The Role of IP Management in Health and Agricultural Innovation

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ABSTRACT

Recent national and international changes in intellectual property (IP) legislative frameworks are likely to have profound effects on the ways in which health and agricultural innovations reach the poor and on how public and private research and development institutions pursue their work. Whereas IP rights are sometimes viewed as creating barriers to access to innovations in health and agriculture, we argue that it is not intellectual property, *per se*, that raises barriers, but rather how intellectual property is used and managed, particularly by public sector institutions. Above all, we argue that intellectual property is only one of six components of innovation. It is rarely the most important component.

The chapter reviews recent dramatic developments in institutional aspects of intellectual property, as well as global policy shifts and international studies that, among other outcomes, affected the environment for the creation of MIHR and PIPRA. In the field of health, changes have been particularly pronounced with the founding of a new form of institution for innovation: product-development partnerships (PDPs). As a result, we make the case for a fundamental shift in the way in which IP management in health and agricultural innovation is viewed and conducted. In addition, we argue that IP management should be seen as an important element in developing countries' strategies to become more innovative in addressing diseases of poverty, the alleviation of poverty, and malnutrition. The public sector can employ new ways to achieve its goals within the evolving IP framework. These new ways can help it better mobilize the resources to take a product through the process of innovation. These new ways should include, a) creative licensing practices that ensure global access and affordability, b) improved institutional IP management capabilities, c) the formulation of comprehensive national IP policies, and d) the strengthening of IP court systems and patent offices.

These are what best practices in IP management are all about, and what this *Handbook* seeks to help bring about and promote.

1. INTRODUCTION

Changes in both national and international legislative frameworks have profoundly affected how innovation reaches the poor and how public and private research and development institutions pursue their work. In this regard, the experience of the United States with the Bayh-Dole Act of 1980, which harmonized the numerous IP ownership policies of U.S. government agencies, is quite instructive.[1] The act significantly changed how academic institutions manage intellectual property. Universities had to adapt to an increasingly knowledge-based economy, a trend that is continuing and even intensifying. And because of the increasing interaction between developed and developing economies and the increased number and complexity of relationships between the public and private sectors, the need for understanding these partnerships and how they can best operate is becoming compelling. Some of the major changes in this environment of the last decade in health, agriculture, and intellectual property itself are shown in Box 1.

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In addition, the last several years have been marked both by big changes in institutional IP infrastructures and by dramatic developments in the world of non-governmental organizations (NGOs), public sector research institutions, and public–private partnerships (see Box 2 for a discussion on agricultural biotechnology-related aspects). These developments promise to reshape the global IP environment, especially for developing countries. Some of the more significant of these events include:[2]

- 2003: The founding of the African Agricultural Technology Foundation (AATF)
- 2003: The founding of the Centre for the Management of Intellectual Property in Health Research and Development (MIHR)
- 2003: The creation, within AUTM, of the Technology Managers for Global Health (TMGH) group
- 2004: The founding of the Public Intellectual Property Resource for Agriculture (PIPRA)

In the field of health, the changes have been no less dramatic. A number of product-development partnerships (PDPs), concerned with most of the high priority diseases in developing countries, emerged during the 1990s and 2000s. PDPs must deal daily with IP management issues, and the lessons they are learning about the role of intellectual property are of great interest. MIHR has convened two meetings to analyze IP management in PDPs, both of which took place at the Aeras Global TB Vaccine Foundation, the first in December 2004 and the second in July 2006.[3] In fact, MIHR's founding and development in

Box 1: Major Recent Events in the Global IP system

Concerning IP in General

- 2002: Report of the Commission on Intellectual Property Rights of the United Kingdom[4]
- 2005: Entry of many low- and middle-income countries into TRIPS on January 1

