Introduction

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WHY INTELLECTUAL PROPERTY RIGHTS IN BIOTECHNOLOGY INNOVATION?

Intellectual property rights feature prominently in all innovation systems, yet characterizing their role is a difficult task, one that always fosters debate. Intellectual property rights (IPRs), particularly in the form of patent rights, are widely viewed as catalysts for innovation in high-value, knowledge-intensive sectors like biotechnology because they reward risk-taking innovative behaviour while providing public access to invention disclosures. Some challenge this incentive–access paradigm, claiming that IPRs’ principal function is to coordinate actors in innovation systems. Others are sceptical about IPRs’ capacity to stimulate innovation, and point to cases in which IPRs act as impediments to innovation by setting a high entry barrier to an innovation system, generating patent thickets, creating anti-commons or leading to defensive or blocking behaviour. Moreover, differences of opinion about the correct description of the role of IPRs in innovation systems are typically aggravated when the discussion migrates from descriptive to normative issues. Heated disagreement dominates discussions regarding the design and reform of intellectual property systems, the rules, institutions and practices they support, and the conditions under which regional and national innovation systems thrive.

At least four problems stand in the way of having a complete understanding of the role of IPRs in innovation systems. The first is that ‘innovation system’ is a term of art the meaning of which is often derived from the context in which the term is being used. Freeman, who coined the term, described innovation systems as ‘the network of institutions in the public and private sectors whose activities and interactions initiate, import, modify and diffuse new technologies’ (Freeman 1987). While this definition encompasses the structures and dynamics of the social framework in which innovation can occur, its openness to interpretation means that it can be substantiated with many different kinds of real-life cases. Consequently, as will be amply demonstrated throughout this book,
‘innovation system’ can mean: all innovation, in some abstract or global sense; regional innovation systems spanning country borders; national innovation systems; sector-specific innovation, or clusters of innovation. This diversity is important to remember, for while no particular stand on what ‘really’ constitutes an innovation system will be advanced in this book, authors of chapters work with different conceptions of the term. Their focus is on IPRs; differing conceptions of ‘innovation system’ lurk in the background.

The second problem arises because the relationship between IPRs and innovation is difficult to describe. The link between IP and innovation is difficult to delineate in a way that allows one to evaluate the effects of IPRs, particularly patents, on innovation. IPRs are among a number of elements in an innovation system. These elements include licence arrangements, trade secrets, contracts, business models, institutional culture, risk taking behaviour and other factors such as lead time generated by business practices, complementary asset management, financing, marketing and firm-to-firm collaboration. Innovation cannot be attributed to any one of these elements in isolation from the others, and yet IPRs, particularly patents, are often discussed as if their role can be wholly disaggregated from the other elements and treated in isolation. Given that innovation is a complex phenomenon arising in dynamic and quickly changing scientific, technological, business and governance contexts, attempts to understand the role of IPRs separate from other elements is not likely to be a fruitful approach. The implication is clear: to understand how IPRs contribute to innovation requires consideration of the entire system of innovation.

The third problem is methodological. Studying IPRs is challenging because there are different kinds of intellectual property protection, each of which occupy a slightly different niche in innovation systems. These niches are not well-described, which means that evaluating the effects of patents on innovation, for example, is not a straightforward undertaking. Part of the problem is that governments, industry and universities frequently assume patents have a positive impact on the rate of innovation. The traditional argument takes the form of a positive feedback loop in which patents reward risk takers by providing limited-term rights to exclude others. Since the role of IPRs in innovation is not fully understood, the reliability of this feedback loop is questionable. What if growth in innovation and more patents are coincidental, not causal? Or what if there are better ways to manage intangible assets than patents in knowledge-intensive industries where patenting has not had a significant historical role? If either of these turns out to be true, then it is more than misguided to make policy based on the traditional view that IPRs provide an incentive structure that increase rates of innovation. In particular,
such an analysis ignores not only potential negative feedback loops – for example, slowing the next generation of innovation – but other positive roles that IPRs may have. These may include, for example, coordinating the flow of information between people and institutions, creating distribution channels or acting as markers of technological capacity in order to attract foreign investment.

