The potential use of Intellectual Property as a tool for regulating genetically modified crop risks

A sociological investigation of the management of risks associated with unauthorised GM crop production, and the application of Intellectual Property as a tool for regulating those risks.

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Summary

Transgenic pollen flow and transgenic seed spread are undesirable possible effects of genetically modified (GM) crop production. These effects are regarded as risks of GM crop production, as they can lead to undesirable environmental changes, e.g. changes to genetic diversity of wild and domestic crop relatives, species diversity and habitat composition. National and international regulatory systems are in effect, to minimise these potential risks, which creates conditions for authorised and unauthorised GM crop production. The construction and adequacy of regulatory measures is a matter of debate however. It has been proposed that Intellectual Property (IP) could be an appropriate tool for regulating unauthorised GM crop production and associated environmental risks, such as pollen flow and seed spread. This thesis research examines the potential for that proposed use of IP.

Firstly, the rationale and functioning of the proposed use of IP-based regulation are outlined, and conceptualised using an adapted Actor-Network Theory perspective. Secondly, the potential for applying IP-based regulation in the context of the current international biotechnology and IP policy landscape is evaluated. Thirdly, the current and potential roles of IP-based regulation are examined in the context of five cases of GM crop production, and applied to the adapted Actor-Network Theory framework, to further investigate the potential of the use of IP as a regulation tool. Latour´s concepts of diplomacy (as per his work in *Politics of Nature*) and flattened landscape, and Foucault´s concepts of disciplinary power, individualising techniques and totalising procedures are applied in this final analysis to gain insights into the potential barriers to IP-based GM crop risk management which lie within the assumptions of that strategy. Finally, suggestions are made for the application of IP-based GM crop risk regulation, and the development of an evaluative framework for GM crop risk policies based on the findings of this thesis.

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iii) List of Abbreviations

ANT	- Actor-Network Theory
APHIS	- Animal and Plant Health Inspection Service (US)
BIOTEC	- National Genetic Engineering and Biotechnology Centre (Thailand)
BoS	- Bureau of Standards (Jamaica)
Bt	- *Bacillus thuringiensis*
CaMV	- Cauliflower Mosaic Virus
CBD	- Convention on Biological Diversity
Cornell	- Cornell University
CP	- Cartagena Protocol (on Biosafety to the Convention on Biological Diversity)
DoA (R&D)	- Department of Agriculture (Research and Development Office) (Thailand)
EPA	- Environmental Protection Agency (US)
EU	- European Union
FAO	- Food and Agriculture Organisation of the United Nations
FDA	- Food and Drug Administration (US)
GATT	- General Agreement on Tariffs and Trade (Uruguay Round)
GEAC	- Genetic Engineering Approval Committee (India)
GM	- Genetically Modified
GMO	- Genetically Modified Organism
HARC	- Hawaii Agricultural Research Center
IP	- Intellectual Property
IPPC	- International Plant Protection Convention
ISO	- International Organisation for Standardisation
ITPGRFA	- International Treaty on Plant Genetic Resources for Food and Agriculture
JADF	- Jamaica Agricultural Development Fund
LMO	- Living Modified Organism
Mahyco	- Maharashtra Hybrid Seed Co. (India)

MoAF - Ministry of Agriculture and Fisheries (Jamaica)

MoH - Ministry of Health (Jamaica)

MTA - Material Transfer Agreement

N/A - Not applicable

NBC - National Biosafety Committee (Jamaica)

NCST - National Commission on Science and Technology (Jamaica)

NEPA - National Environment and Planning Agency (Jamaica)

NIF - Not In Force

Non-GM - Not Genetically Modified

PAC - Papaya Administrative Committee (Hawaii)

PCT - Patent Co-operation Treaty

PGR - Plant Genetic Resources

PRSV - Papaya Ringspot Virus

RASFF - Rapid Alert System for Food and Feed (European Commission)

Thai NBC - National Biosafety Committee (Thailand)

TRIPS - Agreement on Trade-Related Aspects of Intellectual Property Rights (WTO)

TUA - Technology Use Agreement

UH - University of Hawaii

UNEP - United Nations Environmental Programme

UPOV - International Union for the Protection of New Varieties of Plants

US - United States (of America)

USDA - US Department of Agriculture

UWI Mona - University Of the West Indies, Mona

WIPO - World Intellectual Property Organization

WTO - World Trade Organization

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1: Introduction

1.1 Problem Statement

Intellectual property has been suggested as a tool for regulation of genetically modified crop risks, but the potential for using intellectual property in this way requires a more comprehensive analysis and evaluation.

1.2 Problem Description

Predictions of future food crises are abundant in academic agricultural settings. Population projections of 9 billion people by 2050 spur on the food crisis discussion, underpinned by the recent global food crisis experiences of 2007-2008 (Headey, 2013; Godfray et al., 2010). Intertwined with these predictions are proposals for how to adapt to such food crises. These proposals face a second challenge, in the form of ongoing and projected environmental change. Thus environmental and agricultural concerns need to be considered simultaneously, commonly leading to strategies of 'sustainable intensification'. While the strategy is strongly supported, the approaches to achieving it are multiple and hotly debated. One approach which holds promise is the use of genetically modified organisms (GMOs) in agriculture to enable equivalent or better yields and quality while reducing resource inputs (Godfray et al., 2010).

Genetically modified (GM) crops are the most extensively cultivated type of agricultural GMO. They hold the potential to improve agricultural practice and livelihoods, but have also been implicated in environmental and social conflict (Bernauer, 2003; Stein, 2004). One aspect of that conflict is the potential for environmental risks arising from GM crop production. These include unintended spread to wild plants, potential harmful effects on herbivores, and negative effects on biodiversity including genetic diversity, and species diversity and abundance within habitats, particularly if the transgenic crop becomes weedy or confers weedy traits to relatives (Kwit, Moon, Warwick and Stewart, 2011; Desplanque, Hautekèete and Van Dijk, 2002). Other unintended consequences of GM crop production include the potential for effects which undermine the economic advantage of the crop, such as increased weed herbicide resistance or insect resistance to transgenic traits due to intensive cultivation of the transgenic crop and practice (Ammann, 2014).

Biosafety regulations and risk assessment provide frameworks for management and regulation of GM crop risks, and international policies such as the Cartagena Protocol the Convention on Biological Diversity have been instrumental in establishing standards of practice for GMO risk management. Unauthorised GM crop production still poses risks however, whether accidental or intentional, as it occurs outside of the regulated environment.

Intellectual Property (IP) refers to a collection of legal property rights, facilitating ownership of ideas and innovations by people or organisations. It is theorised that IP can be used as a policy mechanism to minimise GM crop risks and create incentives for private sector innovation (Banik and Thomassin, 2007). The particular IP forms most commonly associated with agricultural GMO production are patents, Breeder's Rights and Material Transfer Agreements (Lesser, 1997; Paarlberg, Gruhn, Goletti and Yudelman, 2000). In combination with licence agreements specifying conditions for use, IP can reduce risks such as gene spread, as growers must be extremely cautious in their farm management. The licence agreement-IP combination

can also be used to prohibit seed-saving, ensuring profit returns to seed-producing companies and creating private sector innovation incentives (Endres, 2007). In theory, IP has strong potential to be used as a regulation tool for GM crop risks (Banik and Thomassin, 2007).

However, current applications of IP do not appear consistent with the above theory. Deviation in practice, production and provision of GM seeds and environmental diffusion of GM crops confirm the risk potential which persists despite the presence of agrobiotechnology IP in the context of GM crops. Kothamasi and Vermeylen (2011) describe the case of *Monsanto Canada Inc. v. Schmeiser* [2001] in which gene flow reportedly occurred from a herbicide-resistant GM crop in the area to the crops of Schmeiser, which he cultivated without entering a licence agreement or respecting the transgenic technology patent. Kothamasi and Vermeylen (2011) and Herring (2007) also describe the development of unauthorised GM seeds, or 'stealth seeds', in India, which proliferate despite containing patented transgenic technology.

These cases indicate that the use of IP as a risk regulation tool may assume exclusive power and capacity for responsibility among particular actors which does not reflect the context in which it might operate in practice. These assumptions can be contested on the grounds that a) IP does not appear to prevent unauthorised agricultural GM crop production in cases where it has been applied , and b) IP allocates responsibility and power among specific actors to provide leverage for regulatory action, but does not recognise the potential for autonomous action of other actors.

Bearing in mind the proposed use of IP as a GM crop risk regulation tool, and the critiques of that proposed use, this thesis research investigates the potential use of IP as tool for regulating GM crop risks. To do so, the theoretical foundations of the proposed risk management strategy and the potential barriers to successful implementation of IP-based GM crop risk management have been investigated. Points 1.3 to 1.5 describe the approach taken to conduct the research, while point 1.6 summarises the findings. ISO (2009) describes risk as the “effect of uncertainty on objectives”, and in the context of risk management, this definition will be adopted for this research – that is, the management of the effects of uncertainty on objectives.

1.3 Research Aim

To investigate the policy and practice environment for application of IP as a tool for regulating GM crop risks, in order to evaluate the potential of IP to be used as a GM crop risk regulation tool.

1.4 Research Questions

1. What way does IP-based GM crop risk management operate?

a) What are the theoretical conditions for IP-based GM crop risk management, as described in the literature?

b) What is the role of IP in GM crop risk management strategies currently in practice?

2. What are the potential barriers to IP-based GM crop risk management?

a) What role do international policies play in enabling or obstructing IP-based GM crop risk management?

b) What is the compatibility of IP-based GM crop risk management with existing GM crop risk management practices?

1.5 Methodology

This section gives a brief outline of the research methodology employed to address the research questions. Further details on research methodology are included in the chapters which address the research questions. That is: Ch.2 for question 1a); Ch. 3 for question 2a); and Ch. 4 for question 1b) and 2b).

1. What way does IP-based GM crop risk management operate?

a) What are the theoretical conditions for IP-based GM crop risk management, as described in the literature?

The rationale and functioning of the proposed use of IP-based regulation are outlined, based on relevant economic, legal and biotechnical literature. The theoretical basis for IP-based GM crop risk management is conceptualised, using an adapted Actor-Network Theory perspective, to give rise to a conceptual framework for IP-based GM crop risk management functioning and theoretical conditions for the functioning of IP as a regulatory tool.

b) What is the role of IP in GM crop risk management strategies currently in practice?

The GM crop risk management strategies of five cases of GM crop production are examined, with attention to the current application of IP as a part of those strategies. Five cases have been selected, representing experimental and commercial GM crop production, successful and unsuccessful GM crop risk management, and a range of crop types, transgenic traits, and geographical regions. These are listed in Table 1.1. Information on the nature of GM crop risk management strategies and the role of IP was gathered from literature produced by people directly involved in the cases, including journal articles, organisation reports, and court proceedings, and for some cases, using data from personal interviews with people involved in the risk management process. Technical crop information relating to the case studies is provided in Annex 1 and a list of interviews and other communications used for this research is provided in Annex 2.

Table 1.1: List of case studies, indicating region, crop type, transgenic trait, timeframe, nature of production, success of GM crop risk management.

Region	Crop	Trait	Timeframe	Production	Risk management status
Hawaii, US	Papaya	Virus-resistance	1986 – 2013	Commercial	Successful
Jamaica	Papaya	Virus-resistance	1994 – 2013	Experimental	Successful
Thailand	Papaya	Virus-resistance	1995 – 2004	Experimental	Unsuccessful
India	Cotton	Insect-resistance	1996 – 2013	Commercial	Unsuccessful

Canada/Contiguous US	Canola	Herbicide-tolerance	1985 – 2013	Commercial	Unsuccessful

2. What are the potential barriers to IP-based GM crop risk management?

a) What is the scope for the use of IP as a GM crop risk regulation tool within the current international policy environment?

Six international policies, selected on the basis of their relevance to IP, GMO risk management, and the five nations in which the case studies are located are examined. From analysis of the text, and where relevant, observations of the implementation of the policy in the case study nations, the implications of each policy for the use of IP as a GM crop risk regulation tool are examined.

b) What is the compatibility of IP-based GM crop risk management with existing GM crop risk management practices?

The theoretical conditions for IP-based GM crop risk management and case study data gathered in the investigation of Question 1 are also used to address this question. Different theoretical perspectives are applied to investigate compatibility and divergence between the theoretical GM crop risk management strategy and GM crop risk management strategies applied in the five case studies listed in Table 1.1. Alternative perspectives are derived from the theories of Latour and Foucault, particularly Latour´s concepts of diplomacy and flattened landscape, and Foucault´s concepts of disciplinary power, individualising techniques and totalising procedures. Although not explicitly complementary theorists, other scholars of ANT such as Law have made reference in the past to the importance of Foucault´s work for the development of ANT (Fox, 2000). It is easy to link the two, especially concerning Foucault´s emphasis on exposing the social construction of practices and beliefs using relativistic analysis techniques such as genealogy. Foucault however explicitly deals with human actors rather than the identity-neutral approach taken by ANT scholars, in particular Latour.

1.6 Summary of Findings

This research found that the application of IP as a GM crop risk regulation tool is plausible form an economic and legal theory perspective, is possible within the international policy environment, but is not used in this way in most GM crop risk management contexts currently, and the potential for it to be successful in the majority of GM crop risk management contexts is low. Further development of the conceptual framework used in evaluation of the potential of IP- based risk regulation in socially and environmentally dynamic settings could lead to a more discriminating evaluation of the type of contexts in which an IP-based GM crop risk regulation strategy is likely to be useful.

2: Rationale for Use of Intellectual Property as a Regulation Tool for Genetically Modified Crops

2.1 Introduction

This chapter describes the theoretical background of GMO IP, and outlines the theoretical premises of how IP operates as a GMO regulation mechanism. The literature used is from the fields of economics, legal studies and biology, specifically studies which discuss IP as a GMO regulation mechanism.

The review focuses on two main areas of regulation associated with IP, industry regulation and environmental risk regulation, to understand why IP is theoretically appropriate for GMO risk regulation. Industry regulation refers to the management of competition and product reliability. Environmental risk regulation refers to the management of environmental risks arising from unauthorised GM crop production, such as feral GM crops or hybridisation with wild relatives. There are two primary motivations for using IP in industry or environmental regulation contexts. Firstly, IP is considered to be a tool to stimulate innovation and competition (WIPO, 2013a). Second, IP is a means of recognising product inventors, purchasers and users, knowledge which can be used to improve product quality and reliability, and identify user liability (Banik and Thomassin, 2007; Lea and Hall, 2004). The fields of economics, legal studies and biology have been chosen as the focus of the literature research because of their strong relationship with industrial and environmental risk regulation, and contributions to GMO IP theory.

2.1.1 General Background

IP refers to private property rights which are created over the products of knowledge. In the neoliberal economic style of governance, IP is important for stimulation of the economy, particularly the knowledge economy, and for distribution of public goods deriving from knowledge (Lave, Mirowski and Randalls, 2010). Many nations have some form of IP in their trade laws. In the 20th century, multilateral agreements such as the Paris Convention were formed, to establish standards of IP across different nations. The most recent of these which has had substantial effects on global IP practice is the Agreement on Trade Related Aspects of Intellectual Property (TRIPS). TRIPS is a multilateral agreement, established in 1994 and administered by the World Trade Organization (WTO). It must be adhered to by all WTO member states. TRIPS expanded on earlier agreements, creating new standards in the material to be covered by IP, and in the enforcement and dispute settlement procedures for TRIPS parties. The inclusion of so many parties, and extensive standardisation of IP rules and practices has strengthened global IP capacity, including in agricultural biotechnology (Su, 2000). Ch. 3 addresses the significance of TRIPS for international IP standards in greater detail.

Following TRIPS, there is greater consensus concerning the type of IP which is appropriate for agrobiotechnology, including GM crops (Strauss, 2009), although specific IP decisions are limited to the nation in which they are agreed (WIPO, 2004b). The particular IP tools most commonly associated with GM crops are Material Transfer Agreements, Breeder's Rights, and

patents (Lesser, 1997; Paarlberg et al., 2000). TRIPS has made it necessary for all parties to have some form of IP concerning plant material, but provision has been made for parties to develop additional unique IP tools, known as *sui generis* systems (Agreement on Trade-Related Aspects of Intellectual Property Rights).

Material Transfer Agreements (MTAs) are tailor-made contracts for the sharing of material between agreeing parties, usually employed by researchers. They may specify conditions of ownership, use, and acknowledgement and royalty arrangements in case a discovery becomes profitable (Correa, 2006; Streitz and Bennett, 2003). Although there have been efforts to standardise the conditions and protection granted by MTAs on an international level, such as the MTA model agreed upon in the International Treaty on Plant Genetic Resources for Food and Agriculture, the terms of the contract are specific to the agreeing parties and the IP available through MTAs are not as powerful as the IP rights provided by Breeder´s Rights and patents (Correa, 2006).

Breeder's Rights are another form of exclusive ownership rights, strictly concerned with new plant varieties, whether developed by traditional or genetically engineered means (Act of 1991 International Convention for the Protection of New Varieties of Plants). Varieties protected by Breeder's Rights can be afforded multilateral protection in all member states of the International Union of the Protection of New Varieties of Plants, also known as UPOV (Act of 1991 International Convention for the Protection of New Varieties of Plants). The members of UPOV are not as numerous as the parties to TRIPS (UPOV, 2013), and patents are considered to offer more comprehensive IP rights for GM plant material than Breeder's Rights (Moschini and Yerokhin, 2007).

Patents are government-recognised, time-limited exclusive ownership rights, which apply to a broad range of inventions. They enable the patent-holder to selectively authorise use of the invention (WIPO, 2004b). An invention is any new, non-obvious and useful solution to a specific technical problem which is recognised as patentable subject matter (WIPO, 2004b; Hemphill, 2012). TRIPS contains guidelines on what can be considered for, or excluded from, patent protection (WIPO, 2004b). This thesis research concentrates primarily on the use of patents, as they are the IP tool which is favoured by the agrobiotechnology industry and which offers the greatest potential to act as an environmental risk regulation mechanism (Endres, 2004) and MTAs due to the role they play in alternative/*sui generis* agrobiotechnology IP systems such as that developed in Hawaii for governance of the PRSV-resistant papaya (Goldman, 2007) (see Ch. 4 for further details) and promoted by the International Treaty on Plant Genetic Resources for Food and Agriculture.

2.2 Stimulating Innovation and Competition in Agrobiotechnology

The use of GM crops is a relatively recent phenomenon. The first GM crop, the FlavrSavr tomato, became commercially available twenty years ago. IP use in agriculture and plant-breeding is a much older phenomenon, however. Kesan (2007) describes IP use in agriculture dating back to the 18th century. As with most agricultural technology, engineered elements of GM crops fall under the 'industrial property' branch of IP, in the World Intellectual Property Organization (WIPO) classification (WIPO, 2004b). Scientific discoveries and naturally-occurring phenomena cannot be protected with IP, but a technical application of scientific knowledge

and natural phenomena has the potential for protection by IP (WIPO, 2004b). Innovative ideas such as technical applications of scientific knowledge are essentially public goods (Moschini and Yerokhin, 2007), which provide social benefit by increasing public knowledge and capacity to create solutions to problems (WIPO, 2013b).

2.2.1 The Appropriability Problem

The public good nature of ideas or inventions can discourage inventors from disclosing their idea to the public. In the absence of IP, disclosed ideas can usually be easily copied and shared with little to no acknowledgement of the inventor, financial or otherwise (Banik and Thomassin, 2007). Where resources have been invested in the creation of an idea or invention, this lack of formal acknowledgement requirements could mean that the investment cost would never be recovered and the investor would operate at a loss. This aspect of knowledge-based goods is also known as the 'Appropriability Problem', and theoretically results in a lower level of research and development investment, and innovation disclosure (Dam, 1994). The provision of a means by which to transform knowledge-related public goods into private, excludable goods resolves the Appropriability Problem (Dam, 1994). By limiting access to the good, inventors can effectively create rules regarding access to their knowledge, and profit from their ideas (Endres, 2007). The creation of exclusive property rights, that is, IP, for technical innovations is considered by WIPO (2013b) to provide incentives for new inventions, by creating a system which recognises creativity and enables material reward.

IP: A legal solution to the Appropriability Problem

Converting the economic theory described above into a legal mechanism, such as patents and Breeders' Rights, creates a viable solution to the Appropriability Problem. These legal tools enable legitimate penalties for those who, with or without intent, fail to recognise the property-owner (WIPO, 2013a). Just *et al.* (2006) assert that the patent system acts in society's benefit by encouraging research and development, which is further described as an incentive mechanism which provides a balance of producer and consumer benefits. Producers gain profit from the monopoly granted by their patent, while consumers gain from the emergence of competing producers and products. Theoretically, the strengthening of an IP regime should stand to benefit countries whose property regimes are weak, on the premise that IP facilitates and encourages innovation (Endres and Giffin, 2012). This logic has motivated efforts to standardise IP regimes, using multilateral treaties and agreements such as the Patent Co-operation Treaty and TRIPS.

2.2.2 Criticisms of IP : Tragedy of the Anticommons

There is quite some literature in the biological and agricultural sciences regarding the bureaucracy introduced by IP on research materials. One of the most frequent criticisms is that IP might inhibit research, termed a 'Tragedy of the Anticommons' (Hemphill, 2012).

A Tragedy of the Anticommons occurs when an abundance of exclusive property claims exists, making it more difficult to negotiate the use of the property or properties, and ultimately resulting in under-use of the resource and a reduction in social benefits (Heller and Eisenberg, 1998). In the case of IP in scientific research, the resource is knowledge, which could be used for creation of further knowledge and ultimately public benefit, but which is often tied up with the technological applications of the knowledge, which can involve numerous components bearing separate IP claims, e.g. a gene vector in GM research. The amount of IP claims which

might need to be considered and negotiated in the course of biotechnology research might act as a barrier (Hemphill, 2012) and result in no follow-up research on inventions, particularly when very strong IP such as patents are employed (Moschini and Yerokhin, 2007). This is an issue particularly in public research where much of the research is aimed at public goods, and finance is not usually obtained by means of business-related loans (Dunwell, 2005). There have also been assertions that patent proliferation has created an overemphasis on research to produce patents and create profit as reported by Schachman (2006) in his account of changes in biological science, *From "publish or perish" to "patent and prosper"*. This potentially steers money away from research projects for public benefit, traditionally carried out by public research institutions, due to the low capacity to harness returns for the recovery of patent-related costs of such research (Dunwell, 2005). There is some research to suggest that this scenario is not the case however, and that in fact, many researchers incorrectly perceive a 'research exemption' for patented materials, and therefore do not experience the restrictions proposed by critics (Walsh, Cohen and Cho, 2007). Evidently, the Tragedy of the Anticommons is not applicable for all researchers and research areas, but might be problematic for some research, particularly that which is specifically directed at public benefit but not profit.

2.2.3 Criticisms of IP: Deepening the North-South Divide

The requirements of TRIPS oblige participating nations (WTO members) to create intellectual property protection for plant material, via a patent system or a *sui generis* system specific to their nation. These requirements have created speculation that TRIPS mandates a US-style plant gene patent system for other countries (Stein, 2004). This is particularly thought to be the case for developing countries, who have not given explicit considerations to plant genetic material in past property right systems, and may not have the resources to develop a *sui generis* system within the timeframe allowed (Sullivan, 2004; Stein, 2004). It is still uncertain if the stronger IP provisions in TRIPS have produced the predicted industrial and social benefits, especially in the case of plant genetic material. Stein (2004) observes that TRIPS has further divided the North and South in terms of benefits derived from agricultural biotechnology development. Meanwhile, Endres and Giffin (2012) find that the theoretical connection between IP and innovation, with particular regard to crops, is much more complex than previously thought, indicating that many other factors should be considered before predictions are made about what benefits stronger IP can create. This is in contradiction to the general assumption in neoliberal economics that stronger IP creates greater benefits for society on a global and national level (Endres and Giffin, 2012), and also runs contra to policy efforts to assist development in the South through strengthening and standardising IP regimes.

2.3 Means of Recognition

Property rights provide a means of recognition for the inventor, and necessitate an agreement between the inventor and users in order for authorised use to take place. In this way users of the invention are known to the inventor, and unauthorised use becomes easier to identify. In theory, strong property rights such as patents eliminate 'free-rider issues', whereby parties other than the inventor could profit from sale of the invention without carrying the costs of research and development (Endres, 2007). Where a patent is in place, 'free-riding' becomes an illegal act, which can be regarded as 'patent infringement' or, in the context of GM crops, 'seed piracy' (Freeman, 2008). In this way, IP, and particularly strong IP such as patents, are an effective industry regulation tool. The negotiation of agreement between inventor and user

enables extension of production standards into the negotiation. With such an extension, the reliability of a product can be improved, and health and environmental impacts of the product can be reduced (Endres, 2007). The coupling of production standards to IP also improves the capacity to identify and prosecute defaulters who do not use the property as per the agreement, or use the property without agreement, e.g. in the case of unauthorised GM crop production, as they can be considered patent infringers and prosecuted accordingly.

2.3.1 Recognising IP in the Biotechnology Industry

According to WIPO (2013a), the purpose of a patent is to provide exclusive invention ownership rights to an inventor. Inventions can be granted patents as long as they are new, non-obvious and useful (Hemphill, 2012). Since the *Diamond v. Chakrabarty,* [1980] US Supreme Court ruling it has been recognised that patents can include life-forms which constitute a "non-naturally occurring manufacture or composition of matter" . This ruling clarified the US Patent Act 1952, which stated that "anything under the sun made by man" had the potential to be patented, an ambiguous statement when applied to living things. *Diamond v. Chakrabarty*, [1980] is widely acknowledged as clearing a path for biotechnology patents generally, especially gene patents (Mueller, 2006). A later case, *Ex parte Hibberd*, [1985] affirmed the court recognition of patents for plant material, giving certitude to plant germplasm patent applications, reversing previous court decisions on plant material patents. Although an international patent system does not exist, various treaties, particularly TRIPS, and bilateral agreements between the US and other countries, have ensured that the outcomes of biotechnology related cases like *Diamond v. Chakrabarty,* [1980] and *Ex parte Hibberd,* [1985] have almost global consequences (Strauss, 2009). It is important to note that according to international patent standards such as those introduced by TRIPS, an invention can be patented, but a discovery cannot (WIPO, 2004b). Only a new, non-obvious technology which is intentionally engineered into an organism and is shown to have a useful effect can be covered by patent (product patent). The process by which such engineering takes place, if it is new, non-obvious and useful, can also be patented (process patent). Thus patent rights may apply over useful applications of discovered genetic sequences, and modified genetic sequences such that patent rights extend over the organism, but discovered organisms and GMOs, as entire entities cannot be patented (although Breeders' Rights may apply).

2.3.2 Extending IP into Biotechnology Regulation

Patent protection can be extended via licence agreements or technology usage agreements. Such an agreement creates conditions of sale, in which the patent-holder permits technology purchasers (e.g. farmer) to use the technology under specific usage conditions (Endres, 2007). A technology agreement may contain prohibitions on seed cultivation, such as inclusion of buffer zones around GM crop fields in which non-GM crops are cultivated, and post-cultivation procedures and product uses, for example banning the use of any saved seed. An example of such an agreement and the provisions for environmental protection and seed-saving entailed within is the Monsanto Technology/Stewardship Agreement (Monsanto, 2014).

Licence agreements are used to extend the ownership rights of the patent-holder (Endres, 2007) and are the grounds for the use of IP as a biosafety regulation, enabling the patent-holder to require certain licensee practices (Endres, 2007; Banik and Thomassin, 2007). Such use of the IP system can result in negative externalities, i.e. inappropriate shifting of the

burden of liability such that the social costs of invention use are greater than the private costs (Banik and Thomassin, 2007). As these regulatory mechanisms are constructed as legal agreements however, the transfer of liability for misuse and damages to the technology-user has been accepted and upheld by courts and international trade organisations (Mueller, 2006; Banik and Thomassin, 2007; Strauss, 2009). Under the standard construction of plant biotechnology patents in TRIPS, and particularly in internationally influential nations for IP use such as the US, unauthorised use of patented agrobiotechnology, including cultivation of GM crops, can be considered an infringement of patents. TRIPS encourages stronger plant material IP protection (Strauss, 2009), in turn enabling the technology use agreements for biotechnology products, which enables the use of IP as a safety regulation tool. By using a technology use licence or agreement (TUA), liability for intentional or unintentional damages caused to an individual, organisation or society as a result of patented technology use, the burden of liability can be transferred from patent-owner to the licensee. This can be used to ensure licensee adherence to stewardship or best practice conditions for environmental and consumer safety (Banik and Thomassin, 2007; Monsanto, 2014).