Primarily Health-Related

- 2001: Meeting of the 4th Ministerial Conference of the World Trade Organization (WTO), which adopted the Doha Declaration concerning the TRIPS Agreement and Public Health[5]
- 2005: Approval of the amendment to the TRIPS Agreement providing for the supply of drugs manufactured under compulsory licenses for developing countries without manufacturing capability
- 2006: Report of the WHO Commission on Intellectual Property Rights, Innovation and Public Health[6]

Primarily Agriculture-Related

- 2001: Creation of the World Intellectual Property Organization (WIPO) Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore[7]
- 2001: Creation of the International Treaty on Plant Genetic Resources for Food and Agriculture, under the Food and Agriculture Organization of the United Nations (FAO)
- 2002: Establishment of the Global Crop Diversity Trust, by FAO and the World Bank
- 2002: Adoption of the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising out of Their Utilization, under the Convention on Biological Diversity

Box 2: Putting Public-Sector Agricultural Intellectual Property to Work

During the 1990s, the field of agricultural biotechnology was consolidated. A few large companies owned important elements of the enabling technology platforms. That ownership, coupled with strong R&D capability, existing marketing and distribution networks, and substantial cash flows from agro-chemicals and seeds, gave the companies incentives to invest heavily in the development of agricultural biotechnology products. With these increased R&D investments, the companies became the dominant providers of new crop genetics and genetically modified crops.[8] During the same period, biosafety regulatory requirements led to greatly increased R&D costs that slowed public sector developments of agri-biotechnology crops, especially public sector crop breeding programs.[9] Research on minor crops and on traits of low economic value in developing country agriculture also decreased, even though these crops and traits have high social, humanitarian, and environmental value.[10]

A significant turning point in the relationship between the public sector and intellectual property in agriculture occurred when a freedom-to-operate (FTO) review, commissioned by the Rockefeller Foundation, led by one of us (AK), of pro-Vitamin A-containing Golden Rice showed that around 70 patents and patent applications were applicable to the improved rice.[11] Fortunately, all of these constraints were resolved in a few months by a straightforward IP management strategy (grant back of rights to a single entity that could use the rights for the benefit of developing countries). The rapid resolution of these obstacles demonstrated, first of all, how effective IP management, coupled with strong collaborations between the public and private sectors, can help achieve humanitarian goals. The IP constraints did not delay the development of the product, and their resolution did not cost much, especially when compared to the overall R&D costs. The FTO review, moreover, served as a wake-up call to the public sector to pay more attention to IP management as a powerful tool.

Concern about potential constraints on public sector research and innovation in agriculture spurred the public sector's interest in intellectual property. One important response was work that led to the formation of the Public Intellectual Property Resource for Agriculture (PIPRA).[12] Supported by the Rockefeller and McKnight foundations, among others, PIPRA is a public sector initiative that recognizes that continuing and enhancing relationships with the private sector are critical components of successfully utilizing intellectual property to meet public sector goals.

As part of its initial work, PIPRA began a study of the structure of IP ownership in agricultural biotechnology. In the words of the study's authors, Richard C. Atkinson and colleagues:

This study found that roughly one-fourth of the patented inventions were made by public-sector researchers, which is substantially larger than the IP portfolio held by any single agricultural biotechnology company. It is, however, highly fragmented across institutions and across technology categories. And much of this IP has been licensed, often under terms that are confidential but which have likely resulted in greatly restricted access to the underlying technologies. This study suggested that, apart from a few important exceptions, public-sector scientists have invented many of the types of technologies that are necessary to conduct basic biological research and develop new transgenic plant varieties. For instance, they have developed technologies to transfer genes into plant cells; have characterized specific DNA elements that drive unique patterns of gene expression; and have identified many genes that confer important plant traits. Such discoveries underscore the fact that public-sector research institutions have been significant sources of technological innovation ... .[13]

We believe that these innovations can be put to work more directly to help the poor with more focused public sector IP management.

many ways reflect, and perhaps have helped to influence, the changing environment of IP management. We summarize here the story of MIHR's founding to help understand the major changes that have occurred and are underway.

