The Policy and Legal Environment for Innovation

Changes in both national and international legal frameworks have profoundly affected how companies manage their intellectual assets in furtherance of economic and strategic business objectives and how they pursue their R&D. Moreover, the changes have enabled a broader distribution of health-related technology to people in developing countries. Public sector institutions likewise have had to adapt to an increasingly globalized knowledge-based economy. One adaptation is the ever-increasing interaction between developed countries and developing economies, particularly more innovative developing countries (for example, Brazil, China, India, Korea, South Africa). A second adaptation is the increased complexity of interactions between public and private sector actors. A third involves an evolution in the judiciary: toward a clearer judicial structure with more reliable and predictable mechanisms of dispute resolution. Many innovative developing countries are undergoing far-reaching changes within the judiciary, and experience from the creation of the Court of Appeals for the Federal Circuit (CAFC) in the United States offers many useful insights.

In order to help revitalize flagging technological innovation in the faltering economy of the late 1970s in the United States, a fundamental **change in the judicial structure** took place in 1982. As a judge at the CAFC, Newman[1] describes the creation of the CAFC (the national appellate court that would hear all patent appeals) as the first profound change in over 100 years concerning IP-related dispute resolution. A single appellate court would better understand and **correct policy misperceptions**, largely created by judicial decisions that had negatively influenced investment incentives in relation to patenting. A uniform and predictable application of the law across the United States and a concomitant end to forum shopping would promote innovation. And indeed it has. The effects have been dramatic: industrial activity, based on strengthened patent incentives, has surpassed the most optimistic expectations.

In addition to the establishment of the CAFC, two other critical events at the beginning of the 1980s catalyzed the growth of the biotechnology industry. In 1980, the Supreme Court's landmark decision in *Diamond v. Chakrabarty*, despite dire predictions to the contrary concerning the patenting of life forms, opened the nation's economy to biotechnology as an industry, enabling investment and commercialization in this nascent field. Also in 1980, the Bayh-Dole Act catalyzed the revitalization of commercial products arising from government investments in academic research. The combination of the CAFC, the Chakrabarty decision, and the Bayh-Dole Act synergistically drove the biotechnology revolution in the United States.

Because of rapid scientific developments, new issues of law constantly arise. Advances in

Krattiger A, RT Mahoney, L Nelsen, JA Thomson, AB Bennett, K Satyanarayana, GD Graff, C Fernandez and SP Kowalski. 2007. 3: The Policy and Legal Environment for Innovation. In *Executive Guide to Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (Krattiger A, RT Mahoney, L Nelsen et al.). MIHR (Oxford, UK), PIPRA (Davis, USA), Oswaldo Cruz Foundation (Fiocruz, Rio de Janeiro, Brazil), and *bio*Developments-International Institute (Ithaca, USA). Available online at www.ipHandbook.org.

health and agriculture raise legal questions for which there are no direct precedents and about which there is no consensus. Therefore, **the courts take an incremental approach** to such questions, building on indirect precedents that attempt to balance the competing visions of patent theory and that respond to the quick pace of scientific discovery. In other words, the present builds on the past to create a coherent and stable body of law.

When technology and biology are involved, the overview of jurisprudence (as well as decisions in individual cases) will affect the nation's economy and the public interest, and, additionally, have an even broader global impact. This *Handbook* arises from the premise that **the development of the products of science and technology profoundly benefits the public and that both scientific and industrial participation are required in order for their benefits to be realized**. This is a many-faceted concept; yet we exist in a time of such pervasive scientific and technological advance that the development of these benefits and their movement into commerce among nations warrant our most concerted efforts.

But are public research institutions really delivering public goods? This question might appear foolish. In the past 50 years, the intensity of research and the pace of discovery in the biomedical and health fields have accelerated dramatically, not only in the United States, but in many parts of the world, particularly in the more innovative developing countries. As a result, the number of safe and effective drugs, vaccines, and medical devices for a broad range of illnesses and conditions has skyrocketed, as have sales in developed countries. But in an increasingly global world—in which the risk of disease and the benefits of research can come from any corner—the **benefits from public sector health investment should be global**. Keusch and Nugent,[2] therefore, argue, on the basis of their experiences in the United States, that the public-benefit aspect of government-sponsored research investments should include (the poor) in countries outside the United States.

