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An eJournal Sharing Creative and Innovative Ideas in Intellectual  
Property Strategies and Management related to Global Development  
and Biotechnology in Agriculture, the Environment and Health

**No. 8-2004**

## **Financing the Bioindustry and Facilitating Biotechnology Transfer**

**Anatole F Krattiger**

*bioDevelopments* LLC (International Consultants), USA/Switzerland  
and *swiftt*, Cornell University, USA

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<b>Published by:</b>	bioDevelopments—International Institute Inc., Ithaca, NY <a href="mailto:info@bioDevelopments.org">info@bioDevelopments.org</a> in collaboration with the Strategic World Initiative For Technology Transfer (SWIFTT)
<b>ISSN:</b>	1534-6447
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<b>Citation:</b>	Krattiger, AF. 2004. Financing the Bioindustry and Facilitating Biotechnology Transfer. <i>IP Strategy Today</i> No. 8-2004.
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<b>Submission of Papers:</b>	Send an email to any of the Editorial Board Members (only electronic submissions are accepted)
<b>Instruction to Authors:</b>	Please visit: <a href="http://www.bioDevelopments.org">www.bioDevelopments.org</a>
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<b>Concept and Design:</b>	Anatole F Krattiger, bioDevelopments LLC (International Consultants), Interlaken, NY.
<b>Funding:</b>	We are grateful to the Rockefeller Foundation, to the Department of Plant Breeding and to the International Program of the College of Agriculture and Life Sciences (IP/CALS) at Cornell University for support.  This paper was written on behalf of the United Nations Industrial Development organization (UNIDO) as a briefing paper in preparation of the Global Biotechnology Forum jointly organized by the Government of Chile and UNIDO and held in Concepcion, Chile, March 2-5 2004.
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# Contents

	<i>Notes .....</i>	<i>ii</i>
	<i>Executive Summary .....</i>	<i>1</i>
<b>1. Background and Objectives .....</b>		<b>6</b>
<b>2. From Biotechnology Innovations to Markets .....</b>		<b>6</b>
2.1 Biotechnology: The Millennium Technology .....		7
2.2 Intellectual Capital, Intellectual Property Rights, and Innovation.....		9
2.3 Patents: From National Sovereignty to International Systems and the Post-TRIPS Era.....		10
2.4 Technology Transfer in the Context of Multi-stakeholder Partnerships and Globalization.....		15
2.4.1 Forms of Technology Transfer .....		15
2.4.2 The Interactive Nature of Technology Transfer .....		17
2.5 Regulatory Aspects .....		18
<b>3. A Review of Existing Technology Access and/or Transfer Systems and Investment Services ..</b>		<b>18</b>
3.1 Introduction .....		18
3.2 Royalty Collection Agencies .....		19
3.3 Information Clearing Houses .....		20
3.4 Technology Clearing Houses.....		21
3.4.1 "Online" IP Exchanges.....		21
3.4.2 "Managed" IP Exchanges .....		22
3.5 Open-Source Innovation Clearing Houses .....		22
3.6 Honest-Brokers and Other Forms of Facilitators .....		23
3.7 IP Management Services .....		25
3.8 IP Commercialization Agents .....		26
3.9 Merchant Banks.....		27
3.10 Patent Pools.....		28
3.11 South-South and South-North Technology Transfer Aspects .....		30
3.12 Other Aspects of Technology Transfer Mechanisms .....		30
<b>4. Options for UNIDO to Facilitate Biotechnology Access and Transfer .....</b>		<b>31</b>
4.1 Introduction and Problem Statement: The "Integration" of Institutions, or from "Intellectual Capital" to "Social Capital" .....		31
4.2 Proposed Strategic Responses by UNIDO to the Advent of Industrial Biotechnology.....		32
4.3 Criteria for Prioritization .....		33
4.4 Focused Initiatives .....		34
Strategic Goal 1. Improve the institutional IP management capabilities in developing countries by promoting authoritative institutional IP management.....		34
Strategic Goal 2. Reduce the transaction costs of in-licensing by pooling certain technologies .....		35
Strategic Goal 3. Develop policies and precedents to facilitate and enable open source licensing. ....		37
Strategic Goal 4. Catalyze the creation of tailor-made investment services and IP brokering initiatives.....		38
Strategic Goal 5. Support capacity building and training in industrial biotechnology. ....		42
4.5 Broad Initiatives .....		42
Strategic Goal 6. Act as a policy advocate, or coordinate policy advocacy, to persuade governments across the world to institute policies conducive to technology transfer. ....		42
Strategic Goal 7. Enhance developing countries' IP management capabilities by promoting sound practices and policies.....		42
Strategic Goal 8. Lobby for good government policies that are conducive to private sector investments in industrial biotechnology development.....		42
<b>5. Conclusions .....</b>		<b>43</b>
<b>References .....</b>		<b>43</b>
<b>List of Abbreviations and Acronyms .....</b>		<b>45</b>

## Notes

This paper was written on behalf of the United Nations Industrial Development organization (UNIDO) as a briefing paper in preparation of the Global Biotechnology Forum jointly organized by the Government of Chile and UNIDO and held in Concepcion, Chile, March 2-5 2004. The data contained in the paper along with the views and conclusions are those of the author and do not necessarily reflect any official policies of nor constitute an endorsement by UNIDO.

Every attempt has been made to formulate the paper in plain language without using unnecessary technical terms and legal jargon. Definitions of key technical and legal terms, or so-called “terms of art,” can be received by contacting the author or from McCarthy’s Desk Encyclopedia of Intellectual Property, Second Edition, available at [usinfo.state.gov/products/pubs/intelprp/glossary.htm](http://usinfo.state.gov/products/pubs/intelprp/glossary.htm) (McCarthy JT. 1996. The Bureau of National Affairs, Inc.: Washington DC). Similarly, excursions into the intricacies of patent systems and related aspects of proprietary technology have also been kept to a minimum.

Also, please note that the term “developing country” is used in a broad sense to include all types of developing countries, including economies in transition. This approach might appear to risk oversimplification, but the simplicity is deliberate since it allows the reader to focus on more fundamental strategic questions.

Finally, whereas the document focuses on the transfer of industrial biotechnology, many of the principles, priorities, and proposals discussed here are applicable—with or without modifications—to the life sciences in general.

# Financing the Bioindustry and Facilitating Biotechnology Transfer <sup>1</sup>

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## Executive Summary

**Industrial biotechnology:** Undoubtedly, the next major wave of biotechnology applications will come from industrial biotechnology—the application of biotechnology to traditional and novel manufacturing processes or the production of biomaterials through bioprocesses. These are perhaps the most far-reaching biotechnology applications to emerge and include the use of naturally occurring and genetically modified microorganisms, enzymes, and derivatives to produce a plethora of products, including biomaterials (novel types of textiles, bio-based materials to replace existing materials or modify existing ones), biofuels, biocatalysis, biochemicals (fine and specialty chemicals and bio-polymers), and bioremediation. The traditional chemical industry has already enthusiastically embraced biotechnology R&D: it is estimated that by 2010 industrial biotech will exceed 20% of today's \$280 billion chemical market.

Overall, recent scientific, commercial, and investment developments in biotechnology are impressive (Section 2.1). Despite a downturn in the global economy over the past few years, investments and sales have far exceeded expectations. Recent scientific breakthroughs have spurred investments to near all time highs, and biotech products and services generated \$42 billion in sales globally. While the majority of sales are pharmaceuticals, the biggest new investments are in industrial biotechnology.

**Rationale for the briefing paper:** Patents and other forms of statutory protection are national rights, and the criteria for patents is determined by nation states. The TRIPS accord under the WTO, however, is leading to more homogenous systems globally, and patent filings in developing countries are expected to increase. Nonetheless, this increase and the homogenization of intellectual property rights (IPRs) will not solve the problem of technology transfer from industrialized to developing nations. For even when technology transfer is unencumbered by patents, it frequently does not occur. This is often because obtaining the license for a patent does not mean that it can be applied to new inventions, especially complex ones in new technological fields. This is especially the case for biotechnology, where know-how is often more important than patents, as are access to markets, trademarks and more.

When patents do come into play, the time-consuming, complex, and specialized practice of IP management also restricts the transfer of technology. This is especially the case when exports are involved or when the development of a product requires a technology bundle made up of an intricate tangle of pat-

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<sup>1</sup> Krattiger, AF. 2004. Financing the Bioindustry and Facilitating Biotechnology Transfer. *IP Strategy Today* No. 8-2004.

This paper was written on behalf of the United Nations Industrial Development organization (UNIDO) as a briefing paper in preparation of the Global Biotechnology Forum jointly organized by the Government of Chile and UNIDO and held in Concepcion, Chile, March 2-5 2004. The data contained in the paper along with the views and conclusions are those of the author and do not necessarily reflect any official policies of nor constitute an endorsement by UNIDO.

I would like to thank George Tzotzos for constructive comments on an earlier version of this paper and to all participants of the UNIDO Biotechnology Consultation Meeting, 21 November 2003, Vienna, and of the UNIDO European Consultative Meeting, 9-12 December, UNIDO, Vienna for valuable feed-back to oral presentations of this paper. My thanks also go to Richard T Mahoney and Peter WB Phillips for useful comments on an earlier version of this manuscript.

ents. Even for simple applications, the myriad number of patents granted to basic inventions and enabling technologies increases transaction costs and thereby impedes the transfer of biotechnology.

What makes assisting developing countries with the transfer of industrial biotechnology so urgent and important is that in today's "knowledge economy" intellectual capital is king and the old rules of economic growth no longer apply. Development has ceased to follow the rules of "convergence", whereby returns on new investments are higher where capital is more scarce, thus gradually converging the economies of developed and developing countries. Innovation and technology, unlike capital, are not converging forces. The more a country innovates, the more it is likely to innovate in the future.

**Intellectual capital, innovation, and technology transfer:** Intellectual capital, or "intangible assets", comprises IP (patents, copyright, trademarks, trade secrets, etc.), goodwill, any knowledge that can be converted into value (e.g., product/market knowledge for differentiation as a key competitive advantage), human capital (tacit knowledge, know-how, relationships), and other forms of intellectual assets (codified, know-how, customer lists, and relationships). Some see all of this as proof that we live in a knowledge economy. The knowledge economy, however, is essentially over. Increasingly, what counts today is "social capital". People make networks work. Human networks make things happen, not the inert, underlying data and information. This is relevant to IP because its value depends upon its use. And in order to get IP used by as many people or institutions as possible, one has to sell or license it. This requires transactions between people who know and trust each other.

The comprehensive discussion of IP management and technology transfer in Sections 2.2 to 2.4 reveals that IP systems work through the power to exclude. This places the deprived at a further disadvantage and is one of the aspects of the biotech revolution that should greatly concern UNIDO. The ability to exclude has fragmented technologies, led to an abundance of exclusive licensing practices, and in developed countries allowed commercial interests to determine government policies instead of global needs. In addition to IP regimes and IP management practices, there are a myriad of other criteria that need to be satisfied in order to generate and capture added value. Without the latter, private sector investments will not grow much.

A complex mix of factors drives technological innovation, but they essentially boil down to national policies, international agreements, and market dynamics. Innovation is the starting point for making inventions commercially and socially useful, but innovation alone will not lead to technological products that can produce goods or services. An invention must be assembled by putting together the patents and other forms of IP from third parties—marketable technologies and technology platforms are bundles of IP. By itself, however, mere assembly will not make an invention commercially useful; another step of technology transfer is needed that generally involves multiple players, product development, regulatory aspects, and alliances with third parties. These forms of technology transfer can be grouped into six different types:

1. turn-key investments (typically through foreign direct investments or FDI);
2. mergers and acquisitions (M&As);
3. strategic alliances (collaborations, joint ventures, corporate partnerships);
4. licensing (principally IP bundles comprising an entire range of inventions required to practice, also called freedom-to-operate);
5. donations; and
6. capacity building.

The key capacities that the developing world lacks are 1) the management of innovation and IP, and 2) networks for partnership building and financing. The mere transfer of IP or the donation of rights to certain patents is insufficient for sustainable growth. As proof, consider that the overwhelming majority of biotechnology patents are not protected in developing countries and could now be freely utilized—yet only a few are being productively used.

**A review of existing investment services and technology access and transfer systems:** The following table comprehensively reviews and discusses a dozen types of mechanisms, all specifically dealing with technology transfer, IP transfer, and facilitating investments (Section 3). The review is not exhaustive; it emphasizes the methodologies of different institutional mechanisms to assist technology transfer and investments.

Type of Mechanism or Service	Characteristics	Examples
<b>Royalty collection agencies:</b> Collection of royalties for a small fee by one entity on behalf of its members.	Useful if licensing industries are already established; can be created by industry itself	American Soc. of Composers, Authors and Publishers; British Soc. Plant Breeders
<b>Information clearing houses:</b> Broad term denoting a mechanism matching providers of goods, services or info.	Useful for the exchange of specific information related to an activity or industry; does not facilitate tech transfer <i>per se</i>	BioBin, BINAS; portals to countries or industries bio-tech, training programs
<b>Technology clearing houses</b> 1. Web-based IP auctions and licensing, including business-to-business.	Appropriate for general purpose technologies, platform technologies, bundles; limited ability to spread tech transfer further	Virtual trading floors, patent auctions
2. Public sector initiatives dealing with training, good practices, and the bundling of technologies	Appropriate for development; furthers tech transfer	Public Intellectual Property Resource for Agriculture (PIPRA)
<b>Open-source innovation clearing houses:</b> Sites where anyone can post ideas or inventions and anyone is allowed to turn the ideas into products	Potentially appropriate for open-source licensing and diffusion of tangible research materials	Barry Nalebuff and Ian Ayres "Why Not?" or Half-Bakery
<b>Brokers and other forms of facilitators:</b> Typically focused on creating public-private partnerships, providing "managed" tech transfer.	Appropriate for charting new territory and bringing public and private actors closer	African Agricultural Technology Foundation (AATF); Global Alliance for Vaccines and Immunization (GAVI)
<b>IP management services:</b> Comprises a wide range of entities, both public and private, assisting institutions in managing their IP assets.	Good for addressing systemic issues; establishes new modes of interaction.	Law firms, management consultants, global non-profit entities (e.g., MIHR), and academic training
<b>IP commercialization agents</b> 1. Commercial entities dedicated to commercialization of 3 <sup>rd</sup> party IP.	Highly effective business model; useful to learn from their experiences and adapt to serve nascent private sectors.	BTG Ltd.; certain specialized law firms.
2. Mixed commercial and public good objectives	Useful to learn from their experiences and adapt the model to other biotech sectors	E.g. Concept Foundation
<b>Integrated commercial services:</b> A range of services for M&As, spin-offs, including IP audits, business valuation, due diligence etc.	There could be a need for a non-profit merchant-bank-type institution to provide services to small/medium size enterprises	Merchant Banks; venture capital investment services.
<b>Patent pools:</b> A voluntary agreement between two or more patent owners to license one or more of their patents to one another or third parties	Pooling unlikely to change the underlying structural barriers to tech transfer; difficult to establish because industry players have divergent strategic interests; in partial/modified form, effective for tech transfer	Internal, company specific pools; portfolio pooling. co-operative pooling, third party aggregations, forced pooling
<b>Other public tech transfer and financing mechanisms</b>	These range from education and training institutions, to consortia in health, and to certain specialized UN programs (incl. south-south transfers).	
<b>Company-to-company arrangements</b> (including collaborations, joint ventures, strategic partnerships, and corporate partnering)	Some of the most ubiquitous and efficient systems of tech transfer, rarely requiring public sector assistance; different government policies either encourage or thwart them. This is certainly an area where many governments could do much to reform their policies and regulations, especially by reducing the red tape and administrative burdens on foreign private investments.	

Source: Anatole. Krattiger.

### **Proposed Strategic Responses by UNIDO to Encourage Access to Industrial Biotechnology:**

The number of actors in biotechnology, technology transfer, and IP has increased multi-fold. At the same time, the sphere of influence of each actor is diminishing. The private sector responds to this through mergers and acquisitions, but development institutions are fragmenting and multiplying, hardly a recipe for efficiency, growth, impact, and sustained success. The proposals in Section 4 aim to address these difficulties, and all proposals fall within UNIDO's mandate and strategic plan. Given the importance of biotechnology for sustainable development in general, and particularly for sustainable industrial growth, UNIDO may wish to support access to technologies and to reward their transfer either directly through its existing programs or indirectly by catalyzing new initiatives. Eight possible options are categorized below into six groups according to their impact:

	<b>Focused Activities</b>	<b>Broad Activities</b>
<b>Short-term impact</b>	1. Improve the institutional IP management capabilities in developing countries by promoting authoritative institutional IP management. 2. Reduce the transaction costs of in-licensing by pooling certain technologies.	6. Act as a policy advocate, or coordinate policy advocacy, to persuade governments across the world to institute policies conducive to technology transfer.
<b>Medium-term impact</b>	3. Develop policies and precedents that encourage open source licensing and facilitate technology access. <b>4. Catalyze the creation of a tailor-made investment and IP brokering service.*</b>	7. Enhance developing countries' IP management capabilities by promoting sound practices and policies.
<b>Long-term impact</b>	5. Support capacity building and training in industrial biotechnology.	8. Lobby for good government policies that are conducive to private sector investments in industrial biotechnology development.

