Intellectual Property Protection for Plant Derived Vaccine Technology: Here They Come Are we Ready or Not?

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Introduction

The emergence of new technologies to address previously unsolvable health issues is no longer merely an anticipated possibility, but has become an almost a foregone conclusion. Hand-in-hand with fast-paced innovation arise queries regarding the force of intellectual property ("IP") protection to be granted to new technologies. IP protection, despite its title, is not a uniform class of right, but rather a group of distinct rights. IP protection is commonly touted as necessary to promote creativity and to provide creators with a reason to aspire to producing more efficacious innovations. Although this belief has recently come under criticism, it still represents the foundation of most IP regimes.[1]

In the environment of pro-technological advancement it behooves us to recognize that appropriate protection for new technologies must be well-contemplated and tailored to fit each class of invention. Just as one would not wear socks outside in the rain instead of boots to protect one's feet from the wet, the mere fact that an IP regime exists and is available does not necessarily make it the best means of protecting a particular technology. By their very novelty, some new technologies challenge the limits of existing IP regimes and fail to fit comfortably within the boundaries of established innovation categories. In fact, complex technologies may actually fit, at least partially, within many protective regimes and categories. Therefore, the question must be asked: which form of IP protection should a creator choose? And more importantly, who should a creator turn to for guidance when selecting a protection strategy from many available options? Surely setting up a unique IP regime for each new category of technology would be an administrative nightmare and is therefore not a feasible solution. However, ignoring the situation is not an appropriate response either.

An example of a new category of technology which may confound existing IP regimes is plant derived vaccines ("PDVs"). The make-up of this innovation is just as its name suggests – a vaccination product derived from plants. Although there is no trick to understanding the nature of PDVs, deciding which IP regime may be utilized to protect this invention can prove to be troublesome. Due to the fact that the technology ties together several elements which have previously stood alone as distinct technological categories, PDVs fit simultaneously within several existing categories, each of which offers unique aspects of protection. In basic terms, a PDV is a plant variety, a drug, a biotechnological innovation and a developing nation-focused product all-in-one. It is therefore difficult to categorize PDVs for the purpose of IP protection.

This paper will examine the new category of invention represented by PDVs as an example of the difficulties that new technologies can pose to the attainment of adequate IP protection. Part I of the paper will describe the PDV category of technology and set-out the IP rights which

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[1] Robert T. Hughes and John H. Woodley, *Hughes and Woodley on Patents*, looseleaf, Markham, Buttersworth, 1984, para. §1.This principal is often referred to as the bargain theory, which supports the grant of an intellectual property right to a creator in exchange for disclosure of the creation. In this manner the public benefits from disclosure, while the exclusive right granted to the creator provides an incentive to undertake further creation. The Supreme Court of Canada has also articulated in several judgements that a balance of IP rights must be achieved between the private and public. See, Theberge v. Galerie d'Art du Petit Champlain inc., [2002] 2 S.C.R. 336; CCH Canada Ltd. v. Law Society of Upper Canada, [2004] SCC 13; Apotex Inc. v. Wellcome Foundation Ltd., [2002] 4 S.C.R. 1; Harvard College v. Canada (Commissioner of Patents), [2002] 4 S.C.R. 45.

inventors have applied thus far. Part II of the paper will discuss the existing categories of protection which PDVs may be fit within. Both the nature of each category and the fit, or ill-fit, of PDVs within the category, will be examined. Part III of the paper will generally discuss the difficulties that are posed by the normal course of establishing an IP protection strategy for new categories of technology, such as PDVs. Part IV will propose a proactive means of remedying the confusion created by new categories of technology. Namely, that an expert panel be convened to evaluate new categories of technology at the point when a creator working in the field first seeks protection. The panel would offer guidance as to the best mode of protection for the category of technology as a whole, that could be relied upon by future innovators working in the same category of technology. This solution would overcome the confusion created by PDVs and other new technologies and ensure the new categories of innovation attain comprehensive and tailored IP protection.

Part I – PDVs

PDVs are not available on the public market as of yet, but some are entering the final phases of research and development ("R&D") and will be ready for human consumption shortly. This means it is a perfect time to be contemplating the scope of IP protection for this new category of invention. A key factor in ensuring proper protection is achieved is understanding the nature of PDVs.

The science of PDVs is a relatively new approach to the creation of vaccination products, based upon transgenic plants developed from the recombination of DNA through the isolation of genes. The genes which are utilized must have enzymes that can be cut and pasted into DNA strands. Once modified the genes may be utilized to cultivate a transgenic plant or seed. After a PDV is grown, the transgenic plant materials may be ingested by a human or animal to trigger an immunogenic response. One of the benefits of PDVs is that transgenic plants can regenerate and therefore significant amounts of recombinant DNA may be produced. The result is that a large supply of this form of vaccine may be cultivated at a low cost.

In basic terms, PDVs represent the cultivation of genetically-modified plant material – such as a leaf, fruit or vegetable – which has a genetic make-up that causes it to act a vaccination upon ingestion. An example of a PDV is a genetically-modified potato plant engineered to invoke an immune response to hepatitis B surface antigens when the potato is fed to a human or animal.[2] The purpose of all innovations within the PDV category of technology is to propagate a vaccination from plant materials. The resulting products have many benefits. Most notably, PDVs offer the chance to literally eat our medicine.

In fact, PDVs were originally dubbed "edible vaccines". This name was given because early research focused upon administration through ingestion of raw plant materials, such as a tomato, to attain the immunization effect. Since that time research has shown that consistent doses cannot be assured in raw plant materials, and thus scientists now focus upon using dried PDV plant materials to create a product that may be administered orally, such as a pill, capsule or powder. The use of capsules is particularly beneficial because the coating applied can be engineered to dissolve in a particular area of the stomach. This means that the vaccination can be released in a specific area of the body. By directing the medicine the efficiency of PDVs is increased.

[2] Canadian Patent Application No. 2,321,260, filed October 12, 2000.

PDVs have several other benefits which cause them to be of particular interest for application in developing countries – low price, easy transportation, long-term storage potential, no cold-chain logistics, non-technical administration, and public health protection.[3] Traditional vaccine products must be kept cold, require specialized training to administer, and are derived from microbial fermentation sources and insect and mammalian cell cultures sources which are expensive to reproduce. Together these attributes raise the price of each vaccine dosage and limit the potential range of distribution. PDVs overcome the hurdles facing traditional vaccines and represent a low-price product that is easy to replicate, transport and administer.

Wide scale vaccination is an important step in preventing the contraction of certain diseases and eventually eradicating diseases in targeted areas. Several diseases that are presently rampant in developing countries raise not only health issues within a community, but also have economic, administrative and social effects. Three such diseases are Hepatitis B, Rabies and Cholera.

Hepatitis B[4] — Hepatitis B virus is a DNA virus that causes hepatitis B infection in humans, which can lead to short-term acute disease, or long-term chronic disease. Patients who contract an acute infection are at risk of dying within weeks or days of the onset of symptoms. Those with a chronic form of hepatitis B may escape immediate fatality, but will carry the disease for years and may develop liver cirrhosis or primary liver cancer as a result. The hepatitis B virus is carried in the blood and blood-derived bodily fluids of infected persons and can be transferred through contact with a carrier's blood caused by unsafe injections or transfusions, sexual contact, tattooing and scarification. In India the number of hepatitis B carriers is estimated to be over 40 million. Studies have established that childhood hepatitis B immunization in India is a cost-effective means of combating the disease.

Rabies[5] — Rabies symptoms are initially non-specific involving the respiratory, gastrointestinal and central nervous systems. However, at the acute stage the signs are clearer – hyperactivity and paralysis are followed by coma and ultimately death due to respiratory failure. Without treatment a patient will generally die within a week. The most common mode of infection is through contact with infected animals. It is estimated that 98% of human rabies occurs in areas with large numbers of both stray and domestic dogs. Presently rabies is incurable, and therefore pre-exposure vaccination is recommended for all persons with a high risk of exposure to the rabies virus. However, vaccination is problematic for persons of low incomes because available rabies vaccines are expensive – costing approximately $30 to $100 USD per dosage.

Cholera[6] — Cholera is a disease transferred by the ingestion of contaminated food or water which triggers an acute intestinal infection. The infection causes dehydration which eventually may lead to death. In areas where clean water is available the risk of cholera infection is very low, however, natural disasters, such as the 2004 tsunami which affected southeast Asia, create a

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[3] Royal Society of London, et al., *Transgenic Plants and World Agriculture*, London, National Academy Press, 2000, p. 12, <http://books.nap.edu/html/transgenic/>.

[4] This section has been entirely developed with data extracted from WHO, *Prevention of Hepatitis B in India*, South-East Asia, Regional Office, 2002 and *Introduction of Hepatitis B vaccine in the Universal Immunization Program,* India, Child Health Division, 2002.

[5] This section has been entirely developed with data extracted from WHO, 2003 and JK Dutta, "Human Rabies in India: Epidemiological Features, Management and Current Methods of Prevention", Tropical Doctor, n°29, 1999, pgs. 196-201.

[6] This section has been entirely developed with data extracted from the WHO cholera information website found at <http://www.who.int/topics/cholera/en/>.

risk of cholera epidemic. In 2003 WHO data recorded 2,893 cases of cholera and 2 deaths. These numbers are estimated to represent 5-10% of the actual cases worldwide. Moreover, the number of cases and deaths is expected to increase significantly for 2005 due to the tsunami.

In sum, the benefits that available and affordable vaccination products offer to developing nations are significant.[7] However, as the affordability and availability of products can be directly affected by IP rights, merely creating a PDV does not ensure efficacy. No matter what the nature of a technology is, if IP rights are wielded so as to jealously protect a particular market sector, the result will likely be an increase in the price of the innovation, which in turn creates an access hurdle. Thus, appropriate IP protection is just as important as rigorous scientific R&D if PDVs are to live up to their potential.

A. How are PDVs presently protected?

Presently the most common source of IP protection sought for PDVs is a patent. PDVs may also be protected as trade secrets. Trade secret protection is not grounded in statute, but is rooted in business practices which protect confidentiality of information relating to an innovation.[8] Trade secret protection relies upon confidentiality rather than registration and is understood to be an alternative to patent protection.[9] Reliance upon confidentiality renders trade secret a fragile IP right, because the protection can be immediately and irretrievably lost upon disclosure. Nowadays, due to innovations which promote quick and wide-spread distribution of information, such as the internet, trade secret protection can literally be lost at the push of a button. The upside of trade secret protection is the competitive advantage that it can provide because, unlike patents, no public disclosure is required. In an environment where adequate confidentiality measures are in place and enforceable, trade secrets provide an effective means of concealing information from the public and thereby securing a market sector monopoly.[10]

Although trade secrets can be effective, the fragility of the right causes many parties to opt to seek patent protection for an invention instead. Surety of protection is integral to researchers, including those working with PDVs, due to the need to raise investor capital to fund research initially and later commercialization of an invention.[11] Commercialization assistance is of particular concern to PDV researchers as they will likely need to seek partnerships with groups able to undertake large vaccination efforts, such as the *World Health Organization* (the "WHO"), in order to sell their invention.[12]

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7 *Supra* note 3 at 13.