Because of the "public goods" aspect of health, governments should fund health research, and indeed they do. For similar reasons, they also fund agricultural research and extension services. Such publicly supported research fills knowledge gaps that private industry ignores, even though public sector inventions are usually brought to market by private sector product development. The choice of whether to develop new ideas into products is largely left up to the private sector. Thus, technology development from public research proceeds largely according to private sector priorities. So **what role do public agencies have in ensuring that the public benefits from its investments in health research?** The answer is not obvious. Under current arrangements, the public sector has limited capacity and experience in the *downstream* steps of developing and delivering biomedical products to patients. These steps typically require a significant investment of money. They are also not aligned with the public sector's comparative advantages.

The public sector, therefore, needs to be creative, and Keusch and Nugent outline several ways that decision makers can **strengthen and reorient the public sector's intellectual property (IP) strategies** to expand the ability of developing countries to access the benefits derived from public research investments. They discuss several strategies that public institutions can adopt to increase the resources and tools devoted to the public health needs of the developing world:

- At the *upstream* end, the public sector can direct funds toward research on diseases in developing countries and can partner with private and nonprofit entities wishing to do the same.
- At the *downstream* end, public sector institutions can directly provide products to users in poor countries, reduce barriers to the transfer of technology that benefit developing countries, or partner with industry and academia to expedite the development of products from research.

As much as the Bayh-Dole Act successfully created a large body of intellectual property from publicly funded research, it has reduced, in some regards, the availability of public goods for health and agriculture. Current practice undervalues the

public-benefit aspect of the mandate, especially for the poor. **As developing countries increasingly consider implementing Bayh-Dole-related legislation, these countries should carefully study the conclusions from this chapter so they may improve upon the experiences in the United States**. It should be pointed out that the intent of Bayh-Dole was not to produce supplemental revenue streams to universities. Rather, it was to encourage private innovation and increase the use of technology for economic development.

Graff[3] surveys the opportunities available in 18 developing countries[4] for new technologies to flow to the private sector and the public policy issues needing to be addressed to facilitate this. Three key aspects of public policy are considered:

1. The availability of IP protection
2. The designation of IP ownership
3. The existence of the infrastructure needed to make IP protection and ownership a reality

The chapter reveals that strong IP protection capabilities are correlated with robust scientific research efforts, to the strength of the countries' IP laws through history, and support of, through membership in, international trade agreements, particularly the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) and the International Union for the Protection of New Varieties of Plants (UPOV). Regarding IP ownership issues, policies in most countries are moving toward granting the rights and responsibilities of ownership to research institutions. Finally, **sophisticated institutional IP management is correlated to research capacity and to government investment in public sector and university research and development**. Generally speaking, vigorous IP protection policies and the capacity to enforce and manage them are mutually strengthening. The biggest factor for this strengthening is the amount of research and development a country conducts, followed by **the ability of its economy to absorb new innovations into existing or new industries.** Those seeking to use intellectual property as part of an integrated strategy to grow the economy through public financing and commercialization of innovation will find these trends worth considering.

In the chapter by Finston,[5] the discussion moves away from broad national policies to specific technology transfer policies. Finston reveals, using many colorful examples, how such policies can have a broad-ranging, positive impact for a country, raising the standard of living, improving the economy, and opening many commercial opportunities. Primarily addressing government policymakers, this chapter defines the **policy conditions needed for a robust national technology transfer system:**

1. Government support of science education, research, and related infrastructure that together will create an enabling environment
2. Rule-of-law protections (predictable laws, fair enforcement, judicial remedies), including those relating to intellectual property
3. A reliance on market forces, which foster informed risk-taking and private sector investment, to determine which technologies and products should be developed

Finston argues that these three factors are mutually interdependent and should all be present to create a favorable environment for technology transfer. To support her claims, the experiences of five geographically and developmentally diverse countries with existing technology transfer policies are described: Brazil, Israel, Jordan, India, and Ireland. As a result of technology transfer reforms, these countries enjoyed growth in R&D, technology transfer, and economic activity. If one or more of the above three requirements were missing, a country would not have advanced as far technologically or economically.

The key lesson offered by her chapter is that the strength of government and of the private sector can be synergistically applied to improve the lives of all. Technology transfer works best when there is strong, consistent government support of basic research, including science education and technology-related infrastructure and robust IP protection.