In addition to the challenges raised about description and methodology, a gap in evidence dogs all discussions of IPRs in innovation systems. Empirical economic studies of IPRs are few in number, and have different methodologies and outcomes. The fourth problem, then, is that one cannot simply point to ‘the data’ and settle arguments about how patents are linked to innovation, and whether that linkage on balance stimulates or slows innovation. Innovation systems can be roughly divided into different sectors of activity, which further confounds the potential for having accurate and meaningful data from which to draw comparisons and generalizations. The IP protection the pharmaceutical industry believes necessary to protect its products in a costly and lengthy product development pipeline is not mirrored by the agricultural biotechnology sector, and the data available for each sector are rarely an apples-to-apples match of indicators. In addition, even the most thoughtful contributions of industry participants are inherently limited. They can report on how they believe that IPRs relate to their current business strategies and market structures, but can rarely say much about how different business models that rely less (or more) on IPRs would actually function. Experiential data will not settle the discussion about the role of IPRs in innovation in general. Furthermore, industrialized countries are likely to collect data, or have the collection done for them by international organizations, but developing countries do not tend to collect data. Consequently whatever data exist cannot lead to conclusions for the vast majority of countries.

Motivated by ongoing disputes about IPRs, and in light of the problems of description, methodology and verification, the purpose of this book is to bring together into one volume a collection of original contributions on the role of intellectual property rights (IPRs) in near- and medium-term innovation. This book pursues two related objectives. The first is to bring clarity, rigour and fresh perspectives to the analysis of IPRs in innovation systems. Without good descriptive work that delves deeply into the main issues at the crossroads of innovation and IPRs, it will always be difficult to evaluate claims of the positive and negative impact of IPRs on innovation. The second objective is to evaluate how IPRs actually operate in innovation systems, not just from the perspective of theory but grounded in the contexts in which they appear – global, regional, national, present and historical. To meet these objectives, this book draws on perspectives
from several regions of the world and from a variety of disciplinary and professional perspectives. The aim is to uncover deeply held assumptions about the role intellectual property rights have in innovation systems and move debate beyond these assumptions by encouraging the authors of these original chapters to engage in frank exchange across regional and disciplinary perspectives.

Each of the original contributions made in this book seeks to resolve aspects of the four challenges just mentioned, and they have come together in an effort to develop a more complete understanding of the role of IPRs in innovation systems. This approach will have immediate appeal to a diverse audience of scholars of science and technology innovation, academic and public or private sector specialists in IP, and to students of innovation theory, regulation and intellectual property law. Furthermore, there are five ‘unique selling propositions’ that are worth pointing out: first, this book situates IPRs within the broader context of innovation systems theory, an uncommon approach that facilitates the study of IPRs in their social and historical context unrestricted by economic and legal considerations alone. Second, the book provides new insights on IPRs’ capacity to foster or retard innovation in different jurisdictions and historical periods. Third, several chapters in the book provide useful methods for measuring the contribution of IPRs to innovation systems, and provide concrete examples demonstrating the consequences of making changes to IPR policies and practices. Fourth, taken as a whole, the book offers the beginning of a consensus view that the role of IPRs in innovation systems is less about strictly legal rights and duties and more about the economic and social impact of the ways in which researchers, industry and governments deploy IPRs to bring new technology forward. Finally, this book makes an important contribution by being among the first directly to investigate the role of IPRs in biotechnology innovation specifically, an area of intensive scientific and technological change, with correspondingly little research on the role of IPRs in biotechnology innovation. As life science and associated biotechnology continues to grow and diversify, knowing how to evaluate the contribution of IPRs to biotechnology innovation will become increasingly important.

THE STRUCTURE OF THIS BOOK

This book is comprised of six parts, each of which begins with a short introduction, followed by three chapters in which different facets of the role of IPRs in innovation are critically examined. The first part, ‘Intellectual Property Rights in Innovation Systems’, takes the view that intellectual
property is one among many components that constitute an innovation system. Starting with innovation systems as the overall context for IPRs, it is then possible to make decisions about how IPRs are defined, measured, and how they are related to other factors comprising innovation systems. Furthermore, one can then study how IPRs are used by governments, industry and academe to achieve specific goals. For example, changes to university invention ownership policies are almost always deliberate, but do not always attain the goal of fostering more innovation. In this way, this part of the book provides the perspective necessary for thinking about IPRs within the broader context of innovation systems, and is the crucial first step toward evaluating the relative contribution of IPRs to near- and medium-term innovation.