8 Trade secrets are referenced in some Canadian legislation, notably the *Quebec Civil Code* and *Trade-Marks Act*, but there is no single statute devoted solely to trade secrets.

9 As a right of enforcement, the owner of a trade secret is permitted to take action against any party who breaches confidentiality. Three elements must be proven in order to establish a breach of confidentiality: 1) the information had the necessary quality of confidence about it; 2) the information had been disclosed in circumstances imparting an obligation of confidence; and 3) unauthorized use of the information constituted a detriment to the party who first communicated it. Lac Minerals Ltd. v. International Corona Resources Ltd., [1989] 2 S.C.R. 74 at 638.

10 This benefit may be lost if a technology may be easily reversed-engineered.

11 Richard T. Mahoney, et al., "The introduction of new vaccines into developing countries II. Vaccine financing", Vaccine, n°18, 2000, p. 2625.

12 Richard T. Mahoney and James E. Maynard, "The introduction of new vaccines into developing countries", Vaccine, n°17, 1999, 646 at 649.

Patents rights are granted nationally for a term of twenty years after the examination of a filed patent application, which must prove the disclosed invention to be novel, useful and non-obvious.[13] The invention can represent a product, method or process. Once granted a patent holder has the exclusive right to make, construct, use and sell their invention.[14] This is broad protection which allows the patent holder to have essentially full control over the use of their invention by the public. Tools of control include an assignment of patent right, license agreements and other contractual arrangements between a patent holder and the public. As such, the owner of a PDV patent has the option to make the technology freely-available to others who could benefit from it, or to reserve access solely for those who offer substantial amounts of compensation in exchange for the use of the invention. This choice will have serious implications for PDVs once they reach the marketplace.

1. PDV patents and patent applications

Existing PDV patents and applications exemplify that this form of technology can be formulated in many ways to combat a variety of diseases. Presently, the majority of PDV patent applications have been filed with the patent offices of the United States, Canada and Europe.[15] Some of these applications are filed under the *Patent Co-operation Treaty*.[16] The majority of the inventors listed are residents of the United States, and ownership of the filed patents is claimed by both private companies and governmental bodies.[17]

The filed patents and applications teach a variety of aspects of PDVs and include process, method and product claims. The following exemplifies claimed methods and processes: a method for genetic alteration of a plant; a method for isolating a protein expressed in plant material; and a method of oral administration of a plant derived vaccine. Whereas product claims include: an edible transgenic plant; a plant cell; a plant seed; an immunogenic composition; and a transgenic plant comprised of cells that elicit an immune response when consumed as food stuff. Immunization against a variety of diseases is disclosed – hepatitis B, hepatitis A, human papillomavirus, are some of the viruses claimed.

A variety of genetic-engineering techniques to produce transgenic plants capable of expressing immunogenic polypeptides in quantities sufficient to elicit an immune response are disclosed in the filed patents and applications. One method is to scar a plant, such as a tobacco leaf, potato or

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13 *Patent Act*, R.S.C. 1985, c. P-4, as amended S.C. 1993, c. 15, ss. 2, 28.3 & 44.

14 *Ibid*. at s. 42.

15 This is noteworthy, as the patent laws in each of these countries differ. In particular the issues of patenting of genes and higher life forms are not uniform (e.g. plants are not patentable in Canada, but are in the United States). The outcome is that patent applications filed by the same inventor for the same PDV invention in each office will not be identical.

16 *Patent Co-operation Treaty* applications allow the applicant to reserve the right to file national patent applications in multiple countries at a future date.

17 See, Richard T. Mahoney et al., "The introduction of new vaccines into developing countries III. The role of intellectual property", Vaccine, n°22, 2004, p. 786. It is noteworthy that presently PDV applications are filed primarily in developed nations. These patents are filed to protect not only the final product, but also aspects of the research process ("research tools"), which is likely undertaken in developed nations. However, as a main benefit of the technology is its application in the developing world, the act of seeking patent protection solely in developed nations means that PDVs will not be provided protection where they may ultimately be most widely applied. This choice may be affected by the anticipated profits from PDVs which will have application in both developed and developing nations, but may be sold at a higher price in developed nations. Thus, any copying of PDVs in developed nations will be costly for the patent holders and patents rights will help them combat such abuses.

a tomato fruit, and to introduce a plasmid vector, comprising a DNA sequence encoding a specific capsid protein operably linked to a plant-specific promoter and gene encoding selection marker expression vectors, into the scar tissue. The seeds from the resulting plant or fruit may be harvested and utilized to regenerate a whole transgenic plant having fruit or leaves that contain a vaccine element. Alternatively, the plasmid vector can be introduced into sterile seeds which are caused to grow, thereby producing a whole transgenic plant. The seeds from the transgenic plant will then be harvested to grow other transgenic plants. The means of administering PDVs include mixing plant materials with an adjuvant, ingestion of pure plant materials, spraying a dose, a patch and intravenous injection.

The foregoing describes only some of the filed PDV patents and applications. The range of the inventions claimed exemplifies the breadth of the category of technology represented by PDVs. Many methods, processes and products are claimed incorporating a variety of plants and targeting a range of diseases. As scientific discovery in this area has really only just begun, PDVs have the potential to represent a very important category of technology from IP, economic and health viewpoints.

2. PDVs & risks

Due to their unique make-up, PDVs raise some significant issues. Foremost amongst these is the fact that PDVs may pose serious risks to the public if they are not handled with the utmost care.[18] For example, environmental issues and biodiversity concerns are raised by any transgenic seeds or plants that escape into the wild. Moreover, as PDV plant materials cannot be distinguished from non-PDV versions of the same plant – e.g. a PDV tomato looks like a traditional tomato – there is a risk of misadministration, which in its most heinous form could represent an act of bio-terrorism. The processing of plant materials raises further issues. A main concern is the biomass which is created during the PDV processing and manufacturing stages.[19] These leftovers contain genetically-modified genes and must be destroyed in a responsible manner so as to ensure that no biomass is left unaccounted for. To combat these risks PDV plants are produced and grown in a regulated environment to avoid biosafety hazards. These and other risk-aversion measures ensure that some level of control is influenced over PDVs to protect society. These risks should be acknowledged in the shaping of an IP protection strategy for PDVs.

Part II – IP protection options & issues for the multiple attributes of PDVs

Despite the fact that patent protection has become the standard form of PDV IP protection, this is not the only form of right available. Generally IP protection strategies are applied to accord with established categories of technology – biotechnology, computer software, sound recordings, etc. Each category applies aspects of existing IP regimes – patents, copyright, trade secrets, etc. The result is that two categories of invention protected by the same base IP regime, such as patents, may seek protection in distinct ways that reflect the specific attributes of the class of innovation. As PDVs do not fit neatly into any presently recognized category of innovation, several protection options may be pursued. If a PDV was the object of a game of twenty-questions it

[18] *Supra* note 3 at 20.

[19] *Supra* note 3 at 6. One proposed solution to the problem of the accumulation of transgenic plant biomass is to use it to create a sustainable fuel source.

might start off like this: is it a plant, a drug, a biotechnology? And the answer would be yes across the board. PDVs fit within all three categories at once. The collection of so many attributes in one innovation makes it difficult to categorize a PDV in traditional terms, and this in turn means it is hard to authoritatively determine how best to protect a PDV.

This section will examine the characteristics of PDVs and the various established categories of IP protection they may fit within due to the fact that a PDV is a plant, a drug, a biotechnology and a developing nation product all-in-one. Each category will be reviewed, as will the IP issues it raises that are relevant specifically to PDVs. The context of the discussion will be Canadian law, but as similar protections are available in many countries, including the United States and European nations, the analysis will have a broad relevance.

A. A plant

A primary characteristic of a PDV is that, in all of its manifestations, the innovation is either in the form of a plant, or includes plant materials, having an unique genetic make-up. It is this constitution that causes the PDV to act as a vaccine when ingested. The distinct make-up of a PDV may also mean it falls within the category of a plant variety.

In general terms, PDV plant varieties may be genetically-engineered so as to include at least one of two unique characteristics. First, a PDV may be generated to target a specific disease and provide a immunogenic response effective against that illness, such as hepatitis B virus, cholera, rabies, etc. Second, a PDV may be created using a particular type of plant – a tomato plant, potato plant, tobacco plant, etc. As such, two PDVs may both be created from banana plants, but each may be genetically-modified differently, so that one constitutes a PDV effective against hepatitis B and the other is effective against malaria. Another two PDVs may be represented by different plants, a potato plant and a tomato plant, but both may be effective against cholera. Any PDV combination of targeted disease and plant may represent a distinct plant variety and therefore be eligible for plant variety protection.

1. Canadian plant variety protection

Plant variety protection is established in several countries, including Canada. The Canadian *Plant Breeders' Rights Act*[20] (the "PBRA") protects species of sexually and asexually reproduced plant varieties. To garner protection a plant variety must be new, which means it must be "*distinguishable from other varieties, stable in its essential characteristics and sufficiently homogenous*."[21] A plant breeders' right-holder is granted the following exclusive rights over a plant variety in Canada: to sell and produce propagating material; to use the propagating material to develop a new plant variety; and to permit others to do these acts.[22] These rights extend for a term of eighteen years.

The PBRA was created in response to the *Pioneer Hi-Bred Ltd. v. Canada (Commissioner for Patents)*[23] decision of the Supreme Court of Canada (the "SCC") which found that plants were

[20] R.S.C. 1990, c. 20.

[21] Eileen Morin, "Of Mice and Men: The Ethics of Patenting Animals", Health L.J., n°5, 1997, p.147, at 192. *Supra* note 20 at s. 4.

[22] *Supra* note 20 at ss. 5.1 & 6.

