THE INTELLECTUAL PROPERTY–REGULATORY COMPLEX

OVERCOMING BARRIERS TO INNOVATION IN AGRICULTURAL GENOMICS

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Introduction

EMILY MARDEN, R. NELSON GODFREY, AND RACHAEL MANION

In recent years, the lack of success in translating significantly funded research insights into commercial products has been the subject of much discussion among policy makers, researchers, analysts, and funders. This concern has been voiced across the spectrum of genomics research, where significant investments in research have yet to generate the rates of return – in terms of identifiable economic measures – that were initially expected. This volume addresses this issue specifically in the agricultural arena with respect to potential causes of difficulties in translating funded agricultural genomics research into socially beneficial products.

Stakeholders and academics have identified many challenges to translating agricultural innovation arising from genomics research into products for end-users. Broadly speaking, such challenges include, but are not limited to, the cost of sustaining genomics research for the duration of time it takes to translate an innovation into a useful product; an inability in some cases to access inputs that are necessary for development but are protected by intellectual property (IP) rights; complex biosafety regimes that make any required product approvals expensive and difficult to obtain; and uncertainty about the market acceptance of innovations in light of sustained opposition to genetically modified organisms (GMOs) in agriculture. All of these issues have been explored in the past. To date, however, little attention has been paid to the particular challenges facing innovations arising specifically out of

agricultural genomics beyond GMOs. Even within that context, less attention has been paid to the overall significance of what we call the "Intellectual Property–Regulatory Complex" or the "IP–Regulatory Complex."

In our view, the IP–Regulatory Complex refers to the sum total of domestic and international intellectual property and biosafety regimes pertaining to agricultural genomics, which operate independently of, and, more often than not, in tension with one another. We believe that the IP–Regulatory Complex materially impacts outcomes of (and funding for) innovation in agricultural genomics in ways that cannot be fully appreciated when examining intellectual property or biosafety regimes in isolation. In our view, without a full appreciation of the IP–Regulatory Complex, it will be difficult to address the potential barriers to implementing innovations in agriculture. This volume is intended as a first step in that conversation.

The IP–Regulatory Complex takes into account both IP and biosafety regimes. Within this context, IP refers to legal mechanisms for protecting and incentivizing innovations in agricultural genomics, which coexist with counter-movements to the proliferation of global intellectual property regimes, in the form of sharing regimes and mechanisms. Biosafety, in turn, refers to the regulatory regimes developed to ensure the human or environmental health and safety of innovations introduced into domestic or international agriculture. IP and biosafety regimes are distinct legal entities and are thus treated as distinct subjects in academic spheres and policy discussions. In reality, however, intellectual property and biosafety regimes *collectively* impact incentives for and potential outputs of agricultural genomics research and investment. Ultimately, as discussed in the chapters in this volume, the net collective impact of the relevant IP and biosafety mechanisms may actually run counter to the policy intent of a single IP or biosafety regime or framework. Furthermore, the net effect of the IP–Regulatory Complex as a whole may not be taken into consideration when research is funded, with the result that when innovations emerge or are intended for global use, initial assumptions made in the context of IP or biosafety may prove to be inadequate. Ultimately, a lack of appreciation of the IP–Regulatory Complex may frustrate uptake of genomics research.

When we speak of the IP–Regulatory Complex in this volume, we refer to the full range of domestic and international IP or biosafety regimes that govern innovations arising from agricultural genomics. Thus, in terms of biosafety regimes, the IP–Regulatory Complex includes domestic approaches, such as Canada's Plants with Novel Traits (PNT) regime (discussed in more detail in Chapter 1) as well as process- or product-based

approaches in other jurisdictions. Many of these biosafety regimes were shaped, at least in part, as a response to perceived issues raised in the context of agriculture by recombinant technologies, or GMOs. Because national regimes take different approaches to biosafety regulation, the resulting domestic regulatory frameworks can be inconsistent with one another, both conceptually and often, as discussed in more detail in Chapter 4, in their application. Further, these domestic regimes sit within an international framework shaped by the *Convention on Biological Diversity* (CBD), discussed further in Chapter 1, which specifically allows for widely divergent application of biosafety principles. Taken together, the variability among biosafety regimes can greatly complicate efforts to develop and bring an innovative product to market.