The second part, ‘Intellectual Property Management in Biotechnology’, begins by drawing the distinction between tangible and intangible assets in the portfolios of firms and other institutions. The idea of the knowledge-based economy may be relatively new, but in merely four or so decades since innovation and the knowledge economy became talking points it has become commonplace for a firm’s intangible assets to account for 80 per cent or more of the firm’s worth. This inverts the conventional ratio of tangible to intangible assets observed in the 1970s. IPRs, the most conspicuous form of intangible assets, need to be actively managed. A firm wishing to add value, or capture it from innovations, faces complex management decisions. It must evaluate options such as an intellectual asset focus versus a competitive intelligence focus, and it needs to make decisions about how it can make the most effective use of intellectual property within its organization and in competition or partnership with other organizations. This part provides an overview of management goals in the private and public sectors, an identification of the forms of intellectual property that are routinely overlooked, as well as those the importance of which are over-emphasized. The study of strategies for intellectual property management leads to a more subtle understanding of how firms believe that IPRs stimulate innovation, and the tactical steps they take to stay competitive. In addition intellectual property management highlights how factors such as market performance, capacity building and strategies for technology transfer subtly structure the relationship between firms managing IP portfolios and the rest of society.

A measurement problem is one of the greatest obstacles to a full understanding of the role of IPRs in innovation systems. IPRs, particularly patents, are often promoted as measurable outputs of innovative activity. The third part, ‘Intellectual Property Rights in Relation to Other Measures of Innovation’, addresses the value and accuracy of using IPRs as measures of innovation, typically by counting the number of patents
filed and granted. Of course, measurement implies that an innovation, whether a product, process, organization or market, can be quantified with standardized units of measurement. The temptation to use patents as direct measures of innovative activity tends to arise in situations where the dominant discourse interprets patents as cash substitutes magically caught at the bottom line. IPRs may be poor substitutes for cash, with no impact on GDP, and yet they may be useful indirect measures of what is valued in an innovation system, by whom, and what social relations will be maintained to produce valuable goods and services. When the simple story about creating value by filing patents is discarded, the role of IPRs in measuring and valuing the output of innovation systems becomes much more complicated.

Patent length is one of the most discussed aspects of IPRs since it is foundational to the nature of the limited monopoly granted to patent holders. Those who uphold the incentive–access paradigm will argue that longer patent length induces innovative activity because limited monopoly rewards accrue for longer. Innovators will see longer term patents as a way to off-set past losses and to balance taking greater risks in the future. Yet patent length is not the only method by which one can manipulate an innovation system to generate different kinds of outcomes, possibly even to trigger greater levels of innovation. The fourth part, ‘Beyond Patent Length’, considers different forms of incentives apart from patent length, and apart from patents themselves. It addresses the impact of various forms of intellectual property protection (patents, copyrights, trademarks, trade secrets, and plant breeders’ rights), and examines the effects on consumers, producers and governments of alternative strategies for stimulating innovation. These include identification and manipulation of underlying political-economic conditions, open source strategies and treating IPRs as mechanisms for coordinating knowledge flows between people and institutions. While often starting with generic issues in regional and national innovation systems, the chapters in this part anchor the discussion in biotechnology innovation. Additionally, since it could be conjectured that industrialized countries suffer innovation gaps only with respect to small differences in comparative advantage, this part also examines the pressing issue of how innovation can be stimulated in developing countries.