Source: Anatole Krattiger.

\* Proposal No. 4 is considered most important because it integrates many of the other services and initiatives.

Not all initiatives are appropriate for all countries, and we must proceed with careful circumspection when planning programs focused on key technology platforms within priority regions. In addition, technology transfer requires investments in capital and people; unless financing is available, few partnerships and networks will last. In terms of prioritizing UNIDO's efforts, short term focused initiatives should generally be given priority. This will allow individuals to gain experience and training in different areas related to IP management, and these people can then serve as important voices in formulating broader policy initiatives. Of all the above options, however, Strategic Goal No. 4 is particularly important since it integrates many of the solutions provided by the others.

The implementation of Strategic Goal No. 1 would include compiling current capacity building programs in this area, sharing the information with key stakeholders, identifying a few, and then jointly developing activities in industrial biotechnology IP.

Strategic Goal No. 2 would entail a feasibility study to determine what specific technological areas would assist existing small and medium size enterprises (SMEs) in developing countries and how the SMEs would benefit from the service. Part of the study would broadly identify technology owners and initiate preliminary discussions with them. Furthermore, workable models would need to be developed, including a blueprint for the organization with options and recommendations.

Strategic Goal No. 3 could take many different forms. This paper proposes that information about the downsides of patenting research tools and about the opportunities of open-source licensing be provided to policy makers. To kick off the initiative, a special session during the Global Biotechnology Forum in Chile could be organized that ended with a press release calling upon countries, organizations, and companies to change their practice. Model policies on open-source licensing could also be developed.

Strategic Goal No. 4 is considered most important because it integrates many of the proposed strategic goals and program initiatives, including policy advocacy. In order to spur biotechnology transfer, an integrated service is required to assist both SMEs and public institutions in business development. This would include securing technologies and investments, offering due diligence audits, assisting with in-licensing negotiations, identifying business opportunities in partnering (both for technology in-licensing and the export of products and services), and arranging financing. The service would assist with small (<\$2 million) and medium-sized (\$2-10 million) deals. The integrated list of services provided would foment business growth through technology upgrades, in-licensing, and investments.

UNIDO is well positioned to be the crucial catalyst for such a service by commissioning a full-fledged feasibility study (Phase I) that would outline an implementation plan and consider options related to the service's mandate, specific objectives, modes of operation, strategies for implementation (including



structure, staffing, location, and possible affiliation), legal status and governance, cost projections, and funding options. A steering committee would need to be created (Phase II) to make important decisions about the selection of initial geographic areas, types of biotechnology inventions, and applications. Once the pilot program is established (Phase III), the steering committee would become the founding board, setting policies, overseeing implementation, assisting with building partnerships with institutions that provide related services, and encouraging participation by financial institutions. After the initiation of successful operations, the service would be expanded to serve a wider range of countries and different biotechnological applications (Phase IV).

Strategic Goal No. 5 essentially encourages UNIDO to underscore more strongly the importance of long-term capacity building in industrial biotechnology. The broader policy initiatives proposed under Strategic Goals No. 6, 7 and 8 will establish a neutral policy platform that would efficiently and authoritatively promote them. This platform should emphasize bringing together partners engaged in the research, development, and commercialization of industrial biotechnology. It should assist governments with the design or enhancement of policies, strategies, and instruments that will promote investment in industrial biotechnology within a new economic context, especially in regards to the developing world. This would include advocacy activities aimed at national policy makers and planners, assisting governments with developing or enhancing technology transfer programs, and promoting the collective efficiency of SME clusters/networks by formulating action plans. UNIDO already successfully undertakes all of the above activities, albeit not in the context of industrial biotechnology. This proposal would enhance all (or most) of UNIDO's existing programs by integrating into them issues specifically related to industrial biotechnology, thereby empowering them to effectively lead the way towards technology transfer that is more innovative, efficient, and equitable.

**Conclusions:** Initiatives are urgently needed to more strongly integrate SMEs in developing countries with the world economy. They should not only assist technology transfer but also licensing and financial investment services. Encouraging technology transfer alone will only show results in the very long term, hardly a good proposition for most developing countries. In addition to technology transfer, stronger partnerships are required to transfer know-how and to integrate the developing world's emerging private sector into the social networks that are becoming as important as "knowledge" *per se*. In the future, business will not be driven by "intellectual capital" but "social capital". Technology transfer and its requisite partnerships can be used to build social networks founded on mutual benefits and centered around common goals. These transfers, whether company to company or public-private partnerships (PPPs), require additional funding to work. Because public investments and philanthropic funds are limited, other sources of funding—or financing—need to be leveraged, which is why this paper emphasizes partnership building activities that include investment services.

Developed countries are investing enormous sums in industrial biotechnology because of its far reaching commercial, social, and environmental promise. It will dramatically change the creation of value in a range of manufacturing processes. Developing countries, however, will once again be excluded from economic growth and the benefits of new technologies if they do not take part in this revolution.

## 1. Background and Objectives

Whether strict intellectual property (IP) regimes stimulate innovation and productivity or merely raise the cost of technology has not been fully established empirically. This is because the interface between IP systems and innovation, technology transfer, and development, is highly complex, constantly evolving, and specific to localized circumstances, industry types, and changing government policies. The developed world, however, is committed to IP protection and it has become one of the corner stones of an increasingly global economy.

In developed countries, the disadvantages of IP rights regimes—as opposed to property rights regimes<sup>2</sup>—sometimes outweigh the advantages. While developed countries are able to establish legal mechanisms to overcome or at least mitigate the negative effects of IPRs, developing countries are often not as fortunate. They find themselves attempting to enter a market in permanent flux, and they deserve all the assistance they can get. Furthermore, the humanitarian needs are enormous—billions of people are excluded from the market and modern technologies.

UN agencies seek to spur development and economic growth while concurrently addressing the humanitarian needs of entire regions of the world that are “technologically excluded” (i.e., neither technological innovators nor adopters [Sachs 2000]). Accordingly, this brief was commissioned to serve as a basis for discussions at the European Regional Meeting of the Global Biotechnology Forum (GBF)<sup>3</sup> and later as a brief for the GBF, 2-5 March 2004 in Chile. The concept of a GBF stemmed from a UNIDO meeting in Uruguay, the Regional Biotechnology Forum, 28-30 March 2001. A briefing paper had been commissioned for that meeting focusing on public-private partnerships in ag-biotech to facilitate biotechnology transfer and to bring about increased private sector investments (Krattiger 2002). The proposals in the present document build on these earlier ones.

The objective of the present document is to provide:

- an introduction to multi-stakeholder partnerships in the context of the national and global issues surrounding biotechnology transfer to developing countries, including an analysis of technology access issues, particularly regulatory and policy matters affecting access to proprietary biotechnologies;
- options on facilitator mechanisms to permit technology access;
- financial and institutional ramifications for the proposed options/mechanisms; and
- a discussion of the prospective roles for multinational institutions generally—and for UNIDO in particular—to implement relevant technical cooperation programs.

## 2. From Biotechnology Innovations to Markets

This section reviews and discusses elements of the biotechnology industry in order to understand 1) its emerging global importance and 2) how industry drives technology development. Factors related to the management of IPRs and licensing are also discussed, as are related technology transfer issues. The section, however, is not intended to be a comprehensive treatise on the subject. It emphasizes aspects that point to major conclusions that will provide a foundation for subsequent sections. The paper is thus neither a critique nor a defense of current IPR systems. Nor does it consider the pros and cons of patenting regimes or their ethical dimensions. Both subjects, among others, have recently been reviewed (e.g., see Barton *et al* 2002 for a comprehensive treatise).

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<sup>2</sup> Primarily those of land, but also of other material possessions.

<sup>3</sup> The GBF has been created by UNIDO to “explore the technical and economic feasibility of possible objectives in biotechnology. It will be structured around four main thematic sessions—biopharmaceuticals, agro-biotech and food processing, bioremediation and other industrial applications of biotechnology, plus four transversal sessions—technical assistance and capacity building, regulatory regimes (intellectual property rights, biosafety, etc.), industrial financing and trade, and public perception. The conclusions of the four transversal sessions would build a matrix which should contain the key elements necessary for the identification, formulation and development of field activities, focused on the industrial applicability of biotechnologies” (UNIDO internal document).

## 2.1 Biotechnology: The Millennium Technology

During the first two years of this millennium—marked this year by the 50<sup>th</sup> anniversary of the discovery of DNA—the biotechnology industry experienced a major re-structuring: share prices in industrialized countries dropped 40-80%. At the same time, there were major breakthroughs in the science of biotechnology. In the USA alone, during 2002 over 35 new biotechnology drugs were approved (an all time high), 370 more entered clinical trials (another all time high), industry raised over \$10 billion in new biotechnology directed investments and generated almost \$8 billion through partnering arrangements, and a series of new biotechnology crops received regulatory clearance in several countries around the world. Although environmental biotech applications lag behind, there were significant investments. The sale of biotech products increased from \$29 billion in 1999 to \$42 billion in 2002 (96% of which comes from pharmaceuticals), a staggering 15% annual increase. During that same period, R&D investments increased \$5.5 billion to \$14 billion annually for private life sciences companies.<sup>4</sup>

The recent success of the life sciences is perhaps capped by the mapping of the mosquito genome and the parasite that causes malaria. Over 24 research papers were published almost simultaneously on the subject (October of 2002 in *Nature* and *Science*; e.g., De Gregorio & Lemaitre 2002; Holt *et al* 2002). This tremendous achievement is a first step towards developing new drugs and vaccines against malaria. It demonstrates the astonishing power of these new technologies: consider that in the past 20 years only 4 anti-malaria drugs entered the market—this in a world where every 30 seconds a child dies from malaria.

**Industrial biotechnology**<sup>5</sup> is poised to become the next major wave of biotechnology. The traditional chemical industry and related industries are embracing biotechnology in a big way. It promises to provide the most far reaching range of biotech applications so far envisaged and is directly relevant to the core of UNIDO's mandate.

Industrial biotechnology is diverse and far reaching, and includes the use of naturally occurring and genetically modified microorganisms, enzymes, and derivatives to produce a plethora of products, such as:

- biomaterials, including novel types of textiles (e.g. DuPont's microbial 1,3 propanediol for Sorona 3GT polymer production) and bio-based materials of all sorts to replace existing materials and to create new ones (e.g., orthopedic materials, synthetic bone grafts, tissue engineering, collagen);
- biofuels (e.g. ethanol, biodiesel, hydrogen)
- biocatalysis (e.g. biocatalysts to replace the harsh chemicals in paper manufacturing)
- biochemicals including fine and specialty chemicals, bio-polymers (note that McKinsey & Co<sup>6</sup> estimate that by 2010, biotechnology will exceed 20% of the \$280 billion chemical industry today)
- bioremediation (soils, rivers, lakes, etc.).

The key trends with **biotechnology in general** are:

- the biotechnology industry in general will undoubtedly continue to consolidate, yet despite the consolidation IP ownership is increasingly fragmented;
- increased emphasis will be placed on the interface of biotechnology with information technology and nanotechnology;<sup>7</sup>
- the above will include significant investments in systems biology and related areas such as proteomics, metabolomics, and clinical R&D;

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<sup>4</sup> This estimate, and several other figures in this section, are from Burrill & Company, 2003.

<sup>5</sup> Industrial biotechnology is defined here as the application of biotechnology to traditional and novel manufacturing processes, or the production of the application biomaterials through bioprocesses.

<sup>6</sup> [www.McKinsey.com](http://www.McKinsey.com)

<sup>7</sup> On 3 December 2003, the President of the US signed into law the *21st Century Nanotechnology Research and Development Act*, a \$3.7 billion R&D spending bill for public research into nanotechnology over 4 years. For the full bills, visit <http://www.acm.org/usacm/Legislation/TechLeg108th.htm>

- the expanding nutraceutical sector will continue to grow significantly as consumers throughout OECD countries discover herbs, supplements, and specific foods that help preserve health (the global market for functional foods, herbs, supplements, and other specialized nutrition products already exceeds \$150 billion, led by the USA [\$53 billion] and Europe, followed by Japan, Asia, Canada, Latin America, Australia and Eastern Europe [at \$2 billion]);
- the diagnostics market will surge as high value diagnostics that link patients to the right medicine or improve the monitoring of drug “cocktails” gain importance;
- increased investments are likely to occur in Southeast Asia, Scandinavia, and parts of Eastern Europe where acceptance of biotechnology is strong;
- agricultural biotechnology has seen reasonable growths in the late 1990s and is poised to recover within a few years from the *StarLink*™ scare and other regulatory and public acceptance hiccups (such as the “monarch butterfly story” or the ProdiGene “fiasco”); current licensing fees of \$1.6 billion will exceed \$2.5 billion by 2006; other agricultural applications, such as biopesticides and animal hormones, will continue to be low at around \$130 and \$350, respectively; due to very low commodity prices, farmers are continuing to move towards value added genetically modified (GM) crops;
- the market for agricultural pesticides has been declining over the last decade but is still estimated at \$26 billion globally, and the seed market is valued at \$12 billion;
- beyond 2010 the contribution of agricultural and crop based biotechnology will be staggering;<sup>8</sup> biopharming<sup>9</sup> will most certainly make a major impact on value added to farmers in the USA.

**Internationally**, the debate over GM crops and biotech foods has put biotechnology through some tumultuous years. There are, however, other more positive developments in global biotechnology that are related to government policies and public and private investments.

In Europe, for example, the public widely accepts medical biotechnology applications, and governments have created favorable investment climates since the mid-1990s. The most notable shift has been in Scandinavia, where the Medicon Valley has come to fruition. Israel, Canada, the Asia-Pacific region, China, India, and to a small degree South Africa, Brazil, and Mexico are also pursuing biotechnology.

For companies in developing countries the major challenge is the lack of relatively cheap money (venture capital, stock markets, bonds, and other forms). Despite this, in Asia alone there are over 1,000 biotechnology companies.<sup>10</sup> Korea leads the way with 300 companies, followed by Australia (220), Japan (130), and China (120), while India, Taiwan, Hong Kong, Singapore, and Malaysia each have fewer than 100.

The difficulty of raising private capital is somewhat offset in countries where governments have recently invested significant amounts. Singapore’s government, for example, invested \$4 billion over five years in contract biotech manufacturing; South Korea’s government is currently investing \$5.5 billion with matching private contributions over five years in the same area; China has invested some \$19 billion over five years; India recently launched a \$400 million plus program in agriculture, nutraceuticals, and biomaterials.

Biotechnology is clearly becoming increasingly big business, even in developing countries. One must note, however, that most of the investments in the Asia-Pacific region to-date have not yielded many products for the global market. Overall, the region is hampered by negative investor’s perceptions of their indigenous biotech companies, high taxation, low patent protection, frequently inconsistent government policies caused by the conflicting policies of different ministries, a lack of well trained scientists, and a thin home market.

<sup>8</sup> The editor-in-chief of *Science*, Donald Kennedy, aptly described this aspect: “Over the next 20 years, the rice genome will make more of a difference to global health than the human genome” (as quoted by Uehling 2002).

<sup>9</sup> Biopharming is defined here as the use of transgenic crops to produce therapeutic proteins and industrial enzymes.

<sup>10</sup> Ernst & Young 2003. [www.ey.com](http://www.ey.com)

## 2.2 Intellectual Capital, Intellectual Property Rights, and Innovation<sup>11</sup>

During the last two decades, intangible assets (i.e., those based on intellectual property, primarily trademarks, patents, and trade secrets) have increased significantly. According to the Brookings Institution, whereas in the early 1980s intangible assets made up 20% of the total value of non-financial companies, this has increased to over 70% at the turn of the millennium (Blair and Wallman 2001). The management of IP and Intellectual Capital has thus become an increasingly important focus for most corporations.

Intellectual capital, sometimes termed “intangible assets,” comprises IP (patents, trademarks, etc.), goodwill, any knowledge that can be converted into value (e.g., product/market knowledge for differentiation as a key competitive advantage), human capital (tacit knowledge, know-how, relationships), and other forms of intellectual assets (codified, know-how, customer lists, and relationships) that belong to a company and not to its creators. Some see this as proof that we live in a knowledge economy. The age of the knowledge economy, however, is already over. What counts today is “social capital”. People make networks work. Human networks make things happen, not the underlying data, information, or computer networks. This is an important consideration in regards to IP, since IP is principally useful only if it is used. In order to get something used by as many people or institutions as possible, one must sell or license it. This requires transactions, and these happen between people who know, trust, and value each other.