These biosafety regimes coexist with myriad IP regimes that also impact the translation of innovations arising from agricultural genomics, but the two regimes were not developed to complement each other. In fact, the existence of IP regimes applicable to plants and agriculture represents a relatively recent legal development. For many years, proprietary rights for agricultural innovations were generally regarded as unavailable because germplasm was presumed to be a communal resource to be freely shared.[1] Thus, for most of recent history, agricultural practices permitted – and even expected – the saving and replanting of seeds and their sale to other farmers.[2] It was not until the development and widespread use of hybridization techniques[3] in the early twentieth century and the growth of a more robust seed industry that proprietary protections and in-kind responses to such protections became available for agriculture (Kloppenburg 1988, 11).[4]

With respect to proprietary rights, the *International Convention for the Protection of New Varieties of Plants* (the UPOV Convention) was signed in 1961 and adopted by most large agriculture- and seed-producing nations. Under the UPOV Convention, member nations are required to adopt legislation that institutes proprietary protection for all plant "varieties"[5] that are new, distinct, uniform, and stable (Article 5[1]).[6] Many countries have developed plant variety protection regimes that largely reflect the UPOV Convention provisions, although there is some diversity among them in the version of the convention adopted, and hence in their associated breeder's rights and farmer's privileges. Although conventional patent regimes have generally not been interpreted to be applicable to plants, a few countries, including the United States (as discussed further in Chapter 1), have deemed plants to be patentable subject matter. In these countries, then, plant variety and plant patent protection are both available.

At the same time, there are distinct international regimes that enshrine practices of sharing of germplasm in agriculture. Toward this end, the CBD and the *International Treaty for Plant Genetic Resources for Food and Agriculture* (ITPGRFA), discussed in greater detail in Chapter 5, expressly recognize the importance of proprietary rights in fostering innovation, particularly national proprietary interests in domestic genetic resources. In some cases, these mechanisms mandate the sharing of innovations derived from agricultural resources in a manner that may work at cross-purposes with proprietary IP protections (Marden and Godfrey 2012). The source of germplasm used for an innovation in agriculture can determine whether and to what extent proprietary protections are available, or whether, conversely, the innovation must be shared in a manner consistent with the CBD and the ITPGRFA.

Ultimately, to translate an innovation arising from agricultural genomics into the commercial sphere, the researcher or developer must come to terms with both biosafety regimes and IP regimes in jurisdictions of interest. This is no simple task. Each of the many domestic and international biosafety and IP regimes was developed in a certain context with a particular purpose at a specific time, resulting in layers of obligation and effect that stakeholders in the agricultural arena must address.

This volume represents an effort to arrive at a baseline understanding of the IP–Regulatory Complex, in terms of both its origins in the byzantine map of biosafety and IP regimes and its effects on innovation in the agricultural genomics arena. The contributors identify and examine aspects of these multiple regimes within the IP–Regulatory Complex that may affect agricultural genomics research. They also discuss how intellectual property and regulatory regimes may be viewed cumulatively as elements of the IP–Regulatory Complex, and speculate on impacts of the IP–Regulatory Complex on innovative research in the genomics space and the distribution of genomics products; in some cases, GMOs are used as a point of reference as such innovations have been present in the market and in the innovation cycle for a sustained period. With this understanding of the IP–Regulatory Complex as the foundation, solutions are proposed to facilitate greater efficiency in meeting the aims of IP and regulatory regimes while enabling innovative research (Chapters 7 and 8).

Part 1 of this collection articulates the concept of the IP–Regulatory Complex and introduces the current challenges posed by it. In Chapter 1, Emily Marden, Robert Nelson Godfrey, and colleagues review selected IP and regulatory regimes that may impact development of agricultural

genomics products in the context of a publicly funded sunflower genomics project. They also discuss the challenges that the Canadian and international IP and biosafety regimes pose to such a project, one goal of which is to develop a sunflower intended for use in the developing world as an improved source of both food (from the plant's oil) and fuel (from a woodier stalk). The contributors to Part 1 also discuss regulatory instruments in the context of genomics and issues surrounding the translation of research into useful products. Building on the discussion of the potentially complicating role of biosafety regulation, they provide perspectives on the relevance of regulatory regimes to the development of genomics products, drawing on experiences with genetically modified organisms in particular.

