industry though it tends to be focused on upstream or basic research. In comparison, industrial investments in R&D tend to be focused on downstream or applied research.[15] A 1994 US study showed that industry funding of basic research in the biopharmaceutical area only amounted to about 12% of all such funding; government funding accounted for the remainder.[16] Blurring the generalization that government funds basic research and industry funds applied research is that the relationship between basic and applied research is particularly close in the biotechnology industry.[17]

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[13] A.K. Rai, "Regulating Scientific Research: Intellectual Property Rights and the Norms of Science" (1999) 94(1) Northwestern University Law Review 77 at 77.
[14] Walsh *supra* note 5 at 335.
[15] A.K. Rai, "Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust" (2001) 16 Berkeley Technology Law Journal 813 at 819; I. Cockburn & R. Henderson, "Public-Private Interaction in Pharmaceutical Research" (1995) 93 Proceedings of the National Academy of Science USA 12725 at 12726.
[16] J.M. Golden, "Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System" (2001) 50 Emory Law Journal 101 at 138-139. 12% of all funding still amounted to about $1.5 billion US.
[17] F.M. Scherer, "The Economics of Human Gene Patents" (2002) 77 Academic Medicine 1348 at 1361; R.S. Eisenberg, "Proprietary Rights and the Norms of Science in Biotechnology Research" (1987) 97 Yale Law Journal 177 at 195 [hereinafter Eisenberg: Norms of Science article]; R.S. Eisenberg & R.R. Nelson, "Public vs. Proprietary Science: A Fruitful Tension?" (2002) 77(12) Academic Medecine 1392 at 1393 [hereinafter Eisenberg: Fruitful Tension article].

Table 1 provides a summary of several recent initiatives taken by governments in nine different countries to support their local biotechnology industry. The United States government has been particularly active in supporting their biotechnology industry, spending more than 5 times as much as the Canadian government on a per capita basis.[18]

Table 1 Worldwide Biotechnology Initiatives[19]

Country	Program
Canada	In 2001-2002 government expenditures on biotech were $513 million[20]
US	The US Homeland Security initiative is pumping billions into biotechnology, providing fuel for the industry's development. The National Institutes of Health (NIH) budget was doubled to $23 billion (US) for basic research.
France	In December 2002, announced a tax-cutting plan that would exempt biotech companies from a 60% surcharge on salaries and 100% relief on corporate taxes.
Germany	Injected billions of dollars into biotech startups. Approximately 20% of Europe's biotech concerns are based in Germany.[21]
China	Spent over $180 million (US) between 1996 and 2002 to develop a life science industry. Funding is expected to increase to $600 million (US) by 2005.
India	Created a separate Dept. of Biotechnology in 1986, which is working to capitalize on the expected biotech wave and leverage the countries' successes in IT.
Malaysia	BioValley project to be ready by 2006. Hopes to attract 150 biotech companies and pull in US$10.5 billion in investment over the next decade
Singapore	$1.7 billion (US) over five years to make it Asia's global hub for biomedical sciences. Targeted an output of $7 billion (US) by '05.
Taiwan	In May of 2002, Taiwan pledged NT $52 billion in government support over the next five years. Hopes that private investment will be double that figure over the same period.

[18] Industry Canada Report *supra* note 2 at 16.

[19] Reproduced from BIOTECanada Report *supra* note 7.

[20] Government funding in Canada is divided between the Canadian Institutes of Health Research (formerly the Medical Research Council); the Network Centres of Excellence Program; and Genome Canada; the Canadian biotechnology industry also benefits from federal and provincial R&D tax incentives that have been characterized as being among the most generous in the world: Industry Canada Report *supra* note 2 at 6, 16.

[21] Although government subsidies played a significant role in the growth of the biotechnology sector in Germany, most of the firms are small and have a much smaller market capitalization and fewer drugs in clinical development than in the United Kingdom: Industry Canada Report *ibid.* at 11.

The biotechnology industry is dominated by many small, privately held companies that depend heavily on private funding to survive.[22] Venture capital firms commonly provide most of the industry's startup funds and initial operating capital in exchange for stock and some degree of management control.[23] Before the company can market a product derived from their research, virtually all new biotechnology companies require significant additional funding. This funding typically comes in one of three forms: by entering into a research collaboration agreement with another company; by making an initial public offering of stock; or by licensing their intellectual property to other companies.[24]

The biotechnology industry is also growing rapidly in Canada. More than 18,000 products and processes were being developed in Canada in 2001. Revenues from the biotechnology industry were over $3.6 billion in 2001, a 400% increase over 1997. Compared to other countries in the world, the biotechnology industry in Canada is ranked third behind only the United States and the United Kingdom in generating revenues. While revenues more than quadrupled, spending on biotech R&D nearly tripled, from about $494 million in 1997 to more than $1.3 billion in 2001. Canada is now ranked first in the world in R&D expenditure per employee.[25] Despite this impressive Canadian growth, the biotechnology industry is still in its infancy. While Canada may be third in revenues, Canada has the second highest number of companies after only the United

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[22] D.C. Hoffman, "A Modest Proposal: Toward Improved Access to Biotechnology Research Tools by Implementing a Broad Experimental Use Exception" (2004) 89 Cornell Law Review 993 at 1021-1022; K. Boyd, "Nonobviousness and the Biotechnology Industry: A Proposal for a Doctrine of Economic Nonobviousness" (1997) 2 Berkeley Technology Law Journal 311 at 313.
[23] Hoffman *ibid.* at 1021-1022; Boyd *ibid.* at 313, 316.
[24] Hoffman *ibid.* at 1021-1022.
[25] BIOTECanada Report *supra* note 7.

States. This means that many of those companies are still small and are not making any revenues. With approximately 400 companies located in Canada, approximately two thirds and have not yet put a product through the lifecycle to commercialization.[26] Table 2 provides a summary of the state of the biotechnology industry in Canada.

Table 2 Canadian Biotechnology Industry Profile[27]

	1997	1999	2000
Number of companies	282	358	375
Number of companies per size of company:			
Small	214	270	267
Medium	37	51	62
Large	31	37	46
Number of public companies	59	N/A	94
Revenues declared (CDN millions)	$813	$1,900	$3,600
Number of firms declaring revenue	176	225	252
R&D expenditures (CDN millions)	$494	$1,210	$1,337
Products and processes on the market	1,752	6,597	18,020
Employment in biotech-related companies	N/A	~62,000	62,242

A typical company is a small- or medium-sized firm with a high cash burn rate dealing with the costly and time-consuming product development and review process. The size of the companies tend to be small with 47% having 1-10 employees and 83% of the companies having less than 50. 69% were focused on therapeutics and diagnostics in 2003 and 80% of the companies in the biotechnology industry are in early stages. Most

[26] BIOTECanada Report *supra* note 7.
[27] Reproduced from BIOTECanada Report *ibid.*

companies, especially in the health and therapeutics sectors, are years away from making revenues.[28]

One of the features of the biopharmaceutical innovation is the length, expense and risk of the cumulative process that leads to a drug that is ready for clinical testing. The time from initial discovery of a new molecule to market entry of a new drug is seven to twelve years and may cost as much as $400 million. For every 10,000 drug candidates created in the lab, only 1,000 will be tested in animals and of those 1,000, only one will eventually reach the market.[29] Human testing alone can take two to five years.[30] Because of the cost and delay, few biotechnology startups ever get a product onto the market. For many companies, a patent portfolio is the only potentially lucrative asset available for exploitation and it is generally accepted that most such firms will fail.[31] The typical strategy is to take a product through to phase II of clinical testing to demonstrate proof of concept before finding a partner for the more comprehensive phase III clinical testing.[32] In addition to supplying additional financing to complete phase III testing, the partner will typically provide manufacturing and marketing expertise rarely found in the biotechnology start-up company.

1.1 The "Tragedy of the Anticommons"

Patents have played an important role in the development of the biotechnology industry: in attracting capital investments; and in protecting competitive advantages.

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[28] BIOTECanada Report *supra* note 7.
[29] Malinowski *supra* note 2 at 205.
[30] Malinowski *ibid.* at 205; Rai *supra* note 15 at 822.
[31] Hoffman *supra* note 22 at 1022; Golden *supra* note 16 at 118.
[32] Industry Canada Report *supra* note 2 at 11.

This does not mean, however, that all patents are equally important. For example, the argument for broad protection of early-stage upstream invention is conceptually distinct from the argument for broad protection of downstream drugs.[33] Thus the ample empirical evidence that patents on downstream drugs are crucial for the industry does not bear on the case for patents on early-stage invention.[34]

A widespread view is that the patent system is in danger of stifling further R&D.[35] In particular, the concern is that broad patent rights on upstream innovation may limit the use of these discoveries in subsequent innovation (follow-on research) and limit the pace of innovation and the development of medical treatments.[36] This concern is particularly acute when patents cover a particular receptor implicated in a disease.

The use of a patent to prevent follow-on research seems counter to the overall goal of the patent system to encourage the progress of science.[37] For example, consider the gene patent application held by Human Genome Sciences (HGS) on the gene for the CCR5 protein.[38] When HGS filed for the gene patent, they knew little about the ultimate role of the protein though they did speculate about the protein's possible role in diseases ranging from cancer to allergies to arthritis. At least four different research teams

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[33] Rai *supra* note 15 at 828.
[34] Rai *ibid.* at 828.
[35] C.M. Correa, "Internationalization of the Patent System and New Technologies" (2001-2002) 20(3) Wisconsin International Law Journal 523 at 536.
[36] Walsh *supra* note 5; Eisenberg *supra* note 42 at 1383; Correa *supra* note 68 at 529-530.
[37] J. Barton, "Patents and Antitrust: A Rethinking in Light of Patent Breadth and Sequential Innovation" (1997) 65 Antitrust Law Journal 449 at 454; see also the U.S. Constitution, Article I, Section 8: "to promote the progress of science and useful arts by securing for limited times to authors and inventors the exclusive rights to their respective writings and discoveries" and the TRIPs Agreement, art. 7, *infra* Ch. III notes 251-254 and accompanying text.
[38] CA 2,399,593, Roschke *et al.*, *Antibodies to CCR5*, pending application, PCT filing date Feb. 9, 2001.

subsequently found that the protein plays a role in HIV infection and each of those four teams are seeking patent protection covering their research. If these patents are granted, a blocking situation may arise since, absent a licence, neither HGS nor any of the improvers, nor any other company, would be able to conduct further research on AIDS that uses the CCR5 protein without infringing one or more patents.[39] The CCR5 protein represents only one possible disease target. This is particularly problematic as any further research may result in the discovery of a small-molecule pharmaceutical that does not itself infringe any of the patents.[40]

When there are numerous patent rights claiming separate building blocks necessary for some product or line of research, a separate licence agreement or material transfer agreement (MTA) must be negotiated for each tool. The transaction costs to separately negotiate all of the necessary patent rights can escalate.[41] Negotiations may either break down or licence fees may be stacked to the point of overwhelming the value of the ultimate product. Michael Heller and Rebecca Eisenberg have argued that this may be inhibiting further research in biomedicine and have described this in their seminal 1998 article as a "tragedy of the anticommons" which is described as follows: [42]

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[39] A classic "blocking" situation involves grant of an original patent, called the "dominant" patent, by a first firm and then grant of an improvement patent, called the "subservient" patent, by a second firm. These patents are "blocking" since the first firm cannot practice the improvement without a licence from the second firm but neither can the second firm without a licence to the dominant patent. See also H. Chang, "Patent Scope, Antitrust Policy, and Cumulative Invention" (1995) 26 Rand Journal of Economics 34 at 36; Rai *supra* note 15 at 847.

[40] Barton *supra* note 37 at 454.

[41] Walsh *supra* note 5 at 287; A.K. Rai, "Intellectual Property Rights in Biotechnology: Addressing New Technology" (1999) 34 Wake Forest Law Review 827 at 839-40.

[42] M. Heller & R.S. Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research" (1998) 280 Science 698; Scherer *supra* note 17 at 1363; Walsh *ibid.* at 287.

> The tragedy of the anticommons refers to the more complex obstacles that arise when a user needs access to multiple patented inputs to create a single useful product. Each upstream patent allows its owner to set up another tollbooth on the road to product development, adding to the cost and slowing the pace of downstream biomedical innovation.

Heller and Eisenberg argue that biomedical research and innovation is particularly susceptible to breakdowns and delays in negotiations for three reasons. Firstly, there are typically numerous rights holders with various claims on the inputs into the discovery process or on elements of a given product. This increases the likelihood that the licensing and transaction costs of bundling those rights are greater than the ultimate value of the innovation.[43] Secondly, when those rights are held by different kinds of institutions with different goals, norms and managerial practice and experience, the difficulty and cost of reaching agreement increases. Such heterogeneity is typical of the biotechnology field with the presence of large pharmaceutical firms, small biotechnology start-up firms, large chemical firms (e.g. DuPont and Monsanto) and universities.[44] Thirdly, there is uncertainty over the value of rights. This latter problem is common when considering the value of a patent right but is particularly acute for upstream discoveries and research tools.[45] The result is a breakdown in negotiations over rights, royalty stacking and "excessive" licence fees.[46]

Robert Merges and Richard Nelson have also raised concerns about the restriction of access to upstream discoveries. From a social policy perspective, Merges and Nelson point out that there is nothing inherently wrong with limiting access to intellectual property for the purposes of subsequent discovery as long as the patent holder, or

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[43] Heller *ibid.*
[44] Heller *ibid.*
[45] Heller *ibid.*; Walsh *supra* note 5 at 290.
[46] Walsh *ibid.* at 297.

licencee, can exploit the tool or input as fully as other potential downstream users. Unfortunately, this is unlikely for several reasons. Firstly, firms and universities are limited in their capabilities. Secondly, there is a significant amount of uncertainty about the best way of building on prior discovery and as a result, the input or discovery is best exploited by taking a variety of approaches. No single firm, or even a small number of firms, are likely to be able to fully explore, or possibly even conceive of all the approaches.[47]

The problem of limited lines of attack may be greater when exclusive access to a set of targets is held by a smaller firm with limited capabilities. For example, many university technology transfer offices license biomedical inventions to small firms on an exclusive basis. These small firms are likely to have particular strengths and capabilities in exploiting targets and to use these strengths exclusively. Conversely, they are likely to to ignore approaches where they lack such strengths.[48]

Stronger patent rights on upstream discoveries mean that efficient licensing is critical to follow-on innovation. This leads to a greater sensitivity in the industry to any market failures in licensing.[49]

These concerns are supported by an empirical study conducted in 1997 and 1998 by the National Institutes of Health (NIH) Working Group on Research Tools. The study documented frustration with the high transaction costs of licensing negotiations over

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[47] Walsh *ibid.* at 290-291. This argument follows the economics of innovation theories discussed in detail *infra* Ch. II notes 149-164 and accompanying text.
[48] Walsh *ibid.* at 311.
[49] M. Lemley, "The Economics of Improvement in Intellectual Property Law" (1997) 75 Texas Law Review 989 at 998-999.

research tools. However, even low-cost transactions may not go forward due to the difficulty in accurately predicting which research will ultimately become valuable.[50]

One strategy of dealing with excessive negotiation costs is defensive patenting. Defensive patenting involves exhaustively patented every component of the firm's proprietary technology. The firm then has a stronger bargaining position when access to another firm's technology is needed. Patents can be cross-licensed at little cost to either firm. This strategy also minimizes the chances of an expensive, time-consuming infringement dispute since each side would have a substantial patent portfolio, and thus each side would have an incentive to settle and cross-license patent rights.[51] However, defensive patenting also imposes significant costs. Filing a relatively straightforward patent in the US typically costs $10,000 to $15,000 in attorney, filing, issue and maintenance fees. Expanding coverage to ten European countries over the life of the patent routinely costs in excess of $95,000.[52] This compares with litigation costs of millions of dollars. Patenting is thus seen as a legitimate strategy to reduce negotiation costs and avoid disastrous litigation costs. Unfortunately, the resulting "patent thicket" presents a significant barrier for new entrants as well as university researchers who do not have their own extensive patent portfolio.[53]

The increased emphasis on patenting all aspects of biotechnology, particularly within the university context, will also have a negative effect on the traditional public

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[50] National Institutes of Health, *Report of Working Group on Research Tools*, Presented to the Advisory Committee to the Director (June 4, 1998) available at <www.nih.gov/news/researchtools> (accessed June 14, 2005) [hereinafter NIH Report]; Rai *supra* note 15 at 832.
[51] Hoffman *supra* note 22 at 1024.
[52] Hoffman *ibid.* at 1026.
[53] Hoffman *ibid.* at 1024-1025.

sector values that have been the drivers of basic scientific and technological research. With universities increasingly patenting discoveries, university administrators have developed vested interests in intellectual property rights. Such an intrusion of proprietary rights on basic science ultimately threatens the general commitment to free disclosure among scientists.[54]

John P. Walsh, Ashish Arora, and Wesley M. Cohen recently surveyed pharmaceutical firms, biotech firms, universities, patent lawyers and government and trade association personnel in order to try to ascertain whether anticommons failures have occurred and if so, the extent of the problem.[55] In general, the results of this survey were encouraging in suggesting that there was not an extensive anticommons problem in biotechnology.[56] For example, although most R&D executives report that the number of licences needed for a new project has increased over the past decade, that number is still considered manageable.[57] Also, royalty stacking, though presented as a potentially serious issue, has not in fact been a threat to on-going R&D efforts for several reasons. Most importantly, the total of fees paid typically does not push a project into a loss and if the stacking of fees threatens a loss, compromises tend to be struck across the various IP

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[54] Golden *supra* note 16 at 174.
[55] Walsh *supra* note 5 at 292.
[56] The ALRC also believes that there is little evidence that gene patents have had any significant adverse effect to date on the conduct of genetic research in Australia. The evidence that does exist of an anticommons is limited and anecdotal though the ALRC also recognizes that the situation could easily change, particularly if the participants become more active in enforcing their patent rights: Australian Law Reform Commission, *Genes and Ingenuity: Gene Patenting and Human Health* (ALRC99) (2004) available at <www.alrc.gov.au/inquiries/title/alrc99/index.html> (accessed Dec. 15, 2004) [hereinafter ALRC Report] at 12.78-12.80.
[57] Walsh *supra* note 5 at 295.

holders. To the extent that such problems might occur, they tend to be anticipated.[58] The more difficult question of what projects were not initiated due to the anticipation of royalty stacking was addressed and it was suggested that this would not be a significant problem either.[59] Firms have also developed a series of "working solutions" to avoid any anticommons problems which include inventing around, ignoring patents, going offshore where there are no patent rights, creating public databases and challenging patents in court and licensing when necessary.[60]

The survey concluded that the anticommons problem has not been particularly problematic and that access to foundational upstream discoveries has not yet impeded biomedical innovation significantly. Nevertheless, the study warned that the prospect for such harms exists and ongoing scrutiny is warranted.[61]

Despite these encouraging conclusions, it was recognized that dealing with research tool patents caused delays and increased the cost of research.[62] Similarly, the working solutions imposed social costs even if the problem was not as extensive so as to create an "anticommons."[63]

Some commentators have argued that the transaction costs associated with a patent thicket will present only a temporary problem, since owners of such rights who are repeat players in a given market will develop market mechanisms to address these

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[58] Walsh *ibid.* at 299-300.
[59] Walsh *ibid.* at 303.
[60] Walsh *ibid.* at 324.
[61] Walsh *ibid.* at 331.
[62] Walsh *ibid.* at 314.
[63] Walsh *ibid.* at 333.

difficulties.[64] Patent pools represent one such example where patent owners have reduced transaction costs by pooling patent rights and establishing efficient cross-licensing packages. However, there are three reasons why patent pools are unlikely to be more than an isolated occurrence in the biotechnology industry. Firstly, these types of arrangements typically emerge in industries where the parties have long-term relationships and are relatively homogenous.[65] In other words, patent pools are unlikely to occur in a biotechnology industry composed of universities, non-profit organizations, small start-up companies and big pharmaceutical companies. Secondly, the likelihood of patent pools developing also depends on how much agreement there is among parties on valuating the different patent rights. This has been particularly problematic in the assessment of research tools in the biotechnology industry.[66] Finally, the lack of a substitute for certain tools may increase the leverage of the patentee and thereby aggravating any hold-out problem. A simple free-market solution is thus unlikely to arrive in response to a "tragedy of the anticommons," absent any governmental intervention.

One market solution has been the use of "reach-through" royalties on research tools. In a reach-through royalty, the patentee on the research tool allows royalty-free use of the tool in exchange for a royalty on any products invented as a result of use of the

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[64] Rai *supra* note 41 at 840; R.P. Merges, "Contracting Into Liability Rules: Intellectual Property Rights and Collective Rights Organizations" (1996) 84 California Law Review 1293 at 1340-1347.
[65] Scherer *supra* note 17 at 1363; Rai *ibid.* at 840; A.K. Rai, "Genome Patents: A Case Study in Patenting Research Tools" (2002) 77 Academic Medicine 1368 at 1371; Rai *supra* note 13 at 131-133.
[66] Rai *supra* note 13 at 133; NIH Report *supra* note 50.

tool.[67] While the patentee may be foreclosed from unilaterally claiming reach-through royalties through the patent grant, there is no reason why royalties cannot be negotiated between the parties in this manner. The patentee thereby loses a guarantee of a small royalty on use of a tool in exchange for the chance to share in the much more lucrative product. While this also allows access to the tool with minimal up-front cost, reach-through royalties are generally unpopular among tool users: with a patent thicket and a multitude of patent rights and patent holders, reach-through royalties may result in conflicting obligations being owed to different patent holders. Mounting royalty obligations will also reduce the value of any patent rights and this may adversely affect the ability of the firm to partner, or otherwise obtain additional financing to bring the invention to market. There will also likely be increased transaction costs in tracing a particular discovery to prior use of a research tool and ensuring that appropriate reach-through royalties are paid.[68]

Even if the problems have not developed to the point of creating an "anticommons", there are still significant concerns about patenting research tools, since patents by their nature are designed to restrict access to the underlying invention. A pilot survey conducted by Jon Merz of the University of Pennsylvania reported that of seventy-four laboratory physicians surveyed, patents caused 25% to abandon a clinical test that they had developed and 48% not to develop a clinical test at all.[69] Jon Merz also

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[67] R.S. Eisenberg, "Why the Gene Patenting Controversy Persists" (2002) 77(12) Academic Medicine 1381 at 1384.
[68] Eisenberg *ibid.* at 1384; Heller *supra* note 42.
[69] Golden *supra* note 16 at 175.

reviewed a sample of 27 disease gene patents and found that 14 of them had been exclusively licenced as of the date of the survey.[70]

The risks of patents on research tools creating a patent thicket or an anti-commons has led to calls in the United States by the National Institute of Health for the free dissemination of the tools and subject matter of basic science. These guidelines condemn reach-through royalties or product rights, unreasonable restraints on publication and academic freedom, and improper valuation of tools. The guidelines also advise industrial firms to minimize the encumbrances on the academic use of research tools.[71] Many major research universities have similarly adopted policies providing for a presumption against obtaining patents on basic molecular biology research when it is far removed from specific commercial development.[72]

Pharmaceutical firms have also joined in the call for a strong public domain and limited patent rights in disease targets. For example, private pharmaceutical firms sponsored the Merck Genome Initiative and the SNP Consortium in order to make DNA sequence information freely available.[73]

Before progressing any further, it is important to clearly define what is meant by a research tool. This is done in the next part 1.2 of this chapter.

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[70] Golden *ibid.* at 198.
[71] NIH Report *supra* note 50; Golden *ibid.* at 176; Rai *supra* note 65 at 1371 .
[72] Examples of such universities include MIT, Harvard University and Standford University: Rai *supra* note 13 at 112-113; to the extent these universities follow these guidelines and it is repeated by other institutions, this voluntary approach may address many of the potential abuses since United States universities are the leading holders of human-gene patents, see L. Bendekgey & D. Hamlet-Cox, "Gene Patents and Innovation" (2002) 77(12) Academic Medicine 1373 at 1378, though it should also be noted that the potential abuses are not limited to gene patents.
[73] Eisenberg *supra* note 67 at 1384.

1.2 Definition of Research Tools

There are a myriad of different types of research tools used in biotechnology. Examples include animal models,[74] cell lines,[75] monoclonal antibodies, reagents, growth factors, tissue samples, methods for introducing DNA into cells, clones and cloning tools (such as PCR), methods, laboratory equipment and machines, databases and computer software, receptors[76] and combinatorial chemistry libraries.[77]

While downstream researchers may view such inventions as essential research inputs, upstream patent holders may view research tools as valuable end products in themselves.[78] A further complicating factor is that some research tools have uses other than in research. For example, a patented DNA sequence may be used as part of a diagnostic test, as well as in research to better understand the role of the relevant gene in disease.[79] This was seen in 2001, when Myriad Genetics, Inc. obtained four patents covering the BRCA1 and BRCA2 genes that have been implicated in breast cancer.[80]

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[74] E.g. CA Patent No. 1,341,442, Leder *et al.*, *Transgenic Animals*, Oct. 7, 2003; *Harvard College v. Canada (Commissioner of Patents)*, [2002] 4 S.C.R. 45 [hereinafter *Harvard College*].

[75] E.g. US Patent No. 5,061,620, Tsukamoto *et al.*, *Human hematopoietic stem cell*, Oct. 29, 1991 cited in Barton *supra* note 37 at 449.

[76] E.g. US Patent No. 5,328,987, Maliszewski, *IgA Fc receptors*, July12 1994 cited in Barton *ibid.* at 449.

[77] Industry Canada Report *supra* note 2 at 25; NIH Report *supra* note 50; ALRC Report *supra* note 56.

[78] ALRC Report *ibid.* at 12.5; NIH Report *ibid.*

[79] ALRC Report *ibid.* at 12.37.

[80] CA 2,196,797, Shattuck-Eidens *et al.*, *In-Vivo Mutations and Polymorphisms in the 17-Q Linked Breast and Ovarian Cancer Susceptibility Gene*, Oct. 10, 2000; CA 2,196,795, Skolnick et al., *Method for Diagnosing a Predisposition for Breast and Ovarian Cancer*, April 3, 2001; CA 2,196,790, Skolnick et al., *17Q-Linked Breast and Ovarian Cancer Susceptibility Gene*, Oct. 10, 2000; CA 2,239,733, Kamb *et al.*, *Chromosome 13-Linked Breast Cancer Susceptibility Gene*, April 3, 2001; E.R. Gold, "From Theory to Practice: Health Care and the Patent System" in *Health Law Journal Special Edition 2003* (Edmonton: University of Alberta, 2003) 21 at 34-35; B. Williams-Jones, "History of a

Myriad Genetics obtained patent claims directed to the genes themselves, a diagnostic test using the genes to determine susceptibility to cancer as well as methods for screening for cancer therapeutics using the genes. This latter use is as a research tool for the discovery of a cure for cancer though Myriad Genetics' main business model is based on diagnostic testing of the gene. As a further complication, clinical diagnostic testing may be crucial in better understanding the gene and its role in cancer.[81] In other words, in some contexts diagnostic testing may be used as a clinical procedure to determine a particular patient's predisposition for disease and in other contexts, the same diagnostic testing may be used as part of a research study to better understand the disease. Generally speaking, the same technique may be a research tool in one context and a downstream, end-product in another.

One definition of research tools encompassed any tangible or informational input into the process of discovering a drug or any other medical therapy or method of diagnosing a disease.[82] The Australian Law Reform Commission (ALRC) defined research tools as resources used by scientists where those resources have no immediate therapeutic or diagnostic value.[83] The ALRC has proposed categorizing the different types of research tools as follows:[84]

1. Research Techniques: laboratory techniques that molecular biologists use in research, such as the Cohen-Boyer techniques (for gene-splicing) and

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Gene Patent: Tracing the Development and Application of Commercial BRCA Testing" (2002) 10 Health Law Journal 123.

[81] Walsh *supra* note 5; Eisenberg *supra* note 67.

[82] Walsh *ibid.* at 287.

[83] ALRC Report *supra* note 56 at 12.28-12.29.

[84] ALRC Report *ibid.* at 12.28-12.29.

the polymerase chain reaction (PCR) methodology (for DNA amplification).

2. Research Consumables: enzymes or reagents that are used in the laboratory, such as Taq polymerase (used in PCR) and restriction enzymes (used in cloning and other applications).

3. Disease Targets: genetic materials (genes or proteins) that are implicated in disease and targeted in research, for example by developing therapeutics (e.g. EPO) or small-molecule drugs (e.g. for the COX-2 enzyme for pain, CCR5 receptor for HIV, or telomerase for cancer).

This is a useful categorization of the different research tools, particularly between research techniques and consumables and maintains a distinction commonly seen in patent law with respect to the types of claims granted, namely process claims and product claims.

One commentator, Arti Rai, developed two categories for research tools depending on whether the tool is pioneering or not. Pioneering research tools are fundamental research platforms that open up new and uncharted areas of investigation.[85] A contemporary example provided by Rai of such a fundamental research platform included human embryonic stem cell lines. A research tool would be fundamental if there are no other reasonable alternative tools available to the researcher to achieve his goals in an efficient manner. Under this definition, some disease targets may be such a fundamental research platform but typically would not.[86] For example, the corresponding rat gene may be an acceptable, if imperfect, substitute in some situations. If so, the

[85] Rai *supra* note 65 at 1369.
[86] Rai *ibid.* at 1369.

human gene would not be a pioneering research tool. This distinction adopted by Rai is also reflected by the court system that grants broader patent scope to pioneering inventions.[87]

A third way to distinguish between different research tools is to consider whether the research tool is best prepared by the researchers themselves (a researcher-supplied tool) or whether the tool is best supplied by an outside firm for the researcher (a market-supplied tool). For example, in preparing Taq polymerase for PCR, there may be significant efficiencies of scale so that a firm can benefit from supplying the research consumable to the researcher. Similarly, there may be specialized equipment for the PCR technique that can be sold to the researcher that makes the technique simpler and more efficient. Without commercial supplies, the researcher may still be able to perform the PCR experiment but it would likely involve more time and money to accomplish the same goal. In other cases, specialized equipment or consumables can be developed just as easily by the researcher from standard equipment and supplies such that there would not be any benefit to the researcher from obtaining the tool from the market. This distinction also holds with regards to research techniques. For example, there may be a significant sunk-cost in obtaining specialized equipment needed to perform the technique, such that it becomes more efficient for a single firm to purchase the equipment and to then provide the technique for researchers as a commercial service. In other cases, there are no efficiencies of scale or significant barriers and the technique is easily performed by the researcher.

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[87] *Proctor v. Bennis* (1887), 36 Ch. D. 740 (C.A.); compare with K. Feng, "*Plant Genetic Systems v. DeKalb*: The Pioneer Doctrine Cannot Substitute For Defective Enablement" 45(1) Jurimetrics 93.

In comparison, disease targets remain in a category by themselves. Typically, disease targets are the subject of research and used to gain a better understanding of the molecular basis of disease and the search for new therapeutic targets.[88] While most drugs on the market interact with proteins, a patented disease target may be either the protein or the genes that encode for the protein.

These three different ways of categorizing research tools will be used throughout this thesis. In some contexts, it will be more useful to refer to market-supplied tools whereas in other contexts the main issue may be whether the tool is pioneering or a research consumable.

1.3 The Patent System

Patents may be issued at different stages of research from foundational upstream discoveries to downstream products. Patents may also be issued on research tools used in the R&D of both upstream and downstream inventions. Researchers who wish to use a patented research tool either need to purchase the tool from the patentee, or obtain a licence from the patentee.[89]

There is no longer any serious debate about the patentability of research tools, even those directed to disease targets and human genes.[90] As long as the traditional

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[88] Industry Canada Report *supra* note 2 at 9: techniques used on the disease targets include the use of "cloned receptors as screens or transgenic organisms created through gene knock-out technologies to determine protein function."
[89] Federal Trade Commission, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy (October, 2003) at 19 [hereinafter FTC Report].
[90] L. Westerlund, *Biotech Patents: Equivalency and Exclusions Under European and US Patent Law* (New York: Kluwer Law International, 2002) at 32-35.

patent criteria are met (novelty,[91] non-obviousness,[92] utility,[93] written description[94]) patents are available for any research tool, including genes and proteins. In fact, there has been a flurry of activity before the patent offices as parties attempt to patent the genome. More than 28,000 gene patent applications have been filed with the US Patent Office.[95] This is particularly impressive given that there are only 35,000 to 54,000 genes in the entire human genome that may, in combination, express 100,000 proteins though many of these patent applications may be duplicative and many others may be allowed to lapse before they ever issue.[96] However, many of these patent applications may be duplicative and many others may be allowed to lapse before they ever issue.[97]

Licence agreements or material transfer agreements (MTAs) may restrict the use of the tool to specific uses, for example to non-commercial, academic research.[98] Typically, royalty payments are made only on the use of the tool itself and do not extend to any inventions developed as a result of the use of the tool. In other cases, the royalty agreements may be structured to allow royalty-free use of the tool with any royalties coming due on a commercial product realized through use of the tool. This type of royalty-scheme is known as a "reach-through royalty." This is a popular approach among patentees who may wish to forego immediate royalties in return for a chance to benefit in

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[91] Patent Act, R.S.C. 1985, c. P-4, s. 28.2 as amended S.C. 1993, c. 15, s.33.
[92] Patent Act, s. 28.3 as amended S.C. 1993, c. 15, s. 33.
[93] Patent Act, s. 2: definition of invention is new and "useful".
[94] Patent Act, s. 27(3) as amended S.C. 1993, c. 15, s. 31.
[95] Hill *supra* note 3 at 241.
[96] Scherer *supra* note 17 at 1348; Hill *ibid.* at 241; Nicol *supra* note 11 at 361.
[97] Nicol *ibid.* at 361.
[98] NIH Report *supra* note 50.

the rewards from a successful product. It is much less popular among researchers who fear royalty stacking.[99]

There have been a couple of cases in the United States where patent holders have attempted to expand the scope of patents on research tools to include products developed as a result of use of the tool. The first case dealt with importing a product discovered through use of a patented research tool. A general principle of patent law in both Canada and the United States is that there is infringement of a patent when a product is imported into the country even though the patent only claims the process of making the product and not the product itself.[100] This is codified in the US under 35 U.S.C. §271(g).[101] In *Bayer AG v. Housey Pharmaceuticals, Inc.*, the patentee obtained patents on a screening method to determine whether a substance is an inhibitor or an activator of a protein.[102] The patentee then sought to prevent the importation of substances discovered as a result of using the research tool outside of the US under §271(g). The Federal Circuit rejected this argument and limited the scope of §271(g) to products derived from patented manufacturing processes.

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[99] FTC Report *supra* note 89 at 24; NIH Report *supra* note 50.

[100] *Lido Industrial Products Ltd. v. Teledyne Industries Inc.* (1981), 57 C.P.R. (2d) 29 at 38 (F.C.A.).

[101] 35 U.S.C. §271(g) reads in pertinent part:

> Whoever without authority imports into the United States or sells or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, sale, or use of the product occurs during the term of such process patent.

[102] *Bayer AG v. Housey Pharms, Inc.*, 340 F.3d 1367 (Fed. Cir. 2003).

In a related example, the University of Rochester filed a patent application describing how to screen for compounds capable of selectively inhibiting Cox-2.[103] As in *Bayer v. Housey*, the University of Rochester wanted to generate royalties on any drugs developed as a result of their screening process. As a result, the University of Rochester also pursued claims directed to methods of administering compounds that can selectively inhibit Cox-2, even though they only invented the research tool and did not specifically describe any such selective inhibitors. This type of claim has been colloquially described as a "reach through" claim.

The University eventually received a patent that included the reach through claims, and sued several major drug manufacturers, notably Pfizer, for infringement based on sales of selective Cox-2 inhibitors including the multibillion dollar drugs Celebrex® and Bextra®.[104] Pfizer prevailed on a summary judgment motion in the Federal District Court for the Western District of New York with an argument that the patent failed to either properly describe, or teach one how to practice, the subject matter of the reach through claims. The Court stated that the compounds were only described functionally and that the patent only enabled one of skill in the art to "attempt to discover" (i.e. screen) the compounds necessary for practicing the claimed method. The University lost on appeal to the Court of Appeals for the Federal Circuit, which affirmed the District Court's finding that the patent lacked sufficient written description to support the claimed methods. The Court specifically stated its belief that the application lacked

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[103] *University of Rochester v. G. D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004); US Patent No. 6,048,850, Young *et al.*, *Method of inhibiting prostaglandin synthesis in a human host,* April 11, 2000.

[104] Celebrex is a registered trade-mark of GD Searle LLC (CA TMA 527,792, May 16, 2000) and Bextra is a registered trade-mark of Pharmacia & UpJohn Company LLC (CA TMA 634,955, March 10, 2005).

any description of the specific compounds necessary to practice the claimed method as the rationale for their decision.

Despite some creativity on the part of some patent holders, the courts have affirmed that patents on research tools only cover the tool itself or its research within the patented jurisdiction. The patent itself does not cover products discovered through use of the tool. However, even when patents on research tools are granted with an appropriate scope, the patent rights may be used in such a way as to impede the progress of science.

1.4 The Focus of This Thesis

Science and technology is only able to progress by building on earlier work. This is true when the field is "cumulative" whereby gradual advances build on earlier inventions as well as in "discrete" fields where a new invention is developed to meet a specific need. In either case, access to earlier knowledge is required.[105] In new and rapidly developing industries, patent rights may restrict access to earlier technology thereby limiting new advances. The patent system then acts as a barrier for the development of new technologies. This is of particular concern in the biotechnology industry where a proliferation of patents on basic and fundamental research tools risk hindering additional follow-on innovation.