[23] [1989] 1 S.C.R. 1623.

unlikely to meet the criteria for patentability in Canada. The issue before the court in *Pioneer* was whether a plant which had been cultivated by means of artificial cross-breeding of three plant varieties was an invention in accordance with the *Patent Act*. The *Patent Appeal Board* who initially heard the case determined that cross-breeding as a technique involves a lesser degree of human intervention than does genetic manipulation and, therefore, the cross-bred plant at bar did not qualify as an invention. Ultimately the SCC unanimously dismissed the appeal on the basis of inadequate disclosure, holding that "*the statutory requirement of an adequate description of an invention cannot be met solely by the deposit of a sample of the plant variety*."[24]

Thus, the SCC avoided answering the question whether plants may ever represent patentable subject matter. However, the court did make an interesting distinction when it commented upon the methods of breeding plants. Specifically the SCC stated that there are two types of genetic engineering: i) cross-breeding, which involves natural growth techniques manipulated through human intervention; and ii) recombinant DNA technology, which involves human directed alteration of the genetic code of plants. Cross-breeding was at issue in *Pioneer* and the SCC held that this technique does not alter the plant "*reproductive process, which occurs in accordance with the laws of nature*."[25] Thus, cross-breeding appears to be too close to the natural reproductive process to be patentable.[26]

Due to the fact that the SCC focused upon cross-breeding and failed to offer further comment on recombinant DNA technology, the door was left open for DNA genetic-engineering to be deemed patentable. However, since *Pioneer* the SCC has revisited the issue of the patentability of higher life forms, a category which encompasses plants, in *Harvard College v. Canada (Commissioner of Patents)*.[27] The outcome is that higher life forms are not patentable in Canada. Thus, *Harvard* shut the door.

In comparison to the *Patent Act*, the PBRA offers a form of protection that is limited. This makes sense as a plant breeders' right is intended to be granted to plant technologies which fall short of patentability criteria. In particular, the PBRA does not require utility. However, the act does set out a number of strict guidelines. Of primary concern are the requirements that a plant breeder disclose his or her plant variety and that propagating material be maintained.[28] In fact, the scope of a plant breeders' right is limited to the propagating material specifically, which includes the cuttings, seeds or other parts of the plant. No right over the plant as a whole is granted.

Not only is the scope of the right limited but its application is also curbed. For example, the PBRA does not prohibit another breeder from using protected varieties to develop new plant varieties or stop a farmer from retaining the seeds from a protected variety crop to grow new plants the next season.[29] A further diminution of the scope of a plant breeder's right may be

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[24] Morin, *supra* note 21 at 164.

[25] *Supra* note 23 at para. 18.

[26] It is a tenet of patent law that mere discoveries are not patentable. This issue has recently been reiterated by Canadian courts in Calgon Carbon Corporation v. City of North Bay, [2005] F.C. 838.

[27] *Harvard*, *supra* note 1.

[28] *Supra* note 20 at ss. 9 & 30. Details regarding disclosure are provided in the *Plant Breeders' Rights Regulations*, 1991, SOR/91-594 at s. 19(1)(g).

[29] The practice of saving seeds is commonly referred to as a farmer's privilege. Contractual arrangements are applied by some companies to overcome this privilege. For example, *Monsanto Canada Inc.* requires farmers who purchase their genetically-modified canola seeds to sign a technology user agreement, which prohibits retention of seeds from one year to the next.

undertaken by the commissioner, who can grant a compulsory license to any person over any protected plant variety for the purpose of ensuring the availability of the plant variety at a reasonable price, establishing a wide distribution of a plant variety, maintaining the quality of a plant variety, and providing the rights-holder with reasonable remuneration.[30] Each of these sanctioned uses of plant varieties exemplify limitations upon a plant breeder's right and are exempt from constituting the foundation of any charge of infringement of the right against an offending member of the public.

2. *International plant variety protection*

National plant breeders' rights are supported at the international level by the *Union for the Protection of New Varieties of Plants* ("UPOV") which established the *UPOV System of Protection of Plant Varieties* in 1961 in Paris, with the adoption of the *International Convention for the Protection of New Varieties of Plants* (the "UPOV Act"). Subsequent amendments to the UPOV Act, in 1978 and 1991, have furthered its goal to encourage the development of new plant varieties and ultimately benefit society through the grant of a *sui generis* IP right to plant breeders. The criteria for protection under the UPOV Act are novelty, distinctness, uniformity and stability.[31]

The UPOV Act sets out that plant breeders are to be granted exclusive rights pertaining to production, reproduction, conditioning for the purpose of propagation, offering for sale, selling, or marketing, importing, exporting and stocking. The rights granted to breeders have become the focus of attention following recent amendments to the UPOV Act. A change to the act extended rights to include an "*essentially derived variety*" of plant. This modification raises questions regarding the scope of the granted right. Further controversy has surrounded provisions that cause a farmer's right to save seeds and reuse them for their own benefit to be subject to a payment of royalties to the breeder.[32] This modification is offensive to some because it is possible that the requirement that royalty payments be made to a breeder upon the reuse of seeds could present a significant hurdle for farmers in developing countries and augment food insecurity issues.[33] A further notable provision introduced at the time of the 1991 amendment to the UPOV Act states that *ordre public* considerations can supersede infringement, as long as equitable remuneration is offered. The effect of *ordre public* may be to override the need to seek the consent of the rights-holder prior to utilizing a protected plant variety. All of these changes to the UPOV Act have raised the voices of critics who are concerned about the perceived injustice

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30 *Supra* note 20 at s. 32.

31 Michael Halewood, "Indigenous and Local Knowledge in International law: A Preface to Sui Generis Intellectual Property Protection", McGill L.J., n°44, 1999, p. 953 at 962. The requirement of novelty was added as of the 1991 UPOV amendments.

32 See, "Undermining farmers' rights to their seed", National Farmers Union, 2004, <http://nfu.ca/seedsavercampaign/NFU_Seeds_Fact_Sheet_2.pdf>, and Hope Shand, "Legal and technological measures to prevent farmers from saving seed and breeding their own plant varieties", In J. Janick (ed.), *Perspectives on new crops and new uses*, Alexandria, ASHS Press, 1999. p. 124–126.

33 See, Vandana Shiva, "The Indian seed act and patent act: sowing the seeds of dictatorship", ZNet, 14 February 2005, <http://www.zmag.org/content/print_article.cfm?itemID=7249&sectionID=56>.

of UPOV. In particular, the opponents argue that UPOV offers insufficient solutions to the problems facing developing countries.[34]

Canada has been a member of UPOV since March 4, 1991.[35] Members are required to *grant and protect breeders' rights* pursuant to article 2 of the UPOV Act. Article 4 permits individual nations to grant breeders' rights within their borders as long as such rights are extended in accordance with the UPOV Act and "*without prejudice*". This means that the Canadian PBRA must conform to the principles of the UPOV Act.

3. PDVs and plant variety protection

Although neither the UPOV Act nor the PBRA offer perfect protection for plant varieties, it is clear that PDVs may seek this type of *sui generis* right. PDVs are plant varieties created through recombinant DNA technology and are distinguishable from other plant varieties. This was acknowledged as a form of genetic-engineering by the SCC in *Pioneer* and thus may be deemed to have been within the consideration of the drafters of the PBRA. Thus, if the breeder of a PDV so wishes, he or she may submit an application for plant breeders' rights protection. However, it should be reiterated that this type of right is limited and that it extends solely to the propagating materials and not to the plant itself. Thus, it is not the PDV plant which is ultimately protected, but the plant variety and the materials from which plants having the same genetic make-up may be grown. However, this right is not entirely without influence. It can be wielded by the holder to prohibit others from making use of a variety of plant without the consent of the breeder. For PDVs, this offers a level of control over the growth of transgenic plants which is crucial in light of the risks associated therewith.

B. A drug

The purpose of the creation of PDVs is to produce a new form of vaccination product. Vaccines are described by the WHO as "*relatively complex biological products.*"[36] It is the biological nature of vaccines that distinguishes them from other types of medical treatments, such as medicines comprised of chemical compounds.[37] Vaccines are included in the category of biologics by the *United States Food and Drug Administration* and are given the following definition: "*Biologics, in contrast to drugs that are chemically synthesized, are derived from living sources (such as humans, animals, and microorganisms). Most biologics are complex mixtures that are not easily identified or characterized, and many biologics are manufactured using biotechnology. Biological products often represent the cutting-edge of biomedical research and, in time, may offer the most effective means to treat a variety of medical illnesses and conditions that presently have no other treatments available.*"[38]

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[34] Jan Wendt and Juan Izquierdo, "Biotechnology and Development: A balance between IPR and protection and benefit-sharing" Electronic Journal of Biotechnology, 2001, at 3, <http://www.agbios.com/docroot/articles/01-361-002.pdf >.

[35] UPOV, Members List, <http://www.upov.int/en/about/members/pdf/pub423.pdf >.

[36] Christopher Garrison, "Background paper for WHO workshop: Intellectual Property Rights and Vaccines in Developing countries" WHO, 2004, at 9.

[37] For the purpose of this paper chemical compound drugs will be referenced as distinct from the category of "vaccine", which specifically includes biological elements.

[38] U.S. Food and Drug Administration, Centre for Biologics Evaluation and Research, "About Us", <http://www.fda.gov/cber/about.htm>.

The WHO recently published a report on the topic of vaccines and IP protection.[39] A background paper released prior to the report outlined the three main methods of protecting vaccines that are presently applied. These include: i) patent rights over the vaccine product, the process of creating the vaccine, as well as inventions related to upstream research (known as research tools);[40] ii) trade secrets to protect know-how necessary to produce the vaccine; and iii) undisclosed data derived from tests or other aspects of the R&D process which are held confidentially.[41] This section will focus upon patents.

Although patent protection and trade secret protection may seem straight-forward it is crucial that we look at these forms of protection in the context of drugs specifically. Patents in particular may initially appear to represent a means of protection that is common to many of the characteristics of PDVs. Particularly that a PDV is a drug and biotechnology. This may, at first glance, be considered a positive fact that would suggest that patent rights may easily protect many aspects of a PDV simultaneously. However, it should be noted that protection for drugs, and PDVs specifically, involves some unique conditions to which patents for other categories of inventions, and therefore other aspects of PDVs, are not subjected. These issues unique to the drug element of PDVs include co-operative legislation, international recognition of the role of *ordre public* in public health, compulsory licensing and food issues. Each will be discussed individually.

1. Co-operative legislation

In order to address the unique issues surrounding drugs, both the food and drugs and patent regimes in Canada have been attuned one to another so that they may function harmoniously. This synchronization has been undertaken to assuage concerns that patented drugs raise regarding public health. Indeed ethical and emotional issues surrounding health issues have been cited as the reason why medical treatments in and of themselves are not patentable.[42] David Vaver points out that members of the medical profession are expected to "*share their skills and should not foreclose others from applying them.*"[43] Patents are seen as hindering an environment of sharing. To help curb fears and calm emotions, which are indivisible from health issues, previously separate legislative efforts are now linked through co-operative legislation - namely,

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39 WHO, "Intellectual Property Rights and Vaccines in Developing Countries" WHO/IVB/04.21, 2004.