2.3.3 Biotechnology Researcher Perspectives on IP-Based GM Crop Risk Regulation

In biological and agricultural science journals, the use of IP for GM crop regulation is rarely written about. Articles advocating for more comprehensive risk assessment prior to product approval sometimes feature, however. Ervin *et al.* (2003) describe many faults with the pre-assessment phase of GM crop approval, finding that pre-assessment usually contains insufficient detail for adequate liability remuneration to be made. Aside from these aspects, they consider GM regulation in the current fashion to be sufficient. Ervin *et al.* (2003) indicate that technical solutions and the minimisation of risk are more relevant to the biotechnical researcher perspective than possible legal or political approaches to managing biotechnology risks. Some implicit recognition of farmer agency to act contrary to regulation requirements, and possibly of plant agency to act outside of farmer control, was also to be found in these journals. Consideration of policy means to manipulate this was absent however. Desplanque *et al.* (2002) consider the unlikelihood of a farmer being completely successful in removing all potential transgene carrying weeds when describing solutions to the hybridisation of herbicide-resistance sugar beet with weedy wild relatives. Desplanque *et al.*(2002) do not consider the potential of regulatory approaches, such as IP, to motivate a farmer to be more efficient at removing suspected GM weeds, but rather focus on technical solutions to prevent the GM weeds from arising. This emphasis on technical, rather than market-based solutions to GM crop risks, and implicit recognition of farmer, and possibly even plant, agency, sets the biological science perspective somewhat apart from the neoliberal economic motivations for IP use described above.

2.4 Discussion

The points above detail how IP can theoretically lead to public benefits, particularly in a neo-liberal government vision. IP stimulates innovation and competition through economic and legal means. By providing the means for recognition of inventors, IP adds value to the invention or innovation for the inventor, allowing inventors to recover their costs. As a legal tool, IP gives inventors the means to enforce their exclusive claim over the invention or innovation, and scope for prosecution of patent infringers. With the conditions of use which also form part of the legal agreement and negotiation deal between inventor and user, IP can

also be used to ensure product reliability and identify user liability. Technology use licences or agreements (TUAs) connected to patents are particularly used for this purpose, including by Monsanto. Such licences protect inventor interests but can also be used to protect social and environmental interests, and prohibit practices which might cause risks to emerge.

2.4.1 Conditions for the Functioning of IP-Based Regulation of GM Crop Risks

From the theoretical foundation described above, building particularly on the frameworks for IP-based GM crop risk management discussed by Endres (2007) and Banik and Thomassin (2007), as presented in section 2.3.2, some conditions for the functioning of IP-based regulation of GM crop risks can be defined.

IP enables recognition of the inventor, and the inventor´s right to limit use of the property. Particularly in the case of patent rights over transgenic traits contained in the organism, the IP-holder of a component of a GMO has the capacity to enforce IP and prosecute infringers, if IP is unobstructed by other overlapping legislation such as Plant Breeder´s Rights, or Farmer´s Rights. This provides the IP-holder with the potential to take legal action against individuals found to be 'using' GM crops in an unauthorised way, creating the capacity to regulate against unauthorised GM crop production, utilising IP. This aspect of IP-based GM crop risk management generates market-based incentives for farmers to act with caution in relation to potentially infringing acts, such as cross-breeding with other varieties; and to take action to prevent GM crop risks associated with unauthorised production, such as seed spread, and cross-fertilisation of non-transgenic relatives. These incentives theoretically contribute to management of potential threats to genetic diversity and habitat composition within and outside of the agro-ecosystem.

Patent protection provides IP-holders the potential to create specific, enforceable terms of use as conditions for licensing the patent to a customer, in the form of a TUA. MTAs have the potential to provide a similar capacity on a case by case basis. This possibility lends even greater potential for IP to be applied as a GM crop risk regulation tool. The IP-holder can transfer liability for potential environmental damages arising from GM crop risk incidence to the licensee e.g. GM crops becoming feral and weedy, or cross-pollinating relatives which do so as a result, by specifying actions which they must take to prevent such risk incidence. Actions to prevent the incidence of other GM crop risks, such as harmful effects on consuming organisms (e.g. herbivores), and the development of resistance in target pests (requiring producers to use alternative pest management means), can also be specified in this way, e.g. the specification of refuge inclusion in crop-producing areas. As Banik and Thomassin (2007) discuss, this can result in high social costs versus private costs. The balance of the cost of practicing licence conditions must also be balanced with the profits from crop production in order for the technology to be used. However, if the environmental costs of GM crop risks, in the case of incidence are considered as a negative externality, increasing the cost of GM crop production through application of patent rights and TUA/MTA conditions can be considered a means to internalise that externality.

2.4.2 Actor-Network Conceptualisation of IP-Based GM Crop Risk Management

A characterisation of the conditions for IP-based GM crop risk management can be approached by adopting an economic theory perspective, as described above. Banik and Thomassin (2007)

in particular investigate the potential of IP-based management strategies extensively from a legal and economic perspective. In such a perspective, particularly from a neo-liberal economic stance, IP-based GM crop risk management has strong potential for success, under certain assumptions. Those assumptions include the presence of IP legislation sufficient to provide the conditions described in section 2.4.1, the rational behaviour of the farmer in perceiving and responding to the incentives created by IP and TUA/MTA conditions to follow certain practices, and the response of the plant material in question to the risk management practices of producers in the predicted manner (i.e. the absence of unpredictable environmental events).

The brief assessment of the perspective of biotechnology researchers regarding biotechnology IP indicates that the assumptions of rational action and capacity to control plant material, implicit in the economic and legal construction of potential IP-based risk management strategies, are not consistent with farmer and plant behaviour. This observation indicates that the potential of IP-based GM crop risk management might appear differently using a different frame of human and plant material behaviour. To provide an analysis of IP-based GM crop risk management which adds to and extends the analyses made from an economic perspective, explicit consideration of human and plant material agency is given in this thesis, in particular in the analysis of case studies in Ch. 4. In order to evaluate the potential use of IP-based GM crop risk management as described within this chapter, a conceptualisation of the management framework is made which corresponds to the legal and economic perspectives from which the strategy is borne, but to which alternate assumptions of human and plant material agency can be applied.

For this purpose, a modified form of Actor-Network Theory (ANT) as described by Latour (2007) is adopted, due to the requirement for a market-based network to mediate IP-based regulation, and the potential for different arrangements and structures between actors/actants[1] according to the context in which the IP-based management strategy operates. The actor-network conceptualisation of the IP-based strategy described in 2.4.1 thus begins from the premise that IP-based management operates within a market network, within which subjects interact according to different arrangements. The framework described in 2.4.1 depends upon a hierarchy of IP-holders, enabled by IP regulations and associated authorities, which have exclusive rights to objects that licensees must acknowledge and request access to, and use only in accordance with the conditions of the IP-holder, or face penalties. This is very different to Latour´s ANT which adopts a ´flattened hierarchy´ to critically assess the role of all actors, regardless of the power they may be perceived to have, and takes a more critical position on the capacity of objects/subjects to have agency, as all objects/subjects may be perceived as actors. These aspects are removed from the conceptual framework of networked IP-based risk management applied here, and a more positivist perspective of the network structure and object/subject agency is applied. Thus in this conceptualisation, a hierarchy exists within the network, as per the description in 4.2.2, which has the capacity to establish conditions to structure the actions of subjects (licensees), which in turn have the capacity to control (material) objects (GM crops). This concept of the actor-network is accordingly called the Actor-Network Control framework, as the assumption of rational farmer/licensee actions

[1] Actors is adopted as the preferred term in this thesis, referring to both human and non-human or material agents, unless specified otherwise.

and very limited plant agency are incorporated to integrate the assumptions of IP-based GM crop risk management.

The conditions under which IP-based crop risk management is successful under the Actor-Network Control are further conceptualised and depicted in Fig. 2.1. By negotiating who can use the property, the IP-holder chooses who can gain access to the network. Using the conditions of use, the inventor and users can also negotiate the transfer of liability in a discrete and legally legitimated way. These aspects together create a **specific liability network** (Condition A), allowing the regulation of GM crop risks to happen within a limited space of actors, all of which are identifiable and bear a clear liability relationship to potential risks.

When the potential to specify practices related to health and environmental protection are included in the conditions of use, e.g. in a TUA, is coupled with the conditions which created the network, **enforceable conditions of action** (Condition B) can be brought into play. These can be extended through the liability network in a flexible manner, according to discrete arrangements with network actors. These enforceable conditions of action can prohibit or make necessary certain practices related to the technology, and have the legal weight to be used as grounds for prosecuting patent infringement.

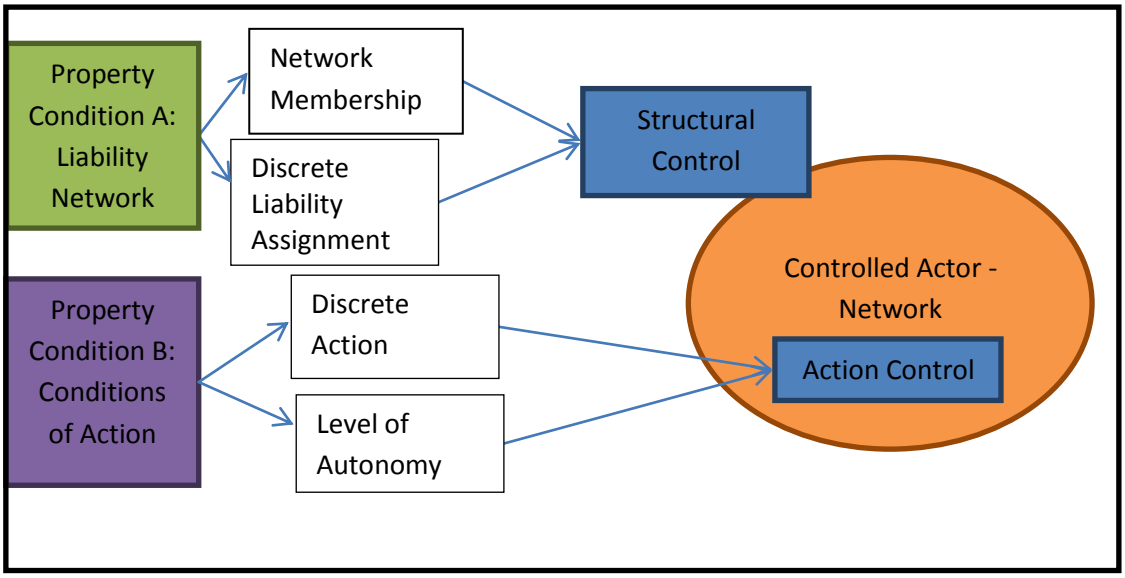

Figure 2.1: Actor-Network Control Framework

Structural Control

Condition A and condition B produce two modes of network control, arising from the application of IP. Condition A enables network membership limits, controlling which objects can enter and exit, and specific liability assignment, controlling the order of connections between objects. Thus condition A is more concerned with controlling the peripheral limits and network structure, and the mode of control arising from this is termed structural control.

Action Control

Applying condition A alone does not address the actions of subjects being managed. This is addressed by condition B, which addresses the actions of subjects and specifies certain practices which are necessary and enabled, punctuating their potential for agency. Condition B also plays a role in constructing material objects, which can and should be managed by human

subjects in specific ways as they have negligible or limited agency. Condition B enables legally legitimated instruments of control to operate within the network, determining the subjects and objects and the ways in which they should behave. This mode of control will be termed action control. Condition B thus mobilises the structure of the network, as created by Condition A, and reinforces that network.

The IP-based GM crop risk management strategy which arose from economic and legal theory as described in this chapter, thus takes on a sociological rather than purely economic perspective when conceptualised according to the Actor-Network Control framework. The relativist perspective associated with ANT has been amended to shape the framework to the construction of IP-based GM crop risk management under the assumptions discussed above. This conceptualisation indicates the ideal state under which IP-based GM crop risk management would have the most potential to succeed, and as such provides a reference scenario of the situation in which IP has excellent potential to be applied as a regulation tool for GM crop risks.

2.5 Conclusion

From a legal and economic perspective, IP is a useful industry regulation tool because it creates social benefit (knowledge disclosure) while prohibiting free-riding and thus enabling acknowledgement of inventor efforts, legally and financially. As an environmental safety or GMO risk regulation tool, the information available is less plentiful, but presents IP as an acceptable form of liability assignment and therefore safety regulation, if the legal infrastructure is sufficiently strong and the range of IP tools is appropriately used. Critics find fault with some aspects and outcomes of IP, suggesting that the effects of IP on innovation and research are more complex than previously considered. Based on legal and economic theoretical perspectives, IP is presented as having the potential to be a market-based GM crop risk regulation tool. Some assumptions which underlie those perspectives indicate that the potential for the use of IP in such a way is not so strong, and that alternative or current strategies might be more appropriate.

To investigate the potential for IP use as described in this chapter, a framework was developed to conceptualise the ideal state in which IP-based GM crop risk management has the greatest potential, and the conditions which create such a state, but also to be applied in a critical sense to ascertain the potential for IP-based GM crop risk management in non-ideal, or real, settings. As described in the discussion, the conditions required for the ideal state in the Actor-Network Control framework emerge as A: the creation of a specific liability network around the GMO technology and B: the creation of enforceable conditions of action for those within the network. In the ideal state these conditions enable IP to function as a GM crop risk management tool.

Ch. 3 and Ch. 4 investigate some possible barriers to the perceived potential of IP-based GM crop risk management as conceptualised here. Ch. 3 explores the scope for application of IP as a GM crop risk management tool within the current international policy environment, and how that relates to the functional premises described in this chapter. In Ch. 4, cases of IP-based GM crop risk management are examined to assess the risk management strategies in practice in the cases, and the role IP has played in GM crop risk management in those cases. Divergence

and compatibility between the potential for IP-based GM crop risk management in the cases and the ideal scenario, as conceptualised in this chapter, is explored. The applicability of the assumptions integrated into IP-based GM crop risk management are explored and questioned using constructivist approaches to governance and social relations based on concepts of Latour and Foucault, with the information obtained from the case studies, also providing an indication of the way in which the assumptions should be addressed to improve the potential for using IP-based risk management or another such network-control strategy to manage GM crop risks.

3: Policy Environment for Applying Intellectual Property as a Regulation Tool for Genetically Modified Crops

3.1 Introduction

This section examines how the use of IP as a tool for preventing unauthorised GM crop production is characterised in international policies dealing with IP, GMOs and risks associated with unauthorised GM crop production. The characterisation of IP as a tool for preventing unauthorised GM crop production, and the relationship between that characterisation and the theoretical conditions described in Ch. 2, are the focus of this chapter. The policies involved are international policies, but also relate to national level policy, as they are required to be integrated in national policy by the contracting parties.

Policy selection

Many international agreements, treaties, and other policies bear relevance to IP and agrobiotechnology, but for the purpose of this thesis research, not all could be examined. A selection was made using the five case study regions examined in Ch. 4 as a selection frame. This gives coverage of the main international policies influencing some of the biggest producers of GM crops, US, Canada, and India, (James, 2012) and countries which develop, but do not commercially produce, GM crops, Thailand and Jamaica (Attathom and Navarro, 2011; Fermin and Tennant, 2011). A number of policy documents remained within this frame, and from this six policies were chosen which have relevance to IP and agrobiotechnology internationally and in at least three of the case study regions. The policies examined include the Patent Cooperation Treaty, 2001 (PCT), the Agreement on Trade-Related Aspects of Intellectual Property Rights, 1994 (TRIPS), the International Plant Protection Convention, 1997 (IPPC), the Convention on Biological Diversity, 1992 (CBD), the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, 2000 (CP), and the International Treaty on Plant Genetic Resources for Food and Agriculture, 2004 (ITPGRFA).[2]

3.2 Characterisation of Policy Documents

The six policies examined have individual characteristics and contexts. They were composed under the initiative of organisations and collaborations with different objectives, and address different aspects of IP or GM crop regulation. They also represent different periods of time, in which distinct normative perspectives on trade, development, and environmental management dominated. They have been divided into two broad groups on the basis of their relevance to the subject matter of this research, IP and GM crop risk management. While the PCT and TRIPS have a clear focus on IP, and are categorised as IP-focused, while the IPPC, CBD, CP, and ITPGRFA deal more directly with the possible risks of GM crop production, and are

[2] In the interest of consistency, the Union for the Protection of New Varieties of Plants (UPOV) Act has not been included, as only two nations under study, Canada and US, are party to this Act, while the four other nations are not. The national Plant Variety Protection laws deriving from this act within Canada and US are relevant to how IP theoretically functions in those countries in relation to GMO crops, however. Both of these nations also have considerable authority in the development and harmonisation of IP legislation in developing countries, such as the other four case nations, as does the UPOV Act (Robinson, 2008).

therefore considered environmentally-focused[3]. Table 3.1 indicates the countries which are party to the IP-focused policies, of the five countries examined in the case studies and the year in which the policies came into force in the nation, as derived from the WIPO LEX database (WIPO, 2014).

Table 3.1: IP-focused policies, year of policy completion, and year of adoption by country, if applicable. *PCT: Patent Cooperation Treaty, 2001; TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, 1994; N/A: Not Applicable.*

Policy	*Year of finalisation*	*US*	*Canada*	*India*	*Thailand*	*Jamaica*
PCT	1970	1978	1990	1998	2009	N/A
TRIPS	1994	1996	1996	2000	2000	2000

Table 3.2 indicates the countries which are party to the environmentally-focused policies and the year in which they brought these policies into force in the nation, as derived from the WIPO LEX database (WIPO, 2014) and the website of the ITPGRFA (ITPGRFA, 2014).

Table 3.2: Environmentally-focused policies, year of policy completion, and year of adoption by country, if applicable. *IPPC: International Plant Protection Convention, 1997; CBD: Convention on Biological Diversity, 1992; CP: Cartagena Protocol on Convention on Biological Diversity, 2000; ITPGRFA: International Policy on Plant Genetic Resources for Food and Agriculture, 2004.NIF: policy is not in force.*

Policy	*Year of finalisation*	*US*	*Canada*	*India*	*Thailand*	*Jamaica*
IPPC	1997	2005	2005	2005	2005	2005
CBD	1992	1994 (NIF)	1994	1994	2004	1995
CP	2000	N/A	2001 (NIF)	2003	2006	2006
ITPGRFA	2001	2002 (NIF)	2002	2002	2002 (NIF)	2006

3.3 IP-Focused Policies

The PCT and TRIPS are characterised as IP-focused policies. This section provides a further characterisation of the position of those policies on IP, and the influence they have on IP use in different nations. National influence is particularly relevant in the case of TRIPS, which has binding obligations. All countries examined in the case studies are a contracting party (see Table 3.1).

3.3.1 Patent Co-operation Treaty

The PCT was finalised in 1970, and most recently modified in 2001. US, Canada, India and Thailand are among the treaty parties, with US being the earliest and Thailand the most recent to join. The patent cooperation treaty enables the filing of international patent applications. Thus, with a single application, an inventor can seek patent protection in any of the countries

[3] The IPPC is difficult to categorise according to these characteristics, as it deals with economic/trade risks associated with plant cultivation practices, rather than environmental or social risks related to agricultural production For this research it has been categorised as environmentally-focused, but is more accurately described as trade-focused.

that have signed the treaty. Each country retains autonomy around the patent review and acceptance process, but applicant barriers and bureaucracy are reduced, as only one application needs to be made.

The PCT strongly integrates the theoretical conditions discussed in the previous chapter, and takes a traditional stance on legal and economic aspects of IP. The traditional perspective is not surprising, given that the treaty is 44 years old, but this perspective has not been changed in any subsequent modifications. Furthermore, the treaty is still drawing new members, indicating that the traditional perspective is important to member parties and is unlikely to be revised. The preamble to this policy describes the ambitions of the treaty to "make a contribution to the progress of science and technology", and "facilitate and accelerate access by the public to the technical information contained in documents describing new inventions", which mirrors the IP theory discussed in Ch. 2, that IP enables knowledge-sharing, stimulates innovation and acts in the public benefit. In particular, there is an implicated position that developing countries should adopt the type of IP systems present in developed nations, with the treaty describing a desire to improve economic development in developing countries "through the adoption of measures designed to increase the efficiency of their legal systems".

The PCT also established a standard examination procedure for patents, and lays boundary lines for what types of inventions can be considered patents – those which "appear to be novel, to involve an inventive step (to be non-obvious), and to be industrially applicable", although this is non-binding. These aspects draw on established European and North American boundaries of what may be considered patentable, fitting with the historical context of the concept of patents (Harbers, 1968), but also suggesting a Western-centric view of what IP should cover.

The PCT is broad in scope, and does not deal with specific areas of technology, or enforcement measures. It is more concerned with establishing an international procedure for patents. What can be drawn from the PCT are the types of benefit that it sees as accruing from IP and IP standardisation, those being scientific and technological progress, economic development, legal efficiency, and public access to technical information. The perception of IP indicated by this treaty corresponds well with the theoretical background described in the Ch. 2. The PCT goes further than the motivations for IP use described in the legal and economic theory examined in Ch. 2, advocating that plural approaches to IP construction restrict the potential for IP to create social benefits, giving rise to the need for international standardisation of IP, particularly patents.

3.3.2 Agreement on Trade-Related Aspects of Intellectual Property Rights

TRIPS was drawn up in 1994 as Annex 1C of the Marrakesh Agreement establishing the World Trade Organization. It was amended in 2005 to include more detail about the conditions under which compulsory licences or exceptions to patent privileges can be made, particularly in relation to pharmaceutical products and health. All countries which are party to the WTO, must also be party to TRIPS. The WTO is primarily occupied with harmonising trade regulations, promoting liberalisation of international trade and settling trade disputes, and currently has 159 member states and more in the process of accession (WTO, 2014). TRIPS is aimed at harmonising IP laws to promote IP, and prevent IP from becoming a barrier to trade.

TRIPS is a more powerful standardisation policy than PCT, with introducing binding minimum standards for IP. It goes into much more depth than the PCT on IP standardisation, such as the materials for which IP must be recognised, and other materials for which IP can be recognised but is not required. TRIPS also established standards on the type of enforcement procedures that should be implemented. The preamble, objectives, and principles of TRIPS also provide information about the perspective employed regarding what IP has to offer. IP is described as a way to reduce trade distortions and barriers, promote technological innovation and dissemination, and produce social and economic welfare benefits. These perspectives of IP are in line with the theoretical background of IP from Ch. 2. TRIPS builds on the rationale of these theoretical points , but takes a more critical stance than the PCT, integrating criticisms of IP by drawing specific attention to the potential for IP abuse and trade barriers resulting from IP. TRIPS uses these potential faults of the IP system as further reason to standardise IP systems. TRIPS also has a very different perspective from the PCT on how developing countries should play a role in the standardisation of IP systems, advocating for "maximum flexibility" in integrating international standards in their laws, "to create a sound and viable technological base". This phrasing is more enabling of plural approaches to IP that correspond to diverse national contexts, which is different to the more Western-centric approach of the PCT.

In the area of patents, TRIPS goes into detail about what constitutes an invention, and the specific circumstances under which inventions can be refused patent protection, including biotechnological inventions such as transgenic components of GMOs. This level of detail is very significant for IP standardisation. Article 27.1 states that patents may not be refused on grounds of the place of invention, and the relation of the place of production to the place of patent application. This provision makes it difficult for national economic interests to influence technology transfer, promoting the global flow of technology. Bias against particular technologies is also prevented in Article 27.1, which explicitly requires that all technology fields be considered equally eligible for patent protection. Plant varieties, for example, must be protected, although freedom is given to do so via national *sui generis* systems or a combination of existing systems (patent, Plant Breeder´s Rights, Material Transfer Agreements) and national *sui generis* rules. There is no restriction on the level to which biological life may be patented, but micro-organisms must be considered eligible for patent protection. Article 27.3 indicates that plants, animals and strictly biological processes may be refused patent protection, but only when a clear rationale is presented, according to the criteria of Article 27.2. These criteria permit national interests in the realm of moral concerns, danger to human, animal, and plant life or health, and 'serious prejudice' to the environment, but explicitly excludes interference from national economic concerns and existing legal prohibitions (Article 27, 2). These aspects indicate that TRIPS is a very strong standardising policy, but incorporates scope for national flexibility around international standards. By enabling IP on all forms of technology, and prohibiting bias from national economic interest or legislative history, TRIPS expresses coherence with the liberal economic movement and adheres to the theoretical premise that IP promotes innovation and knowledge-sharing in all fields of technology. It takes a more open position on IP norms and international development than PCT also, by explicitly recognising the importance of cultural and ethical values in technology acceptance, and providing scope for plural, *sui generis* systems of IP, rather than mandating the type of IP developed in Europe and North America.

TRIPS also goes into detail on enforcement of IP, including criminal procedures. This section of TRIPS makes it clear that enforcement of IP is a significant element of creating national and internationally functional IP systems. Despite the specific description of what kind of enforcement provisions are necessary and need to be explicitly adopted by each TRIPS member, the provisions are framed as guides for IP enforcement which allow for national flexibility. The TRIPS reviews conducted in the five case study regions indicate that members have made good use of that flexibility. Nations diverge significantly in terms of how IP infringement is investigated, trialled and punished, and the level of detail with which they describe these procedures. Thailand, for example, has a highly systematic approach to the investigation of suspected infringement specifying the conditions under which police may investigate an infringement, and how they should do so. Punishment is also very specific, with different levels of punishment according to categories of the extent of infringement. Jamaica exhibits vagueness around the trial and punishment procedures, while India, Canada, and the US have a high level of detail. All use an enforcement framework based on the TRIPS requirements but with procedures specific to the national context.

TRIPS makes significant efforts to coordinate legal standards and practice in relation to IP. In terms of IP protection of agrobiotechnology, broad scope is given to apply IP to this end – indeed it is more difficult to deny than obtain IP for such uses, according to the construction of Article 27. The inclusion of specific measures relating to enforcement and repercussions sets an international standard for the seriousness with which IP should be considered when it comes to claims of unauthorised use. This strengthens the credibility of IP as a tool for preventing unauthorised use of GM crops, as a solid international legal infrastructure for applying and enforcing IP has been created, which prior to TRIPS did not exist in such a detailed and globally relevant form.

3.4 Environmentally-Focused Policies

The environmentally-focused policies includes one policy which addresses international management of plant pests and trade barriers arising from protection measures against pests, the EPPC; two policies which deal explicitly with environmental risks associated with unauthorised GM crop production, the CBD and CP[4]; and one which deals with social and environmental benefits from and threats to plant genetic resources, the ITPGRFA. This section characterises the position of those policies on environmental risks arising from unauthorised GM crop production, and the potential for IP-based GM crop regulation to be applied within the policy context. The case study regions which are party to the policies in this category are listed in Table 3.2.

3.4.1 International Plant Protection Convention

The IPPC is a policy developed under the guidance of the Food and Agriculture Organisation of the United Nations (FAO), an organisation whose primary objective is to achieve “food security for all” (FAO, 2014). This policy was first formulated in 1952, although it did not become a significant multilateral instrument until 1993 (IPPC Secretariat, 2005). The version studied here

[4] The CBD deals with risks to biological diversity, of which unauthorised GM crop production is one. The CP is a policy arising from the CBD, which deals specifically with GMO risks.

is the 'New Revised Text' from 1997, which came into force in 2005. It is concerned with plant health, but has specific relevance to trade relations. This 1993 text was concluded at the Uruguay Round of Multilateral Trade Negotiations of the General Agreement on Tariffs and Trade (GATT), a set of negotiations that also gave rise to the WTO. This lends the IPPC a special significance for trade in plant materials. All five countries examined in this research are parties to the IPPC.

The IPPC has a dual purpose to harmonise and standardise measures to prevent the spread of plant pests, and minimise potential trade restrictions arising from such measures. The IPPC has limited application to other potential risks related to unauthorised GM crop production, such as transgene flow, and is only applicable to GM crop risks in the case of a transgenic crop becoming weedy or a weedy hybrid GM crop-wild relative hybrid being produced. While it is not specifically concerned with IP, these aims make it relevant to the use of a trade-related tool such as IP to manage one potential risk from unauthorised GM crop production, that of weedy feral GM crops. By linking these two aims, the IPPC adds further credence to the rationale of using a liberal economic tool such as IP, to assist in the management of plant pests, if possible.

Although not explicitly promoting the use of IP for regulating plant pest issues, the IPPC creates a context of commitment to exercising plant pest management approaches which do not limit international trade. In this context, the IPPC provides a lot of scope to contracting parties to use a market-based tool such as IP where risks arising from unauthorised GM crop production occur. This is a crucial difference to the other environmentally-focused policies, especially the ITPGRFA, which prioritise plural, culturally embedded approaches to pest management rather than approaches with a minimal impact on trade.

3.4.2 Convention on Biological Diversity

The CBD was developed by the United Nations Environmental Programme (UNEP) in 1992, and is considered a landmark policy in the area of biodiversity conservation (CBD Secretariat, 2014). While all of the case countries have signed it, it is not in force in the US (see Table 3.2).

The CBD promotes the conservation and protection of biodiversity, including genetic diversity. In relation to biotechnology, it has a specific requirement for each state to "regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts" (Article 8). Furthermore Article 10 (b) requires parties to avoid or minimise adverse impacts on biodiversity when using biological resources. These aspects place responsibility at the state level for biodiversity impacts associated with biological resource use. The CBD called for some direct products from its policy, including national biodiversity management strategies (Article 6), a subsidiary body on scientific and technical advice (Article 25) and a protocol on safe transfer, handling and use of living modified organisms (LMOs) (Article 19). In this way, the CBD endorses multiple mechanisms for conserving and managing biological and genetic diversity.

In Annex 1, wherein those aspects of biological diversity of greatest significance for management and conservation are described, the CBD also includes "described genomes and genes of social, scientific or economic importance", indicating a high valuation of genetic

integrity, to which transgenic gene flow is a significant risk. The CBD does not specify IP as a mechanism for managing this risk, however, despite their endorsement of multiple management approaches. The CBD does acknowledge the need to respect IP rights concerning biologically derived products and processes, particularly in Article 16.