While the problem of patenting research tools may not be as pervasive as Heller and Eisenberg feared in creating an "anticommons", there is still substantial evidence that the patenting of research tools has generally increased the cost and complexity of scientific research and occasionally stopped the research completely. The main focus of

[105] Correa *supra* note 35 at 525-526.

this thesis will be on obtaining access to research tools where the patentee refuses to licence or charges exorbitant fees for the tool: in other words, when access to the tool is blocked and the tool is required for subsequent research in a field. Researchers and institutions have complained about delays and administrative burdens that are created by navigating the various patent rights.[106] While addressing this main issue, the secondary problem of administrative burdens getting in the way of good science will also be considered.

Chapters II and III provide a foundation for subsequent analysis and discussion. In chapter II, the economic rationale of the patent system is examined. Patents are primarily economic tools used by the state and accordingly, any discussion of the patent system needs to respect the economic fundamentals. The general economic theories are then applied to the special case of patenting research tools in biotechnology. In chapter III, the Canadian patent system is placed within the international context by considering the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (the TRIPs Agreement). Other international instruments are also relevant such as the Paris Convention and North American Free Trade Agreement (NAFTA),[107] but it is the TRIPs Agreement that provides the most far-reaching and encompassing obligations.

Once the foundation for the patent system has been established in chapters II and III, the next two chapters will examine appropriate mechanisms existing within the patent system to mitigate abuses and excesses. Chapter IV provides a detailed examination of

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[106] NIH Report *supra* note 50.

[107] See for example J.M. Silbermann, "The North American Free Trade Agreement's Effect on Pharmaceutical Patents: A Bitter Pill to Swallow or a Therapeutic Solution?" (1996) 12 Journal of Contemporary Health Law and Policy 607 for a discussion of the requirements under NAFTA for compulsory licensing.

the experimental use exception to patent infringement. Chapter V follows with a detailed examination of the essential facilities doctrine as developed in US antitrust laws and how it can be applied to research tools through the existing compulsory licensing provisions in the Canadian *Patent* and *Competition Acts*.

Throughout this thesis, the main focus will be Canadian law and practice though a comparative analysis will be introduced where instructive. The Heller and Eisenberg article raised several concerns about patenting research tools in biotechnology which led to considerable commentary and analysis in the United States. While there are many similarities between Canadian and US patent law and practice, there are also fundamental differences. The goal of this thesis is to add to the discussion and provide new insights from the Canadian perspective.

CHAPTER II
THE ECONOMICS OF PATENT LAW

2.0 Introduction

The underlying rationale for patent laws has occasionally rested on notions of natural justice and equity: the inventor should benefit from his creation. These arguments conjure up images of the lone inventor working in his basement. Despite the romance associated with these arguments, modern analysis of patent laws relies on economics as the main driving force underlying policy discussions.[108] There is considerable empirical evidence suggesting that technological change has been an important source of economic growth over time.[109] For example, Robert Solow estimated that approximately 80% of the growth in non-farm output per worker in the United States between 1909 and 1949 was attributable to technological change rather than increased capital intensity.[110] Similarly, Frederic Scherer has estimated that research and development (R&D) has been responsible for about half of the annual rate of growth in productivity during the post-war era.[111] The patent laws represent one major social tool to encourage this growth. A multitude of economic theories have been developed to provide a conceptual framework in which to analyze the principal costs and benefits of patents. Before examining these theories, it will be useful to address some of the more general criticisms of the patent system.

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[108] Correa *supra* note 35 at 524.
[109] R. Evenson & Y. Kislev "Research and Productivity in Wheat and Maize" (1973) 81 Journal of Political Economy 1309 at 1324.
[110] R.S. Eisenberg, "Patents and the Progress of Science: Exclusive Rights and Experimental Use" (1989) 56 University of Chicago Law Review 1017 at 1031; M.S. Hart, "Getting Back to Basics: Reinventing Patent Law for Economic Efficiency" (1994) 8 Intellectual Property Journal 217 at 220.
[111] Hart *ibid.* at 220.

There are many costs associated with the patent system. As a society, there are costs in defining the scope of patent rights, as well as providing the infrastructure to both obtain and enforce the rights. Private costs involve the efforts to obtain and maintain rights, to monitor for infringement and to litigate. All of these resources are diverted away from productive opportunities that might otherwise exist.[112]

A main objection to the patent system is that patent incentives may distort economic activity in ways that undermine efficiency. A concern is that competing firms, hoping to make patentable inventions ahead of their rivals in order to win lucrative patent rights, engage in a patent race and spend money quickly when the social benefit of the invention would be optimized by a less accelerated research effort.[113] The patent system is a winner-take-all situation and there are no rewards for losing the patent race. Similarly, the patent system may divert resources away from areas where patent protection is unavailable to research that is more likely to yield profitable patent monopolies.[114] Resources may also be diverted into defensive patenting, where a firm exhaustively patents every detail simply to provide leverage in any litigation or negotiation.[115] Resources used in defensive patenting could otherwise be used more efficiently.

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[112] E. Kitch, "Elementary and Persistent Errors in the Economic Analysis of Intellectual Property" (2000) 53 Vand Law Review 1727 at 1732; J. Barnett, "Cultivating the Genetic Commons: Imperfect Patent Protection and the Network Model of Innovation" (2000) 37 San Diego Law Review 987 at 1005; Correa *supra* note 35 at 528.

[113] S. Scotchmer, "Standing on the Shoulders of Giants: Cumulative Research and the Patent Law" (1995) 5 Journal of Economic Perspectives 29 at 31; Eisenberg *supra* note 110 at 1027.

[114] Eisenberg *ibid.* at 1027.

[115] See *supra* Ch. I notes 51-53 and accompanying text.

Another general criticism of the patent system is that it may hinder progress through its effects on the research efforts of persons other than the patent holder. The existence of a patent may undermine the incentives of other persons to make improvements on patented technologies. Once an invention is patented, only the patent holder and the licencees are able to commercially exploit the improvements as well as the original invention. In the absence of patent rights, there would not be any legal impediment preventing competitors from benefiting from research on improvements.[116]

Competitors may also waste time and effort finding duplicative solutions to "design around" the original solution in order to avoid infringement. This time and effort may represent a significant social cost as it diverts resources away from other productive uses to the task of finding redundant solutions to already solved problems. This is particularly wasteful when the original patent holder engages in efforts to design around solely with the goal of maintaining their monopoly position and preventing competitors from being able to invent around the patent. However, this criticism may actually be a benefit of the patent system since designing around requires further research that in itself may stimulate further progress and the development of superior products or processes.[117]

Just as the importance of patents varies by industry, these criticisms of the patent system are more or less relevant depending on the industry. The subsequent discussion will review various economic theories to better understand the theoretical justifications for the patent system generally. In the final part of this chapter, the various patent theories will be applied to research tools in the biotechnology industry.

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[116] Eisenberg *supra* note 110 at 1027.
[117] Eisenberg *ibid.* at 1028.

2.1 The Economic Theories

To assist with this review, five different patent theories are considered. The first three are what can be considered to be foundational or primary theories of a patent system where patent rights provide incentives to invent, disclose and innovate. The second two theories build on these foundational theories and explain, by way of analogy, the features of the patent system that encourage economic efficiency. These latter theories include the prospect theory and the auction theory. The primary theories can be cumulative where the application of one theory does not affect the applicability of another primary theory. In comparison, the secondary theories discussed herein rely implicitly on the foundational theories, but are exclusive of one another.

2.1.1 The Primary Theories

2.1.1.1 Invention

The theory that patent rights motivate useful invention is the most familiar theory of the benefits of patenting. The basic assumption is that without patent rights, there will be little to no invention. Conversely, stronger patent protection would therefore lead to increased amounts of invention. In this context, stronger patent protection means either longer or broader patent rights.[118]

Invention involves the creation of what economists call "public goods" that possess two main qualities: they are both non-exclusive and non-rivalrous. Non-exclusivity refers to the fact that once the invention is made known, it is difficult to prevent others from using the information except through special legal institutions (such

[118] R.R. Nelson, "The Economics of Invention: A Survey of the Literature" (1959) 32 Journal of Business 101.

as patent laws). Non-rivalrous refers to the fact that information may be "consumed" by many people without depletion.[119] In other words, invention is a public good because any number of additional parties can use the invention absent patent rights without affecting the original inventor's ability to exploit the invention himself. The incentive to invent theory holds that too few inventions will be made in the absence of patent protection because inventions are easily appropriated by the original inventor's competitors who have not shared in the costs of invention. If successful inventions are quickly imitated by free-riders, competition will drive prices down to a point where the inventor receives no return on the original investment in R&D. [120]

The costs of R&D are one-time sunk costs. Once the invention has been made and disclosed, the marginal cost of using the knowledge gained more intensively is zero. There may be other variable costs associated with producing goods and services through use of the invention, such as costs for labour and materials, but the cost for developing the invention itself is fixed in the past and the subsequent frequency of its use no longer matters. In a competitive market, the cost of the goods sold will be driven down to a price approaching the marginal cost of production for all firms, including the inventing firm. While all firms face the same costs of producing the invention, only the inventing firm has incurred the large fixed costs of R&D. The selling price will thus not allow for

[119] R.A. Posner, *Economic Analysis of the Law*, 6th ed. (New York: Aspen Publishers, 2003) at 41; Scherer *supra* note 17 at 1354; Lemley *supra* note 80 at 994-995; Barnett *supra* note 112 at 1003. Other examples of public goods include lighthouses and national defence.

[120] Posner *ibid.* at 38; Scherer *ibid.* at 1349; Hart *supra* note 110 at 220-221; Lemley *ibid.* at 994-995.

any return on the sunk cost of the R&D necessary to make the invention in the first place.[121]

The high risk involved with fundamental research exacerbates the likelihood of underinvestment in invention. Inventions with potentially great social benefits might never come about, or at least might be significantly delayed, unless private returns to investment were increased above their free market levels;[122] alternatively, the firm may decide to keep the invention secret to prevent competitors from exploiting it.[123]

Patents serve to keep private incentives in line with the social value of invention by allowing inventors to use their monopoly positions to extract a price that more closely approaches the value that users receive from inventions.[124] The private rate of return of the patent rights must provide both a surplus over free market returns to cover costs of research and a risk premium to cover research on unsuccessful inventions.[125]

The social benefit of a patent stems from the additional invention induced by the potential of a patent. The most fundamental challenge to the invention theory is that subjecting new inventions to monopoly control restricts their use and thereby reduces the social benefit of patented inventions. However, even with the costs associated with monopoly pricing, consumers are better off as a result of the invention being available.[126] Both patentees and consumers gain from the invention and development of the new product.

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[121] Hart *supra* note 110 at 220-221; Lemley *supra* note 80 at 994-995.
[122] Eisenberg *supra* note 110 at 1025; Hart *ibid.* at 220-221.
[123] Hart *ibid.* at 221.
[124] Nelson *supra* note 118.
[125] Hart *supra* note 110 at 221.
[126] Scherer *supra* note 17 at 1349-1350.

In discussing the social benefits of inventions, a common assumption is that the social benefit derives from use of the invention itself. This is not necessarily accurate and analysing the social benefit relative to the social costs becomes more complicated if the invention is useful, not only as is, but also as a platform for improvements and new products or as an input for further invention.[127] Part of the social value of such an invention is the external or spillover effect on later inventions and discoveries. For example, if the second generation could not have been developed without the first, then the social value of the first invention includes the incremental social surplus of the second generation invention. Similarly, if the first generation invention merely reduces the cost of developing the second generation invention, the social surplus of the first generation includes these cost savings. The reduced cost can be pecuniary or non-pecuniary if for example, use of the first generation invention simply accelerates development of the second.[128] The granting of strong patent rights on the initial invention may also carry significant costs in such a cumulative invention by reducing the rewards available for follow-on invention.[129]

It is not settled that the promise of monopoly power is necessary to stimulate invention. In some cases, the inventor may have sufficient incentive to invent by being first to market and thereby obtaining a head-start over the competition.[130] During the period of time the company has the head-start, supracompetitive prices may be made and it may be sufficient to recover the investment costs in the R&D. Being first to market

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[127] Nelson *supra* note 118; Scotchmer *supra* note 113 at 30
[128] Scotchmer *ibid.* at 31.
[129] FTC Report *supra* note 89 at 5.
[130] Scherer *supra* note 17 at 1350; Eisenberg *supra* note 110 at 1026.

also provides a reputational benefit to the company as an "innovator" which alone may provide incentives to invent.

Similarly, the need to keep up with the technical progress of market rivals may be enough to stimulate invention without further incentives. Non-patent barriers to market entry may also limit the speed at which competitors can copy invention.[131]

All of these factors may make R&D profitable even in the absence of patent protection. Empirical studies have been done to evaluate the role of patents among firms that engage in R&D. The first study in 1986 was conducted by Edwin Mansfield involving 100 U.S. industrial R&D executives to identify the fraction of inventions developed by their firms between 1981 and 1983 that were developed only because patent protections were available.[132] This was followed by a 1987 survey by Richard Levin *et al.* in which 650 U.S. industrial R&D laboratory managers were surveyed about the relative effectiveness of several means for protecting the competitive advantages from new products and processes.[133] An even more extensive survey of 1,478 US R&D laboratory managers was conducted by Wesley Cohen *et al.*[134] Each of these three surveys showed that patent rights play a secondary role for many industries with the

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[131] Scherer *supra* note 17 at 1350; Eisenberg *supra* note 110 at 1027.
[132] Nelson *supra* note 118 citing E. Mansfield, "Patents and Innovation: An Empirical Study" (1986) 32 Management Science 175.
[133] Scherer *supra* note 17 at 1351 citing R. Levin *et al.* "Appropriating the Returns from Industrial Research and Development" (1987) Brookings Papers on Economic Activity: Microeconomics 783-820.
[134] Scherer *ibid.* at 1351 citing W.J. Cohen, R.R. Nelson & J.P. Walsh, "Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)," working paper, Carnegie-Mellon University, January 2000.

notable exceptions of the pharmaceutical and biologic, agricultural chemical and industrial organic chemical industries.[135]

Two main reasons have been identified to explain the relative importance of patent rights in the pharmaceutical industry. Firstly, once a particular molecule is identified as a potentially effective therapeutic, it must undergo expensive and lengthy clinical trials to prove its safety and efficacy: this may involve many years of testing costing hundreds of millions of dollars. Secondly, absent patent protection or regulatory barriers, imitators only need to spend a few million dollars to show clinical equivalency. The imitator is able to free-ride not only on the initial research costs in identifying the therapeutic but also on most of the subsequent clinical testing.[136] To the extent that the biotechnology industry develops medical therapeutic treatments that undergo identical clinical testing, there would be the same concern about free-riding as in the pharmaceutical industry and even when clinical testing is not needed, biotechnology inventions can easily be duplicated.[137] However, this does not mean that every invention developed by either the pharmaceutical or biotechnology industry relies to the same extent on patent protection. In addition, pharmaceutical patents rarely have a broad scope due to the inherent unpredictability of chemical research.[138] In other words, the need for patent rights is not the same as a need for broad patent rights. To the extent that the

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[135] While the three different surveys categorized the industries slightly differently, these three categories (pharmaceuticals and biologics, agricultural chemicals and industrial organic chemicals), they all came to similar conclusions.
[136] Scherer *supra* note 17 at 1351-1352.
[137] Bendegkey *supra* note 72 at 1375.
[138] R.P. Merges & R.R. Nelson, "On the Complex Economics of Patent Scope" (1990) 90 (4) Columbia Law Review 839 at 911.

invention would have occurred without patent protection, the additional monopoly profits protected by patent rights impose an unnecessary burden upon consumers.[139]

2.1.1.2 Disclosure

Under the disclosure theory, inventors are assumed to be able to keep their invention secret. The patent system then encourages the dissemination of scientific knowledge in exchange for the grant of patent rights. In *Cadbury Schweppes* v. *FBI Foods*, Binnie J. described the disclosure theory as being at the "heart" of the patent system as follows:

> A patent is a statutory monopoly which is given in exchange for a full and complete disclosure by the patentee of his or her invention. The disclosure is the essence of the bargain between the patentee, who obtained a 17-year monopoly on exploiting the invention, and the public, which obtains open access to all of the information necessary to practice the invention.[140]

To the extent that inventors are able to keep their invention secret, there is no longer a concern about free-riding: competitors cannot free-ride on the invention if they cannot learn its secrets.[141] In the absence of patent protection, there are two ways in which secrecy can be kept: either the invention is actually kept secret or it is disclosed to select customers or business partners under confidentiality agreements and trade secret

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[139] Scherer *supra* note 17 at 1350.
[140] *Cadbury Schweppes Inc.* v. *FBI Foods Ltd.*, [1999] 1 S.C.R. 142 at para 46. Since 1989, the patent term has extended from the date of issuance to 20 years from the date of application pursuant to section 44 of the *Patent Act*, replacing the previous section 44 which held the patent term as being 17 years from the date of issuance.
[141] Nelson *supra* note 118.

laws. Through such measures, the invention could potentially confer a competitive advantage indefinitely.[142]

By providing patent rights, there is a social benefit to induce disclosure of any invention that occurs. Secrecy prevents the public from gaining the full benefit of new knowledge and leads to wasteful duplicative research.[143] Society as a whole advances as other parties develop new uses for the invention that the original inventor did not know about or was otherwise unable to implement. Disclosure thus enables wider dissemination of the invention and also facilitates licensing in a greater manner than without a patent.[144] Patent rights also create rights in inventions that survive disclosure. This allows inventors to more readily approach potential investors or licencees without relying solely on trade secret protection.[145]

Despite the benefits of disclosure, there are several significant criticisms concerning disclosure theories for patent protection. Economists have questioned whether patents in fact promote disclosure of inventions that would otherwise be kept secret since secrecy is not always a practical strategy. Many technologies can be reverse engineered from a commercially available product. Secrecy may also be impractical when efficient exploitation of the invention requires communication with a large number of firms. In such situations, the public effectively receives no benefit from disclosure of the invention in the patent.[146]

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[142] Rai *supra* note 13 at 117.
[143] Eisenberg *supra* note 110 at 1028.
[144] Nelson *supra* note 118.
[145] Eisenberg *supra* note 110 at 1029.
[146] Eisenberg *ibid.* at 1029.

Where secrecy is possible, patent protection may not be as attractive an option compared to maintaining the invention as a trade secret. For one thing, trade secret protection potentially lasts forever. In addition, detecting infringement of any such patents would be difficult or even impossible. Any technology that can be exploited in secret by the patentee could also be exploited in secret by an infringer.[147] A final concern is that many patentees try to seek patent protection on the broad general concept but keep the details as a trade secret; patent specifications in such cases may not convey enough information to be useful to the public.[148]

2.1.1.3 Innovation

Joseph Schumpeter, a leading economist, made a clear distinction between innovation and invention: invention only refers to the basic creative idea and reduction to practice and patents may be granted on bare ideas or concepts without having proof of working models or commercial embodiments; innovation, however, involves taking these basic inventions and developing them to the point of a commercialized product. As stated by Schumpeter:

> As long as they are not carried into practice, inventions are economically irrelevant. And to carry any improvement into effect is a task entirely different from the inventing of it.[149]

This same point was repeated in a 1994 decision of the U.S. Court of Appeals for the Federal Circuit, *In re Alappat*, where the court quoted approvingly the statement of Irving S. Shapiro, E.I. duPont de Nemours & Co. that "no matter how much money we spend on

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[147] Eisenberg *supra* note 110 at 1029.
[148] Eisenberg *ibid.* at 1029.
[149] Eisenberg *ibid.* at 1039 citing Schumpeter, *The Theory of Economic Development* at 88-89.

research and development, the findings are not going to benefit the public unless there are suitable incentives [for] commercialization."[150]

An assumption of the innovation theory is that a patent is obtained relatively early in the process of bringing an invention to market. The primary purpose of the patent is then to provide an assurance of monopoly power that serves as a further incentive to continue investing and developing the invention to the point of having a commercial product.[151] For example, further research may be needed to establish the commercial feasibility of an invention or to bring it into large scale production. Alternatively, use of the invention may call for the construction of new plant and equipment. In the pharmaceutical and biotechnology industries, further clinical testing is required to meet regulatory requirements and ensure safety and efficacy before the invention can be marketed. These additional investments may dwarf the initial research expenditures and the assurance of a patent monopoly enhances the likelihood that a firm will be willing to undertake such investments.[152]

The innovation theory is related to the disclosure theory in that it gives the original patent holder an incentive to promote its inventions to firms that have the capability to develop and commercialize them. This aspect is particularly important for universities or small firms that are otherwise unable to exploit the invention.[153] Instead of seeking another firm to continue the innovation of the original invention, the possession of a patent enables the patent holder to go to the capital markets for

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[150] *In re Alappat*, 33 F.3d 1526 (Fed. Cir. 1994) at 1571.
[151] The further development work may or may not be independently patentable. If so, such a patent would be referred to as an improvement patent over the parent patent.
[152] Eisenberg *supra* note 110 at 1037.
[153] Nelson *supra* note 118.

development financing. Accordingly, under the innovation theory, a patent provides a small firm faced with large development costs the option of selling the invention, seeking a partner or obtaining financing.[154]

A commentator proposed a "small company" or "resources for innovation" theory for the biotechnology industry generally.[155] This is only a variation on the innovation theory where patents are seen as a means of attracting venture capital and obtaining the necessary funds for additional work. While a separate theory specifically for the biotechnology industry is not necessary, the role of patents in innovation is particularly acute for this industry; the cost and time requirements to bring a product to market are significant, with most companies being small and lacking the resources to fund this work independently.[156] This conclusion was supported by a survey of 118 U.S. start-up companies and it was found that biotechnology firms entered into alliances significantly more frequently than in other technological fields. The alliances included cooperative research, testing and/or marketing agreements or even outright mergers with larger incumbent firms, typically big pharmaceutical companies. Further, firms with at least one patent were significantly more likely to enter into alliances than firms without patent rights: patent protection therefore allows direct financing through venture capital but also indirect access to funds through inter-firm alliances.[157] The prevailing view, particularly

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[154] Nelson *supra* note 118.
[155] Golden *supra* note 16 at 168.
[156] Scherer *supra* note 17 at 1348.
[157] Scherer *ibid.* at 1354 citing J.S. Gans, D.H. Hsu & S Stern, "When Does Start-up Innovation Spur the Gale of Creative Destruction?" National Bureau of Economic Research working paper 7851 (August 2000).

in biotechnology, is that exclusive patent rights facilitate the direct access to venture capital.[158]

The innovation theory gained prominence in the discussions that led to the Bayh-Dole Act in the United States in 1980.[159] The Bayh-Dole Act gave universities the patent rights on inventions that emanated from government-funded research projects. The proposition was that even though the inventions had been achieved with public funding, only companies would be in a position to undertake the development necessary to make them commercial. Under this theory, it is assumed that a company would be unwilling to engage in the development of a university invention unless it held proprietary rights.[160] This is consistent with subsequent studies of university patenting and licensing. From 1980 to 1992, the number of patents granted per year to universities increased from fewer than 250 per year to almost 2700.[161] Any university with any appreciable scientific research program has also developed an associated technology transfer office to facilitate the patenting of university inventions.[162] Canadian universities have followed this trend even though the Bayh-Dole Act only applied to U.S. federal funding at U.S. universities and no comparable Canadian legislation has been enacted. In addition, a 1997 report of 14 case studies of technologies licenced by universities to private firms showed that

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[158] Scherer *supra* note 17 at 1353.
[159] Bayh-Dole Act Pub.L. No. 96-517, §6(a), 94 Stat. 3015, 3019-28 (1980) (codified as amended at 35 U.S.C. §§200-212 (1994).
[160] Rai *supra* note 13 at 97; Nelson *supra* note 118.
[161] Rai *ibid.* at 109
[162] Rai *ibid.* at 94-96; Nelson *supra* note 118.

many of the case study entrepreneurs would not have licenced the technology without an exclusive licence.[163]

A significant difference between the innovation theory and the invention or disclosure theories is that the innovation theory continues to operate even after a patent has issued. There is an ongoing incentive to continue investing in further R&D. In contrast, under the invention and disclosure theories, there is no additional social benefit from the patent once the invention has been made and disclosed.[164]

2.1.2 The Secondary Theories

2.1.2.1 Prospect

The work of economist Joseph Schumpeter holds that entities with monopoly or quasi-monopoly power are the major engines of innovation. According to Schumpeter, monopoly profits give firms security, and therefore freedom to innovate in a manner not available to non-monopoly firms. In addition, monopoly power may help firms appropriate more fully the benefits of their efforts by limiting opportunities for diffusion of knowledge to competitors.[165]

The view proposed by Schumpeter on innovation is relatively straightforward: monopolies foster innovation, particularly risky innovation, because they can appropriate fully (or at least more fully than competitive markets) the surplus generated by such

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[163] Scherer *supra* note 17 at 1353 citing D.H. Hsu & T. Bernstein, "Managing the University Technology Licensing Process: Findings from Case Studies," (1997) 9 Journal of the Association of University Technology Managers 1-33.
[164] Eisenberg *supra* note 110 at 1037.
[165] Rai *supra* note 15 at 819.

investment. Those monopolies that become complacent about innovation are likely to be replaced by new monopolies.[166]

According to the Schumpeterian view, in the rapidly changing conditions of a capitalist economy, investment in innovation requires some sort of hedge against losses. Protection from competition also allows firms the time and space needed for further developments. Finally, the potential of earning more than an ordinary return permits innovators to secure the financial backing of capitalists and to bid productive resources away from their current uses.[167]

Edmund Kitch expanded on the work by Schumpeter and developed a more elaborate analysis of the role of patents in post-invention innovation in what he calls the "prospect theory."[168] The term "prospect theory" highlights an analogy made by Kitch between the functions of patent monopolies and awards of exclusive mineral claims in government owned lands in the American West.[169]

The prospect theory offers a justification for patents consistent with broader theories of patent rights elaborated by Harold Demsetz and Richard Posner. Demsetz and Posner argued that private property rights promote greater efficiency in the use of resources than communal ownership.[170] In a communal ownership system, individuals can be expected to exploit communally owned resources too quickly in order to appropriate the resources for themselves before such resources are depleted by other

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[166] Rai *supra* note 15 at 824.
[167] Eisenberg *supra* note 110 at 1039.
[168] E. Kitch, "The Nature and Function of the Patent System" (1977) 20 Journal of Law and Economics 265; Eisenberg *ibid.* at 1040.
[169] Kitch *ibid.* at 266, 271, 273-274; Eisenberg *ibid.* at 1040; M. Grady & J. Alexander, "Patent Law and Rent Dissipation" (1992) 78 Virginia Law Review 305 at 313-316.
[170] H. Demsetz, "Toward a Theory of Property Rights" (1967) 57 American Economic Review 347 at 354-355; Posner *supra* note 119; Eisenberg *supra* note 110 at 1041.

community members. In other words, the costs of exploitation are borne by the entire community while only a relatively small number of individuals receive the benefit. Private ownership avoids this problem by placing private owners in a position to realize the full costs as well as the full benefits of exploitation.[171] The analogy to a property right is not readily apparent since information in a patent can be exploited by any number of parties indefinitely without being depleted. According to Kitch, the analogy is apt since the resources available to use the information are limited and property rights in inventions can improve the efficiency with which those resources are managed even though the information itself is never exhausted.[172]

In particular, Kitch argued that broad, monopoly conferring patent rights on "prospects" (upstream research far removed from commercial use) are necessary for two reasons. Firstly, broad prospect patents provide incentives for development by allowing the firm that owns the prospect to appropriate fully the benefits of such development. [173] In other words, private ownership provides private incentives to improve and market an invention.[174] This argument borrows from the innovation theory. Secondly, broad prospect patents allow the patent owner to coordinate development efforts, thereby

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[171] Demsetz *supra* note 170 at 356; Kitch *supra* note 168 at 265; Eisenberg *supra* note 110 at 1041; Lemley *supra* note 80 at 1044-45.
[172] Kitch *ibid.* at 275-276; Eisenberg *ibid.* at 1041.
[173] Kitch *ibid.* at 276-277; Rai *supra* note 15 at 824; Lemley *supra* note 80 at 1046; see also Chang *supra* note 39 at 48-49 who also argues for broad protection based on an economic model of the invention theory as "appropriate rewards for inventions with social value that exceeds their stand-alone commercial value. Like basic research, such trailblazing inventions present a strong case for some form of subsidy, because a private inventor is unlikely to undertake such R&D at levels commensurate with their social value. Broad patent protection, then, can help pioneering inventors appropriate the external benefits of their research."
[174] Lemley *ibid.* at 1046.

reducing wasteful duplicative investment in development.[175] As a result, the prospect theory assumes that the utility of a patent comes after an initial invention is made and disclosed.[176]

Kitch's theory relies on broad patent rights being granted over the invention as originally conceived as well as subsequent improvements. The patent holder will therefore benefit from subsequent research to improve the invention while other researchers will have little incentive to pursue further research on a patented invention without first arranging for a licence to the dominating patent.[177] Accordingly, all potential developers will have to identify themselves to the patentee before they begin any such development, and the patentee will be able to eliminate duplicative investment and facilitate the exchange of information among developers.[178]

Mark Grady and Jay Alexander have made the related argument that granting broad patent rights early in the development process reduces the possibility of rent-dissipating patent races.[179] As discussed above, rent-dissipating patent races was one of the major criticisms of the patent system. Accordingly, pioneering inventions that signal many different and possibly patentable improvements should be given a broad scope so as to avoid the possibility of races to patent these improvements.[180] The prospect theory has been hailed as one of the most significant efforts to integrate intellectual property with property rights theory.[181]

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[175] Kitch *supra* note 168 at 276; Rai *supra* note 20 at 824.
[176] Nelson *supra* note 118.
[177] Eisenberg *supra* note 110 at 1043; Lemley *supra* note 80 at 1046.
[178] Kitch *supra* note 168 at 276; Rai *supra* note 15 at 824; Lemley *ibid.* at 1046.
[179] Grady *supra* note 169 at 308.
[180] Grady *ibid.* at 308; Rai *supra* note 15 at 824.
[181] Lemley *supra* note 80 at 1045.

There are however, many criticisms of the prospect theory. The prospect theory relies on three assumptions: information is perfect; all parties are rational; and licensing is costless.[182] Information is, however, rarely perfect, parties are often irrational and licensing may have significant costs. The prospect theory also assumes that the original inventor fully recognizes the scope of the invention, all of the applicable markets, and applications as well as the potential for improvement. [183] In many cases, it is simply unrealistic to expect the original patentee to be able to effectively and efficiently exploit the invention to the fullest. Even if the original patentee attempts to do so, significant costs will likely need to be incurred to accurately identify the best party to improve a technology.

Potential improvers may be reluctant to reveal information about their planned research to the first inventor *ex ante*, before actually doing the proposed research to improve the original invention. At the time the information would be revealed, the information would only be protectable against misappropriation through trade secret law. Further, even if trade secret law is adequate to protect against any misappropriation, there remains a significant amount of uncertainty about the value of the patented invention relative to the value of the improvement.[184] It is difficult enough to value inventions after they have been successfully developed, it would be much more difficult, if not impossible, to adequately value a potential improvement.[185] Both of these factors increase transaction costs making the prospect function less likely to work. Valuation of

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[182] Lemley *supra* note 80 at 1046.
[183] Lemley *ibid.* at 1048-1050.
[184] Rai *supra* note 15 at 834; Lemley *ibid.* at 1053; Rai *supra* note 13 at 126; Barton *supra* note 37 at 453.
[185] Lemley *ibid.* at 1053.

the original invention is also problematic if attempted before the patent grants. Patent pendency, the time between filing a patent application and issuance or abandonment, averages about 45 months in Canada, and 25 months in the U.S. and Europe.[186] The scope of the patent, and thus its value, may change between filing and grant thereby leading to greater uncertainty and greater transaction costs. Transaction costs are also greater under the prospect theory as the original patentee has to negotiate a licence with all potential improvers and not just those who are ultimately successful.[187]

In the real world, the prospect function of patents is unlikely to work since a basic feature of the patent system is that improvements are independently patentable. Accordingly, some researchers may find it worthwhile to conduct unlicenced research in the hope of developing a patentable improvement. The inventor of the improvement may then licence back the improvement to the holder of the patent on the original invention as well as to any licencees of the original patent. The improvement patent may also give the inventor a greater bargaining position in negotiating a licence to the original invention.[188] Thus, in many cases, broad patent rights may actually lead to unauthorized and uncoordinated research contrary to the goals of the prospect theory. This is not necessarily a failure of the patent system though it does show what is probably the most significant failure of the prospect theory. Lack of coordination may lead to duplication but that is not necessarily wasteful. The less routine the scientific effort and the more far-reaching the implications of the results, the less likely it is that overlapping research efforts will actually be duplicative. Multiple research efforts also increase the likelihood

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[186] Industry Canada Report *supra* note 2 at 27.
[187] Lemley *supra* note 80 at 1051.
[188] Eisenberg *supra* note 110 at 1044; Lemley *ibid.* at 1051; Rai *supra* note 13 at 127.

that a problem will be solved quickly.[189] A diversity of approaches also appears to lead to a more dynamic and expansive range of solutions.[190]

Even if the prospect function works and scientists are in a position to control access to their discoveries, patentees are human and suffer all of the foibles of humanity. They might be inclined to favour a narrow range of researchers who share their commitments, and yet to withhold their discoveries from scientists with different perspectives. Allowing earlier researchers to exercise such control may thereby prolong the influence of prevailing theories and stifle creativity and originality.[191] Other non-economic incentives may also be present that prevent the efficient licensing of the invention. For example, the patentee may refuse to licence the technology to someone simply because of personal feelings or because they do not like or trust the other party.[192] More likely, the patentee will refuse to licence the technology to a market rival.[193] This may or may not be rational but assuming that all parties always act rationally is simply inaccurate.

There is another problem identified with the prospect theory. For the social benefit to be maximized, the property owner must make the invention and any subsequent improvements available at a reasonable price. However, in the absence of competition, the patent owner would likely price the invention monopolistically and would have no incentive to price access to the invention at a competitive level approaching marginal

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[189] Scherer *supra* note 17 at 1359-1360; Eisenberg *supra* note 110 at 1063; Rai *supra* note 13 at 123-124; Eisenberg: Fruitful Tension *supra* note 17 at 1397.
[190] Barton *supra* note 37 at 455.
[191] Hart *supra* note 110 at 239.
[192] Lemley *supra* note 80 at 1059-60.
[193] R.P. Merges & R.R. Nelson, "On Limiting or Encouraging Rivalry in Technical Progress; The Effect of Patent Scope Decisions" (1994) 25 Journal of Economic Behaviour and Organization 1 at 7.

cost.[194] This has a social cost as basic economic theory suggests that charging "monopoly licensing fees" would result in fewer improvers than socially beneficial and this would lead to an underproduction of improvements.[195] Kitch recognized this limitation and simply pointed out that patent rights do not necessarily confer economic monopolies, and that in many cases competition will be present from other fungible goods or patent rights.[196] Kitch argued that administratively it would be necessary for the system to treat all patents equally without regard to the market power the patent may give the patentee; however, for pioneering inventions that are typically awarded the broadest patent rights, there is a much greater likelihood that an economic monopoly would be granted in addition to a patent monopoly.[197]

The claim that a broad "prospect" patent is needed to coordinate further research and prevent duplicative research is problematic for another reason. In the absence of patent rights, the main concern is that there would be insufficient investment in R&D not that there would be too much duplicative research.[198] In this aspect, the prospect theory is inconsistent with the invention theory.

Robert Merges and Richard Nelson have collected several historical examples where broad patent rights in cumulative-system technologies were counter-productive.[199] Unless licenced easily and widely, the presence of such patents tended to limit the range

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[194] Lemley *supra* note 80 at 1047.
[195] Lemley *ibid.* at 1067.
[196] Kitch *supra* note 168 at 274; Lemley *ibid.* at 1047.
[197] Kitch *ibid.* at 274.
[198] Rai *supra* note 13 at 123.
[199] Merges *supra* note 138 at 884-894 describing historical examples of cumulative innovation in the electrical lighting industry, automobiles and airplanes, radio, and semiconductors and computers. See also Scherer *supra* note 17 at 1362; Nelson *supra* note 118; Rai *supra* note 13 at 125.

of potential users to those who have access to all components of the technology. After reviewing these examples, Merges and Nelson challenged Kitch's view that coordinated development is better than rivalrous stating that "[i]n principle it could be, but in practice it generally is not."[200]

2.1.2.2 Auction

In response to the prospect theory, Kenneth Arrow argues that competition is essential to innovation, particularly where intellectual property protection for the downstream product is available, and the downstream product would substitute for a product already produced by the monopolist.[201] If a new or superior product would cannibalize the market for the monopolist's existing product, the monopolist will have no incentive to create that product.[202]

Robert Merges and Richard Nelson have similarly argued that although coordination of research by a single patentee may slightly reduce duplication, swift progress in innovation requires competition.[203] While competition may lead to some duplicative investment, at least some redundancy may be more apparent than real. Because the different possible goals of improvement are often unknown at the time that such improvement starts, "racing" among competitors may yield results that would not have emerged if work on improvement had been restricted to a single party (or even to a

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[200] Merges *supra* note 138 at 872; J.F. Duffy, "Rethinking the Prospect Theory of Patents" (2004) 71 University of Chicago Law Review 439 at 442. Other critics of the prospect theory have been much harsher. For example, Frederic Scherer views the prospect theory as "little influenced by any concern for reality."
[201] Rai *supra* note 15 at 819.
[202] Barnett *supra* note 112 at 992; Rai *ibid.* at 825.
[203] Merges *supra* note 193 at 20-21; Merges *supra* note 138 at 843-844; Rai *supra* note 15 at 820.

few parties). Innovators may take different approaches to the same goal and these different approaches may prove to have independent social value.[204] The real risk is underdevelopment in the absence of patent rights and not duplication of effort.[205]

John Duffy recently proposed a different model by analogizing patent rights not to mineral claims in the American West as proposed by Kitch but to competition and regulated industries theory.[206] In particular, an analogy was made between the patent system and Harold Demsetz's proposal for regulating the so called "natural monopoly industries." A natural monopoly industry occurs when a single firm can serve the entire market more efficiently than multiple competing firms. In such a case, the traditional approach has been to grant one firm an exclusive franchise over the market but to then subject the firm to government price regulation. According to Demsetz, private competition could serve the same objective as government regulation. Prior to selecting the firm that would hold the exclusive franchise, each firm would "bid" in terms of the price and quality of service that it would offer customers. Competition in the bidding reduces the monopoly rents and diminishes the deadweight loss associated with the exclusive franchise.[207] The competition to gain the exclusive right would be harnessed to reduce private rents while increasing social surplus.