IP is not only a matter of patents.<sup>12</sup> In addition to patent rights, IPRs include (to name a few): unpublished patent applications, any inventions, improvements, and/or discoveries that may or may not be legally protectable. This includes all know-how, trade secrets, research plans and priorities, research results and related reports, statistical models and computer programs and related reports, market interests and product ideas, as well as databases, customer lists, and so forth. It also includes other forms of statutory protection besides patents: copyrights, trademarks, geographical indications, appellations of origin, and plant variety protection/plant breeders’ rights. IPRs are thus a broad mix of different rights, each with their own advantages and disadvantages, special applications, laws and uses, different geographic coverage, and varying national enforcements. Unfortunately, although companies extract much value from non-patent IP, discussions too often center on the shortcomings of the patenting system.

Additionally, there is more to IP management than IPRs: tangible property rights<sup>13</sup> are closely related to IPRs because in practice intellectual creations are often “embodied” in matter. This adds complexity and a different set of laws to IP management. Specifically, when dealing with the transfer of IP, tangible property is often also included, which makes contracts much more important than patent laws. Indeed, the importance of contracts and licenses is often overlooked in discussions about IP; instead, treatises get bogged down in the intricacies of patentability and other subjects. Similarly, debates about IP are often dominated by anecdotes about litigation that are given as proof that IP is something coercive. In fact, litigation in the area of IP, patents, and licensing is uncommon. A few high profile cases with highly paid lawyers have made prime time news, but these represent less than 1% of all contracts and licenses. Of these, only a few end up in court, and the majority of these are settled out of court. In many cases, disputes are resolved through tough negotiation; in some cases, disputes simply lead to the termination of licenses or collaboration; others lead to acquisitions.

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<sup>11</sup> Innovation and inventions are not used interchangeably in this document. Inventions are typically derived from research activities and can constitute patentable material. Innovation, on the other hand, is a much broader term which essentially describes the process of creating a marketable value from one’s R&D activity (and includes the more formal inventions).

<sup>12</sup> In any case, not all inventions get patented. In the USA, many studies have shown that less than 20% of all inventions get patented. Most never see daylight. Of those inventions that do get patented, around 10% generate more than \$1 million in income. This figure is extremely important to remember when an institution is deciding where to file for a patent. It also underlines the fact that significant financial resources are needed to “play” the patenting game.

<sup>13</sup> Also called material property (which may or may not be synonymous with personal property depending on the context). See also Krattiger 2004b for a discussion on the differences and importance.

Finally, it is worth pointing out that IP *per se* is quite useless unless there is someone somewhere who wants and buys it. At the end of the day, a given patent is only useful if the holder can extract value from it through product sales, licensing, cross-licensing, or strategic positioning. This requires production capacity and market access, and in most instances it also requires more than one partner or entity to work together, often across countries and industries. Contracts govern these relationships. A patent, therefore, is merely the starting point for a joint venture, license arrangement, or collaboration. This leads to an equally complex area of agreements between different entities, whether public or private. Such partnerships are absolutely essential because little, if any, IP is generated and used (i.e., sold) by one entity alone. Different players are almost always involved, with each player extracting value from the IP in one form or another (e.g., directly through licenses, indirectly through strategic advantages). How well an organization manages its IP assets determines how effectively it extracts added value, and successful IP management requires expertise in a number of areas: institutional policies, strategy formulation, freedom-to-operate management, to name but a few. Evidently, the management of IP also encompasses other areas, such as ethical issues, negotiation skills and practices, communication, conflict resolution, inter-cultural aspects, etc.

Figure 1 provides an overview of all major aspects of IP and TP management. The figure depicts a hypothetical but very plausible flow of IP and TP. It begins on the left side, where a local community is granted access by a university to its biodiversity and traditional knowledge holdings for bioprospecting. The rest of the figure shows the possible elements that may be needed to bring different products stemming from the bioprospecting activity to market (e.g., an anti-cancer drug or a drought tolerant plant variety). It includes about every statutory tool available (copyrights, trademarks, patents, etc.), all types of agreements (confidentiality, material transfer, up to sales agreements), all types of key partnerships (university-industry, industry-industry, etc.), and most critical IP management aspects, such as freedom-to-operate, infringement issues, and so forth. All of these are important tools for management to make decisions.

## 2.3 Patents: From National Sovereignty to International Systems and the Post-TRIPS Era

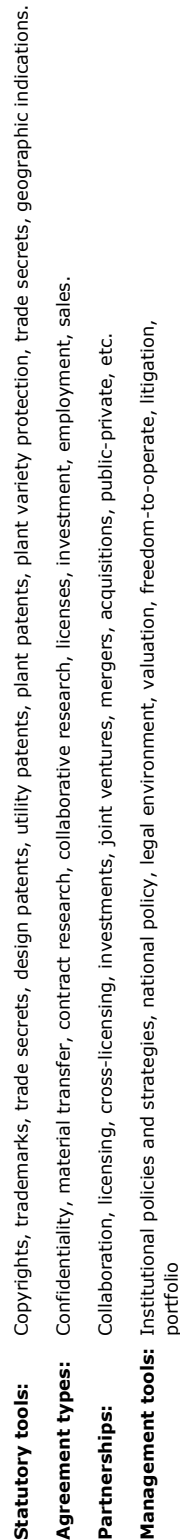
Notwithstanding the preceding section, patents are crucial for generating and capturing added value. They are the indispensable starting point. In simple words, a patent is a grant by a government to an inventor of the right to exclude others from making, using, or selling his or her invention. Broadly, there are three kinds of patents:

- a utility patent on the functional aspects of products and processes<sup>14</sup>;
- a design patent on the ornamental design of useful objects; and
- a plant patent on a new variety of a living plant.

Patents do not protect ideas but only the structures and methods that apply technological concepts. Each patent type confers the right to exclude others from a precisely defined scope of technology, industrial design, or plant variety. In a *quid pro quo*, or as a social contract for the right to exclude, an inventor must fully disclose the details of the invention to the public so that others can understand and use it to further develop the technology. Once the patent expires, the public is entitled to freely make and use the invention.

Utility patents can be further divided into three types, depending on the kind of claims the patent has:

<sup>14</sup> Throughout this paper, when reference is made to patents, it generally means a utility patent. Design patents are specific to certain industries. Like plant patents they bring up an entirely different set of issues (see Krattiger and Potter 2002). It should be noted here that "plant patents" are not synonymous with "utility patents on plants". "Plant patents" typically protect asexually reproduced plants not found in nature, including mutants and hybrids; they exist only in the USA, most European countries, and a few other countries. "Utility patents on plants", on the other hand, are only granted in the USA since the 1985 US Patent and Trademark Office case commonly referred to as "*ex parte* Hibberd *et al*" ( 227 U.S.P.Q.443, pp. 444 – 448) and recently upheld in the US Supreme Court (J. E. M. Ag Supply, Inc., DBA Farm Advantage, Inc., *et al* vs. Pioneer Hi-Bred International, Inc.; No. 99.1996). These cover any plant genotype not found in nature. In addition, many countries allow for plant variety protection, or plant breeder's rights, which is typically for sexually reproduced plants. For the latter, an international convention exists and is called UPOV (administered under WIPO).



Category Today No 8-2004

- products *per se* (a claim of a patent that covers the structure, apparatus, or composition of a product, in contrast to a process claim, which covers a method or process, including yet to be identified products);
- product-by-process (a patent claim in which a product is claimed by defining the process by which it is made. The product-by-process form of claim is most often used to define new chemical compounds, since many new chemicals, drugs, and pharmaceuticals can practicably be defined only by describing the process of making them); and
- processes (a claim of a patent that covers the method by which an invention is performed by defining the steps to be followed, in contrast to a product claim or an apparatus claim, which covers the structure of a product.)

Most patents will contain a mix of the three claims listed above. Claims may be worded to cover products *per se*, products-by-process or uses, or a combination of the three. However, the third category of claims listed above is particularly important because whereas “product *per se*”, “product-by-process” or “use” claims generally extend to the products that embed the new discoveries, “process” claims do not extend to the products. What matters for “process” claims is the location (i.e., in which jurisdiction, or country) where the process is applied. This distinction is extremely important for developing countries, particularly for export products. If the product had been made in a country where those “process” claims have not been issued, then a license for such claimed processes is not required. Here is the crux of the matter: if a product is produced in a country using process X and process X is not patented in that country, then the export of the product so produced using process X to another country where process X is patented does not require a license for process X.

For example, if a product is made in one country where for example *Taq polymerase* is not patented, then the resulting product can be freely exported to a country where the process (in this case the use of *Taq polymerase*) is patented. A recent exception to this emerged in the USA in the specific field of genomics through the so-called *Festo* decision,<sup>15</sup> although the full ramifications of this change are beyond the scope of this briefing paper.

In contrast, “product *per se*” claims extend to any form of the claimed product. A simple scenario would be that if a given entity in a country produces a drug that is patented elsewhere, then that drug may be freely used in that country but not exported to countries where the drug is patented. This is somewhat more difficult to understand with GM crops. Because transgenic crops contain the gene that may be patented elsewhere, export of that crop, or of a product that contains elements of that crop, to a country where the gene is patented constitutes an infringement by the importer of the product.

Despite all the brouhaha about globalization, the biotechnology industry knows all too well that there is nothing even remotely global about patents; a worldwide or global patent does not exist. The World Intellectual Property Organization (WIPO) in Geneva administers the patent cooperation treaty (PCT). That treaty, however, only streamlines patent applications in its member countries (over 100). In most cases the applicant still has to file separate applications in individual countries or through regional patent offices, such as the European Patent Organization (EPO). In each jurisdiction, filing fees, examination fees, issuance fees, and maintenance fees have to be paid separately. That adds significant costs for such things as translation services, hiring a local agent, etc. Typically, if a patent is filed in 130 countries, it will cost \$5 million or more over the patent’s life.

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<sup>15</sup> *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki*. No. 00-1543. SUPREME COURT OF THE UNITED STATES, 122 S. Ct. 1831; 152 L. Ed. 2d 944; 2002 U.S. LEXIS 3818; 70 U.S.L.W. 4458; 62 U.S.P.Q.2D (BNA) 1705; 15 Fla. L. Weekly Fed. S 320. That ruling affects the enforceability of issued patents, license agreements, pending patent applications, and potential patent applications. Patent claims may now be infringed both literally and under the “doctrine of equivalents”. In literal infringement, the accused product or process possesses each and every element of the infringed claim. However, if literal infringement is not found, infringement may still be found under the doctrine of equivalents if the accused product or process uses “equivalent” substitutes for some portions or steps of the invention. Before the *Festo* decision, patentees could successfully sue others for appropriating the invention exactly as claimed in the patent and also for appropriating the general idea of the invention by making only minor changes. This approach took into account what was fair for both the patentee and the accused infringer. *Festo* replaced this consideration of the interests of both parties with clearer rules.



Globalization and the creation of the WTO in 1995 has driven countries towards more harmonized patent systems. For example, in mid-2000, the USA, Japan, Europe, and a few other countries signed the Patent Law Treaty, which charts a path towards the procedural harmonization of patent laws for these countries by 2010. This would significantly reduce the transaction costs for filing in multiple jurisdictions, save industry billions of dollars, and also lower the entry barrier for developing countries. Similarly, countries in Europe agreed to the European Union Patent Convention, which will create a common court in Europe for enforcing patents in all its member countries.

Another crucial development also began when the so-called Uruguay round of GATT concluded in 1995. Until then, most countries in the world did not allow patents for biotechnology or pharmaceuticals.<sup>16</sup> A timetable was agreed upon in 1995 for all WTO member countries (some 130) to enact patent laws that would afford protection after 2004 and provide uniform treatment to health product patents. Product patents will be required in countries that previously granted only process patents for pharmaceuticals. As a consequence, reverse engineering of patented products will not be legal anymore. This impact of TRIPS<sup>17</sup> is already being felt both in the production/supply of pharmaceuticals and in health R&D. It has led to a series of mergers and acquisitions, buy-backs, spin-offs, and other forms of strategic alliances (such as collaborations, joint ventures, strategic partnerships, and corporate partnering) across continents.

The pharmaceutical industry is a good example that illustrates the changes that TRIPS will bring. The industry is roughly composed of two types of companies:

- those in developed countries who invest high amounts into R&D, follow Good Manufacturing Practices (GMP) standards, and actively build and manage a patent portfolio; and
- those in certain selected developing countries (i.e., India, China, Egypt, South Africa, Argentina, Brazil, and Mexico) that typically invest a low percentage of revenues into R&D, who do not meet GMP standards, and who do not typically have an active patent portfolio.

As the January 2005 deadline for the full implementation of TRIPS approaches, these distinctions are beginning to disappear. What is unlikely to change much, however, is where health products are being invented. Large multinational companies will continue to be the main generators of inventions and will serve the markets of developed countries, addressing the illnesses and diseases of people in the rich world. Nevertheless, multinational pharmaceutical companies have recently become more sensitive to the needs of developing countries and have begun to license certain drugs at discounts or to work with non-governmental organizations (NGOs), governments, private foundations, and product specific organizations (PSOs). One of the key constraints for licensing the production of drugs (e.g., antiretrovirals) in the developing countries where they are needed has been the lack of companies capable of producing products following GMP standards.<sup>18</sup> Table 1 below summarizes the changes that TRIPS is likely to bring in the pharmaceutical area.

Although much could be said about the need for patent law reform, this paper does not discuss it because UNIDO lacks a specific mandate in this area. WIPO's mandate falls squarely into this area, however, and a number of working groups are already making progress, albeit very, very slowly. The author of the present report nevertheless believes that reforming patent practices and laws is an important component for an international development strategy. Such reform will not only facilitate biotechnology transfer to the developing world but also reduce transaction costs for companies. There are perhaps two

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<sup>16</sup> Note that many countries, including India, allowed for process patents. As a result, a company may still produce a certain product provided it can invent around the process that is patented. It also gave rise to reverse engineering which refers to a method of obtaining technical information by starting with a publicly available product and determining what it is made of, what makes it work, and how it was produced. This method goes in the reverse direction of usual engineering efforts, which start with technical data and use them to produce a product. If the product or other material that is the subject of reverse engineering was properly obtained, the process is legitimate and legal.

<sup>17</sup> A series of bilateral trade agreements also have IP and patent clauses. An example would be the US-Vietnam Bilateral Trade Accord of 1999, which contains articles on IP and related aspects that exceed the TRIPS standards.

<sup>18</sup> Compulsory licensing is permitted under TRIPS in certain circumstances. In practice, this has almost never been allowed by developing country governments. There are a number of reasons for this. The point here is that although many often state compulsory licensing a way of accessing drugs and other essential products, this seems a most unlikely practical avenue.

factors that contributed more than anything else to the tremendous consolidation of the biotechnology industry, both in pharmaceuticals and agriculture. The first is increasingly high regulatory costs; the second is high IP transaction costs. Paradoxically, purchasing an entire company is nowadays often much cheaper than obtaining a license or resolving patent disputes. Similarly, industry typically pushes patent offices to broaden patentable subject matter when it is just the opposite that is in industry's long-term interest. Consequently, the following patent law reforms in biotechnology would seem in order:

**Table 1: Impact of TRIPS on the Pharmaceutical Industry**

	<b>Globally Important Diseases</b> (e.g., diabetes, cancer, cardiovascular drugs)	<b>Diseases of High Priority in Developing Countries</b> (e.g., vaccines (cholera), malaria, tuberculosis (TB) drugs)
<b>Impact on Large Multinational Companies</b>		
<b>Pre-TRIPS</b>	Were the world's means for innovation of new drugs. Aggressively protected these products with IP. Little interest in marketing in developing countries.	Almost no interest. Have donated some needed drugs in special situations.
<b>Post-TRIPS</b>	Will continue to be the major innovators and will continue to aggressively protect these products through patents. They will be more responsive to developing country needs.	Will participate in development with public leadership through PSOs. Public has to ensure access (affordability, supply, etc.) because this is of no interest to the companies.
<b>Impact on Developing Country Manufacturers</b>		
<b>Pre-TRIPS</b>	Can reverse engineer. Difficult to obtain license and technology transfer for production of new products primarily because multinationals do not want to risk losing control of IP and because the developing country producers do not meet GMP standards.	Major area of activity with focus on production of vaccines and generics. But R&D is low priority because there is little potential for benefit from new innovation.
<b>Post-TRIPS</b>	Cannot reverse engineer, but out-licensing from multinationals with parallel import controls may be a real option. Developing country companies will need to achieve GMP standards if they wish to export or collaborate with multinationals.	Major area of need. Opportunity for collaboration with PSOs. TRIPS will provide developing country companies with IP protection opportunities, thus making R&D more attractive.
<b>Interaction between Developing and Developed Country Companies</b>		
	Developing country companies will still be at a disadvantage. They might do contract manufacturing because of the greater likelihood that the IP of developed country companies will be protected. Developed country companies will insist that developing country collaborators or licensees meet GMP standards. Generous support for R&D by developing country governments is necessary for developing country companies to take part in new technologies or to develop their own IP.	Greatest area for collaboration. Developed country companies will likely seek collaboration with developing country companies. Clinical trial data are very important, and developed country companies should try to control them. Generous support for R&D by developing country governments and donors is necessary for their companies to have involvement in new technologies or to develop own IP.