In Chapter 2, Sarah Hartley provides a historical description of the development of Canada's regulatory framework for agricultural biotechnology. She reveals how regulators privileged science-based risk assessment to the exclusion of assessment strategies and perspectives incorporating social and ethical issues in agricultural biotechnology research. She discusses the important role of ethical considerations when making policies about agricultural genomics technology. As genomics research leads to the development of new avenues in agricultural biotechnology, different social and ethical issues may arise and present new challenges to exclusively science-based risk assessment approaches. According to Hartley, where the federal regulatory framework fails to provide a venue for considering such challenges at an early stage, the robustness and legitimacy of the regulatory regime will be undermined, even as it strains to incorporate newly developed genomics techniques and technologies.

In Chapter 3, Gregory Graff and David Zilberman explore the incentives for innovation created by the IP–Regulatory Complex. They discuss how IP and regulatory systems mutually reinforce one another, and how they can extend the control of a few innovators and favour large markets. The analysis is informed by an empirical study of products of agricultural genomics research that meet a notional definition of "social benefit," such as crops having drought and other stress tolerance traits, crops with improved nutritional content, and crops for clean energy – all of which are areas in which the authors note promising recent endeavours. In order to better understand how to incentivize the development of these socially beneficial crops, the authors explore the impact of the IP–Regulatory Complex on the choices of which crops and traits get developed in the absence of the same profit incentives offered by major crops.

Importantly, as Ron Herring makes clear in Chapter 4, the existence of a regulatory regime per se may have limited impact on how products are adopted and used in any given context. He explores the powerful biopolitics surrounding the commercial introduction of genetic technologies in the developing economies of India and Brazil. He also discusses the impact of a wide array of stakeholders, events, and decisions on the development of local biosafety and bioproperty regimes in India and Brazil. In those countries, the desire of farmers for a cheap alternative to *Bt*– and Roundup Ready–modified crops led them to import, exchange, and use "stealth seeds," which were modified to contain the desired traits despite the regulatory and IP regimes enacted to prevent such activity, thereby undermining the capability and legitimacy of those regimes.

Chapter 4 provides a reality check to debates over policy making for socially beneficial biotechnology and genomics products. Rural farmers are often represented in the discussions that shape such policies, but Herring points out the disconnect between the poor farmer and the activist who claims to represent her. Furthermore, Herring's observations on the flourishing trade involving stealth seeds in India and Brazil raise important questions about the practicality and power of biosafety regimes on the ground in developing countries.

Similar to biosafety regulation, current IP mechanisms are particularly relevant to emerging research in genomics. The chapters in Part 2 provide important perspectives on intellectual property elements of the IP–Regulatory Complex: that of the innovative entity seeking to manage its intellectual property in a global marketplace, and that of the countermovement toward seed sharing and the relevance of the ITPGRFA toward that end.

In Chapter 5, Chidi Oguamanam discusses the implementation experience of the ITPGRFA and associated regimes. He reviews the treaty's major contributions to the existing policy landscape in areas including biosafety, intellectual property, and access and benefit sharing. He takes the position that the treaty and related regimes help to moderate or balance the generally restrictive effects of intellectual property regimes; provide an as yet untested opportunity for greater access to and benefit sharing of innovations and profits in emerging fields, including agricultural genomics; and incentivize research for socially beneficial purposes.

In Chapter 6, Jeremy Hall, Stelvia Matos, and Vernon Bachor analyze the commercialization of genetic technologies in India and Brazil, in the process critiquing intellectual property protection strategies employed by

biotechnology firms in those countries. They suggest that the firms that led the commercialization of transgenic technology in Brazil and India employed IP management strategies that failed to adequately consider both cognitive and socio-political legitimization processes. They also suggest that the institutional policy framework surrounding agricultural biotechnology is complex, with numerous stakeholders representing varied interests throughout. Applying the experience of biotechnology firms to the emerging field of genomics research and commercialization, Hall and colleagues conclude that early-stage IP management strategies – considering not only economic viability and commercial feasibility but also issues relating to social legitimacy and institutional differences – are necessary to assist in the diffusion and commercial adoption of next-stage technologies.