Duffy argues that the patent system fosters competition in a similar manner to a Demsetzian auction. Because competitors can obtain a patent well before commercialization of the invention, patent races for the patent can approximate auctions for patent rights, with the winner being the competitor willing to provide the invention to

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[204] Rai *supra* note 15 at 825.
[205] Barton *supra* note 37 at 455; Merges *supra* note 138 at 873.
[206] Duffy *supra* note 200 at 447.
[207] Duffy *ibid.* at 445.

the public for the least rents.[208] In a Demsetzian auction, the bidders compete with each other to obtain an exclusive right by diminishing their monopoly rents. Within the patent system, competing inventors similarly compete with each other and diminish their monopoly rents by placing their invention in the public domain sooner. The sooner that an inventor applies for a patent, the sooner that the patent will expire.[209] Accordingly patent races should not be viewed as an inefficient use of resources but as increasing the social benefit by having the invention enter the public domain earlier.

According to the auction theory, rivalry and competition provide the greatest benefits to society. The private costs of patent races may still result in social costs if resources are expended at an overly accelerated rate, before the socially optimal time for making those expenditures. The granting of broad patent rights at an early stage before the invention is close to commercialization thus reduces the social costs by allowing patenting before significant research expenditures are made and before much wasteful duplication can occur.[210]

Under the auction theory, competition does not end with the grant of the initial patent right. The holder of a broad prospect patent covering an entire field of technology cannot stop another inventor from searching for, and patenting, improvements to the original invention. In such a case, the original patent holder and the improvement patent holder hold overlapping exclusive rights where each is able to exclude the other from using the improved technology. This situation is referred to as "blocking patents" and is fairly common within the patent system. The law thus fosters another race to capture the

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[208] Duffy *supra* note 200 at 445.
[209] Currently 20 years after the application date, Patent Act, s. 44 as amended S.C. 1993, c. 15, s. 42.
[210] Duffy *supra* note 200 at 444.

rents encompassed by the improvement patent and this race would also follow a Demsetzian auction designed to maximize the social benefits of the invention.[211]

The auction theory thus functions as an alternative to the prospect theory and addresses many of the criticisms of the prospect theory. Features of the patent system such as improvement patents, an experimental use exception and compulsory licensing are also supported by the auction theory even though they are inconsistent with the prospect theory.[212]

Duffy also concluded that the patent system may be less sensitive to the scope of patents than has previously been recognized. Patent racing has a self-adjusting quality where the more valuable the patent rights, the greater the competition to obtain the rights resulting in those same rights entering the public domain earlier. Broad patent rights may therefore result in inventions entering the public domain earlier than under a weak patent rights system.[213]

2.2 Scientific Norms

Government has at its disposal, two main tools in promoting the progress of science and technology: direct R&D subsidies and patent rights.[214] As discussed above, government plays a large role in funding basic research in biotechnology.[215] This is done primarily through university research but also through government research institutes.

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[211] Duffy *supra* note 200 at 485.
[212] The experimental use exception is discussed in detail in Chapter IV and compulsory licensing is discussed in detail in Chapter V.
[213] Duffy *supra* note 200 at 500.
[214] Scherer *supra* note 17 at 1362.
[215] See *supra* notes 15-19 and accompanying text.

The goal of basic scientific research is to simply advance fundamental knowledge about the world, and such basic research does not need to be directly useful nor profitable.[216]

Traditional scientific norms in academic research are based upon three basic principles. The first is that of a large public domain of freely available scientific information: information is seen as a public good and claiming property rights in it is seen as immoral.[217] Similarly, it is against traditional scientific norms to keep inventions secret.[218] This first principle has been called "communalism" in recognition of the dependence of individual scientists on the large body of work that precedes their own.[219] "Free-riding" on the previous work of other scientists is an integral feature of the scientific system and not a problem to be avoided.[220] The second principle provides researchers academic freedom to choose research topics and to criticize the work of others. This second principle may be called "individualism" or "independence."[221] The third basic principle, and perhaps the most important of all, is respect for scientific invention. Scientists and researchers who make original and significant contributions are given the highest levels of peer recognition and prestige.[222] The greater the contribution, the greater the recognition received. This emphasis on originality also encourages a race among scientists not to be preempted by others working in the area.[223] This scientific norm is so strong that secrecy or other aggressive competitive behaviours, in violation of

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[216] Eisenberg: Fruitful Tension *supra* note 17 at 1393.
[217] Rai *supra* note 13 at 90; Eisenberg: Norms of Science *supra* note 17 at 178.
[218] Eisenberg: Fruitful Tension *supra* note 17 at 1393.
[219] Rai *supra* note 13 at 90; Eisenberg: Norms of Science *supra* note 17 at 183; Eisenberg: Fruitful Tension *ibid.* at 1394.
[220] Eisenberg: Norms of Science *ibid.* at 204.
[221] Rai *supra* note 13 at 91.
[222] Rai *ibid.* at 92; Hill *supra* note 3 at 243; Eisenberg: Norms of Science *supra* note 17 at 183.
[223] Rai *supra* note 13 at 92.

the first principle, are tolerated in the short term in the race to be the first to make the scientific contribution.[224]

In considering the economic theories, academic scientists do not need patent rights as an economic incentive to invent or disclose any inventions.[225] Peer recognition and personal contribution provide the strongest motivation for basic research scientists to not only invent and disclose within the academic environment, but also to do so first. Without patent rights, there would still be invention, disclosure and a race to invent. In other words, the invention, disclosure and auction theories do not add anything to this discussion. In fact, to the extent that invention results from government funding, successful inventors would be rewarded twice: through both the grant of government funding and the grant of patent rights.[226]

The prospect theory also provides little justification for patenting academic research. The prospect theory is actually in direct conflict with academic freedom of researchers to the extent that the patentee tries to coordinate further research related to his invention.

The only scope under the patent theories for academic research is under the innovation theory. The academic environment is unlikely to be conducive to doing the necessary work to bring a product to market and patent rights are othen needed to find a private partner willing to assist with this work.

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[224] Rai *ibid.* at 92.
[225] Nelson *supra* note 118.
[226] Scotchmer *supra* note 113 at 40.

In comparison to the norms of academic research, the norms of industrial research vigorously maintain and enforce patent rights and secrecy.[227] The following application of the economic theories to research tools will therefore primarily focus on inventions developed through industry, with only a minor discussion of the innovation as applied to research tools developed in academia.

2.3 Application to Research Tools

What lessons can the different patent theories bring to the question of the proper patent scope for research tools in biotechnology? Would broad availability of research tools to the scientific community encourage scientific progress? Or would such availability compromise the development of the research tool in the first place, and thereby hamper scientific progress? Unfortunately, this would require a detailed empirical analysis of the costs and benefits and is not within the scope of this thesis. Nevertheless, applying the patent theories to research tools in the biotechnology industry can provide some guidance as to the role in which patent protection may play in promoting or impeding the progress of science and technology.

The research tool patent has the potential to be the "quintessential realization of the prospect theory of patenting developed by Professor Edmund Kitch."[228] Kitch argued for broad protection at an early point in the R&D stage. Patents on research tools that are pioneering or fundamental research platforms fit this definition very well. The patents are broad to the extent that lack of access to such tools forecloses an area of research and

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[227] Rai *supra* note 13 at 93.
[228] K.J. Strandburg, "What Does the Public Get? Experimental Use and the Patent Bargain" [2004] Wisconsin Law Review 81 at 124-125.

they occur at an early point before any research is able to occur. According to Kitch, these types of patents are highly desired as they allow the patent holder to direct further research and thereby avoid duplicative effort that can be wasteful and socially costly.[229] However, there is a disconnect between the prospect theory and reality where tools are either widely exploited, or the private firm owning the patent tries to keep the tool as a proprietary, competitive advantage. The latter situation could be socially desirable if the patent owner is the best party to fully use the tool. Unfortunately, this is unlikely to occur for several reasons: the skills necessary to develop the tool are likely to be disparate from the skills needed to efficiently and effectively exploit the tool;[230] there are typically so many possible approaches in research that the patentee would be unable to fully exploit them all even if he tried. In addition, contrary to the prospect theory, duplicative research is unlikely to be a significant problem in rapidly growing areas such as in biotechnology. For these reasons, the prospect theory is rarely, if ever, applicable, though it has been useful in encouraging academics to think about patent law in new and different ways: in fact, the auction theory resulted in part from the many criticisms of the prospect theory. The following analysis in part 2.3.1 will focus on market-supplied and researcher-supplied tools whereas part 2.3.2 will focus on disease targets.

2.3.1 Market-Supplied and Researcher-Supplied Tools

Research techniques and consumables may be developed at any research stage, either basic or applied. Typically, the inventor is working in an area of research, the primary research field, and in doing so comes up with an easier, faster or lss expensive

[229] Strandburg *ibid.* at 125.
[230] Strandburg *ibid.* at 126.

way of conducting the research. The motivation to invent would rarely, if ever, be the prospect of obtaining patent rights over the tool. Instead, the motivation to invent is typically to facilitate research in the primary field; this is as true in industrial research as it is in academic research. Patent rights do not add anything to this motivation and as such there is little in the invention theory for research tools.

In comparison, a more complicated analysis is required in applying the disclosure theory to research tools. Industry promotes a culture of secrecy as a way to maintain and develop competitive advantages. This leads to attempts to keep research tools secret absent any patent rights, and given that most research occurs behind closed doors, such secrecy would be plausible. Add in the difficulty in detecting infringement, many firms may still opt for trade secret protection even with strong patent rights available. Moreover, the firms that do obtain patent rights are likely motivated by the knowledge that independent invention by another private firm or academic researcher would lead to public disclosure sooner rather than later in a competitive industry like the biotechnology industry. The disclosure theory thus suggests that patent rights encourage disclosure of inventions that would eventually be disclosed in any event. The social benefits under the disclosure theory are thus limited to a question of timing of disclosure instead of whether the disclosure would occur.

According to the innovation theory, patent rights on basic inventions stimulate the further development needed to commercialize the basic invention. This theory is directly applicable to market-supplied tools where additional investment is needed to bring the tool to market. For example, additional resources will likely be needed to further develop the tool to realize any economies of scale. Production of most chemicals and equipment

is significantly different at the bench scale than in large scale production. There is also a significant amount of risk associated with investing time and money on a product for a new market that previously did not exist for the research tool. Patent rights provide an additional incentive to invest in developing the new research tool market: this applies with equal force to research tools developed in academia. Patent rights allow for the efficient transfer of the research tool out of the academic environment in which it was created into the private sector where it can be effectively commercialized. In comparison, the innovation theories do not provide any justification in granting patents for researcher-supplied tools: for these tools, there is no development and no commercialization that would benefit from the granting of a patent right.

According to the auction theory, patent rights would establish a race to invent research tools leading to earlier invention, earlier patenting and earlier dedication of the invention to the public at the expiry of the patent rights. Unfortunately, this theory does not accord with reality as there is no race to invent research tool products and processes. The real patent race in biotechnology is in the race to develop downstream end-use products and therapies. Research techniques and consumables are not developed as part of their own independent race but are only developed incidentally in order to make the primary race more efficient. The auction theory simply does not provide any adequate justification for the development of these tools.

To summarize, there is a clear, coherent justification for granting patent rights over market-supplied tools developed either in industry or in academia under the innovation theory. In addition, there is a real, though less significant justification, under the disclosure theory for patenting market-supplied tools developed by private firms. In

comparison, the only justification for researcher-supplied tools developed by private industry is under the disclosure theory. In other words, the case for patent protection is relatively clear for market-supplied tools but much weaker for researcher-supplied tools.

While the distinction between researcher and market-supplied tools has been useful from an analytic perpective, it is not as useful as a practical matter. At the time of invention, it may be difficult or even impossible to accurately predict whether the tool should be categorized as a market-supplied tool or a researcher-supplied tool. This provides an additional practical justification for patenting researcher-supplied tools, namely the inability to restrict patent protection only to market-supplied tools.

2.3.2 Disease Targets

In patent law, disease targets represent a curious mix of basic and applied research. The discovery of a gene or protein implicated in a disease necessarily involves upstream research as the discovery is simply the first step in a long journey to gain a better understanding of the disease, and ultimately develop treatments for the disease. In this manner, the gene or protein is characterized as a disease target, since it is the "target" of significant follow-on research. However, the discovery of the gene or protein may also represent a downstream achievement relatively close to a commercial product or treatment. An example discussed extensively in the literature involves an American company, Myriad Genetics and their patenting of the BRCA1 and BRCA2 genes that show a predisposition for breast cancer. Myriad has claimed patent rights over the genes themselves, use of the genes in diagnostic tests, as well as use of the genes in research to

discover a cure for breast cancer.[231] This latter type of claim is use of the gene as a disease target and could be used to impede further research in breast cancer. In addition to patents on genes, patents can also be granted on proteins implicated in a disease such as the CCR5 protein implicated in HIV.[232] The following analysis examines the theoretical justification for granting patents on such disease targets.

In todays's market, the motivation to discover disease targets is rarely to obtain patent rights in and of themselves. Instead the motivation relies on the ability to develop applied and independently patentable diagnostics and therapeutics based on the disease target. However, this motivation exists whether or not the disease targets are patentable themselves, as long as there are sufficient patent rights associated with the diagnostic or therapeutic, particularly when the upstream discovery of a "disease target" is closely related to a downstream end-use. For example, when Myriad Genetics discovered the utility of the BRCA1 and BRCA2 genes as disease targets, they also realized the potential to use the same genes as a diagnostic test for the predisposition for breast cancer. In such a case, there is no need to grant additional patent rights for the gene sequence as a research tool *per se* as long as there is a motivation to invent the end-use.

The same conclusion is found under the disclosure theory. By patenting a diagnostic or therapeutic end-use treatment, a firm will necessarily also signal the suitability of the gene or protein as a disease target for further research. Separate patent rights as a disease target add nothing to the motivation to disclose the research possibilities of the disease target to the world.

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[231] *Supra* notes 80-81 and accompanying text.
[232] *Supra* notes 38-40 and accompanying text.

Other disease targets may not be so closely linked to a downstream invention. In such a case, the disease targets only represent the first step in a basic research program and without an obvious immediate commercial application. Industrial firms will thus tend to avoid investing in research to discover the disease target absent patent rights unless the tool is otherwise needed in their business model. To the extent that a firm conducts basic research and discovers a disease target, the culture of secrecy mandates that the discovery and any further research be conducted in secret.[233] Nevertheless, the research target will eventually be discovered and disclosed even in the absence of patent rights, either by a private firm or by one of the many academic researchers working in biotechnology. Significant public funds are expended annually in basic research because of the expected underinvestment of private industry. The main effects of granting patent rights on disease targets affects the timing of the discovery and disclosure and not the discovery and disclosure itself.

Granting patent rights under the innovation theory is also problematic. The only value of patent rights on disease targets is to restrict further research in the search for potential diagnostic or therapeutic treatments. Once the disease target is discovered and its role in disease known, there is no need for further development nor commercialization. In this aspect, disease targets are similar to researcher-supplied tools.

While the auction theory may generally be more analytically useful than the prospect theory, it does not easily lend itself to disease targets. Typically, researchers engage in an intense race to discover a disease target and while this race principally involves academic researchers, industrial researchers are also active. According to the

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[233] Eisenberg: Norms of Science *supra* note 17 at 216; Chang *supra* note 39 at 52; Scotchmer *supra* note 113 at 39.

auction theory, the more valuable the patent rights associated with the race, the more parties would be involved, both academic and industrial, and the sooner the disease target would be discovered and eventually dedicated to the public. This would seem to suggest that broad patent rights to disease targets would be justified under the auction theory in order to increase the value of the patent rights and increase the patent race. This could be in addition to any patent rights over downstream end-uses. This, however, is too simplistic an analysis.

From an economic perspective, there is no value only in the disease target itself as a platform for further research. Naturally, there is a "scientific" interest in discovery of a disease target. This is another example of how the scientific norms differ from patent norms which are predicated on economic interests. The economic benefits are only realized from the development and commercialization of downstream diagnostics and therapies. According to the auction theory, further races would occur to develop those subsequent innovations. But these further races require broad access to the disease target to conduct the necessary research. This calls into question the purpose of any patent on a disease target, namely the ability of the patentee to restrict further research on the target. Broad patent rights on the disease target would restrict the more valuable downstream product. However, broad rights to conduct research on the target could leave any patent on the tool without any value. Such broad rights would also reduce the patent's ability to encourage the initial race for discovery of the disease target. A tension is thus established within the auction theory between the race to discover the initial disease target and the race for follow-on innovation to develop a downstream diagnostic or therapeutic treatment. Nevertheless, it is possible to conclude under the auction theory that strong

patent rights on disease targets are counterproductive to efficient development of diagnostic and therapeutic treatments, but that a complete lack of patent rights would be just as counterproductive. This tension within the auction theory mirrors the main problem addressed by this thesis.

2.4 Implications for the Patent System

The analysis thus far has involved examining the theoretical justifications for granting patent rights to research tools in biotechnology and in doing so, a system with no rights was compared to a system with full patent rights. This has simplified the analysis and provided a framework for further discussion. However, it does not need to be an all-or-nothing approach. Edmund Kitch identified one of the "elementary and persistent" errors in the economic analysis of patent rights as the failure to consider the full range of policy alternatives.[234] The answer to any problem of a "patent thicket" or "tragedy of the anticommons" does not need to be a simple refusal to grant patents on research tools. Nevertheless, in examining the full range of policy options, the economic underpinnings of the patent system need to be recognized and respected.

[234] Kitch *supra* note 112 at 1740.

CHAPTER III
THE TRIPS AGREEMENT

3.0 Introduction

Patent rights are national instruments used by states to encourage innovation and the progress of science. In addition to national laws, patent rights have existed within an international framework ever since the *Paris Convention for the Protection of Industrial Property* was adopted in 1883. In 1994, the international patent system fundamentally changed with the adoption of the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (the TRIPs Agreement) under the World Trade Organization (WTO).

The TRIPs Agreement sets minimum standards for countries belonging to the WTO and has been described as "a revolution in international intellectual property law."[235] Through the adoption of these minimum standards, member countries no longer have the full range of policy options to address any abuses to, or excesses of, their patent laws.

The purpose of this chapter is to provide the international context represented by the TRIPs Agreement, within which experimental use and compulsory licensing can more fully be analysed in chapters IV and V respectively. This discussion will start with a brief history of the TRIPs Agreement in part 3.1. This will follow with an introduction to the objectives and principles of the TRIPs Agreement in part 3.2. Parts 3.3 to 3.5 will deal with three specific provisions of the TRIPs Agreement that are of particular

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[235] M.P. Pugatch, *The International Political Economy of Intellectual Property Rights* (Cheltenham, U.K.: Edward Elgar Publishing Ltd., 2004) at 128 citing H.J. Reichman, "Securing Compliance with the TRIPs Agreement after US v India" (1998) 1(4) Journal of International Economic Law 581 at 585; D. Gervais, *The TRIPS Agreement: Drafting History and Analysis* (London: Sweet & Maxwell, 1998) at 11.

relevance to the issue of patenting research tools: article 27 as it relates to non-discrimination between technologies; article 30 that allows member countries to make limited exceptions to patent rights; and article 31 that allows for other use of a patented invention without the consent of the rights holder. The effects of articles 30 and 31 will then be compared in part 3.6 before some concluding comments are provided in part 3.7 about the TRIPs Agreement as a whole, as it applies to research tools in biotechnology.

3.1 Overview of the TRIPs Agreement

The General Agreement on Trade and Tariffs (GATT) was created in the 1940s as a means of centralizing international trade issues. Between 1986 and 1994, the Uruguay round of trade negotiations transformed GATT into a separate and viable organization called the WTO. The Uruguay round also expanded the discussions to include trade in services and trade-related intellectual property and investment issues in addition to trade in goods. On December 15, 1994, the WTO created the TRIPs Agreement to bring intellectual property within its purview.[236]

The TRIPs Agreement is the most comprehensive and ambitious agreement related to intellectual property that has ever been reached. There are three main features that reflect the importance of the agreement to international intellectual property law.

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[236] P. Drahos & J. Braithwaite, "Intellectual Property, Corporate Strategy, Globabalisation: TRIPS in Context" (2001-2002) 20(3) Wisconsin International Law Journal 451; S. Sell, "TRIPS and the Access to Medicines Campaign" (2001-2002) 20(3) Wisconsin International Law Journal 481; Pugatch *ibid.* at 128-131; D. Kripapuri, "Reasoned Compulsory Licensing: Applying U.S. Antitrust's 'Rule of Reason' to TRIP's Compulsory Licensing Provision" (2002) 36(3) New England Law Review 669 at 675.

Firstly, the TRIPs Agreement incorporates the principles of national treatment[237] and most-favoured-nation treatment.[238] These two provisions require that all nationals of any member state be treated the same regarding. Secondly, the TRIPs Agreement establishes a set of minimum standards that member nations must adopt.[239] Within the TRIPs Agreement, provisions specifically refer to copyright and related rights (art. 9-14); trademarks (art. 51-21), geographical indications (art. 22-24), industrial designs (art. 25-27), and patents (art. 27-34). The TRIPs Agreement also incorporates four major international treaties: the 1883 Paris Convention; the 1886 Berne Convention; the Rome Convention; and the Treaty on Intellectual property in respect of integrated circuits.[240] Finally, the TRIPs Agreement provides a Dispute Settlement Understanding (DSU) in order to resolve IP-related disputes between Member states.[241] The lack of any mechanisms to address disputes was one of the perceived flaws in the Paris and Berne Conventions.[242]

A Dispute Resolution Body (DRB) has the sole authority under the DSU to establish panels of experts for each and every dispute, to accept or reject panel findings

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[237] *Agreement on Trade-Related Aspects of Intellectual Property Rights*, Annex 1C to the *Agreement Establishing the World Trade Organization*, 15 April 1994, 33 I.L.M. 1197 (entered into force 1 January 1996) art. 3 available at <www.wto.org/wto/english/docs_e/legal_e/legal_e.htm> (accessed June 12, 2005) [hereinafter the TRIPs Agreement].

[238] TRIPs Agreement, art. 4.

[239] TRIPs Agreement, art 1.1

[240] The 1883 Paris Convention, the 1886 Berne Convention, the Rome Convention, and the Treaty on Intellectual property in respect of integrated circuits are all administered by the World Intellectual Property Office (WIPO) available at < www.wipo.int/treaties/en/> (accessed June 12, 2005).

[241] *Understanding on Rules and Procedures Governing the Settlement*, Annex 2 to the *Agreement Establishing the World Trade Organization*, 15 April 1994 available at <www.wto.org/wto/english/docs_e/legal_e/legal_e.htm > (accessed June 12, 2005) [hereinafter DSU].

[242] Gervais *supra* note 235 at 9.

and decisions and to monitor Member states' compliance with the WTO dispute rulings.[243] If a member fails to comply with a given WTO ruling, the DRB has the power to authorize trade-retaliation measures against that member.[244]

An advantage of the DSU is that it is a relatively quick process. Under the DSU, the members involved in a dispute must enter into consultations with each other.[245] If the consulting members fail to resolve the dispute within 60 days, the DRB will, on request, establish a dispute panel consisting of either three or five experts within a period of 45 days of receiving the request.[246] The panel will then prepare a report and submit it to the DRB and the parties concerned within 6 months of the panel being established.[247] The DRB must then decide whether to adopt or to reject the panel's report within 60 days unless an appeal is launched.[248] The report may only be rejected by consensus, otherwise the report is automatically adopted.[249] Altogether, it should take between 12 and 15 months with an appeal for a given dispute to be resolved.[250]

3.2 Articles 7 and 8: Objectives and Principles

Articles 7 and 8 articulate objectives and principles for the TRIPs Agreement, however, they do not provide much clarity in how the Agreement should be interpreted. Article 7 is entitled "Objectives" and reads as follows:

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[243] DSU, art. 1.
[244] DSU, art. 22.
[245] DSU, art. 4.
[246] DSU, art. 6-8.
[247] DSU, art. 12.8.
[248] DSU, art 16.4.
[249] DSU, art. 16.
[250] Kripapuri *supra* note 236 at 695; Pugatch *supra* note 235 at 132-133.

7. The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

In this article is the recognition that not only do IP rights not exist in a vacuum, but also that they exist so that they can promote technological innovation and disseminate technology.[251] Article 7 also emphasizes that a balance should be respected between intellectual property rights holders and intellectual property users. IP rights that are too strong can stifle competition and work against social and economic welfare.

It has been suggested that respondents in a WTO dispute will try to rely on this article to justify limits to IP rights in their national legislation. In support of this position is the fact that the objectives listed in this article are found within the body of the Agreement itself and are not simply part of the preamble.[252] A general principle of treaty interpretation is that terms in an article are presumed not to be surplus but to provide substantive rights or obligations.[253] The uncertainty, however, arises from the permissive language used in article 7 where it says that: "intellectual property rights should contribute...." In comparison, other articles in the TRIPs Agreement that provide substantive obligations use the term "shall" or its equivalent provisions. It is unlikely

[251] K.M. Saunders, "Patent Non-Use and the Role of Public Interest as a Deterrent to Technology Suppresion" (2001-2002) 15 Harvard Journal of Law & Technology 389 at 438; Kripapuri *ibid.* at 676; Gervais *supra* note 235 at 64-65; UNCTAD-ICTSD, *Resource Book on TRIPS and Development* (Cambridge, Cambridge University Press, 2005) at 126.
[252] Gervais *supra* note 235 at 64.
[253] UNCTAD *supra* note 251 at 118-119.

that an article using the term "should" provision would provide a substantive limit on an article using the term "shall."[254]

Article 8 is entitled "Principles" and reads as follows:

8.1 Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

8.2 Appropriate measures, provided they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

Similar to article 7, article 8 also articulates a balance to the protection of IP rights in areas of public health and nutrition and sectors "of vital importance to their socio-economic and technological development." Appropriate grounds for limiting IP rights are found in the second paragraph of article 8 as follows: abuse of patent rights; competition laws; and adverse affects on the international transfer of technology.[255] This may seem to be broader than article 7 but both paragraphs are limited by the need for any restrictions to be "consistent" with the other provisions of the TRIPs Agreement. In particular, article 8.2 has been criticized as being ineffective in its failure to specify what practices may be anti-competitive.[256]

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[254] Gervais *supra* note 235 at 64.
[255] Saunders *supra* note 251 at 438; Kripapuri *supra* note 236 at 676.
[256] Pugatch *supra* note 235 at 137 further noting that article 40 does refer to specific anticompetitive practices in contractual licensing.

The likely effect of both articles 7 and 8 is that they will be treated as interpretive tools to assist with understanding the scope of the remaining provisions but without creating rights in and of themselves.[257]

3.3 Article 27: Non-discrimination

Article 27 requires that Member states make patent protection available without discrimination "as to the place of invention, the field of technology and whether products are imported or locally produced." This article has been discussed in "one of the most interesting disputes concerning TRIPs pharmaceutical IP agenda,"[258] namely the *Canada-Patent Protection* case.[259] In this case, the EU objected to the inclusion within Canada's *Patent Act* of provisions beneficial to the generic pharmaceutical industry. This is one of the most interesting and important DRB decisions: it dealt with the interpretation of the TRIPs Agreement; it involved a dispute between two developed countries; and it represented a clash among two major segments of the pharmaceutical industry, namely the research based industry and the generic industry.[260]

In the *Canada-Patent Protection* case, the Canadian delegation argued that Member states could discriminate on the basis of technology when drafting an exception under article 30.[261] However, the Panel rejected this contention and concluded that any

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[257] Gervais *supra* note 235 at 68-69.
[258] Pugatch *supra* note 235 at 180.
[259] World Trade Organization, Report of the Panel on "Canada – Patent Protection of Pharmaceutical Products," Complaint by the European Communities and their member States, WT/DS114/R, March 17, 2000 [hereinafter *Canada – Patent Protection*].
[260] Pugatch *supra* note 235 at 181.
[261] *Canada – Patent Protection supra* note 259 at 7.88, see *infra* notes 272-275 and accompanying text for a discussion of article 30.

exception under article 30 is subject to the non-discriminatory requirements of article 27 but in doing so, noted that article 27 only prohibits three areas of discrimation, namely:

1. place of invention;
2. the field of technology; and
3. whether products are imported or produced locally.

The panel also considered a very broad definition of discrimination as used in article 27 that covers both "*de jure*" and "*de facto*" discrimination as follows:

> It is a normative term, pejorative in connotation, referring to results of the unjustified imposition of differentially disadvantageous treatment. Discrimination may arise from explicitly different treatment, sometimes called "*de jure* discrimination", but it may also arise from ostensibly identical treatment which, due to differences in circumstances, produces differentially disadvantageous effects, sometimes called "*de facto* discrimination". The standards by which the justification for differential treatment is measured are a subject of infinite complexity. "Discrimination" is a term to be avoided whenever more precise standards are available, and, when employed, it is a term to be interpreted with caution, and with care to add no more precision than the concept contains.[262]

Governments must therefore be careful in amending patent laws to address issues specific to a discrete industry such as the biotechnology industry. The Panel did note that article 27 does not prohibit *bona fide* exceptions to deal with problems that may exist only in certain product areas.[263] To the extent that the prohibition against discrimination does limit a government's options, this was seen as a deliberate policy choice to ensure that governments do not succumb to domestic pressures to limit exceptions to areas where right holders tend to be foreign producers.[264]

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[262] *Canada – Patent Protection ibid.* at 7.94.
[263] *Canada – Patent Protection ibid.* at 7.92.
[264] *Canada – Patent Protection ibid.* at 7.92.

The concept of *bona fide* exceptions has been characterized as being a distinction between "discrimination" on the one hand that is not permitted under Article 27 and "differentiation" that is permitted. Thus, WTO members are allowed to adopt different rules as long as those rules only differentiate between products and do not discriminate against foreign producers.[265]

The Panel then discussed briefly the relationship between the prohibition against discrimination and the objectives and principles of the TRIPs Agreement as articulated in Articles 7 and 8. The concern was raised that members must be able to discriminate to a certain extent in order to deal with such objectives and policies within their national laws. The Panel however, was more concerned with member countries "succumb[ing] to domestic pressures to limit exceptions to areas where right holders tend to be foreign producers."[266] This suggests that the general objectives and policies in Articles 7 and 8.1 are limited by the more specific principle of non-discrimination in Article 27.1.[267]

It is interesting to note that the TRIPs Agreement explicitly provides for some exclusions to patentability based on technology. For example, WTO members can exclude from patentability: plants and animals;[268] therapeutical, surgical and diagnostic methods;[269] and inventions that are contrary to *ordre public* or morality.[270] However,

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[265] UNCTAD *supra* note 251 at 370-371.
[266] *Canada – Patent Protection supra* note 259 at 7.92.
[267] UNCTAD *supra* note 251 at 129.
[268] TRIPs Agreement, art. 27.3(b).
[269] TRIPs Agreement, art. 27.3(a).
[270] TRIPs Agreement, art. 27.2.

Members are required to protect IP rights of plant breeders either by patents or by any other effective *sui generis* system based on plant breeders' rights.[271]

3.4 Article 30: Exceptions to Rights Conferred

Article 30 allows Member states to make limited exceptions to patent rights and reads as follows:

> 30. Members may provide limited exceptions to the exclusive rights conferred by a patent, 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 account of the legitimate interests of third parties.

In addition to the scope of article 27, the DSB in the *Canada-Patent Protection* case also discussed article 30 within the context of two specific provisions of the Canadian *Patent Act*. The first is commonly referred to as the "early working" or "Bolar" exception: it allows companies to use patented inventions for the purpose of submitting experimental results to a regulatory body.[272] This process is most relevant to the generic pharmaceutical industry that must engage in an extensive regulatory review process before being able to market a generic drug. Without such an exception, the generic pharmaceutical companies would have to wait until the expiry of the patent on the innovator drug before being able to start the regulatory review process, estimated to be between one and two-and-a-half years.[273] The second provision allows generic pharmaceutical companies to stockpile patented drugs during the pendency of the patent

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[271] TRIPs Agreement, art. 27.3(b); in Canada, this is accomplished through the *Plant Breeders' Rights Act*, S.C. 1990, c. 20.
[272] *Patent Act*, s. 55.2(1) as amended S.C. 1993, c.2, s.4.
[273] Kripapuri *supra* note 236 at 696; *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, [2005] SCC 26 at para 11 [hereinafter *BMS*].

protection for sale after the patent expired.[274] Together, the two provisions allow the generic pharmaceutical industry to enter the market the day after the patent expired.

The Canadian delegation argued four main points: the exceptions for early working and stockpiling were limited to pharmaceuticals; they did not conflict with the life of the patent; in any event, they were within Canada's national interest according to Article 7; and they did not prejudice the legitimate interests of the patent holder. Ultimately, The DRB panel found that Canada's early working exception was a "limited exception" to patent rights and therefore consistent with the provisions of article 30 of the TRIPs Agreement. However, the stockpiling exception was considered to be a substantial curtailment of the exclusive rights that patent owners are entitled to under the TRIPs Agreement. The panel based its conclusion on both legal interpretation and economic reasoning. In both cases, the provisions were drawn to reducing post-patent expiry market exclusivity. The difference is that stockpiling reduced what was felt to be a normal part of the patent exclusivity and was inconsistent with expected market effects. On the other hand, the early working exception reduced market exclusivity that only existed as a result of government regulation. To the extent that the exception only reduced artifacts introduced by government regulation it was found to be consistent with the TRIPs Agreement. Both of these provisions are discussed in more detail in Chapter IV.[275]

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[274] Patent Act, s. 55.2(2), repealed by S.C. 2001, c. 10, s. 2(1).

[275] For the Bolar exception, see *infra* notes 349-363 and accompanying text; for the stockpiling exception, see *infra* notes 431-433 and accompanying text. The stockpiling exception was repealed by S.C. 2001, c. 10, s. 2(1).

3.5 Article 31: Other Use Without Authorization

Article 31 of the TRIPs agreement addresses what are commonly referred to as compulsory licences, licences as of right or non-voluntary licences. The article itself refers to such use as "Other Use Without Authorization of the Right Holder."[276] The words "other use" refers to use other than that allowed under Article 30.[277]

Compulsory licensing is an authorization given by a national authority to a person for the exploitation of an invention protected by patent rights against the consent of the patent holder.[278] Article 31 provides a relatively detailed list of 12 paragraphs that must be satisfied before a compulsory licence can be granted. Member states can decide for themselves what grounds, if any, for which a compulsory licence can be granted.[279]

Four situations are explicitly mentioned in article 31 as justifying the grant of a compulsory licence, namely: emergency and extreme urgency; anti-competitive practices; public non-commercial use; and dependent patents. These situations are non-exhaustive and member nations are able to establish compulsory licences on other grounds. For example, it has been proposed that licences should be available to protect the environment or for general reasons of "public interest", the latter already being present in

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[276] Kripapuri *supra* note 236 at 676.
[277] Note to art. 31.
[278] G. Julian-Arnold, "International Compulsory Licensing: The Rationales and the Reality"(1992-1993) 33 IDEA: Journal of Law and Technology 349 at 349; A. Gillat, "Compulsory Licensing to Regulated Licensing: Effects on the Conflict Between Innovation and Access in the Pharmaceutical Industry" (2003) 58 Food and Drug Law Journal 711 at 712; J.A. Yosick, "Compulsory Patent Licensing for Efficient Use of Inventions" (2001) 2001(5) University of Illinois Law Review 1275 at 1276; S.V. Vaughan, "Compulsory Licensing of Pharmaceuticals Under TRIPS: What Standard of Compensation?" (2001) 25 Hastings International & Comparative Law Review 87 at 96.
[279] UNCTAD *supra* note 251 at 468. .

the German patent law.[280] Public interest is also a ground in U.S. law where compulsory licensing is available under the Atomic Energy Act[281] and the Clean Air Act.[282]

On November 14, 2001, the General Council of the WTO adopted the Declaration on the TRIPs Agreement and Public Health (the Doha Declaration).[283] The Doha Declaration was written to provide clarity about the scope of the TRIPs Agreement and member states' abilities to address national emergencies. It is in this context that the declaration specifies that each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are to be granted.[284] In addition, the declaration states that each member has the right to determine what constitutes a national emergency or what other circumstances of extreme urgency justify the granting of a compulsory licence. The declaration provides examples of public health crises as including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics.

Article 31 only provides minimum standards and member states are allowed to be more restrictive in granting any compulsory licences. In addition, any compulsory

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[280] C.M. Correa, "Intellectual Property Rights and the Use of Compulsory Licences: Options for Developing Countries" (October 1999) Trade-Related Agenda, Development and Equity (T.R.A.D.E.) Working Papers 5 at 8.

