Intellectual Property Issues in Agriculture and Agri-Foods

VALGEN

While discussion continues on how best to balance the interests of Canadian farmers (conventional and organic), consumers and industry, Canadian laws and regulatory processes introduce significant uncertainty that diminishes investment and fails to adequately protect the average Canadian. Uncertainty exists with respect to the incentives underpinning research and development, the ability to put new products on the market and the extent of liability when something goes wrong. This backgrounder briefly describes uncertainties that relate to intellectual property in agricultural research and development in particular and the impact of that uncertainty on Canadians and the Canadian economy.

Research and development in the agricultural field is driven both by public and private investment. While the public sector directly funds research at universities and indirectly, through tax credits, within firms, the private sector invests in bringing new products and services to market. One of the tools it uses to do so is intellectual property rights, chiefly patents (we leave aside plant breeders rights since these are rarely used, especially for food or in industrial agriculture). A patent provides its holder with the right to make, use, sell or import an invention for a period of 20 years. Patents are granted on a country-by-country basis and are only valid within that country. Canadian patents effectively protect both methods of making new agricultural products and the products themselves, for example, a grain or animal. While there are technical differences between Canadian patent law and that of the US and Europe, in practice Canadian law provides essentially the same level of protection for holders as does that of other countries. In sum, a Canadian patent provides the equivalent level of exclusivity in Canada as does a US patent in the US.

Both public and private sector research and development and the eventual transformation of that research and development into products and services face significant uncertainty in Canada. This uncertainty crosses the boundaries between questions of research and development, regulation of new products and liability for harm suffered. While we concentrate here on patents, we note that even ten years ago, industry heads in animal biotechnology told the Canadian Biotechnology Advisory Committee that the biggest impediment they faced was the uncertainty caused by the lack of regulations concerning the disposal of waste materials from genetically-engineered animals and the regulation of the sale and use of those animals.

Uncertainty causes underinvestment in research and development as well as the introduction of new products and services onto the Canadian market. Firms either shy away from investing in agricultural biotechnology or hesitate before entering the Canadian market since uncertainty leads to delays and higher costs in trying to mitigate that uncertainty. Similarly, those potentially adversely impacted by the introduction of new technologies (e.g. the organic farmers in *Hoffman*) suffer by not knowing whether and how they might be compensated under Canadian law. Thus, uncertainty is not only a drag on the Canadian economy, it undermines the ability to ensure a fair distribution of the costs and benefits of innovation.

Uncertainty comes in different forms and uncertainty touching on research and development of new agricultural products takes virtually all of these forms.

First, uncertainty takes the form of risk when we know the probabilities of an event happening and its positive and negative consequences but we do not know whether that risk will manifest itself in a particular situation. In the case of patent law, risk comes about in the following ways:

- Just because a patent has been issued in Canada, does not mean that it is valid. One study from the US concluded that courts adjudicating disputes found almost half of all challenged US patents invalid. With

rapid changes in our understanding of genetics and of the possibilities for agricultural biotechnology, the risk that an issued patent will be found invalid is significant. This has two consequences. First, it may result in underinvestment since patent holders may not feel that their patents provide them with enough security. Second, and perversely, this risk may also result in farmers and other researchers refraining from doing perfectly legal activity out of fear that an otherwise invalid patent will be used against them. Given that the cost of patent litigation is very high – at least $2 million per side – the uncertainty over patent validity is a concern both for industry and for farmers. The best way to reduce this risk is to ensure that the Canadian Intellectual Property Office has the resources (financial and human) to properly assess applications before granting a patent.

- There is also a risk that infringement of a patent right – for example, the unauthorized planting of patented canola – will not be detected. This risk leads to leakage that reduces the return on investment to those who invested in the development of the canola. It also increases the risk that certain individuals will plant, without authorization, seed that is covered by a patent. Generally, the very strong enforcement mechanisms in the Patent Act that allow the patent holder to obtain an injunction or damages mitigate this risk.
- A third example of risk is where the creator of a new seed or animal wishes to place that seed or animal on the market but is concerned that a third party patent holder may sue him or her for patent infringement. In an area with many patents covering both methods of production and use of seed and animals, this risk is high. Few companies have the means to either negotiate licences from all those who hold patent rights or to infringe patents and pay out damages after. In Canada, this has resulted in only a few, very large, companies having sufficient 'freedom-to-operate' to sell products in Canada. Any innovator would have to pass through one of these companies, leading to less variety in products and at higher costs. A solution to this problem is to create freedom-to-operate through industry-wide cross-licensing and stronger enforcement of competition law.