We believe that the events of the last decade have led the international development community in health and agriculture to fundamentally reconceptualize the role of intellectual property in health and agricultural innovation, especially in relation to the needs of the poor. In the 1980s and 1990s, many individuals argued that intellectual property and patents were bad for people's health and innovative biotechnology products bad for their food. According to this argument, intellectual property was controlled by large pharmaceutical and agricultural companies that used the power of IP rights to capture markets, limit consumer choice in both health and agriculture, and, above all, raise prices. This not only priced the poor out of the market, but also discouraged further innovation of products needed by the poor.[14]

The claims of these arguments hold, however, only when the public sector responds passively to the global IP system. Like everyone else, the public sector needs to adapt to the changes in this system so that it can seize new opportunities and take advantage of previously unavailable options. Indeed, by neglecting to utilize the IP system effectively, the public sector not only neglects its own interests but the interests of those it serves. Without effective IP management, the public sector risks squandering the new powers that the revised IP system provides. Intellectual property is a tool, and the impact of a tool depends on *who* uses it, *how* it is used, and for *what* purpose.

This perspective has led to new efforts, including the founding of MIHR (see below) and of PIPRA (see Box 3), to make IP management a powerful tool for the benefit of the public sector.

2. THE ROAD LEADING TO MIHR

Toward the end of the 1990s, staff of the Health Equity program at the Rockefeller Foundation became concerned about the possible impact of patents and other intellectual property on the development and availability of new health technologies that addressed diseases affecting people in developing countries. In the 1990s, the staff had observed a significant amount of agricultural intellectual property captured by multinational companies, a situation that made it difficult to conduct certain kinds of agricultural research for the benefit of poor countries. The Rockefeller Foundation staff sought to ensure that a similar situation did not occur vis-à-vis health technology development. The Foundation therefore commissioned a group of individuals, led by one of us (RTM), to assess in detail the needs and opportunities in intellectual property and health. The results of this assessment eventually led to the founding of MIHR.

The study was launched in April 2001. At the time there was a lot of confusion about the role and impact of patents and other intellectual property. It was feared that crucial intellectual property would be controlled by private entities, and that this control would make it impossible to conduct product research and development. With respect to existing products, there was concern that patents provided virtual monopolies for companies—monopolies that the companies would use to extract high rents on the marketplace, making it difficult, if not impossible, for the poor to access the technologies that could benefit them.

The Rockefeller Foundation study immediately faced a practical difficulty: little research had been done on needs and opportunities in intellectual property and health. Only a small body of published literature addressed issues of interest to the foundation. Moreover, few scholars were studying these issues. The study team therefore decided to carry out its work by interviewing a wide array of individuals in the public and private sectors and in developed and developing countries. Nearly 200 individuals were interviewed, sometimes in groups but most often one-on-one. The following highlights some of the study's significant findings.

The study began by contextualizing the problem. In market economies, the private sector is driven by the desire to maximize returns on investment. Modern economic theory holds that

maximizing such returns spurs economic growth. Because selling highly profitable health products to the well-to-do leads to the highest maximization of return on investment, the private sector accords priority to products for these individuals. Conversely, the private sector does not and cannot be expected to accord priority to the needs of the very poor.

The public sector, on the other hand, is driven, in democracies, by its search to maximize human well-being. Modern social theory holds that all humans, regardless of citizenship, economic status, or other demographic variables, should be given the chance to maximize their well-being. Because the poor suffer the lowest quality of health, and because they often cannot afford to buy needed pharmaceuticals, the public sector has the responsibility of according priority to these individuals.

Within this political and economic framework, which is certain to be with us for the foreseeable future, intellectual property has grown increasingly important. Capitalist companies energetically seek and avidly protect intellectual property to obtain adequate returns on investment. Indeed, it is widely accepted that intellectual property is essential for the private sector. But what about the public sector? Does or can intellectual property help achieve important public sector goals?