[281] Atomic Energy Act, 42 U.S.C. 2183 (allowing the Atomic Energy Commission to compel licensing of certain "public interest" patents).

[282] Clean Air Act, 42 U.S.C. 7608 (allowing compulsory licences if use of the patented invention is required to meet emission requirements, no reasonable alternative is available to meet the requirements, and the lack of availability of the patent would tend to lessen competition).

[283] World Trade Organization, Declaration on the TRIPs Agreement and Public Health, Fourth Ministerial Conference in Doha, Qatar, WT/MIN(01)/DEC/2, 20 November 2001 available at <www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm> (accessed May 21, 2005) [hereinafter Doha Declaration]; UNCTAD *supra* note 251 at 474.

[284] Doha Declaration *ibid.*

licence scheme must be consistent with the other provisions of the TRIPs Agreement. The 12 paragraphs (a) to (l) are summarized below.

3.5.1 Individual Merits (paragraph a)

Any compulsory licence must be made on a case-by-case basis after consideration of the individual merits of the application.[285] This provision would seem to prevent entire classes of inventions becoming automatically eligible for compulsory licensing (for example, medicines). However, simply because a licence needs to be considered individually does not mean that there cannot be presumptions in favour of granting compulsory licensing in certain circumstances. The burden would then be on the patent holder to justify why a compulsory licence should not be granted.[286]

3.5.2 Prior Negotiation (paragraphs b and k)

Any applicant for a compulsory licence must have made reasonable efforts and failed to obtain a licence from the right holder on reasonable commercial terms.[287] Exceptions to this requirement may include: cases of a national emergency or other extreme urgency; or, cases of public non-commercial use.[288] If a member state permits a compulsory licence under one of these exceptions, the right holder must be informed of the licence if the user knows or has reasonable grounds to know that the technology is patented. The article specifically excludes any requirement to conduct a patent search.[289]

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[285] TRIPs Agreement, art. 31(a).
[286] UNCTAD *supra* note 251 at 684.
[287] TRIPs Agreement, art. 31(b).
[288] UNCTAD *supra* note 251 at 470-471; Gervais *supra* note 235 at 165.
[289] Gervais *supra* note 235 at 165.

However, if there is no requirement to do a search and the user does not know the technology is patented, this raises the interesting question of how or why a user would seek a compulsory licence in the first place. Unless the applicant knows about the patent, he would not know that a licence under the patent is needed. A further exception to the requirement for prior negotiation occurs when the compulsory licence is granted to remedy an anti-competitive practice.[290]

Reasonableness is not defined in the article but would necessarily depend on several factors including: the technology involved; any practices within the member country; any practices in neighbouring countries; and even any practices on a world-wide scale to the extent that the technology is used on a world-wide scale.[291] Reasonableness also extends to the amount of negotiation time. Patent holders who do not want to licence their technology would likely prolong any negotiations while maintaining only the appearance of good faith. Reasonableness may also vary depending on the technology involved with important life-saving technologies justifying a shorter time-frame.[292]

The Doha Declaration on the TRIPs Agreement also stated that when a country declares a national emergency, there is no need to negotiate a licence in good faith with the patentee before granting a compulsory licence.[293]

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[290] Gervais *ibid.* at 165; TRIPs Agreement, art. 31(k).
[291] Gervais *ibid.* at 165.
[292] UNCTAD *supra* note 251 at 470.
[293] A. Bagchi, "Compulsory Licensing and the Duty of Good Faith in TRIPS" (2003) 55 Stanford Law Review 1529 at 1548; C. Chien, "Cheap Drugs At What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?" (2003) 18 Berkeley Technology Law Journal 853 at 871.

3.5.3 Limited Duration (paragraphs c and g)

The duration of any compulsory licence must be limited to the purpose for which the licence was granted. If circumstances that led to the compulsory licence change such that they would no longer justify the compulsory licence and are unlikely to recur, then there should be a mechanism for the licence to be revoked. For example, at the end of a national emergency, there would have to be some mechanism for the licence to come to an end. There are several different ways this requirement can be satisfied. For example, the compulsory licence can specify a limited term, with or without the possibility of extensions.[294] Alternatively, the licence can extend indefinitely until the expiry of the patent subject to the patent holder seeking a review of the order granting a compulsory licence.[295] The latter option places the onus on the patent holder to vary the order whereas the former option places the onus on the licencee. Either way would satisfy the requirements under the TRIPs Agreement and it is up to the individual member state to decide the best way of meeting their public policy objectives.

In any review, the legitimate interests of the licence holder should also be taken into account. Legitimate interests would include reasonable investments made in reliance on the licence.[296] This helps reassure potential applicants that they do not risk losing their rights under the patent at any time, particularly if they have made significant invenstments in reliance of the licence.[297]

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[294] UNCTAD *supra* note 251 at 475.
[295] Gervais *supra* note 235 at 165-166.
[296] Gervais *ibid.* at 166.
[297] Correa *supra* note 280 at 8.

3.5.4 Limited Scope (paragraph c)

In addition to the duration, the scope of the licence must be limited to the purpose for which the licence was granted. This could be addressed by subjecting only certain claims of a patent to the licence. Alternatively, there may be geographical limitations or field of use limitations placed on the compulsory licence.

3.5.5 General Licensing Terms (paragraphs d and e)

Any compulsory licence granted must be non-exclusive.[298] This allows the patentee to grant licences to other parties within a market. A risk associated with this provision is that the licencee will see significant competition that did not exist prior to the application for a licence from either the patentee or another licencee.[299] This may not be desirable from the perspective of the licencee, but increased competition is almost always beneficial for society as a whole.

In addition, assignments are only permitted to the extent that the entire part of the business enterprise or goodwill which enjoys the use of the licence is assigned.[300] The purpose of this provision is to prevent the development of a market in compulsory licences as instruments with independent value. However, there is no harm in allowing the sale of the entire business that has obtained the compulsory licence.[301]

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[298] TRIPs Agreement, art. 31(d).
[299] UNCTAD *supra* note 251 at 473.
[300] TRIPs Agreement, art. 31(e).
[301] UNCTAD *supra* note 251 at 73.

3.5.6 Domestic Market (paragraphs f and k)

Any compulsory licence must be used to "predominantly" satisfy the domestic market.[302] Some export of the product is permissible as long as the main purpose remains the supply of the domestic market.[303] The word "predominantly" may even suggest that up to 50% of the market may be foreign.[304] The exception to this requirement is provided for in paragraph (k): when compulsory licences are granted to remedy an anti-competitive practice, the resulting licence does not need to be limited to the domestic market. [305]

On August 31, 2003, the General Council of the WTO adopted the Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPs Agreement.[306] The Decision establishes a mechanism under which export of generic pharmaceuticals to countries in urgent medical need of such pharmaceuticals and that do not have the facilities for their own manufacture. Canada and Norway have amended their respective acts to allow for compulsory licences for export under this scheme and a number of other countries are proposing to do so.[307]

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[302] TRIPs Agreement, art. 31(f).
[303] Gervais *supra* note 235 at 166; UNCTAD *supra* note 251 at 474.
[304] UNCTAD *ibid.* at 474.
[305] TRIPs Agreement, art. 31(k).
[306] World Trade Organization, Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health WT/L/540, 2 September 2003 [hereinafter Implementation of Doha]; see also Doha Declaration *supra* note 283; UNCTAD *supra* note 254 at 474.
[307] *An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa)*, S.C. 2004, c. 23; UNCTAD *supra* note 251 at 483-484.

3.5.7 Adequate Remuneration (paragraphs h and k)

The compulsory licence must provide for adequate remuneration.[308] Determining the appropriate royalty rate can be one of the most difficult aspects of granting a compulsory licence. It must be done after considering all of the circumstances of each case, as well as the economic value of the licence. In other words, there needs to be some calculation of the value of an arms length transaction between a willing licensor and a willing licencee. This will vary depending on the technology and the circumstances within the domestic market, any neighbouring markets and the world market.[309] If the licence is granted to remedy an anti-competitive practice, then a lower level of remuneration may be justified even to the extent that the licence becomes royalty-free.[310]

The WTO also allows for a waiver of the requirement for adequate remuneration in the eligible importing member nation when remuneration is paid in the exporting member nation.[311] This avoids the patent holder from receiving compensation twice: once from the exporting member and a second time from the importing member. The level of compensation is also determined "taking into account the economic value to the importing member of the use that has been authorized in the exporting member."[312]

3.5.8 Judicial or Similar Review (paragraphs i and j)

Any decision regarding the authorization of a compulsory licence including grant of the licence, duration, scope, amount of remuneration, renewal or continuation must be

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[308] TRIPs Agreement, art. 31(h).
[309] Gervais *supra* note 235 at 166; UNCTAD *supra* note 251 at 475-477.
[310] TRIPs Agreement, art. 31(k); Gervais *ibid.* at 166; Correa *supra* note 280 at 9; UNCTAD *ibid.* at 476.
[311] Implementation of Doha, *supra* note 306, para. 3.
[312] Implementation of Doha, *ibid.*

subject to review by a higher authority with the power to overturn the decision of the granting authority.[313] Typically this will require some form of judicial review though the use of the words "higher authority" could simply refer to a more senior government person or body than the granting person or body.[314] The general manner in which these provisions are set out allows each member state to adopt some form of review that is consistent with their legal institutions.[315]

3.5.9 Special Cases (paragraphs c and l)

There are two special cases mentioned within article 31, namely semi-conductor technology and dependent patents.[316] For semi-conductor technology, compulsory licences can only be granted for public non-commercial use or to remedy an anti-competitive practice. This is the only technology where the scope for granting compulsory licences has been limited to such an extent.[317]

In the case of dependent patents, use of a second patent (the dependent patent) requires access to a prior, dominant patent.[318] The second patent often represents an improvement over the dominant patent. Typically, a dominant patent holder and a dependent patent holder will cross-licence their patents so that each party can practice both the basic invention and the improvement. However, if the two patent holders cannot come to some sort of agreement, then the dependent patent cannot be exploited by either

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[313] TRIPs Agreement, art. 31(i); any decision relating to remuneration is specifically and separately provided for under art. 31(j).
[314] UNCTAD *supra* note 251 at 478.
[315] UNCTAD *ibid.* at 477-478.
[316] Julian-Arnold *supra* note 278 at 350.
[317] Correa *supra* note 280 at 8-9.
[318] Yosick *supra* note 278 at 1287-1288.

party until the dominant patent expires. This hold-up problem can be quite serious when the improvement patent represents a significant advance over the dominant patent. Several countries allow compulsory licencing of dependent patents for this reason.[319]

Article 31 of the TRIPs Agreement provides several safeguards that must be in place before a country can provide for compulsory licensing of dependent patents. These requirements include:

1. the invention claimed in the dependent patent must involve an important technical advance of considerable economic significance in relation to the dominant patent;
2. the owner of the dominant patent must be entitled to a cross-licence on reasonable terms to use the invention claimed in the dependent patent; and
3. the licence of the dominant patent is non-assignable except with the assignment of the dependent patent.

3.6 Comparison of Articles 30 and 31

Article 30 is titled "Exceptions to Rights Conferred" whereas article 31 is titled "Other Use Without Authorization of the Right Holder." There have not yet been any challenges under the WTO providing greater guidance on how article 31 will be interpreted and only one challenge under article 30. There remains considerable uncertainty as to how both provisions will be interpreted as well as how the two provisions inter-relate. The first indication about the relationship between the two

[319] Canada does not provide for compulsory licensing of dependent patents but this is found in, for example, the patent laws of France and Switzerland: Julian-Arnold *supra* note 278 at 349-351; Drahos *supra* note 236 at 479.

articles is in their relative structures: article 30 is relatively short and broadly written whereas article 31 contains a list of requirements that must be met before a compulsory licence can be granted. In other words, article 30 is a "general exception" whereas article 31 is a "specialized provision."[320]

The basic principle in interpreting the relationship between a general exception and a specialized provision is that specialized provisions dominate.[321] The general exception can only be invoked in situations where the specialized provision does not apply. Further, the general exception can only be used such that it does not dilute the rules applying to the specialized provisions. As applied to the TRIPs Agreement, the specialized provision in article 31, titled "other use," includes cases of use by governments or by third parties authorized by governments. As a result, article 30 should be interpreted in a way that does not include use by governments or by third parties authorized by governments and in a way that does not dilute the requirements for such use. Any other interpretation of article 30 would render the specific requirements of article 31 superfluous.[322]

A compulsory licence under article 31 must be made on a case-by-case basis after an application is made to a relevant authority. In comparison, article 30 allows limited exceptions that operate automatically such as experimental use, early working exceptions, or private and non-commercial use.[323] Another difference is that compulsory licences require "adequate" remuneration to the patent holder whereas an exception under article

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[320] Gervais *supra* note 235 at 159.
[321] Gervais *ibid.* at 159.
[322] Gervais *ibid.* at 159.
[323] Correa *supra* note 280 at 7; these exceptions are discussed in more detail in Chapter IV.

30 only requires that the exception does not "unreasonably prejudice the legitimate interests of the patent owner." While this may allow for some remuneration to be paid to the patent holder under article 30, all that is required is that the legitimate interests not be unreasonably prejudiced. This is generally understood to mean that royalty-free use of the invention is permitted under article 30.[324]

3.7 Application to Research Tools

The TRIPs Agreement provides the legal landscape where Canada, and all WTO Member nations are situated. In dealing with problems associated with the patent system, it is important to be aware of the landscape and the consequences of making proposals that are inconsistent with the TRIPs Agreement.

The lack of challenges under the DSU system means that there remains considerably uncertainty surrounding how the different provisions will be interpreted. Since 1995, there have been a total of 330 disputes brought to the WTO. Until June 2000, approximately 10% of the disputes related to the TRIPs Agreement.[325] It was at this point that the US initiated complaints against both Brazil and Argentina for adequate patent protections on pharmaceuticals.[326] This was a highly unpopular move and the US was under significant political and social pressure both internationally and domestically.

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[324] Correa *supra* note 280 at 7 stating that "the use is not subject to any compensation."
[325] 19 out of 199 disputes involved IP until June 8, 2000; see WTO Dispute Settlement available at <www.wto.org/english/tratop_e/dut_e/dispu_status_e.htm> (accessed June 17, 2005).
[326] World Trade Organization, "Argentina – Certain measures on the protection of patents and test data," DS196, June 6, 2000 available at <www.wto.org/english/tratop_e/dut_e/dispu_status_e.htm> (accessed June 17, 2005) [hereinafter *Argentina – Protection of Patents*]; World Trade Organization, "Brazil – Measures affecting patent protection," DS 199, June 8 2000 available at <www.wto.org/english/tratop_e/dut_e/dispu_status_e.htm> (accessed June 17, 2005) [hereinafter *Brazil – Patent Protection*].

Brazil then retaliated by initiating a complaint against the US.[327] Shortly thereafter, all three complaints were dropped and since then, there has been only one complaint brought by Australia against the EC in April 2003 relating to trade-marks.[328] This represents a drop from 10% of WTO challenges relating to IP before June 2000 to less than 1% since then.

One explanation raised for the dearth of challenges under the TRIPs Agreement is that the resulting ambiguity serves the interests of the developed nations that do not want to risk a binding negative decision by the DSB. The uncertainty resulting from a lack of decisions coming from the DSB has made countries reluctant to rely on articles 30 and 31 for fear of trade reprisals.[329] In addition, the developed nations are able to exploit this ambiguity while still achieving their desired results through bilateral free-trade agreements (FTAs).[330] FTAs have the further advantage since IP represents only a relatively small part of any such agreement. Accordingly, it is much less likely to garner as much negative publicity compared to an overt challenge to a nation's intellectual property laws. The United States has been particularly active in pursuing FTAs that go beyond the minimum standards established by the TRIPs Agreement.[331]

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[327] World Trade Organization, "United States – US Patents Code," DS224, January 31, 2001 available at <www.wto.org/english/tratop_e/dut_e/dispu_status_e.htm> (accessed June 17, 2005).

[328] World Trade Organization, "European Communities – Protection of trademarks & geographical indications for agricultural products and foodstuffs," DS290, April 23, 2003 available at <www.wto.org/english/tratop_e/dut_e/dispu_status_e.htm> (accessed June 17, 2005) [hereinafter *European Communities – Protection of Trademarks*].

[329] M.A. Bagley, "Legal Movements in Intellectual Property: TRIPS, Unilateral Action, Bilateral Agreements, and HIV/AIDS" (2003) 17 Emory International Law Review 781 at 784.

[330] Bagchi *supra* note 293 at 1553; Sell *supra* note 236 at 500-504.

[331] See C. Fink & P. Reichenmiller, "Tightening TRIPS: The Intellectual Property Provisions of Recent US Free Trade Agreements" (International Trade Department,

The WTO has emphasized the importance of R&D in the development of new pharmaceuticals and adopted a Ministerial Declaration on November 14, 2001 which reads at paragraph 17 as follows:

> We stress the importance we attach to implementation and interpretation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement) in a manner supportive of public health, by promoting both access to existing medicines and research and development into new medicines and, in this connection, are adopting a separate declaration.[332]
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> (my emphasis)

The separate declaration referred to in the Minsterial Declaration is the Doha Declaration.[333] The Doha Declaration elaborates on the relationship between articles 30 and 31 within the context of public health concerns.[334] However, R&D as discussed within the Ministerial Declaration and the Doha Declaraiton is presented in a different context than as used within this thesis. Strong patent rights were seen by the WTO as important to encourage new R&D into new medicines but a public health need was also recognized to allow access to existing medicines. Within the context of this thesis, strong patent rights on research tools risk hampering the development of R&D of new medicines. To the extent that the WTO supports the development of new medicines as

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World Bank Insititute, 2005) available at <www.worldbank.org/trade> (accessed June 2, 2005) for a review of recent US FTAs recently signed and approved by US Congress with Vietnam, Jordan, Singapore, Chile, Morocco, Australia; US FTAs recently signed but not yet approvd as of February 2005 with DR-CAFTA (Dominican Republic, Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua), Bahrain; and US FTAs currently being negotiated with Andean Countries (Columbia, Ecuador, Peru), Thailand, Panama, Southern African Customs Union, Free Trade Area of the Americas.

[332] World Trade Organisation, Ministerial Declaration, Fourth Ministerial Conference in Doha, Qatar WT/MIN(01)/DEC/1, 14 November 2001.

[333] Doha Declaration *supra* note 283.

[334] Doha Declaration *ibid.*; see also Chien *supra* note 293; Sell *supra* note 236 at 514-519; C.M. Correa, "TRIPS and Access to Drugs: Toward a Solution for Developing Countries Without Manufacturing Capacity? (2003) 17 Emory Internation Law Review 389 at 390-397.

shown through these declarations, then weaker patent protections on research tools would also be warranted.

Article 27 of the TRIPs Agreement prohibits discrimination by technology and could therefore potentially be of importance in the following chapters since this thesis is directed to a specific problem found within a discrete technological area. However, to the extent that any exceptions under article 30 or compulsory licences under article 31 are for *bona fide* purposes and not to simply discriminate against foreign producers, they will be consistent with article 27, it will, therefore, not be necessary to discuss article 27 further.

In comparison, articles 30 and 31 provide two separate mechanisms within the TRIPs Agreement to address abuses and excesses of the patent system such as those found with research tools in biotechnology. Chapter IV will address the experimental use exception to patent infringement and as an exception to patentability, article 30 of the TRIPs Agreement is of particular relevance to this discussion. Chapter V then follows with a detailed discussion of compulsory licensing currently existing under Canadian patent and competition laws and reference will be made to article 31 of the TRIPs Agreement.

CHAPTER IV
THE EXPERIMENTAL USE EXCEPTION

4.0 Introduction

In the patent system, monopolies are granted to rights holders for a limited time with the ultimate goal of encouraging the progress of science, and ultimately, it is society as a whole that benefits from new technological advancements.[335] There is, however, a tension between patent holders who seek strong patent rights to their inventions and the general public that benefits from access to inventions and a large public domain. The Supreme Court of Canada has recently pronounced on the need to respect the balance between intellectual property rights holders and the general public in several recent and high profile cases dealing with both copyright[336] and patent laws:[337] within the context of patent law this balance is found, in part, in the recognition of an experimental use exception to patent infringement.

In the absence of such an exception, any experimentation on the patented invention would be contrary to the exclusive rights granted under a patent. The scope of the exception varies from country to country, but includes one or more of the following:[338]

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[335] This purpose is codified in the U.S. constitution and in the TRIPs Agreement, art. 7, see *supra* note 37, 251-254.
[336] *Théberge v. Galerie d'Art du Petit Chamlain Inc.*, [2002] 2 S.C.R. 336 at para. 30; *CCH Canadian Ltd. v. Law Society of Upper Canada*, [2004] 1 S.C.R. 339 at para. 10; *Society of Composers, Authors and Music Publishers of Canada v. Canadian Association of Internet Providers*, [2004] 2 S.C.R. 427 at para. 40.
[337] *BMS* supra note 273; *Monsanto Canada Inc. v. Schmeiser* [2004] S.C.C. 34.
[338] *Canada-Patent Protection* case *supra* note 259, Canadian submissions to Panel cited at 75.

1. tests on an invention to determine its sufficiency or to compare it to prior art;
2. tests to determine how the patented invention works;
3. experimentation on a patented invention for the purpose of improving on it or developing a further patentable invention;
4. experimentation for the purpose of "designing around" a patented invention;
5. tests to determine whether the invention met the tester's purposes in anticipation of requesting a licence; and
6. academic instructional experimentation with the invention.

The experimental use exception has alternately been described as an exception, a defence or an exemption. The term exception is used herein to maintain consistency with the TRIPs Agreement but all three terms are equivalent and can be used interchangeably.

The experimental use exception is an essential part of the patent system in fostering the greater dissemination of technical knowledge. One of the main requirements of obtaining patent rights is the full and complete disclosure of the invention so as to enable a person skilled in the art to be able to carry out the invention.[339] It would be antithetical to the purpose of the patent system in promoting the progress of science if the public could not experiment on an invention until the expiry of the patent.[340]

[339] *Patent Act*, s.27 as amended S.C. 1993, c. 15, s. 32.
[340] Hoffman *supra* note 22 at 1038.

Under general principles of patent law, a patent holder is given the exclusive rights to make, use or sell an invention.[341] The "use" in an experimental use exception is much broader than a patent "use" of an invention and includes both making an invention as well as using the invention for the purposes of experimentation thereon. Any manufacture or use of the invention for commercial purposes would be outside of the scope of the exception. Similarly, there is no such thing as an "experimental" sale of an invention and this would remain within the exclusive rights of the patentee.

In this chapter, the scope of the experimental use exception will be examined with the particular goal of seeing how it addresses the issues of allowing access to patented research tools. This analysis will start with an introduction to three related exceptions. In part 4.2, a comparative analysis will be undertaken to show how the exception has developed in different countries, and in part 4.3 some specific issues that arose from the comparative analysis will be examined. Part 4.4 will apply the traditional experimental use exception to research tools, and will show that the current exemption is inadequate to deal with the problems identified in Chapter I. In part 4.5, various proposals for reform of the experimental use exception will be discussed as well as a new proposal that addresses most of the issues of inadequate access to essential tools.

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[341] See *Patent Act*, s. 42 which reads as follows:

s.42 Every patent granted under this Act shall ... grant to the patentee ... the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used ....

Importation has been judicially read into the exclusive rights of the patentee: *Société des Usines Chimiques Rhone-Poulenc v. Jules R. Gilbert Ltd.* (1967), 35 Fox Pat. C. 174 [affd 55 C.P.R. at 209, 69 D.L.R. (2d) 353, [1968] S.C.R. 950]. See also TRIPS, article 28 which lists the exclusive rights as: making, using, offering for sale, selling, or importing.

4.1 Related Exceptions

In this section, three related exceptions to the grant of exclusive intellectual property rights will be introduced. The first exception is for acts doen for private and non-commercial use and the second is for early working of the invention for the purpose of seeking regulatory approvals. The third exception is an experimental use exception found in a related intellectual property scheme, namely plant breeders' rights.

4.1.1 Private and Non-Commercial Use

In addition to an experimental use defence, some jurisdictions explicitly exempt private and non-commercial use from patent infringement. For example, under the Community Patent Convention (CPC), article 27(a) reads as follows:

> 27 The rights conferred by a Community patent shall not extend to:
> (a) acts done privately and for non-commercial purposes.[342]

This provision has been incorporated into the national laws of many States of the European Union including, for example, section 60(5)(a) of the Patents Act 1977 (UK).

While there have not been any cases in Canada, there is some statutory authority that a similar private and non-commercial defence would apply under common law principles.[343] According to UK jurisprudence, the word "privately" can include both commercial and non-commercial acts and is meant to encompass acts done for the person's own use. Privately does not mean the same thing as either "secret" or

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[342] Council Agreement relating to Community Patents No. 89/695/EEC, 15 December 1989, OJ L 401/01. [hereinafter the CPC]. The CPC must be ratified by all European Union member States before it takes effect. Fewer than half of the member States have ratified it: European Union, Patents, available at <www.eurunion.org/legislat/iiprop/patents/htm>

[343] See *infra* note 407 and accompanying text.

"confidential".[344] However, in addition to being private, the use must also be non-commercial. If there is any commercial purpose, even if the dominant purpose were non-commercial, then the defence would not apply. However, if all of the purposes are non-commercial, the fact that the knowledge gained could have some commercial benefit does not prevent the application of this defence. This is a subjective test based on the intent of the defendant.[345]

There is an interesting issue of what constitutes a "commercial use," and there is conflicting international authority on this issue. In the UK decision *Smith Kline & French Laboratories*, the court held that experiments done for legal proceedings in the High Court or in the Patent Office are not done for a commercial purpose.[346] In comparison, in *Smith Kline v. Attorney General*,[347] a New Zealand court looked at the issue of importation of a patented sample and its submission to a regulatory authority. In this New Zealand case, the sample was submitted with a view to obtaining permission to market a drug even though the drug would not actually be brought to market until after the patent expired. Cooke P. held that the defendant acted "for the commercial advantage or springboard" and that "statutory marketing approval is a form of licence and *prima facie* has commercial value.[348]

Even though the New Zealand court was not expressly considering a "private and non-commercial use" exception, it is probably a better expression of the scope of the

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[344] *Smith Kline & French Laboratories Ltd. v. Evans Medical Ltd.* [1989] FSR 513 at 517-518 [hereinafter *SK&F*].
[345] *Ibid.* at 518.
[346] *Ibid.* at 518.
[347] *Smith Kline & French Laboratories Ltd. v. Attorney-General (NZ)* [1991] 2 NZLR 560 [hereinafter *Smith Kline v. Attorney General*].
[348] *Smith Kline v. Attorney General ibid.* at 562.

exception. Every purpose motivating a private firm is essentially commercial in nature and it is unlikely that this particular defence will be used much under either common law or statutory regimes. The main beneficiaries of this defence are academic research institutions and private individuals who may use a patented invention for their own purposes.

4.1.2 Regulatory Approval

In 1993, the Canadian Patent Act was amended to exempt from infringement activities "reasonably related to the development and submission of information required under any law" that regulates the manufacture, construction, use or sale of a patented product.[349] This exemption is of particular importance to the generic pharmaceutical industry due to the extensive and lengthy trials needed to gain regulatory approval to market a drug in Canada.

This type of exemption is known as a "springboarding" provision since it allows competitors to springboard into the market as soon as the patent has expired.[350] Without such an exemption, the patentee would effectively gain an extended term of protection from competition as generic manufacturers would need to wait until the patent expires before starting the relatively lengthy process of: conducting experiments and testing of the material; submitting the material to the relevant regulatory approval process; and getting approval. This regulatory lag may be two years or more.[351] This exemption is

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[349] Patent Act, s. 55.2(1) as amended S.C. 1993, c.2, s.4.
[350] ALRC Report *supra* note 56 at 13.31.
[351] *BMS supra* note 273 at para. 11.

also known as the "early working exemption"[352] or the "Bolar" exemption, named after a 1984 U.S. decision of the Court of Appeals for the Federal Circuit.[353]

In the *Bolar* case, the Federal Circuit held that an experimental use defence did not entitle a generic pharmaceutical manufacturer to conduct experiments with a patented pharmaceutical in order to prepare a regulatory application to the United States Food and Drug Administration (FDA). Shortly after the *Bolar* decision, the United States Congress passed the *Drug Price Competition and Patent Term Restoration Act 1984 (Hatch-Waxman Act)* to overrule the *Bolar* decision and introduce an exemption for activities "solely for uses reasonably related" to the development and submission of information under a Federal law.[354]

While the language in the Canadian early working exemption is broad enough to cover any regulatory approval process, a decision before the Federal Court of Canada ruled that it only applied to the regulatory approval of pharmaceuticals and not to medical devices.[355] This decision is clearly contrary to the clear wording of the exemption in Canada.[356] The Canadian early working exemption was challenged under the WTO by

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[352] *BMS ibid.* at para. 11.
[353] *Roche Products Inc. v. Bolar Pharmaceutical Co.* 733 F. 2d 858 (Fed. Cir. 1984) [hereinafter *Bolar*]; for a discussion of the evolution of the Bolar exception in the U.S. see also G. Fox, "Integra v. Merck: Limiting the Scope of the §271(e)(1) Exception to Patent Infringement" (2004) 19 Berkeley Technology Law Journal 193.
[354] 35 U.S.C. §271(e)(1); *Integra Life Sciences v. Merck KGaA* 307 F 3d 1351 (Fed. Cir. 2002), rev'd 545 U.S. ___ (2005) available at <www.supremecourtus.gov/opinions/04slipopinion.html> (accessed June 13, 2005) [hereinafter *Integra*].
[355] *Visx, Inc. v. Nidek Co.* (1997), 77 C.P.R. (3d) 286 (FCTD); *Patent Act*, s. 55.2(1) as amended S.C. 1993, c.2, s.4.
[356] See *supra* notes 258-271 and accompanying text for a more complete discussion of artricle 27 of the TRIPs Agreement and discrimination according to field of technology.

the European Community and upheld as consistent with the TRIPs Agreement.[357] In comparison, the US Bolar exemption is specifically limited to approval processes for drugs or veterinary products.

On March 31, 2004, the European Union issued a directive requiring all member states to implement a similar early working exemption by October 30, 2005.[358] This represents a reversal of policy considering their challenge in 2000 to Canada's early working exemption under the WTO. New Zealand and Australia have also introduced similar statutory exemptions into their respective patent legislation.[359] Some jurisdictions have viewed early working activities as being included within the ambit of a pre-existing experimental use exemption,[360] other jurisdictions have expressly rejected experimental use as encompassing these activities,[361] and then there are those that have statutorily provided for such an exemption without judicially considering whether or not such activities fall within the experimental use exemption.[362] In any event, early working

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[357] The Canadian early working exemption was characterized as a limited exemption to patentability justified under article 30. See *supra* notes 272-275 and accompanying text for a more complete discussion of article 30 of the TRIPs Agreement.

[358] Directive 2004/27/EC, article 8 amending Directive 2001/83/EC, article 10(6), Official Journal of the European Union, L136/34, 30.4.2004; see also I. Schreiber & C. Nargolwalla, "Harmonization Due for Pre-Expiry Trials in Europe" (March 2005) Managing Intellectual Property 98.

[359] See *Patents Act 1953* (NZ) s 68B and *Patents Act 1990* (Cth) s 78.

[360] For example, Germany discussed *infra* notes 391-394 and accompanying text as well as Japan discussed *infra* notes 380-382 and accompanying text.

[361] For example, the United States discussed *infra* notes 368-379 and accompanying text as well as the United Kingdom discussed *infra* notes 385-390 and accompanying text and New Zealand discussed *infra* notes 403-405 and accompanying text.

[362] For example, Canada discussed *infra* notes 406-422 and accompanying text and Australia discussed *infra* notes 399-402 and accompanying text.

activities are now almost universally regarded as a legitimate exception to a patentee's exclusive rights.[363]

4.1.3 Plant Breeders' Rights

Under article 27(3)(b) of the TRIPs Agreement, member states are required to provide for the protection of plant varieties either by patents or by an effective *sui generis* system or any combination thereof.[364] The most significant internationally recognized *sui generis* system for plant varieties is the International Union for the Protection of New Varieties of Plants (known as UPOV from the French name, Union pour la protection des obtentions végétales). The first UPOV Convention was signed on December 2, 1961, revised on November 10, 1971, again on October 23, 1978 and once again on March 19, 1991. Canada implemented the 1978 UPOV Convention by enacting the *Plant Breeders' Rights Act* in 1990.[365]

The 1978 UPOV Convention provides for a "breeders' exemption" in article 5(3) as follows:

> 5(3) Authorisation by the breeder shall not be required either for the utilisation of the variety as an initial source of variation for the purpose of creating other varieties or for the marketing of such varieties. Such authorization shall be required, however, when the repeated use of the variety is necessary for the commercial production of another variety.

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[363] "Universal" within this context refers only to developed countries. No analysis has been done as to the desirability or impact of such an exemption on developing countries.
[364] TRIPs Agreement, art. 27.3(b)
[365] *Plant Breeders' Rights Act*, S.C. 1990, c. 20; see also S. Benda, "The Sui Generis System for Plants in Canada: Quirks and Quarks of Seeds, Suckers, Splicing, and Brown Bagging for the Novice" (2003) 20 Canadian Intellectual Property Review 323; N.M. Derzko, "Plant Breeders' Rights in Canada and Abroad: What are These Rights and How Much Must Society Pay for Them?"(1993-1994) 39 McGill Law Journal 144.

The breeders exemption is similar to an experimental use exception for creating new and distinct varieties.

In the 1991 UPOV Convention, the breeders' exemption was reformulated in article 15 (1) as follows:

15(1) The breeder's right shall not extend to
- a. acts done privately and for non-commercial purposes,
- b. acts done for experimental purposes, and
- c. acts done for the purpose of breeding other varieties.

Article 15(1) seems quite broad but it is subject to breeders' reach through rights in article 14(5). The reach through rights give breeders' rights not only to their own protected variety but also to varieties that are "essentially derived" from the protected variety. It is not yet clear what essentially derived means but this limits the ability of competitors to benefit from developing new varieties.[366] Canada is now considering acceding to the 1991 UPOV Convention.[367]

4.2 Comparative Analysis of Experimental Use Exception

4.2.1 United States

The United States relies on the common law to provide for what has been interpreted as being a "truly narrow" experimental use exception to patent infringement.[368] The experimental use exception was first recognized in the United States in a 1813 decision wherein Story J. stated:

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[366] 1991 UPOV, art. 14(5)

[367] On March 9, 1992, Canada signed the amended Convention signifying our intent to ratify see: <www.inspection.gc.ca/english/plaveg/pbrpov/ammende.shtml> (accessed April 5, 2005).

[368] *Bolar supra* note 353 at 862; *Embrex, Inc. v. Service Engineering Corp.*, 55 U.S.P.Q. 2d 1161 (Fed. Cir. 2000) at 1166 [hereinafter *Embrex*]; see also M. Cai, "Madey v. Duke

> [I]t could never have been the intention of the legislature to punish a man who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.[369]

Later that year, Story J. stated in *Sawin v. Guild*, that infringement requires "an intent to use for profit, and not for the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification."[370] At least one court has construed the scope of the exception as simply being a specific example of the *de minimis non curat lex* doctrine ("the law does not concern itself with trifles").[371]

The Federal Circuit in particular has looked at this exception and focused on the word "philosophical" and concluded that if the experimentation has any commercial purpose and is not "solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry"[372] then the use does not fall within the exception to infringement. Private firms would never be able to qualify for the exception as any experimentation conducted therein ultimately serves a commercial purpose. Even activities within universities are not covered by the exception as research projects "unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects."[373] Research projects undertaken at

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University: Shattering the Myth of Universities' Experimental Use Defense" (2004) 19 Berkeley Technology Law Journal 175; G.N. Pate, "Analysis of the Experimental Use Exception" (2002) 3(2) North Carolina Journal of Law & Technology 253.

[369] *Whittemore v. Cutter* 29 F.Cas. 1120 (No. 17,600) (C.C.D. Mass. 1813).

[370] *Sawin v. Guild*, 21 F.Cas. 554 (No. 12,391) (C.C.D. Mass. 1813).

[371] *Douglas v. United States*, 181 U.S.P.Q. 170 (Ct. Cl.T.D. 1974); *Pitcairn v. United States*, 188 U.S.P.Q. 35 (Ct. Cl. T.D. 1975) [affd 192 U.S.P.Q. 612 (Ct.Cl. 1976) cert. denied 434 U.S. 1051 (1978)].

[372] *Bolar supra* note 353 at 862.

[373] *Madey v. Duke University* 307 F.3d 1351 (Fed. Cir. 2002) [hereinafter *Madey*].

universities also increase the status of the institution and "lure lucrative research grants, students and faculty."[374]

One commentator has suggested that the Federal Circuit decisions erred by focusing too much on the one word "philosophical" and giving it its current meaning and not the meaning as it would have been understood by Story J. in the early 19th century when it meant "scientific."[375] However, close parsing of the language of a decision made almost two hundred years ago is not the real problem. Rader J. of the Court of Appeals for the Federal Circuit has made it clear that he would eliminate the exception entirely because "the Patent Act leaves no room for any *de minimus* or experimental use excuses for infringement."[376] According to Rader J., the courts already have the requisite flexibility in awarding damages to account for minimal or non-commercial infringement.[377] While Rader's approach deals with the issue of damages, injunctive relief is also typically sought in patent infringement suits and this can have just as serious an effect on subsequent experimentation.