Second, uncertainty can take the form of knowing the possible harms that may result from an activity – say the introduction of a new plant or animal into the environment – but not knowing the likelihood of that harm occurring. For example, when genetically modified canola was introduced onto the Canadian market, it was known that there was a strong likelihood that the canola would adventitiously grow outside the designated field. What was not known, as illustrated in the Saskatchewan Court of Appeal case of *Hoffman*, was the size of that risk. Without knowing the probability of risk, we may spend too much trying to avoid it or, conversely, not take measures to lower the probably of risk to acceptable levels.

Third, uncertainty may take the form of ambiguity, meaning that we disagree on how to measure harm. This problem frequently arises when universities and small firms try to place a value on their innovations. Given that this usually occurs at a very early stage of development – before the product is on the market – the problem is notoriously difficult. Because of this uncertainty, universities and small companies must usually license their innovation at low rates of return. One way to limit this problem is to encourage the creation of partnerships between universities and industry to develop products further so that the distance to market is lessened. When this occurs, traditional means of valuing seed or animals can be used.

Another example of ambiguity is the Canadian rules over the calculation of one form of remedy for patent infringement: an accounting of profit. This remedy permits a patent holder to receive the financial benefit that an infringer made as a result of an unauthorized use of the invention. In many cases, it will be difficult for a patent holder to prove that he or she lost a certain amount but relatively easy to calculate the infringer's gains. Under a series of cases by the Supreme Court of Canada (*Monsanto v. Schmeiser)* and the Federal Court

of Appeal (*Rivett v. Monsanto*), however, these rules are unclear and internally inconsistent. This may lead to either overcompensation or undercompensation for the patent holder. The inability to determine the consequences of infringement will likely result in underinvestment in new technology by patent holders and farmers.

A fourth form of uncertainty manifests itself when decision-makers do not have complete knowledge about the types of harm that may result. This frequently occurs in court decisions about, for example, patent validity, given the lack of scientific expertise on the bench. While judges do their best to understand the underlying science, they make errors – sometimes assisted by the parties or despite the parties' best efforts. One way of minimizing these errors is to introduce, as in Europe, an opposition procedure within the Canadian Intellectual Property Office to challenge patents. Those who are knowledgeable about the science would oversee the procedure and would thus be less likely to err in evaluating, for example, the novelty of an invention.

The fifth type of uncertainty occurs in cases in which there is a fundamental disagreement over the principles and values underlying a question. This indeterminacy occurs when those designing policy – for example, in respect of the transfer of university research to the private sector – fail to understand the dynamics of innovation. The result of this error is the creation, as in Canada, of policies that encourage universities to seek patents when, in fact, both universities and industry may better benefit from working together without the obstructive influence of patents. These types of errors are best addressed through education about science, technology and the social institutions through which research and development takes place as well as increased opportunities for public engagement.

Uncertainty diminishes the value that Canadians can derive from new innovations in the agricultural sector. All actors – universities, industry, farmers, consumers and civil society – suffer when uncertainty leads to lessened investment and less protection from harm. While many, if not most, forms of uncertainty fall outside of the capacity of the legislative process to cure, acknowledging their different forms and concrete effects is a first step to addressing them.

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Value Addition Through Genomics and GE^{3}LS (VALGEN) is a group of Canadian researchers with international partners investigating how Canada can benefit from applications of agricultural genomics, a new science which studies the effects of the entire set of genes making up a particular organism such as our familiar crops of wheat, flax, canola and corn. The project focuses on three crucial factors that affect how scientific discoveries make their way from laboratory to the marketplace. These are democratic engagement (the attitudes of the Canadian public with respect to new agricultural products and opportunities for them to participate in decision-making) governance and regulation (methods of better governing the production and use of new agricultural products) and intellectual property (in particular, collaborative mechanisms through which universities and industry can develop new agricultural products that meet the needs of Canadians). VALGEN is funded by Genome Canada with contributions from its partners which include the Government of Saskatchewan, Western Economic Diversification, Genome Prairie, Genome Alberta, Genome BC, Genome Quebec, the Canola Council of Canada, and SRC Holdings Ltd. None of the core VALGEN researchers is paid out of VALGEN funds.