Given the success of technology transfer in the United States, many countries' expectations of similar programs in their own countries are

grossly overestimated (if not outright misdirected). Indeed, Heher[6] points out that many policymakers in developing countries proclaim that a technology transfer program should become a major source of income. Too often, such programs begin too optimistically, but within a few years, end up disillusioned.

Unless the central reasons for undertaking technology transfer (for long-term social and economic benefits) are understood, a boom-and-bust cycle, replete with unrealistic financial expectations, is likely to prevail at considerable cost to those involved. Indeed, countries have yet to develop answers to basic questions. For example, **what exactly is the nature of success in technology transfer**? And what precisely are the elements that make this success possible? This chapter uses international technology transfer benchmark data to benchmark and understand the implications of promoting technology transfer and the likely outcomes of a technology transfer initiative under realistic conditions.

Heher provides comprehensive data and concludes that income generation from technology transfer is an inadequate—if not inappropriate—reason for an institution to invest in technology transfer. Governments should not expect revenues from technology transfer to be able to fund research institutions. Indeed, the **financial benefits of technology transfer activities are captured primarily at the national economic level through business creation**, with national returns arising from indirect economic effects. The extended time period required for individual institutions to derive benefits together with the fact that the benefits are largely felt by the national economy suggest that appropriate national support measures are needed to encourage technology transfer.

Bringing this realistic approach to the institutional level is the topic of the chapter by Taubman and Ghafele.[7] First, the authors **strongly endorse the indigenous innovation potential of developing countries**. Second, they detail the **inadequacies of a top-down approach** to developing IP management policies and approaches, as such an approach would almost invariably ignore the unique strengths of a particular country or institution. Rather, to seize on such strengths, a thoughtful dialogue between policy-conscious practitioners and practically informed policymakers is advocated by the authors. This requires knowledge one to act flexibly.

Taubman and Ghafele insist that IP management for the public interest should go beyond licensing arrangements and consider the full range of two continuums: degrees of exclusivity and degrees of market engagement. To demonstrate, the efforts of Jordan and Indonesia to manage intellectual property for the public good are examined. Both countries have passed IP legislation and have developed their IP policies in relation to broader public policy goals. The authors conclude that success requires flexible use of market mechanisms and the strategic deployment of the full range of exclusive rights afforded by IP protection. This can lead to some creative solutions. **Public sector institutions should learn to use the rules at least as well as their private sector counterparts to achieve their public policy aims**. This has never been more urgent than with the coming into force of the TRIPS Agreement in most developing countries.

TRIPS mandates minimum IP protections for patented pharmaceutical products.[8] Within this requirement, countries have considerable freedom on many specific aspects of TRIPS, and it is wise (if not imperative) for developing countries to exercise these flexibilities to the maximum extent possible. Thus, TRIPS can have profound effects on innovation, on the scope and magnitude of R&D investments, and on product availability. Product price in low- and middle-income countries is vigorously debated. Predicting and measuring the impacts of TRIPS on innovation is an unwieldy task because of the numerous variables in play and also because TRIPS only came into force in 2005, in many of the innovative developing countries. This is a short time to measure specific impacts; a simple measure like the price of a product is but one of the factors that determine "access" to patented health and agricultural products. Another factor would be the types of drugs or vaccines that are becoming available. Indeed, based on a conference held in India, the conclusion was drawn by Eiss, Mahoney,

and Satyanarayana[9] that much of **the impact of TRIPS will depend on how countries and institutions respond to the new IP regime.**

There is every indication that IP management skills appear to be one of the crucial elements for harnessing the positive potential of TRIPS, and mitigating the negative ones, and such skills will allow developing countries to gain access to emerging tools, technologies, and resources that can dramatically improve the health and welfare of their citizens. Effective IP management can allow public research institutions to use their own research products to benefit the poor and to enter into public-private partnerships that can direct the power of industry to the needs of the poor. Without knowledge of sophisticated IP management techniques, however, such efforts—and their benefits—will be impossible.

The World Trade Organization (WTO) offers many initiatives and instruments that seek to enhance IP capacities in the developing world. Specific initiatives and instruments are also aimed at mitigating the possible negative effects of TRIPS. These are discussed by Watal and Kampf[10] and include compulsory licensing, the Doha Declaration, elements of the Convention on Biological Diversity, traditional knowledge projects, technology transfer programs, and IP capacity building programs.