In *Merck v. Integra*, the US courts had an opportunity to deal with research tools and the experimental use exception. In *Integra*, the plaintiff Integra owned several patents related to a short tri-peptide segment (referred to as the "RGD peptide"). Dr. David Charesh, a research scientist at Scripps, discovered that blocking the RGD peptide inhibits angiogenesis, the process for generating new blood vessels. This led to a realization that finding a suitable inhibitor could lead to a number of potential treatments

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[374] *Madey ibid.*
[375] H.C. Wegner, *The Post Madey Research Exemption* available at <www.foley.com/publications/pub_results.aspx?attorneyID=16325> (accessed March 13, 2005).
[376] *Embrex supra* note 368 at 1352.
[377] *Embrex ibid.*

including treatments to halt tumor growth, treat diabetic retinopathy, rheumatoid arthritis, psoriasis, and inflammatory bowel disease. In other words, the RGD peptide is a "disease target" for research to discover a small molecule inhibitor of the RGD peptide. The defendant Merck then commenced a research program in conjunction with Dr. Charesh to identify a potential drug candidate that might inhibit angiogenesis. Integra then filed a patent infringement suit against Merck. The majority in the Federal Circuit decision and the U.S. Supreme Court focused on whether Merck's activities fell within the scope of the early working exemption with no discussion of the experimental use exception.[378] In comparison, Newman J. wrote a scathing dissent in the Federal Circuit decision arguing for a strong experimental use exception as follows:

> The majority's prohibition of all research into patented subject matter is as impractical as it is incorrect. The information contained in patents is a major source of scientific as well as technologic knowledge. Indeed, in many areas of technology, technical information is not published outside of patent documents. A rule that this information cannot be investigated without permission of the patentee is belied by the routine appearance of improvements on patented subject matter, as well as the rapid evolution of improvements on concepts that are patented.
>
> The subject matter of patents may be studied in order to understand it, or to improve upon it, or to find a new use for it, or to modify or "design around" it. Were such research subject to prohibition by the patentee the advancement of technology would stop, for the first patentee in the field could bar not only patent-protected competition, but all research that might lead to such competition, as well as barring improvement or challenge or avoidance of patented technology. Today's accelerated technological advance is based in large part on knowledge of the details of patented inventions and how they are made and used. Prohibition of research into such knowledge cannot be squared with the framework of the patent law.[379]

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[378] *Integra supra* note 354.
[379] *Integra ibid.*

By focusing solely on the scope of the early working exception, the U.S. Supreme Court declined to re-examine the experimental use exception and give it some real meaning in the United States.

4.2.2 Japan

Japan has an express statutory exemption to patent infringement as follows:[380]

69(1) The effects of the patent right shall not extend to the working of the patent right for the purposes of experiment or research.

There are conflicting lower court decisions on the scope of the section 69(1). Some lower court decisions required that any application of the exception be for research or experimentation that advanced technology. Other lower court decisions questioned whether a scientific advancement or improvement was actually needed to fall within the scope of the experimental use exception.[381]

Without resolving the conflicting authorities, the Supreme Court of Japan has interpreted section 69(1) as including early working activities for the submission of information to a regulatory body. This is a permissible "experiment" under s. 69(1) as any other interpretation would lead to an undesirable and artificial extension of the term of the patent.[382] Unfortunately, there remains considerable uncertainty about the true scope of the experimental use in Japan.

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[380] *Patent Law*, law no. 121 of April 13, 1959, as am. May 6, 1998, effective June 1, 1998, s. 69(1) as cited in S. Ferance, "The Experimental Use Defence to Patent Infringement" (2003) 20 Canadian Intellectual Property Review 1 at 21.

[381] J.A. Johnson, "The Experimental Use Exception in Japan: A Model for U.S. Patent Law?" (2003) 12 Pacific Rim Law and Policy 499 at 512-518.

[382] *Ono Pharmaceuticals Co. Ltd. v. Kyoto Pharmaceutical Industries Ltd.* (1999), 5 Int'l L. Update 55, Case no. 1998(ju)153, April 16, 1999, Second Petty Bench of the Supreme Court (Japan) as cited in Ferance *supra* note 380 at 21; Advisory Council on Intellectual

4.2.3 Europe

The experimental use exception is provided for in article 27(b) of the Community Patent Convention as follows:

> 27 The rights conferred by a Community patent shall not extend to:
> (b) acts done for experimental purposes relating to the subject matter of the patented invention.[383]

While the CPC has not yet been adopted, all European Union member states except Austria have adopted the wording of article 31(b) to provide for an experimental use exception.[384] However, the interpretation of this exception has led to different results in different states. The following discussion will focus on jurisprudence from the United Kingdom, Germany and France.

4.2.3.1 United Kingdom

In the UK, the experimental use exception is provided in section 60(5)(b) of the *Patents Act 1977 (UK)*. While the UK has a long history of recognizing a common law exception to patent infringement based on experimental use,[385] this jurisprudence is no longer of much value in the UK. Section 60 was enacted to make the UK patent law consistent with the corresponding provisions of the CPC and courts have concluded that

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Property, *Issues Paper: Patents and Experimental Use*, February, 2004 available at <www.acip.gov.au/reviews.htm#expuse> (accessed March 26, 2005) at 3 [hereinafter ACIP Issues Paper]; J.A. Johnson, "The Experimental Use Exception in Japan: A Model for U.S. Patent Law?" (2003) 12 Pacific Rim Law and Policy 499 at 516.

[383] CPC art. 27(b).

[384] *A Patent System for the 21st Century*, S.A Merrill, R.C. Levin & M.B. Myers, eds (Washington: The National Academy Press, 2004) at 90 [hereinafter National Academy];

[385] See for example, *infra* note 400 and accompanying text where the 1878 decision *Frearson v. Loe* is discussed.

recourse to the "minutiae of earlier UK patent law" does not aid the interpreting of such provisions.[386]

Under the statutory exception, the purpose of the activity must be experimentation. There may be multiple purposes but the exception will apply as long as one of the purposes is a legitimate, or *bona fide* experimentation. Examples of legitimate experimental purposes include trials carried out to discover something new or to test a hypothesis; however, experimental purposes do not include trials carried out to amass information to satisfy a third party, such as a customer or a regulatory body, that a product works as claimed.[387]

The UK courts have also taken a relatively narrow approach to defining this exception. In *Smith Kline & French Laboratories Ltd.*, the plaintiff possessed three separate but related patents. The plaintiff then sought to amend the third patent. The defendant opposed the application to amend the patent and carried out limited experimentation to show that the application was not warranted. The plaintiff took exception to the experimentation and claimed patent infringement of all three patents. The court in *SK&F* then discussed the phrase "subject-matter of the invention" in s. 60(5)(b) and concluded that experiments with a commercial end in view is permissible (unlike in the US), but the "purposes must relate to the claimed subject-matter of the patent in suit in the sense of having a real and direct connection with that subject matter."[388] The subject matter of the invention is ascertained from the patent as a

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[386] *Monsanto Co. v. Stauffer Chemical Co.* [1985] RPC 515 at 538 [hereinafter *Monsanto v. Stauffer*].
[387] *Monsanto v. Stauffer ibid.* at 542.
[388] *SK&F supra* note 344 at 523-524. See also *Auchinloss v. Agricultural & Veterinary Supplies Ltd.* [1999] R.P.C. 397 [hereinafter *Auchinloss*].

whole.[389] In this case, the experimentation had a real and direct connection with the subject matter of the third patent and was permissible under that patent; the experimentationdid not, however, have a real and direct connection with the subject matter of the first patent and as such infringed the first patent. The patentee was thus able to assert a second patent and thereby prevent experimentation whose sole purpose was to challenge a first patent owned by the same patentee. The court did leave open the possibility that the acts were "private and for a non-commercial purpose" and hence exempt from patent infringement on that basis.[390]

4.2.3.2 Germany

In Germany, the experimental use exception is provided in article 11(2) of the German Patent Act (in force since 1981).[391] There are two leading cases dealing with the experimental use exception, both in the context of clinical trials and early working activities.[392]

In *Clinical Trials I*, the court held that the experimental use exception included any act aimed at obtaining new information about possible further uses of a patented drug. This includes new indications for the drug as long as the experiments were directed to the drug itself.[393] A collateral economic interest such as performing clinical trials to obtain marketing approvals, would not take the activity outside of the exemption.

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[389] *Auchinloss ibid.*
[390] This case is discussed in more detail *infra* note 438 and accompanying text.
[391] Schreiber *supra* note 358 at 100.
[392] Schreiber *ibid.* at 100 citing *Klinische Versuche I*, Federal Supreme court, July 11, 1995, RPC 1997, 623; *Klinische Versuche II*, Federal Supreme Court, April 17, 1997, RPC 1998, 424 (hereafter referred to as *Clinical Trials I* and *II* respectively).
[393] Schreiber *supra* note 358 at 100; ACIP Issues Paper *supra* note 382 at 4.

In *Clinical Trials II*, the court affirmed the decision in *Clinical Trials I* and held that the law exempts all experimental acts from patent infringement and it does not matter whether those acts produce results of scientific interest or commercial interest. In this case, the patent related to a particular DNA sequence used for the expression of a polypeptide product having the primary structural conformation of human erythropoietin (human EPO). Unlike *Clinical Trials I*, the purpose of the experimentation was not to find a new use of the patented invention but only to find out if the product was marketable and whether its activity differed from another product already on the market. This distinction was not considered relevant. The court found that the only statutory condition is that the experiments must be carried out with the intention of gathering knowledge about the subject of the invention, including its use, to overcome an existing incertitude.[394]

4.2.3.3 France

In France, the experimental use exception is provided in article L 613-5 b) of the Intellectual Property Act.[395] The caselaw to date is mixed on the scope of the experimental use exemption. In the first case, *Science Union and Servier v. Cobière and Bellon*,[396] the court ruled that the experimental use exception did not extend to manufacturing drug samples for the sole purpose of obtaining marketing authorization.

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[394] Schreiber *ibid.* at 100.
[395] Schreiber *ibid.* at 99.
[396] *Science Union and Servier v. Cobière and Bellon*, Paris Court of Appeal, November 27, 1984, PIBD 1985, 366, III-118 cited by Schreiber *ibid.* at 99-100.

This was "merely" a commercial act. However, in a second case, *Wellcome v. Parexel*,[397] the court held that clinical trials that did not merely have a commercial objective but also had some other objective did fall under the experimental use exception. Permissible objectives would include experimentation intended to discover either new uses of a patented drug or different modes of administration.

Two subsequent decisions of the First Instance Court of Paris have held that the exclusive rights granted to a patentee do not extend to trials performed in the limited framework of an application for marketing approvals.[398] Accordingly, the activities in those later decisions did not amount to infringement and it was not necessary to consider the application of the statutory experimental use exception of Article L 613-5 b).

4.2.4 Australia

As in the United States, there is no statutory provision in Australia explicitly providing for an experimental use defence to patent infringement. Any such defence in Australia relies solely on the common law, and unfortunately there have not been any Australian cases addressing experimental use as an exception to patent infringement.[399] It is necessary to go back to an 1878 decision of the English Chancery Division, *Frearson v. Loe* to provide any judicial support for the exception in Australia. In *Frearson*, Jessel M.R. discussed the scope of the experimental use defence as follows:

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[397] *Wellcome v. Parexel*, TGI Paris, March 6, 1998, affd on appeal, Paris Court of Appeal, 14th chamber, section A, judgment of January 27, 1999, non-published; see also TIG Paris, 3rd chamber, February 20, 2001, PIBD No 729, III, 530 both cited by Schreiber *supra* note 358 at 100.

[398] *Science Union v. AJC Pharma*, TGI Paris, 3rd chamber, 2nd section, October 12, 2001, PIBD No 739, III-155; *Science Union v. Biophelia*, TGI Paris, 3rd chamber, 2nd Section, January 25, 2002, PIBD No 747, III-342 both as cited by Schreiber *ibid.* at 100.

[399] ALRC Report *supra* note 56 at 13.5.

> [N]o doubt if a man makes things merely by way of *bona fide* experiment, and not with the intention of selling and making use of the thing so made for the purpose of which a patent has been granted, but with the view of improving upon the invention the subject of the patent, or with the view of seeing whether an improvement can be made or not, that is not an invasion of the exclusive rights granted by the patent. Patent rights were never granted to prevent persons of ingenuity exercising their talents in a fair way.[400]

The lack of caselaw in Australia has led to some confusion as to whether the exception even exists in a modern form:[401] the Australian Law Reform Commission (ALRC) has therefore recommended amendments to the Patents Act to clarify any confusion and expressly provide for an experimental use defence to patent infringement.[402]

4.2.5 New Zealand

New Zealand also relies on a common law exception to patent infringement for experimental use. However, in addition to *Frearson v. Loe*, there are at least two New Zealand cases where the courts have accepted the existence of the defence for *bona fide* experimentation.

In the first case, *Monsanto Co. v. Stauffer Chemical Co. (N.Z.)*,[403] the defendants had supplied a patented herbicide to potential customers so that they might conduct field trials with an ultimate view of obtaining regulatory approval for the use of the product once the patent had expired. Eichelbaum J. in the High Court of New Zealand rejected

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[400] *Frearson v. Loe* (1878), 9 Ch.D. 48.
[401] Advisory Council on Intellectual Property, *Options Paper: Patents and Experimental Use*, December 2004) at 34-35 available at <www.acip.gov.au/reviews.htm#expuse> (accessed March 26, 2005 [hereinafter ACIP Options Paper].
[402] See ALRC Report *supra* note 56 at 13.3.
[403] *Monsanto Co. v. Stauffer Chemical Co. (N.Z.)* [1984] F.S.R. 559.

this defence as not being *bona fide* experimentation but instead as a use intended to make potential customers aware of the existence and efficacy of the product.

In the second case, *Smith Kline & French Laboratories Ltd. v. Attorney-General (NZ)*,[404] the issue was somewhat narrower and involved the importation of a sample and its submission to a regulatory authority. This is similar to an early working exemption except that no evidence of actual experimentation was introduced. In *Smith Kline v. Attorney-General*, samples were generaly supplied to regulators even when not explicitly required to do so. In rendering a decision, the court decided to discuss the scope of the experimental use exception in some detail. In particular, Hardy Boys J. concluded that:

> If the person concerned keeps his activities to himself, and does no more than further his own knowledge or skill, even though commercial advantage may be his final goal, he does not infringe. But it he goes beyond that, and uses the invention or makes it available to others, in a way that serves to advance him in the actual market place, then he infringes, for the market place is the sole preserve of the patentee.[405]

According to Hardy Boys J., experimentation then would seem to be limited to "private" testing and would not extend to "public" uses or purposes such as applying for regulatory approvals.

4.2.6 Canada

The Patent Act in Canada does not expressly set out an experimental use exception though there is an oblique reference to a common law exception in section

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[404] *Smith Kline v. Attorney-General supra* note 347. This case is also discussed *supra* notes 347-348 and accompanying text regarding an alternate defence of "private and non-commercial use".

[405] *Smith Kline v. Attorney-General ibid.*

55.2(6) of the Patent Act.[406] Section 55.2(6) specifies that exceptions existing at common law are not affected by the statutory introduction of the early working exemption in 55.2(1). In particular, the language used in s. 55.2(6) is similar to the language in the CPC and refers to two exceptions as follows:

1. acts done privately and on a non-commercial scale or for a non-commercial purpose; or
2. in respect of any use, manufacture, construction or sale of the patented invention for the purposes of experiments that relate to the subject-matter of the patent.

Part (1) refers to private and non-commercial use[407] and part (2) refers to an experimental use exception. While section 55.2(6) explicitly preserves the common law exception, it clarifies neither its nature nor extent.[408]

The main case in Canada dealing with the experimental use exception is a 1972 decision of the Supreme Court of Canada, *Smith Kline v. Micro Chemicals*, where the court expressly approved of the 1878 U.K. decision *Frearson v. Loe.*[409] In *Micro Chemicals*, the defendant was experimenting on a patented pharmaceutical for the

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[406] Section 55.2(6) reads as follows:

55.2(6) For greater certainty, subsection (1) does not affect any exception to the exclusive property or privilege granted by a patent that exists at law in respect of acts done privately and on a non-commercial scale or for a non-commercial purpose or in respect of any use, manufacture, construction or sale of the patented invention solely for the purpose of experiments that relate to the subject-matter of the patent.

Subsection 55.2(1) provides the early working exception discussed *supra* notes 349-363 and accompanying text.

[407] Discussed *supra* notes 342-348 and accompanying text.

[408] Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms* (2002) available at <cbac-cccb.ca/epic/internet/incbac-cccb.nsf/en/h_ah00094e.html> (accessed March 30, 2005) at 14 [hereinafter CBAC Report].

[409] Discussed *supra* note 400 and accompanying text.

purpose of learning if the defendant would be capable of producing the invention commercially. The defendant then planned on applying for a compulsory licence to be able to commercially manufacture and subsequently market the drug. The purpose was clearly commercial and allowed the defendant to springboard into the marketplace as soon as permitted, either through the grant of a compulsory licence or at the expiry of the patent. At trial, Walsh J. found that the experimental use did not apply and was limited to activities carried out for improving the patented invention as in *Frearson v. Loe.*[410] This was reversed by the Supreme Court of Canada who held that "*bona fide* experiments with a patented article" do not amount to infringement. In particular, Hall J. found that the compulsory licensing provisions in the *Patent Act* implied a broader experimental use exception than allowed by Walsh J. and was in fact the "logical result of the right to apply for a compulsory licence."

As the compulsory licensing provisions in the Patent Act have since been repealed, some critics have questioned whether this type of experimentation would still continue to be within the scope of the exception.[411] While there may be some doubt in Canada about the continuing impact of *Micro Chemicals*, this case has been cited internationally as providing support for an expansive view of the experimental use exception that is not necessarily restricted to compulsory licensing.[412]

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[410] *Micro Chemicals Ltd.* v. *Smith Kline & French Inter American Corp.*, [1972] S.C.R. 506.

[411] Ferance *supra* note 380; CBAC Report *supra* note 408 at 14; Bastarache J. repeated these concerns and cited the CBAC Report without comment in *Harvard College supra* note 74 at para 174.

[412] See for example, *Monsanto v. Stauffer supra* note 386; *Smith Kline v. Attorney-General supra* note 347.

In a second important case addressing the experimental use exception, *Astra Pharmaceuticals v. Apotex Inc.*,[413] the defendants had imported small quantities of the bulk material needed to make a pharmaceutical drug called Metoprolol. The defendants then entered into experimental trials and production runs for the purpose of applying for a notice of compliance and a compulsory licence. However, as a result of the experimentation, the defendant amassed an inventory of approximately 1.5 million tablets of the drug in two dosages. On the issue of experimental use, Joyal J. commented that testing prior to a compulsory licence being obtained:

> might be technically infringing on the right of the patentee and it might be technically liable for damages for infringement. The liability of the applicant becomes more than technical if in going through its work-ups, it builds up an inventory of the drug enabling it to hit the market on the very day a compulsory licence is issued to it.[414]

This is a form of "stockpiling" of a patented drug for sale in anticipation of patent expiry. Canada had a provision allowing for stockpiling in section 55.2(2) before it was removed in 2001 in response to the ruling by the DRB panel in *Canada – Patent Protection* case that it was inconsistent with article 30 of the TRIPs Agreement.[415] Stockpiling patented articles under the pretense of experimentation is thus impermissible.

In a third case, *Wellcome Foundation Ltd v. Apotex Inc.*,[416] the defendants had imported a patented drug, acyclovir, for the purposes of pressing the drug into tablets to determine stability and safety. The results of the experimentation were then going to be

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[413] *Astra Pharmaceuticals v. Apotex Inc.* (1984) 1 C.P.R. (3d) 513 (F.C.T.D.) [hereinafter *Astra Pharmaceuticals*].
[414] *Astra Pharmaceuticals ibid.* at 515.
[415] *Patent Act*, s. 55.2(2) repealed by S.C. 2001, c. 10, s.2(1); see also *Canada – Patent Protection* case *supra* note 259.
[416] *Wellcome Foundation Ltd. v. Apotex Inc.* (1990), 32 C.P.R. (3d) 350 [hereinafter *Wellcome Foundation*].

used to support an application for a compulsory licence. The plaintiffs obtained an *Anton Piller* order, an interlocutory order authorizing seizure of the patented medicine imported by the defendants,[417] and the defendants sought an order to set aside the *Anton Piller* order. On the question of experimental use, Muldoon J. distinguished *Micro Chemicals* on two grounds: firstly, Muldoon J. noted that the defendants were not producing the drug in their own laboratories where they "could control and would want to limit its findings to and for itself" but instead were importing the product;[418] secondly, Muldoon J. noted that the regulatory scheme had changed since *Micro Chemicals* such that "first, one obtains the compulsory licence; then one may import for experimentation in order to make appropriate submissions" for a notice of compliance to market the drug.[419] Ultimately, Muldoon J. held that the plaintiffs had established a good *prima facie* case and that the many issues involved were not easy to balance.[420]

The following questions are raised by *Wellcome Foundation*: firstly, does importation make a difference to whether *bona fide* experimentation can be carried out; and secondly, is it necessary for the experimentation to be directly tied to a compulsory licence for the experimental use exception to apply? While Muldoon J. declined to answer these questions in the context of *Wellcome Trust*, neither of these factors should be determinative of any exception. The main question is whether the defendant engaged in *bona fide* experimentation. Whether the product was made internally in Canada or imported does not affect whether there was *bona fide* experimentation. Similarly, the existence of the exception is based on the common law and a need to respect a balance

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[417] Named after *Anton Piller KG v. Mfg. Processes Ltd. et al.*, [1976] Ch. 55 (C.A.).
[418] *Wellcome Foundation supra* note 416 at 355.
[419] *Wellcome Foundation ibid.* at 355.
[420] *Wellcome Foundation ibid.*

between the patent holder and the general public. It is not restricted to applications for compulsory licences.

A couple of additional lower court decisions since *Micro Chemicals* have referred to the experimental use defence without elaborating on the scope of the defence.[421] While not discussing this exception explicitly, the recent Supreme Court of Canada decision *Monsanto v. Schmeiser* can provide some guidance as to how courts may examine this exception in the future. In *Monsanto*, the court examined the definition of a "use" under the *Patent Act* and developed seven propositions, the first three being of interest for this discussion:

1. "Use" or "exploiter", in their ordinary dictionary meaning, denote utilization with a view to production or advantage.
2. The basic principle in determining whether the defendant has "used" a patented invention is whether the inventor has been deprived, in whole or in part, directly or indirectly, of the full enjoyment of the monopoly conferred by the patent.
3. If there is a commercial benefit to be derived from the invention, it belongs to the patent holder.

A focus on commercial benefit and advantage present in these propositions is consistent with an experimental use exception. To the extent that experimentation does not affect a patentee's legitimate commercial interests in exploiting the patent, then the

[421] See for example, *Cochlear Corp. v. Cosem Neurostim Ltee* (1995), 64 C.P.R. (3d) 10 (F.C.T.D.); *Dableh v. Ontario Hydro* (1996), C.P.R. (3d) 129 (FCTD); *Takeda Chemical Industries Ltd. v. Novopharm Ltd.* (1984), 7 C.P.R. (3d) 426 (FCTD); see also Ferance *supra* note 380 where he discusses these cases as well as caselaw examining patent validity and "experimental use" by the patentee prior to application.

experimentation may not even be a "use" within the meaning of the *Patent Act*. This is consistent with article 30 of the TRIPs Agreement, which allows exceptions to the extent they do not unreasonably prejudice the legitimate interests of the patent owner.[422]

4.2.7 The WTO Dispute Resolution Board

While the panel in the *Canada-Patent Protection* case did not expressly deal with the experimental use defences, both parties accepted that such defences comply with the TRIPs agreement, and specifically article 30.[423] It was also noted by both parties that almost all Member states contained some sort of experimental use exception.

In the EC submission to the DRB panel, the experimental use exception was argued to be a "limited" exception by the EC since it only applies to use and not the other exclusive rights granted by a patent, namely offering for sale, selling and importing.[424] The EC also advocated that research uses are not part of the "legitimate interests" of the patent owner and, therefore, the interests of third parties and their balancing with the patentee's interests is redundant for the research exception.[425]

According to the Canadian submissions to the DRB panel, the exception is "limited" as being only a *de minimis* use of the invention or a form of scientific experimentation, i.e. a "fair use". Further, such experimentation does not conflict with a normal exploitation of the patent, nor does it unreasonably prejudice the legitimate

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[422] See *supra supra* notes 272-275 and accompanying text.
[423] *Canada – Patent Protection supra* note 259; the Canadian submission is cited at 75-76 and the EC submission is cited at 56. The DRB Panel referred to the experimental use exception at 7.69 without expressly ruling on its validity under article 30.
[424] An obvious omission from this list is manufacture and limited manufacture would seem to be consistent with an experimental use exception. Compare with *Astra Pharmaceuticals supra* notes 413 and accompanying text.
[425] *Canada – Patent Protection supra* note 259 at 56.

interests of the patent owner, since the patent owner is able to prevent the marketing or sale of any infringing subject-matter during the patent term.[426] Accordingly, the experimental use exception accounts for the legitimate interests of third parties since non-commercial experimentation aids the advance of scientific and technical knowledge, to the benefit of society at large. Without such an exception, the Canadian submission also argued that there would be a "research chill" that would detrimentally affect all of society.[427]

While there seems to be a consensus that some form of exception is justified under the TRIPs Agreement, it is still not clear how broadly the exception can be characterized before running afoul of articles 27 or 30. The main issue is the effect on the normal exploitation of the patent and the legitimate interests of the patent owner.

4.3 Scope of the Experimental Use Exemption

After reviewing the international jurisprudence, several points about the scope of the experimental use exemption arise deserve greater attention before addressing the main issue of this chapter, namely the application of the exemption to research tools.

4.3.1 Commercial Use

Whether or not a statutory exception is added to the Patent Act, any distinction between commercial and non-commercial research is counter-productive.[428] An important purpose of the patent system is to encourage R&D and promote the

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[426] *Canada – Patent Protection ibid.* at 75.
[427] *Canada – Patent Protection ibid.* at 76.
[428] The ALRC came to the same conclusion at ALRC Report *supra* note 56 at 13.89.

commercial exploitation of inventions. This is an important distinction that is recognized almost exclusively outside of the US.[429] This purpose can and should extend to improvements and alternative designs. Any exception should focus on the acts being carried out and whether it is *bona fide* experimentation. As stated by Hardie Boys J. in *Smith Kline v. Attorney General*: "Doubtless experimentation will usually have an ultimate commercial objective; where it ends and infringement begins must often be a matter of degree."[430]

4.3.2 Springboarding Activities

Springboarding refers to types of activities that allow a competitor to enter the market, i.e. make, use and sell the patented invention, as soon as the patent expires. Some springboarding activities are permissible while others are not. Examples of permissible springboarding activities are those that relate to the experimental use exception such as learning how to make an invention on commercial scale as in *Micro Chemicals*,[431] or conducting tests to provide data for regulatory approvals as in *Bolar*.[432] Experimental use, though commercial in nature, is not done on a commercial scale and does not significantly affect the patentee's exclusive rights to make, use or sell the patented invention during the patent term. In comparison, impermissible springboarding activities directly affect the patentees' commercial interests to make, use or sell an invention. An example of an impermissible springboarding activity is stockpiling, which

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[429] See for example, *Smith Kline v. Attorney-General supra* note 347 at 563; ALRC Report *ibid.*; *SK&F supra* note 344 at 522; *Monsanto v. Stauffer supra* note 386 at 538; compare with *Madey supra* note 373.
[430] *Smith Kline v. Attorney General ibid.* at 566.
[431] See *supra* notes 409-412 and accompanying text.
[432] See *supra* notes 353-354 and accompanying text.

involves making a patented product on a commercial scale prior to expiry of the patent. Stockpiling directly affects the patentee's exclusive right to make the patented invention and was found to be expressly inconsistent with the TRIPs Agreement and the normal exploitation of the patent by the patentee.[433]

The Australian Law Reform Commission (ALRC) has recommended a narrower interpretation of the exception where study or experimentation on the subject matter of the invention is the "sole or dominant purpose."[434] According to the ALRC, experimentation as conducted in *Smith Kline* or *Bolar* should not be covered by the exception unless experimentation remained the dominant purpose of the use. The ALRC seems to regard time for experimentation after patent expiry as a normal part of the monopoly granted to the patentee and desirable.[435] However, there is nothing "normal" about this artificial extension of the monopoly. Patent rights only provide rights for twenty years from application and at the expiry of the patent rights, competitors are entitled to make, use and sell the invention. Any restrictions that do not allow the competitors to start preparing for the expiry of patent rights unnecessarily extends the effective monopoly granted to the patentee. Support for this position is found in the *Canada-Patent Protection Case* where the DRB panel agreed that this was not a normal part of the monopoly and only arose as a result of the "combination of patent rights with the time demands of the regulatory process" that gives a greater than normal period of market exclusivity to the enforcement of certain patent rights.[436]

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[433] *Canada – Patents Protection supra* note 259.
[434] ALRC Report *supra* note 56 at 13.111.
[435] ALRC Report *ibid.* at 13.109.
[436] *Canada-Patents Protection supra* note 259 at 7.57.

In addition to early working activities where experimentation is done to complete regulatory requirements, other clinical trials should be covered by the experimental use exception. Clinical trials are research studies conducted to determine whether a new pharmaceutical drug or medical treatment is safe and effective. Known (and possibly patented) drugs or treatments are often used as baseline comparisons. This is simply a variation on designing around the conventional treatment and should be allowed.[437]

4.3.3 Subject Matter of the Invention

Designing around activities are an important part of the patent system in encouraging innovation and the development of new products and as such, these activities should also fall under the experimental use exception. However, in designing around an invention, it is common practice to conduct tests of the design around and compare the results with tests on the patented invention. Comparison to a baseline, even if patented may be the only way to know if the design around works. This type of research should be encouraged, however, according to the UK decision *SK&F*, it might not be consistent with the experimental use exception. It could be argued that any such tests on the patented invention are not "directed to the subject-matter of the invention" since the experimentation is designed to better understand the design around and not the invention itself. This would be an unnecessarily narrow approach.

The better way of looking at designing around activities is as a constant re-evaluation and comparison of both the invention itself and any design around. The comparison goes both ways and the question could just as easily be: how does the

[437] Compare with ALRC Report *supra* note 56 at 13.105 where the ALRC argues that the experimental use defence should not apply as its properties are already well established.

original invention compare to the new design around? There would therefore be no problem applying the experimental use exception to such designing around experimentation.

A more troubling question arises in considering the following hypothetical example raised in *SK&F*:

> Supposing a company seeking to investigate a chemical patent either for the purposes of challenging its validity or for the purposes of improving upon the invention of that patent, carries out the process of the patent using a reagent which is made and marketed by a third party who has patented that reagent. In such circumstances can the experimenter, relying on subsection 5(b), manufacture the reagent without the consent of the patentee of the reagent patent, thereby depriving him of the sale.[438]

The court then concluded that patentees on essential inputs (in this example, the patented reagent), do have the right to prevent experimentation on a main patent, for any purpose. Otherwise, the court felt that the words "subject-matter of the invention" would have no meaning.

The problem arises in situations such as in *SK&F* where the essential input is not commercially available and is patented not by a third party but by the patentee. According to the court in *SK&F*, no experimentation can thus occur for any purpose without the permission of the patentee. Consider also a patentee who obtains a first patent on an invention. Someone, either the patentee or a third party, then obtains a second patent on an improvement. Any further improvement on the second patent would be directed to the subject matter of the improvement, not the subject matter of the basic invention and would therefore require permission of the first patentee. In both situations, an absurdity results where the patentee can hide behind an unrelated patent to prevent

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[438] *SK&F supra* note 344 at 523.

scrutiny of a main patent. Nevertheless, the U.K. decision that led to this absurdity raises a valid point that simply because a researcher is undertaking experimentation on a patented invention does not mean that all patent rights should be safely ignored. Otherwise, patent rights on essential inputs could be stripped of any value to the patentee.

4.4 Application to Research Tools

For most inventions, it is relatively easy to apply the experimental use exception: to better understand the invention or improve upon it. Any experimentation that falls within one of these two categories would be exempt from liability for infringement. However, it is not so easy when the experimental use defence to research tools.

The primary purpose of research tools is to make research easier, cheaper or more efficient. Experimentation involving a research tool can involve either use of the tool in research or experimentation on the tool itself. This distinction is analogous to the problem discussed above regarding experimetentation applying to the "subject-matter" of the invention.[439] The subject matter of the invention for a patented research tool is the tool itself and not the use of the tool to study some other problem. It has been argued that any broad application of the defence that allows any experimentation with a research tool would render patents on such research tools "illusory" and would prevent the effective exploitation of the invention by the patent holder.[440] This argument raises a valid concern but is somewhat simplistic.

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[439] See *supra* note 438 and accompanying text.

[440] ALRC Report *supra* note 56 at 13.56; P. Ducor, "Research Tool Patents and the Experimental Use Exemption" (1999) 17 (17 October) Nature Biotechnology 1027 at 1027; R.S. Eisenberg, "Patenting Research Tools and the Law" in *Intellectual Property*

Consider a hypothetical example where a patent was granted on a new and improved microscope. Under a broad interpretation of the experimental use exception that allowed any experimentation, a third party could make a microscope that fell within the scope of the patent and use it in research without liability for infringement. However, any attempt to make the microscope on a commercial scale and sell it would clearly be outside of any interpretation of the experimental use defence. The patentee would therefore still be able to retain significant rights and benefits to the commercial exploitation of his patented research tool.

In any commercial exploitation of a patented invention, the price that can be charged is limited by other suitable options in the market place. Patent rights do not necessarily confer market power on a patentee, particularly when alternative products are available.[441] In the above scenario, individual scientists would be an additional source of competition to the extent they can make the microscope themselves for their own research purposes instead of purchasing it from the patentee. This will provide some downward pressure on the price that the patentee could charge for the microscope in the absence of this right.

In some cases, significant costs or other structural barriers may prevent individual scientists from pursuing this option and the patentee's patent rights would remain strong regardless of the scope of the defence. This is likely to occur with the microscope example where a biologist using the microscope is unlikely to have expertise in either optics or manufacturing to be able to make a microscope as well or efficiently as the

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Rights and Research Tools in Molecular Biology R.S. Eisenberg *et al.* eds. (Washington: National Academy Press, 1997) 6; Strandburg *supra* note 228 at 88.

[441] Kitch *supra* note 112 at 1729-1738.

patentee. In other cases, there may be minimal barriers preventing the scientist from exploiting the invention for his own use and this could leave little to no scope for the patentee. This latter concern is particularly acute when considering research tools such as research techniques or disease targets where the patent rights could truly become "illusory."

In light of *Monsanto v. Schmeiser* where the Supreme Court of Canada emphasized the economic uses of patents,[442] Canadian courts will be more cognizant of the patentees' legitimate commercial interests in patents and will be unlikely to apply a common law exception in a manner so as to render any patent rights meaningless. This is also consistent with the approach taken in the *Canada-Patent Protection* case where the WTO panel found the early working exception to be consistent with article 30 of the TRIPs Agreement since it respected the normal commercial interests of the patentee.[443]

When applying this principle to research tools, the better approach is to only apply the exception to *bona fide* experimentation to better understand the tool or to make a better tool and not to using the tool for its intended purposes.[444] In other words, the experimental use exception only applies to research *on* the tool and not research *with* the tool.[445]

Another issue regarding research tools is that any experimentation on the tool must be *bona fide* research on the tool. Naturally, any experimentation on a tool will necessarily involve using the tool as intended to some extent. Unscrupulous researchers will try to conduct experimentation *on* a tool under the guise of research *with* a tool. This

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[442] See *supra* note 421 and accompanying text.
[443] See *supra* note 275 and accompanying text.
[444] ALRC Report *supra* note 56 at 13.55.
[445] Ducor *supra* note 440 at 1027.

is analogous to the situation in *Astra Pharmaceuticals* where the defendant had stockpiled a significant amount of the patented drug in the course of doing "experimentation" on the drug. Similarly, excessive experimentation *on* a research tool crosses a threshold and no longer be viewed as *bona fide* research on the tool and instead be seen as research *with* the tool.

In the next sections of this chapter, the experimental use exception will be applied to the specific types of research tools used in biotechnology: research techniques and consumables; and disease targets. In particular, the following analysis will examine if the experimental use defence is appropriate in allowing scientists access to biotechnology research tools.

4.4.1 Research Techniques and Consumables

Under the proper application of the experimental use exception, scientists would only be able to use the exception to better understand the tool or to improve upon it. In this way, research techniques and consumables tools are analogous to the microscope as discussed above. This exception does not provide any benefits to scientists wanting access to the tools for the purposes of their own research.

4.4.2 Disease Targets

The experimental use exception is not easily applied to disease targets, particularly when keeping in mind the desire to respect the legitimate commercial interests of the patentee. When is a researcher conducting experiments *on* a disease target as opposed to *with* a disease target? This distinction is difficult if not impossible to

make reliably.[446] For example, when screening candidate molecules in pharmaceutical R&D with a target DNA sequence, is the researcher investigating the properties of the genetic sequence (research *on* the target) or is the researcher using the genetic sequence to study whether other molecules react with it (research *with* the target).[447] To a large extent, this distinction does not provide any useful guidance. Going back to the microscope example, it is necessary to look at the patent scope remaining for any exception applied to disease targets. Unfortunately, unlike the microscope example, there is no market for patentees to manufacture and sell disease targets. To the extent that a market exists, it is only in the licensing of patent rights to conduct research on the target. This leads to the only reasonable conclusion that the experimental use exception, as it is currently understood, does not exempt researchers infringing patents on disease targets: any other conclusion would render the patent rights meaningless.