The CBD also takes a firm position on “fair and equitable” benefit-sharing (Article 15), the provision of access to genetic resource products for the countries providing the resources, and the facilitation of the objectives of the CBD within national and international IP law (Article 16). These aspects indicate that the CBD is written from a perspective in which IP and pure private property creation are not considered the only tools for fair and equitable benefit-sharing, nor the most appropriate tools. This is different from the position on IP expressed in the theoretical conditions of Ch. 2, and the IP-focused policies above, which adopt a stance more consistent with neo-liberal economic theory on fair distribution of goods.

One of the CBD´s most influential provisions on the use of agrobiotechnology and management of GM crop risks is that of Article 19, “Handling of Biotechnology and Distribution of its Benefits”. Item 3 of Article 19 specifies that contracting parties shall consider “the need for and modalities of a protocol setting out appropriate procedures, including in particular, advance informed agreement in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity”. This section of the CBD led to the creation of the Cartagena Protocol on Biosafety, which has had a significant influence on the regulatory structures governing transgenic organism research and commercial production, within and between nations. The case studies examined in Ch. 4 provide further insights into the significance of this provision and the resulting protocol on biotechnology research.

3.4.3 Cartagena Protocol on Biosafety to the Convention on Biological Diversity

The CP was developed by the Secretariat of the CBD, seven years after the introduction of the CBD, as a result of provisions made in Article 19 of the CBD. Four of the countries under study have committed to the CP, while the US has not and Canada has not yet brought it into force (see Table 3.2). The CP is concerned with biosafety regarding transboundary movement of LMOs and is quite similar to the CBD in the approaches to LMO risk management which it emphasises. Multiple strategies for risk management are outlined, with an emphasis on science-based assessments of risk, but no explicit approval of IP use to manage risk is expressed. Further, the text does not have any section which specifically addresses IP relating to biotechnology or LMOs.

Similar to the CBD, the CP made provisions for new institutions and risk management infrastructure, such as the Biosafety Clearing House specified in Article 20, to handle information regarding LMO characteristics, movement and potential risks. A national focal point for liaising with the CP Secretariat and at least one competent national authority for administering the CP and acting on behalf of the Secretariat are also required under Article 19. The CP also includes a comprehensive guideline for risk assessment of LMO release to the environment, which is a significant contribution from this policy to creating international standards for management of GM crop risks.

The case study of Jamaica, covered in more detail in Ch. 4, gives a strong example of the influence which the provisions of the CP can have on the regulation and management of agrobiotechnology research, while expanding national biosafety regulation capacity. Field trials of transgenic papaya began in Jamaica in 1998, which had required the import of transgenic plant materials. Precautions were taken in the form of creating appropriate legislation and regulating authorities to ensure the import and research procedures were monitored and regulated. This resulted in the Plants (Importation) Control Regulations, 1997, and the National Biosafety Committee (Tennant, Pers. Comm.). Jamaica signed the CP in 2001, and in accordance with the CP requirements, established a Biosafety Clearing House and three national focal points, two at the Ministry of Housing, Water and the Environment and one at the Institute of Jamaica (Biosafety Unit, 2014), while the National Biosafety Committee became the designated national authority. Despite these actions further development of the transgenic papaya and other efforts to commercialise or import/export transgenic crops in Jamaica came to a standstill after the CP was signed (Tennant, Pers. Comm.). The regulatory capacity of Jamaica was still insufficient to meet the requirements of the CP, and while a National Biotechnology Policy and National Biosafety Framework were drafted, with assistance from the United Nations Environment Programme, they remain in the draft stage (Tennant, Pers. Comm.). The CP was finally ratified in 2012, although the draft policies have not been formalised and regulations adequate to commercialise transgenic crops or engage in transgenic export/import activities in the context of the CP requirements are still absent (Biosafety Unit, 2014). The experience of Jamaica indicates that the CP is a comprehensive commitment to biosafety for any country to make, and fulfilling its requirements can significantly restrict national development of agrobiotechnology, while greatly expanding the capacity to regulate and monitor GM crop risks on a national level.

The Jamaica case also emphasises the significance placed on implementing state-based approaches to biosafety in the CP. Scope for public-private or private initiatives is not restricted by the wording of the CP but is also not advocated, while public/state institutions are required, e.g. a competent national authority. As the CP is administered on a national basis, the emphasis on state institutions is not unexpected. However, the very slow progress of Jamaica in building sufficient capacity to actively engage with decision-making around agrobiotechnology use within the CP requirements, while local transgenic crops indicate commercial potential but cannot be further developed, suggests that incentives for private interests to develop the required capacity might be lacking for public institutions.

The omission of material relating to the capacity of IP and private property-based regulations to promote safe LMO management also indicates the significance placed on a public institution approach. In this the CP reflects the position indicated by the CBD. The CP discusses the need for rules and procedures relating to liability and redress in the case of damages from transboundary LMO movement (Article 27), but is vague about the form these rules and procedures might take. There is no indication that IP could be suitable for dealing with liability and redress, despite the theoretical potential of IP for that purpose as described in Ch. 2. The subsequent Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress, formed in 2010 and opened for signature in 2011, addresses the absence of specific liability and redress guidelines and instructions in the CP, but of the five countries which comprise the policy selection frame, only India has signed the Protocol, although it has not yet ratified it. Indeed,

of the 167 countries which are parties to the CP, only 58 have signed it, thus due to its limited relevance to the countries under study and the majority of parties to the CP, it was not examined in detail to assess the scope for IP-based GM crop risk regulation within the Protocol.

3.4.4 International Treaty on Plant Genetic Resources for Food and Agriculture

The ITPGRFA was developed by the FAO, and has been accepted by all five countries under study, although it is not in force in the US and Thailand. This policy is quite exceptional compared to the others examined here, particularly compared to the neo-liberal economic perspectives of the IP-focused policies and IPPC. It explicitly promotes the preservation and equal benefit-sharing of local and culturally relevant plant varieties, rather than the liberalisation of trade. This extends to the recognition of Farmers' Rights, including the practice of seed saving. The objective of the ITPGRFA is to promote the conservation and sustainable use of plant genetic resources (PGR) and, in conjunction with the CBD ,the fair and equitable sharing of benefits from PGR use, for sustainable agriculture and food security.

The preamble of the ITPGRFA describes in detail the importance of sustainable genetic resource use, and introduces the concept of 'Farmers' Rights'. It also elaborates the need for "synergy" between agriculture, the environment and commerce, indicating that it does pay regard to the economic and commercial perspectives of PGR use. Although not explicitly stated, it seems that ITPGRFA takes an even stronger position than CBD and CP on the need for alternative equitable benefit-sharing approaches, rather than pursuit of fair sharing through trade liberalisation. This is in stark contrast to the position of the IP-focused policies on equitable benefit-sharing, as these policies equate trade liberalisation with equitable benefit-sharing.

Part 3 of the treaty goes into further detail on Farmers' Rights. These include the right to protection of traditional knowledge relevant to PGR, right to equitable participation in benefit-sharing from PGR use, and right to participation in national decision-making on sustainable PGR use (Article 9). The description of Farmers' Rights in the preamble describes saving seed for future use, and exchange and sale of farm-saved seed and propagating material as aspects of traditional knowledge. Article 9 indicates that parties to the treaty should take measures to protect and promote these rights. These rights are not easy to merge with the use of IP, and particularly patents, to regulate unauthorised GM crop production. Saving and using patented GM seeds from previous crops, without the consent of the IP-holder, is frequently construed as an illegal infringement of IP (Kothamasi and Vermeylen, 2010), but under Farmers´ Rights as described in the ITPGRFA, IP-holders would not be able to enforce their rights. The application of IP for preventing unauthorised GM crop production as described in Ch. 2 would need significant adjustment to meet the objective and be compatible with Farmers´ Rights.

In part 4, the ITPGRFA develops a framework for a multilateral system of access and benefit-sharing. The objective of this system is to facilitate access to PGR and enable fair and equitable benefit-sharing from this use "on a complementary and mutually reinforcing basis" (Article 10). Article 12 indicates that access to PGR should be provided without the need to track "individual accessions" and at a fee no greater than the cost of providing access. Additionally, while providing that access to IP protected PGR should be consistent with existing regulations

and laws, Article 12 prohibits the claiming of IP rights which would limit facilitated access to PGR, including their genetic components.

This adds further emphasis to the positioning within the preamble and Part 3, that the liberal economic movement has not provided fair and equitable benefit-sharing in the area of PGR use, and discrete adaptive regulations are needed rather than liberal market-based solutions. In Article 12, the ITPGRFA also seems to propose limitations to the extent to which IP can be applied, which could reduce the potential for IP use as a GM crop risk regulation tool.

Despite the strong position communicated in the ITPGRFA that PGR should be an openly accessible community resource for ITPGRFA parties, with a corresponding reduction in the regulatory potential of IP, the treaty does recognise a role for some form of IP in the area of PGR, namely that of MTAs. The facilitated access outlined in the multilateral system of part 4, is, per Article 12.4, subject to a MTA between the Governing Body of the multilateral system and PGR recipient, which subsequently applies to any further transfers of those same PGR. The MTA is highly significant to the operation of fair and equitable benefit-sharing, as outlined in Article 13 (d). Via the MTA, any PGR recipient who commercialises the product shall make a payment into the financial mechanism of the multilateral system, which in turn will be reinvested in the conservation and sustainable use of PGR, particularly in developing and transition economy countries and centres of diversity. In this way it is foreseen that benefits will flow directly and indirectly to farmers in all countries, particularly developing and transition economy countries, which sustainably use PGR (Article 13.3).

The protection of Farmers' Rights becomes relevant again in the description of how the MTA benefit-sharing procedure works. Article 13 d describes that different categories of recipient may be subject to different levels of payment, with the potential of exemption for small farmers in developing and transition economy countries. Article 15 b also describes how treaty parties in which PGRs arise will be given free and unrestricted access without any need for MTAs. These aspects of Farmers' Rights, and the promotion of weak IP such as MTAs to achieve economic fairness, is starkly in contrast with the theoretical conditions of Ch. 2 and the approach of the IP-focused policies to fair and equitable benefit-sharing.

A comparison of the influence of this policy in two case study countries provides an insight into the varied significance this policy has for different nations. Both India and Canada are parties to ITPGRFA, and have experienced IP infringement related to GM crop production. While this infringement occurred prior to the ITPGRFA coming into force, the ITPGRFA can be seen to have had a prominent influence on how the case was resolved in one but not the other. In Canada, the infringing party was taken to court, and found guilty of infringing due to his possession and intended use of transgenic seeds which he maintained were saved from seeds which had accidentally spread to his land (*Monsanto Canada Inc. v. Schmeiser*, [2001]). The ITPGRFA had not been signed when this case originally came before the courts, but it was ratified in 2002, after which the case was appealed twice, and came into force in 2004, when the final case was concluded. In the Supreme Court ruling on the case in 2004, a 5-4 majority ruled in favour of how the infringed patent had been construed in the original case, i.e. that the planting of the seed and cultivation of the plants, in knowledge of the technology they contained but without making use of the technology (herbicide-tolerance) constituted

infringement of the patent *(Monsanto Canada Inc. v. Schmeiser*, [2004]). The four-person minority argued that the saving, possession and cultivation of the seeds without making use of the benefits conferred by the transgenic traits, i.e. the technology, was not an infringement of patent, and that the prior courts had misconstrued the concept of patent use *(Monsanto Canada Inc. v. Schmeiser*, [2004]). While this was not an entire application of ´Farmers´ Rights´ as described in ITPGRFA, it was an argument complementary to the ITPGRFA. The majority ruling indicates that the ITPGRFA does not have much influence in the area of agrobiotechnology IP and related ´Farmers´ Rights´ in Canada, although they have ratified the policy.

In India, IP was not in force at the time of infringement[5], but a year after the infringement occurred, the crop was commercialised and IP was in force. Unauthorised production of the transgenic crop persisted however. Action against farmers continuing to use, save, breed, and exchange unlicensed transgenic cotton seed registered prior to official commercialisation, would have been ineffective, Due to the incorporation of ´Farmer´s Privilege´ in the Indian Plant Varieties and Farmers´ Rights Bill, 2001 (Lalitha, 2004). The bill was created in the same year as ITPGRFA, and India ratified ITPGRFA in the following year, so the inclusion of ´Farmer´s Privilege´, in a manner complementary to the ITPGRFA term, occurred prior to ratification of the ITPGRFA. Nonetheless, formative discussions prior to ITPGRFA finalisation influenced the inclusion and definition of ´Farmer´s Privilege´ in India´s 2001 Bill (Ramanna and Smale, 2004), contributing to the present situation of unlicensed transgenic cotton being produced alongside the licensed varieties. The comparison of the influence of this policy on two contracting parties, dealing with infringement resulting from unauthorised GM crop production, indicates that while the ITPGRFA can strongly support the construction and application of *sui generis* plant variety protection systems, in which agrobiotechnology patents have more limited applications than patents for other products, ITPGRFA might also have no observable effect on national patent systems which embrace the standard construction of product patents with regard to plants.

3.4 Summary of Main Findings

These findings are a summary of the assertions made regarding IP in the policies discussed above. Based on these observations, the compatibility of the policies and the theoretical background of IP, as described in Ch. 2, are examined. Further, the relationship between policy positions on IP and GM crop risk management, and the theoretical premises of IP-based GM crop risk management from Ch. 2 is explored.

3.4 Discussion

3.4.1 Policy Perspectives on IP

The policies under study vary in the perspective they have on IP. The IP-focused policies support the use of IP with a neo-liberal economic perspective, advocating for clearer standards in more powerful forms of IP such as patents. The environmentally-focused policies differ more on the topic of IP, for instance, the IPPC is formulated complementary to the IP-focused policies, while the ITPGRFA is more divergent.

[5] See Ch. 4, section 4.4.2 for more details.

The PCT regards IP as a way to enable scientific and technical progress, and offer greater transparency for the public. TRIPS concurs, also making reference to the potential of IP to improve trade efficiency and produce social benefits. TRIPS also regards IP as an instrument which can be abused and can create barriers. IPPC places less emphasis on IP, but the formulation is enabling for IP-style GM pest management. The CBD values IP, but also reflects academic criticisms of IP described in Ch. 2, as it indicates that IP should not prevent access for public institutions and developing countries, or run counter to fair and equitable sharing of genetic resource usage benefits. In this way the CBD implies that IP is not *always* a tool that provides fair and equitable resource sharing. CP does not address IP, but as a policy borne out of the CBD, it can be considered to have a similar perspective on IP. ITPGRFA describes in detail 'Farmers' Rights', which do not correspond well to IP over plant materials and genetic resources, but can be constructed complementary to the TRIPS provision on *sui generis* plant variety protection systems. Although it does take a stance against strong IP such as patents, it also promotes the use of less powerful IP, particularly MTAs. ITPGRFA, similar to CBD and CP, implies that IP, in the form of the patent, is not *always* a tool which provides fair and equitable resource sharing. None of the policies are specifically anti-IP, but a generalisation can be made that the IP-focused policies advocate for IP and see IP as a way to achieve more liberalised trade and greater access to benefits, including in plant biotechnology, while most of the environmentally-focused policies, bar the IPPC, recognise IP benefits but also show concern for problems arising from IP, including the adequacy of standard IP systems in providing equal access to benefits from technology.

3.4.2 Relevance for International IP Standards Regarding GMOs

The policies differ in their relevance for international IP standards regarding GMOs, as plant and animal material or products of biotechnology. The PCT, TRIPS and ITPGRFA have the strongest stance on IP for transgenic organisms, while the IPPC, CBD and CP are not explicitly advocating or obstructing standardisation of GMO IP or IP-based regulation of GM crop risks. The PCT sets international standards in patentability and enables international patent applications, making it easier to apply for a patent. TRIPS is a highly detailed IP standardisation policy. It specifies the grounds for refusing patents on specific types of technology, including biotechnology. TRIPS also mandates IP for plant material legislation but allows sovereign flexibility in formulation. TRIPS sets detailed standards for IP enforcement. These aspects of TRIPS make it extremely powerful and relevant for global GMO IP standards. The ITPGRFA promotes MTAs, a relatively weak form of IP, as the most appropriate type of IP for genetic resources, which can be extrapolated to include GMOs and the transgenic technology contained therein. This policy acknowledges the legitimacy of existing IP systems and IP laws governing genetic resources, but describes a need for alternative benefit-sharing systems like 'Farmers' Rights', and disallows IP claims on genetic resources gained by 'facilitated access'. The ITPGRFA has relevance to international GMO IP standards, as it goes against the movement to apply increasingly stronger IP to a wider range of material and processes, as expressed by TRIPS and PCT. It is not formulated to contradict or reverse the current standards for IP, but to make it necessary for further layers of complexity to be considered when applying IP, rather than applying patents to "anything under the sun made by man" as in the decisive US Supreme Court ruling on biotechnology in *Diamond v. Chakrabarty* (Sease, 2007).

Fig. 3.1 describes the relevance for international GMO IP standards of the six policies according to the strength of the position taken on IP standardisation, particularly in relation to agrobiotechnology. This figure also describes the perspective indicated in the policy of the adequacy of standard IP systems as fair benefit-sharing systems, and the need for alternative systems. This visualisation of the policy characterisation discussed above provides a graphical depiction of the observation that environmentally-focused policies (CBD, CP and ITPGRFA) are more critical of IP than IP-focused policies (PCT, TRIPS), with the exception of the IPCC. Moreover, the policies which deal primarily with biological diversity risks and plant pests are of less relevance to international GMO IP standards.

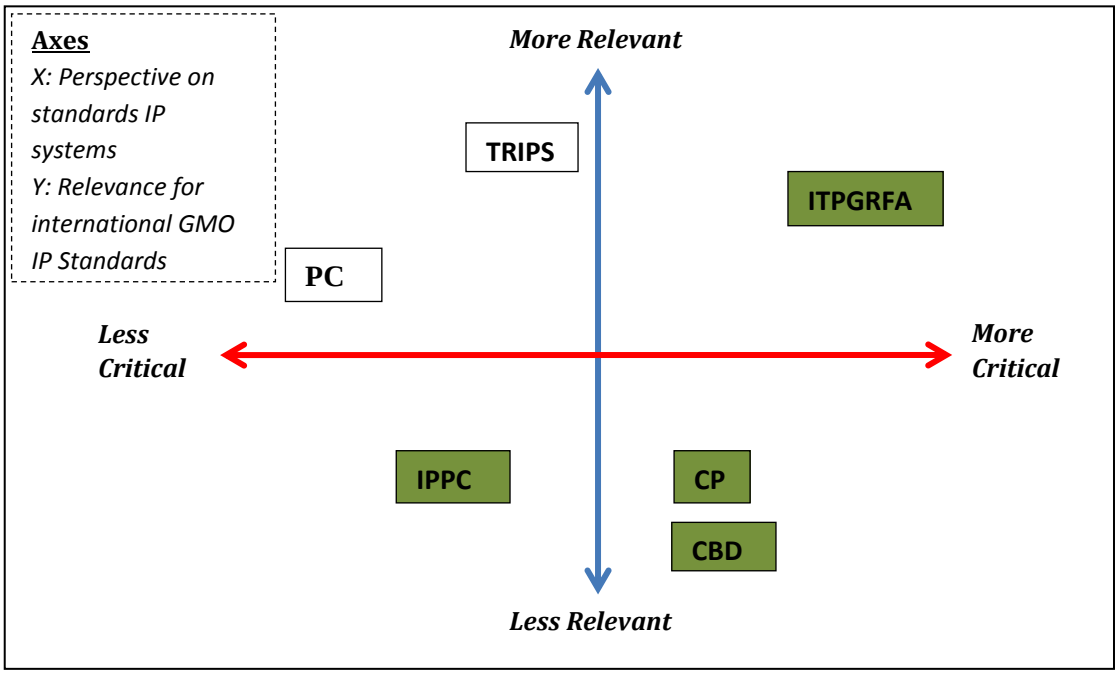

Figure 3.3: Policy perspectives on IP and relevance for global GMO IP standards. *PCT: Patent Cooperation Treaty, 2001; TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, 1994; IPPC: International Plant Protection Convention, 1997; CBD: Convention on Biological Diversity, 1992; CP: Cartagena Protocol on Convention on Biological Diversity, 2000; ITPGRFA: International Policy on Plant Genetic Resources for Food and Agriculture, 2004; Green boxes indicate environmentally-focused policies, white boxes indicate IP-focused policies.*

3.4.3 Compatibility of Policies Examined with IP Theoretical Background

The policies exhibited variation in their level of compatibility with the theoretical background to IP as described in Ch. 2. This is significant for the likelihood of IP-based GM risk management to be compatible with the policy objectives. The theoretical background of IP was described extensively in Ch. 2, but for this discussion IP will be summarised as an economic and legal tool which is particularly useful in neoliberal economic government, which stimulates innovation and public knowledge disclosure, and which allows recognition of inventors and product users, the extension of liability to product users, and the punishment of unauthorised users.

The IP-focused policies both endorse the neoliberal economic vision. PCT and TRIPS promote strong IP law, with TRIPS specifying IP enforcement conditions. TRIPS sets minimum standards

for what can be patented but no maximum standards, indicating strong consistency with the theoretical background of IP. PCT integrated EU court rulings on patentability of material, and both PCT and TRIPS incorporate US court rulings on biological material IP, indicating satisfaction with how IP works in practice, and integrates US and EU court rulings on patentability of material. The IPPC is an environmentally-focused policy which is also consistent with the vision shared by TRIPS and the PCT. The IPPC is not focused on enabling IP, but advocates for means of plant protection which do not obstruct IP potential, reflecting the theoretical vision that IP brings public benefits and technological innovation. Fig. 3.2 describes the greater compatibility of these three policies with the theoretical background of IP.

The environmentally-focused policies are less consistent with the theoretical background of IP. The CBD and CP are highly similar in their relationship with the theoretical background of IP. The CBD does not fully support IP as an ideal benefit-sharing mechanism, which is also an implicit criticism of the neoliberal economic vision. The CP is not as explicit in its regard for IP as a benefit-sharing mechanism. Neither the CBD nor CP explicitly addresses the potential of an IP-based approach to GM risk management, although it advocates for diverse management approaches. The ITPGRFA takes a stronger stance than CP or CBD, actively promoting alternatives to the neoliberal economic position on 'fair and equitable benefit sharing'. ITPGRFA does recognise a need for legal arrangements and regulations of genetic resource use, but promotes IP which is theoretically considered weak, such as MTAs, over stronger IP such as patents. The ITPGRFA recognises Farmer´s Rights, including the right to practice certain ways of agriculture, which might obstruct the extension of liability to product users and capacity to enforce IP. These points indicate that CBD and CP diverge somewhat from the theoretical background of IP, while ITPGRFA actively dissociates from some aspects of IP theory, such as neoliberal economic rationale, while accepting others, such as weak IP for protection of genetic resources.

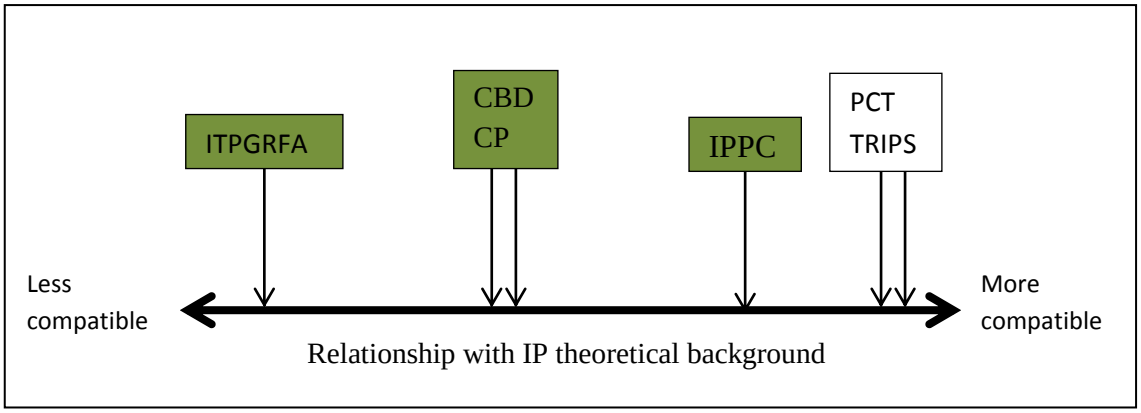

Figure 3.4: Compatibility of policies with theoretical background of IP. *PCT: Patent Cooperation Treaty, 2001; TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, 1994; IPPC: International Plant Protection Convention, 1997; CBD: Convention on Biological Diversity, 1992; CP: Cartagena Protocol on Convention on Biological Diversity, 2000; ITPGRFA: International Policy on Plant Genetic Resources for Food and Agriculture, 2004; Green boxes indicate environmentally-focused policies, white boxes indicate IP-focused policies.*

3.4.3 Policy Positions on IP and Theoretical Premises of IP-Based GM Crop Risk Management

In Ch. 2, two main premises of IP-based GM crop risk management were identified from the theoretical background of IP functioning. These were **A:** the creation of a ***specific liability network*** around the transgenic technology and **B:** the creation of ***enforceable conditions of action*** for those participating in the network. Although none of the policies examined explicitly discussed the use of IP as a GM crop risk management tool, some inferences can be made from the above observations on how the policies relate to the theoretical premises of IP-based GM crop risk management. The IPPC, PCT and TRIPS were found to be more compatible with the background theory of IP, which is also influential for the premises of IP-based risk management. TRIPS and the PCT were also described as less critical of standard IP systems, and of high relevance for international GMO IP standards, while the IPPC was neither distinctly critical of IP or of significant relevance for international GMO IP systems. In the context of these three policies IP-based GM crop risk management according to the premises described in Ch. 2 could be expected to meet few policy obstacles. TRIPS in particular enables condition B of the management approached characterised in Ch. 2, by strengthening IP enforcement standards.

The CP and CBD are very influential policies in the governance and risk assessment of GMOs. They take a somewhat divergent position on benefit distribution from the background theory of IP (Fig 3.2), and are characterised as slightly critical of standard IP systems on the same grounds. They do not deal explicitly with GMO IP however, and are considered to be of low relevance for international GMO IP standards. In the context of these two policies, IP-based GM crop risk management might not be consistent with the perspective on benefit-sharing, and might overlap with other risk regulation tools devised within the provisions of these policies as integrated in national policy, but there appear to be no apparent reasons why it would otherwise be obstructed.

The ITPGRFA takes a strongly divergent stance from the theoretical background of IP described in Ch. 2. It is strongly critical of standard IP systems, apart from less powerful IP such as MTAs. It is also a policy which deals explicitly with genetic resource IP, of which GMO IP can be considered to be a part. The ITPGRFA in particular has the potential to obstruct theoretical premise B from functioning optimally, as it outlines conditions under which farmers should be exempted from conditions of action that would threaten their Farmers´ Rights. It also advocates for MTA use over stronger IP such as patents, which would also act to reduce the enforceability of conditions of action. If the perspectives of this policy and provisions within it were strongly integrated into national policy, IP-based GM crop risk management as described in Ch. 2 would be very difficult to apply. The case of India helps to illustrate how Farmer´s Rights, as advocated in the ITPGRFA, may obstruct this type of GM crop risk management, while the case of Canada indicates that the ITPGRFA does not need to be integrated into national policy in such a way as to create an obstruction to full extension of patent rights over agrobiotechnology products.

In respect to these findings, some observations can be made about the case regions which are more likely to have enabling or obstructing environments for IP-based GM crop risk management. As depicted in Tables 3.1 and 3.2, the US is party to the PCT, TRIPS and IPPC, but has not ratified the CBD or ITPGRFA. Canada has ratified all but the CP, and as observed above the ITPGRFA has been ratified in a way which does not obstruct IP-holders rights in the context

of GM crops. Thailand is a contracting party to all, but has not ratified the ITPGRFA. In these three countries, it appears unlikely that international policy obligations would be a barrier to successful implementation of IP-based crop risk management. India has ratified all of the policies, while Jamaica is not a contracting party to the PCT but has ratified the other five policies. In India the way in which the *sui generis* system permitted under TRIPS has been constructed, and the ITPGRFA ratified, does not seem compatible with IP-based crop risk management. In Jamaica, the lack of clarity regarding biosafety and biotechnology policy and law indicates that IP-based GM crop risk management is not yet relevant there, but the combination of policies ratified indicates that the international policy obligations of Jamaica may pose some barriers to the successful application of such a strategy, particularly the ITPGRFA.

3.5 Conclusion

The policies examined above take some similar and some very different positions on IP. While none explicitly discuss IP use to regulate unauthorised spread of GMOs, it can be derived, from the IP perspectives presented within the policies, that some international policies draw on a perspective which enables and facilitates IP-based GM risk management. These are the policies which express a neoliberal economic perspective, complementary to the provisions for IP-based GM crop risk management characterised in Ch. 2. Conversely, some international policies with an explicit environmental focus can be prohibitive in their position on IP application to GMOs or plant genetic resources. These are policies which are critical of the theoretical background of IP-based GM crop risk management, by seeking alternative benefit-sharing systems or strongly advocating for alternatives to IP.