Of particular relevance here is the **Doha Declaration**, which sought to address the potential constriction brought about by TRIPS regarding access to patented medicines in developing countries. The Doha Declaration emphasizes that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health, and it reaffirms the right of members to use, to the full extent, the provisions of the TRIPS Agreement that provide flexibility in terms of accessing medicines. The Declaration states that each member has the right to determine what constitutes a national emergency, or other circumstances of extreme urgency, and explains that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria, and other epidemics, can represent such circumstances.

By virtue of WTO member states having signed and ratified the agreement, TRIPS constitutes international law. It must be translated or adapted into national law individually by each member state. Though not directly related to TRIPS, the chapter by Bremer[11] provides an overview of key legal provisions in the United States that have profoundly affected the evolution of IP rights and technology transfer. The fundamental basis underlying the transfer of technology as intellectual property is embodied in the country's Constitution, which embraces patents, copyrights, and trademarks within its scope. The terms and provisions governing these forms of intellectual property are codified in various statutes, but two pieces of legislation are especially important.

The first is the Stevenson-Wydler Act enacted to promote the utilization of technology owned by the government and generated with its help. It aids the transfer of that technology to the private sector and government at the state and local levels. The second law is the Patent and Trademark Amendment Act of 1980—known as the Bayh-Dole Act. The Bayh-Dole Act established a uniform federal patent policy and provided the first statutory authority for the U.S. government to take title to and hold patents through its agencies. The success of this act makes it of special interest to countries seeking to establish IP regulatory systems, and this chapter explains the structure and history of Bayh-Dole.

Bremer also discusses **the important interplay between patents and antitrust laws**, recognized as complementary tools that enhance competition. The laws are based on the important premise that patents *per se* do not convey market power. Only when coupled with other assets, or when acquired in order to build a monopolistic behavior, *can patents create* market power. Antitrust scrutiny is triggered when patents (and certain other market positions) are combined with apparent predatory practices that restrain trade and competition. The point of this chapter then becomes very clear: **a country strengthening its patent laws should, concurrently, strengthen its antitrust laws as well as its capacities to enforce them**.

One such enforcement is the capacity of a government to bring about a **compulsory licensing** action. A compulsory license is an authorization given by a national authority to a natural or

legal person for the exploitation of the subject matter protected by a patent; the consent of the patent holder is not necessary. Compulsory licenses may be required to import or produce a given product or to use a patented technology for research. They are especially important when there are no close substitutes for a product or process and a research exception is not available or is too narrow. Compulsory licenses are granted in order to attain various public policy objectives, such as: to address emergencies and public health needs, to counteract anticompetitive business practices, or to permit the exploitation of patents that are not used.

Correa[12] discusses the usefulness of compulsory licensing and provides a **step-by-step guide to obtaining compulsory licenses** to ensure that the R&D of drugs needed by people in developing countries is kept free from unnecessary entanglements in the global IP system. His chapter provides many illustrations and a useful discussion of the patenting and licensing strategies of universities and other public sector research institutions. These institutions often hold patents on research tools, underscoring the importance of the public sector retaining research-use and humanitarian-use rights in all licenses.[13] While there are several ways to circumvent patented upstream technologies, and the compulsory license is especially powerful. But, perhaps due to its power, the strategy also has drawbacks. The flexibility of compulsory licensing should be considered in the context of all of the options available to TRIPS member countries. Importantly, applicants need to be certain that they have the capacity to exploit the licenses and the financial ability to remunerate the patent holder or holders. Nonprofit research institutions may often find this particularly difficult because, even with a compulsory license, commercial partners need to be willing to produce and distribute products developed under compulsory licenses. This is one reason for further investments in technological and IP capacity building and the establishment of strong institutional networks.

Institutional networks are most powerful when formed around geographic clusters. Innovation in health and modern agriculture relies on a sophisticated open system of knowledge sharing. Recent studies suggest that successful innovation indeed requires development of clusters of institutions, businesses, and personnel. "Location, location, location," the battle cry for property realtors everywhere, is heard increasingly with respect to innovation dynamics and knowledge-based growth.