40 The WHO report, *Ibid*. at 12. Dr. Martin Friede presented to the WHO and in the objective of his discussion was to "*highlight the fact that many components and technologies go into making a vaccine, and each of these may be subject to intellectual property*." Some of the components will be tools that are necessary to produce the vaccine product, such as "*a variety of technologies [that] are required to express and purify the antigen, and to formulate it so that it is immunogenic, induces a protective immune response, is stable and can be appropriately delivered. [Intellectual property] on cross-cutting technologies such as expression systems, fusion partners, immunostimulators, adjuvant systems, excipients and delivery devices may be required, and access to each [Intellectual property] component may limit the feasibility of making a vaccine*" (at 12). See also, *Supra* note 3 at 31.

41 *Supra* note 36 at 2.

42 The *Patent Act*, *supra* note 13, does not expressly prohibit the patenting of medical treatments. However, the SCC's decision in Tennessee Eastman Co. v. Canada (Commissioner of Patents) (1970), 62 C.P.R. 117 (Ex.Ct.), held that medical treatments are not patentable, although a compound utilized in a treatment may be patentable. The effect of this decision is affirmed by section 12.04.02 of the *Manual of Patent Office Practice*, looseleaf, Hull, CIPO, 1998, ("MOPOP") which says that medical treatments are not considered to be within the scope of "*invention*", as defined in section 2 of the Act.

43 David Vaver, *Intellectual Property Law,* Concord, Irwin Law, 1997, at 130.

the *Patent Act*, the *Food and Drugs Act* (the "F&D Act")[44] and the *Patented Medicines (Notice of Compliance) Regulations* (the "NOC Regulations").[45]

Due to the fact that many different terms are applied to drug products – pharmaceuticals, medicines, biologics – it is important to review each of the co-operative statutes to ensure that a vaccine invention is included within their purview. Section 79(2) of the *Patent Act* states that, an invention pertains to medicine if it is used either as a medicine or to prepare or produce a medicine.[46] The term "*medicine*" is defined in section 2 of the NOC Regulations as a substance which can be used for "*mitigation or prevention of a disease*". Whereas, the F&D Act, applies the term drugs, which it defines to include substances used in the "*prevention of a disease*".[47] Each of these definitions encompass vaccines applied to prevent diseases in humans. Therefore the co-operative legislative scheme may be assumed to be applicable to vaccine products and PDVs in particular.

Under the *Patent Act* exclusive patent rights may be granted over new drugs. In order to be patentable a drug must be claimed in relation to a specific practical application, or disease. The result is that drug patents correspond not to mere formulations, but to formulations having a designated utility.[48] Once a drug patent is granted a further step must be taken prior to introducing the drug to the marketplace. It must be approved in accordance with the F&D Act. To aid in this process, and as part of the integration of the patent regime and the food and drugs regime, the minister will issue a notice of compliance ("NOC") once the drug is ascertained to be safe and effective. Prior to the issuance of a NOC a drug may not be advertised or sold in Canada. In order to obtain a NOC, a new drug submission must be supported by a detailed compilation of information, data and research, including information about any patent issued for the drug.

Co-operation between the food and drugs regime and the patent regime ensures that the term of a patented drug is respected. In particular generic drug manufacturers are prohibited from attempting to introduce an equivalent drug into the marketplace during the patent term.[49] The effect of the co-operative effort is that, "*the NOC Regulations introduce patent considerations*

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44 R.S.C. 1985, c. F-27.

45 This co-operative effort was initiated as of 1993 with the introduction of the NOC Regulations. Another example of co-operation between the *Patent Act* and the F&D Act is fostered by the *Jean Chrétien Pledge Pledge to Africa Act*, given royal assent May 14, 2004, which amends both statutes to waive certain TRIPs provisions considered to pose barriers to effective responses to health emergencies.

46 Sections 80 to 103 of the *Patent Act* relate to patented medicines specifically.

47 *Supra* note 44 at article 2.

48 Teresa Scassa, "Patents for Second Medical Indications and their Potential Impact on Pharmacare in Canada", Health L.J. 23, n°9, 2001 at 30. Scassa discusses the fact that the requirement that a patented medicine be claimed in conjunction with a specific disease leads to the creation of second medical indications patents. Relying upon the SCC's decision in Shell Oil Co. v. Commissioner of Patents, [1982] 2 S.C.R. 536, which held that a patent can be issued for a new use of a known compound, second medical indication patents are granted for uses for a medicine which are discovered following the original patent disclosing the medicinal compound. For example, Pfizer Canada has two patents for the drug sertraline hyrdrocholoride (Zoloft), the first being issued for the drug to treat depression and the second for use for other approved indications (Scassa, at 23).

49 The introduction of a generic drug into the marketplace prior to the expiration of an existing patent for the same compound is known as spring-boarding and may be the basis for an action against the offending generic drug manufacturer. Aventis Pharma Inc. v. Novopharm Limited, [2005] F.C. 815.

into the regulatory approval process."[50] The link between the patent regime and the food and drug regime will affect IP protection choices for PDVs.

2. Ordre public

A further consideration specific to patented vaccines is the effect of the *World Trade Orgainzation* ("WTO") *Trade-Related Aspects of Intellectual Property Rights* ("TRIPs") agreement. Canada is a TRIPs member state, as are many other nations worldwide. TRIPs sets out specific provisions which members are required to comply with when asserting IP protection within their national borders. TRIPs provisions are flexible to a point, however, any failure on the part of a member to comply with TRIPs poses a risk that the offending state will be brought before the WTO dispute settlement body. Such an outcome can be detrimental to a country's sovereignty in the area of IP enforcement and therefore all member states are wise to remain mindful of their TRIPs obligations.

TRIPs imposes duties upon members, but it also offers some relief from forms of stringent IP protection. One such relief is offered in article 27.2 which recognizes that exclusions to patentability or commercial exploitation may be upheld for the purpose of protecting *ordre public* or morality. This provision is interpreted as expressly extending to the protection of health. Thus, in reliance upon article 27.2, a country may deem certain subject matter non-patentable for the purpose of protecting health. Such subject matter could include vaccines or other drugs (although it seems unlikely that this would ever occur). Moreover, the wording "*necessary to protect ordre public or morality*" has been judicially considered in the context of a WTO decision and the indication is that future interpretation may in fact limit the scope of article 27.2. Still, upon its face this provision opens the door for significant amendments to the definition of patentable subject matter, as long as modifications are made in the name of protecting health.

Section 8 of TRIPs addresses "*measures necessary to protect public health*" directly. In the opinion of Bita Amani, this should be interpreted to mean that "*the protection of [IP rights] should not impede domestic discretion to adopt necessary measures to protect public health and promote public interest in sectors of vital importance to socio-economic and technological development by creating a monopoly on knowledge or a monopoly on health.*"[51] Thus, at the very least, articles 8 and 27.2 place all patents related to health care in greater jeopardy of being subjected to an exemption founded upon *ordre public* or morality than other types of patented inventions. If these exemptions are invoked a patent holder's rights may be diminished if not annihilated. This risk weakens the force of the presumption of the validity for drug patents.

3. Compulsory licensing

Recent debate regarding the accessibility and affordability of pharmaceutical[52] products in developing nations has brought the relation between compulsory licensing and drugs to the

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[50] Scassa, *supra* note 48 at 46.

[51] Bita Amani, "Patents & Public Health: International Trade Obligations and Domestic Policy Development", Health L. Canada, n°22, 2002, p. 76 at 89.

[52] In common discourse the general category of pharmaceutical has been divided so that bio-pharmaceuticals are distinguished from non-biologic pharmaceuticals, such as chemical compound pharmaceuticals. Bio-pharmaceutical is a relatively recent term, which should be understood as having a specific marketplace application.

forefront. The WHO has commented that "*much of the debate on [IP rights] and public health has focused on the possible impact that patents on final products have on the prices paid in developing countries and, hence, their affordability. In the case of vaccines, the nature of their development and production and the nature of the final market may require a different kind of debate*."[53] The report goes on to cite distinctions between pharmaceuticals and vaccines, noting the following: that vaccines have much smaller markets; that the public sector has a greater involvement in the production, pricing and marketing of vaccines; that vaccines as biological products are more complex and costly to produce; that clinical trials may also be much more costly for vaccines; and that it may be much more difficult to copy a vaccine.[54] Although these distinctions make it clear that discussion about the impact of patents upon the accessibility and affordability of vaccines may not be identical to that regarding pharmaceuticals, it is still true that both types of drugs fulfill a significant role in public health. It has been stated that "*despite the 1.5% share that vaccines have in global pharmaceutical turnover in dollars, vaccines represent much more than 1.5% of the capacity to deal with global health problems, because they have positive externalities*."[55]

Due to the important role of vaccines in the maintenance of public health it is imperative that governments take all possible steps to ensure that vaccines are widely available at affordable costs. One such measure at hand is compulsory licensing. This option may be implemented in the name of public health. Both the Canadian *Patent Act* and TRIPs provide for the remedy of compulsory licensing to be applied in the instances of either "*national emergency or extreme urgency*", wherein the invention will be applied to a "*public non-commercial use*".[56]

Both clauses have been considered in the context of public health emergencies. In Canada the *Commission on the Future of Health Care* noted in their 2002 report that the sustainability of health care policies relies upon "*ensuring that sufficient resources are available over the long term to provide timely access to quality services that address Canadians' evolving health needs*."[57] A failure to provide such access may in some circumstances constitute a national emergency. Some authors have noted that it is imperative that other legal options such as licenses, negotiated use and statutory authorization be pursued before resorting to compulsory licensing.[58] However, recent debate about the provision of HIV AIDs drugs to Africa has highlighted the fact that compulsory licensing threatens the rights of holders of drug patents, including patented vaccines.[59] The risk that compulsory licenses will be applied to drug patents is greater than for other types of patents, due to the important role that drugs play in the context of

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The term pharmaceutical has been further distinguished from vaccines by the WHO, s*upra* note 39. For the purpose of this section of this paper pharmaceuticals shall be defined narrowly to include solely chemical compounds and therefore as distinct from biologics.

53 *Supra* note 39 at 4.

54 *Ibid*. at 4-5.

55 *Ibid*. at 6.

56 See, section 19.1(2) of the *Patent Act*, *supra* note 13, and article 31 of TRIPs.

57 Roy J. Romanow, *Building on Values: The Future of Health Care in Canada--Final Report,* Saskatoon, Commission on the Future of Health Care in Canada, 2002 at 1, <http://www.healthcarecommission.ca >. See also, Timothy Caulfield, "A Colloquy on the Romanow Report: Sustainability and the Balancing of the Health Care and Innovation Agendas: The Commercialization of Genetic Research", Sask. L. Rev., n°66, 2003, p. 629.