In light of the complicated interactions between composite biosafety and intellectual property regimes observed in Parts 1 and 2, the chapters in Part 3 recommend strategies for overcoming some aspects of the IP–Regulatory Complex. The diverse nature of the proposed solutions and the target audiences of the chapters reflect the intricate entanglements of the international and domestic IP and biosafety regimes that comprise the IP–Regulatory Complex.

Building on many of the democratic deficits noted by Sarah Hartley in Chapter 2, Regiane Garcia discusses the limitations of the current approach to technical and scientific regulation in Chapter 7. She describes the policy decisions in the current approach as made by experts to the exclusion of the concerns of many stakeholders and citizens, and raises the question of whether regulatory approaches to biotechnology and genomics should be fundamentally retooled in order to be more democratic and inclusive. Drawing on her background in public health policy and governance, Garcia contrasts the classic "regulatory" model with a "new governance" approach to regulatory policy making, and recommends the European Union's *Water Framework Directive* as a possible model for genomics policy that is more in line with the "new governance" approach to policy making.

Finally, in Chapter 8, Rochelle Dreyfuss examines the discordant elements of domestic and international IP regimes as they apply to products of agricultural genomics research. She notes the difficulties in balancing interests in a domestic IP regime, a problem that is compounded in the international arena, where international IP agreements are often conceptualized and concluded in the context of trade discussions. Building on her work with Graham Dinwoodie titled *A Neofederalist Vision of TRIPS: The Resilience of the International Intellectual Property Regime,* she reviews

the core principles that emerge when the IP system, as it applies to agricultural genomics research, is viewed holistically. She suggests that such an approach could preserve national flexibilities in IP law and contribute to a more internally harmonized IP system, where policy makers and decision makers have a more informed understanding of the balance struck between different interests and the flexibilities available in making policy. Dreyfuss suggests that flexibilities in national IP regimes could, in turn, provide mechanisms to balance the impacts of biosafety regimes on products of agricultural genomics research.

Taken together, these chapters present domestic and international regulatory and IP regimes as intimately intertwined. Without a deeper appreciation of the impact of the IP–Regulatory Complex on the development of agricultural genomics products, reforms to each regime alone may not achieve the intended social benefits, and the promise of these technologies may not be fully realized.

Notes

1 Originally the patent system was viewed as an inappropriate restriction on plant life (Llewelyn 1997). The historical role of intellectual property in agriculture was its application to mechanical inventions. Protection of plant varieties developed only recently, and was shaped by the prevailing economic conditions of developed countries (Commission on Intellectual Property Rights 2002). See also Pray and Naseem 2003, which describes the shift from public investment (for the public good) in agricultural research to private (for-profit) investment, and its direct impact on how developing countries access agricultural technology, especially seeds, which they have traditionally accessed through sharing or saving methods.

2 The historical practice of seed saving was a fundamental tenet of agriculture with far-reaching cultural significance (Belsie 1998); see also Weiss 1999 for a description of the role of the United States Department of Agriculture, land grant colleges, and extension services in development of new seed varieties. This research was publicly financed and patents were seldom sought or enforced.

3 "Hybridization, or scientifically combining and breeding seeds, was the first method by which companies were able to control replanting of seeds. For the first time, farmers were able to purchase improved seeds for a better crop. The drawback was that the second generation of crops did not fare as well as the first generation" (Stein 2005).

4 Stein (2005, 164–68) traces the private industry and judicial influences in the development of modern proprietary protections.

5 "Variety" is defined as "a plant grouping within a single botanical taxon of the lowest known rank, which grouping … can be defined by the expression of the characteristics resulting from a given genotype or combination of genotypes, distinguished from any other plant grouping … and considered as a unit with regard to its suitability for

being propagated unchanged" (UPOV Convention, Article 1[vi]). It is worth noting that rights under the UPOV Convention extend to all novel varieties that meet the criteria, regardless of how they are derived, and are thus relevant for varieties characterized by or developed through genomics techniques and/or biotechnology (see Article 5).