Governments actively manage innovation. The fifth part, ‘Innovation Governance’, considers some of the mechanisms, pitfalls and issues that governments need to consider as they adopt policies for controlling IPRs in innovation systems. The issues in this part are broad and diverse, covering the problems that arise in biotechnology innovation at institutional, national and international levels. Part of the issue for governance
of innovation is to be clear about the economic, social and ethical goals of IPRs as a component of innovation governance and consider whether the stated goals are being met. Do people have access to valuable data for downstream innovation? Another problem to address is the quality and quantity of empirical evidence that can be gathered to make evaluations of innovation governance. Governments must also consider the social milieu in which there are ethically charged media portrayals of IPRs, such as patents that allegedly restrict access to crops, diagnostics and medicines. Similar issues arise in thinking about the difference between the approaches to governance which are appropriate in industrialized versus developing countries. Governments have strong incentives to govern innovation systems optimally. Can they plan for the future?

In the last part of this book, ‘National, International and Historical Comparisons’, lessons are drawn for our contemporary situation from other times and other places. Many studies of IPRs often seek general truths about the nature, benefits, challenges and remedies associated with IPRs, but fail to acknowledge the historical contingency of individual IPR systems and their associated innovation systems. Do IPRs have the same role in innovation in a G8 country with elaborate innovation cultures and systems, with access to financing and with legal and scientific infrastructures, as they would in developing countries lacking these significant elements? Equally, does it matter that an IPR system comes into force at a time when professional cultures of science and medicine develop in a similarly evolving legal system? One might ask what modern dynamics arise when developing countries lacking tens or hundreds of years of evolution of their intellectual property and innovation systems find themselves competing with industrialized countries in an environment of globalized world trade.

THE ORIGINS OF THIS BOOK

*The Role of Intellectual Property Rights in Biotechnology Innovation* consolidates papers originally presented at a workshop held in the fall of 2005 at the Robert Schuman Centre for International Studies at the European University Institute in Florence, Italy. The chapters were at first workshop presentations, and then became chapters. They are not all uniform in length, a function of the scope of the topic, length of the workshop presentation, ensuing discussion at the workshop the author wished to incorporate, and revisions in response to referees’ comments. In addition to the variation in length, author style is preserved as much as possible to let the diversity in the authors’ voices prevail.
This workshop was convened by the Intellectual Property Modelling Group (IPMG), a research group based at McGill University in Montreal, Canada. The following discussion of the IPMG’s goals and methodology provides background about the generation of this book and the program of research that led to its development.

The Intellectual Property Modelling Group

The Intellectual Property Modelling Group (IPMG) is a transdisciplinary group of researchers in the fields of law, economics, ethics, philosophy, management, political science and biomedical science coordinated through McGill University’s Centre for Intellectual Property Policy (www.cipp.mcgill.ca). The IPMG seeks new models of intellectual property better to describe, evaluate, and change intellectual property systems (Gold et al. 2002). In light of the complexity of the field of biotechnology intellectual property and the diversity of the IPMG membership, it was necessary for the IPMG to develop a common conceptual framework, vocabulary, and a set of complementary research methods to investigate biotechnology intellectual property. The result is a conceptual and empirical methodology that is designed to provide empirically grounded, systems-level alternative policy strategies to governments, universities and industry.

Conceptual Methodology

The basis of the IPMG methodology was the development of a set of critical questions that can be used to probe aspects of IP systems (Gold et al. 2004). The IPMG used a Delphi method modified to take into account the group structure and composition. The ‘probes’ were developed by enumerating the common assumptions made by specialized academic disciplines about the structure and function of IP systems. Cross-discipline comparison generated a shortlist of widely held assumptions about IP systems which were then problematized by reversing the assumption into a probitive question. With respect to this book’s subject, the role of IPRs in innovation systems, one common assumption made in several disciplines is that IPRs provide a necessary incentive to innovate, and that patents in particular are an optimal policy tool for stimulating research and development. As noted earlier, neither assumption is beyond dispute and neither has compelling empirical support.