These findings can be extrapolated to assess the likelihood of IP-based GM crop risk management to be successfully applied on a national basis, according to the international policy obligations countries are required to adhere to. However, such a judgement without a further investigation of the integration of international policy on a national level does not have strong predictive capacity, as already indicated in this chapter with the case of ITPGRFA application in Canada. Unfortunately, the resources were not available during this thesis research to pursue a full investigation of the national implementation of international policies for the cases under study, apart from TRIPS and the specific examples of the CP in Jamaica and ITPGRFA in India and Canada. An extended research on this topic would benefit from the examination of national and regional policy which incorporate the international policies examined here.

4: Case studies of the Role of Intellectual Property in Genetically Modified Crop Risk Management

4.1 Introduction

In this chapter, five cases of GM crop risk management are examined, in order to investigate the experience of IP as a regulation mechanism for GM crop risks associated with unauthorised GM crop production, and assess the potential of using IP as a GM crop risk management tool. Two of the cases involve successful management of GM crop risks and avoidance of unauthorised GM crop production, while three involve incidents of unauthorised GM crop production. The examination of these cases focuses on the management approach used and the role which IP played in that management approach. This chapter compares the experiences of GM crop risk management, and role of IP within that management, with the rationale for IP-based GM crop risk management described in Ch. 2, and assesses the compatibility of IP-based regulation as described in Ch. 2 with the management approaches applied in the case studies. This discussion on the potential for IP-based management to play a stronger role in GM crop risk management is expanded further by applying sociological perspectives of agency and power, deriving from Latour´s concept of diplomacy (Latour, 2009) and flattened landscapes (Latour, 2007) and Foucault´s concepts of disciplinary power (Foucault, 1977), individualising techniques and totalising procedures (Foucault, 1982), to the case study findings. The management and occurrence of risk are analysed, using literature produced by people directly involved in the cases, including journal articles, organisation reports, and court proceedings, and for some cases, using data from personal interviews with people involved in the risk management process, a list of which can be found in Annex 2. Technical information regarding the crops under study are not discussed in detail in this chapter, but more detailed information about the crop and target pests can be found in Annex 1.

Successful GM crop risk management

The cases of successful management are listed in Table 4.1. The case of PRSV-resistant papaya in Hawaii and Jamaica are examined in detail, particularly the case of Hawaii, the success and management of which has been widely documented. In Jamaica management was successful, but was limited to research production of PRSV-resistant papaya, and did not expand to commercial scale production. The implications of both cases for the use of IP as a regulatory tool for environmental risk related to unauthorised GM crop production are discussed in section 4.3.3.

Table 4.1: Details of cases of successful GM crop risk management. *PRSV: Papaya Ringspot Virus*

Location	*Crop Type*	*Time Period*
Hawaii, US	PRSV-resistant Papaya	1986 – 2013
Jamaica	PRSV-resistant Papaya	1994 – 2013

Unsuccessful GM crop risk management

The cases of unsuccessful management are listed in Table 4.2. Rather than dwell on the management processes, which are broadly similar across all of the cases, the examination concentrates on the specific incidences of risk and the use of IP-based management strategies

in relation to those risks. These cases involve PRSV-resistant papaya development in Thailand, *Bt*-cotton production in India, and herbicide-tolerant canola production in Canada and the contiguous US. Of these, the first is a case which did not progress beyond research production, while the latter two cases involve regions where the crop under study continues to be produced commercially, although not without controversy.

Table 4.2: Details of cases of unsuccessful GM crop risk management. *PRSV: Papaya Ringspot Virus; Bt: Bacillus thuringiensis toxin*

Location	***Crop Type***	***Time Period***
Thailand	PRSV-resistant Papaya	1995 – 2004
India	*Bt* – Cotton	1996 – 2013
Canada/Contiguous US	Herbicide-tolerant Canola	1985 – 2013

4.2 Key Phases in GM Crop Risk Management

The cases are examined with attention to the management structure and strategy at different phases of crop development and commercialisation. Three phases have been characterised with distinct levels of risk knowledge and intensity of risk management, based on the process of developing a transgenic crop variety from gene characterisation and insertion to crop commercialisation and commercial production. As described in Ch. 1, risk is characterised in this research according to the ISO (2009) definition, which describes risk as the "effect of uncertainty on objectives". The three phases are the Development Phase, the Field Trial Phase, and the Commercialisation Phase. The distinctions between these phases are summarised in Fig. 4.1, and below the characterisation of ´risk knowledge´ and ´intensity of risk management´ in each phase is described in greater detail . IP and state governing bodies can have an influence on the type of management practiced in each stage, and in most instances do have such an influence, as are observed in the case studies. At any stage IP in the form of MTAs may be used to exchange materials with other researchers, while patents can be applied for when sufficient knowledge of the processes and products under development is gained.

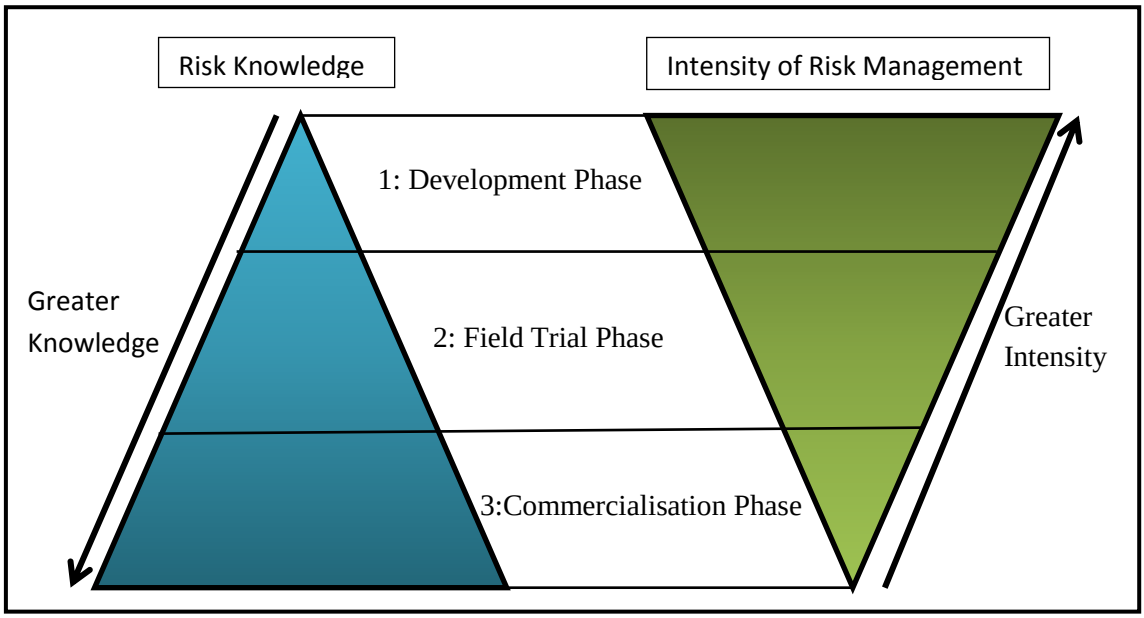

Figure 4.1: Phases of GM crop risk management, showing differences in risk knowledge and intensity of risk management.

1) Development phase

This is the initial phase of crop development, mostly based in the laboratory, and later the greenhouse (Gonsalves, 1998). The transformed plant material is treated as a new material, although characteristics of the contributing materials may be known. Risk knowledge is low, and intensity of risk management is high. Experimentation is carried out to characterise the potential risks of the transformed material and describe consistently expressed traits. The potentially risky GM plant tissue is strictly limited in its interactions, while knowledge is being developed. These interactions are usually restricted to authorised laboratory and greenhouse researchers and other relevant workers, equipment involved in the research and other relevant biological material such as target pests (Gonsalves, 1998). IP plays a role in this phase, as permissions may be needed to use patented products or processes in the development and observation of the crop, and MTAs between researchers using each other´s experimental materials may be formed. The conditions of patent permissions and MTAs can have subsequent consequences for ownership and use of the crop under development, and may also include conditions for management of the material covered by these IP agreements (Nottenburg and Rodríguez, 2008; Kowalski, Ebora, Kryder and Potter, 2002). Permission from state bodies to proceed with crop development may also be required, which can introduce conditions for material management in this phase.

2) Field Trial phase

This involves testing the developed variety under 'field conditions' which are as close to the natural or proposed future environment as possible, to develop further knowledge of the performance of the crop in the intended environment of cultivation (Parker and Kareiva, 1996). Knowledge of potential risks is more extensive, as knowledge has been gained in the Development phase. Risk management is lower in intensity as there is greater knowledge about the type of risk scenarios which are likely or unlikely, and under which conditions they may occur. Nonetheless, knowledge of risks is still developed in this phase, and caution is exercised in relation to risk management. The physical space is less constrained and controlled than the laboratory or greenhouse, but is still confined to a specific, manageable area. Interactions are limited, as in the Development phase, although an expanded range of non-human actors are included, with less human control efforts than in the Development phase, to try simulate ‘natural’ conditions. IP has a similar influence in this phase as in the previous phase, with conditions of use applying to patented processes and products or materials under MTA, as negotiated with the IP-holders. State bodies which had an influence in the development phase may continue to have an influence in this phase, while additional bureaucratic elements, such as national environmental authorities, may also be employed to regulate this phase as the material enters the natural environment which is less restricted than the laboratory or greenhouse.

3) Commercialisation phase

In the Commercialisation phase, the crop which has been developed is released to the intended market for commercial production. Usually, this requires authorisation from state agencies, along with thorough risk assessment to ascertain the potential risks associated with the crop and the way in which these can be managed. Risk knowledge is highest in this stage. Although likely risk scenarios may be managed intensively and with a strict protocol, the intensity of management is lower than in other stages due to the greater knowledge of

potential risks and strategies to deal with them. As well as environmental risks, assessment is carried out to ensure that the product is fit for the intended purpose, e.g. human or animal consumption. No further experimentation to develop risk knowledge is required once authorisation has been achieved, although monitoring may be required.

Restriction of human and non-human actor access is not as stringent as in the previous stages. However, the state authorities and those involved with development and retail of the crop may place limits on human and non-human actor interactions with the crop, based on the potential risks. These limits or conditions may be asserted by the state, through the relevant state agencies, or by the group which developed and commercialised the crop. It is at this point that the IP agreements negotiated in previous stages, and any patents applied for by the development and commercialisation group, are of greatest importance. Agreement to commercialise the crop must be received from any party owning a patented product or process involved in the crop production, and such agreements usually involve a financial transaction (WIPO, 2004a). MTAs may also contain conditions which necessitate negotiation and financial exchange prior to commercialisation of the crop (Kowalski et al., 2002). Patents owned by the development and commercialisation group enable the group to extend conditions of practice to commercial producers via Technology Use Agreements, contracts or licences. This gives the group the capacity to specify the ways in which a producer may cultivate, harvest, store and sell a crop, and to transfer liability for risk incidence to producers, if malpractice can be ascertained. The exercise of this capacity is illustrated by Monsanto´s Technology/Stewardship Agreement (Monsanto, 2014). Malpractice, i.e. non-compliance with these specifications, may be considered as breach of contract, and as the incidence of an environmental risk for which the usage conditions were devised to prevent (Monsanto, 2014).

As can be observed from the description of the three distinct phases above, and in the case studies which follow, the role of IP in the management of GM crop risks becomes greater later in the process of GM crop development. It is of greatest relevance to the final stage, the Commercialisation phase, at which point knowledge of risks associated with the GM crop is also greatest, and the intensity of risk management is reduced, comparative to earlier stages. This is an indication that IP as a management tool for GM crop risks is most useful in the Commercialisation phase, but plays a minor role in the Development and Field Trial phases, while other regulatory tools such as state regulation or physical limitation play a much greater role in those two phases.

4.3 Cases of Successful GM Crop Risk Management

The risk management of PRSV-resistant papaya in Hawaii and Jamaica are examined, including the role of IP in the risk management approach as the GM crop risk knowledge and intensity of risk management moved through the three phases described above. As discussed above, the Hawaii PRSV-resistant papaya case is described first, followed by the Jamaican case, which only involved the first two phases. These two cases are both cases of successful management and offer examples of how GM crop risk management strategies, including IP-based management, can be applied for successful outcomes.

4.3.1 Hawaii PRSV-Resistant Papaya, 1986-2014

The development of PRSV-resistant papaya began in 1986 in the US, and was commercialised in Hawaii in 1998. Prevention of unauthorised production of the GM crop has been consistently successful, although the Hawaii SEED organisation reports finding genetic contamination of domestic non-GM papaya plants following their own private investigation (Bondera and Query, 2006). This thesis research does not have sufficient scope to investigate the validity of these claims and the designation of this case as a case of successful management is based on information from state authorities, University of Hawaii, and relevant journal articles. Both GM and non-GM papaya are cultivated in Hawaii, and organic and conventional papaya farming (non-GM) are practiced for household and commercial purposes.

Development phase 1986-1995

Between 1986 and 1987, Cornell University and Asgrow Seeds collaborated to identify and clone the coat protein gene of a Hawaiian strain of PRSV (Gonsalves, 1998). This collaboration was led by D. Gonsalves of Cornell and J. Slightom of Asgrow Seeds. Asgrow Seeds was a subsidiary of Upjohn Co. at the time but changed hands a number of times in the development of PRSV-resistant papaya which followed.

The US Department of Agriculture (USDA) provided further funding to apply the research of Gonsalves and Slightom to Hawaiian papaya, with the involvement of University of Hawaii (UH) and six UH researchers, led by R. Manshardt (Gonsalves, 1998). This further research concentrated on transformation of Hawaiian papaya with the coat protein gene of Hawaiian PRSV, to confer PRSV resistance to the papaya. The laboratories of all three institutes were used, while the greenhouses of Cornell and UH were predominantly used for growing the resulting GM papaya plants during this stage (Gonsalves, 1998). A gene gun tool developed by a further Cornell researcher, J. Sanford, was required for the transformation and so Sanford, the gene gun, and Sanford's laboratory staff entered the organisational structure temporarily to perform the transformation.

In addition to the PRSV strains and coat protein genes of Slightom and Gonsalves, samples of three varieties of papaya, PRSV coat-protein gene constructs, and the final hybrid of papaya sample and PRSV coat-protein gene construct were the focus of management procedures. National regulations from the US Food and Drug Administration (FDA), Environmental Protection Agency (EPA) and Animal and Plant Health Inspection Service (APHIS) applied to the hybrid plant material. These provided a general regulatory background, limiting environmental exposure, including potential exposure arising from material handling and disposal practices (Office of Science and Technology Policy, 1986). The laboratory protocols of the three research institutions provided more direct regulation of the handling and disposal of all of the concerned materials. Further, D. Gonsalves of Cornell and J. Slightom of Asgrow Seeds/Upjohn Co., and R. Manshardt of UH, were the primary researchers of the respective institutions (Gonsalves, 1998). They specified the laboratory staff who carried out handling and experimentation practices and specified how these actions should be performed, with the aim of controlling and excluding unwanted variables and processes. With such careful control, risk management in the laboratories and greenhouse was intensive, but necessary as knowledge of potential risks was still low. Fig. 4.2 describes the organisational structure of the regulations which applied to the management of PRSV-resistant papaya in the development phase.

A crucial outcome of this phase was that the transformed GM papaya expressed two distinct reproductive morphologies, hermaphrodite and female (Gonsalves, 1998). This had implications for further research and use, as the hermaphrodite flowers had the capacity to pollinate via wind pollination means, and would therefore require more intensive management than the female flowers which do not have the capacity to pollinate.

The role of IP

Fig. 4.2 indicates the IP present in the organisation structure of PRSV-resistant papaya management in the Development phase. J. Slightom and D. Gonsalves filed a patent on the PRSV coat protein genes and gene construct in 1988, on behalf of their respective organisations (Slightom, Quemada, Gonsalves and L´hostis, 1988). This patent was granted in 1990 and granted both researchers and organisations an exclusionary capacity, ensuring UH could not develop a PRSV-resistant papaya involving the PRSV gene construct without the permission of Slightom and Gonsalves. In 1994, Asgrow Seeds was taken over by Seminis and Asgrow`s claim to the PRSV coat protein gene patent was also transferred (Pollack, 2005).

Sanford´s gene gun, which was used for the transformation, was covered under a pending patent, granted in 1991, and also required authorisation to be granted by Sanford and his fellow IP-holders in relation to the use of the resulting material (Sanford, DeVit, Bruner and Johnston, 1991). The PRSV coat protein gene construct which was used to transform the papaya plants involved the use of other patented materials such as the CaMV promoter sequence (Slightom et al., 1988). Permission from organisations and individuals who held IP rights to products and processes involved in the production of the PRSV coat protein gene construct were necessary to use the gene construct for transformation of the papaya. Those organisations and individuals had the potential to influence the management of the Development phase, but it is not apparent from various accounts of the research that such an influence was exerted (Gonsalves, 1998, 2004, 2014; Fermín et al., 2004; Gonsalves, Lee and Gonsalves, 2007). In Fig. 4.2, the influence of Sanford and the relevant IP-holding organisations and their representative individuals is represented by a dashed line to indicate temporary involvement in the case of Sanford, or partial involvement in the case of the IP-holders who did not exert any influence.

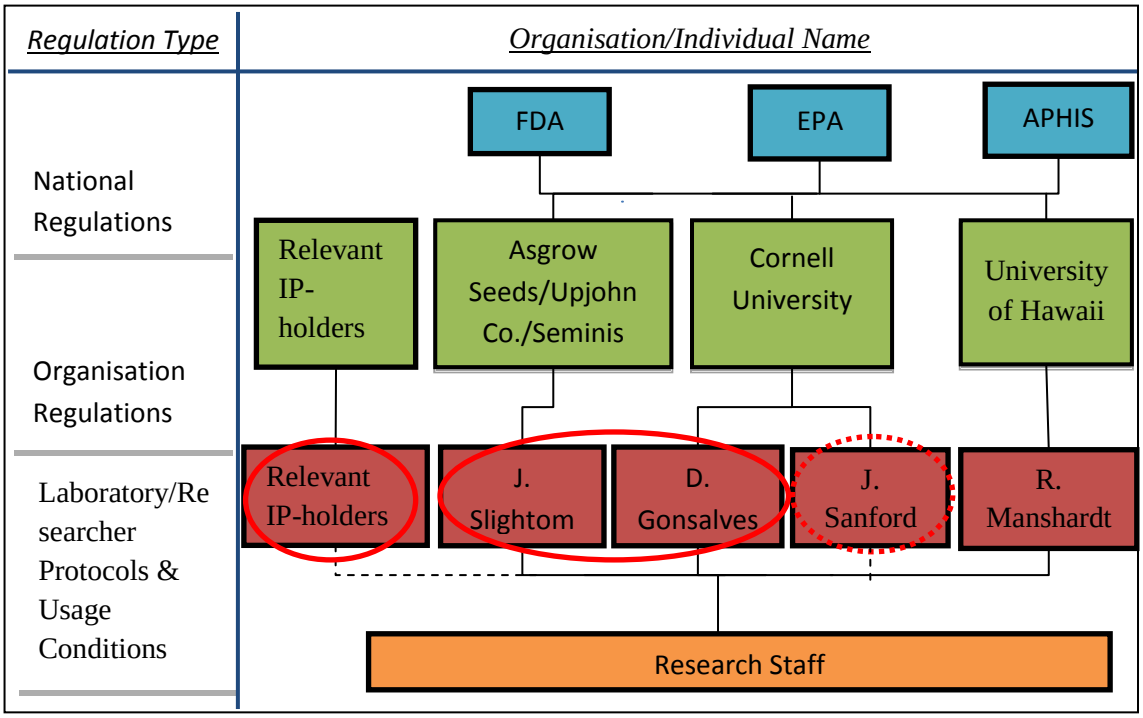

Figure 4.2: Organisation structure of Development phase of Hawaiian PRSV-resistant papaya production. *FDA: US Food and Drug Administration; EPA: Environmental Protection Agency; APHIS: Animal and Plant Health Inspection Service; IP: Intellectual Property; solid red ring indicates patent present; dotted red ring indicates patent pending; solid black line indicates full involvement; dashed black line indicates partial or temporary involvement.*

Field Trial phase, 1992-1998

The Field Trial phase took place in Hawaii, involving two separate field trials. The first was under primary supervision of Manshardt, while the second was supervised by S. Ferreira, both of UH (Gonsalves, 1998, 2014). The main focus of regulation in this phase were the transformed PRSV-resistant papaya plants. Risk management intensity was less than in the Development phase, but caution in relation to potential risks, known and unknown, was still exercised. APHIS took on a stronger regulatory role in this phase, while the role of the EPA and FDA remained the same as in the previous phase (Gonsalves, 1998, 2014). To conduct a field trial in the US, permission must be granted by APHIS, specifying the physical location, material involved and primary researchers involved. The application for the first field trial was made by Manshardt, thus he became the main local regulator, legitimated by APHIS and the other researchers involved (Gonsalves, 2014). In the second trial, another UH researcher, S. Ferreira became the research leader and primary local regulator, subject to the conditions established by APHIS. In this phase APHIS, and Manshardt and S. Ferreira, representing UH, took on stronger regulatory functions and shaped the management approach. Fig. 4.3 describes the organisational structure of this phase.

Manshardt´s field trial involved female plants, and was carried out at Waimanalo Experiment Station, a UH facility on Oahu island, in 1992 (Manshardt, Pers. Comm.). On Oahu , the magnitude of the PRSV problem was such that no commercial papaya production had taken place since the 1950s (Gonsalves, 1998). Manual inoculation of half of the transgenic plants with PRSV was carried out, while the other half were exposed to PRSV from environmental

sources (Manshardt, Pers. Comm.). A deliberate choice to use female plants was used, to prevent any potential transgene movement by pollen dispersal, while any fruits were removed prior to maturity and buried on site, to prevent potential transgenic seed dispersal (Manshardt, Pers. Comm.).

Ferreira´s field trial took place in 1995, on Hawaii island in the commercial papaya growing region of Puna (Gonsalves, 1998). In contrast to the Oahu trial, this trial was intended to mimic commercial growing conditions, using the SunUp cultivar which was shown to be resistant during the field trial, and Rainbow, a hybrid which had been bred during the first field trial of the resistant cultivar and a popular commercial variety (Manshardt, Pers. Comm.; Gonsalves, 2014). The field trial posed more potential risks of transgenic contamination than the Oahu trial, due to the concentration of commercial papaya plantations in the vicinity of the trial (Gonsalves, 1998). Moreover, both female and hermaphrodite plants were used, with the females removed after flowering, as per standard commercial practice (Manshardt, Pers. Comm.). This created greater potential for transgenic pollen spread than in the previous all-female plant trial at Oahu. However, PRSV was also deemed to have rendered papaya production uneconomical within this region, so the potential commercial risk of transgene contamination of non-GM papaya was considered negligible (Gonsalves, 2014). APHIS granted the permit, with the specification that measures to prevent transgenic contamination or cross-breeding should be taken, including isolation of the site from commercial orchards, monitoring any abandoned trees within the area for evidence of cross-breeding, and burial of fruits on site (Gonsalves, 2014).

Disposal of plant material on site, buried in the ground indicates less intensive risk management than, for example, the incineration measures required of material with greater risk potential. In both field trials, control of environmental influences was more relaxed than in the development phase, to simulate natural environmental conditions as closely as possible.

The role of IP

Gonsalves and Slightom continued to retain the capacity to influence the type of management employed by Manshardt and Ferreira, and the manner in which the GM PRSV-resistant papaya would be used, by virtue of their patent on the PRSV coat protein gene construct. There is no indication that this regulatory capacity was employed however, and the involvement of Slightom and Asgrow in particular was less than in the Development phase (Gonsalves 1998; 2014). Asgrow was purchased by Seminis in 1994 (Pollack, 2005), transferring the patent into joint ownership of Seminis and Cornell, represented by Slightom and Gonsalves. These changes are also not reported to have brought any changes to the management structure (Gonsalves 1998; 2014).

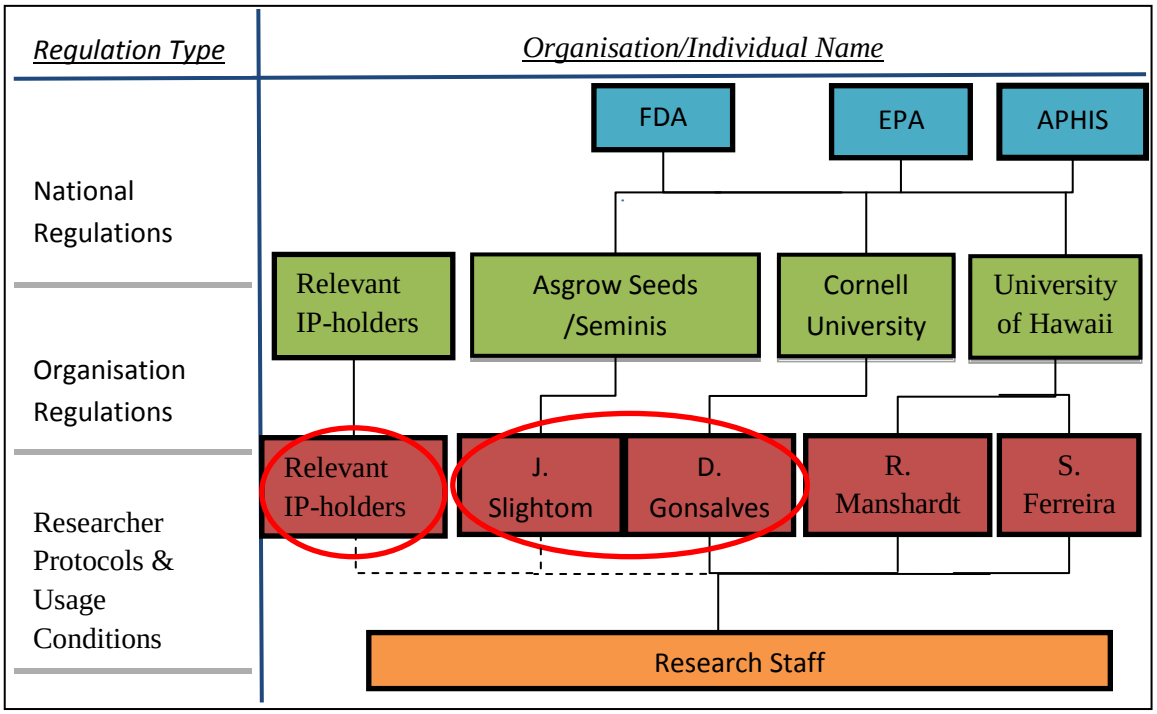

Figure 4.3: Organisation structure of Field Trial phase of Hawaiian PRSV-resistant papaya. *FDA: US Food and Drug Administration; EPA: Environmental Protection Agency; APHIS: Animal and Plant Health Inspection Service; IP: Intellectual Property; solid red ring indicates patent present; solid black line indicates full involvement; dashed black line indicates partial or temporary involvement.*

Commercialisation phase, 1997-2013

To proceed to this phase from the Field Trial phase, the national regulatory bodies from the previous phases, the FDA, EPA, and APHIS, needed to give their consent that the prior regulations were no longer necessary, and that the product was suitable for commercial production with less strict regulations (Gonsalves, 1998). This is also termed ´deregulation´. In 1996 APHIS, granted permission to Manshardt and Gonsalves to grow PRSV-res. papaya without further need for authorisation, and in 1997 the EPA and FDA gave their permission to Manshardt and Gonsalves (Gonsalves, 1998; Payne, 1996). This authorisation from the three national regulatory bodies enabled PRSV-res. papaya to be cultivated, traded and consumed. UH passed the commercial process to the Papaya Administrative Committee (PAC) of Hawaii, a body coordinated by the USDA. The PAC recruited the state research institute, Hawaii Agricultural Research Center (HARC), to produce seed for local farmers (Gonsalves, 1998). Licence from IP-holders to produce PRSV-resistant papaya commercially in Hawaii and distribute seeds to farmers was achieved by M. Goldman, legal counsel to the PAC, in 1998 (Goldman, 2007). The organisational structure of this phase is described in Fig. 4.4 below, wherein the IP-holders listed above, and other IP-holders with whom negotiations were unnecessary, are referred to as ´relevant IP-holding organisations´ and ´relevant IP-holders´.

Potential producers were given seeds for free, under the conditions that they register with the PAC, follow an instruction course about PRSV-resistant papaya cultivation delivered by UH, and sign an MTA/sub-licence with the PAC (Gonsalves, 2006; Goldman, 2007). The instructions do not place emphasis on preventing property right infringement, unlike, for example, the TUA of

Monsanto (Monsanto, 2014).Rather, the instructions emphasise the need to protect the potency of the PRSV-resistant papaya varieties, and prevent PRSV from developing subsequent resistance to the proteins produced by the PRSV-resistant papaya. These instructions include recommendations which are also consistent with TUAs used by other transgenic seed producers, such as using new seeds every time new trees are introduced to the plantation (Nishina et al., 1998). However, rather than encouraging such practices to prevent IP infringement, they are advocated on the basis that seed bred domestically (´saved seed´) might not 'breed true' for PRSV resistance, leading to reduced performance, or important commercial traits associated with the varieties, such as flesh colour, which would damage consumer expectations (Manshardt, Pers. Comm.; Nishina et al., 1998). Growers were also encouraged to prevent mixing of transgenic and non-transgenic fruits at harvest by planting in separate blocks (Nishina et al., 1998). The educational materials reviewed for this thesis indicated that there were no regulations to prevent pollen being spread beyond the grower´s orchard, or prohibition of the spread of GM papaya pollen to non-GM papaya flowers (Nishina et al., 1998; Manshardt, 2002). As emphasised by Manshardt in personal communication, such regulation is neither economical, nor considered necessary as commercialisation in the US requires sufficient risk evaluation in the Development and Field Trial phases to indicate that the plant exhibits no greater risk than a non-transgenic plant of the same variety.