3. THE SOCIAL AND ECONOMIC IMPERATIVES OF PRODUCT DEVELOPMENT AND ACCESS

On the most pragmatic level, intellectual property is important to the public sector because it is important to the private sector. If public sector

Box 3: The Public Intellectual Property Resource for Agriculture (PIPRA)

PIPRA is an international initiative undertaken by universities, foundations, and nonprofit research institutions to make agricultural technologies more easily available for the development and distribution of subsistence crops in the developing world and specialty crops in the developed world.

With the introduction of biotechnology in agriculture, researchers have a unique opportunity to contribute to the development of improved staple and specialty crop varieties. However, developing new crop varieties with biotechnology depends on access to multiple technologies, which are often patented or otherwise protected by IP rights. Ownership of these rights is fragmented across many institutions in the public and private sector, a situation that makes it difficult to identify who holds what rights to what technologies, and in which countries. Such information is necessary, however, to establish whether or not a new crop variety is at risk of infringing those rights. The current situation thus creates barriers to commercializing new staple and specialty crop varieties. PIPRA members believe that if public-sector institutions collaborated in gathering information about and in the use of agricultural IP rights, it would be easier for them to speed up the creation and commercialization of improved staple and specialty crops and thereby fulfill part of their public missions. Specifically, PIPRA focuses on the following principal activities:

- Reviewing public sector licensing practices
- Implementing a collective public IP asset database
- Developing shared technology packages
- Providing information, engaging other organizations, and stimulating discussions
- Engaging private sector organizations

Source: Adapted from PIPRA.[15]

organizations, such as PDPs, want to collaborate with the private sector to develop new, valuable health technologies, they must address IP issues. Many, if not all, of the PDPs have recognized this. In fact, their experiences have led many of them to reassess the role that intellectual property plays in making health and agricultural products available to the poor. Before PDPs, critics contended that intellectual property allowed private pharmaceutical companies to dominate markets, perpetuating high prices and excluding the poor. The experience of PDPs, however, shows not only that intellectual property can be utilized to serve the needs of the poor, but also that its misuse or waste slows the development of new technologies for developing countries.

But how can the public sector best use the IP system? Should it seek to minimize the problems that emerge from patents and other forms of intellectual property? Or should it take a more active role and seek to take advantage of some of the powers provided by intellectual property? To answer these questions, one must be able to see what capabilities and what benefits might accrue from the exercise of these powers.

The study ultimately concluded that there is a very important reason for public sector support of intellectual property: it is an essential tool for achieving safe and effective health technologies. Why? The answer is found in a combination of government actions and economic imperatives. During the latter half of the 20th century, developed countries created whole new systems of drug regulation. Of these, the Center for Biologics Evaluation and Research of the Food and Drug Administration (FDA) in the United States is one of the more influential. One of the motivations for its founding was the death of several children from polio vaccinations; the vaccine turned out to contain live poliovirus.[16] Rules and regulations, therefore, were established to produce and distribute vaccines and drugs that are safe and effective. Over the years, these rules and regulations have become steadily more rigorous, making it increasingly expensive to develop new, safe, and effective pharmaceuticals. As the costs of developing drugs rose, the pharmaceutical industry had to raise greater amounts of capital in order to pay for them. The investors who put up such huge sums naturally sought high returns on their risky investments, and such high returns could not be achieved without IP protection. In fact, the existence of intellectual property allowed the private sector to mobilize the funds necessary to develop safe and effective pharmaceuticals. The public sector could not (or at least did not) provide these funds, nor was it capable of developing the new products that were needed.