58 *Supra* note 51 at 95.

59 Amy Kapczynski, et al., "Addressing Global Health Inequities: An Open Licensing Approach for University Innovations", Berkley Tech. L.J., n°20, 2005, p, 1031 at 1057-1069.

the maintenance of public health. A patent for a PDV which discloses the invention as a vaccine product will be no exception.

4. A food

Now that we have looked at the role of PDVs as drugs specifically, we need to review the options as to the form by which PDVs may be administered. It is the means of oral administration which may raise some confusion regarding the breadth of the nature of PDVs. As has been discussed, PDVs can be administered in the form of an unprocessed, fresh plant material or fruit. Despite problems with administration of PDVs as edible vaccines, specifically relating to dosage issues, this form of invention has not been abandoned in R&D initiatives altogether. Consequently, PDVs may constitute food.

Foods receive special treatment within the F&D Act. *Food* is defined broadly in the act as "*any article manufactured, sold or represented for use as food or drink for human beings, chewing gum, and any ingredient that may be mixed with food for any purpose whatever.*"[60] All foods introduced to the marketplace must conform with a set of regulations under the act that are separate from those applied to drugs. There is the potential for a PDV which is administered by way of consumption of raw plant materials to fall within both the categories of drug and food.

5. PDVs and drug patents

In sum, as a vaccination a PDV is protectable by patent. However, patent rights granted for PDVs may be targets for statutory exceptions such *ordre public* and compulsory licenses, due to the invention's role in public health. The potential for PDVs to be true edible vaccines causes more uncertainty for rights over PDVs as the scope of food and drug regulation which must be applied to PDVs is unclear. Depending on the final embodiment of the invention, a PDV product may be simultaneously both a drug and a food. All of these issues evoke special considerations for PDVs which must be weighed if an effective strategy of IP protection is to be applied to this category of invention.

C. A biotechnology

The nature of PDVs means that they fit into yet another category of invention, namely biotechnology. Biotechnology has been defined as "*the application of scientific and engineering principles to the processing of materials by biological agents to provide goods and services.*"[61] This is a broad definition which appreciates that biotechnology can be applied in a variety of sectors, including health, agriculture, environment and industry.[62] Looking at the health sector specifically, biotechnology is hailed as a possible solution to a wide array of health issues

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[60] *Supra* note 44 at s. 2. The Canadian definition is narrower than other definitions due to the fact that it references the intended use of the food, this can be contrasted with the European Food Authority's (the "EFA") definition which holds that food "*means any substance or product intended to be, or expected to be ingested by humans*", see Dominique Lauterburg, *Food Law: Policy & Ethics*, London, Cavendish Publishing Limited, 2001, at 46. According to the EFA definition PDVs would definitely qualify as foods, whereas in Canada an argument could be raised that PDVs are not necessarily sold or represented for use as food *per se*.

[61] Halla Thorsteinsdóttir, et al., "Introduction: promoting global health through biotechnology", Nature Biotechnology, n°22, 2004, DC3 at DC6.

[62] *Ibid*. at DC6.

occurring worldwide.[63] Plant-made pharmaceuticals have been identified by the *United States Biotechnology Industry Organization* ("BIO") as one of the health applications of biotechnology, "*whereby plants are genetically modified to produce new drugs and biologics that can prevent or treat diseases and save lives*."[64] As PDVs are created through the genetic-modification of plants, they fit squarely within the category of biotechnology. There are two aspects of biotechnology patent rights which are of particular interest to PDVs and will be discussed in this section – patent construction to determine the scope of the patent rights and biological material deposit rules.

1. Patent construction

Biotechnology products can benefit from both trade secret and patent protection. Each of these forms of IP are haunted by considerations beyond the bounds of pure science, which arise in conjunction with the clinical trials and commericialization stages in particular. These include ethical, social and cultural concerns. In the words of E. Richard Gold and Wendy A. Adams, "*the health benefits to individual recipients of the products of biotechnological innovation are self-evident, although far from uncontroversial*."[65] Others have voiced concerns as to whether extending strong IP rights to biotechnological innovation is ethical, or even legally defensible.[66] Specific issues raised by PDVs include liabilities related to the growth of transgenic plants and the production of drugs from these materials. BIO has acknowledged that steps must be taken to minimize the risks associated with the production of plant based genetically modified health technologies, including control of exposure to transgenic plants and their expression products.[67] BIO's caution is the type of issue that will likely be addressed through regulation or policy initiatives to restrict the growth of plants to confined facilities and to ensure that processing, milling and extraction of transgenic plant materials is undertaken separate from commercial food and feed channels.[68] These represent physical protections which may be achieved. Recent case law has examined the legal protections available, through a review of the validity and scope of claims which form the basis of patent rights held in biotechnology inventions.

In 2002, the SCC was asked to determine the patentability of a genetically-engineered mammal. *Harvard College v. Canada (Commissioner of Patents)*[69] involved a patent application claiming a mouse that, due to genetic modification, was more susceptible to cancerous tumours. Ultimately the SCC held that the drafters of the *Patent Act* had not intended higher life forms to fit within

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[63] *Ibid*. at DC3. See also, E. Richard Gold and Wendy A. Adams, "Reconciling Private Benefit and Public Risk in Biotechnology: Xenotransplantation as a Case Study in Consent", Health L.J., n°10, 2002, p. 31 at 32. Gold and Adams highlight some of the health applications of "*modern technology*" including the creation of medications which are matched to the genetic make-up of the patient to "*reduce adverse reactions and maximize positive ones (pharmacogenics)*."

[64] Biology Industry Organization, "Reference Document for Confinement and Development of Plant-Made Pharmaceuticals in the United States", 17 May 2002, <http://www.bio.org/healthcare/pmp/PMPConfinementPaper.pdf>. BIO distinguishes between plant-made pharmaceuticals and an edible vaccine form of PDVs in "Plant-Made Pharmaceuticals: Frequently Asked Questions", <http://www.bio.org/healthcare/pharamaceutical/pmp/factsheet2.asp?p=yes&>.

[65] Gold and Adams, *supra* note 63 at 32.

[66] Lorraine Sheremeta and Bartha Maria Knoppers, "Beyond the Rhetoric: Population Genetics and Benefit-Sharing", Health L.J., n°11, 2003, p. 89 at 92-93.

[67] *Supra* note 64 at 6.

[68] *Ibid*. at 4.

[69] [2002] 4 S.C.R. 45.

the definition of patentable subject matter. Thus, despite the fact that the same invention has been accepted as patentable subject matter in a number of other influential nations, including the United States, Japan and European countries, the SCC held that the onco-mouse, as well as all other forms of higher life, are not patentable in Canada. This represents a significant decision exemplifying that patent rights over biotechnological innovations are by no means certain.

In its 2004 *Monsanto Canada Inc. v. Schmeiser*[70] decision, the SCC revisited the issue of patent rights over biotechnological innovations. At issue was a patent granted for an agricultural biotechnology product, Round-up Ready canola. This time round, the SCC did two remarkable things. First, the majority decision stated outright that the claims did not need to be construed for the purpose of determining the scope of the patent rights at issue. Four years earlier purposive construction had been introduced by the same court in two concurrent decisions, each of which stressed the importance of undertaking a comprehensive construction of patent claims before establishing the scope of granted patent rights.[71] As such, the decision of the SCC to refrain from construing Monsanto's claims was startling. Following this first surprising act, the SCC went on to render a judgement which in effect ignored its stance in *Harvard*, but fell short of overruling the prior decision altogether.

The *Harvard* judgement draws a line between higher and lower life forms. According to the judgement, plants clearly fall into the category of higher life forms. Thus, a decision that complies with *Harvard* would find that patent rights cannot be extended to plants. In the course of *Monsanto* the SCC articulated a doctrine that extends patent scope beyond the written claims if a non-claimed element is determined to have an "*important role in production*".[72] In application this doctrine means that patent scope can be understood to cover both the claimed invention as well as any broader structure that encapsulates or incorporates the invention.[73] A plain language interpretation of this doctrine is that, although it was the genes of the agricultural biotechnology that were claimed in the patent at issue in *Monsanto*, the entire plant is granted patent protection due to the fact that the plant encapsulates the claimed genes.[74] The result of the *Monsanto* decision therefore is that the court extended patent rights to the plant, in defiance of its prior judgement in *Harvard*.[75]

Harvard and *Monsanto* have been described as "*the most significant decisions in the area of biotech patent law anywhere in the world*."[76] The esteem denoted to the decisions makes their inconsistencies that much more disconcerting. The expansive doctrine applied in *Monsanto* is a dangerous precedent as it broadens patent scope beyond the actual patent claims. As a result, "*the chance for error becomes more acute*" and the uncertainty about patent scope for biotechnology is consequently heightened.[77] It is important to note that the SCC rendered the

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70 [2004] 1 S.C.R. 902.

71 Free World Trust v. Électro Santé, [2000] 2 S.C.R. 1024 and Whirlpool Corp. v. Camco Inc., [2000] 2 S.C.R. 1067. See also, E. Richard Gold and Karen Lynne Durell, "Innovating the Skilled Reader: Tailoring Patent Law to New Technologies", I.P.J., n°19, 2005, p. 189.

72 *Supra* note 70 at para. 42.

73 *Ibid*.

74 *Ibid*. at para. 43.

75 Gold and Durell, *supra* note 71 at fn. 138.

76 A. David Morrow and Colin B. Ingram, "Of Transgenic Mice and Round-up Ready Canola: The Decisions of the Supreme Court of Canada in Harvard College v. Canada and Monsanto v. Schmeiser", U.B.C. L. Rev., n°38, 2005, p. 189 at 189.

77 Gold and Durell, *supra* note 71 at fn. 138.

Monsanto judgement in a manner that conflicts with *Harvard*, but does not overrule *Harvard*. Thus, the accepted law in Canada is that higher life forms are not patentable.[78] When read together the only clear message that can be taken from the recent SCC judgements is that the scope of patent rights over biotechnology is unclear at best. The boundaries for patent scope over technologies such as transgenic plant PDVs is especially blurry. Thus, it is virtually impossible to authoritatively state which aspects of PDVs will be held to lie within the fence-posts of patent scope. Precedent jurisprudence is of limited assistance as *Monsanto* and *Harvard* offer different answers to the same question.

2. Biological material deposit

The depth of disclosure that is required for PDVs may require more than a written submission. In some instances merely describing a biotechnological invention in words in the patent application will not be sufficient to meet the standard of disclosure required by section 27(3) of the *Patent Act*.[79] Where words fail to fully describe a biotechnology invention it may necessary for the applicant to provide biological material as part of the patent disclosure.[80] This being said, a deposit of biological material will never replace a written description, but may be required as a supplement thereto.[81] Section 38.1 of the *Patent Act* addresses the deposit of biological material stating that it subsequently becomes part of the specification of the filed patent application.