6 To be "new," a plant variety cannot have been offered for sale or marketed earlier than one year before the application for protection is filed in the source country, or for a period longer than four years in any other country (UPOV Convention, Article 6[1]). To be "distinct," the variety must be "distinguishable from any other variety whose existence is a matter of common knowledge" anywhere in the world (Article 7). Varieties that are "common knowledge" are defined rather simply as any plants that meet the definition of "variety" in Article 1(vi), and includes varieties that have not obtained protection according to the UPOV Convention (International Union for the Protection of New Varieties of Plants 2002). To be "uniform" and "stable," the variety's relevant characteristics must remain true and sufficiently uniform on repeated propagation, subject to the variation that may be expected due to the particular features of its propagation (Articles 8 and 9). See also Dutfield 2008, 35, explaining that "the uniformity requirement also shows the specific nature of the UPOV system, since this requirement cannot practically be the same for species with different ways of reproduction."

References

Treaties and Agreements

International Convention for the Protection of New Varieties of Plants, December 2, 1961, 815 U.N.T.S. 89 (as revised at Geneva on November 10, 1972, on October 23, 1978, and on March 19, 1991) [UPOV Convention].

International Treaty on Plant Genetic Resources for Food and Agriculture, adopted November 3, 2001. S. Treaty Doc. No. 110-19 [ITPGRFA]. ftp://ftp.fao.org/docrep/fao/007/ae040e/ae040e00.pdf.

Secondary Sources

Belsie, Laurent. 1998. "Plants without Seeds Challenge Historic Farming Practices." *Christian Science Monitor,* July 30, 1998. http://www.csmonitor.com/1998/0730/073098.feat.feat.6.html.

Commission on Intellectual Property Rights. 2002. *Integrating Intellectual Property Rights and Development Policy.* London: Commission on Intellectual Property Rights. http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf.

Dutfield, Graham. 2008. "Turning Plant Varieties into Intellectual Property: The UPOV Convention." In *The Future Control of Food: A Guide to International Negotiations and Rules on Intellectual Property, Biodiversity and Food Security,* ed. Geoff Tansey and Tasmin Rajotte, 27–47. London: Earthscan.

International Union for the Protection of New Varieties of Plants. 2002. *The Notion of Breeder and Common Knowledge,* C(Extr.)/19/2 Rev., Annex, paras. 22–24 (August 9, 2002).

Kloppenburg, Jack Ralph Jr. 1988. *First the Seed: The Political Economy of Plant Biotechnology, 1492–2000.* New York: Cambridge University Press.

Llewelyn, Margaret. 1997. "The Legal Protection of Biotechnological Inventions: An Alternative Approach." *European Intellectual Property Review* 19 (3): 115–27.

Marden, Emily, and R. Nelson Godfrey. 2012. "Intellectual Property and Sharing Regimes in Agricultural Genomics: Finding the Right Balance for Innovation." *Drake Journal of Agricultural Law* 17 (2): 369–93.

Pray, C.E., and A. Naseem. 2003. *The Economics of Agricultural Biotechnology Research.* ESA Working Paper No. 03–07. Rome: Food and Agriculture Organization of the United Nations.

Stein, Haley. 2005. "Intellectual Property and Genetically Modified Seeds: The United States, Trade, and the Developing World." *Northwestern Journal of Technology and Intellectual Property* 3 (2): 160–78.

Weiss, Rick. 1999. "Seeds of Discord; Monsanto's Gene Police Raise Alarm on Farmers' Rights, Rural Tradition." *Washington Post,* February 3, 1999. http://www.artsci.wustl.edu/~anthro/articles/monsanto1.html.

PART 1

PERSPECTIVES ON REGULATORY REGIMES

1

Biosafety and Intellectual Property Regimes as Elements of the IP–Regulatory Complex

The Case of Canadian Sunflower Genomics

EMILY MARDEN, R. NELSON GODFREY,
MATTHEW R. VOELL, AND LOREN H. RIESEBERG

In recent years, governments have made significant investments in genomics research on agricultural crops and species. For example, Genome Canada, a Canadian funding body instituted to develop and support Canadian-based proteomics and genomics research, has funded a number of large-scale projects to sequence the genomes of a wide array of species (Genome British Columbia 2013). The United States government has likewise funded genomics research programs on soy, corn, cotton, and wheat, among others, and government grants supporting plant genomics research have reached an all-time high (Waltz 2010, 10; National Science Foundation 2010). According to public researchers, industry leaders, and funders alike, the information resulting from these large-scale projects has the potential to jump-start innovation in agricultural genomics as well as accelerate developments in conventional breeding. Genomics data can lay a foundation of information useful for genetic engineering, but are not necessarily tied to it. Indeed, an understanding of a plant's genome can help scientists better understand the location of traits and thus enable more fruitful conventional breeding to yield desired traits. This research may generate insights that provide wider benefits both domestically and in developing countries.