The CBAC has recommended a statutory amendment to the Patent Act to clarify that the exception applies to activities to: "investigate its properties, improve upon it, *or create a new product or process*" (my emphasis).[448] This was intended to make it clear that researchers can rely on the experimental use provision to use a DNA sequence, for example, to find molecules that bind to it or act upon it.[449] The problem with the CBAC proposal is that it has the real potential to render associated patent rights to the disease target illusory, particularly if the only identified purpose of the target is to find molecules that bind to it or act upon it.

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[446] ALRC Report *supra* note 56 at 13.58.
[447] In National Academy *supra* note 384 at 93, the following example was used: "Is testing a drug against a patented cell receptor 'improvement' or 'seeing how it works' or is it use of a tool in pre-commercial research?"
[448] CBAC Report *supra* 428 at 15.
[449] CBAC Report *ibid.* at 15.

4.5 Proposals for Reform

There have been numerous calls for reform of the experimental use defence as a result of the "truly narrow" scope of the defence in the United States or perceived ambiguities in the law in Australia and Canada. These proposals are sometimes within the context of patenting research tools and other times simply addressing a general problem of allowing further research in an area before expiry of a patent. In this part several of these proposals in the context of their ability to promote the objectives of the Patent Act and address issues of access to technologies before making a modest proposal of my own.

4.5.1 A Three-Pronged Approach

In an oft cited paper, Rebecca Eisenberg examined the experimental use exception to patent infringement.[450] By international standards, Eisenberg adopts a fairly restrictive view on the role of any experimental use exception, though she is willing to accept the need for a more expansive approach than currently adopted by US courts. The scope of the research exemption proposed by Eisenberg would be a three-pronged approach as follows:

1. exception to check the validity of the patent holder's claims;
2. exception to improve upon an invention;
3. reasonable royalty for experimentation to design around an invention.

The first point was seen as a necessary means to ensure that patent holders fulfill their side of the patent bargain by allowing third parties to test the adequacy of their

[450] Eisenberg *supra* note 110.

disclosure.[451] The next two points are inter-related. Eisenberg recognized that a research exemption may be necessary to allow follow-on research to improve upon, or design around, a patented product and as such, no injunctive relief would be available to prevent such follow-on research. Eisenberg was also concerned that allowing researchers to avoid liability completely to the original patentee would "restrict the value of the patent monopoly and reduce ex ante incentives to make patentable inventions."[452] In particular, Eisenberg saw two ways in which an experimental use exception reduces the value of the patent monopoly: by depriving the patent holder of royalties that would otherwise have to be paid in experimentation; and by lowering the cost of developing around, it shortens the patent holder's "effective monopoly."[453] Eisenberg thus felt that it would be appropriate to award a reasonable royalty after the fact to ensure that the patent holder receives an adequate return on investment.

In designing around a patent, a third party is typically not liable for any damages or royalties to the patentee since the design around does not fall within the scope of the patent. Eisenberg would require the third party to pay a royalty in recognition of the benefit derived from using the patent in experimentation to develop the design around.[454] In comparison, when the third party simply improves an invention, the patent holder's interests are adequately protected if the original patent is broad enough in scope to cover the improvement.[455]

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[451] Eisenberg *supra* note 110 at 1074-1075.
[452] Eisenberg *ibid.* at 1075.
[453] Eisenberg *ibid.* at 1175-1176.
[454] Eisenberg *ibid.* at 1077-1078.
[455] Eisenberg *ibid.* at 1077.

Unfortunately, the requirement for a royalty on design arounds is problematic for several reasons. By arguing that a design around will shorten the "effective monopoly" of a patent, Eisenberg assumes that the patent gives the patentee a monopoly that needs to be protected from being shortened. This is not necessarily the case and patents rarely confer market power.[456] Furthermore, Eisenberg implicitly assumes that competitors will be making and using the original design in any research program. Again, this is not necessarily the case; if the disclosure in the original patent is sufficiently clear, it may not be necessary to actually make and use the original invention in a research program. Many researchers may simply rely on the patent disclosure and claims as a starting point for successfully developing a design around. This type of activity does not actually require any form of experimental use exception since the researcher is not using the invention itself in his research. Nonetheless, the researcher still benefits from the patentee's original disclosure in developing the design around. Therefore, there is still an argument that a royalty should be payable under this scenario.

Another possibility is that the researcher independently invents a design around without recourse to the patentee's invention, or even knowledge of the patentee's invention. This is more likely to occur in fast-moving technologies with many groups working independently. A further example occurs when the researcher develops a design around in a neighbouring jurisdiction where the patentee does not obtain patent protection. In these latter two cases, there are no arguments for a royalty being due to the original patentee; any royalty would merely serve to overcompensate the original patentee at the expense of follow-on researchers. The major problem is that it may be

[456] See Kitsch *supra* note 112.

difficult, if not impossible, for the patentee to distinguish between cases when a royalty would be due and when a royalty would not. All the patentee knows is that a competitor has introduced a competing product on the market that does not directly infringe their patent, and that may or may not be independently protected by patent protection. However, the harm to the original patentee is the same, namely increased competition in the market by the introduction of a design around.

The better approach is to consider experimentation for either improving upon or designing around as a normal and desirable part of the patent system. The purpose of the patent system is the promotion of the progress of science and this does not simply end with the original invention but extends to follow-on research. Further, in a patent grant, the patentee is only given the exclusive rights to his invention. By designing around, the third party researcher is creating a new invention. It is not the original patentee's invention and the original patentee should not benefit from a third party's invention. While it may be true that the researcher may not have developed the improvement or design around without the original patent, it is also true that the original patentee did not create his work in a vacuum and ultimately benefited from the work, patented or not, that came before. This is simply the nature of research and should be recognized and embraced by the patent system.[457]

As a final point, Eisenberg did not address the issue of access to research tools in her paper. She did express a concern that any exemption which applied to research tools

[457] The United States Court of Appeals for the Federal Circuit has repeatedly asserted that designing around is to be encouraged. See for example: *WMS Gaming Inc. v. Int'l Game Tech.*, 184 F. 3d 1339 (Fed. Circ. 1999) at 1355; *Westvaco Corp. v. Int'l Paper Co.*, 991 F.2d 735 (Fed. Circ. 1993) at 745; *Yarway Corp. v. Eur-Control USA, Inc.*, 775 F.2d 268 (Fed. Circ. 1985) at 277.

would effectively eliminate the benefit of patent protection for the research tool invention:[458] this is a legitimate concern but one that needs to be balanced against issues of access, particularly in rapidly developing areas such as biotechnology.

4.5.2 Academic Use

One proposal is to implement a broader exemption to protect non-commercial research regardless of whether the research is on or with a patented tool.[459] Many academic researchers already erroneously claim such an exemption.[460] This has been encouraged, in part, by firms that are reluctant to enforce patents against universities because of the low damage awards and the bad reputation that comes from suing a university.[461] However, to the extent that universities are engaging in increasingly commercial activities, this reluctance may diminish.[462]

The first and most prominent problem with this proposal is that it does nothing to address industrial research as it does in promoting academic research. A lot of valuable research comes out of industrial labs and society has as strong an interest in ensuring that this research is productive. Aside from this glaring omission, it can also be difficult to

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[458] Eisenberg *supra* note 110 at 1074.
[459] ALRC Report *supra* note 56 at 13.62 citing a proposal submitted to the ALRC by the Centre for Law and Genetics; Hoffman *supra* note 22 at 1036-1039; D.M. Gitter, "International Conflicts Over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair-Use Exemption" (2001) 76 New York University Law Review 1623 at 1687-1688; S. Zhang, "Proposing Resolutions to the Insufficient Gene Patent System" (2004) 20 Santa Clara Computer & High Technology Law Journal 1139 1170-1171; Derzko *supra* note 365 at 390-391.
[460] Walsh *supra* note 5 at 325; National Academy *supra* note 384 at 88.
[461] Walsh *supra* note 5 at 325-326.
[462] National Academy *supra* note 384 at 88 noting that more universities have received notices asserting patent rights in 2003 compared to 2002.

distinguish between commercial and non-commercial research. Simply because research occurs at an academic setting such as a university does not mean that it is "non-commercial". The US Federal Circuit decision in *Madey v. Duke* illustrated the point that universities are becoming increasing reliant on commercial exploitation of inventions developed on campus.[463] Even fundamental research may have an ultimate commercial use not contemplated at the time the research is undertaken.

This latter problem was recognized and a possible solution was proposed to allow researchers to self-define themselves as non-commercial users of patented invention but in doing so to also undertake to publish the results of their work and refrain from patenting.[464] A "patent-free" zone would then be set up around academic research where research could occur with patented tools but only to the extent that any results obtained using the tool would become freely available. There is a symmetry to this proposal that seems appealing at first. Researchers get free access to patents as long as the results of their research are equally free to subsequent researchers. This is reminiscent of the copyleft movement in software development.

Consider research on a disease target under this proposal: academic researchers would be able to do research on the target and develop a small molecule therapeutic as a result. The drug would then be published and dedicated to the public without any proprietary rights being claimed therein. However, a lack of patent rights on the small molecule drug would act as a disincentive for anyone else to undertake the extensive clinical trials necessary to bring this drug to market.

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[463] *Madey supra* note 373.
[464] ALRC Report *supra* note 56 at 13.63.

A further modification of this academic use proposal has been suggested to allow academic researchers a "buyout" to permit them to avoid losing these opportunities and to subsequently obtain patent rights.[465] The timing of any buyout could be problematic as the researcher would have to realize the commercial significance of the invention before publishing. A one year grace period is allowed in Canada and the United States, but elsewhere, the researcher would lose the ability to file for patent rights if the research results have already been made public.

A further problem with an extensive academic or non-commercial use exception is that some research tools may have academic research as the primary market. Such an exemption may therefore render any associated patent rights meaningless. Any exemption that removes essentially all scope from the patent rights is undesirable.[466]

It has also been noted that research universities have a growing investment in technology transfer and have been aggressively pursuing patent rights and industry-sponsored research. Allowing academic researchers to waive patent rights in exchange for access to tools may lead to increased friction with university administrators over when the waiver option should and should not be exercised.[467]

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[465] National Academy *supra* note 384 at 92.
[466] Eisenberg *supra* note 110 at 1035.
[467] National Academy *supra* note 384 at 93.

4.5.3 Fair Use

Maureen O'Rourke has proposed a fair use doctrine for patent law based on provisions of American copyright law.[468] Under this proposal, any determination of fair use would require an evaluation of five factors:

1. the nature of the advance represented by the infringement;
2. the purpose of the infringing use;
3. the nature and strength of the market failure that prevents a licence from being concluded;
4. the impact of the use on the patentee's incentives and overall social welfare; and
5. the nature of the patented work.[469]

This is an interesting approach from an intellectual perspective and would likely prevent some of the abuses as found in the *SK&F* case. Patentees would not be able to avoid scrutiny of their patent by having a separate patent on an essential input. However, it is unclear how the courts would balance the five factors in other cases. For example, what would constitute "fair use" of a disease target? A new fair use doctrine would be just as unable to deal adequately with disease targets as the experimental use exception. To summarize, this fair use doctrine seems unnecessarily complex and unpredictable.[470]

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[468] M.A. O'Rourke, "Toward a Doctrine of Fair Use in Patent Law" (2000), 100 Columbia Law Review 1177 at 1179.
[469] O'Rourke *ibid.* at 1206-1209.
[470] National Academy *supra* note 384 at 92.

4.5.4 A New Proposal

What is needed is an approach that is simple to administer yet addresses the major issues of allowing access to patented research tools without effectively eliminating any patent rights. Furthermore, this has to be accomplished within the vague international requirements set out in the TRIPs Agreement.

The first step under this new proposal is to exempt any and all *bona fide* experimentation from claims of patent infringement. This exemption would include experimentation *on* as well as experimentation *with* the patented invention and would apply equally to commercial and non-commercial research. The second step would involve imposition of a reasonable royalty for any researchers engaging in research *with* the patented invention. For clarity, this reasonable royalty would apply equally to any research involving disease targets.

This is not a radical departure from current conceptions of experimental use outside of the United States. Experimentation on a patented invention would be treated as before. The only difference is that experimentation *with* a patented invention would now be subject to a reasonable royalty. This proposal has the dual advantage of addressing concerns about access to research tools as well as addressing concerns about a too narrow interpretation of the "subject-matter of the invention" as discussed above. Patentees would no longer be able to shield their patents from scrutiny as in *SK&F* by having a separate patent on an essential input. At most, they would be entitled to a reasonable royalty: exclusive licences on disease targets would also no longer be allowed. Access to these essential inputs would be guaranteed though the patentee would still benefit from patenting the disease target.

While this right to a reasonable royalty would be enforceable in a court, very few cases would likely ever go that far. The simple enactment of a legislative right to a reasonable royalty will encourage both parties to negotiate a voluntary licensing scheme at reasonable terms.[471] Patentees will no longer be able to prevent researchers from having access to their tools and third party researchers, both academic and in private firms, will recognize their obligations to pay a reasonable royalty for access to the tool.

This is similar to a previous proposal introduced by David Parker and Nicole Stafford where the exemption would apply to "making or using of a patented invention in research or experimentation, or in the development of an invention or discovery" but that the sale of any product or process developed as a result of the invention would be an infringement.[472] This has the effect of imposing a reach-through royalty system where any use of a tool would be exempt from infringement, though royalties become due on any commercially successful product.

Reach through royalties are becoming increasingly popular in licences as they allow research tool patentees to benefit from the commercial success that use of their tool allows. Researchers also often appreciate not having to worry about royalties at the initial stages of research. The patentee would take the risk that the research will not be successful in which case no royalty would be payable, but this is typically compensated for by the presence of larger payments on commercial successful products; however,

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[471] J.M. Mueller, "No 'Dilettante Affair': Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools" (2001) 76 Washington Law Review 1 at 65-66.

[472] D.L. Parker & N. Stafford, "Biotechnology Research & Patent Infringement: Should Research Be Exempt from Charges of Patent Infringement" (1998) Journal of the Association of University Technology Transfer Managers available at <www.autm.net/pubs/journal/98/parker.html> (accessed September 14, 2004); see also Mueller *ibid.*, where she argues for an exemption based on reach through royalties.

there is considerable criticism of reach through royalties particularly if multiple tools are required, each imposing a royalty on the final product. This can result in "royalty stacking" and thereby impose significant burdens on commercialization of the end-product.[473]

In this proposal, the form of the royalty can be negotiated by the parties. If adjudicated by the courts, a reasonable royalty would likely be based on actual use of the tool in research but the individual parties would not be required to structure their royalty payments in this way. If the parties so desired, they could easily establish a reach through royalty scheme instead. This proposal simply provides more flexibility to the parties without trying to impose a single solution for all situations.

A further advantage of this proposal over that proposed by Parker and Stafford is that experimentation for the purpose of designing around the patent would not be subject to any form of royalty. The design around is a new invention that the patentee is not entitled to benefit from.

A similar system can be seen in the 1991 UPOV Convention. Traditionally, farmers had rights to save seed from one year to the next. This was recognized as a "farmers exemption" and implicitly protected in the 1978 UPOV Convention. One of the changes of the 1991 UPOV was to extend the breeders' rights to any reproduction of the variety irrespective of purpose in article 14.[474] This would have the effect of eliminating the exemption entirely, though individual nations could reintroduce the notion in article 15(2) as follows:

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[473] N.M. Derzko, "In Search of a Compromised Solution to the Problem Arising from Patenting Biomedical Research Tools" (2004) 20 Santa Clara Computer & High Technology Law Journal 347 at 392.
[474] 1991 UPOV

> Notwithstanding Article 14, each Contracting Party may, within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder, restrict the breeder's right in relation to any variety in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting, on their own holdings, the protected variety or a variety covered by Article 14 (5)(a)(i) or (ii).[475]
>
> (my emphasis)

The traditional farmer's exemption can thus be reintroduced but only if the *legitimate interests* of the breeder are safeguarded. This is done by requiring the farmer to pay the breeder a royalty.[476] In a similar manner, patentees' legitimate interests in a patented research tool are respected by payment of a royalty.

While the present proposal addresses most of the identified problems, there are two potential issues remaining. Firstly, it is not a complete solution to a researcher's inability to gain access to research tools. This approach works well in ensuring that researchers have ready access to researcher-supplied tools and disease targets. However, to the extent that the patentee is not adequately supplying the research market with market-supplied tools, it is unlikely that any type of experimental use exemption will be of any benefit to the researcher.

The second major problem with this proposal stems from the uncertainty surrounding the TRIPs Agreement. There is a general international consensus that some form of experimental use exception is allowed though it is not clear how broad the exception can be without running afoul of article 30 in particular. Exceptions under article 30 have tended to be absolute exceptions where there is no liability at all if the

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[475] 1991 UPOV

[476] Benda *supra* note 365 at 345.

conduct falls within the exception. The present proposal is slightly different in that a reasonable royalty becomes due for certain types of experimentation.

Without the reasonable royalty, the proposal would clearly be contrary to the requirement in the TRIPs Agreement that any exception "do not unreasonably prejudice the legitimate interests of the patent owner."[477] The value of research tool patents would be significantly and deleteriously affected with a not-insignificant number of patents on such tools becoming essentially worthless. However, the requirement for a reasonable royalty means that the patentee is still able to exploit the invention and extract economic value from the patent. The patentee is no longer able to enjoin all experimentation with the tool, nor control follow-on research with the tool but this is not an "unreasonable" limitation on the patentee's legitimate interests.

The major uncertainty is that this proposal is similar to a compulsory licensing scheme that is typically analyzed under article 31 in the TRIPs Agreement, (titled "other use without authorization of the right holder") and not article 30. Compulsory licensing will be discussed in more detail in the next chapter. Nevertheless, the current proposal would not comply with the requirements of article 31.[478] However, as some academics characterize any exemption from the exclusive rights granted by a patent as "royalty-free compulsory licences,"[479] it is not surprising that the present proposal could also be characterized as a compulsory licence.

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[477] TRIPs Agreement, art. 30.

[478] Such as the requirement to assess each licence on its merits or to negotiate with the rights holder prior to issuance of the compulsory licence; see *supra* notes 285-293 and accompanying text.

[479] See for example, Gillat *supra* note 278 at 717; Eisenberg *supra* note 110; Parker *supra* note 472.

The requirements under article 30 are simple: any exception to the exclusive rights must be "limited" and not unreasonably conflict with a normal exploitation of the patent nor unreasonably prejudice the legitimate interests of the patent owner. Under the present proposal, only *bona fide* experimentation would still be exempted. Experimentation is generally accepted internationally as being within the scope of article 30. With regard to research tools, the exclusive right to supply the product commercially in competition with the patentee would remain with the patentee: a third party would only be entitled to make (or import) a tool for use related to experimentation. There would not be any right to make the tool on a commercial scale nor sell it in competition with the patentee. In other words, this is a "limited" exception that does not unreasonably conflict with the normal exploitation of the invention as provided for in article 30. Further, the legitimate interests of the patentee are respected under my proposal by the requirement for a reasonable royalty to be paid for use of a patented research tool.

The current proposal also meets the objectives set out at the beginning of this part: it is easy to administer, allows greater access to research tools while respecting the legitimate interests of the patent holders, and it is consistent with Canada's international obligations under the TRIPs Agreement.

4.6 Conclusion

The experimental use defence is a necessary and important part of patent law. It is through such a defence that a balance is maintained and respected between the legitimate interests of the patentee and the general public. The overall purpose of patent

legislation is also furthered in the promotion of follow-on technological innovation by a broad application of the defence.

Unfortunately, the experimental use defence does not provide any assistance to researchers needing greater access to patented research tools. Under the current understanding of the defence, it is an all-or-nothing exemption. Activities that fall within the exemption produce no liability to the patentee. If this applied to any experimentation with research tools, at least some patents on the tools would become worthless. This in turn could have a significant impact on the incentives built into the patent system to encourage the development and commercialization of such research tools.

What is needed is a two-step system whereby all experimentation, on or with a patented invention, is exempt from patent infringement. In the second step, patentees' interests in research tools is regained through payment of a reasonable royalty for use of the tool. Individual scientists thus have greater access to research tools. At the same time, patentees gain royalties from any use of the tool in research and retain the exclusive rights to make and sell their tools on a commercial scale. For greater certainty, use of disease targets in research would also be subject to the royalty.

This proposal has the further advantage of being simple to administer. Patentees would be encouraged to licence their tools widely and fairly to obtain the largest royalty stream possible. Exclusive licences on disease targets would cease to exist and patent owners would no longer be able to restrict access to their new research tools.

Chapter V
Compulsory Licensing and the Essential Facilities Doctrine

5.0 Introduction

Compulsory licensing has a long history dating back to the UK Statute of Monopolies of 1623.[480] Initially, the patent grant also contained an obligation to work the invention locally, and in some laws failure to work the invention led to forfeiture of the patent right entirely.[481] Compulsory licensing was thus seen as a way to mitigate the severe consequences of losing all patent rights.

Compulsory licenses were part of the Paris Convention in 1883 as an option to prevent abuses of the exclusive rights conferred by the patent. Failure to work was explicitly mentioned as a potential abuse to be avoided by grant of compulsory licence.[482] By the 1990's, about one hundred countries had compulsory licensing provisions within their patent laws and the grounds for compulsory licensing included: local working of the invention; refusal to deal; inadequate supply; governmental use; dependent patents; medicines; public interest; and anti-competitive behaviour.[483] Broad international acceptance of the role of compulsory licensing stands in contrast to the rhetoric coming out of the US that the right to refuse to licence is both "absolute" and "ingrained."[484]

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[480] Correa *supra* note 280 at 3.
[481] For example, in France in the 19th century: see Correa *ibid.* at 3.
[482] Paris Convention, art. 5A.
[483] F.M. Scherer, "Comment" in R.D. Anderson & N.T. Gallini, eds., *Competition Policy and Intellectual Property Rights in the Knowledge-Based Economy* (Calgary: University of Calgary Press, 1998) 104 at 106; D.A. Balto & A.M. Wolman, "Intellectual Property and Antitrust: General Principles" (2003) 43(3) IDEA: Journal of Law and Technology 395 at 428; Correa *supra* note 280 at 4; Nicol *supra* note 11 at 370.
[484] J. Kaufmann, "Afterword" (1998) 66 Antitrust Law Journal 527 at 528; Julian-Arnold *supra* note 278 at 354; Gillat *supra* note 278 at 712-713; Yosick *supra* note 278 at 1277; Saunders *supra* note 251 at 426.

Despite the strong language used by American academics and judges, more compulsory licences have been granted in the US than anywhere else in the world: tens of thousands of patents in the US have been subject to compulsory licences.[485] Part of the disconnect between the reality of compulsory licensing and the discourse in the US is that the US is the only developed nation without compulsory licensing provisions within their patent laws: most compulsory licences have been granted in the US on antitrust grounds.

Empirical evidence has suggested that even though compulsory licensing provisions are common within most countries' patent laws, they are not extensively used.[486] Only Canada and the United Kingdom have used compulsory licensing within their respective patent acts to any appreciable degree.[487] In other countries, applications for compulsory licences have been relatively rare.[488] This may suggest that compulsory licensing is generally not needed and that such provisions are superfluous. However, the more convincing explanation is that the mere existence of compulsory licensing provisions within a nation's patent laws encourage parties to negotiate licences on a voluntary basis. To the extent that the goal of such provisions is to encourage the greater

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[485] Scherer *supra* note 483 at 106; Correa *supra* note 280 at 14-16; on antitrust grounds though one commentator has noted that compulsory licensing has "fallen out of favor" in recent years: Balto *supra* note 483 at 472.

[486] Kaufmann *supra* note 484 at 530 citing D.J. Henry, "Multi-National Practice in Determining Provisions in Compulsory Patent Licences", (1976) 11 Journal of International Law and Economics 325 at 334.

[487] Correa *supra* note 280 at 22.

[488] Correa *ibid.* at 22. For example, in Australia even though section 133 of the *Patents Act* provides for compulsory licensing for failure to work, and dependent patents, these provisions have rarely been used and there is only one reported judicial decision: Nicol *supra* note 11 at 370-371 citing *Fastening Supplies Pty Ltd v. Olin Mathieson Chemical Corporation* (1969) 119 CLR 572.

dissemination of technology, they likely achieve that goal even if it is not readily apparent from the actual numbers of compulsory licences granted.[489]

Compulsory licensing offers a mechanism by which researchers can obtain access to important research tools. The focus of this chapter will be on existing compulsory licensing provisions within the Canadian *Patent* and the *Competition Acts*. To assist with this analysis, the essential facilities doctrine as developed from US antitrust laws can be of assistance.

5.1 The Essential Facilities Doctrine

5.1.1 Development of the Doctrine

The phrase "essential facilities" was not explicitly adopted in any court decision until 1977 but the roots of the doctrine date back to the 1912 US Supreme Court decision *United States v. Terminal Railroad Association*.[490] In *Terminal Railroad*, several railroad companies jointly owned rail facilities that provided the only access to the City of St. Louis as well as rail lines on both sides of the Mississippi River. At the time, railroads were considered crucial to almost every aspect of economic development. One option for the Court was to order divestiture and thereby restore competition. However, the court was swayed by the economic efficiencies generated by joint operation of the facilities and instead ordered that they must provide access to non-participating railroad companies upon reasonable terms that did not discriminate between member companies and non-

[489] Correa *supra* note 280 at 22-23; Yosick *supra* note 278 at 1294; C.M. Fauver, "Compulsory Patent Licensing in the United States: An Idea Whose Time Has Come" (1988) 8 North West Journal of International Law & Business 666 at 667.
[490] *United States v. Terminal Railroad Association*, 224 U.S. 38 (1912) [hereinafter *Terminal Railroad*].

member companies. This case led to the formulation of a basic principle: a monopolist in control of a facility essential to other competitors must provide reasonable access to that facility if it is feasible to do so.[491]

The second US Supreme Court decision cited as support for the essential facilities doctrine is *Associated Press v. United States*.[492] In *Associated Press*, a joint venture of approximately 1,200 leading daily newspapers shared their original news stories. The association's by-laws permitted each member to veto any new application for membership. In this manner, competitor newspapers within a single geographic market would be unable to obtain access to the same variety of news articles. The court concluded that the veto had no legitimate purpose other than to protect incumbent members from their local competitors and ordered that membership be opened on a non-discriminatory basis.

A third leading case from the US Supreme Court is the 1973 decision of *Otter Tail Power Co. v. United States*.[493] In *Otter Tail*, a vertically integrated company produced electricity, transferred it ("wheeled" it) over its proprietary delivery lines and then sold the power at retail prices in Minnesota and the Dakotas. Municipalities that operated their own utilities could purchase power from Otter Tail Power but Otter Tail Power would not wheel power produced by another supplier. The Court held that Otter Tail Power must wheel power from any source as long as it was reasonably able to do so without inhibiting its ability to serve other customers.

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[491] A.B. Lipsky, Jr. & J.G. Sidak, "Essential Facilities" (1999) 51 Stanford Law Review 1187 at 1190-1191.
[492] *Associated Press v. United States*, 326 U.S. 1 (1945). Lipsky *ibid.* at 1198.
[493] *Otter Tail Power Co. v. United States*, 410 U.S. 366 (1973).

In addition to these three supreme court decisions, there have been a considerable number of lower court decisions regarding the essential facilities doctrine.[494] The types of market facilities that have been characterized as essential facilities have varied widely to include: the New York Stock Exchange; a wholesale produce market; the multiple listing services for residential real estate; a computerized airline reservation system; modern rail networks; regional electricity distribution networks; natural gas pipelines; oil pipelines and storage facilities; a municipal pier; an airport terminal; football and basketball stadiums; and the nationwide transmission and switching facilities that once comprised the local telephone network of the Bell System.[495]

From the caselaw, it can be concluded that an essential facility has two main characteristics. Firstly, to be an essential facility, a competitor or potential competitor must have access to it in order to compete in the relevant market. Denial of access to an

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[494] See for example, *United States v. Realty Multi-List, Inc.*, 629 F.2d 1351 (5th Cir., 1980); *Time Warner Entertainment Co. v. FCC*, 93 F.3d 957 (D.C.Cir. 1996) (per curiam); *Mt. Mansfield Television, Inc. v. FCC*, 442 F.2d 470 (2d Cir. 1971); *Phil Tolkan Datsun, Inc. v. Greater Milwaukee Datsun Dealers' Advertising Ass'n, Inc.*, 672 F.2d 1280 (7th Cir., 1982).

[495] Lipsky *supra* note 491 at 1191 (citations omitted). There is an even more impressive list where counsel have creatively but ultimately unsuccessfully argued for the application of the essential facilities doctrine, including:

> hospitals, ski mountains, soft drinks, credit cards, the milk industry, cable television, the apartment rental referral industry, direct all-freight flights between New York City and San Juan, Puerto Rico, the ownership of the National Football League franchises, publications and periodical distributors, the list of vendors willing to provide teletype terminals compatible with the Western Union teletype service network, electronic transmission of advertisements to newspapers, a list of the business classification in which each advertiser in the Miami, Florida *Yellow Pages* spends the greatest amount of money each year, a membership in an appraiser's association, payphone long distance carriers in Puerto Rico, cellular long distance service, microwave facilities for international communications, the home health care market, resistive bands and tubing for exercise equipment, the lignite market, and high performance Intel microprocessors.

Lipsky *ibid.* at 1192-1193 (citations omitted).

essential facility must inflict a "severe handicap" on the competitor or potential competitor.[496] In other words, the facility does not need to be truly "essential" but only reasonably necessary. Secondly, an essential facility is something that for practicable purposes cannot be duplicated or would be economically infeasible to be duplicated.[497] However, simply because a firm has an essential facility does not mean that there will necessarily be liability under the essential facilities doctrine. To find such liability, there must also be:

1. control of the essential facility by a monopolist;
2. a competitor's inability practically or reasonably to duplicate the essential facility;
3. the denial of the use of the facility to a competitor; and
4. the feasibility of providing the facility.[498]

Inherent within this test is the requirement that the owner of the facility possesses monopoly power.[499] Without some degree of market power, it would otherwise be inappropriate to apply antitrust remedies.[500]

These characteristics lead to differential treatment of otherwise similar facilities depending on available substitutes for the output of the facility. Abbott Lipsky, Jr. and

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[496] *Hecht v. Pro-Football, Inc.*, 570 F.2d 982 (D.C. Cir. 1977) at 992, *cert. denied*, 436 U.S. 956 (1978); compare with *In re Air Passenger*, 694 F. Supp 1443 (C.D. Cal. 1988) at 1452 stating that a facility is "essential" only where control of the facility poses danger of monopolization of the downstream market.

[497] *Hecht ibid.* There has not been much discussion of just how essential an essential facility must be: M.L. Azcuenaga, "Essential Facilities and Regulation: Court or Agency Jurisdiction" (1990) 58 Antitrust Law Journal 879 at 881.

[498] *MCI Communications v. American Telegram & Telegraph Co.* 708 F. 2d 1081 (7th Cir.), cert. denied, 464 U.S. 891 (1983); *Hecht supra* note 495.

[499] Lipsky *supra* note 491 at 1211.

[500] Lipsky *ibid.* at 1212 citing *AT&T Corp. v. Iowa Util. Bd.*, 119 S.Ct. 721 (1999).

Gregory Sidak give the example of a shopping mall. A shopping mall located in a geographically isolated community could be an essential facility assuming that there are no other malls nearby. However, the same mall in a large metropolis would not be "essential." Similarly, the analysis can change over time. The first mall located within a specific yet remote area may be essential but as the area grows and new malls are developed, the first mall may then lose its essential quality.[501]

Canadian courts have not yet formally adopted an essential facilities doctrine.[502] The closest the Competition Tribunal came to recognizing an essential facility was in the *Interac* case.[503] The *Interac* case was a consent proceeding brought under an abuse of dominance allegation contrary to section 79 of the *Competition Act*. In the *Interac* case, a group of Canada's leading financial institutions jointly formed the Interac network in the 1970s and 1980s to provide improved electronic access to banking services for their customers. The proprietary network was subsequently expanded to include an additional eighteen members though the new, sponsored members were not admitted on the same basis as the original nine charter members: charter members were entitled to maintain a 'switch' that allowed direct access to the network whereas sponsored member had to access the network through the switch of one of the founding members. Even though the Tribunal did not expressly adopt an essential facilities doctrine, the Interac network can be an essential facility: competitors need access to it to compete effectively and it cannot

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[501] Lipsky *ibid.* at 1216.
[502] M. Trebilcock, R.A. Winter, P. Collins & E.M Iacobucci, *The Law and Economics of Canadian Competition Policy* (Toronto: University of Toronto Press, 2002) at 502.
[503] *Canada (Director of Investigation and Research) v. Bank of Montreal*, (1996), 68 C.P.R. (3d) 527 [hereinafter *Interac*]. See also Trebilcock *ibid.* at 547-552.

be reasonably duplicated.[504] Pursuant to the resulting consent order, direct connection to the network was opened up. Commentators have predicted that it is simply a matter of time before the essential facilities doctrine is formally adopted by the courts, particularly as the importance of network and information based industries dependent on such facilities continues to grow.[505]

5.1.2 Application to Intellectual Property Rights

Some commentators oppose the essential facility doctrine except in a very limited form.[506] There is less controversy in applying the doctrine when there are additional features that lead to the acquisition of market power. For example in *Otter Tail*, development of the essential facility depended on exclusive government grants. Other situations where there is less controversy about using the doctrine include when the defendant seeks to leverage its power into adjacent markets or delay duplication of the facility by employing foreclosure devices.[507]

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[504] Trebilcock *supra* note 502 at 501.
[505] Trebilcock *ibid.* at 502.
[506] L.A. Sullivan & W.S. Grimes, *The Law of Antitrust: An Integrated Handbook* (St. Paul, Minn.: West Group, 2000) at 112; Lipsky *supra* note 491; P. Areeda, "Essential Facilities: An Epithet in Need of Limiting Principles" (1990) 58 Antitrust Law Journal 841; J.C. Burling, W.F. Lee & A.K. Krug, "The Antitrust Duty to Deal and Intellectual Property Rights" (1999) 24 Journal of Corporation Law 527 at 552; H. Hooverkamp, "Symposium: Intellectual Property Rights and Federal Antitrust Policy – Introduction" (1999) 24 Journal of Corporation Law 477 describes the doctrine as "largely discredited" at 482; compare with M. Dolmans, "Restrictions on Innovation: An EU Antitrust Approach" (1998) 66 Antitrust Law Journal 455 at 458.
[507] Sullivan *ibid.* at 113-114.

Part of the concern about the essential facilities doctrine is related to the appreciation that competitors should not be required to share resources.[508] In particular, commentators fear that the essential facilities doctrine would be more apt to apply in cases where the facility is developed only as a result of the skill, initiative and innovation of the owner:[509] by definition, this would include all patent rights. While a valid concern, this is the issue courts grapple with any compulsory licensing scheme of patent rights. Most countries in the world, with the notable exception of the United States, have accepted compulsory licensing as an important and integral part of their patent laws as a means to mitigate possible excesses found in the patent system. It is not an insurmountable problem when compared to the problems that can arise by failing to licence essential facilities.

A second major concern regarding the essential facilities doctrine is the level of control needed to monitor and regulate use of the facility among competitors.[510] Also, the essential facilities doctrine does not apply where it would be necessary to expand the capacity of the facility to include a new user.[511] This latter limit to the doctrine has been justified as necessary to avoid detailed judicial oversight. However, it has been noted that allowing a new entrant access to an undersized facility cannot improve downstream competition without capacity expansion; thus, the essential facilities doctrine does not improve consumer welfare with such facilities.[512] Both of these concerns are obviated

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[508] Sullivan *ibid.* at 112 ; Lipsky *supra* note 491 at 1218-1219; Areeda *supra* note 506; Y.W. Chin, "Unilateral Technology Suppression: Appropriate Antitrust and Patent Law Remedies" (1998) 66 Antitrust Law Journal 441 at 443-444.
[509] Lipsky *ibid.* at 1219; Sullivan *ibid.* at 113-114.
[510] Lipsky *ibid.* at 1222-1223.
[511] Lipsky *ibid.* at 1222.
[512] Lipsky *ibid.* at 1222.

when considering intellectual property as an essential facility. Beyond setting the initial terms of the compulsory licence as courts have done in the past, there is no need for additional monitoring or regulation of the IP right. Secondly, as a non-rivalrous good, there is no limit to the number of new entrants or users of the IP right.

Finally, a major concern about the essential facilities doctrine is the so-called "free-rider" problem. A firm expends considerable resources and assumes significant risk in developing what turns out to be an essential facility. There is no incentive for a firm to assume this risk if competitors can obtain access to the facility under the essential facilities doctrine without assuming any of the risk or cost themselves.[513] For this reason, any competition law remedies under an essential facilities analysis try to compensate the facility owner through imposition of a fee for use of the facility.[514] This can be difficult to determine accurately: fees designed simply to recover the cost of developing the facility would likely be insufficient if the firm exposed itself to significant risk of failure. Hindsight may compound the problem by underestimating the degree of risk actually taken since the initial investment was successful and the facility turned out to be "essential." Fees that are too low may have a chilling effect on investments for facilities that have the potential to become essential. Conversely, fees that are too high overcompensate the facility owner and risk having a negative effect on competition.

These same concerns pervade compulsory licensing of patent rights. Firms assume costs and risks in developing new inventions that are protected by patent rights. Any compulsory licence tries to achieve an appropriate balance between promoting competition in the use of the invention without causing a chilling effect on further R&D.

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[513] Sullivan *supra* note 506; Trebilcock *supra* note 502 at 502-503.
[514] Trebilcock *ibid.* at 502-503.