Although not required to prevent transgenic contamination by US National Organic Program Standards (Manshardt, Pers. Comm.), non-GM and organic papaya producers were required by other market standards, particularly regarding exports to Japan, to prevent pollination by GM papaya plants (Gonsalves, 2014). The threat of rejection by importing nations or organic certification bodies and possibility of a national import ban by importing nations motivated the Hawaii Department of Agriculture to establish a certification scheme, the Identity Preservation Protocol, to support non-GM and organic papaya producers in selling their non-transgenic fruit (Gonsalves, 2014). Organic and non-transgenic papaya growers were advised to practice transgenic pollen exclusion measures instead (Manshardt, 2002).This included the creation of more physical space between GM orchards and non-GM orchards, the use of certified non-GM seed when additional trees were desired, and covering flowers with paper covers to prevent the entry of transgenic pollen if growers wished to use saved seed or go to extensive lengths to prevent possible transgenic contamination of fruit seeds (not necessary for organic certification) Manshardt, 2002). The burden of labour for preventing unauthorised GM papaya production and transgene contamination is thus placed on the parties most likely to be at a loss from such an event, the non-GM producers, rather than on those in a position to cause such an event, the GM producers. There has been subsequent speculation that transgenic contamination of non-GM commercial plants has occurred, but it remains unclear if that has actually been the case (Bondera and Query, 2006).

The role of IP

The regulatory capacity of IP-holding actors took a more central role at this point, following deregulation. Commercial production could not proceed without the permission of relevant IP-holders, and this permission was subject to terms of exchange and use of each IP aspect of the PRSV-resistant papaya (Gonsalves, 1998). The PAC negotiated the patents and MTAs held by various parties, in order to obtain permissions for the commercial production of PRSV-res. papaya. These negotiations were finalised by 1998 (Gonsalves, 1998). Negotiating parties

included Slightom and Gonsalves (Asgrow/Seminis and Cornell), who owned the patent for the PRSV gene construct which was used in PRSV-resistant papaya, but also included the organisations and individuals holding IP for components of the PRSV gene construct, such as promoter sequences and genetic markers. A number of organisations were involved, broadly referred to as ´relevant IP-holders´ and ´relevant IP-holding organisations´ in Fig. 4.4.

Negotiations between the PAC and IP-holders were only necessary in the case of Monsanto, Asgrow, Cambia Biosystems, and Massachusetts Institute of Technology (Nishina et al., 1998; Goldman, 2007). In the negotiations between IP-holders and the PAC, the PAC was granted the capacity to sub-licence the IP protected technologies contained in the PRSV-resistant papaya to farmers who wished to grow the papaya (Goldman, 2007). To adhere to their licence requirements the PAC in turn required farmers to undergo a training session and sign individual MTA/sub-licences in return for seeds (Nishina et al., 1998; Goldman, 2007). Explicit details of negotiations between the PAC and IP-holders are not available, but from the details of the instruction course, it does not appear that the IP negotiations between IP-holders and the PAC, or the MTA/sub-licences between the PAC and farmers, involved strict prohibition of potential IP infringement by saving seed or cross-breeding GM and non-GM papaya, intentionally or accidentally. From these details it can be observed that the potential to use IP as an environmental risk regulation tool for PRSV-resistant papaya in Hawaii was not pursued, as effects of unregulated pollination, such as genetic contamination of domestic non-GM papaya and transgene spread to wild relatives, were not considered to be acts of IP infringement according to the terms of use established.

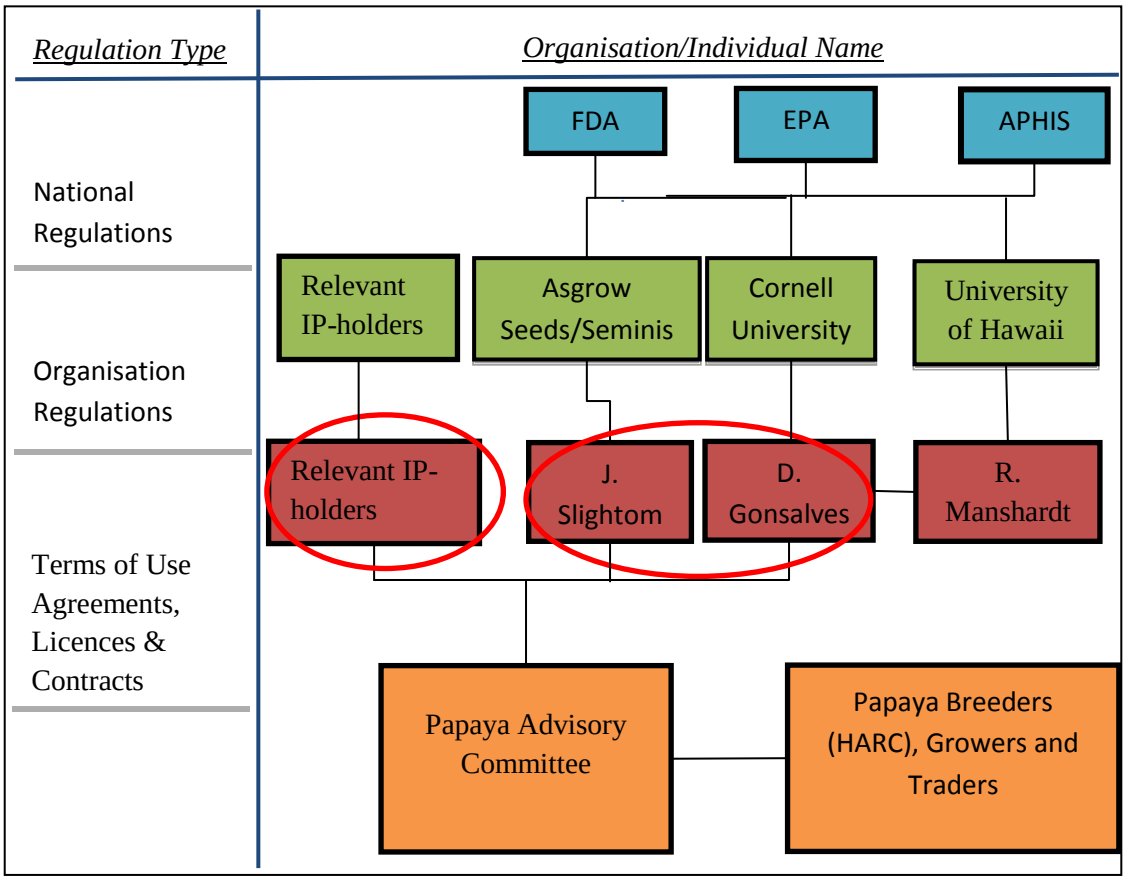

Figure 4.4: Organisation structure of Commercialisation phase of Hawaiian PRSV-resistant papaya. *FDA: US Food and Drug Administration; EPA: Environmental Protection Agency; APHIS: Animal and Plant Health Inspection Service; IP: Intellectual Property; solid red ring indicates patent present; solid black line indicates full involvement.*

4.3.2 Jamaica PRSV-Resistant Papaya, 1994-2013

The development of Jamaican PRSV-res. papaya began in 1994, in Jamaica and the US. Jamaican PRSV-res papaya proceeded to the Field Trial phase. Field trials ended in 2005, however, and the transgenic papaya did not progress any further in Jamaica. No unauthorised production of PRSV-resistant papaya was observed there during the development period, nor has it been observed since the field trials ended.

Development phase, 1994-1998

In response to problematic PRSV outbreaks in Jamaica, the University Of the West Indies, Mona (UWI Mona), with funding from the Jamaica Agricultural Development Fund (JADF), collaborated with Cornell University (Cornell), to develop a PRSV-resistant papaya variety for Jamaica (Tennant, Pers. Comm.). The research was led by P. Tennant of UWI Mona, and involved transfer of transgenic PRSV-resistance technology from Cornell, guided by D. Gonsalves (Tennant, Ahmad and Gonsalves, 2005). P. Tennant had previously completed her PhD research at Cornell, involving the Hawaiian PRSV-resistant papaya, under supervision of D. Gonsalves and with funding from the JADF.

Many regional strains of PRSV exist, and the coat protein genes are one of the ways in which the regional varieties differ (Fermin, Castro and Tennant, 2010). Tennant´s PhD research had revealed that Hawaiian PRSV-resistant papaya is resistant to all PRSV strains found on Hawaii, but are susceptible to other PRSV strains, including PRSV found in Jamaica (Tennant et al., 1994). Further technical information can be found in Annex 1. The Jamaican strain of PRSV was used to create a PRSV coat protein gene construct in Gonsalves´ laboratory in Cornell (Fermin and Tennant, 2011). This construct was similar in theoretical approach to the one developed by Gonsalves and Slightom, but contained different genetic sequences to that of the Hawaii PRSV coat protein gene construct in the regions of the construct which enable the transformation of the plant material and the transfer of resistance to the plant material (Fermín et al., 2004). Genetic transformation of Jamaican papaya tissue took place at Cornell, and Cornell´s greenhouse facilities were used to grow the transformed plants in 1995 (Tennant, Pers. Comm.).

As the research in this phase took place in the US, the three national regulatory authorities which regulated the Development phase in the Hawaii papaya case also had authority over this phase of Jamaican papaya development. Those are the Food and Drug Administration (FDA), Environmental Protection Agency (EPA) and Animal and Plant Health Inspection Service (APHIS) (Office of Science and Technology Policy, 1986). The institutional regulations of UWI Mona, JADF, and Cornell applied to this phase. Cornell had a leading role as most of the research for this phase took place there, using their materials and technologies (Tennant, Ahmad and Gonsalves, 2005). Local regulation was provided by Tennant and Gonsalves, Tennant representing UWI Mona and JADF, while Gonsalves represented Cornell. Although risk knowledge was not as low as in this phase of the Hawaii case, on account of the knowledge

already gained from the Hawaii case, the risk management regulations of the national, institutional and local regulators still ensured more intensive risk management than would be required in subsequent phases. The organisational structure of this risk management is shown in Fig. 4.5.

The role of IP

IP does not appear to play a prominent role during the Development phase of Jamaican PRSV-resistant papaya, either in journal articles which describe this phase, or in interviews with experts on the Jamaican PRSV-resistant papaya. J. Sanford's permission for use of the gene gun was needed, similar to the Development phase of Hawaiian PRSV-resistant papaya, and this gave Sanford the potential to have a temporary regulatory role during the plant tissue transformation part of the Development phase (Tennant, Ahmad and Gonsalves, 2005). Other IP-holders also had the potential to play a regulatory role, as their products or processes were used in the composition of the gene construct and transformation of the plant material, e.g. the CaMV 35S promoter sequence owned by Monsanto. The PRSV coat protein gene construct used was sufficiently different to that developed by Gonsalves and Slightom that the pending patent of both researchers and their respective employers at the time did not have potential to influence the Jamaican PRSV-resistance research, unlike in the Hawaiian case (Gonsalves et al., 2006). It is not apparent that Sanford or the other relevant IP-holders exercised the usage regulation potential granted by IP ownership (Fermin and Tennant, 2011; Fermin, Castro and Tennant, 2010; Tennant, Ahmad and Gonsalves, 2005; Fermín et al., 2004). The role of IP and IP-holders is illustrated in Fig. 4.5, with dashed black lines showing the partial involvement of Sanford and other relevant IP-holding organisations and individuals.

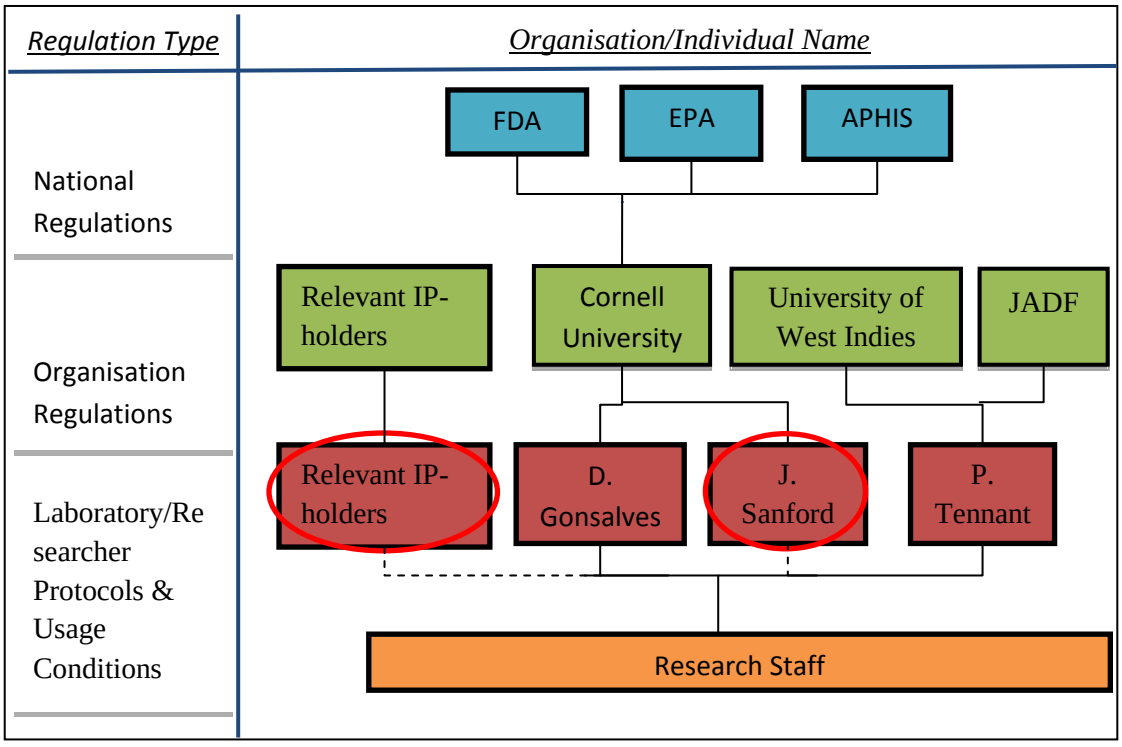

Figure 4.5: Organisation structure of Development phase of Jamaican PRSV-resistant papaya (1994-1996). *FDA: US Food and Drug Administration; EPA: Environmental Protection Agency; APHIS: Animal and Plant Health Inspection Service; IP: Intellectual Property; JADF: Jamaica*

Agricultural Development Fund; solid red ring indicates patent present; dotted red ring indicates patent pending; solid black line indicates full involvement; dashed black line indicates partial or temporary involvement.

Field Trial phase, 1998-2013

Although the Jamaican PRSV-resistant papaya was deemed ready to progress to the Field Trial phase in 1995, the transfer of the plants to Jamaica for field trials was delayed due to a lack of national regulatory capacity (Tennant, Pers. Comm.). UWI Mona and JADF requested a permit to import the plants developed at Cornell from the National Commission on Science and Technology (NCST) (Tennant, Pers. Comm.). The NCST in turn established the National Biosafety Committee (NBC) in 1997. The Plants (Importation) Control Regulations were also created in 1997, mandating the NBC to monitor importation and research regarding transgenic plants (Fermin and Tennant, 2011). Much was known about the potential risks of PRSV-resistant papaya at this point, the Hawaiian variety of which was close to commercialisation in Hawaii, and the Jamaican version of which had been monitored for two years in Cornell's greenhouses. Nevertheless, risk management, particularly with regard to the importation into Jamaica and field trialling of the transgenic papaya was exercised with caution.

A diverse range of national institutions were involved in this risk management. Where APHIS was the primary national regulator in the Field Trial phase of Hawaii, with FDA and EPA playing a secondary role, many more national institutions were involved in Jamaica, with NBC having an overarching regulatory capacity, on account of the Plants Importation Control Regulations (1997). The National Environment and Planning Agency (NEPA) and Plant Quarantine Branch of the Ministry of Agriculture and Fisheries (MoAF) carried out risk assessment of the PRSV-resistant papaya plants (Blair-Thomas, Pers. Comm.). These risk assessments were reviewed by the NBC (Blair-Thomas, Pers. Comm.). The Bureau of Standards (BoS) and Ministry of Health (MoH) contributed on matters of standards and health-related issues which were relevant to the importation ad field trials (Blair-Thomas, Pers. Comm.). The NBC granted a permit for the field trials in 1998 (Tennant, Ahmad and Gonsalves, 2005). The field trials were subject to ongoing safety assessment and monitoring by the NBC, NEPA and MoAF, with contributions from BoS and MoH (Blair-Thomas, Pers. Comm.).

Once the plants were imported from the US to Jamaica, and field trials could began, UWI Mona and JADF became the primary institutional regulators. Cornell was no longer involved at the central level which had been necessary during the Development phase. Tennant led the field trials and was the main local regulator, establishing the experimental conditions in accordance with the institutional and national regulatory bodies, and monitoring their implementation by research staff (Tennant, Ahmad and Gonsalves, 2005; Fermin and Tennant, 2011). The organisational structure of the Field Trial phase of Jamaican PRSV-resistant papaya is described in Fig. 4.6.

The imported plants were first acclimatised in a shade house before transfer to the field site, located on a commercial farm in the PRSV-stricken region of St. Catherine (Tennant, Ahmad and Gonsalves, 2005). Mechanical inoculation of the plants with PRSV was prohibited by the NBC, and the plants were exposed to natural conditions and levels of PRSV exposure in much

the same way as in the Hawaii PRSV-resistant papaya field trials (Tennant, Ahmad and Gonsalves, 2005). Plant pollination and gender were closely monitored as part of data collection procedures of the study (Tennant, Ahmad and Gonsalves, 2005), which contributed to management of the risk of transgene contamination of domestic non-GM papaya plants and wild relatives, as hermaphrodite tree were observed to ensure they were self-pollinated, and any male trees which were produced were observed (Tennant, Ahmad and Gonsalves, 2005).

In 2000 commercialisation of Jamaican PRSV-resistant papaya was projected to take place in 2002 (Fermín et al., 2004). To reach this target, a third field trial took place to build the seed supply and prepare for trials on farmers' orchards, pending deregulation by the NBC (Fermín et al., 2004). The development of PRSV-resistant papaya in Jamaica has not moved past that stage however (Tennant, Pers. Comm.). The necessary regulatory framework to enable deregulation by the NBC, which would open up the possibility of field trials on farmer's orchards and eventual commercialisation, has not been developed (Tennant, Pers. Comm.). Jamaica signed the Cartagena Protocol in 2001, and requires a complete regulatory framework which corresponds to the Protocol requirements, in order to be compliant (Grant and Perkins, 2013; Fermin and Tennant, 2011). A long delay has been experienced in developing this framework, and the corresponding policies and overseeing bodies (Tennant, Pers. Comm.), but Jamaica succeeded in ratifying the Protocol in 2012 (Grant and Perkins, 2013). Field trials have been maintained at St. Catherine by Tennant, and monitored by NBC, during the period of delay (Fermín et al., 2004; Thomas and Salmon, 2005; Thomas S. and Rothschild, 2008). However, there still remains much to be done with regard to the Jamaica Biosafety Policy, which remains in a draft form, and other elements of the biosafety regulatory framework (Tennant, Pers. Comm.; Grant and Perkins, 2013). Meanwhile JADF has withdrawn funding of the project (Fermín et al., 2004).

Despite a lack of clarity around biosafety regulations and the future of the field trialled papaya, no unauthorised use or risk emergence such as transgenic contamination has been reported. This indicates excellent risk management performance, given that cross-pollination of non-transgenic plants could have arisen from both male and hermaphrodite plants in the case of the Jamaican PRSV-resistant papaya, rather than only hermaphrodite plants in the case of Hawaiian papaya.

The role of IP

Similar to the Development phase, IP does not appear to play a significant role in the regulation of Jamaican PRSV-resistant papaya in the Field Trial phase. The permissions for use sought from relevant IP-holding organisations and individuals applied, as per the Development phase. The effect of any conditions of use upon the Field Trial phase does not arise as a matter of importance in written accounts and personal interviews regarding the research. While Tennant (Pers. Comm.) and Ventura (Ventura, 2004) discuss the relevance of IP and in particular TRIPS to the future development of Jamaican biotechnology and compliance of Jamaica with the Cartagena Protocol, the development of Jamaican papaya has not progressed to a point where IP is of critical relevance. If the Jamaican papaya were to progress to the Commercialisation phase, it would probably require greater involvement of relevant IP-holders, as in the Hawaii papaya case.

In 2001, Tennant filed for a patent with Gonsalves and other PRSV-resistant papaya researchers regarding the gene construct used in the development of Jamaican PRSV-resistant papaya, and other regional PRSV-resistant papaya varieties. This patent was granted in 2006, but is indicated in Fig. 4.6 as pending, representing the period between 2001 and 2006. This patent was not present, pending or otherwise, in the period in which most of the research activity for Jamaican papaya was taking place. However, it may have contributed to successful prevention of unauthorised transgenic papaya production and effective avoidance of transgenic contamination in the later stages, during which field trials were still taking place although progress in regulation development was substantially delayed. In communication, Arnoldo Ventura, previously Special Advisor on Science and Technology to the Jamaican Prime Minister, and chairperson of the Steering Committee of the NCST, and Marcia Blair-Thomas, previously of the NCST and NBC, indicated that cultural perceptions of research institutes and theft of physical property were also important factors in preventing unauthorised production of the Jamaican GM papaya.

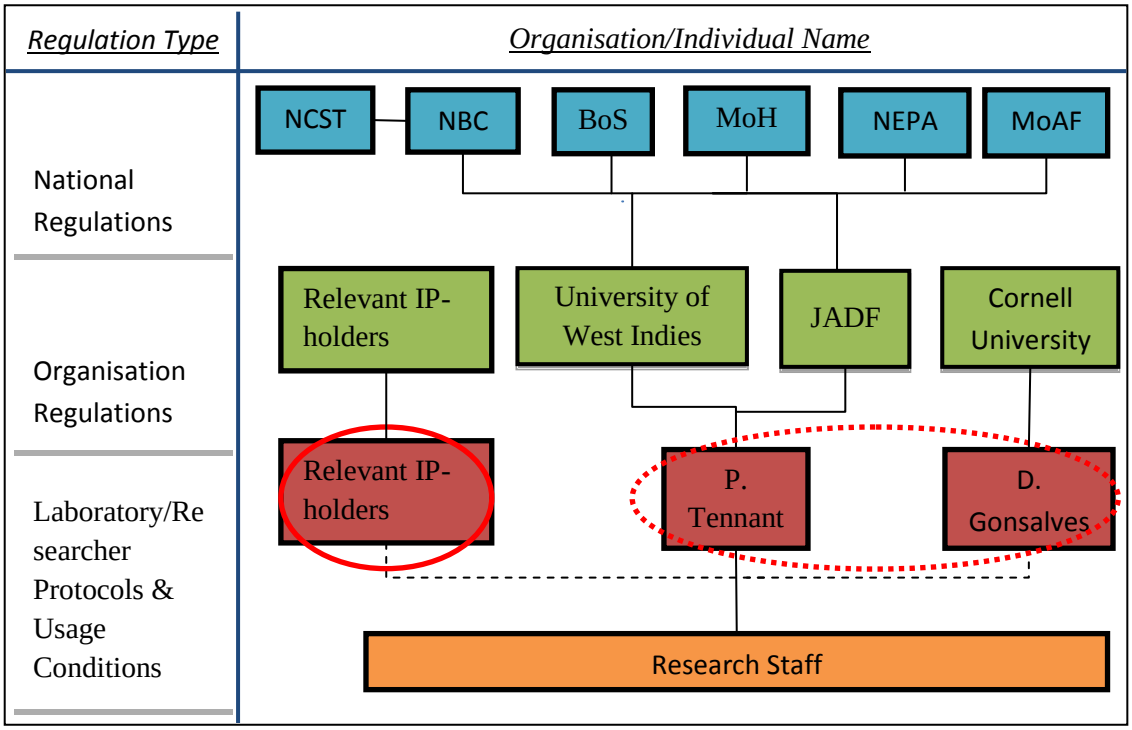

Figure 4.6: Organisation structure of Field Trial phase of Jamaican PRSV-resistant papaya. *NCST: National Commission on Science and Technology; NBC: National Biosafety Committee: BoS: Bureau of Standards; MoH: Ministry of Health; NEPA: National Environment and Planning Agency; MoAF: Ministry of Agriculture and Fisheries; JADF: Jamaica Agricultural Development Fund; solid red ring indicates patent present; dotted red ring indicates patent pending (relevant to 2001-2006 period); solid black line indicates full involvement; dashed black line indicates partial or temporary involvement.*

4.3.3 Indications for IP-Based GM Crop Risk Management

The case of PRSV-resistant papaya production in Hawaii exhibits successful management to date, and although speculation about unauthorised GM papaya plants exists, national regulatory bodies and UH have not found evidence of this. From this case it seems that the

application of IP as a regulatory mechanism in the manner described in Ch. 2 is not necessary for successful prevention of unauthorised GM crop production. The burden of management was not placed on the GM papaya farmer as it would have been if IP was exercised as a risk management tool, according to the rationale described in Ch. 2. Instead, other market-based tools such as certification of non-transgenic papaya fruit were used in Hawaii, and motivated non-GM producers to prevent the spread of GM papaya pollen into their crop. This placed responsibility on the non-GM papaya farmer, with no clear assignment of liability in the case of transgenic contamination of non-GM plants or other instances of ´unauthorised production´. IP is in place for the GM papaya farmers in the form of MTA/sub-licences to encourage certain standards of practice, but not to create boundaries of authorised or unauthorised production.

Although PRSV-res. papaya in Jamaica has not yet proceeded to commercialisation, 12 years on from the projected date of commercialisation, management of potential environmental risks such as transgenic contamination has been highly successful. This is despite the absence of a complete regulatory framework, or strong regulatory influence by IP claims. The successful management of transgenic papaya plants in the Development and prolonged Field Trial phases of this case provide similar indications to that of the Hawaii case, namely that the leverage of IP to prevent environmental risk or other effects of unauthorised GM crop production are not necessary for successful risk management and prevention of unauthorised production. In both cases, the potential for IP to have a role in risk management was present, but was not utilised. Furthermore, it seems from both of these cases of successful management that such a tool is not important in the Development and Field Trial phases.

The Hawaii case indicates that IP becomes more relevant as a tool when the Commercialisation phase is reached and licence/permit negotiations are required to enable distribution of the plant material and production of plants by farmers. Unauthorised GM crop production does not arise as an IP problem in Hawaii, however, unlike cases where IP is leveraged to prevent unauthorised GM crop production, such as *Monsanto Canada Inc. v. Schmeiser* [2004], because the regulation structure does not strictly limit pollen spread, seed saving, seed exchange or other human practices and biological aspects of plant growth.

4.4 Cases of Unsuccessful GM Crop Risk Management

In this section the cases of unsuccessful management of environmental risks associated with unauthorised GM crop production are examined. This includes the case of Thai PRSV-resistant papaya, Indian *Bt*-cotton, and US/Canadian herbicide-tolerant canola. In these cases it is difficult to distinguish between incidents which arose due to accidental occurrence of transgenic pollen spread or other accidental spread of plant material, or intentional unauthorised GM crop production. The examination of these cases focusses on the risk event, and responses to the risk, including whether the risk which emerged was considered to be accidental or an intentional action. The three phases used to describe management in the successful cases are also applied to these cases to indicate the stage of crop development, level of risk knowledge and intensity of risk management observed prior to risk emergence, based on interviews with researchers involved, and findings reported in scientific journals and other secondary sources.

4.4.1 Thailand PRSV-Resistant Papaya, 1995-2004

Similar to the Hawaii and Jamaica cases described above, PRSV is a significant problem for the Thai papaya industry, and efforts have been made to approach this by breeding for resistance, using traditional and transgenic methods (Attathom and Navarro, 2011). Like the Jamaica case, Thai researchers pursued collaborative research and technology transfer from Cornell University to Thailand. Thai PRSV-res. papaya progressed to the Field Trial phase, but the discovery of unauthorised commercial PRSV-resistant papaya production in 2004 called a halt to the research. A moratorium on all GM crop field trials ensued, ending in 2007 (Attathom and Navarro, 2011). However, to date no further research on Thai PRSV-resistant papaya has taken place (Kertbundit and Juĝíþek, 2010). Disputes over the level of transgenic contamination of Thai papaya continue (The Bangkok Post, 2013), but the extent and precise manner of origin of this contamination remain unclear (Davidson, Pers. Comm.; The Bangkok Post, 2013). Fig. 4.7. summarises the development of this crop, and the incidence and management of unauthorised GM crop production.