Source: Richard T. Mahoney, Arizona State University and MIHR-Centre for the Management of Intellectual Property in Health Research and Development. Personal communications.

Raise the non-obviousness standards. This would reduce significantly the number of issued patents. It does not require legal reform but only changes in patent office policies.

- Improve the system of patent examination to reduce the number of wrongly issued patents, reduce the cost for and streamline the re-examination process, and change the presumption of validity. This would specifically address many concerns by developing countries about biopiracy and reduce the misappropriation of traditional knowledge.
- Cut back on the range of patentable subject matter. This is particularly obvious in genomics research, where patents are issued on genomic information that pushes the system to reach into what is intangible.
- Introduce everywhere the concept of “dependency licenses” (or research AND utility exemption), which is only enacted in some legal systems—not in the USA or under TRIPS. Introducing such dependency licenses would reduce significantly the number of licenses required to market an invention.

The fourth point is the only one that would require legal reform, which makes these proposals more feasible and perhaps acceptable. If developing countries could unite and enact these reforms, which are all believed to be within a liberal TRIPS interpretation, then other countries would likely follow. Note that WIPO is currently reviewing the impact of patent systems on developing countries.<sup>19</sup>

## **2.4 Technology Transfer in the Context of Multi-stakeholder Partnerships and Globalization**

### **2.4.1 Forms of Technology Transfer**

Technology transfer is a popular term to express the transfer of knowledge. An essential aspect of development, it has critically shaped our evolution and history. Such transfer, however, is never straightforward—it is a very complex interaction between and among a number of factors, many of which are highly specific to particular circumstances. We can usefully consider it from three different perspectives:

1. From academia to industry (institutional flow)
2. From one country to another (geographic flow)
3. From basic research to the market place (product development flow).

Each of these three aspects of technology transfer has their own dynamics and are strengthened or weakened by government policies, laws and regulations, and structural constraints. The three types listed above are interactive, and all three often occur in the same product or service. It is nevertheless useful to analyze each separately to identify the key drivers, constraints, and opportunities.

The first type of transfer, from academia to industry, is well understood and quite systematic, at least in the USA (e.g., Coffman *et al* 2003 on universities; Keusch and Nugent 2004 on the National Institute of Health). For the last 20 years, the university-industry technology licensing interface has been “regulated” to some extent by the Bayh-Dole Act of 1980, with all major universities having adopted a similar or identical policy as the Act.

The second type of technology transfer, the geographic transfer, is more complex. It includes any of the below, and is often a combination of several:

- the transfer of a turn-key operation where one entity builds and operates (or sells) a finished production unit;
- licensing arrangements, especially those including the licensing of know-how (or trade secrets);
- research collaborations;

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<sup>19</sup> The latest meeting took place during the “Assemblies of the member states of WIPO”, the 39<sup>th</sup> series of meetings in Geneva, 22 September to 1 October 2003. Many interesting papers from that meeting are posted on [www.wipo.int](http://www.wipo.int)

- different types of alliances ranging from collaborations to minority ownerships to joint ventures to strategic and corporate partnering;
- mergers and acquisitions; and
- the long term capacity building initiatives, such as those pursued by many Asian countries who send large numbers of their bright students to the USA or Europe for studies.

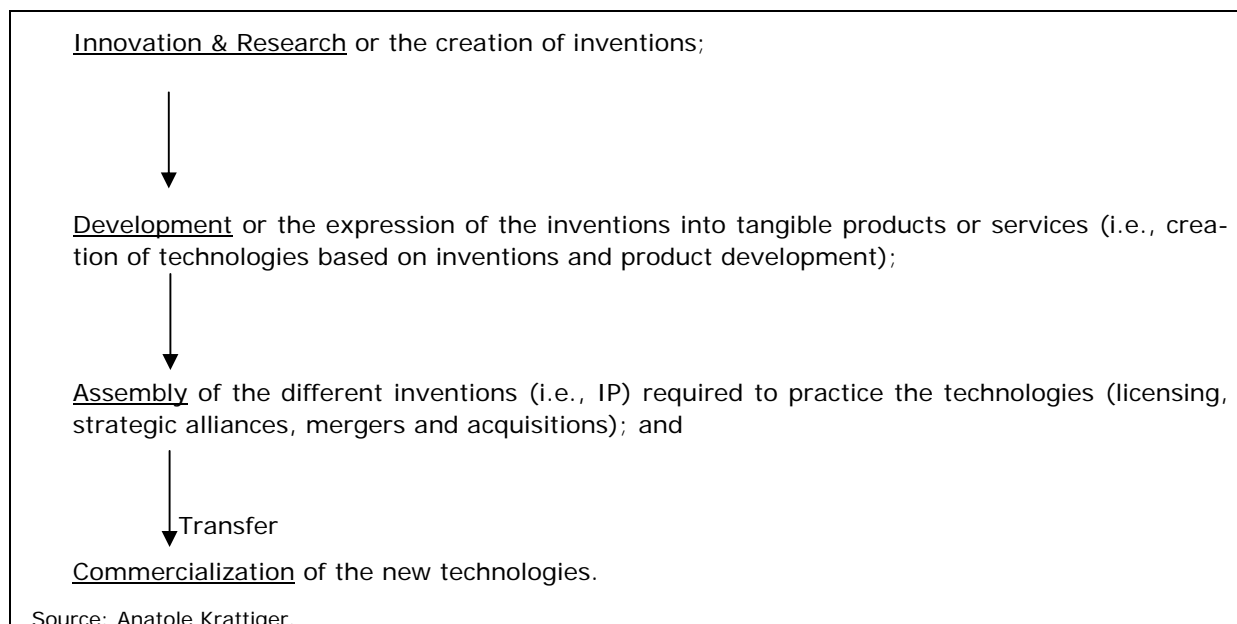
Many factors govern this type of transfer. It is also an area where a plethora of NGOs, Inter-Governmental Organizations (IGOs), university programs, bilateral and multilateral agencies are active, each focusing on a particular aspect or niche. Few initiatives exist to facilitate company-company biotechnology transfer and to easily allow for private investments. Several years ago, the International Finance Corporation (IFC) considered creating a program in this area but to the knowledge of the author the agency never implemented the strategic plan it had commissioned.

The third way of looking at technology transfer, product development flow, is again very complex, primarily because of IP entanglements and the need to “assemble” technologies for even basic inventions. Figure 2 breaks such transfers down into a fairly simple schematized process (Figure 2). There are several distinctive steps, with the overall process strongly market driven. The assembly of the different inventions leading to freedom to operate in the market place is strongly influenced by institutional capacities to manage IP and by institutional strategies related to partnership building. This is undoubtedly one of the most critical areas where developing countries could benefit greatly from assistance. The last step, or the commercialization of new technologies, is also strongly influenced by regulatory hurdles of many different kinds, and these probably add the greatest costs to technology transfer.

Conventional wisdom states that a strong IP regime encourages research investments and thus the creation of inventions. Whether or not this is the case remains debatable, but what cannot be disputed is that IP regimes are spreading globally and that a key challenge for developing countries is to make the best use of them. To fight the system and change it is a strategy with many merits but also with almost impossible challenges. It would, moreover, take a long time to have an impact. Of course, this should not preclude incremental changes in the system, such as open-source licensing, especially for research tools and processes.

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**Figure 2: Moving inventions to the market place**



#### **2.4.2 The Interactive Nature of Technology Transfer<sup>20</sup>**

For a long time technology transfer has been linear, but this linear model of technology transfer has radically changed with the advent of globalization and the emergence of the life sciences (viz., biotechnology). It is now interactive between downstream and upstream actors and interwoven between the public and private sector, which has added several additional layers of constraints and challenges. Particularly in biotechnology, transfers happen in both ways, within and between public/private networks. Those who are outside the network have difficulties getting in, not least because of the high transaction costs associated with IPRs and other regulatory aspects, particularly biosafety.

In international development, technology transfer is further hindered by forces unleashed by globalization. The liberal economic fundamentalism of the 1980s and early 1990s, although somewhat fading in fashion these days, has caused a series of new actors to emerge and forced established actors to assume new roles. For example, the private sector has become an important pillar in development policy,<sup>21</sup> with non-governmental organizations (NGOs) and civil society taking on increasingly complex responsibilities, not least that of technology diffusion. This in itself need not hinder technology transfer, but it often does so in practice because of the multitude of actors.

Most significantly, however, existing institutions that cushioned the negative effects of change in the past have been significantly weakened. This weakening is seen by the fact that economic and development policy formulation is becoming more and more reactive rather than proactive. Bilateral policy by and large is still based on the linear model, with policy makers/advisers strongly oriented by discipline. More importantly, however, bilateral development strategy is inappropriately influenced by geopolitical interests and historical national or personal relationships.

In other words, what Hegel called “lazy existence,” the irrational continuation of outdated institutional structures and practices, is nowhere more strongly entrenched than in bilateral development agencies. Multilateral institutions arguably suffer from the same if not an even wider range of problems limiting their effectiveness, not least their being profoundly under-funded and deeply over-bureaucratic. The major multilateral financial institutions (such as The World Bank and International Monetary Fund [IMF]) continue to promote economic reform, but their programs are rarely accompanied by parallel initiatives and the financial resources required to meet basic human needs in the critical areas of health, agriculture, and energy, especially in the poorest areas of developing countries. Other multilateral institutions, such as the Consultative Group for International Agricultural Research (CGIAR), or the Food and Agriculture Organization of the United Nations (FAO), have not come to terms with fundamental changes in their operating environment, which is far more complex than it was during these institutions’ heyday. The mandate of the CGIAR, for example, has become much broader and more important than a few decades ago, yet its organizational structure over the same time period has grown increasingly inefficient. Its financial resources are absurdly inadequate for the needs. In the end, one has to wonder whether these institutions are still relevant—they can hardly be described as inspirational forces for change. How can they be when the institutions themselves have lost the capacity to change?

To illustrate this point, until the late 1980s agriculture in the developing world had primarily been handled by nation-states and a few multilateral organizations. Globalization has since radically reshaped agricultural research and production to such an extent that the established political and institutional boundaries of institutions created one or two generations ago no longer fit the current realities. The FAO, for example, is not only overly bureaucratic, but its program formulation and strategic priorities are inappropriately influenced by “favoritism”. The multi-stakeholder system of governance in the CGIAR system, on the other hand, has made it moribund: financially in dire straits, arguably leaderless, and unable to institute overdue reforms.

Globalization segments markets, which effectively excludes poor countries from the market economy and accelerates globalization’s other negative effects on the rural poor. Sadly, there are no new institutions adapted to the new world order that can mitigate the social costs of liberalization. Investments to

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<sup>20</sup> This section draws substantively from Krattiger (2004a).

<sup>21</sup> Witness for example the call in Johannesburg (the 2002 World Summit on Sustainable Development) for more public-private partnerships in the energy and water sectors.

transfer and adapt technology—let alone generate it—are wholly inadequate. At a time when the world around the CGIAR has become more complex, with many more actors and spheres of influence, the system has not re-grouped and re-focused but expanded and become more and more diffuse. This is particularly devastating because the strategic and humanitarian work of these centers is more important than ever.

Paradoxically, over the same period, the private sector undertook mergers and acquisitions in agricultural biotechnology, reducing the number of key players from some 20 plus to a mere five or so. This happened during a time when development agencies, NGOs, and numerous other service organizations increased and multiplied.

## **2.5 Regulatory Aspects**

There is arguably no higher expense to bringing health-related and agricultural biotechnology to market than regulatory costs. In agriculture, for example, it is estimated that to move a new transgenic or GM crop through the biosafety and food safety regulatory system costs between \$8-12 million per transgenic event. One reason for the high cost is that deregulation must simultaneously occur in a series of countries, since most agricultural products are traded. In the medical field, clinical trials are even more expensive: costs of several hundred million dollars for regulatory compliance in the USA for a new drug are not unusual.

But regulatory hurdles come in many forms, ranging from the above to regulations on capital transfers to foreign countries (e.g., foreign direct investments), product labeling, ownership structures, and so forth. The aim here is not to review and discuss them to point out that regulatory obstacles add more to technology transfer costs than IP related issues.

The case of generic drugs, however, is worth discussing in more detail. The generic drug industry is now over 30 years old. It is nascent in several developing countries, most notably India. In 2002, the Hatch-Waxmann act in the USA granted the generics industry significant advantages and it is opening the markets considerably. Nevertheless, a generic drug must still obtain Food and Drug Administration (FDA) approval to be marketed in the USA. It must be demonstrated that it contains the same active ingredient as the original patented drug, is identical in dosage, strength, and route of administration, includes mostly the same use indications, meets the same batch requirements for identity, strength, purity, and quality, and is manufactured under the same FDA GMP<sup>22</sup> regulations. These requirements are not, of course, minor, and they will effectively exclude many potential drug companies in the developing world from entering the US market unless they considerably upgrade their manufacturing technologies and know-how. Furthermore, biotechnology-derived drugs are, in most cases, more complex to manufacture, and brand manufacturers possess considerable know-how that they vigorously guard as trade secrets. Although developing countries are often seen as benefiting hugely from generic drug manufacturing, this is unlikely except for some traditional chemicals.

## **3. A Review of Existing Technology Access and/or Transfer Systems and Investment Services**

### **3.1 Introduction**

While the few years of financial difficulty in the 1990s led industry to streamline, focus, and partner in ingenious ways to survive and flourish, the public sector engaged in no major new alliances and did not pursue innovative approaches to accelerate society's use of its inventions. By and large the public sector in many developed countries protects its major inventions and offers to license them to industry. This approach has prevailed since the USA Bayh-Dole Act in 1980. In developing countries, however, no

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<sup>22</sup> [www.fda.gov/cdrh/devadvice/32.html](http://www.fda.gov/cdrh/devadvice/32.html)

clear policies exist. Most technology is transferred either by the private sector directly (Foreign Direct Investments (FDI), joint ventures, other forms of collaborations) or through a plethora of NGOs and bilateral/multilateral programs, often focusing specifically on humanitarian needs.

This section reviews the types of mechanisms that specifically deal with technology transfer, IP transfer, and the facilitation of investments. The review is not institutionally exhaustive; rather, it emphasizes the methodology or approach of different institutional mechanisms that assist technology transfer and investments. In practice, some mechanisms/institutions given as examples may fall into different categories, but they are discussed in terms of particular mechanisms to illustrate an aspect of their function.

### 3.2 Royalty Collection Agencies

In its simplest form, a license collection agency is a mechanism whereby one entity collects royalties on behalf of its members for a small fee. In this situation, the members make deals and set the royalty rates, either bilaterally or multilaterally. The multilateral system is best known in the music business. Many restaurants and bars, for example, have jukeboxes with hundreds of CDs where customers insert some money and select songs from individual CDs. Each time a song is played, a percentage of the revenues goes to the publisher of the CD and artist. The challenge for such a system is to determine how many times a particular CD has been played within a certain period of time. To monitor each bar would cost more than the royalties that the system would generate, and so a system of “averages” has been developed: selected locations are monitored to establish the royalty payment for all other pubs. Such systems exist in most countries, including the developing world (e.g., the Copyright Organization of Trinidad & Tobago<sup>23</sup>). Another prominent example is royalty collection for public performances. In the USA, the American Society of Composers, Authors and Publishers (ASCAP), composed of over 170,000 artists and publishers of every kind of music, protects the rights of its members by licensing and distributing royalties for the non-dramatic public performances of their copyrighted works.<sup>24</sup> ASCAP makes giving and obtaining permission to perform music simple for both creators and users of music, and its licensees encompass all who want to perform copyrighted music publicly.

Other examples of a mixed bilateral/multilateral system are the British Society of Plant Breeder's<sup>25</sup> and SICASOV<sup>26</sup> in France. Similarly to the music business, these generally non-profit societies agree to collect royalty fees from users in return for a percentage of the royalties or for a flat annual fee. Royalty rates are set by the members, and some societies advocate for the protection of IP in their respective industries, countries, or regions.