At the international level biological material deposits are supported by the *Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure*, as established in 1977 and adopted in Canada on September 21, 1996.[82] The Budapest Treaty authorizes depositaries to collect and store materials. Each recognized depositary is known as an International Depositary Authority ("IDA") and only deposits made with recognized IDAs will be considered to comply with the requirements of the Canadian *Patent Act* and *Patent Rules*. According to Canadian patent legislation certain steps must be complied with for a biological deposit to be considered part of the patent disclosure. Initially, once a deposit is made with an IDA the applicant must advise the commissioner of patents of the name of the depositary and the date of the deposit. A single deposit with an IDA may be referenced in multiple national patent filings. To ensure that a deposit is readily available to the public, a depositer is required to make a biological sample available for a period of at least 30 years from the date of deposit, and for at least five years as of the date of the most recent request to the IDA to provide a sample of the materials.[83]

Another disclosure requirement that must be complied with by biological inventions, such as PDVs, involve sequence listings. Specifically, patent applications disclosing a nucleotide or amino acid sequence that has not been previously disclosed are required to provide a sequence listing in their content. Compliant sequence listings must include the actual sequence as well as associated information in accordance with the format set out in the *Patent Rules*.

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78 MOPOP, *supra* note 42 at 12.04.01.
79 *Ibid*. at 17.03.
80 *Supra* note 13 at s. 38.1.
81 MOPOP, *supra* note 42 at 17.03.
82 MOPOP, *supra* note 42 at 17.04.
83 *Regulations under the Budapest Treaty*. WIPO, adopted on April 28, 1977 and amended on January 20, 1981 and October 1, 2002, rules 6 and 9.

3. PDVs and biotechnology

The aforementioned patent requirements specific to biotechnology inventions are significant for PDVs. Most alarming is the recognition that whether a PDV patent extends rights to the plant element is unclear. Moreover, listing and biological material deposit requirements pose a risk of deficient disclosure that is unique to biotechnology inventions. Applicants for PDV patents should be aware of the hurdles facing the attainment of IP protection for this category of invention.

D. A developing nation product

Several characteristics of PDVs cause them to have particular benefits for developing nations. For example, vaccine materials may be propagated quickly, in large quantities, at a low cost, and may be easily transported even to remote areas. These qualities suggest that issues such as access and affordability, which hinder the application of many existing medicines in developing nation environments, may be overcome by PDVs. Nonetheless, the fact that PDVs are expressly intended to be applied in developing nations raises notable considerations for IP protection strategies. For instance, the fact that views on IP protection differ between developing and developing countries is of import as the balance of intellectual protection for PDVs can become very difficult to attain because PDVs play a role in both worlds.[84] PDV innovations are owned by developed world researchers, but may ultimately be applied primarily in developing nation environments.

There is a concern that strong IP rights, and patent rights in particular, may negatively affect the accessibility of vaccine technologies in developing nations because they foster the monopolization of marketplace sectors, and in turn inflate prices.[85] Although patent rights are not the only barrier to access to medicines in developing nations – infrastructure and investment also play a role – rights-holders' activities can exacerbate the problem.[86] In the words of one commentator, support for innovation should be put into perspective as it is, "*a leap of faith for investors in industrialized countries; imagine how hard it is in countries where R&D expenditures may be only a fraction…of gross national product, skilled and educated labor is at a premium, intellectual turf wars stifle collaboration, economic difficulties and inflation are rampant, venture capital investors are an unknown species, intellectual property protection is murky and political turmoil is a frequent backdrop*."[87] Although an exact price tag has not been attached to the cost of bringing a new vaccine into the public sector in developing countries, it is estimated that in the case of a hepatitis B vaccine, "*from first licensure in a developed country, it can take an additional 10-15 years or more and substantial financial resources to introduce such a vaccine into significant numbers of developing country national immunization programs*."[88] This means committed funding over a long period is required. Many commentators agree that

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84 *Supra* note 66 at 92. In general developed nations are more likely to support regimes which impose strong intellectual property rights than developing nations. Strong IP rights allow a holder to wield substantial power over the access and price of an innovation. This can be detrimental for developing nations, creating barriers for access to innovation.

85 *Supra* note 17 at 789.

86 S*upra* note 59.

87 Andrew Marshall, "Open Secrets", Nature Biotechnology, n°22, December 2004, DC1 at DC1.

88 *Supra* note 12 at 646.

patent rights must be part of the solution,[89] what is unclear is the strength of the patent rights that must be granted

Many partnerships[90] and major global funds[91] have been formed to work on the issues relating to vaccine implementation in developing nations. Simultaneous with these developing nation programs, developed nation efforts on vaccine production have taken on greater significance in light of concerns about the potential for pandemics.[92] Although no clear solutions have emerged as of yet regarding how to most effectively apply vaccines internationally, the issue of IP rights is of primary concern in the context of the debate. This is particularly true in developing nations that are plagued with preventable diseases. Two elements which may greatly influence any solution regarding the force of IP rights over vaccine products, such as PDVs, are the TRIPs provisions for least-developed countries ("LDCs") and the open source patent initiative.

1. TRIPs & LDCs

Article 66 of TRIPs directly addresses IP rights to be applied in LDCs. Specifically the article exempts LDCs from compliance with most of the provisions of TRIPs due to "*their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base*."[93] This is not an exemption for all time, but for a term of ten years from the date when the state becomes a member country, with the possibility of a further extension period upon request.[94] Hand-in-hand with the LDC exemption in TRIPs is an admonition to developed nations to create incentives for corporations within their borders to engage in technology transfers to LDCs, "*in order to enable [LDCs] to create a sound and viable technological base*."[95]

Thus, the effect of article 66 is that LDCs are granted a reprieve from implementing national IP regimes for a time. This is both good and bad for LDCs. Because a LDC does not have to grant IP protection copying of inventions is permissible and market monopolies may be averted. However, one of the reasons why LDCs have been granted an exception from TRIPs is because they lack the financial and scientific infrastructure to produce and support innovation internally. Therefore, LDCs need to import innovations from other countries.[96] As has been previously

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[89] See, Carlos Morel, et al., "Health Innovation in Developing Countries to Address Diseases of the Poor", Innovation Strategy Today, n°1, 2005, p. 1 at 3; *Supra* note 17 at 787; and *Supra* note 3 at 29.

[90] Such as the *International AIDS Vaccine Initiative*, the *International Partnership for Microbicides*, the *Medicines for Malaria Venture*, *Malaria Vaccine Initiative*, and the *Global Alliance for TB Drug Development*. See, Morel, *supra* note 89 at 3.

[91] Such as the *Vaccine Fund* which works with *Global Alliance for Vaccines and Immunizations* and the *Global Fund to Fight AIDS, Tuberculosis and Marlaria*. See *Ibid*.

[92] See, David S. Fedson, "Preparing for Pandemic Vaccination: An International Policy Agenda for Vaccine Development", Journal of Public Health Policy, n°26, 2005, p. 4, and Chris L. Barrett, et al., "If Smallpox Strikes Portland", Scientific American.com, 21 February 2005, <http://www.scientificamerican.com/article.cfm?chanID=sa006&colID=1&articleID=000BBC08-CEA3-1213-8EA383414B7FFE9F>. Fedson quotes the European Commission's comment that "*the next pandemic is imminent*" (at 4).

[93] See, article 66(1) of TRIPs.

[94] WTO members have since decided to extend the ten-year period to at least 2016 for pharmaceutical products. See "TRIPS Council Agreements on Extension for LDCs on Pharmaceutical Patents", Bridges, vol. 6, n°25, 3 July 2002, <http://www.ictsd.org/weekly/02-07-03/story1.htm>.

[95] TRIPs, article 66(2).

[96] See, *supra* note 12 at 647.

mentioned, it can be difficult to attract national investment if the LDC cannot offer market returns, which are normally gleaned due to market monopoly made possible by exclusive patent rights. The result is a vicious-circle. LDCs are not required to have patent regimes in place because they do not create innovation due to the fact that they lack the infrastructure – laboratories, trained scientific staff, sophisticated equipment, etc. – to do so.[97] Consequently, LDCs fail to attract the investment necessary to build an internal infrastructure because they do not offer the benefits of national patent rights to investors.[98] The cycle is self-perpetuating.

So on the one hand national patent rights cannot a hinder access to drugs in LDCs because they do not exist, but on the other hand the lack of patent rights may pose a barrier to access to drugs in LDCs since the drugs must be imported from developed nations where patent rights are offered. The imported drugs are likely sold at a premium price as a result of the patent rights. Moreover, since pharmaceutical companies cannot attain patent rights for their products and processes in LDCs there is a lack of interest in facilitating the production of drugs within LDCs. Copying of drugs may be permissible in LDCs, but at the same time it is impossible for LDCs to undertake an initiative to copy a drug due to a lack of sophisticated infrastructure.[99] In sum, despite the TRIPs exception, patent rights are not meaningless for LDCs.

2. *Open source patents*

In order to surmount the hurdle that patent rights pose to the development and accessibility of vaccines and other drugs, and in light of the serious threat of tropical diseases[100] and preventable diseases,[101] new forms of IP rights are evolving. One such alternate right is referred to as open source patents. Basically open source means that rights in an innovation will not be wielded to produce a marketplace monopoly for a holder. The purpose of open source in some biotechnology projects is to "*counteract the phenomenon in certain research areas in which progress is hampered by the rights structure surrounding basic investigative tools*."[102] Another benefit of open source is to provide ease of access to final product inventions. When viewed in a more idyllic light, open source may be seen as an attempt to return to earlier perceptions of scientific R&D, which viewed scientific innovation as belonging to the scientific community as a

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97 *Supra* note 3 at 29.

98 See, *supra* note 11. A lack of patent rights is by no means the sole reason why LDCs fail to attract investment. Political instability and a lack of a lucrative market are other notable reasons.

99 It is worth observing that TRIPs has initiated problems for non-LDC countries as well. In order to comply with TRIPs India, a developing nation but not an LDC, was required to expand their patent laws to include pharmaceutical products. Previously, solely the process of producing pharmaceuticals was patentable. This change greatly affects the generic pharmaceutical industry, which prior to the amendment flourished in India. Pre-TRIPs, multiple processes could be patented to produce a single pharmaceutical. Thus, it was impossible for one patent holder to monopolize a drug product in India's marketplace. Post-TRIPs monopolization of a drug product by a single patent holder is possible. The effect of this change will not effect only India, but many other developing nations, as India's generic drugs were distributed to many developing countries. See, Ragavan S. "Can't We All Get Along ?: A Case for a Workable Patent Model", Ariz. St. L.J., n°35, 2003, p. 117.