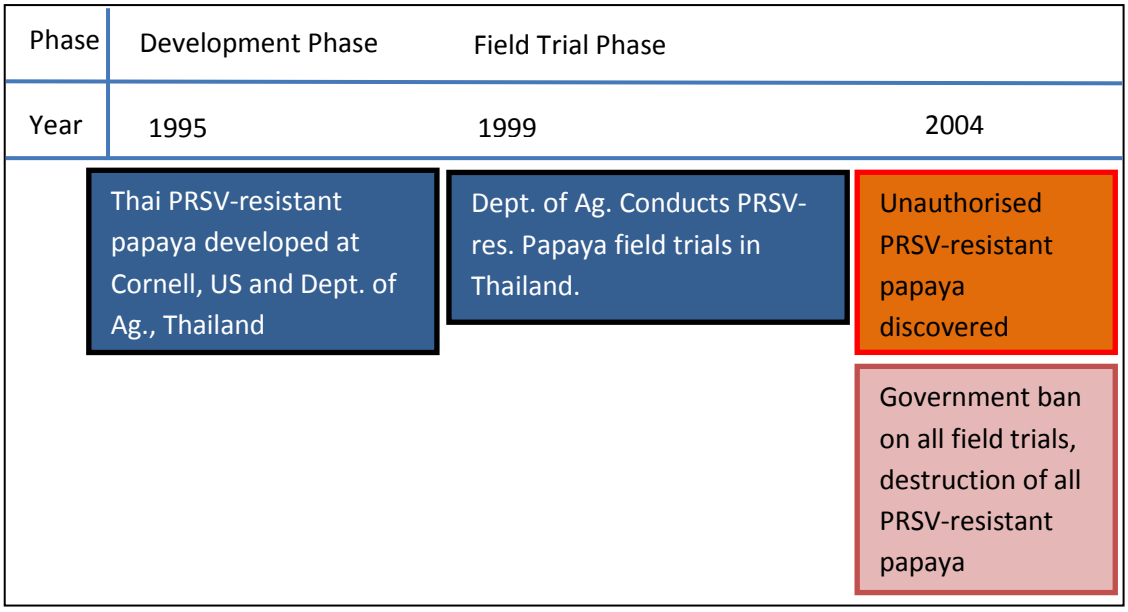

Figure 4.7: Thai PRSV-resistant papaya development, including incidence and management of unauthorised GM crop production. *Dept. of Ag: Department of Agriculture*

Crop development

In 1995, Thai researchers from the Department of Agriculture Research & Development Office (DoA R&D) in Thailand initiated a collaboration with Cornell University, US (Gonsalves and Vegas, 2006). The collaboration was initially led by D. Gonsalves of Cornell University, also involved in the development of Hawaii and Jamaica PRSV-resistant papaya, and N. Sarindu and V. Prasartsee of the DoA R&D (Gonsalves and Vegas, 2006). A regional strain of Thai PRSV was used to construct a coat protein gene construct with a similar function to that used in Hawaii, but different composition. The Thai PRSV coat protein construct was constructed in the same way as that being used for the Jamaica PRSV-resistant papaya project and other regional transgenic papayas being developed in collaboration with Cornell at the time (Gonsalves and Vegas, 2006; Davidson, 2008). The transformation of Thai papaya cultivars was carried out at Cornell laboratories and greenhouses (Gonsalves and Vegas, 2006). Similar to the Jamaica

project, risk knowledge was moderately high due to the research done for the Hawaii papaya development. Risk management by the EPA, FDA and APHIS at the national level, Cornell at the institutional level, and the lead researchers at a local level, particularly Gonsalves and Sarindu, who carried out the development at Cornell, and Sanford, whose gene gun method was applied, placed strong boundaries on what practices were permitted and prohibited in the research (Office of Science and Technology Policy, 1986; Gonsalves and Vegas, 2006; Davidson, 2008).

In 1997, a selection of plants was transferred from Cornell´s greenhouse to the DoA R&D in Khon Kaen (Gonsalves and Vegas, 2006). Prior to importation of the transgenic material, permission was required by the Director-General of the DoA, based on recommendations by the National Biosafety Committee (Thai NBC) (Kertbundit and Juĝíþek, 2010). Greenhouse research continued at Khon Kaen from 1997 to 1999, under the direction of Prasartsee (Gonsalves and Vegas, 2006). The National Genetic Engineering and Biotechnology Centre (BIOTEC) acted as a national regulating body for laboratory procedures, via the Biosafety Guidelines in Genetic Engineering and Biotechnology for Laboratory Work (1992), the implementation of which was monitored by the Thai NBC (Kertbundit and Juĝíþek, 2010).

The field trial phase began in 1999 at the DoA R&D research station in Khon Kaen. The DoA and Thai NBC issued the permit for the field trial, and BIOTEC also acted as a national regulator, via the Biosafety Guidelines in Genetic Engineering and Biotechnology for Field Work and Planned Release (1992), also monitored by Thai NBC (Kertbundit and Juĝíþek, 2010). In 2001, a moratorium on open field trials was issued by the Thai parliament, in response to issues which arose with Monsanto´s *Bt*-cotton trials (Attathom and Navarro, 2011). The DoA R&D´s trials were sufficiently confined to still be permitted (Kertbundit and Juĝíþek, 2010). In 2004, discovery of unauthorised PRSV-resistant papaya production caused the Minister of Agriculture to order both the DoA´s field trials, and the plantation where transgenic papaya was discovered, to be destroyed, while the Prime Minister extended the moratorium to cover all field trials (Davidson, 2008; Attathom and Navarro, 2011). This event is described further below, and summarised in Fig.4.7. Despite the ending of the enclosed field trial ban in 2007, and open field trial moratorium in 2009, no further field research on PRSV-resistant papaya has taken place in Thailand (Attathom and Navarro, 2011; The Bangkok Post, 2013).

IP did not play a very strong regulatory role in the regulation of the field trial phase in Thailand. Cornell´s Technology Transfer Office successfully negotiated the use of patented material for field trial, on behalf of the DoA R&D (Davidson, Pers. Comm.). Sarindu filed for a patent on the Thai PRSV coat protein gene construct in 2002, with Gonsalves and other researchers who had worked on regional PRSV coat protein constructs, including Tennant from the Jamaica case, which was granted in 2006 (Gonsalves et al., 2006). The patent is held by the researchers on behalf of Cornell, but discussions were in place between Cornell and DoA to sign a Memorandum of Understanding regarding use of the patented technology, prior to the field trial ban (Kertbundit and Juĝíþek, 2010).

Unauthorised production

In 2004, Greenpeace members gained entry to the DoA field trial area and began to remove plants, claiming that DoA field trials needed to be stopped as their tests indicated transgenic

contamination in packets of seeds bought from the DoA (Davidson, 2008; Inbaraj, 2004a). They urged the government to act upon the negligent actions of the DoA (Kertbundit and Juĝíþek, 2010). The DoA initially reacted by filing property destruction charges against two of the Greenpeace members (Inbaraj, 2004a). The Prime Minister announced a month later that the ban on field trials would be lifted, only to reverse the decision ten days later after, stating it was "a debatable issue academically with controversy among various groups" (Gov. spokesperson J. Penkair, in (Inbaraj, 2004b); Kertbundit and Juĝíþek, 2010). Two weeks after this decision, the accusation of unauthorised GM papaya was confirmed from DoA´s own testing, which revealed transgenic papaya at one of 239 farms to which they had sold seeds (Davidson, 2008).

In response to the confirmation of unauthorised GM crop production, the Minister for Agriculture ordered that all PRSV-resistant papaya be destroyed, in the field trials and at the farm that tested positive (Xinhua General News Service, 2004). Other field trials in the country were stopped, on government orders (Agence France Presse, 2004b), and the government enforced a complete ban on field trials (Davidson, 2008). The DoA agreed to release the details of all farmers who had purchased seeds at their research station (Kertbundit and Juĝíþek, 2010; Greenpeace Southeast Asia, 2006), and continued testing farms which had bought seeds from the Khon Kaen research station. Within a few weeks, the DoA found eight more farms growing transgenic papaya (Agence France Presse, 2004a).

The DoA engaged in a court case with Greenpeace from 2005-2006, regarding the illegal trespass of their field trials and property theft, from which the Greenpeace members were acquitted in 2006 (Attathom and Navarro, 2011). The National Human Rights Committee reported finding further production of transgenic papaya among farmers in 2005, and Greenpeace subsequently brought a case against the DoA in 2006 (Agence France Presse, 2006; Kertbundit and Juĝíþek, 2010). This was acquitted in 2008, with the court finding that the DoA were not guilty of negligence during the field trials or in dealing with the finding of unauthorised transgenic papaya production (Thai News Service, 2008). Greenpeace appealed the trial and it was taken to the Supreme Court later in 2008, which again found the DoA innocent in 2013 (Thai News Service, 2013). Meanwhile in 2012, Hawaiian transgenic papaya was reported to be present on Thai farms (Sarnsamak, 2012). It remains unknown how PRSV-resistant papaya ´escaped´ from the Thai DoA, or how the transgenic Hawaiian plants came to be present on Thai farms (Sarnsamak, 2012; The Bangkok Post, 2013), and it is unlikely that the ´full truth´ will ever be known (Davidson, Pers. Comm.). While various organisations and media outlets have claimed widespread contamination of Thai papaya, the European Commission Rapid Alert System for Food and Feed (RASFF) first reports finding transgenic papaya in Thai papaya exports in 2012, reporting 10 cases in that year, with 26 cases in 2013 and 3 in 2014 (RASFF, 2014). This information indicates that unauthorised GM papaya production continues to occur in Thailand, despite the extensive DoA and government response to the initial findings of transgenic contamination in 2004. However, the European Commission import control measures have only reported transgenic papaya contamination of Thai exports since 2012, when Hawaiian transgenic plants were discovered on Thai farms.

IP did not play a significant role in the response to the unauthorised transgenic contamination in Thailand. If applied in the manner outlined in Ch. 2, there would have been greater capacity

for the DoA and Cornell to implicate farmers in the incidence of unauthorised GM papaya production. This could have led to active farmer engagement in testing and eradication of transgenic papaya plants, due to the possibility for farmers to be found guilty of illegal activities. The PAC and IP-holders of Hawaiian transgenic papaya also have the potential to apply similar measures to removing the reported Hawaiian papaya, but so far no intention for such actions has been indicated. It seems from the data obtained from RASFF that without the application of more powerful regulation or incentives to prevent transgenic papaya production in Thailand, there will be little to no reduction in unauthorised papaya production there.

4.4.2 India *Bt*-Cotton, 1996-2013

Monsanto commercialised a transgenic variety of cotton between 1995, which carried genes from a soil bacterium, *Bacillus thuringiensis,* also called *Bt* (James and Krattiger, 1996). The *Bt* genes provided resistance against the bollworm, a significant cotton pest. Unlike the PRSV-resistant papaya varieties which are only effective against specific regional virus strains, the bollworm responded similarly to the proteins expressed by the *Bt* genes in all cotton-growing regions (Qaim, 2003). Further technical information can be found in Annex 1. The following paragraphs give information about the development of this crop in India, and the incidence and management of unauthorised crop production. This information is summarised in Fig. 4.8.

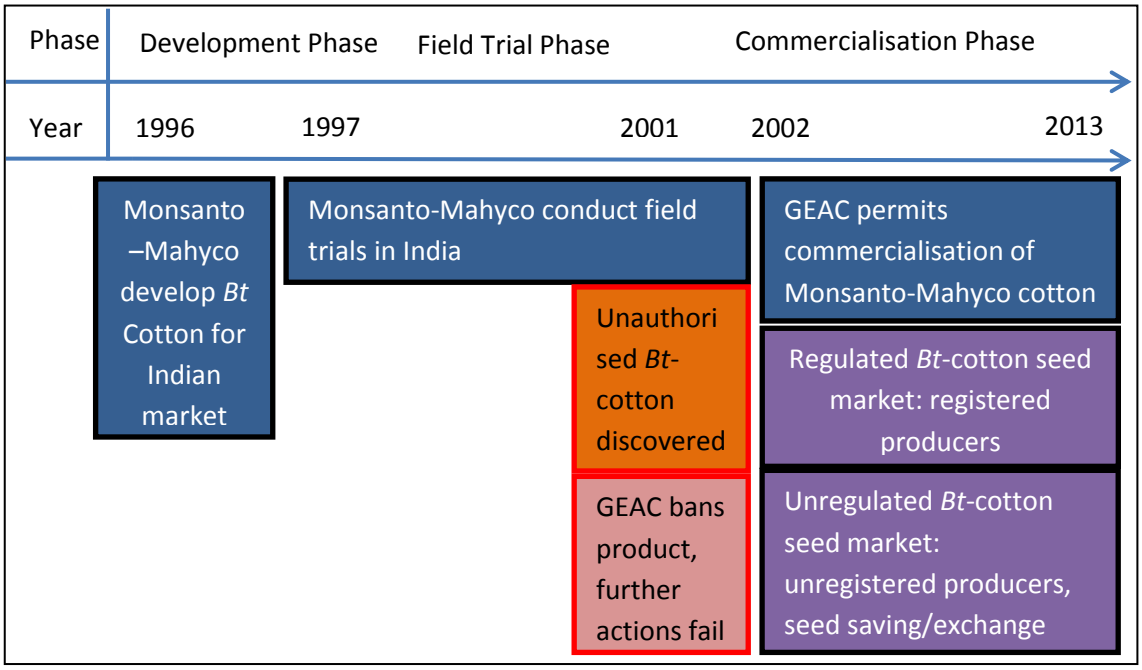

Figure 4.8: Indian *Bt*-cotton development, including incidence and management of unauthorised GM crop production. *GEAC: Genetic Engineering Approval Committee.*

Crop development

The Development phase of Indian *Bt*- cotton began in 1996, when Indian company Maharashtra Hybrid Seed Co. (Mahyco) purchased a licence to use Monsanto´s *Bt* technology in Indian cultivars (Qaim, 2003; Lalitha, 2004). Monsanto exported US *Bt* cotton cultivars to India, and the two companies collaborated under the title of Monsanto-Mahyco (Qaim, 2003). Most of the technical development had already occurred in the US, led by Monsanto, but some further technical development was necessary in India, such as hybridisation with Indian cotton varieties developed by Mahyco (Qaim, 2003). Risk knowledge was extensive, as Monsanto´s

Bt-cotton had already proceeded to commercial production in the US (James and Krattiger, 1996). As the technology was not new, but only transferred to a new environment and crossed with Mahyco's cotton cultivars, it is unlikely that risk management was very intensive. However, it was not possible to obtain sufficient information during this thesis research to make a judgement of the intensity of risk management exercised, except to note that risk management in this phase was adequate. National regulation was in place from the Genetic Engineering Approval Committee (GEAC), a biotechnology regulatory body under the administration of the Indian Ministry of Environment and Forests (Qaim, 2003).

The Field Trial phase began in 1997, with the Monsanto-Mahyco *Bt*-cotton varieties known as Bollgard (Qaim, 2003). These field trials, the first GM crop trials in India (James and Krattiger, 1996), were also regulated by the GEAC (Qaim, 2003). Similar to the previous phase knowledge of the technology was extensive, and thus risk knowledge was high. Due to the broader environmental exposure required for the field trials, the trials were initially managed with intensive attention to risk, a requirement which diminished over the next four years (Qaim, 2003). Despite this, unauthorised production, including hybridisation of *Bt*-cotton with local cultivars was discovered in 2001 (Kothamasi and Vermeylen, 2010), as illustrated in Fig. 4.8.

In 2002, the Commercialisation phase of Mahyco-Monsanto´s *Bt*-cotton officially began (Qaim, 2003). The GEAC initially authorised *Bt*-cotton for a provisional period of three years (Qaim, 2003), under the stipulation that any area of *Bt*-cotton should be surrounded by a refuge of non-GM cotton of the same variety of at least five rows of cotton or 20% of the crop, whichever is greater (Stone, 2004). The GEAC authorisation has since been extended, and Monsanto actively exercises their IP rights via licensing of their technology to 28 seed companies in India (Monsanto, 2011), while four more *Bt* resistance traits have been developed and approved for commercial use by Indian research institutes and companies since 2006 (ISAAA, 2012). The importance of the GEAC stipulation has been underpinned by the emergence of *Bt*-resistant bollworms in recent years (2009-10), although low implementation of refuges is considered to have resulted in the afore-mentioned risk being realised (Monsanto, 2009; Duncan, 2011).

Due to the unauthorised hybrid varieties which emerged during the Field Trial phase, and the absence of IP-based agreements or other instruction prohibiting re-use and exchange of seeds, the *Bt*-cotton industry in India has been comprised of two markets since official commercialisation occurred (Herring, 2006, 2011). The first is the regulated market, comprising all companies selling seeds authorised by the GEAC, while the second is the unregulated market, which existed prior to commercialisation and continues to exist, consisting of companies and individuals selling unauthorised seeds, and farmers breeding, using and exchanging seeds of their own varieties. Both markets are depicted in Fig. 4.8. The following two paragraphs discuss the management response to the risks which emerged in the Field Trial phase (unauthorised production) and the Commercialisation phase (insect resistance), elaborating further on the role which IP played in those responses.

Unauthorised production

In 2001, a severe bollworm outbreak in India revealed that the cotton in Gujarat exhibited bollworm resistance (Kothamasi and Vermeylen, 2010). Monsanto-Mahyco reported the

unusual resistance to the GEAC (Herring, 2007). The GEAC carried out an investigation regarding the origin of bollworm resistance in the resistant Gujarat variety, Navbharat 151, and discovered that the resistance was conferred by the same *Bt* transgenes which were integrated in the varieties under field trial by Monsanto-Mahyco (Kothamasi and Vermeylen, 2010).

It is largely believed that Navbharat Seeds intentionally acquired Monsanto-Mahyco cultivars by illegal means, and crossed them with their own cultivars (Herring, 2007). Navbharat *Bt*-cotton seeds were then bred with local cultivars by other plant breeders and farmers to produce a multitude of unauthorised varieties, creating a 'cottage industry' in some states, such as Gujarat (Herring, 2006). Navbharat claimed they bred the cultivar from a cotton plant which had remained undamaged in a field of otherwise bollworm susceptible plants (Jayaraman, 2001).

The GEAC responded by bringing a case against Navbharat, on the grounds that they had violated the Environment Protection Act (1986), by commercially cultivating transgenic material which had not been approved by the GEAC or been subjected to an environmental impact assessment (Jayaraman, 2001). The material was not protected by patent law in India, which would have given Monsanto-Mahyco grounds to claim property theft (Kothamasi and Vermeylen, 2010).

On account of the violation of environmental law, the GEAC banned the transgenic variety, which was registered as a conventional hybrid with the Gujarat local government, and further ordered any growing crops to be burned (Kothamasi and Vermeylen, 2010). The Gujarat farmers refused to burn their crops, while the local government also refused to enforce the orders (Herring, 2007).

In January 2002, the local government of Maharashtra further defied the GEAC orders by officially authorising production of *Bt*-cotton, of any variety, within the Maharashtra district (Kothamasi and Vermeylen, 2010). The GEAC authorised Monsanto-Mayhco´s *Bt*-cotton varieties a few months later, as described in the preceding information on crop development. This event marks the unofficial end of the efforts of the GEAC to govern the unauthorised production of *Bt*-cotton (Herring, 2007; Kothamasi and Vermeylen, 2010), with the outcome that two market streams were created in India´s *Bt*-cotton industry (Kothamasi and Vermeylen, 2010; Jayaraman, 2004), one regulated and one unregulated, as described in Fig. 4.8.

Insect resistance

The previous risk event occurred in the Field Trial phase and had lasting effects on the Commercialisation phase. In recent years in the Commercialisation phase, bollworm species have started to show resistance to the *Bt* traits incorporated in Monsanto-Mahyco´s original Bollgard varieties, commercialised in 2002 and licenced to a range of Indian seed producers (Monsanto, 2009, 2011). These traits are also the traits incorporated into the varieties which predominate in the unregulated market (Jayaraman, 2004; Kothamasi and Vermeylen, 2010).Tolerance is suspected to have developed due to poor implementation of regulations regarding pest resistance risks, such as refuge creation, which farmers are required by the GEAC to follow (Stone, 2004). While seed producers are required to include educational

material about the implementation of risk management practices at the time of seed purchase (Stone, 2004), they do not appear to apply TUAs, MTAs, sublicenses or any other IP-based approach to requiring farmers to adopt particular practices, as they have done in other countries (Stone, 2004; Monsanto, 2014; Lalitha, 2004; Herring, 2006). Furthermore in the unregulated market, the stipulations of the GEAC have no relevance (Jayaraman, 2004).

In response to the resistance outbreaks, the registered seed producers responded by accepting liability for bollworm resistance failure, on account of the resistance guarantee which they had offered on their crops, and reimbursed farmers who could provide proof of purchase (Kothamasi and Vermeylen, 2010). The recommendations of Monsanto-Mahyco are to purchase only their second generation cotton varieties, which incorporate more traits than those to which the bollworm show resistance, and to continue applying the practices advised by the GEAC (Monsanto, 2009; Duncan, 2011). Unregistered 'cottage industry' producers did not accept any liability for damages. This is considered to be a motivating factors for farmers to move towards the regulated network in recent years, despite increasing seed prices among the registered seed producers (Kothamasi and Vermeylen, 2010).

As described in Ch. 2, and partially illustrated by the case of PRSV-resistant papaya, IP-based regulations such as MTAs or TUAs may have been useful to encourage better implementation of pest resistance management procedures in India. Mandatory education sessions prior to seed purchase, also employed in Hawaii, may also have encouraged greater adoption of the recommended practices. The analysis of biotechnology related IP law in India provided by Lalitha (2004) indicates that while India´s biotechnology and plant related IP law is compliant with TRIPS and integrates a number of elements of UPOV, the relevant domestic law, the Indian Plant Varieties and Farmers´ Rights Bill, 2001, prevents TUAs or MTAs from having any bearing on farming practice. This is due to the elaboration of ´Farmers Privilege´ within that Bill, which allows farmers to cultivate registered plant varieties, and save and replant seeds, as practiced prior to the Bill coming into force, excluding sale of the seeds (Lalitha, 2004). This privilege makes the application of IP-based tools as a means to require farmers to carry out certain practices almost impossible. It does not however limit the potential of IP-based tools or other means to require more extensive education on the application of risk management practices. In this way IP could still have a useful role to play in the promotion of risk management practice, if not in the regulation of risk management practice, within the regulated market of *Bt*-cotton at least.

4.4.3 Canada/Contiguous US Herbicide-Tolerant Canola, 1985-2013

A number of varieties of herbicide-tolerant canola have been commercialised in the US and Canada since 1998 and 1996 respectively (James, 2012; Schafer et al., 2011), the most popular version of which is glyphosate-resistant canola such as Monsanto´s RoundUp Ready variety (Duke and Powles, 2008).The development of herbicide-tolerant canola began c. 1985 (Shah, Rogers, Horsch and Fraley, 1990), and proceeded through the field trial phase to commercialisation without any notable issues (Schafer et al., 2011). Further technical information regarding crop development can be found in Annex 1. Since commercialisation, some incidences of unauthorised production have occurred in Canada and the US (Schafer et al., 2011). A selection of these events and the management response to those events is described below, including the role of IP in these events. The development process of the

varieties of herbicide-tolerant canola is not discussed, due to the success of the development process in preventing unauthorised crop production or other environmental risk incidence, and the in-depth discussion provided elsewhere in this chapter of the general characteristics of how that process is managed, particularly in the US.

Unauthorised production

One specific case of unauthorised herbicide-tolerant canola production is examined, a Canadian case of unauthorised cultivation of the crop, while the other Canadian and US cases are covered more briefly. The Canadian *Monsanto Canada Inc. v. Schmeiser* case is a case of a private institution taking the lead in the management of unauthorised crop production, including the application of IP for this purpose . The outcome of Monsanto´s actions were successful, in that the particular incident of unauthorised GM canola production ceased, and the capacity for legal action to be taken by IP-holders in that regard was made evident by the court rulings. It is nonetheless included in the discussion of unsuccessful GM crop risk management, as unauthorised GM canola production continues in Canada in fields and non-agricultural habitats, where herbicide-tolerant occurs as a weed which farmers and other land managers must contend with (Knispel and McLachlan, 2010; Dawson, 2011).

In 1997 and 1998, Monsanto took samples of the canola crop grown by Canadian farmer P. Schmeiser, under suspicion that he was growing RoundUp Ready canola, a transgenic glyphosate-tolerant variety sold by Monsanto and containing genes conferring glyphosate-tolerance for which Monsanto held a patent (*Monsanto Canada Inc. v. Schmeiser*, [2001]). Monsanto´s tests of the seed samples found that RoundUp Ready canola was present in Schmeiser´s fields in 1997 and that his crop almost entirely consisted of RoundUp Ready Canola in 1998. In 1998, Monsanto began legal proceedings against Schmeiser for patent infringement, as Schmeiser had neither purchased the seeds, which contained transgenic technology patented by Monsanto, nor attempted to obtain a licence for use of the seeds (*Monsanto Canada Inc. v. Schmeiser*, [2001]). Farmers were required to attend a ´Grower Enrolment Meeting´, and sign a RoundUp Ready grower agreement, to certify their capacity to use the technology of herbicide-resistant seeds plus herbicide and enable them to purchase seed from certified Monsanto sales agents; and sign a TUA upon every seed purchase, elaborating conditions of production (*Monsanto Canada Inc. v. Schmeiser*, [2001]). Schmeiser had not pursued any of these avenues of obtaining authorisation to grow herbicide-tolerant canola.

The court found that the presence of RoundUp Ready canola in Schmeiser´s fields in 1997 was not relevant to the infringement claim, but his cultivation of the crop in 1998, in the knowledge that the seeds were tolerant to RoundUp, was an infringement of Monsanto´s IP rights to their technology (*Monsanto Canada Inc. v. Schmeiser*, [2001]). The Federal Court imposed a fine on Schmeiser to the order of the profits he made on the crop *(Monsanto Canada Inc. v. Schmeiser*, [2001]). Schmeiser appealed the case twice, first to the Federal Court of Appeals, who confirmed the prior court ruling, and lastly to the Supreme Court *(Monsanto Canada Inc. v. Schmeiser*, [2004]). In all cases he was found to be infringing *(Monsanto Canada Inc. v. Schmeiser*, [2004]). Schmeiser removed all potentially transgenic material from his fields in 1999, under advice of his legal counsel (*Monsanto Canada Inc. v. Schmeiser*, [2001]). In light

of the court ruling in favour of Monsanto, this removal of all unauthorised material would have happened as part of the case outcome if Schmeiser had not already done so himself.

In response to the unauthorised GM crop production event, Monsanto were thus able to leverage their IP rights to the technology contained within the plants being cultivated to ensure the unauthorised material was removed, to assert recognition of their property and right to determine its usage, and extract financial reward for their contribution to the infringer´s profits (found in the Supreme Court appeal to be none, thus no rewards were due (*Monsanto Canada Inc. v. Schmeiser*, [2004]). Monsanto used their IP in this way to punish infringers found to be actively cultivating the escaped GM plants. They do not appear to have used it to take action against authorised farmers who were in breach of the TUA or otherwise failing to restrict the spread of canola seeds and pollen, either in relation to the spread of seed onto Schmeiser´s land in 1997, or onto the land of other farmers who gave testimony in the Federal Court case (*Monsanto Canada Inc. v. Schmeiser*, [2001]). Rather, Monsanto accepted liability for cases of canola spread which were reported to them by farmers seeking a way to remove it (*Monsanto Canada Inc. v. Schmeiser*, [2001]).

The possibility of seed spread due to unexpected natural events, or farmer negligence was outlined during the Federal Court case, making clear that the plants in 1997, from which the patent-infringing 1998 crop was produced, could have arisen on Schmeiser´s land accidentally, without Schmeiser´s intent. This included a specific event of wind blowing RoundUp Ready canola seed from a neighbouring field into one of Schmeiser´s fields in 1996, a farmer potentially spilling seed while transporting a broken bag of Roundup Ready canola seed past Schmeiser´s field in 1996, and the same farmer potentially spreading seed from loosely covered loads of harvests in 1997, as well as other examples of uncultivated RoundUp Ready canola arising in the fields of other farmers (*Monsanto Canada Inc. v. Schmeiser*, [2001]). The possibility of pollen flow from neighbouring transgenic crops resulting in hybridisation was also examined, and considered a potential means by which unauthorised GM canola production could have occurred, but not to an extent sufficient to give rise to Schmeiser´s 1998 crop (*Monsanto Canada Inc. v. Schmeiser*, [2001]). From the various testimonies for the plaintiffs and defendants, some insights regarding unauthorised transgenic canola production in Canada emerge. Firstly, that such production occurs due to intentional action (e.g. Schmeiser´s 1998 crop), accidental or negligent action by authorised farmers (e.g. in transportation of seeds and harvest), unpredictable natural events or insufficient control capacity (e.g. winds blowing seeds further than predicted), and hybridisation with wild or agricultural non-transgenic canola (e.g. pollination from neighbouring transgenic fields). Secondly, Monsanto accepted liability and took direct action to remove unauthorised GM canola plants, as reported to them. Thirdly, action was taken, using IP, to prevent intentional cultivation of unauthorised GM canola plants. Lastly, no clear action was taken to identify or remedy the source from which the plants arose, so as to prevent future incidents. These observations are important for the discussion regarding the application of IP as a tool for regulating unauthorised GM crop production.