A cluster is a group of similar things positioned or occurring closely together. Although companies and various not-for-profit entities in the same sector or product market have traditionally located themselves in close geographic proximity (rather than spreading out evenly across the geography or economy), the express search for ways to encourage clustering has only recently begun. One paradigm, as discussed extensively by Phillips and Ryan,[14] is that **local competition is the primary engine behind cluster development and sustainability.** Additionally, innovation now involves and generates significant externalities; innovators increasingly rely on an array of formal and informal collaborators, and the efficacy of those relationships will determine their ability to successfully launch an innovation into product development.

Offering an overview of recent research on clusters in Canada, this chapter observes that **one factor encouraging cluster formation is the development of a cost-effective, efficient IP management syst**em. Equally important is the use of ***social capital***, which can lead to less formal collaborations that can better disseminate and utilize discoveries. While the traditional strategy of protecting infant industries in order to develop them made some sense in the industrial world, its value in a knowledge-based world is unclear. Knowledge-based development is inherently different from traditional industrial development. Indeed, multiple types of knowledge are involved in such a system, and Phillips and Ryan address how clusters integrate four distinct types of knowledge: "know-why," "know-what," "know-how," and "know-who." A cluster's ability to use and share these types of knowledge is largely what empowers individual entities within the cluster to innovate. Basing their ideas on varied illustrations and deep analysis, the authors conclude that governments have an important role to play in the

process of cluster formation and that ensuring a mix of "local buzz" and "global reach" is part of the recipe for success.

A specific experience of cluster development and the role of government are presented by Viljamaa,[15] who discusses the case of Turku, Finland. The city is home to a large concentration of biotechnology activities. This model can be described as a science-led strategy, led from above, with a range of important lessons for policymakers and institutional leaders alike. The experiences suggest that sharing facilities with companies and combining forces with other universities and R&D institutes are vital ways of building clusters and momentum in innovation. Active partnerships with larger entities are important, as is a global network of scientists. Viljamaa offers many ideas that are particularly pertinent to developing countries that wish to encourage the formation of clusters. One is that **building clusters from scratch is basically impossible; success comes from building upon existing strengths**. Many successful clusters have been based on older but related industries.

Probably the most famous example of a cluster that is grounded on entrepreneurship is the biotechnology cluster of the greater Boston area, which encompasses Massachusetts Institute of Technology (M.I.T.), Harvard University, Boston University, and others. M.I.T., some argue, has led the translation of university-generated research from the laboratory to the private sector through the cultivation of an entrepreneurial culture. Indeed, the entrepreneurial activities of M.I.T. have served as an incubator for generation after generation of entrepreneurial engineers and scientists who view risk as an opportunity. **Seeing risk and opportunity as two sides of the same coin**, students at M.I.T. don't utter, "Why do you want to do that?" but instead proclaim "Hey! Why not?" This positive attitude, this sense of self-confidence, typifies M.I.T.'s culture, from professors to students to its licensing professionals.

Nelsen[16] points out that M.I.T.'s licensing office also has served as a focal point for the formation of the greater Boston area's biotechnology cluster. By coordinating the management of M.I.T.'s intellectual property, the office contributes to the robust development of many companies that form the cluster. This promotes further development, economic progress, investment in innovation, creation of networks, and ultimately, success. Although Boston is quite unlike most developing-country cities, the fundamental principles that drive its economic development are universal.

With respect to working with developing countries, M.I.T. recognizes that there are often special circumstances requiring creative practices (for example, preferential pricing for developing country public sectors, strategic patent filing, and differential licensing practices). Hence, with M.I.T. licensing, **there are no rigid written policies guiding how technologies are handled** (the exception to this is clear and nonnegotiable conflict of interest policies and practices); instead, the choices are left open in order to creatively craft agreements to maximize access. This flexible management fuels the innovation engine, and this approach can be adapted by many other regions.

But what are the potentials for individual countries to develop thriving cluster complexes without misspending scarce funds? What variables are essential for cluster development? In another chapter, Phillips and Ryan[17] identify six factors: manufacturing capacity, domestic market, export market, R&D, an IP system, and a functioning drug regulatory system. The authors explore these factors across three development stages to measure a country's cluster capacity. The authors go further and provide a **five-stage process for realistic cluster building**:

1. Assessing capacities, resources, and opportunities
2. Choosing an anchor strategy (different cluster approaches will have different sets of requirements, leaders, and tactics, and different success rates.)
3. Identifying organizational and institutional leaders to take the lead in developing the cluster.
4. Adopting proactive tactics, spanning numerous areas, including having the necessary legal and social structures, efficient mechanisms to protect and adjudicate property, the lowest possible barriers for

entering or exiting key input and output markets, the ability to trade domestically and internationally, and effective tax, regulatory, and trade rules.