**Table 2: Summary and Pros/Cons of Royalty Collection Agencies**

Pros	Cons	Conclusions
Encourages widespread use of the agencies' offers (music, films, etc.) Easy to set up Low cost of collection Little overhead No antitrust considerations	Useful only if many players or an entire industry participates Difficulty in having an entire industry agree on flat royalty rates Need to set up national organizations in each country	Useful if licensing industries already established Can be created by industry itself Needs little support from governments/multilateral agencies

<sup>23</sup> [www.cott.org.tt](http://www.cott.org.tt)

<sup>24</sup> [www.ascap.com/index.html](http://www.ascap.com/index.html)

<sup>25</sup> [www.bspb.co.uk](http://www.bspb.co.uk)

<sup>26</sup> [www.sicasov.com](http://www.sicasov.com)

### 3.3 Information Clearing Houses

The term “clearing house” derives from banking institutions and refers to the mechanism by which checks and bills are exchanged among member banks so that only the net balances need to be transferred in cash. Today, the term has much broader meaning and includes any mechanism whereby providers or goods, services, and/or information are matched.

Clearing houses for science have been discussed for a long time, and one was finally set-up in the late 1990s. The Convention on Biological Diversity (CBD)’s clearing house<sup>27</sup> for biodiversity aims to promote and facilitate technical and scientific cooperation, develop a global mechanism for exchanging and integrating information on biodiversity, and develop the necessary human and technological network. The CBD Secretariat also created the “Cartagena Protocol on Biosafety Clearing-House,”<sup>28</sup> a model for many national biosafety clearing houses (e.g., Belgium<sup>29</sup>) and for multilateral biosafety clearing houses, such as BioBin,<sup>30</sup> a co-operative resource on safety in biotechnology developed between OECD’s BioTrack<sup>31</sup> Online and UNIDO’s BINAS.<sup>32</sup> The latter is the Biosafety Information Network and Advisory Service of UNIDO, which monitors global developments in regulatory issues in biotechnology, provides a one-stop portal to national biosafety regulations and focal points, and also offers important training resources in biosafety, such as the biosafety decision tree.

Finally, information clearing houses also provide entry to a country’s biotechnology (e.g., Finland<sup>33</sup>), as do training clearing houses that offer training for biotechnology technicians (e.g., BioLink<sup>34</sup>), and industry links, updates, news, and job markets (e.g., BioPortfolio<sup>35</sup>).

It should be mentioned that a myriad of other forms of information clearing houses exist, including such general web search engines as the ubiquitous Google<sup>36</sup> and the clever Kartoo<sup>37</sup>, as well as patent search sites.<sup>38</sup>

**Table 3: Summary and Pros/Cons of Information Clearing Houses**

Pros	Cons	Conclusions
Relatively easy to set up Easy global accessibility	Only useful if comprehensive Requires constant maintenance to be up-to-date, comprehensive, and user friendly Difficult to keep updated In some areas (e.g., biosafety), there are almost too many clearing houses, although each one focuses on slightly different aspects; some see the need for a clearing house of clearing houses	Useful for the exchange of specific information related to an activity or industry Does not facilitate technology transfer <i>per se</i> Very useful if also offering analytical services/tools

<sup>27</sup> [www.biodiv.org/chm/](http://www.biodiv.org/chm/)

<sup>28</sup> [www.biodiv.org/bch/default.asp](http://www.biodiv.org/bch/default.asp)

<sup>29</sup> [www.biosafetyprotocol.be/intro.html](http://www.biosafetyprotocol.be/intro.html)

<sup>30</sup> [www1.oecd.org/ehs/biobin/](http://www1.oecd.org/ehs/biobin/)

<sup>31</sup> [www.oecd.org/departement/0,2688,en\\_2649\\_34385\\_1\\_1\\_1\\_1\\_1,00.html](http://www.oecd.org/departement/0,2688,en_2649_34385_1_1_1_1_1,00.html)

<sup>32</sup> [www.binas.unido.org/binas/](http://www.binas.unido.org/binas/)

<sup>33</sup> [www.vyh.fi/eng/environ/bdclearh/gene/biotech.htm](http://www.vyh.fi/eng/environ/bdclearh/gene/biotech.htm)

<sup>34</sup> [www.bio-link.org/resCurriculum.htm](http://www.bio-link.org/resCurriculum.htm)

<sup>35</sup> [www.bioportfolio.com](http://www.bioportfolio.com)

<sup>36</sup> [www.google.com](http://www.google.com)

<sup>37</sup> [www.kartoo.com](http://www.kartoo.com)

<sup>38</sup> E.g. paid services such as [www.delphion.com](http://www.delphion.com), [www.mogee.com/](http://www.mogee.com/), [www.m-cam.com](http://www.m-cam.com) or [www.micropatent.com](http://www.micropatent.com) or free services such as [www.uspto.org](http://www.uspto.org), [ipdl.wipo.int/](http://ipdl.wipo.int/), [www.surfip.gov.sg/sip\\_home.htm](http://www.surfip.gov.sg/sip_home.htm), [www.ep.espacenet.com](http://www.ep.espacenet.com), [www.patent.gov.uk](http://www.patent.gov.uk) or [www.cambiaip.org/cambiaIP/Home/welcome.htm](http://www.cambiaip.org/cambiaIP/Home/welcome.htm)



### 3.4 Technology Clearing Houses

As the preceding section revealed, clearing houses in IP and technology are varied. Much depends also on how broadly one interprets the term. In a general sense, the royalty collection schemes described under Section 3.2 are forms of clearing houses as well. The term, however, is not widely used in corporate environments and belongs much more to the international development terminology of the UN system.

This section describes two types of technology clearing houses: web-based IP auction and licensing sites and a special public sector initiative called the Public Intellectual Property Resource for Agriculture (PIPRA).

#### 3.4.1 "Online" IP Exchanges

During the "dot com" boom of the late 90s, many new web sites sprung up to facilitate direct sales and marketing to businesses. These so called "business-to-business" or "B2B" operations were in effect virtual trading floors, primarily for products. Many went bust and only a few substantial ones remain<sup>39</sup> but the principles have been widely incorporated into business models and strategies.

One subset of B2Bs are online IP exchanges. The systems are quite simple, by and large consisting merely of a list of cross-referenced technologies and patents, allowing prospective sellers (licensors) and prospective buyers (licensees) to initiate negotiations. Some sites are auctions, very much like the now famous eBay<sup>40</sup> for consumer products. Again, more than half of those founded in the last ten years no longer operate.<sup>41</sup>

The rationale for these sites was simple: markets do not operate efficiently and transaction costs are high because buyers and sellers do not have access to the same detailed information. A comprehensive web-based clearing house would lower the transactions costs and increase participation. In practice, however, such gains have not been realized with IP exchanges. The reasons are obvious: the applications specified in patents are highly heterogeneous, often difficult to define, and can only be valued after considerable experimentation and refinement has taken place and then only within the technological application (Graff and Zilberman 2001). There are, of course, exceptions. One such relates to general-purpose research methods, such as the Cohen/Boyer patent,<sup>42</sup> which has been broadly licensed to hundreds of institutions for a flat yearly royalty fee.

There are several other reasons that IP exchanges are not very common. Few of them are complete enough to allow a prospective licensee to assemble all the needed licenses to obtain freedom-to-operate (FTO). In addition, actually negotiating with a company often not only allows for cross-licensing but also for the transfer of know-how or trade secrets. And finally, IP owners typically use their patent portfolios as a strategic tool, a practice not conducive to wide licensing. Merely clicking on a web, downloading a standard license, and wiring money is rarely sufficient for technology transfer to occur.

On the other hand, many companies do pursue liberal out-licensing. For example, HP's out-licensing strategy is perhaps considered the computer industry's most aggressive.<sup>43</sup> HP files over 5,000 patents per year and enters into hundreds of licenses, bringing in well over \$1 billion in royalties, much of which

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<sup>39</sup> e.g. [www.alibaba.com](http://www.alibaba.com)

<sup>40</sup> [www.ebay.com](http://www.ebay.com)

<sup>41</sup> Operational IP exchanges as of this date include: [www.inventionregister.com](http://www.inventionregister.com), [www.ipex.net](http://www.ipex.net), [www.ipmarketplace.com](http://www.ipmarketplace.com), [www.newideatrade.com](http://www.newideatrade.com), [www.patentauction.com](http://www.patentauction.com), [www.pl-x.com](http://www.pl-x.com), and [www.yet2.com](http://www.yet2.com). Specialized sites in the biotech are include: [www.knowledgeexpress.com](http://www.knowledgeexpress.com), [www.pharmalicensing.com](http://www.pharmalicensing.com), and [www.techex.com](http://www.techex.com); one specializes in university technologies: [www.techtuesday.com](http://www.techtuesday.com)

<sup>42</sup> US Patent No 4,237,224 . Dec. 2, 1980 Process for Producing Biologically Functional Molecular Chimeras. [patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=/netahtml/srchnum.htm&r=1&f=G&l=50&s1=4,237,224.WKU.&OS=PN/4,237,224&RS=PN/4,237,224](http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=/netahtml/srchnum.htm&r=1&f=G&l=50&s1=4,237,224.WKU.&OS=PN/4,237,224&RS=PN/4,237,224)

<sup>43</sup> [www.hp.com/hpinfo/newsroom/feature\\_stories/2002/patents02.html](http://www.hp.com/hpinfo/newsroom/feature_stories/2002/patents02.html)

goes directly to the company's bottom line profitability. Just 5 years ago HP closely guarded many of its patents.

### 3.4.2 "Managed" IP Exchanges

PIPRA is an initiative by universities, foundations and non-profit research institutions to make agricultural technologies more easily available so that subsistence crops for humanitarian purposes in the developing world and specialty crops in the developed world can be more rapidly developed and distributed. The initiative stemmed from a Rockefeller Foundation program and has recently been announced by several presidents of US universities (Atkinson *et al* 2003).

The rationale for PIPRA is that IP is often unwillingly encumbered. Universities, for example, typically grant world wide exclusive licenses. Changing these licensing policies and retaining the rights for humanitarian uses in the developing world would make it much easier to transfer IP and TP from universities to the developing world.

Conceptually related to this problem in the developing world is the situation of specialty crops in the USA. Many minor crops are important for economic development within certain regions or states, and their economies depend on universities to develop new crop varieties with higher productivity, better nutritional value, enhanced resistance to diseases, and reduced impact on the environment. Public and private organizations that serve such specialty interests, however, often find it difficult and expensive to obtain FTO for a particular biotechnology application. PIPRA thus brings together public sector institutions to collaborate and bundle their licensed and un-licensed technologies ("shared technology packages"), making them more readily available to member institutions for commercial licensing or for designated humanitarian or special use. As part of this effort, a database of patented agricultural technologies is being developed to inform researchers on FTO, allowing them to modify their research plan to include more licensable technologies (IP and TP) or public ones.

**Table 4: Summary and Pros/Cons of "Online" Technology Clearing Houses**

Pros	Cons	Conclusions
Cheap to maintain Low transaction costs	Difficult to get "critical" technology mass Difficulty in valuation limits participation	Appropriate for general purpose technologies, platform technologies, bundles Limited in furthering wide-spread technology transfer

**Table 5: Summary and Pros/Cons of "Managed" Technology Clearing Houses**

Pros	Cons	Conclusions
Effective in well-defined niches	Costly to set up compared to online systems Limited applicability	Appropriate in development Furthering technology transfer in special cases

## 3.5 Open-Source Innovation Clearing Houses

One special category of clearing houses is especially worth mentioning. Consider a web site initiated by two Harvard Business School professors, economist Barry Nalebuff and law professor Ian Ayres, to prove that innovation is a skill that can be taught. One hotly debated idea at the site in recent months is the so-called "reverse 900 number"—where telemarketers pay people to accept calls. Their system of

innovation is growing on the web<sup>44</sup> and explained in a recent book (Nalebuff and Ayres 2003) that deploys economics, game theory, psychology, and contract law to argue that innovation can be routinized and institutionalized.

Another web site is available for anyone to post ideas for innovative products and services. Anyone can turn the ideas into marketable products if they wish, without the need for licenses. HalfBakery<sup>45</sup> started with the slogan “Muffin ventured, muffin gained”(!) but it quickly gained international fame when what may have appeared as “half baked ideas” were turned into commercially successful products. One of the ideas recently posted is the “Coffee Cup Watermark: A mug with your seal on the bottom”. It is a regular-looking coffee mug, but on the bottom (in relief) is the mirror image of your coat of arms, seal, or logo. Now, when you carelessly put your cup on an important piece of outgoing correspondence, instead of leaving an unsightly coffee ring, it imprints an official-looking watermark, or “coffeemark” if one is drinking coffee. Although this may seem a useless idea—it actually is quite useless—CoffeeMark Mugs are already on the market. The case illustrates how ideas can be transferred to the market place without patent protection (except trademarks).

More related to biotechnology is so-called “open-source” licensing. Open-source licensing is essentially the licensing of inventions without patent protection—the only requirement is that any licensee must agree to also make available to others any improvements in the invention or technology. Perhaps there is a need for a biotechnology clearing house, whereby anyone can post biotechnology inventions that are not IP protected. More importantly, at least for research purposes, an exchange could also be useful whereby non-proprietary materials (vectors, plasmids, expressed sequence tags [ESTs], etc.) are posted and sent to anyone who wants to use them (perhaps for a simple production, maintenance, and mailing fee).

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**Table 6: Summary and Pros/Cons of Open-Source Innovation Clearing Houses**

Pros	Cons	Conclusions
Low cost exchange of ideas, inventions, and materials	Applicability in biotechnology untested	Potentially appropriate for open-source licensing and the diffusion of tangible research materials

### **3.6 Honest-Brokers and Other Forms of Facilitators**

“Honest broker” is a term often used in peace negotiations but it has also been used by non-profit organizations engaged in public-private partnership building. One self-proclaimed honest broker is the International Service for the Acquisition of Agri-biotech Applications (ISAAA<sup>46</sup>). It operates primarily as a facilitator, matching available technologies to meet identified needs, brokering technologies, and building capacity by transferring knowledge and know-how between companies in developed countries and the public sector in developing countries. ISAAA also addresses other constraints in biotechnology transfer, such as regulatory and public perception issues.

The initial concept of ISAAA some 12 years ago was to broker many IP transfers but the organization quickly learned that deals for royalty-free IP licensing alone do not allow resource poor farmers to benefit from new ag-biotech products. It subsequently focused more on downstream partnership building activities with some considerable success.

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<sup>44</sup> [www.whynot.net/](http://www.whynot.net/)

<sup>45</sup> [www.halfbakery.com](http://www.halfbakery.com)

<sup>46</sup> [www.isaaa.org](http://www.isaaa.org)

A similar, more recent institutional mechanism is the African Agricultural Technology Foundation (AATF<sup>47</sup>). Like PIPRA, it is also emerging from a Rockefeller Foundation initiative. AATF recognizes that new and unique public-private partnerships are needed to remove many of the barriers that have prevented smallholder farmers in Africa from gaining access to existing agricultural technologies. Focusing on the creation of these public-private partnerships, it seeks to dramatically improve access to agricultural technologies, materials, and know how, at the same time promoting efforts to create sustainable markets.

AATF has two unique characteristics: it is prepared to in-license technologies from the private sector, which it then sub-licenses to its partners in Africa, and more importantly it strongly focuses on downstream activities, including the creation of local, national and regional markets for the products produced from transferred technologies. The goals are to create more sustainable technology transfer mechanisms and to allow national institutions to more effectively absorb new technological concepts and adopt them for productive use.

AATF's decision to in-license and then sub-license technologies is of particular interest. One reason companies are somewhat reluctant to donate IP and technologies for humanitarian use is the potential recipient's inability to steward the donation. Companies cannot provide the requisite infrastructure to developing country institutions, and the significant senior management time any development project takes significantly raises costs for private sector participation, both directly and in lost opportunity costs. Having a non-profit intermediary that is willing and able to strengthen technological stewardship and can absorb some liabilities and management functions is of high value.

A similar organization in human health biotechnology is the Global Alliance for Vaccines and Immunization (GAVI<sup>48</sup>). Created in 1999, it functions as a broker for private and public sector entities committed to expanding the use of vaccines in the developing world. International organizations, governments, vaccine industry, research institutions, and major philanthropists collectively form a dedicated partnership serving the shared GAVI objectives. It includes as a subsidiary, or as a financial arm, The Vaccine Fund, which sponsors GAVI's objectives in poorer countries. The alliance also has programs to stimulate the vaccine industry to develop and supply vaccines that are vital to low-income countries. GAVI acts more at the product transfer level, whereas ISAAA and AATF function somewhat more upstream. ISAAA initially also aimed at charting new territory and creating models (which are more time consuming) rather than transferring large quantities of technologies.