Unauthorised GM canola continues to be an issue in Canada, and has also emerged as an issue in the US. State agricultural advisors in Canada release warnings about the likely scale of volunteer RoundUp Ready Canola based on weather predictions and sowing intensity, but

management options are restricted as there is only one permitted herbicide that can combat the glyphosate-resistant plants (Dawson, 2011). Knispel and McLachlan (2010) describe the need for a multi-stakeholder, landscape-level approach, as localised farm-level efforts are insufficient to manage the plants, which have become significant agricultural weeds. Evidence was given in *Monsanto Canada Inc. v. Schmeiser* ([2001]) that Monsanto assisted in removing weedy herbicide-tolerant canola plants when contacted by farmers. Personal communication with Monsanto Canada further indicates that they take "necessary precautions to assist farmers who have not grown glyphosate-resistant canola in the past 4 years to help them manage any unwanted plants on their property" (Aly, Pers. Comm.). However, it seems from the management strategies outlined by information providers regarding weedy herbicide-tolerant canola (Dawson, 2011), and the extent of the canola problem described by Knispel and McLachlan (2010), that these 'necessary precautions' are insufficient to minimise or eliminate the problem.

Similar issues beset farmers in the US. In North Dakota, one of the top canola-growing states in the US, herbicide-tolerant canola is a wide-spread weed. The weedy canola plants are mostly composed of glyphosate or glufosinate-tolerant varieties, although a small amount of hybrids expressing tolerance to both herbicides also exist (Schafer et al., 2011). The transgenic weeds are mostly found in canola-growing regions, and along transport routes to harvest-processing plants, but are also found in regions with little relevance to the canola industry. Schafer *et al*. (2011) indicate that one of their primary concerns about their research findings is the absence of other similar reports about the extent of the issue in the US after ten years of herbicide-tolerant canola production. Their findings clearly indicate the existence of weedy transgenic canola, which, in the absence of similar reports, raises questions about the national capacity to manage and monitor the issue of unauthorised GM canola production (Schafer et al., 2011). While the report of Schafer *et al.* (2011) deals with glyphosate and glufosinate-tolerant canola, Monsanto have issued a response to the article in relation to their glyphosate-tolerant canola varieties, describing management of herbicide-tolerant canola. This involves mowing for roadside canola, and providing information for users of Monsanto´s products regarding management of volunteer weeds, while T. Nickson, Environmental Policy Lead at Monsanto, draws attention to the decision of US and Canadian regulatory authorities when canola was being released that "like traditional canola, biotech canola would volunteer, and depending on where it was found, might require management" (Monsanto, 2010).

More recently, Munier and Brittan (2012) have described issues with herbicide-tolerant c canola in California, a state not engaged in extensive commercial canola production. Herbicide-tolerant canola has been grown in California infrequently as a commercial crop, and in field trials at an experimental scale. Despite the small scale and inconsistent production, the GM canola has emerged as a significant weed in other crops and uncultivated habitats such as roadside verges (Munier and Brittan, 2010). Conversely, wild relatives of the plant are not common agricultural or roadside weeds (Munier, Brittan and Lanini, 2012). The nuisance of weedy herbicide-tolerant canola is exacerbated in California due to extensive restrictions on the use of herbicides to which the transgenic canola is sensitive. These restrictions are critical to the grape and cotton-growing regions of California, due to their sensitivity to the same herbicides (Munier and Brittan, 2010). A crucial point made by Munier, Brittan and Lanini (2012) is in relation to other herbicide-tolerant crops such as maize and cotton, which do not

pose any unauthorised and undesired production problems after a decade of commercial production in California, while herbicide-tolerant canola, a rarely cultivated crop, has become an issue. Distinction between the risk potential of species, varieties, etc. under different environmental conditions is not a new concept in risk management. However, the elucidation of the relevance of such distinctions in the California herbicide-tolerant Canola case bears significance for the application of IP-based regulation, a tool predicated on a streamlined regulatory approach grounded in neo-liberal economic theory. This point is elaborated in the Discussion section and Ch. 5.

4.5 Discussion

The cases described above provide information regarding management approaches of GM crop risks associated with unauthorised GM crop production, and the current and potential role of IP-based regulation in GM crop risk management. Due to the density of information presented above, the management approaches and role of IP are summarised below. This summary is followed by an assessment of the compatibility of the case experiences with the conceptualisation of IP-based regulation provided in Ch. 2[6], and further a discussion of the compatibility of IP-based regulation theory and experience of GM crop risk management, when a selection of relevant sociological concepts are applied.

4.5.1 Summary of Case Findings

The examination of the cases as described above will be summarised here to provide an overview of the risk management approaches applied, and the role of IP in those approaches.

GM crop risk management approaches

In the beginning of this chapter, three phases in crop development were characterised on the basis of risk knowledge and risk management intensity typical for different stages in the research and commercial production of a transgenic crop. These three phases, the development, field trial, and commercialisation phase, were applied to the five cases, to examine the GM crop risk management, and the role of IP. These phases were examined in particular detail for the Hawaii and Jamaica cases, including mapping of the organisational structure in each phase. For the other three cases, the examination was focused more on the management response to risk incidence, than on risk management throughout the three phases. The organisational structures were also not mapped, as the emphasis was not on management over the entire period of crop development. Table 4.3 summarises the characterisation of risk knowledge and risk management intensity based on the findings from the case studies. This characterisation is carried out for each phase of development in each case, with the exception of Jamaica and Thailand, which did not proceed to the commercialisation phase, and Canada/contiguous US for which only the commercialisation phase was examined as risk management was successful in all prior phases. As discussed in the India case study, insufficient information was acquired during this thesis research to assess the level of risk management intensity in the development phase of Indian *Bt*-cotton, except to note that the risk management was successful, and thus deemed adequate.

[6] The Actor-Network Control framework of IP-based regulation of GM crop risk management.

Table 4.3: Risk knowledge and management intensity per phase, for each case. *PRSV: Papaya Ringspot Virus; Bt: Bacillus thuringiensis toxin*

Case	*Development Phase*	*Field Trial Phase*	*Commercialisation Phase*
Hawaii PRSV-resistant papaya	Low risk knowledge, high risk management intensity	Moderate risk knowledge, moderate risk management intensity, decreasing with knowledge increase	High risk knowledge, low risk management intensity
Jamaica PRSV-resistant papaya	Moderate risk knowledge, high risk management intensity	Moderate risk knowledge, moderate risk management intensity	N/A
Thailand PRSV-resistant papaya	Moderate risk knowledge, high risk management intensity	Moderate risk knowledge, moderate risk management intensity (unsuccessful)	N/A
India *Bt*-cotton	Moderate risk knowledge, adequate risk management intensity	Moderate risk knowledge, moderate risk management intensity, decreasing with knowledge increase (unsuccessful)	High risk knowledge, low-moderate risk management intensity (regulated market); no formal risk management (unregulated market) (unsuccessful)
Canada/contiguous US herbicide-tolerant canola	Not examined, but management successful	Not examined, but management successful	High risk knowledge, low-moderate risk management intensity (unsuccessful)

From the table, it is evident that the cases can be characterised as mostly consistent with the characterisation of risk knowledge and risk management intensity in the three phases of development. Exceptions are the level of risk knowledge in the three cases involving technology transfer, Jamaica, Thailand, and India. In these three cases, development phase knowledge was higher than characterised, as prior knowledge had been obtained by the developer transferring the technology. Despite this increased level of risk knowledge, risk management intensity remains high, suggesting that the relationship between the two is not as linear as described above and in Fig. 4.1.

In the Field Trial phase, differences between successful and unsuccessful risk management occur, but without discernible differences between levels of risk knowledge or the intensity of risk management, as characterised in the case studies. While the Thai DoA researchers who led crop development at this stage were accused of negligence, they were found not guilty after extensive court investigation, and it was concluded that they had practiced all necessary risk management procedures for enclosed field trials. In India, risk management is reported to

have been intensive in the beginning[7] of the phase, becoming less as knowledge increased. No question of negligence was raised at the time of risk incidence.

Only three cases continued to the commercialisation phase, and of those one was successful while the other two were unsuccessful in preventing risk incidence. In the India case, this poor success in managing risk incidence can be attributed at least in part to the unsuccessful risk management in the field trial phase and the existence of both a regulated market and an unregulated market, which presents a considerable barrier to risk management efforts. In the Canada/contiguous US case, risk management has experienced mixed results. There has been some success in direct action by the seed companies, in response to requests for assistance from farmers and in response to incidents of intentional unauthorised GM canola production. These actions seem to be insufficient however, in the context of the continued presence of weedy herbicide-tolerant canola in Canada and more recently the US. The response of seed companies to requests for assistance has shifted from direct action to assist farmers experiencing problems with weedy canola to information provision and direct action for farmers who have not grown the crop in the past four years. The role of information provision is also shared with regional government services. Meanwhile the relevance to farmers of herbicide-tolerant canola as a weed, and intensity of farmer-led management of the plants has increased. Thus it can be observed that the intensity of risk management can be characterised as between low and moderate, with more actors and specific strategies becoming involved as the risk incidence has increased, particularly in Canada, but persistence of weedy herbicide-tolerant canola nonetheless.

Hawaii has had successful results practicing a low intensity risk management strategy, where growers are encouraged but not required to follow practices which reduce risk incidence, and the incorporation of non-GM papaya producers in the management strategy. This is in contrast to the India and Canada/contiguous US cases, where risk management is between low and moderate, with a greater degree of freedom regarding practices than during the research phases, but with specific strategies to be practiced by growers of the crops such as refuge provision, but without specific strategies for non-GM and organic growers[8].

Actor inclusion in risk management strategies.

From this analysis it appears that the success of GM crop risk management is not dependent on the overall intensity of the risk management strategy and degrees of freedom allowed for growers/researchers, in the field trial and commercialisation phases at least. It is possible that events occurred in the unsuccessful cases, which, if they had occurred in the successful cases, would also have caused problems for risk management and control of unauthorised production. Differences can be observed between the actors integrated in the risk management strategy in the successful and unsuccessful cases however. The India case in particular, with its formal and informal markets and unsuccessful management strategies,

[7] Described as moderate in Table 4.3 as there was nonetheless an intention to expose plants to field conditions rather than control all conditions in the laboratory.

[8] Monsanto's advice for farmers regarding the use of pesticide and cultivation techniques to manage herbicide-tolerant canola weeds could be applied by non-GM conventional farmers, while the cultivation techniques could be applied by organic farmers, but the advice is directed towards RoundUp Ready canola growers, not tailored for these farmers as per the Hawaii papaya management strategies.

gives a strong indication that the integration of all participants directly involved with the crop is important for management strategy success. To clarify this distinction between the cases, the management strategies have been characterised according to the actors integrated in the risk management strategies. This characterisation is made on the basis of the management strategies employed during the final phase of crop development in each case, as described in the case studies, or the most recent set of strategies applied in the case of India and the US. Integrated actors are those which are given specific regulatory positions, responsibilities, or whose contribution is otherwise specified in GM crop management strategies, as described in the case studies. This characterisation is summarised in Table 4.4.

Table 4.4 Characterisation of final development phase management strategies by primary risk managers per case. *PRSV: Papaya Ringspot Virus; Bt: Bacillus thuringiensis toxin*

Case	***Integrated actors***	***Management Strategy Characterisation***
Hawaii PRSV-resistant papaya	Seed developers, distributors, product users (farmers), affected parties (organic/non-GM farmers), local and national government.	Community management
Jamaica PRSV-resistant papaya	Researchers and national government	Developer/Public institution management
Thailand PRSV-resistant papaya	Researchers and national government	Developer/Public institution management
India *Bt*-cotton	(Registered) Seed companies, (registered) product users (farmers), local and national government	Direct participant management
Canada/Contiguous US herbicide-tolerant canola	Seed companies, product users (farmers), local and national government.	Direct participant management

All strategies incorporated the national government to some extent. In all of the cases, national governments had a regulatory role regarding permitted practices regarding GM crop research and commercial production, as the responsibility of specific public agencies, if not as part of direct departmental responsibilities. Considering the international policy context regarding agrobiotechnology as discussed in Ch. 3, such as the specifications of the Cartagena Protocol, and the requirements of TRIPS, the involvement of national government in GM crop risk management could be considered a fundamental, if not unavoidable, aspect of management strategies in most countries.

Direct participant management

India and Canada/contiguous US are both characterised as having 'Direct participant management' strategies. This characterisation is made on the basis that for most of the incidents of unauthorised production in those cases, the management approach engaged those directly involved with the production of the transgenic crop, i.e. the private companies producing transgenic seed and the users of the seed. Local government of the region where the risk occurred was also included in both cases, although they were not direct participants in

crop production. The role of the local government in India was to implement national government strategies, such as ordering farmers in Maharashtra to burn the unauthorised *Bt*-cotton crops. In Canada, the local government plays a supporting role by providing advice to farmers in regard to the strategies they can practice to deal with weedy transgenic herbicide-tolerant canola[9].

A key differences between how these similar strategies are practiced in India and Canada/contiguous US are in relation to the roles of government and private seed companies. In both cases incidents involving intentional unauthorised production of the crop occurred. In India, this occurred at a point when IP was not in place with regard to the transgenic technology, and the GEAC, a national government agency responded to the issue by taking a case against the company which had acquired the unauthorised seeds for breaking an environmental protection law, and recruiting the local government to carry out actions to remove plants, seeds and sources of seeds. The seed company at fault was permitted to continue operating, while the seed company where the seeds were originally developed, Monsanto-Mahyco, did not play any role in the management strategy. The local government did not carry out all of the actions requested by the GEAC, and later the seeds developed by Monsanto-Mahyco were given authorisation to be commercialised, leading to the creation of a regulated and unregulated markets (Fig. 4.8). At the same time the Indian Plant Varieties and Farmers´ Rights Bill, 2001 was passed by the national government, which includes a 'Farmer's Privilege' provision, making it difficult for private companies to impose seed use restrictions on farmers or otherwise influence practices relating to saved seed and seed exchanged between farmers. The capacity for private companies to play a more active role regarding amendment of the unregulated market situation is thus very limited, and their role in the regulated market is restricted to an advisory capacity regarding best practice.

In contrast, in the Canadian example the private company from which the seeds originated, Monsanto, took a very active role in remediating the unauthorised production of the crop, with the additional authority available to them by way of patent rights. As a result, the unauthorised crop was destroyed, the infringer was fined, and a clear message was communicated that Monsanto was actively pursuing issues of unauthorised GM crop production. The government, national and local, took a back seat on the issue. Neither party takes a strong remediation stance regarding the current unauthorised production issues however, and the strategy is similar in the US, leading farmers to be more centrally integrated as managers of the transgenic weeds. This is similar to the approach taken in India by private companies and local and national government regarding the current pest resistance issues.

Community management

In Hawaii, the only case of successful GM crop risk management with a commercially produced crop which is studied in this thesis, additional actors are integrated in the management strategy. This strategy is characterised as 'Community management' due to the integration of

[9] The role of local government regarding herbicide-tolerant canola management in the US could not be ascertained within the timeframe of this thesis research.

the developers of the crop[10] and actors affected by the crop, as well as those parties directly involved in crop production and the local and national government. Seeds are distributed for free by the PAC, while advice and instruction regarding risk management practices and strategies is given by UH and UH's cooperative Extension Service. Some terms of use are agreed in an MTA/sub-licence agreement signed between farmers and the PAC, but risk management strategies are mostly encouraged, rather than required at risk of penalty. As the entrance restrictions for producing transgenic papaya are minimal (free seeds and a mandatory educational session), there appears to be no motivation for intentional unauthorised production.

Both GM and non-GM /organic farmers were given advice and support regarding the measures they could take to reduce risks of unauthorised GM papaya production. For both groups, there were economic incentives to following the strategies. For GM farmers producing the popular hybrid variety, control of seed sources and pollination was necessary to ensure continued PRSV resistance and the presence of consumer-desired traits, while for non-GM/organic farmers, there was market demand from the export and organic market respectively to provide transgene-free papayas. The Hawaii Department of Agriculture also established a scheme to certify non-transgenic papaya, creating a means for papaya producers exporting to countries where transgenic papaya is prohibited to continue to profit from the export market.

The credibility of strategies to farmers, and thus their attentiveness when practicing them, may have been increased by the absence of private gains to be made by the PAC in administering the MTA/sub-licence, and by UH in providing risk advice and support. As UH were not only a research institution but also the crop developers this may have further increased the credibility of strategies to GM and non-GM/organic producers, increasing the likelihood of strategy adoption. R. Manshardt, one of the UH professors engaged in education and risk management support for GM and non-GM papaya farmers, commented that he advocates for good communication between growers, to minimise confrontation (Manshardt, Pers. Comm.).

There was not sufficient capacity in this thesis to investigate those potential reasons for successful management of GM crop risks in Hawaii, but the GM crop risk management approach taken there has a distinct community character, inclusive of actors directly involved with transgenic papaya production, and those with the potential to be directly affected by the incidence of GM crop risks. Further there is an absence of apparent private gains to the seed developers or distributors, an emphasis on economic gains from certain risk management practices, rather than punishments for malpractice, and communication between the different types of papaya producer.

Developer/Public institution management

Neither the case of Jamaica nor Thailand proceeded beyond the Field Trial phase. The risk management strategies practiced in both cases are characterised as 'Developer/Public

[10] In the India and Canada/contiguous US cases, the crop developers and seed companies are integrated, as the developers also fit in the seed companies category, but in Hawaii the integration of the crop developers in crop risk management was not necessary as the developers and distributors are separate organisations.

institution management' strategies, as only the crop development researchers and national government and associated regulatory institutions were involved. In Jamaica, the management of potential risks was successful, but the lack of national regulatory capacity to manage and monitor commercial production has put a halt to field trials since 2004. This judgement has been made by the national government, with influence from international regulatory bodies, in accordance with their obligations under the Cartagena Protocol and WTO rules and obligations. The involvement of the national government is thus critical to the management strategy practiced in Jamaica.

The management strategy in Thailand is similar, with the national government having a strong regulatory capacity, and also obligations with regard to the Cartagena Protocol and WTO. In Thailand, the seed developers were also connected with the national government, as a research and development arm of the DoA. Thus this could also be considered an entirely government-operated risk management strategy. There is no other discernible difference between how this strategy and that of Jamaica operated, and why one was successful while the other was not. The response of Thailand to the risk was also extensive, exercising considerable national and local government power in destroying any identified transgenic papaya crops and banning all field trials for three years, followed by very limited permissions for field trial research, but withholding permission for further PRSV-resistant papaya research. Nevertheless, the transgenic contamination persists, which appears to have intensified in recent years, according to the EU RASFF, and according to Thai research includes Hawaiian PRSV-resistant papaya, which there is little economic incentive for farmers to produce as it does not confer resistance to Thai papaya. The analysis offered serves to highlight the unusual characteristics of this situation, but more information would be required to discern even plausible suggestions as to why transgenic PRSV papaya production has persisted and increased, despite the stringent government intervention at the time of initial risk incidence.

Role of IP in GM crop risk management approaches

The strategies employed have been examined in terms of how they were applied during the case studies, the variation in intensity of management at different levels of risk knowledge and crop development, and the integration of actors into the management strategies. This has provided a management strategy context for each case, and an understanding of certain management strategy characteristics which may have had an influence on the success of GM crop risk management. The role of IP in the management strategies has been described in the case study descriptions but is now examined in more detail.

Table 4.5 summarises the role which IP played in GM crop risk management at different phases in each case, and the application of IP as a risk management tool. In the Development and Field Trial phases of all of the papaya cases, IP played only a minor role. Agreement with IP-holders was necessary to proceed with experimental use in both phases, but from the written accounts and interviews regarding the development of these crops which were used in this thesis, there is no indication that IP was a strong factor in determining how research was conducted and experiments were designed. Of much greater influence were national regulatory bodies, such as APHIS and the NBC, which established the permitted scope of transgenic crop research and monitored practices. In the Thai case, when the unauthorised

production of GM papaya came to the attention of the IP-holders, no action was taken. This continues to be the case even though illegal GM papaya continues to be produced in Thailand.

In the *Bt*-cotton case, IP played a small regulatory role, as Mahyco were required to obtain a licence from Monsanto, by virtue of their IP over the transgenic crop, in order to import it to India. The conditions of Monsanto-Mahyco's subsequent partnership are unclear from the reports obtained during this thesis research, but it seems that after the licence was obtained IP did not play any further significant role. Indeed, when unauthorised *Bt*-cotton was discovered during the Field Trial phase, Monsanto's IP did not extend to India, and was thus ineffective against the unauthorised transgenic crop growers or merchants, who would have otherwise been regarded as patent-infringers.

The case studies indicate that IP has the greatest influence on risk management strategies in the commercialisation phase. This is consistent with the characterisation of the commercialisation phase in section 4.2. In all three cases to which the commercialisation phase applies IP is recognised and incorporated into the risk management strategy to avoid infringement. Hawaii is the only case where infringement has been avoided however, while Canada/contiguous US is the only case in which IP has been used to regulate infringement, in a remediation action.

In Hawaii, the PAC is the official IP licence-holder and growers of papaya are required to make MTA/sub-licence agreements with the PAC to acquire seeds. There are some requirements associated with the MTA/sub-licences which are intended to prevent infringement, such as a requirement to attend an educational session, but IP is not used as a way to motivate growers to adopt certain practices[11], or to establish other terms of use. IP is also not used as a regulation tool in India. As described in the case study section, the provision of a 'Farmer's Privilege' in the Indian Plant Varieties and Farmers´ Rights Bill, 2001 makes it very difficult to extend IP for the development of TUAs specifying certain practices, or otherwise leverage IP as a way to regulate farmer practices, even in the realm of saving and exchanging seed. Due to the existence of an unregulated 'cottage industry' market simultaneous to the regulated market consisting of registered companies, either one of the many licensees of Monsanto's *Bt* technology, or one of the other developers of such technology, regulation of patent infringement by IP-holders is difficult to assert, particularly considering the broad scope given to farmers to cross-breed plants they have cultivated, and save and exchange seeds[12]. IP therefore does not play a major role in GM crop risk management in India, and also does not have much scope to do so. Alternatively, it could be used as per the approach in Hawaii, to require farmers to engage more with educational materials which emphasise the long-term economic gains to be made from certain GM crop risk management practices such as refuge creation, and monitoring intentional and accidental cross-breeding to help conserve agricultural genetic diversity.

In the Canada/contiguous US, IP was used to take effective action against intentional infringement in the production of herbicide-tolerant canola. In the case of *Monsanto Canada Inc. v. Schmeiser*, the Federal Court, Federal Appeals Court and Supreme Court all found

[11] That is, practices intended to avoid IP infringement.

[12] Provided there is no financial gain.

Schmeiser to be guilty of infringement and importantly defined the parameters of how patents and patent use are construed in Canadian law, with respect to agrobiotechnology. This use of IP is an application of IP as a regulation tool for certain IP risks, such as those arising from intentional unauthorised GM crop production. Monsanto, and other IP-holding companies associated with herbicide tolerant, have not used their IP as a regulation tool for other environmental risks associated with GM crop production, however. In the TUAs made with growers certain practices are specified as being prohibited or required, which can be applied as a way to use IP as a regulatory tool. There is no indication from the materials examined for this thesis that action is taken when farmers are found to be in breach of TUAs however, except where it might constitute an intentional act of unauthorised crop production. Instead, the companies adopt an advisory role, and in the past have offered direct assistance to farmers with complaints regarding weedy herbicide-tolerant canola, in Canada. Despite the capacity for IP-holders to play a stronger role in regulating the incidence of weedy herbicide-tolerant canola and the spread of transgenic seeds and pollen, unauthorised herbicide-tolerant canola continues to be an issue in Canada and the US, without being associated with any intentional action.

The findings from the cases indicate that application of IP for GM crop risk management is not necessary for successful risk management, as evident in the Hawaii case, but it can be useful as a tool for enforcing regulations and standards of practice in relation to GM crop risk management. However this potential is only partially exploited in the cases studied, namely that of herbicide-tolerant canola production in Canada/contiguous US. In other instances where it could be employed more actively to improve the effectiveness of GM crop risk management strategies, such as in India, where national and local government coordination of risk management strategies have proven insufficient, it is obstructed by national policy from being used to its fullest capacity. The experience of incomplete use of IP as a regulatory tool in Canada/contiguous US also indicates that there may not be sufficient incentives for companies to use IP to remediate situations of unintentional unauthorised GM crop production. Thus it appears that IP has potential to be used as a regulatory tool for GM crop risk management, but its use and success are limited by the policy environment in which it operates, and the incentives for companies to use it in this way, beyond the remediation of intentional infringement of their IP rights.

Table 4.5: Application of IP in cases of GM crop risk management, per phase. *PRSV: Papaya Ringspot Virus; Bt: Bacillus thuringiensis toxin*

Case	*Development Phase*	*Field Trial Phase*	*Commercialisation Phase*
Hawaii PRSV-resistant papaya	Minor – Experimental use permission	Minor – Experimental use permission	IP recognised; Not used as regulation tool.
Jamaica PRSV-resistant papaya	Minor – Experimental use permission	Minor – Experimental use permission	N/A
Thailand PRSV-resistant papaya	Minor – Experimental use permission	Minor – Experimental use permission	N/A

India *Bt*-cotton	Minor – Licence to import	No IP recognised	IP recognised but possibly infringed; Not used as regulation tool.
Canada/Contiguous US herbicide-tolerant canola	Not examined	Not examined	IP recognised but infringed; Used as regulation tool (remediation of infringement).

4.5.2 Compatibility of IP-Based GM Crop Risk Management Theory with Case Experiences

The cases examined in this chapter took similar approaches to GM crop risk management in the research phases of crop development, particularly the Development phase, and became more different as crops neared the end of the Field Trial phase and became commercialised. Canada/contiguous US was the only region which used IP to regulate against a type of GM crop risk, unauthorised GM crop production, but did not apply IP for the purpose of regulating GM crop risks as proposed in Ch. 2.

In Ch. 2, the conditions for successful use of IP as a GM crop risk regulation tool were explored, and conceptualised. Two conditions for network control emerged from this, a specific liability network creating structural control, and enforceable conditions of action, creating action control. Fig 2.1 illustrates the conceptualised framework of how IP can be used as a GM crop management tool.

The examination of GM crop risk management strategies in the case studies makes it evident that the successful strategies employed in those cases are quite divergent from the IP-mediated management envisioned in the Actor-Network Control framework. Hawaii, which continues to experience successful risk management of the commercialised PRSV-resistant papaya, employs a risk management strategy which does not enforce conditions of action, although the ´community management´ structure contributes to the creation of a liability network in which different stakeholders have roles to play in the GM crop risk management, including those likely to experience problems as a result of risk incidence. PRSV-resistant papaya in Jamaica, successfully employs a Developer/Public institution management structure, but the crop has not been commercialised there yet, and IP does not have a significant regulatory role. The liability and scope of action of the developers is strictly governed by the scientific practice protocols of the developers and their research institutions, and the public institutions and their relevant international obligations such as the Cartagena Protocol. In that sense, the structural and action control of the conceptualisation of IP-based GM crop risk management can be considered to be in place in a compatible but different fashion in Jamaica, indicating that the conditions for IP-based regulation have the potential to form the basis of a successful strategy.

The case of Thailand provides an opposing finding however. The Thai case also involves PRSV-resistant papaya, which was never commercialised, and was managed within a similar Developer/Public institution structure as the Jamaica case. In Thailand management was unsuccessful, despite no negligence being apparent on the behalf of the developer, a strong response of destruction of all PRSV-resistant papaya from the public institutions involved, and

a subsequent ban on all field research. Conditions of action were in place, and a discrete liability network existed, as exposed by the response to and subsequent investigation of the incident of unauthorised GM crop production. The issue of unauthorised transgenic papaya being produced in Thailand persists almost ten years since it was first reported, indicating that, in contrast to the findings of the Jamaica case, structural and action control as conceptualised in Ch. 2 are insufficient for GM crop risk regulation. This further indicates low potential for IP-based GM crop risk management to be successful within the Thai context and nature of the risk event.

In India, efforts to enforce conditions of action and distribute liability for unauthorised *Bt*-Cotton production through a discrete liability network were unsuccessful, with regional government resistance undermining efforts to enforce regulation in a manner consistent with both conditions for network control. The subsequent introduction of Farmer´s Rights, which run counter to the conceptualisation of IP-based GM crop risk management, exacerbates the prior existing difficulties in applying network control. Consequently, a controlled network and unregulated network exist within the Indian *Bt*-market, conditions in which IP-based GM crop risk management is highly unlikely to be successful. The Indian case indicates that the agency of network actors such as licensees and governing authorities, is crucial to the potential for applying IP-based GM crop risk management or any other similar strategies which is predicated on conditions of network control.

The case of herbicide-tolerant canola in Canada/contiguous US is the only case in which IP-based control has been applied to some extent, to control intentional unauthorised GM crop production. Despite the existence of the conditions necessary for adequate network control, as can be observed from the successful outcomes of related court cases, unauthorised herbicide-tolerant canola continues to proliferate, as a result of unintentional actions, and to hybridise with relatives. This unsuccessful management of GM crop risks can be considered to be due in part to negligence on behalf of private companies to pursue network control over risks which are not directly infringing on their IP rights, and to enforce conditions of TUAs. However, it calls into question the validity of actor control measures, as exercised by licensees, to prevent spread of the plant beyond the permitted area. This example, more than any of those described above, indicates the potential for plant material agency to undermine IP or network control-based strategies.