The development of the analytical probes allowed the IPMG to begin a process of mapping out IP systems, including all of the variables, and the relationships between them, that are involved in biotechnology IP systems. The IPMG was able to record the knowledge it was accumulating
and share analyses among team members and between IPMG and other interested parties, including its research partners and advisory board. Over the course of a few years, the IPMG has developed two principal research tools that take the form of an ontology and the formulation of the dynamic hypotheses. The dynamic hypothesis is represented by an influence diagram, a two-dimensional diagram of empirically-grounded variables and their inter-relationships. Each variable is nested in a common set of definitions that cross traditional disciplinary boundaries. The ontology represents the relationship between the variables that the IPMG has identified (for example, providing funding to develop an invention prototype) and particular policies and strategies (for example, income tax credits for research and development expenditures). The ontology is used in the development of policy alternatives from the results of modelling the interaction of variables in the dynamic hypotheses. These research tools are further described in the following descriptions of the empirical methodology and the IPMG’s impact through the development of policy recommendations.

**Empirical Methodology**

The conceptual methodology developed by the IPMG provides a framework for analysing intellectual property. It goes further by providing justification for which data collection methods are appropriate, and for providing guidance in the collection and interpretation of data. Three inter-related data collection tools have been incorporated into the IPMG methodology: Dynamic simulation modelling, case studies, and workshops.

1. **Dynamic Simulation Modelling**

   The IPMG provides such a framework by modelling IP systems as a dynamic system rather than as a static set of legal rules. The methodological basis is adopted from systems theory used by the IPMG to understand the interactions of various factors, or variables, in leading to the creation, dissemination and use of biotechnological innovation over time. Causal relationships between the variables, for example a relationship between patent terms and the availability of generic products, consist of probabilistic inferences in the form of either positive or negative feedback loops. The IPMG has identified approximately 130 variables and thousands of inferential relationships between them. It has also gathered empirical data on those variables necessary to perform a dynamic simulation of the process of biotechnological innovation under various real-world conditions. Where possible,
existing or researched data are collected. Where not possible, inferences from incomplete data sources are used.

The IPMG’s simulation model begins with a dynamic hypothesis about relationships between variables in a qualitative representation of the IP system. This hypothesis is then translated into a computer-based simulation model built with dedicated simulation software in which variables are represented as stock and flow interactions on a diagram. The simulation model permits testing of the hypothesis, and enables predictions. This simulation model is generic, in the sense that it aims to show the behaviour of specific variables over time, based on the underlying theory that pertains to these variables, or other historical data and information available about that structure. Since the model is generic, the selection of some, and elimination of other variables allows for problem- or topic-specific models to be spawned from the generic model. For example, as discussed below, a model containing mainly variables relevant to the issue of IPRs in innovation has been developed, which allows for specific kinds of policy questions to be answered. In another respect, models of specific case studies can also be developed, discussed next.

2. Case Studies
Case studies have many purposes and are used extensively by the IPMG. Retrospective case studies are an effective way of validating the dynamic model. Prospective case studies use the validated model to make predictions about the value of individual variables and the relationships between the variables in the model. For example, it is possible to model the effect of increasing patent length on the value of a patent. There are currently six case studies being conducted by IMPG that are related to the topic of this book: plant-derived vaccines’ technology diffusion; Canada’s access to medicines regime; the politics around blocking patents; knowledge flows; a comparative case study of traditional and indigenous knowledge in Brazil, Kenya and Canada; and a case study on Indonesia’s phytomedicines industry.

Case Study 1: Plant-Derived Vaccines
Plant-derived vaccines involve the introduction of a gene into a plant species, such as a tomato or tobacco, to produce a vaccine for serious communicable diseases such as Hepatitis B. Plant-derived vaccines offer many benefits over their conventional counterparts, and may revolutionize the way that vaccines are delivered, particularly in developing countries. Challenges requiring scientific and technological innovation remain but, assuming they are overcome,
regulatory obstacles (intellectual property, import/export, plant varieties legislation and environmental legislation) will determine the rate and extent of the technology’s diffusion. This case study compares different scenarios under which plant-derived vaccines can be manufactured and distributed, and includes a semi-quantitative, dynamic simulation model developed to surpass educated guessing and speculation about new technology innovation and diffusion. The case study will be published in book form by John Wiley and Sons in 2010.