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**Table 7: Summary and Pros/Cons of Honest-Brokers/Facilitators**

Pros	Cons	Conclusions
<p>Oversee/encourage technology stewardship</p> <p>Typically fulfill a range of integrated functions (capacity building, brokering, distribution, etc.)</p> <p>May be highly effective in transferring products (e.g., GAVI)</p>	<p>Demands complex institutional arrangements and significant funding</p> <p>May be limited in transferring large volume of technologies</p> <p>Limited to serving non-profit, directly humanitarian activities</p>	<p>Appropriate to chart new territory and bring public and private actors closer together</p> <p>Effective in setting new models of collaboration specific to geographic areas, technologies, industry types, or needs</p>

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<sup>47</sup> [www.aftechfound.org](http://www.aftechfound.org)

<sup>48</sup> [www.vaccinealliance.org](http://www.vaccinealliance.org)

### 3.7 IP Management Services

The best known IP management services are law firms specializing in patenting and licensing and management consultants like KPMG, the Boston Consulting Group, Ernst & Young, and many others. These commercially-oriented entities are discussed in the next section; let us first focus on the non-profit players in this field.

From the non-profit and international development perspective, a new organization headquartered in Oxford, UK, called MIHR<sup>49</sup> (also stemming from a recent Rockefeller Foundation initiative), essentially acts as a service to public sector organizations in developing countries (and some private ones) to manage their IP (in-house generated, in-licensed, to-be in-licensed) more authoritatively. It assumes that health programs that manage IP well are more effective at mobilizing resources, technologies, and partners to deliver improved health care to the poor. As such, MIHR sees itself addressing a critical step in business development. Specifically, the organization has the following strategic goals:

- define effective licensing practices for public sector management of IP so that new and improved products can become more readily available to the poor in developing countries (an IP management handbook will be published in early 2004 by *IP Strategy Today*<sup>50</sup>);
- promote the development of new norms for licensing and other management of IP;
- become an international mechanism for effectively exchange information in the rapidly evolving field of IP management in health research;
- deliver training to increase capacity in IP management for health technology R&D in developed and developing countries; and
- promote coordination and synergy in public sector product R&D.

MIHR has worked with several companies and institutions, including VACSERA,<sup>51</sup> which it helped to formulate an IP strategy and internal IP management practices, and the Medical Research Council of South Africa,<sup>52</sup> which it assisted with IP management. In both cases, MIHR emphasized sound institutional policies and the implementation of strategies designed to aid partnership development, either to commercialize in-house IP or in-license IP and know-how. In a sense, MIHR works more at the institutional IP management level, laying the groundwork for commercial deals that address the needs of the poor.

There are evidently many other entities that broadly fall within this category. To name but a few:

- national entities such as SARIMA, the South African Research and Innovation Management Association;<sup>53</sup>
- the embryonic Public Interest Intellectual Property Advisors (PIIPA<sup>54</sup>), an organization that helps developing country clients locate intellectual property professionals worldwide who are willing and able to advise them on a voluntary basis;
- the more technology focused CAMBIA<sup>55</sup> and its Intellectual Property (IP) Resource for International Agricultural Biotechnology; and
- university based programs, such as the Strategic World Initiative for Technology Transfer (SWIFTT<sup>56</sup>) at Cornell University.

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<sup>49</sup> Center for the Management of IP in Health R&D; [www.mihir.org](http://www.mihir.org)

<sup>50</sup> [www.biodevelopments.org/ip/index.htm](http://www.biodevelopments.org/ip/index.htm)

<sup>51</sup> VACSERA is a premier manufacturer of vaccines and biological products in Egypt and in the Arab world. Privatized in 2002, until then it was a government organization. See [www.vacsera.com](http://www.vacsera.com)

<sup>52</sup> [www.mrc.ac.za](http://www.mrc.ac.za)

<sup>53</sup> [www.sarima.co.za/index.asp](http://www.sarima.co.za/index.asp)

<sup>54</sup> [www.piipa.org](http://www.piipa.org)

<sup>55</sup> [www.cambia.org](http://www.cambia.org)

<sup>56</sup> [www.swifft.cornell.edu](http://www.swifft.cornell.edu)

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**Table 8: Summary and Pros/Cons of IP Management Services**

Pros	Cons	Conclusions
Typically provide integrated services including institutional capacity building and personnel training Often well trusted	Not typically effective at commercial interfaces Need to invest significantly into fundraising	Good to address systemic issues Setting of new modes of interactions between public and private sectors

### 3.8 IP Commercialization Agents

Many types of “consulting” services broadly fall within this category, but only one institution is solely dedicated to the profitable commercialization of third party IP in the fields of health, medicine, and other biotechnologies: BTG Ltd. ([www.btgplc.com](http://www.btgplc.com); formerly known as the British Technology Group). Perhaps the world leader in commercializing novel technologies, the company operates globally with a focus on Europe, North America, and Japan. The firm combines a strong commercial focus with a deep understanding of how to develop innovation, enhance IP, and achieve critical development milestones. Clients include public research centers and global technology companies, from start-ups to multinational companies. It functions as a retainer for technology innovators, charging fees and sharing in revenues generated from its services.

In addition to services in several areas (see below), the company seeks licenses for the technologies they manage. This includes assistance in seeking venture capital, the management of startups around platform technologies, and R&D funding to ensure that the technologies in BTG’s portfolio become commercially viable. To accomplish this, BTG acquires or in-licenses promising technologies, assists in patent protection of inventions, forms alliances to advance inventions through an R&D phase, and develops technology marketing strategies. In effect, BTG pools necessary technologies centered on the core innovations it manages in order to increase the value of its portfolio.

The company currently manages over 350 technologies, over 6,000 patents or patent applications, and more than 400 license agreements (half of which are generating annual royalties). Starting as a government funded agency, BTG has been around for over 50 years in different forms. In 1999, its revenues were in excess of \$50 million with a \$1.4 million profit before tax.

On the development side, the most prominent enterprise is the Concept Foundation<sup>57</sup> headquartered in Bangkok, which for this author is one of the most effective institutions set up by UN agencies: “With the realization that large commercial pharmaceutical companies are not interested in sponsoring several of WHO/HRP’s new contraceptive technologies, WHO/HRP is faced with immediate problems in completing development of these products. After much deliberation within the World Health Organization, the United Nations Population Fund, and the World Bank, and as a direct response to the need of the WHO Special Programme, a decision has been taken to create an independent non-profit entity for the management of intellectual property relating to products required for the public sector in developing countries” (WHO 1998).

In short, the Concept Foundation provides a mechanism to turn IP, developed or owned by international organizations, into competitive and cost-effective products to be distributed at the lowest possible cost, especially into the public sector health care channels of developing countries. This intellectual property is typically owned in the form of data from medical research and clinical trials, data from pharmacological studies, manufacturing instructions, etc. In some cases, the IP owned by international organizations such as WHO is enhanced through IP donations from pharmaceutical manufacturers to utilize it for pub-

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<sup>57</sup> [www.conceptfoundation.org](http://www.conceptfoundation.org)

lic sector health care services in the developing world. The licenses are negotiated by highly experienced Foundation staff led by a former senior executive in pharmaceuticals.

Importantly, the Foundation also ensures that these products are manufactured under international quality and manufacturing standards (e.g., GMP), properly registered and licensed, distributed, and marketed with appropriate training and counseling services. The Foundation in-licenses and then sub-licenses IP, serving as the IP custodian.<sup>58</sup> Well structured sub-licensing agreements allow the Foundation to ensure high quality production, marketing, and humanitarian distribution. It is not afraid of revoking a license if milestones, quality or quantity-wise, have not been met.

**Table 9: Summary and Pros/Cons of IP Commercialization Agents**

Pros	Cons	Conclusions
<b>Purely Commercial</b>		
Typically highly effective Can be profitable to agents and IP holder	Can be very costly to IP holders No guarantee of success Typically aggressive (a necessary trait in this type of business) and thus not ideally placed to exclusively serve public sector institutions	Very interesting business model Useful to learn from their experiences and adapt them to specifically serve the nascent private sector in the developing world, perhaps through a mix of public funding and profit driven activities
<b>Mixed Commercial/Humanitarian</b>		
Stimulates developing country pharmaceutical manufacturer's industry while currently addressing humanitarian needs Costs assumed by donations	Too few Concept Foundation type entities exist (!) Requires highly skilled business people willing to work for a non-profit entity	Very interesting business model Useful to learn from their experiences and adapt the model to other biotechnology sectors

### 3.9 Merchant Banks

The term "merchant bank" was developed hundreds of years ago to describe well financed organizations that sought high returns on their investment in return for predictable risk (which was also the original idea of a limited liability company). The most famous of the original merchant bankers were the Dutch West India Company and the East India Company, which financed trade with newly discovered colonies and held virtual monopolies in all of their trading markets throughout the colonial world. Today, merchant banking has become a sophisticated business, advising and consulting on all matters relating to acquisitions, takeovers, mergers, strategic alliances, and even bridge loans. Often, merchant banking also involves financial partnerships with client companies.

Today's investment bank services include IP audits, business valuation, due diligence and fairness opinions,<sup>59</sup> acting as confidential advisor in preparing divestiture, managing the entire process of Initial Public Offerings (IPOs), marketing divestitures, finding acquisition targets, structure transactions, providing financing, facilitating financing, and refinancing existing debt.

<sup>58</sup> The Concept Foundation mandates in all of its license agreements with pharmaceutical companies that it will make its licensed products widely available to people living in developing countries, at preferential public sector prices. All licensees of Concept Foundation are bound to public sector distribution in developing countries as their top marketing priority over sales in private markets.

<sup>59</sup> A fairness opinion provides an independent objective analysis of a proposed deal's financial aspects from the point of view of one or more of the parties to the transaction. Any number of factors in deals involving both public and private companies can trigger the need for a fairness opinion. These documents are frequently used to protect the interests of company directors, stockholders, investors, and involved parties with any kind of fiduciary responsibility. Fairness opinions are often requested in deals involving public offerings, leveraged buyouts, or major refinancing/restructuring.



The reason for briefly discussing merchant banks, or rather the services they provide, is related to the importance of cross-border mergers and acquisitions (M&As) for leveraging foreign direct investment (FDI), and for upgrading management practices and technologies. According to the *Economist Intelligence Unit*,<sup>60</sup> between 74 and 85% of FDI inflows to developing countries have been through M&As from 1999 to 2002 (although the yearly totals fell significantly in 2001 and 2002 except in China, where cross-border M&As increased more than the growth in Chinese GDP).

Merchant Banks are essentially one stop shopping centers for M&As, managing finances, agreements, required government filings, antitrust issues, valuations, due diligence, etc. Their services are crucial for any type of business, large or small. But not every M&A is successful. One of the principal reasons why cross-border M&A's are risky is because so many have failed due to valuation errors, culture clashes, and unrealized savings.<sup>61</sup>

This also directly relates to the overall scarcity of venture capital in developing countries. Acquisition strategies for biotechnology activities in developing countries have been unsatisfactory because there are not enough sound, indigenous firms available to assist with M&As, which compels industry to take the slow, expensive, risky road of *de novo* development. This limitation is particularly apparent in biotechnology: there is a dearth of medium-sized quality deals (\$2-10 million) and complications frequently arise from management re-structuring, a lack of trained managers, the need for technological upgrading, and the failure to implement predictable exit strategies. Since one of the exit strategies for venture capitalists is through sales (or acquisitions by others), thin M&A activity works to the detriment of those seeking venture capital.

The need may exist for a non-profit, merchant-bank-type institution to provide the same integrated services as a merchant bank. UNIDO is doing its part: it convened an International M&A Summit in Beijing (19-20 November 2003) to bring together investors, accounting firms, strategy consultancy firms, law firms, investment banks, and government institutions eager learn about the latest Chinese government policies, regulations, and developments in the field of M&As.

It would be inappropriate to list in table form the pros and cons of a merchant bank. The bank types are extremely diverse, ranging from large multinational companies to small venture capital investment services. In general, their services are not cheap, but as is often the case, one gets what one pays for. The advantages are certainly considerable, not least because their integrated services allow access to both high-risk venture capital and low interest capital (i.e., bond issues, IPOs, etc.).

### 3.10 Patent Pools

One of the biggest public concerns voiced against the United States Patent and Trademark Office (USPTO) for its practice of granting of patents for inventions in biotechnology, particularly in genomics, is the difficulty of accessing patented inventions for basic biological research and R&D.<sup>62</sup> One solution to this constraint is to form patent pools, a mechanism successfully implemented by other industries.

A patent pool is a voluntary agreement between two or more patent owners to license one or more of their patents to one another or third parties. In other words, they are "the aggregation of intellectual property rights which are the subject of cross-licensing, whether they are transferred directly by patentee to licensee or through some medium, such as a joint venture, set up specifically to administer the patent pool" (Klein 1997). One of the first such patent pools was created for the manufacturing of sewing machines in the mid-19<sup>th</sup> century (Merges 1999). Other examples of early patent pools include aircraft manufacturing, glass manufacturing, and radio technology. In both cases, the pools contributed significantly to industry standards (e.g., radio waves). More recently, patent pools were created to en-

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<sup>60</sup> [www.eiu.com](http://www.eiu.com)

<sup>61</sup> McKinsey ([www.McKinsey.com](http://www.McKinsey.com)) states that 74% of cross-border deals fail to create shareholder value. KPMG ([www.kpmg.com](http://www.kpmg.com)) states that the failure rate is 83%

<sup>62</sup> Note that in the USA, there is no statutory research exemption. The only exemptions are for uses of "idle curiosity" or for "purely philosophical pursuits" (see also Nottenburg *et al* 2001 for an extensive discussion on research exemptions and the non-profit sector).



able standard settings in Digital Versatile Discs (DVDs), video games, and Motion Picture Experts Group 2 (Standard-Compressed Video at 4-9 Mbps (MPEG2) compression technology. Interestingly, the latter was formed in 1997 by Columbia University, Fujitsu, General Instrument, Lucent, Matsushita, Mitsubishi, Philips, and Sony.)

In biotechnology, standard setting is not really an issue, which may explain why patent pools have not been necessary for industry to commercialize products. Perhaps another reason is that U.S. antitrust law often precariously places patent pools on the borderline between allowed monopolies and antitrust violations. Although the legalities of forming patent pools exceed the scope of this paper, it is worth noting that the U.S. Department of Justice has published guidelines for patent pool applications and requires an opportunity to review applications for them. Among other considerations, the patent pools must include patents that are valid and not expired, cannot constitute an aggregation of competitive technologies by setting a single price for them, must have an independent expert to determine whether a patent is essential to complement technologies in the pool, the pool agreement must not disadvantage competitors in downstream product markets, and the pool participants must not collude on prices outside the scope of the pool (i.e., on downstream products)

In a rapidly changing field such as biotechnology, patent pools can also have significant pro-competitive effects and may improve an industry's ability to survive. For developing countries, patent pools may be even more important because companies can easily obtain the licenses required to practice a particular technology, which reduces transaction costs and facilitates the rapid deployment of new applications. Typically, however, patent pools are constituted by members who each contribute patents in their respective fields. Whether or not developing country institutions would qualify to become members is uncertain.

The following types of patent pools exist today:

- internal, company specific (e.g., DuPont combining technologies through internal development or Syngenta complementing its internal portfolio with outside technology through licensing and M&As); the critical challenge is to keep internal innovation ongoing and tightly managed;
- portfolio pooling, whereby internal technology is supplemented with third party technologies (e.g., Microsoft and others); the critical challenge is to have a dynamic team handling in-licensing and aligning strategies closely with the overall corporate strategy;
- cooperative pooling, whereby companies agree to combine their technologies and allow them to be managed by a separate entity, typically for standard-setting purposes; the critical challenge is to avoid anti-trust issues;

**Table 10: Summary and Pros/Cons of Patent Pools**

Pros	Cons	Conclusions
Integrates complementary technologies Reduces transaction costs Clears blocking positions Avoids costly infringement litigation Promotes the dissemination of technology Levels the playing field	Difficult to agree on the value of individual patents contributed to a pool Complex to set up and avoid anti-trust problems (collusion and price fixing) May inflate licensing costs through non-blocking or unnecessary patents Complex when many patents are under litigation, as is the case with biotechnology May shield invalid patents and thus prevent much technology from entering the public domain	Pooling unlikely to change the underlying structural barriers to industrial biotechnology transfer to developing countries Difficult to get going because industry players have divergent strategic interests and use their IP portfolios heavily to strategically position themselves Appropriate for the biotechnology industry to create Unlikely to benefit from UN involvement In modified form, potentially effective for technology transfer

- third party aggregations, such as the strategy practiced by BTG Ltd.; the critical challenge is to work around anti-stacking provisions that are very common in biotechnology licenses; and
- forced pooling (rarely enforced compulsory licensing would be one example; another might be the pooling forced by the US government shortly after radio was invented).