The study therefore concluded that the IP regime plays an essential role in achieving an important public sector goal: the development of safe and effective pharmaceuticals. Accordingly, its next question was whether or not intellectual property had some additional practical benefits for the public sector. The study consequently identified a number of licensing practices that public sector organizations have used for the public's benefit. If the public sector owned valuable intellectual property, it could license that intellectual property to private sector companies with conditions that benefited the public sector. For example, the licensing terms could require favorable pricing to the public sector. Moreover, by licensing to more than one company, the public sector could foster competition that could lead to lower prices for consumers. And finally, the public sector could require that the product be made available to both the lucrative private sector market and to the public sector.

In addition, the emergence of Innovative Developing Countries (IDCs),[17] such as Brazil, China, and India, is changing the face of global health and agricultural innovation. These countries and others like them will certainly contribute significantly to biomedical R&D in the near future. A major unresolved question, however, is whether their innovations will benefit the poor within their own borders and in other less well-off countries. It is important to identify innovation strategies and IP management policies and practices that will help ensure that the investments of IDCs in R&D benefit the poor.

The study also concluded that the public sector, especially in developing countries, had very little capability—in terms of staff, policies, and

practices—to extract the benefits that could be obtained were they to implement enlightened licensing practices. The study therefore proposed programs to document best licensing practices and capacity-building initiatives. These are two of MIHR's major programs, and this *Handbook* addresses both of these goals: it seeks to document best practices and to be a teaching and capacity-building resource.

As noted above, one of the concerns the study addressed was the extent to which the existence of patents and other intellectual property might inhibit or prevent the development of products needed by the poor in developing countries. The study, like that of Golden Rice (see Box 2 above), concluded that intellectual property rarely, if ever, blocks product development. This conclusion was supported by interviews with individuals in both the public and private sectors. They noted that there were several ways that companies or product developers could address "blocking patents." First, one could seek a license from the patent owner. If this attempt was unsuccessful, other courses of action could be taken. For example, if an expert opinion determined that the blocking patents might not withstand legal challenge, then one could proceed without a license. In addition, Europe has a general research exemption that allows one to undertake research using a patented technology without having to obtain a license for that technology. In the United States, however, "safe harbor" provisions[18] greatly facilitated the development of a vigorous generic drug industry through a research exemption of the patent laws allowing them to make and use (but not to sell) a drug during its period of patent protection. This exclusion was critical to developing data necessary for regulatory approval once the patents had expired. A third option is to "invent around" intellectual property: in other words, to create a similar technology that does not infringe on any existing patents. For vaccines, this is a common practice because it is often difficult to secure one or more dominating patents (that is, patents that would make it nearly impossible to invent around). Yet another strategy is to develop and market the products in countries where patents have not yet been filed.[19] This was the strategy used by several Korean manufacturers that jointly developed a hepatitis B vaccine.[20]

The study's analysis concluded that intellectual property is almost never the most important factor affecting the development and availability of pharmaceuticals and vaccines. Instead, the most important factor seems to be the existence or absence of a market for those pharmaceuticals. Hepatitis B again presents a cogent case study. From a price of greater than $18 a dose, hepatitis B vaccine cost fell to less than $0.30 a dose once the public sector "made a market," i.e. started buying tens of millions of doses per year.[21] This finding about the relative lack of importance of IP led Rockefeller Foundation staff to study all of the major issues affecting the development and availability of pharmaceuticals. Briefly, the analysis revealed that the other factors were: support for research and development, the existence of domestic markets (including national health systems), the existence of international trade in the products (including procurement by international public-sector procurement agencies), the operation of capable regulatory systems, and the ability to manufacture products to high standards. Intellectual property was only one of six factors—and rarely the most important. These six factors are referred to as the "components of innovation."