Case Study 2: Intellectual Property Governance and Non-State Actors: The Case of Bill C-9
This case study provides a greater understanding of how to bring non-state actors (civil society and industry) into decision-making around health care innovation policy. Specifically, the project identifies ways in which non-governmental organizations contributed constructively to policy development in relation to health research, development and commercialization. The case study is based on interviews with leading members of civil society, documentary and media analysis, and analysis of the political debates. It explores how civil society influenced the passage of Bill C-9 in Canada – called the Access to Medicines Regime – and contributed to health, innovation and patent policy. The case study deals specifically with an amendment to the Patent Act to help provide medications through compulsory licensing to developing countries in need. The case study follows the work of non-state actors from the Cancun Ministerial Meeting in 2003 that provided a mechanism through which actually to import these medications to their lobbying for Bill C-9, An Act to Amend the Patent Act and the Food and Drugs Act, which aims ‘to facilitate access to pharmaceutical products in the developing world, in order to address public health problems, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics’. The Bill, the first of its kind among developed nations, became law on May 14, 2004. Only in the summer of 2007 did any country, however, actually make a request to use it. That country was Rwanda, which sought a first-line triple therapy for HIV/AIDS.

Case Study 3: The Politics of Blocking Patents
This case study examines how a small Utah biotechnology company’s patent and business model erupted into an international debate about blocking patents. The company is Myriad Genetics and the technology is a genetic predisposition test for breast and ovarian cancer.
Based on academic literature, news reporting, and a workshop of the principal industry and governmental actors involved with the dispute, the case study illustrates how communication and institutional failures combined with a lack of trust combined to transform a poorly adapted business model into an international *cause célèbre*. The case study points to the need for a greater recognition that biotechnology patents exist within a different cultural and social context from most other inventions and that those who fail to account for this may pay a significant price.

**Case Study 4: Knowledge Flows in Biotechnological Innovation**

Knowledge and innovation flows can be tracked with new methods in bibliometrics and scientometrics, for instance, by looking at the fields of mouse genomics and stem cell research. To analyse the flow of knowledge from pure science via technology innovation into public discourse, a case study will explore research methods in three distinct fields: (a) citation analysis for scientific publications and patent literature; (b) word and concept analysis for summaries or full texts of scientific, patent, policy and media documents; and (c) social network analysis. Different sources of data for large-scale analyses, and verified or obtained appropriate licences for large-scale searches and downloads have been identified, including Medline/PubMed, ISI Web of Science, Elsevier’s Scopus database, Delphion and national patent databases, Lexis/Nexis and Factiva for media and national government sites for policy documents, committee reports and political speech.

**Case Study 5: Comparative Case Study of Traditional and Indigenous Knowledge**

As numerous international fora and organizations attempt to map out a strategy to recognize and protect traditional indigenous knowledge, little attention has been paid to whether there is a coherent meaning to this knowledge that transcends the different cultures and societies involved. This case study remedies the gap by comparing the types, cultural meanings and legal protection offered to traditional and/or indigenous knowledge in three places: Brazil, Kenya and Canada’s North. The goal of the study is twofold. First, it seeks to determine whether there is a single overarching concept of traditional knowledge that applies in all of these places. Second, it attempts to determine whether, given the nature and meaning of such knowledge, it is best viewed through the lens of legal ‘property’ or as a component of sovereignty and autonomy of the peoples involved.
Case Study 6: Indonesia’s Phytomedicines Industry

This case study explores how Indonesia can convert its advantages in plant diversity and in traditional medicine into the development of new medicines that address the country’s essential health needs. Indonesia – and, by extension, similar developing countries – could take full advantage of modern biotechnology to meet its health concerns, but three obstacles have been identified: first, there needs to be better alignment of health research with health needs in the country. Second, trained managers are needed to move innovative products from the laboratory to the patient. Third, finding ways to stimulate the Indonesian market to accept and encourage locally invented and produced medications is a must.