100 Stephen M. Maurer, et al., "Finding Cures for Tropical Diseases: Is Open Source and Answer?", Minn. J.L. Sci. & Tech., n°6, 2004, p. 169 at 169. It is estimated that tropical diseases affect more than 500 million people, or 1/10 of the global population, while only 1% of new drugs are developed to treat these diseases.

101 *Supra* note 59 at 1031. The number of people dying in middle and low income countries from preventable diseases is in the millions. For example, AIDs alone killed over 3 million people in 2004.

102 Robin Feldman, "The Open Source Biotechnology Movement: Is it Patent Misuse?", Minn. J.L. Sci. & Tech., n°6, 2004, p. 117 at 123.

whole, and endorsed freely-available information.[103] As there are multiple modes of achieving these goals open source is not a single form of right, but rather a category encompassing various means all having a common purpose.

The open source concept originated in the realm of copyright where the IP right is granted immediately without any formal application or registration process.[104] Due to the fact that there must necessarily be a right granted for copyright, open source in that realm functions as a type of license agreement. Specifically, open source copyright involves non-exclusive license agreements which provide free access to protected materials. Drawing from the copyright experience some open source patent initiatives build a free-flow of information upon the foundation of a granted patent right.[105]

The *Public Patent Foundation* ("PPF") is an open source project which facilitates the creation of a commons wherein patents may be pooled and made freely available to other participants.[106] In basic terms PPF grants a non-exclusive and payment-free license to all participants. The *Biological Innovation for Open Society* ("BIOS") also collects patented technologies, although its undertaking is more focused upon research tools than final products. BIOS' goal is to "*assemble groups of enabling technologies that together provide the pieces necessary for a particular form of research investigation.*"[107] The BIOS approach recognizes that the monopolization of research tools can be just as detrimental to innovation as exclusive rights over a final product. PPF and BIOS both require participants to execute a license agreement, however the terms of the agreement created by each group will likely differ.[108]

Still another approach is taken by the *Tropical Disease Initiative* ("TDI"), which does not seek patent rights at all.[109] TDI is focused upon creating a website providing database access to a collection of information, such as "*searching for new targets, finding chemicals to attack known targets, and posting data from related chemistry and biological experiments.*"[110] An added benefit of TDI's format is that the information is easily accessible by researchers in developing nations. TDI believes that their form of open source will aid virtual pharmas in particular –

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[103] David W. Opderbeck, "The Penguin's Genome, or Coase and Open Source Biotechnology", Harv. J. Law & Tec., n°18, 2004, p. 167. Opderbeck points out that "*where the law once supported the norm of disclosure, it now encourages a norm of strategic behaviour*" (at 186).

[104] Feldman, at 117. See, *ibid*. Opderbeck tries to draw a clear relation between software open source and biotechnology opens source by analogizing the layers of software machine and program code to the layers of DNA.

[105] "Open Source Genomics", Symposium on Bioinformatics and Intellectual Property Law, April 27, 2001, Boston, Massachusetts, B.U. J. Sci. & Tech. L., n°8, p. 254 at 255-56. Dan Burke comments that "*free*" in this context does not mean no cost. Rather, free information means information that may be used at the discretion of the person who accesses it – this may mean manipulating the innovation described to improve upon it or to create a new invention, or it may mean using the information for specific purposes to further another project. The information is not controlled by proprietary rights, but can be used by those who need such information in any manner that is required.

[106] *Supra* note 102 at 126.

[107] *Ibid*.

[108] *Ibid*. at 128. BIOS allows its licensees to seek patents on any inventions created, but it also requires them to "*grant back any improvements in the core technology and to make such improvements freely available to all others on the same terms that BIOS provided for the original technology*."

[109] *Supra* note 100 at 171.

[110] *Ibid*.

organizations that are not engaged in in-house development, but utilize a grouping of commercial and academic partnerships to create a portfolio of promising drug innovations.[111]

No matter what format is enforced, open source is an alternative to traditional patent monopolies. It is a grassroots initiative based upon a cry from the people – researchers, scientists, students and developing nation advocates – who recognize that patent rights may no longer act to promote innovation, but instead may hinder it. The plea for change is evidence that "*an open source community must develop from the bottom up; it cannot be imposed from the top down.*"[112]

3. PDVs and developing nation products

The aforementioned points highlight that the developing nation product element of PDVs may cause owners to wield their patent rights in a weak manner, or to forego IP protection altogether. LDC exemptions mean IP rights are not available in some areas where PDVs may be applied. Moreover, some inventors may endorse open source patent initiatives and reject the exclusive nature of patent rights. As such contractual agreements may carry the bulk of the burden for the protection of PDVs. Such agreements could even dictate the scope of an inventor's ability to engage in consultation and co-ordination with organizations capable of implementing a vaccine initiatives where the vaccine products are most needed.[113] These agreements will be a key factor for the emergence of PDVs in the marketplace. No matter what IP protection options an inventor considers, concerns regarding access to PDVs in developing nations, where they have the potential to significantly reduce fatal disease, should remain foremost. These concerns should be an integral aspect of the IP protection strategy applied to PDVs.

Part III – PDVs as a new category of technology

Now that the varied nature of PDVs has been outlined, along with the many categories of technology that pertain to attributes of PDVs, as well as the issues relevant to each category, we have the necessary tools to engage in a discussion about the category of IP protection for PDVs. More importantly we can address who should undertake the required analysis. Presently, it is the inventor who decides the type of protection to be sought. Of course, the inventor may seek the advice of a patent agent, or other legal professional, but ultimately the final judgment rests solely in the inventor's hands. It is not clear that this is the best means of ensuring that an appropriate IP protection scheme is achieved.

As the average inventor is unlikely to be an IP expert, it is conceivable that decisions regarding protection for a new category of invention, such as PDVs, do not routinely involve a weighing of all of the relevant issues surrounding innovation protection. Moreover, it is probable that subsidiary considerations, such as economic gain, may be given undue weight and ultimately cloud the decision. It is understandable that concerns regarding economic return should be given import, considering the high cost of developing and testing a new vaccine product. Any inventor of a PDV would of course be interested in reaping as much of a financial benefit from his or her invention as possible. However, as we have discussed, there are many aspects of IP protection which are not influenced by economic factors which can widen or narrow the scope of the right

111 *Ibid*. at 170.
112 *Supra* note 103 at 192.
113 *Supra* note 12 at 651.

that is granted. Whether too much or too little protection is achieved is really a value judgement,[114] but a carefully crafted protection strategy will diminish the risk that the protection will not match the technology.

Another danger of leaving complete control over the solicitation of IP rights in the hands of the inventor is that once a mode of protection has been launched for a first technology in a category of new innovation, it is likely that subsequent inventors will follow suit. The result is that the pioneer strategy becomes the norm for the category of invention. This is because subsequent inventors want equal shares of the market-pie and therefore need to claim commensurate protection for their inventions. As such, the decisions made by the initial inventor will have a great impact and may set the standard for the technology category as a whole. The standard in turn will affect other means of protecting an innovation, such as contracts and licenses, all of which derive their power from the scope of the granted IP rights.[115] The unfortunate truth is that, whether the protection decisions were soundly made, or based upon clouded judgment or faulty information, the initial inventor's choices will have a wide effect.

Drafting patent claims is one aspect of an IP protection strategy that may be particularly troublesome for new categories of technology. The claims of a patent set-out the scope of the rights which are granted to the holder. The SCC has stated in several recent cases that patent rights are intended to be balanced with the interests of the public,[116] and has commented that public interests may be adversely affected by "*cluttering the public domain with useless patents*."[117] Useless patents may be those that are poorly drafted or those that disclose frivolous inventions. Thus, the mode of claiming an invention should be well thought-out. This is especially true for new technologies, such as PDVs, which cover several traditional categories of patentable subject matter. Patent claims are to be drafted so that the public "*will be able to know not only where it must not trespass but also where it may safely go*."[118] In other words the claims should clearly define the scope of the patent rights.[119] Unfortunately it is rare to find a set of clearly drafted claims, as "*patent drafters seem congenitally unable to employ plain language*."[120] Of course the complexity of the invention will affect the complexity of the claims, but the clarity of patent claims is not assisted by the fact that patent agents attempt to push the boundaries of patent scope to be as wide as possible and sometimes employ expansive language to further this pursuit.[121] For PDVs, a patent protection strategy will not be aided by claims that ignore the issues of the categories linked to the various characteristics of the innovation. Each attribute is directly related to the means by which rights over PDVs must be divided between society and the inventor, and consequently to the achievment of balance.

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[114] David Vaver, "Need Intellectual Property be Everywhere? Against Ubiquity and Uniformity", Dalhousie L.J., n°25, 2002, p. 1 at 4.

[115] "Discussion Following the Remarks of Mr. Phillips and Ms. Erickson", Proceedings of the Canada-United States Law Institute Conference on Multiple Actors in Canada-U.S. Relations, Cleveland, Ohio, April 16-18, 2004, Can.-U.S. L.J., n°30, 2004, p. 289 at 289.

[116] See, note 1.

[117] Apotex, *supra* note 1 at para. 66.

[118] Free World, *supra* note 71 at para. 14 citing *Minerals Separation North American Corp. v. Noranda Mines, Ltd.*, [1947] Ex. C.R. 306.

[119] Whirlpool, *Supra* note 71 at para. 42. It is a tenet of patent law that what is not claimed is deemed to be disclaimed.

[120] *Supra* note 43 at 141.

[121] MOPOP, *supra* note 42 at chapter 11.

An ill-considered protection strategy not only sets a bad precedent, but it is difficult to reverse without wreaking havoc. Once a mode of protecting an innovation is adopted generally for a category of technology the only means of thwarting its application is to challenge the protection. For example, a patent that is challenged all the way to litigation will cause a court to determine issues of validity or infringement of patent rights. The trouble is that by the time a court hears a patent challenge many years have passed since the application for the invention was first filed. At this point the strategy of protection is likely deeply entrenched. Any court decision which denounces any aspect of the strategy has the potential to affect many other innovations along with the one at bar. More concisely, an early poor strategy put in place by an inventor may not be recognized as problematic until a much later date, at which point the commentary may adversely affect a large number of inventions within a category of technology.