5. Sustaining the lifecycle of the cluster (Recognizing that the evolutionary dynamics of markets are unavoidable, clusters should re-invent themselves every now and then to prevent cluster decay.)

Importantly, clusters thrive when local strengths are nurtured rather than when companies are lured with subsidies. Building infrastructure does not fill the buildings with innovative enterprises, but rather, innovative enterprises make buildings happen. Hence different types and sources of capital flow are needed at different stages of cluster development. Government money sometimes gets in the way of private money and vice versa.

The real and most effective catalysts for change are key individuals who serve as ambassadors or entrepreneurs for geographic regions; they cross-fertilize public-private partnerships which, in turn, alert the public sector to market demands and provide companies with access to basic research, infrastructure, and people capacity. This is why many institutions look for "people policies" to nurture clusters. Indeed, people are at the center also of these intellectual assets. **Knowledge-based development is inherently different from traditional industrial development.** Today's innovation potential requires, above all, global, institutional, and personal links and networks. They are the necessary fertile ground that enables innovation to flourish. ■

All chapters refer to: *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices*. 2007. A Krattiger, RT Mahoney, L Nelsen, JA Thomon, AB Bennett, K Satyanarayana, GD Graff, C Fernandez, and SP Kowalski (eds.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org. The online version contains for each chapter a detailed Editor's Summary, Implications, and Best Practices.

1 Chapter 3.1 by P Newman titled The Courts and Innovation, p 147.

2 Chapter 3.2 by RA Nugent and GT Keusch titled Global Health: Lessons from Bayh-Dole, p. 153.

3 Chapter 3.3 by GD Graff titled Echoes of Bayh-Dole? A Survey of IP and Technology Transfer Policies in Emerging and Developing Economies, p. 169.

4 The countries are Argentina, Brazil, Chile, China, Ethiopia, India, Indonesia, Jordan, Kenya, Malaysia, Mexico, Philippines, Poland, Russia, South Africa, Tanzania, Uganda, and Vietnam.

5 Chapter 3.4 by SK Finston titled Technology Transfer Snapshots from Middle-Income Countries: Creating Socio-Economic Benefits through Innovation, p. 197.

6 Chapter 3.5 by AD Heher titled Benchmarking of Technology Transfer Offices and What It Means for Developing Countries, p. 207.

7 Chapter 3.6 by A Taubman and R Ghafele titled Public Sector IP Management in the Life Sciences: Reconciling Practice and Policy-Perspectives from WIPO, p. 229.

8 TRIPS requirements are broader than this. They also include the application of basic principles of the trading system and other international IP agreements; adequate enforcement of IP rights in member countries of the World Trade Organization (WTO); IP dispute settlement between Members of the WTO; and special transitional arrangements for the introductory period of the new system.

9 Chapter 3.7 by R Eiss, RT Mahoney, and K Satyanarayana titled Developing Countries and TRIPS: What Next? p. 247.

10 Chapter 3.8 by J Watal and R Kampf titled The TRIPS Agreement and Intellectual Property in Health and Agriculture, p. 253.

11 Chapter 3.9 by H Bremer titled U.S. Laws Affecting the Transfer of Intellectual Property, p. 265.

12 Chapter 3.10 by CM Correa titled Compulsory Licensing: How to Gain Access to Patented Technology, p. 273.

13 See also Section 2 of the Handbook discussed on pages 11-20 of this *Executive Guide*.

14 Chapter 3.11 PWB Phillips and CD Ryan titled The Role of Clusters in Driving Innovation, p. 281.

15 Chapter 3.12 by K Viljamaa titled What Does It Take to Build a Local Biotechnology Cluster in a Small Country? The Case of Turku, Finland, p. 295.

16 Chapter 3.13 by L Nelsen titled The Activities and Roles of M.I.T. in Forming Clusters and Strengthening Entrepreneurship, p. 309.

17 Chapter 3.14 by PBW Phillips and CD Ryan titled Building Research Clusters: Exploring Public Policy Options for Supporting Regional Innovation, p. 317.