There is also a symmetry in the "free-rider" concerns between patent laws and the essential facilities doctrine.[515] Under patent laws, free-riding is prevented by the grant of a time-limited exclusivity over what would otherwise be in the public domain whereas free-riding under the essential facilities doctrine is prevented by imposing a fee for use of what would otherwise be a proprietary facility.

The two bodies of law come together when you consider patents as an essential facility.[516] This is a controversial proposition in the United States where courts have consistently held that the patent holder may refuse to licence patent rights free from liability under the antitrust laws "[i]n the absence of any indication of illegal tying, fraud in the Patent and Trademark Office, or sham litigation."[517] In 1998, this principal was codified in the patent laws in section 271 that "[n]o patent owner otherwise entitled to relief for [patent] infringement ... shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of ... refus[ing] to licence or use any rights to the patent ...."[518]

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[515] See Chapter II, *supra* notes 120-121 and accompanying text for a discussion of the free-rider problem as a justification for the patent system.

[516] Chin *supra* note 508 at 445; Correa *supra* note 332 at 405 citing J. Talada & J. Carlin Jr., "Compulsory Licensing of Intellectual Property Under the Competition Laws of the United States and European Community" (2002) 10 George Mason Law Review 443 at 443-444.

[517] *In re Independent Service Organizations (Antitrust Litigation)*, 203 F.3d 1322 (Fed. Circ. 2000), cert. denied, sub. nom. *CSU, L.L.C. v. Xerox Corp.*, 121 S.Ct. 1077 (2001) [hereinafter *Independent Service Organizations*]; *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195 (2d Cir. 1981) at 1206; compare with *Intergraph Corp. v. Intel Corp.*, 195 F.3d 1346 (Fed. Cir. 1999) [hereinafter *Intergraph*]; *Image Technical Services, Inc. v. Eastman Kodak Co.*, 125 F.3d 1195 (9th Cir. 1997); Yosick *supra* note 278 at 1282-1284.

[518] 35 U.S.C. §271(d); *Independent Service Organizations ibid.* at 1135; D. McGowan, "Networks and Intention in Antitrust and Intellectual Property" (1999) 24 Journal of Corporation Law 485 at 493-494.

The European approach to intellectual property is much more open to the concept of treating intellectual property rights as essential facilities. This is reflected in the 1995 Magill decision of the European Court of Justice (ECJ). In *Magill*, a publisher wanted to create a new weekly television guide containing the broadcasting timetables of all the various broadcasters in Ireland. The broadcasters held a copyright in their respective timetables which they declined to licence to the publisher. The publisher initiated a complaint before the Competition Commission alleging an abuse of dominance and the Commission ordered the broadcasters to grant the necessary licences. On appeal to the ECJ, the Court rejected the broadcasters appeal and held that the mere exercise of the exclusive rights of an intellectual property right may, in "exceptional circumstances" constitute abuse conduct.[519] For exceptional circumstances to exist, three cumulative conditions must be satisfied:

1. refusal to licence is preventing the emergence of a new product for which there is potential consumer demand;
2. refusal is not justified by objective considerations;
3. refusal is such as to exclude any competition on a secondary market.

These conditions were discussed in a little more detail in the recent case *IMS Health GmbH v. NDC Health GmbH*.[520] In *IMS*, the ECJ held that there must be both a primary

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[519] *Radio Telefis Eireann (RTE) and Independent Television Publications Ltd. (ITP) v. Commission of the European Communities*, joined cases C-241/91 P and C-242/91 P (E.C.J., April 6, 1995) at para. 51 available at <europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!CELEXnumdoc&lg=en&numdoc=61991J0241> (accessed May 21, 2005) [hereinafter *Magill*]; see also Dolmans *supra* note 518 at 461-463.

[520] *IMS Health GmbH v. NDC Health GmbH*, case C-418/01 (E.C.J., April 29, 2004) available at

market and a secondary downstream market. The party requesting the licence can be a competitor on the secondary market but must be offering a new product on that market not offered by the owner of the intellectual property right. It would not be an abuse of dominance if the party were simply going to duplicate the goods or services already offered on the secondary market by the owner of the intellectual property right.[521] Further, it is "determinative" if two different stages of production may be identified and the upstream product is "indispensable" for the supply of the downstream market.[522] To determine if a product or service is indispensable, it is necessary to determine if there are any economically viable alternatives available.[523] While the absence of a business justification was listed as an element of the test, the ECJ did not elaborate in Magill nor IMS on what this would mean.[524] This test developed by the ECJ and used in both *Magill* and *IMS* to justify granting of compulsory licences to intellectual property rights is substantively similar to the essential facilities doctrine developed in the United States.

5.1.3 Application to Research Tools

In any analysis under the essential facilities doctrine, it is necessary to consider the relevant market.[525] This is related to the requirement that the facility owner must possess market power before using an antitrust doctrine such as the essential facilities

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<europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!CELEXnumdoc&lg=en&numdoc=62001J0418> (accessed May 21, 2005) [hereinafter *IMS*].

[521] *IMS ibid.* at para 49.

[522] *IMS ibid.* at para 45.

[523] IMS *ibid.* at para 28

[524] See Dolmans *supra* note 506 at 469-470 for an academic discussion on possible justifications.

[525] W. Blumenthal, "Three Vexing Issues Under the Essential Facilities Doctrine: ATM Networks as Illustration" (1990) 58 Antitrust Law Journal 855 at 858.

doctrine.[526] In addition, the relevant market must be a downstream market. For research tools, the important market to consider is the downstream "innovation" market and not the market for the tool itself.

There are three different types of markets: goods markets, technology markets and innovation markets.[527] Goods markets are the most familiar market and include goods or services that are bought and sold within a market; this would also include the sale of research tools themselves. Technology markets instead are directed to the intellectual property rights that may be licenced or sold and any close substitutes. Close substitutes include technologies or goods that are close enough substitutes to constrain the exercise of market power with respect to the respective intellectual property rights. Technology markets arise when intellectual property rights are marketed separately from any products encompassing the intellectual property. Finally, innovation markets represent the market for innovation in and of itself. An innovation market has been defined by the US Federal Trade Commission (FTC) as the "research and development directed to particular new or improved goods or processes, and the close substitutes for that R&D."[528] Close substitutes include R&D efforts, technologies and goods that significantly constrain the exercise of market power with respect to the relevant R&D. The FTC first used innovation market theory in a 1997 proposed merger between pharmaceutical companies

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[526] Lipsky *supra* note 491 at 1213.
[527] Balto *supra* note 483 at 417; U.S. Department of Justice and the Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property* (April 6, 1995) at 11available at <www.usdoj.gov/atr/public/guidelines/ipguide.htm> (accessed April 13, 2005) [hereinafter DOJ Guidelines].
[528] DOJ Antitrust Guidelines *ibid.* at 11.

Ciba-Geigy and Sandoz to create the new company Novartis.[529] The FTC alleged the existence of a market for the development of gene therapy products even though there were no gene therapy products available at that time. The two merging firms had dominant patent portfolios around gene therapy such that any other firm wanting to do research in this area needed to contract with one or the other of these two firms.[530] Competition between the firms helped ensure the development of joint ventures and contracts on reasonable terms. However, the FTC feared that the merged firm Novartis would not be so inclined to licence out its technology thereby blocking access to the broad future gene therapy market. In other words, the FTC was concerned that research within the innovation market for the development of gene therapies would be reduced. In the consent order, the FTC's concerns were allayed by the licensing out of certain gene therapy technology to a third, large pharmaceutical firm Rhone-Poulenc Rorer.[531]

Under the essential facilities doctrine, both the facility owner and the facility user must compete in a downstream market that requires access to the essential facility.[532] For research tools, a tool would be an essential facility if it is reasonably necessary to efficiently conduct research within a downstream innovation market. To be essential, there must be no close substitutes for the tool and there must be no close substitutes for the research project that requires the use of the tool: this would occur when the tool is a pioneering or fundamental research tool. For there to be liability under the essential

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[529] See for example, *Ciba-Geigy Ltd.*, 123 F.T.C. 842 (F.T.C. Mar. 24, 1997) (consent order Dkt. No. C-3725) available at <http://www.ftc.gov/os/caselist/c3725.htm> (accessed May 21, 2005) [hereinafter *Ciba-Geigy* Consent Order]; see also Gillat *supra* note 282 at 729.

[530] *Ciba-Geigy Ltd.*, (F.T.C. complaint Dkt. No. C-3725) available at <http://www.ftc.gov/os/caselist/c3725.htm> (accessed May 21, 2005).

[531] *Ciba-Geigy* Consent Order supra note 535; see also Balto *supra* note 486 at 425-427.

[532] *Intergraph supra* note 517.

facilities doctrine the four part test provided above must also be met.[533] Applying this test to research tools: (1) the patent rights give the patentee control over the facility; (2) assuming that there are no reasonable alternatives available to the researcher, the patent rights prevent the researcher from duplicating the facility; (3) the patentee has refused to licence; and (4) as a non-rivalrous right, it is always feasible for the patentee to provide access to the facility.

This doctrine applies well to the discussion of research tools as it has been pointed out that there is no "research tool issue" if the tool is not essential. For example, there is no issue if there are close substitutes available for the researcher. Similarly, there is no issue if the patentee commercializes the research tool and sells it on the open market. In either case, researchers have options available to them to compete within the innovation market. The researcher may be somewhat disadvantaged if the substitute is not as good as the patented tool or if the patentee charges monopoly prices for access to the tool but these costs are a reasonable cost inherent to the patent system. Only when the tool is an essential facility, such that there are no reasonable alternatives and the patentee does not licence or sell the tools for a reasonable cost, is there a risk for a serious and adverse impact on researchers and society at large.[534]

A different concern regarding the application of the essential facilities doctrine to IP is that it reduces the incentives otherwise available to develop alternatives to the research tool. Without access to the tool, the competitor would be forced to either give up a line of research or invest resources in developing alternatives to the tool. In some

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[533] See *MCI supra* note 498 and accompanying text for a discussion of the elements necessary for liability.
[534] Strandburg *supra* note 228 at 124; Mueller *supra* note 471.

situations, this may be considered socially wasteful as resources are expended to duplicate and design around the research tool. However, research often provides unexpected results such that an even better tool may be developed. Courts should therefore be reluctant to declare a tool to be "essential" if alternatives could be developed, even if such alternatives are not currently available. To the extent that alternative tools become available at a later time, the patentee should have recourse to terminating the compulsory licence.

Patent rights can thus be an essential facility and refusal to licence can bring liability under the essential facilities doctrine. The next part 5.2 will examine whether there is a statutory scheme within the *Competition Act* that allows for an application of the essential facilities doctrine to intellectual property rights.

5.2 Compulsory Licensing Under Canadian Competition Laws

While it may appear as though patent and competition laws have vastly different purposes, the ultimate goal of both patent and competition laws is to promote an efficient economy.[535] It has been said by the Court of Appeals for the Federal Circuit in the United States that:

> [T]he aims and objectives of patent and antitrust laws may seem, at first glance, wholly at odds. However, the two bodies of law are actually complementary, as both are aimed at encouraging innovation, industry and competition.[536]

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[535] Competition Bureau, Government of Canada, *Intellectual Property Enforcement Guidelines*, 2000 at 1 available at <competition.ic.gc.ca> (accessed April 13, 2005) [hereinafter Competition Bureau Guidelines]; DOJ Guidelines *supra* note 527 at 2; Balto *supra* note 483 at 396; J.M. Cohen & A.J. Burke, "An Overview of the Antitrust Analysis of Suppression of Technology"(1998) 66 Antitrust Law Journal 421 at 423-424.

[536] *Atari Games Corp. v. Nintendo of America, Inc.*, 897 F.2d 1572 (Fed. Circ. 1990) at 1576.

There are two main sources of law in the United States dealing with antitrust issues: the first is statutory pursuant to the *Clayton Act*[537] or the *Sherman Act*,[538] and the second is a common law doctrine of patent misuse. Patent misuse developed out of a clean-hands doctrine stating that a patentee who has abused their patent rights may not come to court to try to enforce those rights. In comparison, there is no common law defence to patent infringement in Canada and the only available remedies are statutory under the *Competition Act*.[539] The Competition Bureau in Canada has described the purpose of competition laws as being to "prevent companies from inappropriately creating, enhancing or maintaining market power that undermines competition without offering offsetting economic benefits."[540]

There are three possible provisions in the *Competition Act* that could be invoked in a situation involving refusal of a patentee to licence patent rights to a research tool required by a researcher in order to compete effectively in an innovation market: abuse of dominance provisions in sections 78 and 79; refusal to deal in section 75; and section 32 that deals expressly with intellectual property.[541]

5.2.1 Abuse of Dominance

The abuse of dominance provisions prevent dominant actors in a market from using their position and market power to anti-competitive effect. Within the abuse of

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[537] Clayton Act, 15 U.S.C. §12(b).
[538] Sherman Act, 15 U.S.C. §1-7.
[539] Section 65 of the *Patent Act* does provide remedies for "abuse" of patent rights but abuse in this context refers primarily to non-use in Canada by the patentee, see *infra* notes 589-635 and accompanying text for a discussion of patent abuse.
[540] Competition Bureau Guidelines *supra* note 535 at 3, 5.
[541] *Competition Act*, R.S.C. 1985, c. C-34.

dominance provisions, there is an express exception at section 79(5) relating to intellectual property. Specifically, section 79(5) states that "an act engaged in pursuant only to the exercise of any right or enjoyment of any interest derived under the ... Patent Act ... is not an anti-competitive act" for the purposes of abuse of dominance.

Within trade-mark law, the Competition Tribunal had the opportunity to discuss section 79 and the exclusive rights granted by trade-mark law in *Canada (Director of Investigation and Research) v. Tele-Direct (Publications) Inc.* In *Tele-Direct*, the Tribunal stated:

> The respondents' refusal to licence their trade-marks falls squarely within their prerogative. Inherent in the very nature of the right to licence a trade-mark is the right for the owner of the trade-mark to determine whether or not, and to whom, to grant a licence; selectivity in licensing is fundamental to the rationale behind protecting trade-marks. The respondents' trade-marks are valuable assets and represent considerable goodwill in the marketplace. The decision to licence a trade-mark – essentially, to share the goodwill vested in the asset – is a right which rests entirely with the owner of the mark. The refusal to licence a trade-mark is distinguishable from a situation where anti-competitive provisions are attached to a trade-mark licence.[542]

The analysis applies equally to patent rights: a simple refusal to licence a patent, whether it is a research tool or otherwise, would thus be outside of the scope of the abuse of dominance provisions of the Competition Act. Only if a firm with significant market power attached anti-competitive provisions to a licence could there be a violation of the abuse of dominance provisions.

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[542] *Canada (Director of Investigation and Research) v. Tele-Direct (Publications) Inc.* (1997), 73 C.P.R. (3d) 1 at 32.

5.2.2 Refusal to Deal

The refusal to deal provisions are provided for in section 75 of the *Competition Act*. The general rule is that there is no requirement for anyone to deal with anyone else. A refusal to deal only becomes anti-competitive and contrary to the competition laws when:

> (a) a person is substantially affected in his business or is precluded from carrying on business due to his inability to obtain adequate supplies of a product anywhere in a market on usual trade terms,
>
> (b) the person referred to in paragraph (a) is unable to obtain adequate supplies of the product because of insufficient competition among suppliers of the product in the market,
>
> (c) the person referred to in paragraph (a) is willing and able to meet the usual trade terms of the supplier or suppliers of the product,
>
> (d) the product is in ample supply, and
>
> (e) the refusal to deal is having or is likely to have an adverse effect on competition in a market.[543]

In *Canada (Director of Investigation and Research) v. Warner Music Canada Ltd.*,[544] Warner Music had the right to grant licences to manufacture and distribute sound recordings of performances on their master recordings. BMG wanted to licence these copyrights but Warner Music refused. Without such a licence, BMG was unable to offer its customers the broad range of products available through Warner Music and claimed that it could not continue offering a mail-order record club in Canada. As a result, the Director of Investigation and Research brought an application to the Competition Tribunal alleging that the refusal to grant copyright licences contravened the refusal to

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[543] *Competition Act*, s. 75.

[544] *Canada (Director of Investigation and Research) v. Warner Music Canada Ltd.* (1997), 78 C.P.R. (3d) 321 (Comp. Trib.) [hereinafter *Warner Music*].

deal provisions in section 75 and that the refusal to deal would have an adverse effect on competition in a market, namely the mail-order music market.

The Competition Tribunal concluded that as a matter of copyright law, there is a general right of refusal to licence copyrights. The Tribunal further concluded that even though the definitions of "article" and "product" in section 2 of the Competition Act are broad enough to encompass a copyright right as a form of personal property, licences are not a product as that term is used in section 75 of the Act.[545] In particular, the Tribunal held that there cannot be an "ample supply" of legal rights over intellectual property and that there cannot be "usual trade terms" when licences may be withheld. Further, the Tribunal concluded that there was nothing in the legislative history to suggest that section 75 could operate as a compulsory licensing provision for intellectual property.[546]

While the Competition Tribunal has not yet had the opportunity to discuss refusal to licence patent rights under refusal to deal, it will likely come to the same conclusion unless there are additional circumstances involved beyond the mere refusal to licence. However, this is not necessarily appropriate when dealing with refusal to deal with an "essential facility."

While section 75 clearly covers more traditional products, the Competition Bureau admitted that the definition of "article" and "product" was broad enough to encompass intellectual property rights. The references to "ample supply" and "usual trade terms" should not be enough to take intellectual property rights outside of the section. Since patent rights, as a form of information, are non-rivalrous and can be

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[545] *Warner Music ibid.*; article is defined in part in section 2 of the *Competition Act* as follows: "'article' means real and personal property of every description including ...."
[546] *Warner Music ibid.*

consumed by many people without depletion, there will always be an "ample supply" available. Further, "usual trade terms" for a licence can easily be determined contrary to the Tribunal's assertions and have been established by the courts in the past.[547] Finally, simply because the legislative history is silent with respect to intellectual property rights does not mean that it cannot be used as a compulsory licensing provision under the right circumstances. Clearly, not every patent right would be subject to a compulsory licence under section 75, but when the refusal to deal involves an essential facility section 75 should apply. *Warner Music*, however, states the current law regarding section 75 and unless it is legislatively or judicially overturned, there appears to be no remedy for mere refusal to deal with an intellectual property right under section 75, even one covering an essential facility.

This leaves section 32 which expressly deals with intellectual property. It mirrors the position adopted by the Competition Bureau that actions involving the "mere exercise" of a patent right are covered by section 32, whereas conduct that goes beyond that granted by statute is covered by the general provisions of the *Competition Act*.[548]

5.2.3 **Section 32**

The Competition Bureau's current position is that section 32 can be invoked "only in very rare circumstances."[549] The Federal Court is empowered by section 32 to act in

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[547] Most notably *infra* notes 563-567 and accompanying text.
[548] Competition Bureau Guidelines *supra* note 535 at 8; examples of conduct beyond that granted by statute includes such activities as abuse of dominance, refusal to deal, conspiracy, bid rigging, and market-allocation agreements.
[549] Competition Bureau Guidelines *supra* note 535 at 9; W. Grover, *The Interface of Biotechnology Patents and Competition Law* (Ottawa: Canadian Biotechnology Advisory Committee, 2001) at 20.

one of four situations, namely when use of the exclusive rights and privileges conferred by one or more patents:

> (a) limits unduly the facilities for transporting, producing, manufacturing, supplying, storing or dealing in any article or commodity that may be a subject of trade or commerce,
>
> (b) restrains or injures, unduly, trade or commerce in relation to any such article or commodity,
>
> (c) prevents, limits or lessens, unduly, the manufacture or production of any such article or commodity or unreasonably enhance the price thereof, or
>
> (d) prevents or lessens, unduly, competition in the production, manufacture, purchase, barter, sale, transportation or supply of any such article or commodity.[550]

The Tribunal in *Warner Music* compared section 32 to refusal to deal in section 75 and found four main differences:

1. section 32 is specifically directed to the use of copyright rights (it is also directed to patent rights);
2. a competition impact test must be met before an order will be made;
3. the Attorney General of Canada and not the Director is the applicant (in addition, any person may apply to the Tribunal for leave to make an application under section 75 but only the Attorney General can make an application under section 32); and
4. there is a defence based on treaty provisions.[551]

Section 32 has rarely been used in Canada.[552] There are no reported decisions yet which have been brought under section 32 though there have been two cases brought

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[550] *Competition Act*, s. 32.

[551] *Warner Music supra* note 544. My observations are included in brackets under points (1) and (4). A further difference is that an application is made to the Competition Tribunal under section 75 but to the Federal Court under section 32.

under earlier legislation and both settled. Both of these cases involved Union Carbide. In the first case, Union Carbide licenced a patented machine that extracted polyethylene film from resin. Licencees could purchase resin from Union Carbide or from a group of select suppliers and pay lower royalties or they could pay higher royalties if they imported resin from other suppliers. By the time the case was brought by the Crown, the patents had expired but the restrictive conditions continued to be enforced. The Crown argued that this practice caused an undue lessening of competition in the market for resin. In the second case, several practices engaged in by Union Carbide were alleged to be anti-competitive: sliding scale royalties believed to be discriminatory against small suppliers; royalty payments beyond the patent life; restraints on patent challenges; and field of use restrictions. Both complaints settled after Union Carbide agreed to cease all of these practices.[553]

With reference to research tools, there are two main issues that need to be discussed in more detail before finding a violation of the *Competition Act* under section 32: there must be an "article or commodity that may be a subject of trade or commerce;" and there must be an "undue" limit, restraint, injury, or lessening of competition. The remainder of the paragraphs are relatively straightforward and self-explanatory. Both of

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[552] N.T. Gallini & M.J. Trebilcock, "Intellectual Property Rights and Competition Policy: A Framework for the Analysis of Economic and Legal Issues" in *Competition Policy and Intellectual Property Rights in the Knowledge-Based Economy* (Calgary: University of Calgary Press, 1998) 17 at 29.

[553] Grover *supra* note 549 at 13; Gallini *supra* note 557 at 29; D.G. McFetridge, "Intellectual Property, Technology Diffusion, and Growth in the Canadian Economy" in R.D. Anderson & N.T. Gallini, eds., *Competition Policy and Intellectual Property Rights in the Knowledge-Based Economy* (Calgary: University of Calgary Press, 1998) 65 at 90-91.

these issues will be dealt with in turn below, followed by the approach adopted by the Competition Bureau.

5.2.3.1 Article or Commodity Subject to Trade or Commerce

There are four different types of patented research tools when considering the language of section 32. In the first type of patented research tool, the patent is on a research consumable or a method of manufacturing a research consumable. In either case, there is a physical object that may be subject to trade or commerce. Examples would include reagents, enzymes, specialized equipment, etc. that may be traded among willing buyers and sellers. These are clearly articles or commodities within the meaning of section 32.

In the second type of patented research tool, the tool itself may not be an article or commodity but the use of the tool results in the development of such an article or commodity. An example of this second type of research tool would be a disease target where the researcher uses the target to screen for pharmaceuticals effective for treating the disease. The target itself may not be subject to trade or commerce but the use of the target results in a product that is. In other words, there is a clear link between use of the exclusive rights and privileges conferred by the patent on the research tool and an article or commodity that may be subject to trade or commerce, namely a pharmaceutical product.

For the third type of patented research tool, there may not be such a clear link or nexus between the tool and any resulting product. For example, the research tool may be used in research further upstream to discover the mechanisms or causes of disease. The

only direct product that results from use of the tool is information. While this information will likely be used in a subsequent research program to develop novel treatments or therapies, at the time of use of the research tool it would not be clear what form these eventual treatments or therapies will take.

It could be argued that a patent could result from the use of the research tool even if a specific product does not. In particular, the term "article" as used in the *Competition Act* has been judicially defined in *Warner Music* as being broad enough to include intellectual property rights.[554] The main question is whether such patent rights could be subject to trade or commerce as also required by section 32.

While it may not be a common way of viewing patent rights, there is no reason why section 32 should be interpreted in a manner to exclude patent rights as an "article or commodity". An example of patents being a subject of trade or commerce comes from the recent technology bubble of the late 1990's. Many internet companies developed strong patent portfolios and when these companies went bankrupt, their patents were often purchased by "patent speculators."[555] The patent speculators would then seek royalties from other companies that use the invention in their products. Patent speculators have no other business model except the trade and licensing of patent rights. This is similar to the business model of many technology transfer offices at universities where patents developed from research at the university are then licensed or sold to others. The technology transfer offices are not in a position to make any products for sale in trade or commerce but use the patent rights themselves to bring revenue into the

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[554] *Warner Music supra* note 544.

[555] Patent speculators have also been referred to as "patent trolls": R. Dreyfuss, "Patent Reform Proposals" (Address to the 2005 High Technology Summit, University of Washington, Seattle, Washington, July 22, 2005) [unpublished].

university. This latter example is particularly relevant since many technology transfer offices own patents on research tools.

To the extent that use of the research tool is reasonably expected to result in a patent right then that resulting patent right could therefore also be an article or commodity within the meaning of section 32. The problem is that not all research will result in a patent nor have any expectation of a patent. Using the example discussed above, no patent can be granted on the mere mechanism of a disease. On its own, this is an unpatentable discovery of a natural phenomenon. To be patentable, there must be some sort of utility or industrial application of the discovery.[556] To summarize, if a patent is expected to result from use of the research tool, then section 32 could apply. Unfortunately, for many upstream research programs, the only result may be an unpatentable discovery without any immediate expectation of there being an "article or commodity" as required by section 32.

It could be argued that section 32 should apply as long as there is a reasonable expectation that use of the patented tool will eventually affect trade or commerce in an article or commodity. Research using the tool may not directly lead to a treatment or cure and it may take years, but the research is an important step in the development. The effect of this approach is that it would effectively encompass every research tool. Very little research in a disease is conducted without the expectation that at some point the information gained from the research will help in finding a cure or treatment. There may be a close nexus between the results of the research and the treatment as in the case where the tool is used in screening for a pharmaceutical or there may be a more indirect

[556] *Patent Act*, s. 1 under the definition of "invention."

connection. In either case, the use of the research tool eventually affects the trade or commerce of an article or commodity. Unfortunately, there is no caselaw yet on section 32 and it is unknown how broadly the courts will be willing to interpret the section.

Under the fourth type of research tool, the result of the research is a method or process. Since section 32 is directed only to articles or commodities and not services or methods, it would appear as though section 32 did not apply to such methods unless the methods were patentable. If so, the resulting patent could be an "article" as discussed above. However, when considering whether the method is patentable, it must also be kept in mind that methods of medical treatment are not patentable subject matter in Canada.[557]

To summarize, there must be an "article or commodity" before section 32 can be used with research tools and for many tools, this article or commodity will be either the tool itself or a product developed through use of the tool. For other tools where there is no direct product resulting from use of the tool, it is not clear whether section 32 can be used. In some cases, a patent right may be considered to be an "article" under section 32 or the applicant may be able to argue that as long as trade or commerce in an article or commodity will eventually be affected then it is sufficient for section 32: unfortunately, the lack of caselaw in this area makes it difficult to know how broadly section 32 will be interpreted. Finally, if the tool is used to develop a method of medical treatment, then section 32 would not apply.

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[557] *Tennessee Eastman Co. v. Commissioner of Patents*, (1972) 8 CPR (2d) 202 (S.C.C.). Methods of medical treatment are also unpatentable in Europe but are considered to be patentable subject matter in the United States.

5.2.3.2 Undue

The word "unduly" attaches to each of the paragraphs of section 32. This is necessary since the normal exercise of most patent rights will inevitably result in some type of limit on an associated article or commodity. That is inherent in the nature of patent rights and section 32 is not intended to make every use of the patent rights a violation of the *Competition Act*. There must be something in how the patent holder uses the patent rights to "unduly" limit, restrain, injure, prevent or lessen competition.

When the research tool is an essential facility within an innovation market, limits on reasonable access to the tool will likely lead to an undue limit. This is consistent with the approach advocated by the Competition Bureau. Before the Bureau will request that the Attorney General of Canada make an application to the Federal Court under section 32, three factors must be present. The first factor is that the patent holder must be dominant in the relevant market.[558] This is a recognition that patent rights do not necessarily confer market power but if they do, then the patent holder may be in a position to abuse those rights. The second factor that must be present is that the patent rights are an "essential input or resource for firms participating in the relevant market."[559] This second factor reflects a concern that refusal to licence patent rights may prevent other firms from competing in a downstream market. The third factor involves an examination of whether the refusal to licence is stifling further innovation.[560] The purpose of the *Patent Act* is to promote innovation but if the ultimate effect is a reduction in innovation, then the Competition Bureau will consider it an abuse under section 32.

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[558] Competition Bureau Guidelines *supra* note 535 at 9.
[559] Competition Bureau Guidelines *ibid.* at 9.
[560] Competition Bureau Guidelines *ibid.* at 9

Ultimately, these three factors represent a simplified variation on the essential facilities doctrine.

While not every use of patents rights will be a violation of the *Competition Act*, section 32 should cover failure to licence a research tool reasonably required for competition in an innovation market (i.e., an essential facility for the innovation market). In such situations the requirement of an "undue" limit under section 32 will be met.

In the event that section 32 is found to be violated, the Federal Court has broad powers to direct that any act be done or omitted to prevent the violation including: declaring void, in whole or in part, any agreement or licence; directing the grant of licences on terms and conditions the court deems proper; and revoking the patent.[561] However, the Federal Court cannot make an order that is contrary to any treaty or convention of which Canada is a party.[562] The primary obligations are the TRIPs Agreement and NAFTA.

5.3 Compulsory Licensing Under Canadian Patent Laws

Canadian patent laws have been particularly open to compulsory licensing. Three grounds for a compulsory licence have traditionally existed under Canadian law: for patented medicines, governmental use and patent abuse. The most used provisions were those granting compulsory licences for medicines.

Compulsory licensing for medicines was first introduced in Canada in 1923 and allowed compulsory licences to be granted for their manufacture, use and sale. The

[561] *Competition Act*, s. 32(2), note that other remedies are also available under section 32(2).
[562] *Competition Act*, s. 32(3).

purpose of the compulsory licences was to make the product (patented medicines and foods) "available to the public at the lowest possible price consistent with giving to the inventor due reward for the research leading to the invention."[563]

In 1969, compulsory licensing became available for importation as well as manufacture of patented medicines. These licences had a significant effect in reducing prices as well as in developing a strong generic pharmaceutical industry in Canada.[564] In 1983, this compulsory licensing scheme reduced the cost of pharmaceutical drugs by US$ 211 million. In 1991-1992, consumers saved US$171 million as a result of the compulsory licensing of pharmaceuticals.[565] From 1969 until 1983, almost 80% of the applications for a compulsory licence were granted. This resulted in an average of 20 compulsory licences being granted per year.[566] The standard royalty rate was 4-5% of the net sales price of the patented medicine in final dosage form or 15% of the net selling price of the drug in bulk.[567] In 1993, Canada repealed these provisions in the *Patent Act* to conform to NAFTA and the TRIPs Agreement.[568] It was thought that compulsory licensing of medicines would be incompatible with Canada's obligations that prevent discrimination on the basis of technology.[569]

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[563] *Hoffmann-La Roche Ltd. v. Bell-Craig Pharmaceuticals*, [1966] S.C.R. 31 at 319.
[564] Chien *supra* note 293 at 876.
[565] Correa *supra* note 280 at 19.
[566] Chien *supra* note 293 at 876-877 citing the Eastman Commission.
[567] *BMS supra* note 273 at para 8; E. McMahon, "NAFTA and the Biotechnology Industry" (1996) 33 California Western Law Review 31 at 38; Sell *supra* note 236 at 506.
[568] *North American Free-Trade Implementation Act*, S.C. 1993, c. 44.
[569] NAFTA, art. 1709(7); see also TRIPs Agreeement art. 27 discussed *supra* Chapter III at 258-271; *BMS supra* note 273 at para10; Correa *supra* note 280 at 19; McMahon *supra* note 567 at 32.

The 1993 amendments to the *Patent Act* also restricted the compulsory licensing provisions related to patent abuse and governmental use. The following sections will discuss both of these grounds in more detail.

5.3.1 Governmental Use

Traditionally, the Crown had an unfettered right to practice a patented invention since the patent grant was simply an exercise of the royal prerogative.[570] As a result of Canada's obligations under the TRIPs Agreement and NAFTA, this unfettered right has been significantly limited.[571] Before a federal or provincial government can use a patented invention, the relevant government body needs to apply to the Commissioner of Patents for a compulsory licence under sections 19 and 19.1 of the *Patent Act.* The Commissioner will then consider whether a licence should be granted and on what terms. Sections 19 and 19.1 set out several requirements:

1. the government must have made efforts before making an application to obtain a licence on reasonable commercial terms from the patentee and have been unsuccessful within a reasonable period;[572]
2. any licence granted under section 19 must be non-exclusive[573] and supply the domestic market;[574]

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[570] *Feather v. R.* (1865), 122 E.R. 1191 (QB); *Formea Chemicals Ltd. v. Polymer Corp. Ltd.* (1967), 49 C.P.R. 251 (Ont. C.A.), affd (1968) 55 C.P.R. 38 (S.C.C.); *Slater Steel Industries Ltd v. R. Payer Co. Ltd.* (1968), 55 C.P.R. 61 (Ex. Ct.).
[571] McMahon *supra* note 567 at 36.
[572] *Patent Act*, s. 19.1(1).
[573] *Patent Act*, s. 19(2)(b).
[574] *Patent Act*, s. 19(2)(c).

3. the scope and duration must be limited to the purpose for which the licence is granted;[575]

4. any royalties due under the licence must take into consideration the economic value of the licence;[576] and

5. any decision made by the Commissioner can be appealed to the Federal Court.[577]

For semi-conductor technology, there is an additional requirement that no licence can be authorized other than for a public non-commercial use.[578]

The United States has made extensive use of compulsory licensing for governmental use.[579] Under the principle of "eminent domain," the U.S. government can use a patent without negotiating for its use, however, this is considered to be a "taking" under the Fifth Amendment of the U.S. Constitution.[580] The patentee can then seek redress for "reasonable and entire compensation for such use."[581] By 2003, almost 300 cases had been brought before the courts by patentees seeking reasonable compensation.[582] Government use, including use by contractors on behalf of the government, is almost certainly much more significant since this figure would include

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[575] *Patent Act*, s. 19(2)(a).
[576] *Patent Act*, s. 19(4).
[577] *Patent Act*, s. 19.2.
[578] *Patent Act*, s. 19.1(4).
[579] Chien *supra* note 293 at 863; Correa *supra* note 280 at 18.
[580] K.W. Lee, "Permitted Use of Patented Inventions in the United States: Why Prescription Drugs Do Not Merit Compulsory Licensing" (2003) 36 Indiana Law Review 175 at 186-187; Kripapuri *supra* note 236 at 679-680; D.R. Cahoy, "Treating the Legal Side Effects of Cipro®: A Reevaluation of Compensation Rules for Government Takings of Patent Rights" (2002) 40 American Business Law Journal 125 at 134.
[581] 28 U.S.C. 1498.
[582] Chien *supra* note 293 at 863.

neither cases resolved prior to initiation of litigation nor cases of infringement that are not detected by the patentee.[583]

The National Institute of Health (NIH) issued a report concluding that access to patented research tools was assured, in part, because

> as a government agency, NIH may use and manufacture any patented invention whether or not developed with federal funds, and authorize its use and manufacture by others for the United States, without a licence, subject to liability for 'reasonable and entire compensation' under 28 U.S.C. §1498.[584]

The extent to which the US government has availed itself of compulsory licensing has attracted the attention of the European Union, and in 1997 the European Commission issued a report finding, in part, as follows:

> Under US law (28 US Code Section 1498) a patent owner may not enjoin or recover damages on the basis of his patent for infringements due to the manufacture or use of goods by or for the US Government Authorities. This practice is particularly frequent in the activities of the Department of Defence but is also extremely widespread in practically all government departments. For obvious reasons, this practice is particularly detrimental for foreign right-holders because they will generally not be able to detect governmental use and are thus very likely to miss the opportunity to initiate an administrative claims process.
>
> Article 31 of the TRIPs Agreement introduces a requirement to inform promptly a right holder about government use of his patent, but no action has been taken by the US so far to bring their legislation into conformity with this provision.[585]

After the September 11th, 2001 terrorist attack in the United States, a bio-terrorism scare gripped the United States as well as Canada. Politicians in the United States started pushing for a broader compulsory licensing program to ensure adequate

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[583] Chien *supra* note 293 at 863.
[584] NIH Report *supra* note 50; Cahoy *supra* note 580 at 136.
[585] Correa *supra* note 280 at 18 citing European Commission (1997) *Report on United States Barriers to Trade and Investment* Brussels.

supply of Cipro®, an antibiotic effective in treating anthrax and covered by patent rights.[586] The Canadian government ignored the compulsory licensing provisions in section 19 and ordered 1 million pills from a generic producer. The Canadian government subsequently cancelled this order but only after negotiating a substantial price concession from the patentee.[587]

These provisions could be used by government researchers in Canada to obtain access to patented research tools and this could include some government research institutes comparable to the NIH. In *McKinney v. University of Guelph*, the Supreme Court of Canada examined the issue of whether or not the university was a governmental actor for the purposes of the Canadian *Charter of Rights and Freedoms*.[588] The court concluded that while universities are statutory bodies performing a public service and may be subjected to the judicial review of certain decisions, this does not in itself make them part of government within the meaning of the Charter. A similar result would likely occur when considering academic researchers at a university under section 19 of the Patent Act.