There is no reason that a novel type of patent pool, centered on preferential licensing terms to developing countries, could not be established.

### **3.11 South-South and South-North Technology Transfer Aspects**

As stated earlier, one reason technologies often are not easily transferred is that large markets for their end products do not exist or cannot be accessed. To overcome this, south-south and south-north technology transfer should be promoted since over time it would give companies in developing countries better access to markets in developed countries, generating cash flow and, in turn, the means to in-license more technologies.

India has been actively pursuing such transfer for many years and it has just announced that it is stepping up its bilateral biotechnology collaborations with other developing countries, such as Cuba, Brazil, Mauritius, Syria, and others.<sup>63</sup>

One related aspect is the commercialization of biodiversity for bioprospecting and biopiracy. This made a lot of news in the early and mid-1990s (coinciding with the Rio conference, UNCED), and there were high expectations in the developing world that bioprospecting would become the new “cash cow” of biodiversity-rich countries. In practice, the hype and talk led only to a dramatic reduction in new bioprospecting agreements, partly because of the legal and public perception uncertainties.

At the moment, countries that desire to market their genetic resources and companies that seek access to these materials are still uncertain how to proceed under the new expectations brought about largely by the CBD. A few countries established predictable and professionally managed institutions, such as Costa Rica (The National Institute of Biodiversity or INBio<sup>64</sup>). Because technology transfer is also defined as the geographic movement of productive capacity, genetic material is also a technology: it is the means for developing a range of new products and is an unrefined form of productive capacity. But purchasing this technology is significantly different from other types of technology transfer. Most importantly, the transfer is predominately south-north and secondarily south-south as opposed to the familiar north-south movement. The materials, moreover, are natural products, which creates technical and institutional complexities. Large companies in the north have easy access to materials and alternative technologies (such as recombinatorial chemistry, metabolomics), as well as established contacts and networks. Smaller companies in developed countries, however, lack such access and often find it difficult to identify suitable partners and negotiate their way through what are often irrational expectations for bioprospecting royalty rates. Although to the best knowledge of this author there are today no clearing houses for identifying sellers and buyers and assisting in negotiations for genetic technology, such a mechanism could benefit all parties, public and private, and perhaps re-initiate more bioprospecting activities.

### **3.12 Other Aspects of Technology Transfer Mechanisms**

It would be inappropriate not to at least mention other types of technology transfer facilitators, ranging from education and training institutions (e.g., universities across the world), to international agricultural research centers (e.g., the CGIAR), to health consortia (e.g., the Program for Appropriate technology in

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<sup>63</sup> *Financial Times*, 15 November ([news.ft.com/home/us](http://news.ft.com/home/us)).

<sup>64</sup> [www.inbio.ac.cr](http://www.inbio.ac.cr)

Health (PATH)), or the many specialized UN programs from UNEP to UNIDO to ICGEB (the latter an independent inter-governmental institute).

It should also be reiterated that company-to-company arrangements (including collaborations, joint ventures, strategic partnerships, and corporate partnering) are some of the most ubiquitous and efficient systems of technology transfer. They rarely require public sector assistance, although they are subject to government policies that either encourage or thwart them. This is certainly an area where many developing country governments could do much to reform their policies and regulations, especially by reducing the red tape and administrative burdens on foreign private investments. The international development community often ignores the efficiency of the private sector and seeks to set up new, redundant mechanisms outside efficient and established tech transfer systems. Though well intended, many of these initiatives make no measurable impact.

## **4. Options for UNIDO to Facilitate Biotechnology Access and Transfer**

### **4.1 *Introduction and Problem Statement: The “Integration” of Institutions, or from “Intellectual Capital” to “Social Capital”***

According to Jeffrey Sachs (2000), today's world is divided not by ideology but by technology. He ranks the world's regions into technological innovators (15% of the earth's population), technological adopters (50%), and the technologically excluded (35%). It is not easy for countries to move up the technological innovation scale, and only a few have managed to do so in recent decades: Taiwan, South Korea, and Israel moved from being adopters to innovators; Tunisia, coastal parts of China, and southern Brazil moved from the excluded to adopters.

What makes assisting developing countries with the transfer of industrial biotechnology so urgent and important is that in today's “knowledge economy” intellectual capital is king—the old rules of economic growth no longer apply. Development has ceased to follow the rules of “convergence”, whereby returns on new investments are higher where capital is more scarce, thus gradually converging the economies of developed and developing countries. Innovation and technology, unlike capital, are not converging forces. The more a country innovates, the more likely it is to innovate in the future. Unfortunately, developing countries lag far behind in innovation. Many of them have yet to formulate, much less implement, government policies for science and technology. When such policies do exist, they are usually limited to public research and rarely address the relationship between academia-and industry.

Similarly, intellectual capital no longer primarily drives the knowledge economy. Equally important today is “social capital.” People make networks work. Human networks make things happen, not the inert, underlying data and information. This is crucially important for technology access and transfer because they are based on transactions between people and institutions, public and private. Efficient transactions require people who know, trust, and value each other.

As previously discussed, IP works by excluding others from using an invention in a country where it has been patented. This appears to be a necessary but not sufficient condition for private sector investments and their overall social benefits. Private capital, government policies that are conducive to private sector investments, and an adequate technological capacity, among other requirements, must all be available. This excludes many poor countries, industries, and consumers from the benefits of new technologies, leads to the fragmentation of technology (as is the case with biotechnology in general), and encourages a commercially driven agenda that is unlikely to optimize social benefits for the global community. The fragmentation of biotechnological inventions is a particularly troublesome obstacle. Despite the consolidation of industry, technology fragmentation is increasing, making the assembly of technologies and inventions particularly challenging, especially for outsiders. There are still more addi-

tional challenges for developing countries, including an overall lack of critical mass in a range of technologies and uncertainties associated with TRIPs.

Responding to the challenges outlined in chapter 2, therefore, requires not only incremental improvements or changes to the patent system, but a stronger “integration” of institutions in developing countries with the technological innovators in industrialized and certain more advanced developing countries. *Such an effort would be a coherent component of UNIDO’s mandate and strategy.*

#### **4.2 Proposed Strategic Responses by UNIDO to the Advent of Industrial Biotechnology**

UNIDO’s mandate is to “assist developing countries in their industrialization efforts to enable them to enhance their capacities for promoting sustainable industrial development for economic growth and poverty alleviation” (UNIDO 2003). To accomplish this, UNIDO has identified eight strategic thrusts with the following rationales:

1. Business investment in training and plant and equipment technology enhances productivity and enables sustainable economic growth.
2. There are widening productivity differentials between and within countries.
3. The increasing marginalization of least developed countries (LDCs) is a consequence of their inability to master technologies and take advantage of market-opening measures in advanced industrial countries.
4. The small and medium enterprise sector in developing countries is often seen as a way to generate low-skilled jobs and fight poverty. This implies a neglect of the Small and Medium Size Enterprise (SME) sector’s important contribution to fostering growth, specialization, technological innovation, and exports.
5. Weak cooperation links between economic agents, markets, and institutions in developing countries prevent them from drawing effectively on international trade and investment flows.
6. Agro-based industries have a predominant role in the development prospects of developing countries, especially LDCs.
7. Industry makes sub-optimal use of natural resources and can be a significant source of pollution and waste.
8. The energy efficiency of industry can be greatly improved.

UNIDO’s 2003 strategic plan mentions no specific goals for industrial biotechnology, but given the importance of biotechnology for sustainable development in general, and particularly for sustainable industrial growth, UNIDO may wish to support access to technologies and to provide rewards for transferring technologies, either directly through its existing programs or indirectly. The following eight initiatives have been categorized into six groups according to their impact (short, medium, and long-term) and whether they are focused or broad initiatives (Table 11).

Not all initiatives are appropriate for all countries. Prior to implementing any recommendation, a country’s development level must be carefully considered; most specifically, whether the country is a technological innovator, adopter, or technologically excluded.

For technological adopters, the key thrusts to increase the speed of technological adaptation—leading over time to enhanced technological innovation—are activities that:

- encourage foreign direct investment (FDI) (multinational company setting up production around proprietary technology);
- facilitate the licensing of technology and of know-how; and
- integrate governmental policy making into development goals and capacity building.

**Table 11: Possible Types of Strategic Responses by UNIDO to Encourage Access to Industrial Biotechnology and Rewards for Technology Transfer**

Impact \ Type of Activity	Type of Activity	Focused	Broad
<b>Short-term</b>		1. Improve the institutional IP management capabilities in developing countries by promoting authoritative institutional IP management. 2. Reduce the transaction costs of in-licensing by pooling certain technologies.	6. Act as a policy advocate, or coordinate policy advocacy, to persuade governments across the world to institute policies conducive to technology transfer.
<b>Medium-term</b>		3. Develop policies and precedents that encourage open source licensing and facilitate technology access. 4. Catalyze the creation of a tailor-made investment and IP brokering service.	7. Enhance developing countries' IP management capabilities by promoting sound practices and policies.
<b>Long-term</b>		5. Support capacity building and training in industrial biotechnology.	8. Lobby for good government policies that are conducive to private sector investments in industrial biotechnology development.

For technologically excluded countries, the following activities with somewhat different key thrusts are required for them to become technology adopters:

- accelerate the transfer of technology embodied in capital and goods, primarily for humanitarian purposes;
- set the foundation for the licensing of technology and know-how through improved policies; and
- integrate governmental policy making into development goals and capacity building.

Different responses for these two types of countries will not be discussed further, but they should be considered when identifying geographic priorities.

#### **4.3 Criteria for Prioritization**

Irrespective of a country's development level, initiatives are needed to assist the integration of small and medium size companies (SMEs) in developing countries with the world economy, beginning with technology transfer and related investments. Encouraging technology transfer alone will have an impact only in the very long term. In addition to technology transfer, therefore, stronger partnerships to transfer know-how are required. We must be realistic and recognize, however, that these partnerships, especially public-private partnerships, will only be sustainable if we invest in them.

This document emphasizes proposals that broadly fall within UNIDO's corporate strategy (UNIDO 2003) and mandate. Numerous other proposals that are not outlined here may be equally important, yet if they fall outside UNIDO's mandate and strategy it is unlikely that UNIDO would facilitate their implementation. The previous section explained that in regards to industrial biotechnology and the developing world UNIDO's mandate encompasses eight strategic objectives. Some of them are already being pursued by UNIDO. For example, UNIDO was most instrumental in establishing ICGEB in Trieste and New Delhi, which specifically works to enhance biotechnology capacity in developing countries. Indeed, capacity building is an essential strategic element for any effort to enable developing countries to benefit from industrial biotechnology, and the proposals in this paper specifically focus on

the management of proprietary science and IP in a broad sense, including legal, economic, management, organizational, and policy aspects.

Not surprisingly, the multilateral agencies currently involved lack, by and large, both the necessary governing structure and resources to dramatically improve technology transfer. Consider, for example, that the World Bank's lending and grants for science and technology to the entire developing world is not even 10% of the R&D budget for a single major pharmaceutical company: the R&D budget in 2002 for Merck & Company was \$2.9 billion whereas the Bank loaned out less than \$300 million for R&D globally.

Technology transfer does not require grand, ostentatious schemes but a few, key facilitating initiatives that invest in capital and people, for without financing few partnerships and networks will last. Recognizing that public investments and philanthropic funds are limited, other sources of funding—or financing—need to be leveraged. Accordingly, the following sections briefly discuss other ideas but emphasize issues related to technology transfer and financing. In terms of priorities for UNIDO, short term focused initiatives appear most appropriate. Through these initiatives individuals will gain experience and obtain training in different areas related to IP management, allowing them to serve as important voices in formulating broader policy initiatives in their countries.

More specifically, this paper concludes that catalyzing the creation of tailor-made investment services and IP brokering initiatives (Strategic Goal No. 4) is particularly important and urgent. There is much that can and must be done to broaden support in this important area.

#### **4.4 Focused Initiatives**

*Strategic Goal 1. Improve the institutional IP management capabilities in developing countries by promoting authoritative institutional IP management*

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##### Rationale:

Transferring new ideas and inventions from academic and corporate R&D to the marketplace is essential to benefit society and fuel economic activity. But it is a complex process to get proprietary tools and products into the hands of people who can optimize their use, a process even more complicated in an international development context. Any institution, public or private, that seeks to obtain technologies must authoritatively manage intellectual property with a sound IP strategy. Such management encompasses a series of activities, ranging from contracts to policies to patenting strategies to partnership building, with the latter being most important (see also Section 2.2 and Figure 1). Indeed, there is nothing more difficult than negotiating a license with someone who has no negotiation experience, especially if that person works for an institution with no formal IP policy.

##### Programmatic Aspects:

There are several components to training and capacity building in this area:

1. Short term courses and seminars, including on-line distance learning;
2. Short, medium, and long term internships;
3. Under-graduate and graduate courses;
4. Specific institutional assistance, such as developing an IP strategy after a thorough IP management review; and
5. Learning by doing.

Item 4 is perhaps the most important catalyst for developing sound IP management, and it is discussed in more detail under Strategic Goal 4. Many seminars, courses, and services in this area are already offered by a myriad of organizations, but more tailor-made courses for industrial biotechnology are very much needed.

UNIDO's specific role in this area could be to encourage tailor-made programs in industrial biotechnology by third parties who already have programs in IP management. The organization could also convene regional awareness activities and act as a facilitator with the private sector, whose contributions should neither be ignored nor underestimated. Companies big and large have been quite open to hosting short-term interns in science and research and there is no reason this could not be extended to IP management. Interns would benefit from real life experiences, and their new relationships with industry could lead to various forms of collaborations and technology licensing in the future.

#### Implementation:

- a. Compile a review of existing capacity building and training programs in this area.
- b. Disseminate the information to key UNIDO contacts and stakeholders (for example, by setting up something like an information clearing house; see also section 3.3).
- c. Identify and jointly develop a few activities in industrial biotechnology with related IP aspects.
- d. Seek funding through governments, multilateral agencies, and directly from beneficiaries.

#### Cost considerations:

One of the fallacies about authoritative IP management is that it takes a lot of resources away from research endeavors. This belief partly stems from the perceived threat of multi-million dollar lawsuits—something extraordinarily unlikely. On the other hand, many would argue that institutions with authoritative IP management also conduct better science. For example, laboratory notebooks are not only a key tool for managing IP but also promote more systematic note taking and more careful consideration of experiments. Institutions unconcerned with IP rarely institute laboratory notebooks. This report contends throughout that authoritative IP management does not add costs except during a transition phase. It is thus an investment with short-term returns.

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### *Strategic Goal 2. Reduce the transaction costs of in-licensing by pooling certain technologies*

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#### Rationale:

Researchers, especially those in the public sector, are often uncertain about their ability to access the biotechnology components needed for the distribution of their research products. Some researchers have discontinued or re-aligned their research projects because they could not access required components. Others have continued without appropriate licenses or even research-only agreements. In all such cases, this uncertainty causes valuable resources to be consumed ineffectively and hinders the transfer of inventions from the public sector to the nascent private sector in developing countries.

The objective here is not to establish a patent pool as described in Section 3.10 (page 26)<sup>65</sup>, but to offer small and medium sized enterprises (and also the technology owners and non-profit public sector) with a convenient, trusted, and professional one-stop service for exchanging IP and tangible research materials. It directly ties into Strategic Goals 3 and 4 discussed below. A type of managed technology exchange is proposed (see Section 3.4; page 19), initially on a non-commercial basis but evolving towards the commercial area.

#### Programmatic Aspects:

The proposed service would negotiate in advance with IP and TP owners to license terms for non-commercial and commercial uses, ensuring that the entire range of IP necessary to obtain FTO would be available. Entire platforms could thus be sub-licensed to SMEs and other players. Providing a one-stop

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<sup>65</sup> The author believes that establishing a full-fledged patent pool in biotechnology is currently not feasible but should be reviewed in a few years.

center for obtaining a significant portion of technologies, the service would provide technology owners and companies with a trusted, professional, and efficient way to deploy their technologies for both humanitarian and commercial purposes in the developing world. Technology owners could efficiently and inexpensively expand the use of their technology for the benefit of developing countries without jeopardizing their legitimate licensing income.