Despite this significant public investment in genomics research on agricultural crops and species, relatively little attention has been paid to how existing legal frameworks affect the realization of national research goals. In particular, there has been minimal consideration of the collective role of

applicable biosafety and intellectual property (IP) regimes on product development in the agricultural genomics arena.

In general, biosafety regulations are directed toward ensuring the safe development and market entry of novel plant products. Intellectual property regimes have a different goal – that of creating property interests in innovative products in a manner that provides incentives for development and encourages access to these innovations by users. Yet, developers of new products must consider navigating both biosafety regimes *and* IP regimes while developing a strategy to make their innovations widely available (commercially or otherwise). Thus, to the extent that biosafety regulations add a complex set of approval obligations, IP regimes may be necessary to maximally capture value to deliver a return on investment. In an analogous fashion, it may be that where biosafety issues are minimal, a developer may opt to facilitate uptake through less proprietary approaches to IP. Throughout this volume, the net operation of biosafety and IP regimes *in toto* on a particular product (both national and international) is referred to as the "Intellectual Property–Regulatory Complex" or the "IP–Regulatory Complex."

In general, the academic literature has paid little attention to the impact of the Intellectual Property–Regulatory Complex on publicly funded agricultural genomics, particularly with respect to publicly funded projects that, unlike projects in industry, may lack the potential for significant economic return (whether in terms of domestic market return or because their products are intended primarily for export to developing countries). Moreover, where domestic or international regulatory or IP regimes have been analyzed, they have generally been analyzed separately rather than as constituent elements of an "IP–Regulatory Complex" that affects the development and delivery of such products.[1]

In this chapter, we provide an overview of selected international IP and regulatory regimes that may be applicable to the development of agricultural products arising from (largely publicly funded) genomics research. We then narrow the focus to similarly applicable IP and regulatory regimes in a particular nation – Canada – to illustrate how the complex of these regimes operates at the national level through the implementation of national policies corresponding to the international regimes. We draw on our own experience as the social science research team for a sunflower genomics project, where we have found that a putative dual-use food/fuel sunflower would face potentially insurmountable obstacles due to multiple layers of biosafety and IP regimes. The variety of national schemes that have been designed to

implement the key international instruments surveyed here is another element of the IP–Regulatory Complex that can complicate product development and increase upstream costs. A number of contributors to this volume have framed their analyses and case studies around Canadian policy choices, but other national approaches to IP and regulation of genomics and related products, and their relevance to the notional "IP–Regulatory Complex," are discussed where appropriate throughout this volume.

In the next section, we explore the nature of the sunflower, its importance as an agricultural/horticultural crop, and its potential as a socially beneficial dual-use food/fuel crop. Next, we introduce certain international legal instruments, comprising international regulatory and trade instruments, on the one hand, and intellectual property and related regimes, on the other. These regimes include a suite of World Trade Organization (WTO) agreements (foremost among them the *General Agreement on Tariffs and Trade* [GATT] and the *Agreement on the Application of Sanitary and Phytosanitary Measures* [SPS Agreement]); the *Convention on Biological Diversity* (CBD) and the *Cartagena Protocol on Biosafety* (Secretariat of the CBD 2000)*;* and, in the context of intellectual property, the *International Convention for the Protection of New Varieties of Plants* (UPOV Convention), the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS Agreement), and the *International Treaty on Plant Genetic Resources for Food and Agriculture* (ITPGRFA).

Following this, we review Canadian IP and regulatory regimes that may impact the approval of and protections available for agricultural products, as a case study of national policy making in the context of the foregoing regimes. These Canadian regimes include the following: in the biosafety context, the Plants with Novel Traits (PNT) and Novel Foods regimes under the *Seeds Act* and *Food and Drugs Act* and their associated regulations; and, in the context of IP protection, the *Plant Breeders' Rights Act* and case law pointing to the patentability of certain plant matter under the *Patent Act.* Finally, we offer some suggestions on the net effects of this multilayered legal landscape as a "complex" affecting the development and delivery of products arising from agricultural genomics research, particularly as it pertains to the development of the putative dual-use sunflower genomics product discussed earlier in the chapter.