The differences which arise between the ideal conditions for IP-based GM crop risk management and the conditions present and strategies practiced in the cases indicate some pertinent observations regarding the usefulness of the IP-based or network control approach. Hawaii case indicates that a network control approach as conceptualised in this thesis is not necessary for successful GM crop risk management. Both the Thai papaya and Indian cotton cases indicate that unauthorised escape or IP infringement can be a result of both accidental and intentional human actions, while the Canada/contiguous US case indicates that plant material can carry out acts of reproduction and seed spread which can undermine network control efforts, in particular TUA-specified practices or action control. These latter two observations in regard to human and plant material agency reflect that the assumptions of IP-based GM crop risk management, of rational farmer/licensee responses to TUA conditions and predictable plant behaviour and environmental conditions, are important for the ideal functioning of this management strategy but can deeply undermine the control efforts of similar management strategies in reality.

From these findings regarding the assumptions underlying IP-based GM crop risk management, it appears that the potential for use of IP-based GM crop risk management is dependent on the context in which it is used, with greater potential where the assumptions of human and plant material agency implicit in the conditions for IP-based network control are likely reflect reality, and very low potential where those assumptions are unlikely to reflect reality, e.g. in the cases of India or Canada/contiguous US.

4.5.3 Power in the Actor-Network

The above analysis indicates that the assumptions underlying IP-based GM crop risk management, as conceptualised in Ch. 2, do not always reflect realistic contexts, and therefore contribute to the failure of network control. It does not give an indication of why those assumptions may be relevant in some contexts but not in others. From the cases, it can be observed that how actors can be obedient to action control measures, but can also build relationships with others and challenge the network hierarchy, including material actors. To address these assumptions the theme of power within the actor-network is examined.

Applying Diplomacy and a Flattened Hierarchy

The non-anthropocentric approach of Latour, specifically the concept of a flattened hierarchy, and diplomacy with nature can contribute to gaining greater insight into why the assumptions of IP-based GM crop risk management or similar network control based strategies are relevant to some contexts, such as Jamaica, but not to others. Using the concept of a flattened hierarchy, any object in the network which carries out an action will be considered an actor. Actors may form connections by acting upon or with other actors. Applying this relativist perspective opens up the possibility for all assumptions of identity and behaviour to be questioned. Thus the assumption of an objective hierarchical structure, in which laws and governing authorities can sufficiently empower IP-holders to enforce conditions of action, and in which plant materials become objects, characterised and managed according to predictable behaviours, is exposed as a social construction. This construction may go unnoticed as in Jamaica, while elsewhere it may be overthrown, to be replaced by an alternative construct, as in India.

Using the flattened hierarchy concept, the potential to overthrow structural control measures and defy action control can be considered to always be present, but it does not always emerge. An exploration of power dynamics then becomes more significant with the application of this concept, as the structure of the network hierarchy is no longer important but rather the relationships within the hierarchy. It is then necessary to extend the framework further by deploying more appropriate tools for the exploration of power dynamics.

Latour has tried to extend ANT to provide scope for examination of power dynamics within it, notably in his 2009 book, *Politics of Nature* . Politics of Nature distinguishes three types of power, the power to take into account, the power to put in order, and the power to follow up. Latour describes how these concepts of power can be applied to make a critical assessment of the influence of different power dynamics within the network. However, Latour connects these types of power with the concept of ´diplomacy´ within the actor-network, between human and material actors, rather than ´mastery´. Under this concept of diplomacy, the assumptions of a network control-based framework are fundamentally flawed, as they serve as

a means to achieving an end which is founded on a false premise of the possibility of mastery. Although this may be the case, most kinds of natural resource management strategy becomes difficult to justify under this concept of diplomacy with nature, and thus the use of this concept to address different expressions of power dynamics between actors does not substantially add to the critique. With these objectives, the concepts of power as described by Foucault, specifically disciplinary power, as presented in *Discipline and Punish: The Birth of Prison* (Foucault, 1977), and individualising techniques and totalising procedures, as presented in *The Subject and Power* (Foucault, 1982), are applied instead. These concepts are used by Foucault with regard to human power relationships, rather than a broader scope of actors including plants and other material agents. However, through Foucault´s philosophical perspectives on the relativistic existence of social phenomena and identity, his detailed exploration of power dynamics in social networks and network governance innately integrates the constructivist critical perspectives which are also crucial to Latour´s ANT.

Applying Disciplinary Power, Individualising Techniques, and Totalising Procedures

As described above, Foucault´s analytical approach to, and concepts of, power emerge are complementary to an ANT analysis which seeks to delve deeper into the flow of power within the actor-network, for the purpose of understanding the possibilities for ´mastery´ or control, rather than seeking to validate the ´diplomacy´ approach.

Foucault´s vision of power in *Discipline and Punish: The Birth of the Prison* , power is "perceived not as a property, but as a strategy", "exercised rather than possessed" (1975). In this sense, power is present in action, or practices, and as such cannot be held by an individual or group, nor can it be lost. Despite this, individuals and organisations can and do attempt to steer and hold power to their advantage. In this way we can discern that power is present through group and individual practices and flows between connected actors via joint practices. In the exercise and flow of power, dynamics and structures are created within and between actors, in what Foucault regards as the 'microphysics of power' (1975). Foucault describes modern 'government', in terms of how it differs from the 'sovereign power' which dominated global governance in centuries past. In the exercise of government, the objective is not always to dominate or destroy freedom, but also to produce societal benefits and norms which can enable individual freedom and happiness. Social decision-making is incorporated and societal norms produced, by using 'individualisation techniques' and 'totalising procedures' (1982). The use of these techniques and procedures is akin to the 'disciplinary power' concept which Foucault uses to describe punishment regimes and dominating strategies (Foucault, 1977), and the outcomes are similar. Individualisation produces an identity which separates and liberates one from the population, but also creates recognisable parameters of the self, the "trap" of visibility (1975). Totalising procedures meanwhile enable the production of societal norms which selves become relative to and also producers and re-producers of, in recognition of these norms by submission or resistance, "caught up in a power situation of which they are themselves the bearers" (1975). An extreme application of simultaneous individualisation and totalisation, which Foucault describes in terms of the ideal disciplinary institution, Bentham´s Panopticon, is to "induce in the inmate a state of conscious and permanent visibility that assures the automatic functioning of power" (1975).

This conceptualisation of individualising and totalising strategies to shape the flow of power dynamics is an aid in understanding the 'microphysics of power', particularly the ways in which power shapes and is shaped by the self, and relations between selves, to form patterns and structures with varying degrees of fluidity. This 'fluidity' arises from Foucault´s conceptualisation of power on account of varying levels of resistance. The hegemonic power can be considered to be strongly resisting the different interests of the repressed, while a student may exercise low resistance towards a teacher and vice versa, creating a more fluid power dynamic with almost continuous feedback and flow as opposed to stepwise change in the former (Oksala, 2012).

Incorporating the microphysics of power as described above, we can observe that action carries similar properties to power. In applying Foucault´s conceptualisation of power, action, which is so crucial to identifying actors in ANT, and power become inseparable. Power can be used to describe effects of action and the capacity for action, and may be exercised without the acknowledgement of multiple parties, or effect, like the concept of agency. This distinction is important in the 'microphysics of power', to gain understanding into how actors shaping actions can be perceived as being without agency, or go unnoticed in the actor-network, and how resistance may emerge and destabilise a power structure where no such agency of involved actors was perceived.

What Foucault´s conceptualisation of power adds which Latour does not is a concept of how governance can be achieved in a structured fashion. To define how a natural resource management strategy such as GM crop risk management could have any potential for success, without assuming an objective hierarchy or limits to human or material agency, conceptual tools are required which enable an understanding of how a hierarchy and conditions to control practices can be constructed. It is not sufficient to assert that reality can be deconstructed, as per the above critical concepts, but it is also important to credibly posit ways in which it can be constructed, if the potential of a management strategy is to be evaluated, taking account of its integral assumptions regarding reality.

According to Foucault´s conceptualisation in *The Subject and Power* (1982), the recognition and characterisation of selves by individualising mechanisms reduces the potential for change in resistance of possible self-identities, reducing the potential diversity of selves or identities which could otherwise emerge from single actors. By totalising, frames of exclusion and inclusion such as norms and shared traits are produced, which also limits the potential actor identities, the relationships they form and the resistance they produce and re-produce. In tandem then these two techniques can enable the development of stability within and between selves, or dominance of particular frames of conduct and existence, which is maintained and even produced to a large degree by the actors, individually and in the network.

Evaluation of Actor-Network Control according to conceptualisations of power

By this conceptualisation, individualising and totalising mechanisms should be sufficient to assert control in the actor-network such that the actors produce and reproduce the desired control. It is not immediately apparent that the theoretical conditions of the actor-network control framework lead to structural and action control such that individualising and totalising mechanisms are exercised on all actors. Certainly, the conditions exercise individualising and

totalising effects on human actors. Actor identities relative to the network are stabilised by both condition A, the liability network and condition B, conditions of action, but particularly in the assignment of discrete liability as a result of condition A. Recognition of certain individual rights and responsibilities as part of an action by the self to gain access to the network exerts strong individualising pressure. Both conditions also produce totalising effects, but the creation of network membership limits and determination of what actions and level of autonomy are appropriate for which actors are especially effective in creating a totalising effect. In this way frames of exclusion and inclusion are produced and norms are created for actors covered by either frame. Thus for human actors it is apparent that individualising and totalising effects are created by the conditions. It is not clear if these effects are theoretically sufficient for actors to produce and reproduce these effects however, as the threat of legal process and potential punishment is still necessary to make these theoretical conditions 'effective'. Hence, the actors do not mediate the control of the network as in the idealised form of disciplinary power or control proposed by Foucault, but rather they are adherents to the conditions imposed by overall structuring actors found to reside in the courts, and national and international governing institutions.

While the individualising and totalising effects may be apparent for human actors, even though they may not be as effective as they could be, it is less clear if non-human actors are subject to the same effects. Moreover, the uncertainty about the capacity of these effects to create production and reproduction of control by the actors in the network also casts doubt over the potential for these effects, arising from the property conditions in Fig. 2.1, to extend through human actors to non-human actors. Some non-human actors, such as the transformed plant material, are explicitly included in the structural and action control efforts as examined in the empirical cases. This inclusion can be observed in the specification of which transformed plant materials will be included in the network, and the characterisation of what that plant material is like and can express. Others are implicated in the action 'norms' for human actors, such as potential pollinators, although the extent to which these non-human actors are explicitly acted upon by human actors varies over the phases of GM crop development and production as described in the case studies.

As observed in the cases under study, the explicit inclusion of non-human actors, with or without proven agency to create risk, changes as the network expands and knowledge of agency capacity of non-human actors increases, from a high level of consideration to a more reduced level, with particular consideration given in human action conditions to the non-human actors with the greatest known agency capacity, such as wind in the case of wind-pollinated plants. These agents cannot be controlled per say, but conditions are specified for their exclusion and effective resistance, based on characterisation of potential agency which emerges from the development and field trial phases. For both non-human actors included in the actor-network control framework created by IP conditions and those excluded but explicitly acknowledged by the norms created for those actors which are included, the exercise of totalising mechanisms can be observed. The construction of parameters for 'population' or 'phenomena' level identities, such as for an entire variety of plants rather than individual plants, or the entire phenomenon of wind in specific dimensions of space or place, rather than individual bodies of wind, and integration of these actor groups into the control strategy based on such parameters is one of the more tangible effects of these totalising mechanisms.

Individualising mechanisms to control non-human actors however do not seem to be present in the construction of non-human actor control by IP conditions. This is possibly one of the reasons why the outcomes of structural and action control efforts in the cases are variable and do not confirm the rationale of the network control conditions.

Those non-human actors which do not seem to have agency are neither explicitly included nor excluded but rather not acknowledged. As demonstrated in Fig. 2.1, this does not indicate that they do not act upon actors in the network, but rather that high levels of resistance are exercised by the acknowledged actors upon which they act, such that their action does not have agency. However, by not acknowledging such actors and the potential for changes in the power dynamic or resistance such that their actions may carry agency, no control is exercised over elements which can be possible agents of change in the actor-network such that the conditions of risk might change. The potential for change in the capacity for agency of such actors could create act upon included actors in the controlled actor-network directly, or via connections with other non-acknowledged or explicitly excluded actors. This aspect of power in the actor-network and absence of acknowledgement of this aspect of actor-network power in the theoretical conditions of IP-based control could also contribute to the varied outcomes of IP-based control efforts.

4.5 Conclusions

The potential for IP use as a GM crop risk regulation has been addressed from many perspectives in this chapter, building on the experiences of GM crop risk management in five case study regions. An analysis through many layers of perceptions of reality was carried out, to garner insights from the reported reality of the case contexts, and potential other constructions of reality. This analysis ascertained that within the context of the cases studied, some cases had greater potential for adoption of IP-based GM crop risk regulation than others. However, IP-based regulation or similar network control based regulation of GM crop risk management did not perform better than other strategies, and indeed were outperformed by other strategies in their adequacy for dealing with GM crop risks in the case contexts.

This divergence between the idealised framework for employing IP-based GM crop risk regulation as described in Ch. 2, and the potential for such a strategy to be successful in the context of the cases studied was further investigated using social constructivist concepts of power. That analysis provided the insights that the assumptions underlying the premises for IP-based GM crop risk management are critical in undermining the potential of that strategy where the context differs from the assumed perspective of reality. This includes assumptions regarding the behaviour of human and material actors. This analysis also revealed the potential of IP-based GM crop risk management to be limited in its capacity to create a powerful regulatory system operating similar to ideal systems of governance theorised by Foucault, which exploits individualising techniques and totalising procedures to create self-perpetuating governance systems.

Clearly, the latter form is also an ideal governance system founded on assumptions of behaviour. However, this multi-level analysis, using very liberal relativist concepts of power, e.g. flattened hierarchy, and more critical concepts with an agenda practical for the evaluation of a resource management-oriented policy proposition, such as those of Foucault, but unlike

Latour´s diplomacy with nature, can contribute to an evaluation of the potential of a proposed natural resource management policy such as IP-based crop risk management. The specific contribution made is the critical consideration of the adequacy of the policy for the context in which it will be in place, bearing in mind the assumptions made within the policy, the relationships between, and agency of actors, human and material, and the adequacy of the policy to construct a system which governs those dynamic relationships and expressions of agency, or ´individualise´ and ´totalise´.

On the basis of the findings of this chapter, IP-based GM crop risk management is considered to be of limited use in contexts which differ from the assumptions underlying the conditions for management strategy operation, and where network relationships and agency, or the context of power, are dynamic and have potential to change. This provides a very limited range of contexts in which IP-based GM crop risk management might be useful. Inclusion of further conceptual tools to characterise identity and social dynamics might broaden the scope of this assessment, which will be discussed further in the Conclusion chapter, Ch. 5.

5: Conclusions and Recommendations

5.1 Introduction

The research described in this thesis addresses the theoretical functioning of IP-based regulation of unauthorised GM crop production, the experiences of IP-based GM crop risk regulation in specific case studies, and the role of power dynamics in the functioning of IP-based GM crop risk regulation. Conclusions are drawn from these specific aspects, and in relation to the research as a whole.

5.2 Rationale of IP-Based GM Crop Risk Regulation

Background from academic literature

Ch. 2 describes the legal and economic perspective of IP as a GM crop risk regulation tool, and specifies the rationale underlying IP use as a GM crop risk management tool. As described in the discussion, these emerge as A: the creation of a specific liability network around the transgenic technology and B: the creation of enforceable conditions of action for those within the network, creating a system of structural control and actor control, as conceptualised in the Actor-Network Control framework. From a neo-liberal economic perspective, these premises are the conditions for IP functioning as a GM crop risk management tool.

5.3 Compatibility of IP-based Regulation with IP and GMO Risk Regulation Policies

Ch. 3 examines several IP and GMO regulation policies, to investigate the compatibility of the international policy environment with the premises for IP-based GM crop risk management. This compatibility analysis looks at how policies enable or obstruct IP-based GM crop risk management in their wording, and the tools and economic systems they endorse, using a selection of relevant policies. The policies selected are applicable to most, if not all, of the case studies examined later in the research. This analysis therefore gives an indication of the policy environment in which IP-based GM crop risk management operates in the case studies examined, which helps to understand the divergent outcomes of this management tool in GM crop production.

5.4 Experiences of GM Crop Risk Regulation

The role of IP in GM crop risk management strategies currently in practice

Ch. 4 examines five case studies to gain a better understanding of how GM crop risk regulation works in practice and what role IP currently plays. The findings indicate that successful GM crop risk management strategies do not require the conditions theorised for IP-based management, nor does IP play a strong role in current GM crop risk management strategies.

Compatibility of IP-based GM crop risk management with existing GM crop risk management practices

A deeper analysis of the implications of the assumptions present in IP-based management indicates that IP-based management as described in Ch. 2 can contribute to effective risk-control strategy in certain contexts, but is insufficient to create successful GM crop risk management in more dynamic contexts.

The final section of Ch. 4 addresses the role of power dynamics in the functioning of IP-based GM crop risk regulation. The rationale behind IP-based management asserts that human actors shall respond to IP stipulations if the rewards and repercussions are sufficient, and in turn exercise power over other people and material. Latour´s concepts of a flattened hierarchy and diplomacy with nature, and Foucault´s concepts of disciplinary power, individualising techniques and totalising procedures, are used to examine the construction of ´power´ in the rationale of IP-based management, and the validity of this construction in the cases studied. This alternate model conceptualises dynamics of power within and between selves to understand how actors seem to suddenly emerge as important agents, and act in a networked fashion. This analysis finds that the rationale underlying IP-based management strategies are based on assumptions of material agency and human capacity to exercise power that do not correspond to the cases in question. This difference between the assumptions of power on which the rationale for IP-based GM crop risk regulation are based, and the experience of power in the cases studied, indicate that a tool such as IP, which exerts control over human actors and motivates human actors to exert control over other actors, is inappropriate for managing risks such as GM crop risks, which arise from human and material actors and networks of those actors.

5.5 Recommendations

The potential use of Intellectual Property as a tool for regulating genetically modified crop risks

The findings of this research indicate that while IP is theoretically a potentially useful GM crop risk regulation tool from an economic and legal perspective, consideration under alternative perspectives and conceptual frames indicate that it´s use is more limited. From the policy evaluation it can be observed that national policies under international obligations can legitimately render IP-based GM crop risk management ineffective, but there is also scope for IP-based regulation within the international policy environment. The case study research indicates that IP does not play an active role in GM crop risk management strategies at present, nor there is a strong indication that it could improve GM crop risk management strategies. A further evaluation of the potential of IP-based GM crop risk regulation under conditions different to the assumptions of the theoretical basis motivating the use of IP in this way, indicates that this regulation approach has strong potential in contexts which are complementary to the assumptions and quite static, socially and environmentally. In more dynamic contexts, where current network arrangements and power dynamics may change, IP-based GM crop risk management is considered to have low potential. The research elucidates the need to consider the adequacy of GM crop risk management strategies to deal with variable power dynamics. Agency and networking capacity were critical to the capacity for power to be exercised in order to manage the risk of unauthorised GM crop production.

Developing a framework for assessing adequacy of GM crop risk management strategies

This research has made some contributions to the development of a framework for evaluating GM crop risk management strategies, and possibly other natural resource management strategies, which takes into account the potential for human and material agency and network dynamics. The hybrid framework used in this thesis explores some significant aspects for

assessing the adequacy of GM crop risk management strategies, such as agency and networking capacity, the actors involved, and taking account of human and material actors, as material actors may also have the capacity to undermine management efforts.

For some contexts, or context components, such as material actors, agency and networking may not be as relevant as for others however. To recognise this would require characterisation of actors potentially involved, facilitating an evaluation of the applicability of the strategy to the 'multiplicity' and 'unity' of actors as Latour would put it, or the adequate use of individualising and totalising mechanisms, in Foucault's words. This is an element which was outside of the scope of this thesis, and opens up questions regarding how knowledge can be created or characterisation performed such that it is adequate to address the potentially dynamic network and actor contexts . Latour's flattened hierarchy suggests that all actors in an actor-network may have been relevant to the incidence of an event, and for the purpose of analysis should be assumed to have equal agency and networking capacity to enable an investigation of the event without prejudice to any set of actors. This is applicable to retrospective analysis, but does not discriminate sufficiently to be useful for a predictive analysis, as required when evaluating the adequacy of risk management strategies to deal with potential risks and dynamic contexts. Absolute management of risks appears impossible due to the immense complexity of each contributing actor having many potential states. This advocates for a management of risk based on the probability of risk incidence, calculated according to previous knowledge of the factors and actors we can identify as contributing to the risk, which is no different from current approaches to risk management and does not consider potential context dynamics.

The inclusion of more discriminating concepts which are still compatible with a constructivist approach that takes heed of potential changes in network relations and agency is likely to contribute to an improvement of the analysis performed here. With the inclusion of Bourdieu's work on social ´fields´ and habitus, it is possible that a more discriminating framework could be constructed, which would have the conceptual capacity to include aspects such as formation of knowledge/characterisation in a policy evaluation, while being complementary to the constructivist concepts applied in this thesis and pragmatic agenda of a GM crop risk management or other natural resource management policy.

5.6 Conclusion

This research found that the application of IP as a GM crop risk regulation tool is plausible form an economic and legal theory perspective, is possible within the international policy environment, but is not used in this way in most GM crop risk management contexts currently, and the potential for it to be successful in the majority of GM crop risk management contexts is low. Further development of the conceptual framework used in evaluation of the potential of IP- based risk regulation in socially and environmentally dynamic settings could lead to a more discriminating evaluation of the type of contexts in which an IP-based GM crop risk regulation strategy is likely to be useful.

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vi) Annex 1: Technical Information Regarding Case Study Crops

PRSV-Resistant Papaya

Three cases concerning papaya were examined for this research, in Hawaii, Jamaica, and Thailand. In all cases papaya is popular for commercial and domestic production, with commercial production targeting both domestic and export markets. The papaya in question is Papaya Ringspot Virus-resistant papaya. Papaya Ringspot Virus (PRSV) is one of the most serious diseases affecting production of papaya, and is predominantly spread by aphids, from plant-to-plant, but wild relatives of papaya can also be reservoirs of PRSV without showing any symptoms (Fermin, Castro and Tennant, 2010). PRSV can cause up to 100% loss in some cases (Tennant *et al, 2007*, in Fermin, Castro and Tennant, 2010*)* and is considered a limiting factor to papaya production globally (Gonsalves, 1998). PRSV is a disease of the 20th century, first officially described in 1945 in Hawaii, diverse regional genetic varieties (Fermin, Castro and Tennant, 2010; Gonsalves 1998). When PRSV-resistant Papaya was first developed in the countries under study, no varieties of papaya had full resistance to PRSV, while Florida and Thai varieties showed partial resistance, particularly to regional PRSV variants (Gonsalves, 1998; Gonsalves and Vegas, 2006)

PRSV-resistant Papaya derives resistance from the insertion of the coat protein gene of PRSV into the papaya genome. As all regional variants have differences in the specific genetic code for coat proteins, PRSV-resistant Papaya must be developed on a regional variant basis and does not provide broad-spectrum resistance to all PRSV variants (Fermin, Castro and Tennant, 2010; Gonsalves, 1998). For this reason, transfer of PRSV-resistant papaya from the region of development to other regions is not a simple process, but requires development of PRSV-resistant varieties which are effective against local strains of PRSV. The first PRSV-resistant papaya was developed in Hawaii. This is the only case of successful commercial production of PRSV-resistant papaya since the technology was developed. Regional variants have been developed elsewhere, including in Jamaica and Thailand, the other three PRSV-resistant papaya cases examined below. However, none have proceeded to the commercialisation phase, encountering issues in the development and field trial phases.

Environmental risks of unauthorised GM papaya production are mostly concerned with the potential for gene spread to non-GM papaya via wind-borne pollination. Such spread could reduce agricultural genetic diversity and, of much greater commercial relevance, could damage the integrity of papaya marketed as organic or non-GM. Development of weediness from possession of PRSV-resistance is not an issue (Gonsalves, 1998), nor is gene spread to wild relatives, as wild and domestic species prove hard to cross-breed under laboratory breeding conditions (Coppens, Drew, Kyndt and Scheldeman, 2014)

Bt-Cotton

Cotton (*Gossypium* spp.) is a crop which is used for food, as cotton seed oil and animal fodder, and fibre, for the production of cloth. Although of global relevance, two thirds of the crop was produced in Asia in 2012, of which 25% was produced by China and 20% by India, the top two global producers (FAOSTAT, 2014). Cotton is afflicted by a number of insect pests, of which *Lepidoptera* species are the most relevant, in particular cotton bollworm (James, 2001).

Bacillus thuringiensis is a soil bacterium which produces proteins which have a lethal insecticidal effect on a number of insect species, including cotton bollworm. The premise of transgenic *Bt* technology is the insertion *B. thuringiensis* genes encoding the insecticidal proteins, of which there are over 50 (Krattiger, 1996), into affected plant species (James, 2001). The advantages over *Bt* sprays includes no additional machinery or labour requirements and reduced dependency on abiotic factors such as the weather.

Cross-breeding between GM cotton varieties and wild varieties is not a significant risk as wild relatives do not usually occur in the same geographic region as cultivated species (James, 2001). James (2001) also considers crosses with other domestic/commercial cotton varieties to be insignificant due to low compatibility between the varieties. However, the relative ease with which local farmers and industries have crossed local varieties with transgenic varieties to produce illegal 'stealth seeds', now considered a 'cottage industry' in India (Herring, 2006), would suggest that the assertion of James (2001) is not valid.

A second environmental risk, which is also not strongly present with GM papaya, is that of insect resistance development. This would reduce the benefits of seed use and undermine the value of the seeds. A number of strategies have been proposed, from multiple gene insertion (gene stacking) to integrated pest management with a minimum area of refuge of non-*Bt* cotton in the surrounds of a *Bt* crop (James, 2002, 2001). These strategies require a certain level of commitment from farmers to practising the specific strategies, individually and collectively. Multiple gene insertion requires the least commitment from a farmer, but due to the development costs and multiple royalties involved, is also a more expensive product.

Herbicide-Tolerant Canola

RoundUp is a commercially successful, broad-spectrum herbicide produced by Monsanto. The main active ingredient of is glyphosate, a chemical which is deadly to plants but has low toxicity to animals, birds and aquatic life. RoundUp is more toxic than glyphosate alone, in particular for aquatic life, but nonetheless is generally considered less toxic than other herbicide products which can achieve the same results (Extoxnet, 1994). Glyphosate acts on an enzyme, the EPSPS enzyme, which is essential for the production of certain amino acids. By transforming the plant with a bacterial variant of the EPSPS gene, which produces an EPSPS enzyme of a different shape, plants can be made resistant to the action of glyphosate, or RoundUp (Plant & Soil Sciences eLibrary, 2014).

Using RoundUp Ready crops enables agriculture which satisfies certain paradigms of sustainability. More toxic broad-spectrum herbicides should not be necessary, and no-till cropping is more easily practiced, which reduces soil degradation. Potential environmental risks of RoundUp Ready crops include increased weediness of the transformed crop, as it becomes harder to control except by more toxic or specific herbicides, and the crossing of the transformed crop with non-GM domestic varieties or wild relatives, which can reduce agricultural genetic diversity, natural genetic diversity (as the wild relative gains a competitive advantage in situations of human environmental management) and increased weediness of wild relatives. Realisation of these risks can result in greater financial costs for the farmer or other environmental managers, and the general public, and complex environmental and public health damages, including the possibility of reverting to more toxic herbicides (Shaner, 2000) .

These risks have proven to be easily managed in some crop types, such as RoundUp Ready soybean, which can be attributed to the reproductive characteristics of the crop, or lower agency capacity on account of those characteristics. In others, such as RoundUp Ready Canola, management of those risks is not so easy, as reproductive characteristics such as wind-borne pollination, allow for a much greater range of possibilities for transgenic contamination. Canola is of particular importance for the oil produced from its seeds which can be consumed by humans and livestock, and also put to industrial and bio-diesel use. The GM varieties have proven popular with Canadian and US farmers, with adoption rates of 97% and 93% respectively in 2012 (James, 2012).

vii) Annex 2: List of Interviews and Email Communications

Date	Organisation	Person	Relevance	Mode
25/02/2014	National Commission on Science and Technology	Dr. Arnoldo Ventura	Chair, Steering Committee of National Commission on Science and Technology (JAM); Former Science and Technology advisor to Prime Minister (JAM).	Phone, email
11/03/2014	National Biosafety Committee	Dr. Marcia Blair-Thomas	Recommended by Dr. A. Ventura, member of National Biosafety Committee (JAM)	Email
Contact via Dr. A. Ventura	University of West Indies, Mona	Prof. Paula Tennant	Lead researcher on PRSV-resistant papaya in Jamaica	Email (*via* Dr. A Ventura)
03/03/2014	Cornell University	Prof. Sarah Davidson Evanega	Conducted research about development of and obstacles to PRSV-resistant papaya in Thailand	Phone, email
11/08/2014	University of Hawaii	Prof. Richard Manshardt	One of lead researchers on PRSV-resistant papaya in Hawaii	Email
12/08/2014	Monsanto Canada (CustomCare)	Aly	Manufacturer of RoundUp Ready canola, a popular variety of herbicide-tolerant canola in Canada	Email