3. Workshops

The dynamic simulation model and the case studies are supported and cross-referenced by means of international workshops at which members of the IPMG adopted the view that workshops provided an obvious and important dissemination opportunity, but equally they provided an opportunity to collect and validate data that would be used in the model and in the case studies. Accordingly, the IPMG has held many workshops, of which the event in Florence that led to this book was the fourth. Participants were invited to the workshop to examine the role of IPRs in innovation systems, and to provide their views about this issue from their disciplinary and regional backgrounds. There was considerable diversity of opinion at the workshop, and the collected wisdom and expertise were crucial to the methodology of IPMG’s project insofar as they helped uncover deeply held assumptions about the role of intellectual property rights in innovation systems. The workshop was successful in not only generating this book, but also assisting IPMG members in their efforts to select, quantify and relate variables that are directly relevant to the issue of IPRs’ role in innovation systems.

A similar workshop hosted by the IPMG was entitled ‘Intellectual Property, Biotechnology Capacity and Development’. This workshop was held in Buenos Aires on September 25 and 26, 2006, and was hosted by the Argentinian Agencia Nacional de Promoción Científica y Tecnológica, and the Centre for Intellectual Property Policy. The workshop brought together policy-makers, non-governmental organizations, industry and academics to examine how developing countries can configure their intellectual property systems to attract and retain scientists and investment in local research and development. The focus was on policy options available to Latin America and the Caribbean.
to enhance their scientific infrastructure in the biotechnology field. These options include practices drawn from actual experience in developing and industrialized countries and new models put forward to overcome identified problems in innovation systems. Some of the novel mechanisms given special attention in this workshop are new venture capital structures for start-up technology firms, collaborative and open science mechanisms and novel reward systems for innovation. Perhaps the greatest issue identified in this workshop is how cutting edge social science research on innovation systems and intellectual property can be used to overcome the tremendous diversity in levels of innovation, diversity of resources, and social infrastructure in the region.

The Impact of IPMG

The IPMG has developed a conceptual model of how IP-related laws, practices and institutions actually work together to create or inhibit the production and dissemination of new knowledge in relation to biotechnological innovation. IPMG research demonstrates that: (a) IP laws do not operate in isolation from practices and institutions, and thus the implications of implementing particular legal rules cannot be assessed without a more comprehensive understanding of the relationship between rules, practices and institutions; and (b) while policy-makers generally rely on IP rules to achieve policy objectives concerning innovation, these objectives could be met through complementary or alternative practices and different institutional structures.

One of the challenges that the IPMG addresses is how to draw on this understanding of IP systems, better to develop understanding on how best to deploy IP laws, practices and institutions to meet social and economic goals. The IPMG distinguishes between ‘old’ IP and ‘new’ IP eras to highlight the changing attitudes toward the role of IP, the changing roles of institutions which rely on IP, and evolving IP practices. To make this transition, the final report of the IPMG, *Toward a New Era of Intellectual Property: From Confrontation to Negotiation*, describes a detailed framework of actions to be taken by governments, patent offices, universities and the scientific community (The International Expert Group 2008). These include: developing greater trust between actors; more and better communication; generating new models of IP; enhancing science, technology and engineering in the developing world; cross-cutting thinking about IP; and developing improved data sets and metrics. If followed, the framework of actions ought to increase short- to medium-term innovation levels; increase scientific infrastructure (particularly in developing countries and
in economically or socially disadvantaged regions of developed countries); and increase access to technology.

A simulation model specific to the issue of IPRs’ role in innovation has been developed. It incorporates the interactions amongst the selected variables, according to system dynamics modelling principles. At the time of writing, the model is being evaluated for its realism and accuracy using scenario analyses of policy changes that target specific variables to induce changes within the model. This evaluation includes checks for the model’s internal validity (consistency with theory, links amongst variables of specific feedback loops, expert knowledge, empirical evidence from research), the model’s external validity (consistent with historical data collected, gaps between calculated values from the model and historical data), and the sensitivity analysis of key parameters on overall model behaviour and performance on targeted policy parameters.

The motivations for the book are quite clear when one considers that policy and academic literatures often portray IPRs as the catalyst for biotechnology innovation. This role is contested by some commentators, but, as mentioned above, the problem is that decisive empirical data are missing. More important to the IPMG is that even if the relevant data exist, they need to be collected and understood within a rigorous framework that takes into account the complexities of the IP system in biotechnological innovation.

REFERENCES