The decision in *Kirin Amgen v. Hoechst Marion Roussel Ltd.*[122] exemplifies the potential breadth of effect that a court decision can have upon patent rights over a biotechnology invention. In *Kirin Amgen* the *House of Lords* construed claims over a gene and accepted the finding of the *English Court of Appeals* that held, "*to seek to monopolise use of the sequence when not isolated by inserting a construct into a human cell would provide a monopoly not properly supported by the description in the specification.*"[123] The *House of Lords* limited the viable patent monopoly solely to isolated genes. *Kirin Amgen* stands as a precedent decision which affects the construction of claims in other patents which were drafted in a like manner, and causes the patent scope of those other patents to be similarly limited. As such, a decision such as Kirin Amgen, has the potential to "*change research priorities and force firms to (re)consider their research and commercialization priorities.*"[124] Post-*Kirin* future patent applicants will likely alter their claims as a result of the decision. Thus, *Kirin* also exemplifies how changing a protection strategy partway through the emergence of a technology can create a gap between protection granted to technologies within the same category according to the date when protection is sought.

Furthermore, confusion about adequate IP protection may be caused by the availability of multiple forms of IP regimes to protect a single category of technology. An example of this situation is evident in the software sector. Software inventions are protectable both by the copyright and patent regimes. The relationship between these two forms of protection was unclear when software was first gaining a foothold in the marketplace. Since time is of the essence for patenting, due to the first-to-file rule, it is not surprising that early in the emergence of software no one took the time to complete a comprehensive analysis of the relationship between the regimes and to determine how to achieve the optimum IP protection for software innovations. The result is that this area of IP protection is still a bone of contention for some and a source of confusion amongst scholars and industry.[125]

Achieving tailored IP protection is of the utmost importance to PDVs and should be addressed now while they are still an emerging category of technology. PDVs bring together many elements into a single invention and, like software, are therefore rife with confusion. Even the

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122 [2004] UKHL 46.

123 [2002] EWCA Civ. 1096, at para. 60.

124 Peter W.B. Phillips, "Agriculture: Farmers, Agrifood Industry, Scientists and Consumers", Proceedings of the Canada-United States Law Institute Conference on Multiple Actors in Canada-U.S. Relations, Cleveland, Ohio, April 16-18, 2004, Can.-U.S. L.J., n°30, 2004, p. 273 at 284.

125 Karen Lynne Durell, "Intellectual Property Protection for Computer Software: How Much and What Form is Effective?", Int'l J.L. & I.T., n°8, 2000, p. 231.

form of patent applications that should be filed for PDVs is an important issue, as the choice can have a variety of implications depending on which aspects of the innovation are disclosed. Moreover, there may be additional filing steps that relate to some elements of PDVs. As has been discussed, biotechnology applications may require supplemental filings, such as nucleotide sequence lists, or biological material deposits to be considered complete; whereas the drug element of PDVs may require NOC listings to truly be effective in the marketplace. It is an unavoidable fact that much information and many issues must be weighed to determine the IP rights to be granted to PDVs. All forms of protection available to PDVs as well as the issues raised by each relevant to the category of technology must be assessed in order for comprehensive IP protection to be achieved.

Due to the fact that an attempt to change a protection strategy for a category of innovation after it is entrenched can be very difficult, analysis should take place as early as possible. Waiting for the courts to point out mistakes many years down the road is too late to for effective change to occur. In fact, such an initiative may be likened to trying to patch a dam while water is running over it – a task that will never be perfectly achieved. In light of this fact, it seems obvious that continuing to allow pioneer inventors to devise a protection strategy for a new category of technology is inadvisable. Inventors do not necessarily collect all of the relevant information before implementing a strategy. Now is the time to develop another approach.

Part IV – proposed approach for IP protection for new technologies

It is a well-established principle that IP protection must be supported by effective regulation and that such regulation must be derived as a result of well-informed and thoughtful analysis.[126] In light of this accepted tenet we must ask; should there not also be a concentrated effort to study the best IP protection for new technologies as they emerge? Recognizing that the inventor does not necessarily have the expertise or information to fully analyze all of the issues relevant to IP protection for a new category of technology, it seems to make sense that someone else take on this role.

An upfront approach to planning IP protection strategies for new technology categories may avoid the exploitation of a invention and undue monopolization of a market sector, a present plague occurring internationally.[127] A proactive approach may also reverse the lag in legislative response to scientific change, which currently creates gaps in protection.[128] The act of merely "gap-filling" has been noted as dangerous because this type of action does not promote a coherent scheme and may even "*choke the very innovation it was meant to nourish.*"[129] Clearly addressing IP protection early is key.

The foregoing leads us to the conclusion that questions of how to instigate the analysis and who should undertake it are critical. Looking at the situation in practical terms, it would seem that

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126 Timothy Caulfield, "Underwhelmed: Hyperbole, Regulatory Policy, and the Genetic Revolution", McGill L.J., n°45, 2000, p. 437 at 440.

127 *Supra* note 124 at 283.

128 *Supra* note 31 at 963-965. Halewood provides several examples of instances when intellectual law lags behind advancing technology, including UPOV provisions that plant varieties be essentially derived from existing varieties, and geographical indications which reward the standardization of production techniques and thus, old ties rather than innovative advancements.

129 Jay P. Kesan and Thomas S. Ulen, "Intellectual Property Challenges in the Next Century", U. Ill. L. Rev., 2001, p. 57 at 59.

analysis may be best instigated at the patent office level. Nowadays, it can be assumed that most inventors seek patents, due to the potential economic incentives offered by that form of protection. Thus, the patent office is a logical place to set-up a means of identifying new categories of technology. Identification could be easily undertaken if upon the receipt of a patent application that discloses a new category of innovation, one which has never been dealt with previously, the patent office flags the application.[130] The act of flagging an application would then be followed by a meeting of a review panel, having members representing expertise in the traditional categories of innovation which are covered by the patent application – e.g., for PDVs biotechnology, plants, drugs, developing nation products – as well as IP law.[131] The panel would then review the innovation and analyze the IP protection options which are open to the new category of technology it represents. Ultimately the panel would create a set of guidelines which would set-out how innovators in the field should protect their inventions. The guidelines would address a best method of protection, considerations relating to protection of specific aspects the new technology, as well as the relationship between forms of protection and elements of the technology. The guidelines would not necessarily be binding upon innovators but would primarily provide an educational tool. Inventors would thereby be provided with information they may not have been privy to otherwise about relevant issues that should influence the development and application of IP protection strategies.

Obviously an immediate, first-response objection to this proposal is that invoking an expert panel and the process of analysis is time-consuming. However, as it takes several months before a patent application reaches the examination stage, the option of convening a panel prior to commencing patent prosecution should not be too onerous. To aid in this endeavour a list of qualified persons would be kept in the patent office and panel members would be chosen therefrom, according to the expertise required to address a category of invention. Moreover, applications for other inventions fitting within the new category would be subsequently flagged and none would be examined prior to the creation of the guidelines. All applicants will thereby be kept on an even playing field.

Deliberations of the panel will be related to the new category of invention, rather than a specific invention disclosed in a flagged patent application. The flagging of a patent application upon receipt is merely a means of triggering a panel. A second method of instigating a panel review may be applied as well. Inventors who realize that they will likely be interested in filing a patent application for a new category of innovation in the near future, could provide the patent office with the relevant details about the technology and request that a panel be convened prior to the filing of the patent application. In the implementation of either option, the goal is early detection.

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[130] New categories of innovation should not be mistaken with new inventions. Every patent application is required to disclose a novel invention. New categories of innovation refer to groups of innovations based upon a technology that is distinct from prior existing categories.

[131] The panel members would be expected to have expert credentials in either a particular field of research or a form of intellectual property. Both forms of expertise should be represented as their deliberation will address issues related to the innovation category as well as the forms of intellectual property available. This being said the number of people involved in a panel should be kept to a minimum to avoid long drawn out deliberations. Richard E. Gold has proposed the implementation of a panel to determine intellectual property issues in the context of specific technologies for another purpose and makes an important point that is relevant to the proposed panel of this paper, not only scientists or academics should be represented on the board, see Richard E. Gold, "Biomedical Patents and Ethics: A Canadian Solution", McGill L.J., n°45, 2000, p. 413 at 421. Ideally the panel would have representatives from legal practice, scientific research, industry and academia represented.

For the purposes of this paper, the most important aspect of this proposal is that it is a proactive solution. One which attempts to address issues relevant to new categories of technology in an enlightened manner before other less-considered means of protecting those innovations and of thinking about those innovations become entrenched. To formulate guidelines, experts will sit down together and address the nature of a new technology before problematic practices become the standard. The effectiveness and importance of panel deliberations has been cited in the context of other technology policy initiatives.[132] As complex inventions, such as PDVs, do not fit existing IP protection moulds, they therefore require concentrated analysis to achieve a comprehensive approach recognizing the unique aspects of their nature. Moreover, reviewing a new technology in the early stages of its emergence is crucial because it ensures that the law of IP protection is "*(re)connected to mainstream principles about technology*."[133] In sum, a proactive approach does not only facilitate appropriate IP protection, it also aids the continuation of a balanced and cohesive IP approach in Canada.

Conclusion

PDVs are hailed as a new category of technology which promises to effectively combat disease worldwide through the provision of a cost-effective and easy to administer vaccination product. Whether PDVs actually fulfill their promise will be determined to some extent by the IP protection strategy that is applied to this class of technology. Due to their varied nature PDVs will be forced to cut their own protection path and will be unable to fit entirely within any existing category of technology. IP protection for PDVs must recognize the established technology categories relevant to PDVs – plants, drugs, biotechnologies and developing nation products – as experiences gleaned from each of these categories are instructive to PDV protection deliberations. However, as PDVs combine these categories in a single product, consequently forming a new category of technology, PDVs will have to forge their own way to achieve appropriate IP protection.

As we may consider ourselves to be forewarned that PDVs will raise unique issues and require a distinct protection strategy, it seems obvious that action should be taken to determine the best method of IP protection for PDVs as soon as possible. Establishing guidelines early will avert gaps in protection down the road, which may occur should it be left to inventors to create a strategy and courts to modify it after it is entrenched. A further aspect of proactive PDV analysis which should be implemented to formulate protection guidelines is expert opinion. The strategy of giving inventors full-rein over the establishment of protection strategies poses the risk that the resulting solutions may be clouded by superfluous concerns, or a lack of information. The fallout from subjecting PDVs to inappropriate protection could be problematic on a number of levels, due to the complexity of the technology. The protection of a technology with so much potential should not be left to chance or in inexpert hands. PDVs exemplify a category of technology that, not only would benefit from, but basically cries out for, a comprehensive, informed, tailored approach to the implementation of an IP protection strategy. PDVs are an emerging innovation and a new category of technology, the time to act is now.

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[132] "Edited and excerpted transcript of the symposium on the law and technology of digital rights management", February 28 and March 1, 2003, Berkeley Centre for Law and Technology, Berkeley Tech. L.J., n°18, 2003, p. 697, at 755.

[133] *Supra* note 129 at 62.