Background

The common sunflower (*Helianthus annuus* L.) is a globally important oilseed, food, and ornamental crop. The species ranks eleventh among world

crops in terms of total acreage, with a farmgate value between US$7 billion and US$11 billion (Food and Agriculture Organization 2014).[2] Sunflower oil is considered to be a premium vegetable oil because of its high unsaturated fatty acid composition, high levels of vitamin E, and low linolenic acid content.

That the sunflower could also be a source of firewood or charcoal has only recently been recognized. The closest relative of the cultivated sunflower is a drought-tolerant annual species, the silverleaf sunflower (*Helianthus argophyllus*), known for its woody stalks that grow three to four metres tall and up to ten centimetres in diameter in a single season. Domesticated sunflower varieties with this trait would enable farmers to grow small, woody "trees" in a single year. The sunflower seeds could still be harvested for food, but the woody stalks could also be used for fuel. The wood is similar in quality to the wood of quaking aspen, suggesting that it could also serve well as building material or roof thatching.

The Genomics of Sunflower project, funded by Genome Canada and Genome British Columbia, is an international research program that aims in part to understand the genetics of wood formation in sunflowers and to develop woody sunflower cultivars that are well adapted to the conditions of subsistence agriculture. The wood-producing cultivars will be developed using traditional sexual breeding approaches, which may be accelerated through marker-assisted selection. Marker-assisted selection can also ensure that other chromosomal segments, which may have negative effects on seed or oil quality, are not accidentally introduced during the breeding process. The research team aims to direct germplasm from the most productive woody cultivars to several agricultural research institutes across sub-Saharan Africa for evaluation and distribution.

Although genetic analyses are well underway, no studies have been performed to determine whether there is a trade-off between wood production and yield or whether wood production would make wild sunflowers more weedy or invasive. It seems likely, however, that the diversion of energy from seed to stem development would lead to a reduction of oil yield in cultivated plants, as well as to reduced reproductive fitness in wild or weedy populations. Thus, while rates of hybridization between cultivated and wild sunflowers can be as high as 37 percent (Arias and Rieseberg 1994), and the fitness disadvantage of F1 hybrids is fairly small (Snow et al. 1998), researchers believe that wood-producing genes are unlikely to escape and spread because of their negative effects on fitness.

International Regulatory and Intellectual Property Regimes

The regulatory pathways required for approval of novel agricultural products are designed to achieve multiple, often conflicting ends. Thus, for example, Canadian regulation of novel agricultural products reflects both an attempt to minimize regulatory burdens on the agricultural sector (see Abergel 2007 for a summary emphasizing the importance of the agricultural industry to the Canadian economy and the necessary export market accessibility as reasons for the deregulatory position of the Canadian government in the agricultural sector), and an effort to ensure the safety of products for humans and the environment. Alternatively, some international regulatory regimes represent efforts to ensure that free trade is not impeded by unfounded barriers to new agricultural products, whereas coexisting international regimes allow the same governments to place import or development restrictions around novel technologies in the interests of national environmental and health biosafety.

International Regulatory Framework

In the international policy arena governing the development of agricultural products, the relevant regimes work at cross-purposes to some extent. With respect to trade, international and bilateral agreements (including the *General Agreement on Tariffs and Trade* and the *Agreement on the Application of Sanitary and Phytosanitary Measures*) play a significant role in national biosafety policy making. At the same time, the *Convention on Biological Diversity* outlines biosafety and health measures for novel plants. These different agreements coexist and coordinately affect policy development despite the inherent tensions between them. We begin with a brief examination of the trade regimes developed by the World Trade Organization that apply to its global membership base.

The GATT impacts any commodity that moves in international trade, including seeds and products arising from agricultural research. It promotes a liberal trade environment, which may be restricted only by individual member states' national policies in limited circumstances. To that end, the GATT permits national regulatory measures beyond taxes, duties, and tariffs (Article XI) only where such measures are *necessary* to protect human, animal, or plant health (Article XX[b]), emphasis added).