FOR GOVERNMENT POLICYMAKERS

- ✔ Countries have considerable freedom to control the effects of TRIPS. Indeed, **the impact of TRIPS will depend on how countries and institutions respond to the new IP regime**. At a minimum, countries should take full advantage of the flexibilities offered by TRIPS, in line with the Doha Declaration. For example, a country strengthening its patent laws should concurrently strengthen its antitrust laws as well as capacities to enforce them.

- ✔ Technology transfer efforts can be powerful when combined with government's efforts to **reorient the public sector's IP strategies** to enable the poor to benefit from public investments in innovation. To be effective, this should acknowledge the **inadequacies of a top-down approach** to developing IP management policies and approaches. Each institution has its unique strengths. To seize on these strengths, thoughtful dialogue between policy-conscious practitioners and practically informed policymakers should be encouraged.

- ✔ Public institutions' IP policies should address the institution's obligation, whenever possible, to retain humanitarian-use rights to its inventions, and the **government's right to a license for technology developed with public funds**, in case the public benefit is not being served adequately. Under extreme, well-defined circumstances, this may include full "march-in rights". The potential for such government action will encourage companies to make products widely available in the market.

- ✔ P**ublic-private collaborations within publicly funded R&D programs** can be powerful arrangements for optimizing public research investment.

- ✔ Public-private partnerships aimed at product development are effective arrangements through which industry can invest and apply its expertise to address the needs of the poor. In many contexts such **product-development partnerships (PDPs) are now driving the drug-development pipeline in neglected-disease R&D**. National institutions in developing countries should be encouraged to participate in PDPs.

- ✔ The ability of the local and national economy to absorb new technologies into existing industry or business sector can be strengthened through the encouragement of **cluster formation**. They require a long-standing and durable commitment to science education, research and related infrastructure, a strategically situated anchor institution with a proactive technology transfer office, and reliance on market forces as the engine for technology transfer.

- ✔ Overall, **public funds should be directed at product development partnerships** that create collaborations, as opposed to buildings with bricks and mortar. Such strategies have proven most effective in strengthening and sustaining clusters.

- ✔ Governments should support local entrepreneurship with much attention given to endogenous development, specifically to **local, small- to medium-size enterprises and to spinouts**. An effective short-term strategy may be to attract foreign companies to the area. They will bring jobs and often knowledge and expertise.

Given that IP management is heavily context specific, these Key Implications and Best Practices are intended as starting points to be adapted to specific needs and circumstances.

FOR SENIOR MANAGEMENT

(UNIVERSITY PRESIDENT, R&D MANAGER, ETC.)

- ✔ In an increasingly global world—in which the risk of disease and the effects of agricultural disasters span borders and the benefits of research can come from any corner—the society that **benefits from public sector health investment will be global**. The public-benefit aspect of government-sponsored research investments should include the poor in every society, including those of neighboring countries.

- ✔ There are many **strategies available to increase the resources and tools devoted to the public good** that do not run counter to economic development goals and private sector interests. At the upstream end, funds can be directed toward research in developing countries, and partnerships with private and nonprofit entities can be effective. At the downstream end, funds can directly provide products to users in developing countries, reduce barriers to the transfer of technology that benefits these countries, or partner with industry and academia to expedite the development of products from research.

- ✔ The main issue for universities is to ensure a high level of education, comprehensive partnerships with other universities, and **collaboration with the private sector**. This requires clear IP policies, transparent IP management practices, and sound management of conflicts of interest.

- ✔ **Public-Private Partnerships and Product-Development Partnerships** (PDPs) are novel, tightly focused organizations, dedicated to providing products to benefit the poor in developing countries. PDPs require that scientists put a priority on delivering global benefits and that universities fully embrace their larger role in society and the global community.

- ✔ A major policy objective is to **find a balance between public benefit and economic returns**. A university can include a public-benefit clause in its licenses to the private sector, invest part of its royalty stream in a foundation, establish an "ethical" investment fund, license technologies to nonprofits or others who would develop and manufacture products for developing countries, and bundle technologies to encourage development of medicines aimed at diseases of the poor.

- ✔ The ability of the local and national economy to absorb new technologies into existing industry or an entrepreneurial sector can be strengthened through the encouragement of cluster formation. But **robust innovation clusters** are not created from scratch. They require a long, durable commitment to science education, research, and related infrastructure; a strategically situated anchor institution with a proactive technology transfer office; and reliance on market forces as the engine for technology transfer.