We believe that placing intellectual property in a broader product-development context is necessary to improve the development and availability of health technologies for the poor. Conversely, any strategy that focuses only on IP issues is bound to fail and may be counterproductive. Thus, efforts to promote compulsory licensing to get low prices for pharmaceuticals in developing countries must overcome not only IP difficulties but also the obstacles presented by other components of innovation: the existence of capable manufacturing facilities that meet international standards, the availability of funds to procure the products for both domestic and international distribution, and the cost of obtaining regulatory approval for products manufactured under compulsory licenses. These are all significant, costly hurdles; any one of them could prevent a compulsory license from being useful

or cost effective, i.e. the cost of production under a compulsory license may be greater than the cost that could have been obtained through direct procurement of bulk quantities either individually by nations or through mechanisms such as the GAVI Alliance. (The Global Fund to Fight AIDS, TB and Malaria is [as of mid-2007] reconsidering it procurement policies. Rather than allowing each country to do its own procurement, the Fund is considering doing bulk procurement to ensure getting the best prices.)

4. INNOVATION AND IP MANAGEMENT IN A POST-TRIPS WORLD

Shortly after the MIHR study began, the Doha Declaration was approved. It called for according higher priority to public health than to trade concerns, and it emphasized that countries were free to use the "flexibilities" of TRIPS to protect public health. A few years after MIHR was established, the Doha Declaration was approved as an amendment to the TRIPS agreement. In the interval between the Doha meeting and the approval of the amendment, there were vigorous debates about the potential impact of TRIPS on access to medicines in developing countries. Some felt that TRIPS would be disastrous for developing countries. There were fears that it would suppress R&D, cause generics to disappear, and rapidly raise drug prices. Others felt that TRIPS would create a surge of support in developing countries for R&D, encourage joint ventures between pharmaceutical companies in developed and developing countries, and have little if any impact on the availability and prices of generics.

In January 2005, India and many other developing countries came under the rules of TRIPS. In December 2005, MIHR and the Indian Council of Medical Research convened an international symposium to examine the impact of TRIPS. The full report of the symposium has since been published.[22] In short, the meeting's conclusions tend to support the positive predictions mentioned above. Of perhaps greater importance, however, the meeting emphasized the need for developing countries to increase their capacities to manage intellectual property in ways that meet their own needs. The meeting also concluded that innovation is such a complex process—of which intellectual property is only one component—that it would be very difficult to document the impact of TRIPS on innovation; conversely, any impacts will be the result of a combination of factors, and will never be due to intellectual property alone.

Toward the end of the MIHR study that began in 2001, but before the establishment of MIHR, the UK Commission on Intellectual Property Rights (CIPR) issued its report,[23] which was read with great interest by the MIHR study team. A core conclusion of the CIPR report was that a one-size-fits-all approach to intellectual property was undesirable. Each country should have some freedom to adopt and implement laws and regulations that fit its own needs. Most recently, the WHO Commission on Intellectual Property Rights, Innovation, and Public Health (CIPIH) report has emerged. It takes an even broader view of intellectual property and innovation than the CIPR report. Both reports come to the following conclusions:

- Innovation takes place in a complex environment in which intellectual property is only one factor, and rarely is the most important.
- Developing countries need to determine what kinds of rules and regulations best address their particular needs.
- IP management capabilities in developing countries need to be rapidly improved in order to ensure that intellectual property is used to improve health.

An analysis of IP management and innovation by Morel and colleagues[24] found that donors have already marshaled significant resources and created organizational structures that accelerate the development of new health products and that procure and distribute drugs and vaccines for the poor. Their analysis concluded with a proposal for complementary strategies to improve health equity: national governments should support product-development efforts, and the public and private sectors need a coherent strategy to address each of the six interrelated components of innovation, also called determinants.[25]

5. CONCLUSIONS

The Rockefeller Foundation launched in-depth evaluations of the role of intellectual property in innovation of health and agricultural technologies that benefit the poor, especially those in developing countries. Its efforts and those of the many individuals and organizations that have worked in this space to date have helped to reconceptualize the relationship between the global intellectual property system and developing countries. This reconceptualization has the following elements:

- The dominant political/social framework of capitalism, markets, and democracy accords high priority to the protection of intellectual property. This framework is going to be with us for the foreseeable future, and so the public sector needs to find ways to achieve its goals within this framework.
- Intellectual property is important to the private sector because it helps investors achieve high returns on their investments.
- Intellectual property is also of importance to the public sector because:
  - It mobilizes the resources that are needed to take a product through the process of research and development (especially those steps that are designed to ensure the product's safety and efficacy).
  - It can help the poor. Creative licensing practices, for example, can help ensure global access and affordability.
- IP management capabilities need to be improved, particularly in developing countries, so that intellectual property can be managed for the benefit of the poor.
- Intellectual property is only one of six components of innovation and is rarely the most important. Efforts to meet the needs of the poor must also:
  - Support R&D
  - Develop national health programs and agricultural extension systems that are sustaining domestic markets, including distribution systems in both the public and private sectors
  - Be conducive to facilitating trade in health and agricultural technologies and products (both input and output)
  - Encourage high-quality manufacturing of drugs and vaccines and investments in high-quality seed production and that of other agricultural inputs
  - Adopt policies and develop safe and effective regulatory systems (for drug and vaccine registration; biosafety and food safety for applications of biotechnology in food, feed, and fiber; and seed quality certifications)
- Each country needs to take advantage of the freedoms granted by TRIPS and formulate and implement policies and practices that best meet its own needs. Short-cut solutions to technology needs in medicine and health, such as compulsory licenses, are unlikely to be as effective or sustainable as are collaborative efforts between the public and private sectors. Countries would benefit substantially from developing their internal IP management capabilities, strengthening their IP court systems and patent offices, and according priority to meeting the needs of the poor.

When it comes to increasing developing countries' access to fundamental innovations in health and agriculture, success requires knowledge, capacity, and active engagement. These are what best practices in IP management are all about and what this *Handbook* seeks to help create and promote. ■

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1 The Patent and Trademark Amendment Act of 1980 (35 U.S.C. §§ 200–211). See, also in this *Handbook*, chapters 3.2 By RA Nugent and GT Keusch and 3.4 by SK Finston.

2 While these developments trace their origins to many

sources, it is important to note that the Rockefeller Foundation played a lead role in each.

3 See, also in this *Handbook,* chapter 2.3 by R Eiss, KE Hanna and RT Mahoney.

4 Commission on Intellectual Property Rights. 2002. Integrating Intellectual Property Rights and Development Policy. Final Report of the Commission on Intellectual Property Rights. DFID: London. www.iprcommission.org.

5 WT/MIN(01)/DEC/W/2, 14 November 2001. www.wto.org (full text in Annex I).

6 www.who.int/intellectualproperty/report/en/index.html.

7 www.wipo.int/tk/en/.

8 Graff GD, GC Rausser and AA Small. 2003. Agricultural Biotechnology's Complementary Intellectual Assets. *Review of Economics & Statistics* 85(2):349–363.

9 Wright BD. 1998. Public Germplasm Development at a Crossroads: Biotechnology and Intellectual Property. *California Agriculture* 52(6):8–13; Kowalski S. 2007. Rational Risk/Benefit Analysis of Genetically Modified Crops. *Journal of Intellectual Property Rights* 12:92–103.

10 Krattiger AF. 2000. Food Biotechnology: Promising Havoc or Hope for the Poor? *Proteus* (Special Millennium Issue on Food) 17: 3–8; von Braun J, M Qaim and AF Krattiger (eds.) 2000. *Agricultural Biotechnology in Developing Countries: Towards Optimizing the Benefits for the Poor*. Kluwer Academic Publishers. The Hague. p. 433; Wambugu FM. 1999. Why Africa Needs Agricultural Biotech. *Nature* 400(6739):15–16.