The SPS Agreement expounds on the GATT exemption, requiring that "any sanitary or phytosanitary measure [regulation] is applied *only to the extent necessary* to protect human, animal or plant life or health" (Article 2.2,

emphasis added) and that "such measures [regulations] are *not more trade-restrictive than required* to achieve their appropriate level of sanitary or phytosanitary protection" (Article 5.6, emphasis added).[3] A trade measure is "more trade restrictive than required" if there is another measure that is reasonably available, taking into account technical and economic feasibility, that achieves the appropriate level of protection and is significantly less restrictive to trade (Article 5.6, footnote 3). Further, any measures must be supported by "scientific justification" and may not be inconsistent with any other provision of the SPS Agreement (Article 3.3, footnote 2). Such measures may not be inconsistent with Article 5.1 or other substantive provisions of the SPS Agreement (*Appellate Body Report*, *EC Measures Concerning Meat and Meat Products,* para. 186). The GATT and other WTO agreements thus stand as legal regimes that, for the most part, prevent member countries from regulating trade in agricultural products except where demonstrably necessary for health reasons.

The CBD, in contrast, aims to generally reduce or eliminate risks posed to a nation's biological diversity by particular products and categories of activities. Thus, Articles 7 and 8 mandate that parties "identify processes and categories of activities which have or are likely to have significant adverse impacts on the conservation and sustainable use of biological diversity" (Article 7[c]), and "regulate or manage the relevant processes and categories of activities" (Article 8[1]). To those ends, Article 14(a) requires that parties "introduce appropriate procedures requiring environmental impact assessment of its proposed projects that are likely to have significant adverse effects on biological diversity." As a result of the CBD, numerous countries, particularly those rich in biodiversity, have complex regulations pertaining to how plant material and genetic resources are imported, exported, and shared between nations (Carrizosa et al. 2004).

It is worth noting that although the CBD applies in some measure to all novel plants, regardless of how they are developed, specific provisions exist for agricultural biotechnology products. The CBD requires that parties "establish or maintain [the] means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology" (Article 8[g]). The *Cartagena Protocol on Biosafety,* an addition to the CBD, allows for further regulation with respect to genetically modified plants – referred to in the protocol as "living modified organisms" (LMOs)[4] – that "*may* have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health" (Article 4, emphasis added; see Secretariat of the CBD 2000).

Controversially, the protocol goes on to permit precautionary measures for regulating LMOs as long as they are conducted in a scientifically sound manner and take into account recognized risk assessment techniques.[5]

The net impact of international biosafety and trade regimes on the development and delivery of genomics products is difficult to address summarily. Nations emphasize trade and biosafety priorities to differing degrees, in line with national trade priorities, policy goals, social preferences, and environmental conditions. Some nations agree with the WTO emphasis on free markets, whereas others draw on the precautionary measures permitted by the *Cartagena Protocol* and the CBD (Safrin 2002; Phillips and Kerr 2000). The net impact of the sometimes overlapping and often distinctive biosafety and trade regimes is to present developers of genomics products with a daunting and complicated portion of the IP–Regulatory Complex to be considered in concert with domestic biosafety legislation and intellectual property regimes. We return to the question of domestic biosafety regimes later, in our discussion of Canada's biosafety policies.

International Intellectual Property Regimes

Regulatory regimes are directed toward ensuring the safe development and market entry of novel plant products. Intellectual property regimes, by contrast, have the goal of creating incentives for innovation in exchange for the public disclosure of new technological developments. Thus, IP regimes play a critical role in facilitating, and creating incentives for, the development of products from agricultural genomics. It is important to recognize that national decisions on the form and substance of IP regimes can have significant downstream impacts on the uptake and ultimate utility of innovations (see, e.g., Rimmer 2008; Van Overwalle 2009; Hope 2008; Goulding et al. 2010). In this section, we briefly outline the possible forms of IP protection for plants available internationally. Later in this chapter, we review the IP laws applicable to the development of novel plant varieties in Canada, as a case study of national implementation of the international agreements surveyed here.

The application of IP regimes to plants is a relatively recent development. Historically, there was a general consensus that it was better to maintain the free exchange of new plant materials and information in order to ensure the widest dissemination of the best possible plant varieties (Llewelyn 1997, 117; Pray and Naseem 2003). It was not until the mid-twentieth century, and the emergence of a robust seed industry seeking to create property rights in its innovations, that intellectual property protection for plants became a subject of policy making.