Given that IP management is heavily context specific, these Key Implications and Best Practices are intended as starting points to be adapted to specific needs and circumstances.

FOR SCIENTISTS

- ✔ Global changes in IP regimes, especially changes that affect developing countries, have been tremendous. Within the evolving IP regime, your country has considerable freedom to control the effects of these changes. Indeed, much of **the impact of these changes will depend on how countries and institutions respond to the new IP regime**.

- ✔ An important response is the **creation of an effective technology transfer program**. Your role in this process is essential.

- ✔ As a scientist, you understand the **interrelatedness of science, R&D, technological advance, and commercial investment**. Share these insights with your institution's technology transfer office, as well as with its senior managers.

- ✔ Countries engaged in reforming their R&D and technology transfer efforts are today often including royalty-sharing provisions for scientists in publicly funded research institutions. This approach also comes with obligations to assign ownership rights to your institution and a duty to disclose inventions. All of these changes should be seen as **incentives to turn inventions into innovations that benefit society**.

- ✔ As your institution implements IP policies and patenting strategies, **your right to publish** is not jeopardized. IP protection and licensing are but one form of knowledge transfer that, if well undertaken, can very much be in the public interest.

- ✔ While access to foreign technology is integral to development, it is increasingly important to **focus directly on capturing the national (or indigenous) innovation potential** of developing countries. Through the activities of your research program, you may be positioned to facilitate such capture and development of the benefits arising from indigenous innovation and traditional knowledge. These efforts should be coupled with benefit-sharing provisions.

- ✔ Understand the obligations that are attached to different funding sources when funds are used within the same program. The **impact of joint public and private financial support** can be complex but will increase, particularly as your institution positions itself strongly within an innovation cluster and engages in product development.

- ✔ As a scientist, you play an **increasingly important role in knowledge-based innovation clusters**. Do not shy away from becoming an entrepreneur yourself.

- ✔ Collaboration is often based on establishing personal contacts, for example, **building close connections and networks** to other scientists and research groups in the same field via conferences and reciprocal visiting arrangements; these all foster the formation of collaborative research projects and are fundamental for effective sharing of know-how and show-how.

FOR TECHNOLOGY TRANSFER OFFICERS

- ✔ Traditionally, the mission of a technology transfer program was to bring university-generated intellectual property into use as rapidly as possible. But **public sector technology transfer has evolved to serve broader purposes**: to enhance the reputation of the institution. Successful technology transfer can help it achieve its missions of education, research, and community outreach; to ensure social impact; and to provide funds for further research.

- ✔ The laws relating to new technologies are evolving. Recent **court decisions may have an impact** on business and technological matters relevant to the operations of your technology transfer office (TTO).

- ✔ A TTO has much **responsibility in creating incentives to move discoveries into the product development arena**, motivating public sector researchers, not by the promise of revenue streams (which rarely appear), but by the satisfaction of seeing their work developed and applied to serve the public good.

- ✔ An understanding of not only the law, but also the public policy that underlies it. For example, with the Bayh-Dole Act in the United States, the **policy rationale is not directed toward revenue generation**, but rather toward moving publicly funded R&D into the marketplace to serve the public good.

- ✔ Financial **benefits from technology transfer can take many years to realize**—if they ever do materialize—so it is important to be realistic when making forecasts about expected income. International benchmark data indicate that a positive return can take eight to ten years to achieve. It is prudent not to justify the cost of technology transfer functions on the basis of financial returns.

- ✔ **The difficulties of managing and promoting technology transfer within a smaller research institution need to be recognized**, and the office should actively seek partnerships with other entities, such as local venture capital firms, incubators, and business development agencies. Alliances with other institutions, or a central TTO for several institutions, may also constitute viable alternative strategies.

- ✔ In a dynamic **innovation cluster**, authoritative IP management capacity, technology transfer, and licensing are all essential. Flexibility in licensing and partnership arrangements, and speedy action and decision making are equally important.

- ✔ TTOs are often ideally placed to **define and nurture an entrepreneurial culture** in the faculty. There can be large gains from such efforts.

- ✔ TTOs can, if appropriately structured, become a source of **creative networking and collaboration**, generating both academic and commercial success. Hence, this role in driving the success of clusters will be absolutely essential.

Given that IP management is heavily context specific, these Key Implications and Best Practices are intended as starting points to be adapted to specific needs and circumstances.