Some governmental research institutes will have a sufficient nexus with the government so that their researchers could avail themselves of section 19 of the *Patent Act*. However, university and private sector researchers will need to look at other

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[586] Ciproflaxin is manufactured and marketed by the German pharmaceutical company Bayer, A.G. under the brand name Cipro® (Cipro is a registered trade-mark of Bayer, A.G., CA TMA 356,070, Feb. 26, 1986); US Patent No. 4,620,007, Grohe *et al.*, *6-fluoro-7-chloro-1-cyclopropyl-4-oxo-1,4-dihydro-quinoline-3-carboxylic acid*, Oct. 28, 1986; CA Patent No. 1,322,334, Grohe *et al.*, *1-cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-7-piperazino-quinoline-3-carboxylic acid-containing compositions and uses thereof*, Sept. 21, 1993; see also Lee *supra* note 580 at 175; Kripapuri *supra* note 236 at 693-694; Sell *supra* note 236 at 515 and Cahoy *supra* note 580 at 125-129.

[587] Kripapuri *ibid.* at 693-694; Sell at 515

[588] *McKinney v. University of Guelph*, [1990] 3 S.C.R. 229.

provisions for compulsory licensing of patented research tools. Within the *Patent Act*, the only other compulsory licensing regime is found in the patent abuse provisions.

5.3.2 Patent Abuse

Patent abuse is defined in sections 65-71 of the patent act. Sections 65(2)(c) to (f) define the activities that constitute patent abuse as follows:

> (c) if the demand for the patented article in Canada is not being met to an adequate extent and on reasonable terms;
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> (d) if, by reason of the refusal of the patentee to grant a licence or licences on reasonable terms, the trade or industry of Canada or the trade of any person or class of persons trading in Canada, or the establishment of any new trade or industry in Canada, is prejudiced, and it is in the public interest that a licence or licences should be granted;
>
> (e) if any trade or industry in Canada, or any person or class of persons engaged therein, is unfairly prejudiced by the conditions attached by the patentee, whether before or after the passing of this Act, to the purchase, hire, licence, or use of the patented article or to the using or working of the patented process; or
>
> (f) if it is shown that the existence of the patent, being a patent for an invention relating to a process involving the use of materials not protected by the patent or for an invention relating to a substance produced by such a process, has been utilized by the patentee so as unfairly to prejudice in Canada the manufacture, use or sale of any materials.

Sections 65(2)(a) and (b) were repealed in 1993 but also included local working as a potential abuse and were based on sections 27 of the UK *Patents Act*.[589] When these sections were part of the *Patent Act*, courts concluded that the very purpose of patents on new inventions was

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[589] *NAFTA Implementation Act supra* note 574; *Celotex Corp. c. Donnacona Paper Co.*, [1939] Ex.C.R. 128 [hereinafter *Celotex*]; the history of the corresponding provisions of the English Act is described by Luxmoore, J. in *Re Brownie Wireless Co. Ltd.* (1929), 46 R.P.C. 457 at 469 [hereinafter *Brownie Wireless*].

> not only to encourage inventions but to secure that new inventions shall, as far as possible, be worked on a commercial scale in Canada, without undue delay; that is, and always has been the spirit of the several Patent Acts in force in this country, at least for a long time.[590]

While local working may historically have been part of the "spirit" of the Patent Acts, that changed as a result of the 1993 amendments to the *Patent Act*.[591] These sections were considered to be inconsistent with section 27 of the TRIPs Agreement and article 1709 of NAFTA that prevented discrimination on the basis of whether products are imported or locally produced.[592]

This interpretation is not unanimous and Brazil continues to have a requirement for local working of patents and argues that it is consistent with their obligations under TRIPs.[593] In support of Brazil's position, it has been noted that the Preamble of the Agreement as well as articles 7 and 8 make it clear that one of the objectives of the TRIPs Agreement is to promote technology transfer. One way of ensuring technology transfer may be to provide compulsory licensing on grounds of non-working the invention locally.[594] Even though Brazil has not actually used the compulsory licensing provisions, their mere existence has given Brazil a strong negotiating position with the brand name

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[590] *Celotex ibid.* at para 14; see also *Gordon Johnson Co. and Graham Metal Products Ltd. v. Callwood* (1960), 34 C.P.R. 73 [hereinafter *Gordon Johnson*]; *Defrees and Betts Machine Co. v. Dominion Auto Accessories Ltd.* (1966), 51 C.P.R. 42 (Ex. Crt); *Sarco Co. Inc. v. Sarco Canada Ltd.* (1969), 57 C.P.R. 193 [hereinafter *Sarco*]; *Re McKenzie Bros. Ltd.* (1934), 551 R.P.C. 461 at 468 per Luxmoore, J.

[591] *NAFTA Implementation Act supra* note 574.

[592] See C. Vorndran, "Biotechnology and Intellectual Property Protection from U.S. Law Through NAFTA" (1997) NAFTA: Law and Business Review of the Americas 103 at 122; Grover *supra* note 549 at 6.

[593] Sell *supra* note 236 at 495; see also M. Halewood, "Regulating Patent Holders: Local Working Requirements and Compulsory Licences at International Law" (1997) 35 Osgoode Hall Law Journal 243 for a reasoned analysis of why the local working requirements are consistent with both the TRIPs Agreement and the NAFTA Agreement.

[594] Correa *supra* note 280 at 9.

pharmaceutical industry and resulted in large price discounts on life-saving pharmaceuticals.[595] The negotiating history of the TRIPs Agreement also showed that members differed strongly on the issue of local working and that there is no direct prohibition. This may leave room for local working requirements as long as they are adopted for *bona fide* (*i.e.*, non-discriminatory) purposes.[596] The United States initiated a challenge against Brazil's local working compulsory licensing provisions in 2001 but never followed through with the challenge because of intense political pressure.[597]

While the threat of compulsory licensing has worked well for Brazil in negotiating cheaper medicines, economics suggests that "local working" is typically counter-productive. Business will tend to manufacture, in whole or in part, where it is cheapest to do so. Local working requirements will force the patentee to manufacture the product in a more expensive country and this will result in more expensive products. From an economic perspective, this is socially wasteful; it, however, may be politically expedient as a means to protect local industries.

Between 1935 and 1998, there were 96 applications for licences under section 65 (or its predecessor, section 67). 57 of these 96 applications were abandoned or withdrawn before a decision was made by the Commissioner of Patents. Only 17 compulsory licences were granted by the Commissioner and only 15 applications were

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[595] Lee *supra* note 580 at 175-176; Sell *supra* note 236 at 495.
[596] UNCTAD *supra* note 251 at 482.
[597] Gillat *supra* note 278 at 736; Sell *supra* note 236 at 495; *Brazil – Patent Protection supra* note 326.

refused.[598] Since 1998, there has only been one Commissioner's decision relating to the patent abuse provisions.[599]

Most of the applications have relied upon the now repealed local working requirements of paragraphs (a) and (b) and only one licence has ever been granted on any of the other paragraphs of section 65(2).[600] Even though the paragraphs are not mutually exclusive,[601] applicants have rarely relied upon paragraphs (c) to (f). This is likely due to the relative ease in proving patent abuse for not working the invention locally. The applicant only needed to establish that the patented invention was capable of being worked in Canada and that it had not been worked in Canada on a commercial scale.[602] Part of the working could have been carried out abroad as long as the "essence" of the invention was carried out in Canada.[603] The onus then shifted to the patentee to justify the use made of the monopoly.[604] Abuse is established as of the time of the application for compulsory licence though activities up to the time of hearing may be relevant to

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[598] These numbers were obtained by adding the results of two reports: one covering the period from 1935 to 1970 by the Economic Council of Canada *Report on Intellectual Property*. Ottawa, 1971 cited by McFetridge *supra* note 553 at 79; and the second covering the period from 1970 to 1998 also cited by McFetridge *ibid.* at 79. One application was still pending at the time of the Economic Council report and 6 were pending at the time of the McFetridge study: see McFetridge *ibid.* at 79.

[599] C. Choinière, Information Officer, Canadian Intellectual Property Office, personal communication, May 4, 2005; this decision was appealed to the Federal Court of Canada, see *Torpharm Inc. v. Canada (Commissioner of Patents)*, [2004] 4 F.C.R. 29 (F.C.T.D.).

[600] McFetridge *supra* note 553 at 95-96; see *Puckhandler Inc. v. BADS Industries, Inc.* (1998), 81 C.P.R. (3d) 261 (Patent Appeal Board and Commissioner of Patents) where a licence was granted under 65(2)(c).

[601] *Celotex supra* note 589 at para 3.

[602] *Rodi & Wienenberger Aktiengesellschaft v. Metalliflex, Ltd.*, [1966] S.C.R. 593 [hereinafter *Rodi*].

[603] Celotex supra note 589; *Mackay Specialties Inc. v. Proctor & Gamble Co.* (1983), 45 N.R. 158 (F.C.A.).

[604] *Rodi supra* note 602.

refute or confirm any reasons for non-working.[605] Failure to locally work the invention could be excused if the market were not sufficient to ensure a successful return on investment,[606] or if infringement made the market hard to estimate and hold.[607] Under article (b), a consideration was whether importation hindered or prevented working of the invention in Canada or if import was "necessary to stimulate that demand by selling, demonstrating, advertising."[608]

In comparison, the requirements under the remaining provisions are more complex. There are three main elements under article (d):

1. the patentee has refused to grant a licence to the applicant;
2. a trade or industry in Canada, or the establishment of a new trade or industry is prejudiced by such refusal; and
3. it is in the public interest.[609]

Further, an applicant must prove that a clear request for a licence was made and the onus to suggest reasonable terms is also on the applicant.[610] Reluctance and unwillingness to grant a licence is not the same as a refusal to licence.[611] In addition, the patentee is not obligated to discuss licences with an alleged infringer as it might give the appearance of consent to any such infringement.[612] In general, the courts have recognized that this

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[605] *Sarco supra* note 590, activities up to the hearing may also be relevant in determining the appropriate remedy
[606] *L.P.A. Plastics (1976) Ltd. et al. v. Windsurfing Int'l Inc.* (1981), 59 C.P.R. (2d) 188 (Comm'r Patents) [hereinafter *LPA Plastics*]; *Debro Products Ltd. v. Burke Co.* (1980), 65 C.P.R. (2d) 162 (Comm'r Patents).
[607] *LPA Plastics ibid.*, compare with *Rodi supra* note 602.
[608] *LPA Plastics ibid.*
[609] *Sarco supra* note 590 citing *Brownie Wireless supra* note 589.
[610] *LPA Plastics* supra note 606.
[611] *Sarco supra* note 590.
[612] *LPA Plastics supra* note 606.

section has a considerable amount of flexibility in what is meant by "reasonable," "trade or industry," "the establishment of any new trade or industry," "prejudiced" and "the public interest."[613] In particular, public interest is very broad and includes the purchasing public, traders and manufacturers, the patentee and licencees, and inventors generally.[614]

The elements under article (c) may be a little easier to establish: demand for a patented article is not being met in Canada under reasonable terms. Economic studies of demand and supply may be one, relatively complex method of establishing that demand is not being met in Canada. In *Torpharm Inc. v. Canada (Commissioner of Patents)*,[615] the applicant Torpharm wanted to obtain a licence for the manufacture of patented bulk chemical, lisinopril, that it would then turn into tablets for export to a country where there were no patent rights. The issue in Torpharm was whether the applicant had established enough of a case for the application to proceed to the next step, namely serving the application on the patentee and publication in the *Canada Gazette* and the *Canadian Patent Office Record*. The Federal Court held that the applicant had passed this hurdle and in doing so made two significant conclusions: (1) demand for the bulk material is not the same as demand for the tablets that the patentee was supplying on the Canadian market;[616] and (2) absence of a specific request for the bulk material was not "more significant than the absence of a specific offer to supply the bulk lisinopril by the patentee."[617]

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[613] *Sarco supra* note 590 citing *Brownie Wireless supra* note 589.
[614] *Sarco ibid.*
[615] *Torpharm supra* note 599.
[616] *Torpharm ibid.* at para. 28.
[617] *Torpharm ibid.* at para. 27.

There are two issues the courts are going to have to eventually deal with in considering any unmet demand for a patented article. Firstly, a demand for a particular product may only be created by the expenditure of resources to increase awareness about their product and thereby create a demand.[618] Even if a demand is not currently present in the market-place, the courts should not be too quick to turn down an application for a compulsory licence if there is the prospect that the licensor would be able to create this demand. Secondly, even if the patentee is supplying the domestic market, according to basic economic theory, a monopolist will intentionally undersupply goods in order to maximize profits.[619] Assuming that the patentee possesses market power,[620] there will be a resulting unmet demand. This latter type of insufficient demand is a normal part of the patent system that courts should not be too quick to grant licences to eliminate.

Once an abuse has been established, the powers of the Commissioner are established in section 66 of the *Patent Act*. In general, the Commissioner can:

1. order the grant of a compulsory licence on terms that the Commissioner thinks appropriate;[621]
2. revoke the patent in its entirety;[622] or
3. refuse the application without making any order.[623]

In the original enactment, the only remedy available was for the Commissioner to revoke the patent in its entirety forthwith, or after a reasonable interval. This was seen as

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[618] *Celotex supra* note 589 at para. 14.
[619] Fauver *supra* note 489 at 669.
[620] However, this is rarely a safe assumption: Kitch *supra* note 112.
[621] *Patent Act*, s. 66(a)
[622] *Patent Act*, s. 66(d)
[623] *Patent Act*, s. 66(e).

impractical or oppressive at times.[624] Typically, an order will be made for a compulsory licence or revocation of the patent once an abuse has been made out but equitable considerations may lead a court to decline to make such an order, particularly if the applicant was implicated in the abuse of the patent rights.[625]

Within the context of this thesis, only market-supplied research tools easily fit within common usage of the terms used in section 65. With market-supplied tools, there is a demand for a product in Canada that may not be met (article (c)); or a trade or industry that may be prejudiced (articles (d) and (e)). When considering other research tools, researcher-supplied tools or disease targets, it is necessary to consider the effect of the patentee's actions on the "innovation" market.

Assuming that an innovation market in Canada requires access to a patented research tool, this could easily constitute a "demand" for a patented article under article (c). If there are alternative tools available to the researcher, demand could be satisfied by access to one of these alternatives. However, if the tool is an essential facility and there are no other reasonable alternatives, then failure to allow access to the tool would mean that a demand for the tool is not being met.

For an abuse to be found under article (c), it must be a patented "article" for which demand is not being met and not a patented process. This obviously limits the types of research tools that could fall under article (c): research consumables and disease targets, but not any research techniques. The interesting issue around innovation markets and research tools is that the only way to efficiently meet demand for the tool may be to provide a licence under the patent. For example, for disease targets, there is no physical

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[624] *Gordon Johnson supra* note 590.
[625] *Sarco supra* note 590.

article that needs to be supplied to the researcher by the patentee. The demand is simply a right to use the tool under the patent.

A similar analysis can be made under articles (d) or (e) where the "trade or industry of Canada" could be an innóvation market. This is consistent with Thurlow J.'s contention in *Sarco* that the phrase "trade or industry of Canada" should be given a wide, general interpretation.[626] Failure to licence the tool on reasonable terms may prejudice competition in the innovation market and therefore prejudice an "industry of Canada." As long as it is in the public interest, there would then be an abuse of patent rights contrary to section 65(d). Similarly, if the patentee attaches conditions to a licence for a research tool and these conditions unfairly prejudice the innovation market, then there could be an abuse of patent rights contrary to section 65(e). Articles (d) or (e) apply to patents on either articles or a processes. However, the requirement for prejudice to an innovation market means that the research tool must be an essential facility for the innovation market.

Once an innovation market is defined and the researcher demonstrates that a tool is an essential facility, then patent abuse under any of paragraphs (c), (d) or (e) can be easily shown. Unfortunately, the paucity of caselaw means that there remains some uncertainty about the exact scope of any of these abuses. There is a possibility that a court would adopt a narrower construction of the abuses than proposed above. For example, a court may conclude that a "demand for a patented article" was not intended to encompass access to a patented tool or disease target by way of licence. Similarly, a court may conclude that an innovation market is not equivalent to a "trade or industry in

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[626] *Sarco supra* note 590 at 473-474 citing *Brownie Wireless supra* note 589.

Canada." However, even if the courts narrowly construe the provisions of section 65(2), patent abuse can still be found. Section 65(2) is a deeming provision and accordingly is expansive and does not purport to be an exhaustive listing of the grounds of abuse.[627] It is sufficient for there to be an abuse analogous to those activities enumerated under section 65. In this context, failure to licence a patented essential facility on reasonable terms such that researchers are unable to efficiently conduct research within an innovation market would at least be analogous to the abuses listed in section 65(2) if not directly covered by one or more of the listed abuses.

The main stumbling block to use of section 65 in the context of patented research tools is not the definition of abuse: instead, it is the requirement that three years elapse from the date of grant of the patent before an application for a compulsory licence can be made.[628] This requirement stems from article 5(A)(4) of the Paris Convention that provides in part as follows:

> A compulsory licence may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last ...

Article 5(A)(2) of the Paris Convention provides a general right to "take legislative measures providing for the grant of compulsory licences to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work." Since failure to work is no longer a ground for compulsory licensing in Canada, it also follows that the three year from grant time period is no longer required to be consistent with the Paris Convention.

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[627] *Torpharm supra* note 599 at para. 3 citing *R. v. Verrette*, [1978] 2 S.C.R. 838 at 845-846 overruling *Celotex supra* note 589.
[628] *Patent Act*, s. 65(1).

The three year delay in applying for a compulsory licence was intended to give the patentee an opportunity to work the invention personally before a compulsory licence is sought by a competitor. This rationale makes sense when applied to patented articles where a reasonable amount of time is needed before the patentee can reasonably be expected to supply the market.[629] Business and market plans, manufacturing equipment, establishing distribution networks, etc. all take time to properly develop and implement. However, these concerns do not apply to essential facilities where demand can only be met by licensing the tool to the researcher. In such a case, there is no manufacturing equipment, no distribution and no sales of physical products. The only product is a patent licence for which reasonable terms need to be negotiated and established. A possible justification for this three year delay is that it grants to the patentee a head-start in the innovation market as part of the reward for being the first to patent. In reality however, there is much more than a three year head-start.

A patentee does not need to request examination of a patent application until five years after the application date.[630] Assuming that it takes two to three years for examination of the patent application, it could easily be eight years after filing of the patent application that the patent is granted. It would then be eleven years after filing the patent application before an application for a compulsory licence could be made under section 65. Delays in prosecution could result in even more time elapsing before a patent issues.[631] The researcher would also need to stop all activities from the time of grant

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[629] Yosick *supra* note 278 at 1302.
[630] *Patent Rules*, SOR/96-423, s. 96.
[631] Before grant of the patent, a researcher could use the tool without any licence from the patentee but would be liable to the patentee for "reasonable compensation" once the

until a compulsory licence is granted. This would be at least three years and very disruptive.

There are tools within the *Patent Act* for third parties to mitigate some of this uncertainty. Third parties do not have to wait for the patentee and can request examination themselves.[632] Further, third parties can request expedited examination if failure to advance the application is likely to prejudice that person's rights.[633] These requests can only be made once the application has been published, normally 18 months after the filing date, or any priority date. Assuming that examination would take approximately a year with expedited examination, the patent would likely issue about two and a half years after the application date. Add the three years required by section 65, and a researcher would have to wait five and a half years before applying for a compulsory licence. This is the minimum amount of time that would be expected were a third party researcher inclined to speed up the process. While this is significantly shorter than the 11 years identified above, it still represents a significant amount of time that a researcher must wait before conducting valuable research.

One commentator has argued that a patentee should have a period of exclusivity before any compulsory licences should become available.[634] What this ignores is that the patentee already has a natural head-start from all of the pre-patenting R&D that went into the patent as well as the eighteen month confidentiality period before the application

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patent issues for use of the invention from publication of the patent application to grant: *Patent Act*, s. 55(2).

[632] *Patent Act*, s. 35(1).

[633] *Patent Rules*, s. 28(1).

[634] Strandburg *supra* note 228.

publishes.[635] No additional period of exclusivity is warranted. Further, applicants should be able to apply for a compulsory licence even before a patent is granted. This would give researchers confidence and certainty that their research programs would not be disrupted by the grant of a patent right.

5.4 Conclusion

The essential facility doctrine has not been formally adopted in Canada though it is likely only a matter of time before that happens. This doctrine is of particular importance in the present discussion because there is only a problem with failure to licence research tools when those tools are required to efficiently perform the scientific research; i.e. when those tools are an essential facility for the downstream innovation market. Fortunately, there are mechanisms within the existing provisions of the *Patent Act* and the *Competition Act* to allow the compulsory licensing of essential research tools.

In the current *Patent Act*, the abuse provisions in section 65 are broad enough that they could be interpreted to include research tools either directly under the existing provisions or as an analogous abuse. The main criticism of the patent abuse provisions is the length of time needed before a compulsory licence can be sought. For researcher-supplied tools and disease targets, there is no justification for making researchers wait three years after grant of a patent before seeking a compulsory licence on what is fundamentally an essential facility.

Section 32 of the *Competition Act* also allows for the compulsory licensing of essential research tools and there is no period of time specified before an application can

[635] Yosick *supra* note 278 at 1292.

be brought before the Federal Court. However, there are two main criticisms directed to this section. Firstly, there is some uncertainty about how section 32 could apply, if at all, to many types of research tools. Secondly, only the Attorney General of Canada is empowered to make an application under section 32. Any researchers who want access to an essential patented tool need to lobby the Attorney General before it even gets to the courts. This makes the provision almost meaningless from a practical perspective as evidenced by the fact that no cases have ever been judicially decided under this section.

The limited caselaw under the patent abuse provisions in the *Patent Act* and the complete lack of caselaw under section 32 of the *Competition Act* creates some uncertainty in how these provisions could be applied to research tools. Further, as both existing provisions are subject to significant criticisms, a new provision should be provided explicitly providing for compulsory licensing of essential facilities. Within this framework, an essential facility compulsory licence is better addressed through the patent system than through competition laws.[636] Compulsory licensing provisions generally encourage voluntary licensing and the use of the technology such that the two parties agree on terms without the cost, delay or uncertainty associated with litigation.[637] By having the provisions within the *Patent Act* itself, the licences become part of the bargain with the state in granting the patent in the first place. This not only gives the appearance of more legitimacy but further encourages voluntary licensing.

While Canada repealed certain patent abuse provisions as a result of TRIPs and NAFTA, article 1704 of Chapter 17 of NAFTA provides:

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[636] Kaufmann *supra* note 484 at 530.
[637] Kaufmann *ibid.* at 530.

> Nothing in this Chapter shall prevent a party from specifying in its domestic law licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. A Party may adopt or maintain, consistent with the other provisions of this Agreement, appropriate measures to prevent or control such practices or conditions.

One commentator has noted that this was an express invitation for Canada to introduce appropriate legislation based on anti-competitive practices.[638] Anti-competitive practices are also explicitly mentioned in article 31 of TRIPs as warranting the grant of compulsory licences.[639] While Canada has not yet implemented any such legislation, it would certainly be open to do so as long as the other obligations under NAFTA and TRIPs are met. In doing so, Canada should take advantage of the jurisprudence that has developed primarily in the United States around essential facilities. Even though U.S. courts are reluctant to find intellectual property rights to be an essential facility, there is clear international support from the European Court of Justice to conclude that intellectual property rights can properly be treated as an essential facility. A Canadian commentator has also suggested that the essential facilities doctrine should be included within the Canadian *Patent Act*.[640]

This proposal has several advantages. Firstly, the requirement for three years to elapse could be removed for compulsory licensing of essential facilities. The purpose of this delay is to allow the patentee adequate time to supply the market before the courts will impose a compulsory licence. It does not make sense when considering access to an essential facility where licensing the patent is the only way to supply the innovation market. The patentee does not need any additional time, much less three years, in order

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[638] Grover *supra* note 549 at 7.
[639] Correa *supra* note 280 at 8; see *supra* note 279 and accompanying text.
[640] Grover *supra* note 549 at 7, 22.

to meet any demand in the innovation market. Secondly and more importantly, by expressly providing for essential facilities, perhaps with reference to research tools as an example, there would be much more clarity to the law that would avoid long and protracted litigation otherwise needed to establish that research tools can be an essential facility and that refusal to licence an essential facility is a legitimate ground for a compulsory licence under either the existing abuses or as an analogous abuse under section 65.

CHAPTER VI
CONCLUSION

There is a tension between patent laws and the pubic interest: the former seeks to provide proprietary rights over inventions, and the latter seeks to have greater access to those inventions. Many economists have looked at this tension and concluded that the benefits of innovation are of far greater importance to the economy than the harms resulting from limiting access to the innovations.[641] Among economists, innovation efficiency is regarded as the most important type of efficiency, as it provides the greatest enhancement of social wealth.[642] Patent rights can provide the incentive for private parties to invest in innovation, disclose new inventions publicly and commercialize new products. However, patent rights "cannot be viewed as an end by themselves, but as a tool to attain certain economic and social objectives."[643] When patent rights themselves are used to block additional follow-on innovation, innovation efficiency is hampered and the public interest is ultimately damaged. This problem has been particularly acute in biotechnology where there has been a proliferation of patents on fundamental research tools.

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[641] Balto *supra* note 483 at 412-413 citing: M.A. Carrier, "Unravelling the Patent-Antitrust Paradox" (2002) 150 University of Pennsylvania Law Review 761; W.F. Baxter, "Antitrust Law and Technological Innovation" (Winter, 1985) Issues in Science & Technology 80 at 82; F.M. Scherer, "Antitrust, Efficiency, and Progress" (1987) 62 New York University Law Review 998 at 1018; and D.F. Turner, "Basic Principles in Formulating Antitrust and Misuse Constraints on the Exploitation of Intellectual Property Rights" (1985) 53 Antitrust Law Journal 485 at 485.

[642] J.J. Flynn, "Antitrust Policy, Innovation Efficiencies, and the Suppression of Technology" (1998) 66 Antitrust Law Journal 487 at 494: innovation efficiency is the most important followed by production efficiency and finally allocative efficiency.

[643] Correa *supra* note 35 at 546.

For follow-on research to be effective, researchers need access to pioneering research tools. Fortunately, there are mechanisms in place in Canadian and international law that allow for access to patented inventions. The first mechanism examined in this thesis was the experimental use exception. Current conceptions of the experimental use exception lead to a distinction being made between experimentation *on* a patented research tool that falls within the exception as opposed to research *with* a patented research tool that falls outside of the exception. Without such a distinction, any patent rights on the tool *per se* would be rendered meaningless which would thereby lead to less investment in developing research tools in the first place.

In this thesis, a possible solution is proposed to apply the exemption broadly so as to cover all *bona fide* research. Appropriate incentives for research tools are restored by making the researcher liable for reasonable compensation for use of the tool in research (i.e., research *with* the tool). There still would not be any liability for research *on* a reseach tool. An existing model is already present in the *Patent Act*. Even though an infringer only becomes liable for patent infringement once a patent issues, this same party is also liable for "reasonable compensation" between publication of the application and issuance. Liability is thus imposed for a period of time when there is no patent grant *per se* but is tied to the existence of a valid patent eventually issuing.[644] Similarly, reasonable compensation could be imposed on research *with* a patented research tool even though *bona fide* research is considered outside of the patent grant. For certainty, research involving gene patents and other disease targets would be considered to be research *with* such research tools.

[644] *Patent Act*, s. 55(2)(4).

This represents a more expansive experimental use exception than previously adopted anywhere in the world which is not necessarily a problem as long as the exception remains compliant with Canada's international obligations, notably the TRIPs Agreement. While exceptions under article 30 are commonly considered to be absolute exceptions, reasonable compensation could theoretically be part of any such exception. Further, reasonable compensation ensures that the legitimate interests of the patent holder are respected as required by article 30.

The legitimate interests of the patent holder are further respected since a researcher would only have the right to make and use the patented tools for their own research needs. There would not be an experimental use exception to make the tool on a commercial scale nor to sell it to other researchers. This exception thus remains rather limited. However, the vagueness of the language used in the TRIPs agreement means that there is also a considerable amount of uncertainty about the true scope of the article. It should be noted that both United States and European governments, home of large pharmaceutical companies, have adopted restrictive interpretations in the past and it is likely that they will continue to push for restrictive interpretations in the future.

The alternative approach advocated in this thesis was through the express introduction of an essential facilities doctrine into the *Patent Act*. Existing provisions in both the *Competition Act* and the *Patent Act* likely allow for the adoption of the essential facilities doctrine to some extent, though neither act fully addresses all of the issues surrounding the licencing of research tools in biotechnology.

The essential facilities doctrine initially developed out of the competition laws in the United States. While the doctrine does not currently extend to IP rights in the US, a

variant of it has been applied to provide for the compulsory licensing of copyrights in Europe. Section 32 in the Canadian *Competition Act* could allow for adoption of this doctrine for intellectual property in Canada though no decision has yet been brought before the courts under section 32: such lack of caselaw creates uncertainty about the full scope of the provision. The fact that only the Attorney-General of Canada can bring an application under section 32 also makes it unlikely that section 32 will ever be used broadly.

The existing patent abuse provisions in the *Patent Act* are a more effective means of accommodating the essential facilities doctrine, either through the enumerated abuses or as an analogous abuse. Most of the caselaw that has been brought under the patent abuse provisions related to local working requirements, an abuse that is no longer part of the *Patent Act*. No case has yet expressly considered failure to licence an essential facility as a patent abuse nor have any compulsory licences yet been granted on an analogous abuse. As with section 32, the lack of caselaw creates some uncertainty in the law.

In this thesis, legislative action is suggested to allow for compulsory licensing of essential facilities as soon as the patent grants without having to wait three years before an application can be made as currently required under the patent abuse provisions. By legislatively adding the doctrine to the *Patent Act*, the grant of patent rights would also be explicitly conditioned on the patentee allowing access to essential facilities.

Frederic Scherer analyzed the extent to which the granting of compulsory licences affected R&D expenditures and whether such licences diminished or destroyed the incentives to undertake R&D by patent holders. After examining 70 companies, Scherer

found no negative effect on R&D in companies subject to compulsory licences. Counterintuitively, Scherer actually found a significant rise in such companies' R&D expenditures relative to companies of comparable size that were not subject to such licences.[645] A study done in Canada examining the effect of compulsory licensing of pharmaceuticals also concluded that compulsory licensing did not significantly affect innovation in Canada.[646]

One theory has argued that compulsory licensing only has a significant effect on innovation when it is both predictable and implicates significant markets.[647] According to this theory, Scherer did not see a significant effect on innovation because antitrust actions are by their nature unpredictable and there is considerable uncertainty whether a compulsory licence will be granted. In comparison, the compulsory licensing provisions for medicines in Canada were predictable since 80% of applications for compulsory licences were granted. However, the Canadian pharmaceutical industry was seen as being too small to have much of an impact on decisions relating to world-wide R&D in pharmaceuticals.

There may be any number of reasons to explain the results observed in both the Scherer and Canadian studies.[648] Assuming that the theory is correct, however, predictability is generally preferred in any compulsory licensing scheme. While

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[645] Scherer *supra* note 486 at 107-108.
[646] Chien *supra* note 293 at 877 citing Eastman Commission; note that this study was in 1983 before the provisions granting compulsory licensing of medicines were repealed in 1993: see *supra* note 568-569 and accompanying text.
[647] Chien *ibid.* at 879.
[648] See for example Gillat *supra* note 278 at 721-722 providing reasons why the Scherer *supra* note 483 results do not apply generally; compare with Yosick *supra* note 278 at 1292-1293 supporting the general proposition that compulsory licensing would only have a marginal impact.

unpredictability may not affect incentives for R&D, it increases other costs and may otherwise cause a chilling effect if businesses do not know how to proceed without losing their rights or worse.

According to this theory, predictable compulsory licensing would also have minimal to no effect on the incentives for R&D if the affected market were to be relatively small. A smaller country such as Canada should therefore be allowed to act more aggressively in granting compulsory licences than countries in larger markets such as the United States, Europe and Japan. However, even in larger markets, a narrowly targeted but predictable compulsory licensing scheme directed only towards research tools and essential facilities, would likely not have an effect on incentives for innovation. Any negative effects on incentives on innovation would also be mitigated by the imposition of an appropriate remedy.

There are two major advantages in considering a research tool to be an essential facility instead of adopting an expanded experimental use exception: scope, and compliance with the TRIPs Agreement. Regarding scope, lack of access to patented research tools only becomes an issue when the tools are essential facilities for a downstream innovation market. If there are reasonable alternatives available to a researcher, then those alternatives should be adopted without restricting the rights of patent holders. This is appropriately addressed in the essential facilities doctrine since compulsory licences would only be granted on tools when there is an actual need for a compulsory licence. In comparison, an expanded experimental use exception is both too broad and too narrow in scope: it is too broad in scope because it treats all research tools the same, regardless of whether they are actually required or not; it is too narrow in scope

because there is no remedy if the tool cannot be efficiently made by the researcher himself.

The second major advantage is that incorporating the essential facilities doctrine within the *Patent Act* is more likely to be compliant with the TRIPs Agreement. There is considerable uncertainty surrounding all of the provisions in the TRIPs Agreement. On the one hand, this uncertainty allows arguments to be easily made that both proposals are compliant but it also creates a general reluctance of governments to act. This is a reality that cannot be ignored. There are three main reasons why the essential facilities doctrine is more likely to be compliant with article 31 than an expanded experimental use exception would be compliant with article 30. Firstly, there are likely to be fewer concerns with an exception based on article 31 that is a specific provision and not a general provision as provided in article 30. Secondly, many countries have varying compulsory licensing regimes of different scopes such that the present proposal for the essential facilities doctrine is relatively modest and narrow: it already exists in the current *Patent Act* to a large extent through the patent abuse provisions. In comparison, the experimental use exception as proposed in this thesis would be broader than those already adopted in any other developed country. Thirdly, antitrust is specifically mentioned as a ground for compulsory licensing in the TRIPs Agreement. Since the essential facilities doctrine is based on established antitrust law principles developed in the United States and used, in essence if not in name, in Europe, it is more likely to be recognized internationally as legitimate grounds for a compulsory licence.

The principle advantage of adopting an expanded experimental use exception is that it more effectively accomplishes the goal of quickly putting the necessary tools into

the hands of researchers who need them. Before the expanded experimental use exception would apply, there are two issues that must be settled: whether it is a research tool and what the appropriate level of compensation is. The first issue is relatively straightforward and can be easily determined for the vast majority of research tools. The second issue is more difficult and could lead to litigation and delays before the parties or the courts settle on an appropriate royalty. In comparison, the essential facilities doctrine introduces two potentially contentious issues: is the tool an essential facility and if so what is the appropriate level of compensation. Defining whether some tool is an essential facility would also be difficult since both an innovation market would need to be defined as well as what is "reasonably" necessary to efficiently conduct research within that innovation market. All of this must be done before the parties or the courts even start discussing an appropriate royalty.

The expanded experimental use exception therefore provides a more efficient system with fewer litigation costs and fewer delays in allowing the researchers to have access to the tools they need. To the extent that the existing patent abuse provisions in the *Patent Act* already allow for compulsory licensing of essential facilities, future revisions of the *Patent Act* should make this explicit and remove the three year delay in making an application. Nevertheless, the more immediate focus should be on providing an expanded experimental use exception as proposed in this thesis.

The only issue remaining would be the level of compensation owed to the patent holder for use of his tool in research. Unfortunately, this can be a difficult proposition under any regime: experimental use; patent abuse; essential facilities. One common criticism is that compulsory licensing generally only represents a modest return on

invested capital.[649] For example, courts in Canada have traditionally only looked at the cost of the research needed to develop the invention.[650] However, there is always a certain amount of risk associated with any research project. Royalties ignoring this risk premium are unlikely to provide any real return on the entire investment.[651] In comparison, courts in the United Kingdom take the better approach by considering these additional costs of unsuccessful research investment when assessing royalties for compulsory licences.[652] Royalties that are too low not only fail to properly compensate the patentee but also serve to discourage investment by the patentee or others in developing alternatives to the research tool subject to the compulsory licence. On the other hand royalty rates that are too high over-compensate the patentee. The full cost of the additional research does not necessarily need to be accounted for as long as the risk is adequately addressed. The patentee should not necessarily be compensated for all of his failures.[653]

The main benefit of compulsory licensing provisions however is that their mere incorporation into patent laws encourages parties to negotiate among themselves for an appropriate royalty without involving the courts.[654] Private parties are always able to arrive at the appropriate royalty rate more efficiently than the courts. Ultimately, whether the parties negotiate an appropriate remedy themselves or recourse is made to the courts,

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[649] Kripapuri *supra* note 236 at 670; Gillat *supra* note 278 at 725.
[650] See for example, *Hoffmann-LaRoche Ltd. v. Frank W. Horner Ltd.* (1970), 64 C.P.R. 93 at 106; *BMS supra* note 273.
[651] M.L. Lauroesch, "General Compulsory Licensing in the United States: Good in Theory, But Not Necessary in Practice" (1990) 6 Santa Clara Computer & High Technology Law Journal 41 at 53.
[652] See for example, *J.R. Geigy S.A.'s Patent*, 1964 R.P.D. & T.M. 391 at 398-400 cited in Lauroesch *ibid.* at 53.
[653] Lipsky *supra* note 491 at 1240.
[654] Yosick *supra* note 278 at 1298.

researchers should have access to the tools they need to create advances in knowledge, technology and medicine while properly respecting and rewarding those who came before. This is already part of the Canadian patent landscape through the patent abuse provisions, but improvements and efficiencies could be realized by explicity recognizing the essential facilities doctrine in the *Patent Act* and by adopting an expanded experimental use exception.

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