11 Kryder D, SP Kowalski and AF Krattiger. 2000. The Intellectual and Technical Property Components of pro-Vitamin A Rice (*Golden*Rice™): A Preliminary Freedom-to-Operate Review. *ISAAA Briefs* No 20. ISAAA: Ithaca, NY. www.isaaa.org/kc/bin/isaaa_briefs/index.htm. Vitamin A deficiency (VAD) is one such problem. In many areas of the world where rice is a basic staple food, thousands of impoverished people lose their eyesight because of VAD. In fact, severe VAD (xerophthalmia, also called night blindness) leads to permanent blindness: 500,000 people, 250,000 of them children, go blind every year. VAD also leads to a depressed immune system that increases the incidence and severity of infectious diseases and infant mortality rates. See also www.goldenrice.org/Content2-How/how9_IP.html.

12 Graff G, A Bennett, B Wright and D Zilberman. 2001. Intellectual Property Clearinghouse Mechanisms for Agriculture: Summary of an Industry, Academia, and International Development Round Table. *IP Strategy Today* No. 3-2001. pp 15–38. www.bioDevelopments.org/ip.

13 Atkinson RC, RN Beachy, G Conway, FA Cordova, MA Fox, KA Holbrook, DF Klessig, RL McCormick, PM McPherson, HR Rawlings III, R Rapson, LN Vanderhoef, JD Wiley, and CE Young. 2003. Public Sector Collaboration for Agricultural IP Management. *Science* 301(5630):174–175.

14 't Hoen E. 2002. TRIPS, Pharmaceuticals, Developing Countries, and the Doha "Solution." *Chicago Journal of International Law* 3(1): 27–48.

15 www.pipra.org/.

16 The Center was first established within the National Institutes of Health but was later moved to the FDA.

17 Morel CM, T Acharya, D Broun, A Dangi, C Elias, NK Ganguly, CA Gardner, RK Gupta, J Haycock, AD Heher, PT Hotez, HE Kettler, GT Keusch, AF Krattiger, FT Kreutz, S Lall, K Lee, R Mahoney, A Martinez-Palomo, RA Mashelkar, SA Matlin, M Mzimba, J Oehler, FG Ridley, P Senanayake, P Singera and M Yun. Health Innovation Networks to Help Developing Countries Address Neglected Diseases. *Science* 309: 401–4.

18 Hatch-Waxman Act (Drug Price Competition and Patent Term Restoration Act of 1984).

19 For a comprehensive discussion on FTO strategies, particularly for the public sector, see, also in this *Handbook,* chapter 14.1 by A Krattiger.

20 See, also in this *Handbook*, chapter 1.2 by RT Mahoney.

21 Advances in molecular pharming, the so-called third generation biotechnology plant products, are bringing agricultural biotechnology and health innovations closely together. For a recent review, see Arntzen C, B Dodet, R Hammond, A Karasev, M Russell and S Plotkin. 2004. Plant-derived Vaccines and Antibodies: Potential and Limitations. *Vaccine* 23:1753–1885. See, also in this *Handbook*, chapter 17.23 by A Krattiger and RT Mahoney.

22 See, also in this *Handbook*, chapter 3.7 by R Eiss, RT Mahoney and K Satyanarayana.

23 See *supra* note 2.

24 Morel C, D Broun, A Dangi, C Elias, C Gardner, RK Gupta, J Haycock, T Heher, P Hotez, H Kettler, G Keusch, A Krattiger, F Kreutz, K Lee, R Mahoney, RA Mashelkar, Hong-ki Min, S Matlin, M Mzimba, J Oehler, R Ridley, P Senanayake, H Thorsteinsdóttir, PA Singer and Mikyung Yun. 2005. Health Innovation in Developing Countries to Address Diseases of the Poor. *Innovation Strategy Today* 1(1):1–15. www.biodevelopments.org/innovation/index.htm.

25 Mahoney R. 2004. Policy Analysis: An Essential Research Tool for the Introduction of Vaccines in Developing Countries. *Journal of Health, Population and Nutrition* 22: 331–37.