#### Implementation:

A full feasibility study would be required to determine the specific technological areas the service should focus on to benefit existing SMEs in developing countries. The study should also broadly identify the technology owners and initiate preliminary discussions with them. In addition, models would need to be developed and the following issues addressed, both in close collaboration with technology owners:

- strategy to seek licenses for selected biotechnology components;
- modalities of sub-licenses;
- how to differentiate pre-granted licenses to public and private entities;
- types of sub-licenses to researchers for research only use;
- types of sub-licenses to public-sector researchers for commercial use;
- possibility for no-fee licenses for domestic use in selected developing countries;
- possibility for low-fee basis for domestic use in selected developing countries;
- modalities for export from/to selected developing countries (low-fee basis or no-fee basis);
- modalities of sub-license to private sector researchers for commercial use;
- which technologies/products could be “banked” (placed in the Technology Escrow Account);
- availability for which crops, traits, countries, etc.;
- definition of commercial, limited commercial, and humanitarian use;
- liability and indemnification clauses for different recipients;
- qualification of sub-licensees, if any;
- criteria for accepting a technology/product;
- definition of developing country/ies;
- distribution of licensing income, if any.

In addition, the feasibility study would need to develop a blueprint for the organization(s), including options and recommendations as follows:

- a. prioritization of functions and specific objectives;
- b. detailed short, medium, and long-term implementation strategies;
- c. structure, staffing, and location options;
- d. legal status and governance;
- e. possible institutional affiliation, bearing in mind that the entity would need to be neutral and impartial in order to be effective and credible;
- f. cost estimates for implementing potential functions and specific objectives of the Facilitator over the short and medium-term;
- g. the possible need for a sunset clause and its implications; and



- h. funding options (e.g., fixed-term support versus core support, donor support group, not-for-profit versus commission-based, initial support versus longer-term options).

A team with a senior advisory board could carry out the feasibility study. It should be commissioned to a team of experts in this area, relying heavily on experienced managers in related fields.

One of the key components of the study would be to “lobby” with a number of key industries to ensure that they are given an opportunity to contribute to the refinement of the concept and are behind it. It should be stressed that the initiative could equally benefit industry as well as SMEs in developing countries. In terms of UNIDO’s specific role, the organization should act as a catalyst in bringing key players together, initially focusing on a certain geographic region and a particular set of technologies. UNIDO is well placed to commission a detailed feasibility study as outlined below.

#### Cost considerations:

The proposed service would assume royalty bearing sub-licensing to SMEs, which could provide technology owners with an added incentive to participate. This would also allow the service to retain a small portion of the royalty fees as a commission. However, relying exclusively on commissions to finance the service is unrealistic: significant additional funding (several million US\$ per year) would be necessary to establish and operate it. UNIDO should consider taking an active role in promoting such a service and actively seek contributions and support through its links with other UN agencies, including the IMF, World Bank, and regional development banks.

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### *Strategic Goal 3. Develop policies and precedents to facilitate and enable open source licensing.*

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#### Rationale:

“Private goods” are typically traded in markets: if the market agrees on a price (e.g., for cakes), the ownership or use of the good (e.g., the cake) or services is transferred. A “public good”, by contrast, is a good or service that meets two characteristics simultaneously:

- its use by one person does not compete with or rival its use by another person (non-rival), and
- no person can exclude other persons from its use (non-excludable).

Sunlight, traffic lights, street signs, national defense, peace, the eradication of smallpox, etc. are examples of public goods. Who provides the public good is not important: governments provide both public goods (e.g., defense, roads) and private goods (private housing, medical care). Similarly, the private sector in many instances provides public goods (e.g., technical norms, street lights). But because of non-excludability, the private sector rarely contributes to the creation of a public good—although it often manufactures such goods, which through sales to the public sector become public goods. Corporations also frequently enhance existing public goods. As streetlights or stop signs illustrate very well, the private sector may make a certain good that, once purchased by someone (either public or private), becomes a public good. Finally, it is worth pointing out that creating a public good is not necessarily free of costs. Costs may have been borne by society at large (e.g., street signs), but its enjoyment or use is free to any and all individuals who pass through that particular street.

The same could be the case for research tools and enabling technologies: costs of public research at universities and research establishments are borne by society and the results could be free for all to use. Yet these institutions are often encouraged to seek IP protection to ensure that private capital can be raised to bring inventions to markets. For biotechnology, moreover, even the research tools are protected through patents. When such IP is licensed to third parties, licensing agreements quite often contain reach-through clauses that grant the owner of the research tool certain rights in the final product or in discoveries made with that research tool (see Krattiger 2004b for a more in-depth discussion). As a result, innovation requires a vast number of licenses, which can make obtaining FTO daunting. Further, many biotechnology licenses do not contain provisions for stacking licenses (some estimate as many as 60% of biotechnology licenses), which can result in prohibitively high cumulative royalty rates.

An alternative would be to ensure that all enabling technologies or research tools are not patented. These inventions would be placed in the public domain and made available for anyone to use, provided that any improvements in the technologies would also be placed in the public domain. Patents would only be allowed for specific products developed from using the tools.

#### Programmatic Aspects:

This initiative could take many different forms. This paper proposes to share information with policy makers around the world to inform them about the downsides of patenting research tools and to let them know about the opportunities available under open-source licensing. Recipients should include government ministries that oversee patent offices, research and technology ministries, ministries of education (to influence the universities), and policy makers at institutional levels (primarily universities). In a second phase, biotechnology companies with significant R&D investments would be brought on board, an activity for which UNIDO is particularly well-suited.

#### Implementation:

A special session could be organized during the Global Biotechnology Forum in Chile to jump-start the initiative, which would end with a major press release calling upon countries, organizations, and companies to change their practices.

As part of the initiative, model policies on open-source licensing could be developed and tailor-made for universities, companies, and other entities.

#### Cost considerations:

Insignificant.

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*Strategic Goal 4. Catalyze the creation of tailor-made investment services and IP brokering initiatives.*

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This proposal is the most important for UNIDO to support because it would not only catalyze IP investment services and brokering initiatives but also activate and give momentum to many other proposals discussed in this document. It offers the most bang for the buck.

#### Rationale:

As mentioned above, even when a technology is unencumbered by patents, developing countries usually never obtain it. This is often because obtaining the license for a patent does not mean that it can be applied to new inventions, especially complex ones in new technological fields. This is especially the case for biotechnology, where know-how is often more important than published patents.

In addition, any form of technology transfer—including donations for humanitarian reasons—requires additional investments. Yet overall there is a lack of investor confidence in many developing countries, and venture capital is scarce. This is further complicated by inadequate government support, weak infrastructure, and small national markets that make major investments unprofitable without tapping into export markets. When exports are envisaged, licenses for patents are usually needed because many biotechnology products are protected in the more lucrative markets. Consequently, developing countries must wrestle with the complexity of obtaining freedom to operate (FTO) by negotiating for myriad licenses.

Thus in order to spur biotechnology transfer, an integrated service is required that would assist SMEs and public institutions alike by 1) developing complementary new business/investment models through innovative institutional arrangements, 2) offering FTO services and due diligence audits to ensure that a company owns all its IP and is not infringing on the IP rights of third parties in conducting its business, 3) assisting with negotiating in-licensing arrangements, 4) identifying business opportunities in partner-

ing, both for technology in-licensing and the export of products and services, and 5) arranging financing for transactions to bear fruit. Today, business growth in developed countries occurs primarily through two strategies:

- a. mergers and acquisitions (M&As) of operating assets, which leads to short-term growth; or
- b. traditional market development.

Biotechnology M&A strategies in developing countries have been either unsatisfactory or non-existent because there are few sound national/indigenous companies available for acquisition. There have only been a handful of small (under \$2 million) and medium-sized (\$2-10 million) quality deals, with complications arising from management re-structuring, a lack of trained managers, technological upgrade needs, and the failure to implement predictable exit strategies due to investor unfriendly government policies. Industry has therefore been taking the slow, expensive, and risky road of *de novo* development.

As a consequence, biotechnology in developing country markets has been almost exclusively a sideshow as far as innovation and near term business opportunities are concerned. Unless specific initiatives are developed to accelerate investments (such as this proposed service) the technologies will be significantly exploited only in the very long term, if at all. Indeed, relying exclusively on market-driven approaches is unlikely to lead to increased technology transfer and improved economic prospects. Hence, the present proposal.

This proposed service would essentially integrate many of the proposed strategic goals and program initiatives outlined in this section, including:

- the improvement of institutional IP management capabilities through learning-by-doing (Strategic Goal No. 1);
- the reduction of transaction costs for in-licensing because certain technologies could be pooled (in other words, one technology bundle could be licensed to one entity in one country/region as well as to another entity in a different country/region; Strategic Goal No. 2);
- the development of precedents that facilitate and enable open source licensing (Strategic Goal No. 3); and,
- over time, the creation of a policy advocate for improved technology transfer and investment policies (Strategic Goal No. 6), encouraging good government policies conducive to private sector investments (Strategic Goal No. 8), and promoting through examples sound practices and policies in IP management (Strategic Goal No. 7).

#### Programmatic Aspects:

The service would gradually offer an integrated list of services to foster business growth (primarily through technological upgrading and in-licensing) and investments. In terms of priorities for services, within a reasonable period of time assistance in the following four principal areas should be provided:

- 1) Identifying SMEs and public sector institutions, as appropriate, that would benefit from technological upgrades, small and medium size investments, and export opportunities.
- 2) Identifying technologies and technology bundles for appropriate developing countries.
- 3) Negotiating licenses from key developed country players in the field, including partnering arrangements where feasible.
- 4) Arranging financing so that transactions pay off.

Put otherwise, the service would provide business advisory services, support national investment and technology-related institutions in their efforts to develop business alliances with foreign partners, and promote access to potential technology suppliers and investors.

Ideally, UNIDO would select a geographic region, such as countries with economies in transition, and develop a pilot program.

#### Implementation:

Establishing the service requires making a series of strategic decisions:

- The new service could not operate in all developing countries right from the start, and so a geographic area would have to be carefully selected. The criteria for the selection should include both high impact and high feasibility; in other words, a small set of countries with indigenous SMEs already operating with relatively predictable and investor friendly government policies.
- It will be important to build internal capacity, and service staff would need to be familiar with the range of technologies and industries the service offers. Accordingly, care should be taken to select a limited set of biotechnologies. Service staff should include some experts in the selected technologies or rely on consultants to evaluate them. In either case, the range of technologies should initially be limited and focused.
- The service should emphasize a set of proven core technologies that lend themselves for transfer. Initial areas that could be considered might include fermentation technologies in antibiotics and bio-pesticides, biological systems for toxic substances removal in textiles, genomics services, phyto-medicines, and nutraceuticals.

The service could be established in four phases:

Phase I: Commission an authoritative feasibility study.

The feasibility study would need to address the following issues

- The proposed mandate of the service and succinct description of the need.
- Prioritized list of functions and specific objectives.
- Strategies for the implementation of each function.
- Proposed structure, staffing plan, and location options.
- Options on legal status and governance.
- Possible affiliation, bearing in mind that the service needs to be independent, neutral, effective, and credible.
- Cost estimates and projections.
- Funding options for the service.
- Sources of financing for investments.

Special emphasis would need to be placed on:<sup>66</sup>

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<sup>66</sup> Sector reviews may feature technology assessment, relevance to developing countries, needs assessment (including future constraints such as water, salinity, etc.), business players, cost and returns, markets and market outlook, risk factors, the enabling environment, government policies, intellectual property constraints and opportunities, trade aspects, sub-sector aspects, technological maturity, and cross-over synergies (e.g., edible vaccines for animal and human health, nutraceuticals, and phytomedicines). Geographical aspects will place specific emphasis on regionalization and similarities in institutions (e.g., ASEAN, Eastern Europe) or the environment (e.g., toxic soils). Institutional investment studies would pay particular attention to differences between technologically poor countries, adopters of foreign technologies, and tech-

- A detailed strategy for sustaining a flow of quality deals, including examples.
- Proposals on options for UNIDO participation, possibly with other agencies such as the IFC, the World Bank, regional development banks, and private merchant banks.
- Investment scale and returns/risk analysis.
- Biotechnology sector reviews.
- Sourcing of deal flows (country studies, financial partner identification, 3<sup>rd</sup> country technical partner identification, existing 3<sup>rd</sup> country services, and possible services from 3<sup>rd</sup> parties).
- Case study based analysis of possible investment forms (e.g., direct investor, investor in a fund, equity, loans, including types of businesses such as joint venture, public/private, virtual company, start-ups, licensing).

Care should be taken to ensure that the service neither displaces the private sector nor indirectly provides subsidies. Rather, new monies should attract additional private sector monies. The novel institutional arrangements noted above will serve as mechanisms to attract and channel those funds. The initial feasibility study should also identify principal hurdles and propose manners in which these can be overcome, making private sector investments less risky and more profitable. Its analysis should focus on identifying and overcoming bottlenecks or market failures through the adroit placement of new investment funds. Each of the above two strategic directions will each have three main thrusts:

- a. viable ways for the service to strategically position itself and offer appropriate management development and investment services;
- b. realistic options to finance SMEs as well as local start-ups in different countries, taking into consideration available human resources, the R&D environment, national policies, etc.
- c. examples of creative partnerships, explored through case studies and model projects, including public-private partnerships.

Phase II: Establish a steering committee and develop partnerships with existing institutions with related mandates.

A steering committee would review the feasibility study and then make critical decisions about the different options proposed by the study. The committee would also serve as the first founding board of the service, define policies, and oversee the programmatic implementation. The steering committee would be composed of stakeholders, including representatives from SMEs, merchant banks, and other entities that already provide related services.

Phase III: Launch the pilot phase in a limited geographic and technological area to demonstrate its feasibility and to win additional players after the first successful deals have been concluded.

Phase IV: Expand the service to serve a wide range of countries and different biotechnological applications.

#### Cost considerations:

There are three types of costs to be considered. One is the cost for the feasibility study, which would include inter-agency consultations and meetings with financial institutions (IMF, World Bank, private banks, regional development banks, etc.), technology suppliers, and SMEs among others. The second cost type consists of expenditures associated with establishing the service regionally, and the third consists of the yearly operating expenses needed to keep the service going and expand its geographic and technological basis. The feasibility study would need to address very carefully all three aspects and provide conservative and optimal projections. Our best analysis suggests that once established, the service would need significant funding to operate but could grow through commissions leveraged on previous investments.

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nology innovators, undoubtedly leading to differentiated investment strategies for technology generators, technology adopters, and technology diffusers.

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*Strategic Goal 5. Support capacity building and training in industrial biotechnology.*

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As discussed in Section 3.12, capacity building comes in many forms and a critical mass of capacity is a prerequisite for technologies to be absorbed. No new initiatives are proposed here; the strategic goal is nevertheless listed to underscore the importance of long-term capacity building. In addition, ICGEB and other institutions are already active in this area. UNIDO's specific role, however, would be in more strongly promulgating capacity building in this area. The types of activities to achieve this are essentially those outlined in Section 4.5 below but with a more specific and targeted focus.

#### **4.5 Broad Initiatives**

The "broad" initiatives identified above will be discussed together as one group. Overall, they are of relatively low priority and include:

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*Strategic Goal 6. Act as a policy advocate, or coordinate policy advocacy, to persuade governments across the world to institute policies conducive to technology transfer.*

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*Strategic Goal 7. Enhance developing countries' IP management capabilities by promoting sound practices and policies.*

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*Strategic Goal 8. Lobby for good government policies that are conducive to private sector investments in industrial biotechnology development.*

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Many policy advocacy groups exist today, including many NGOs, public sector groups and companies. What is needed, however, is a neutral policy platform that can authoritatively and efficiently serve the above three goals by:

- serving as a neutral forum to bring together the key partners engaged in research, development, and commercialization of industrial biotechnology through consultations, conferences, workshops, and meetings;
- assisting governments with designing or enhancing policies, strategies, and instruments for investment and industrial biotechnology promotion within the new economic context, strengthening as well their related legal and regulatory frameworks;
- encouraging investments in capacity building;
- facilitating and promoting the process of greater public awareness and understanding related to IP and technology transfer;
- promoting the use of industrial biotechnology in the developing world through advocacy activities targeted at national policy makers and planners;
- assisting governments with the development or enhancement of technology transfer programs to design their future orientation in accordance with rapid technological change
- identifying problem-solving research to facilitate industrial biotechnology transfer;
- promoting industrial biotechnology to ensure benefits to the society;
- amplifying the voice related to specific policy implications, particularly the benefits and uses of industrial biotechnology in a sustainable industrial growth program;
- promoting the collective efficiency of SME clusters and networks by formulating and encouraging network/cluster action plans and establishing cooperation with similar networks/clusters for benchmarking and exchange of best practices;

- building multi-sector partnerships and strategic knowledge alliances between UNIDO, transnational corporations, SMEs, business associations, research, and other civil society organizations within specific industrial biotechnology sub-sectors that are aimed at integrating SMEs into global value chains.

All of these 11 points are activities already undertaken by UNIDO but not yet in the context of industrial biotechnology. The proposal is to enhance existing UNIDO programs by turning their attention to specific issues related to industrial biotechnology and integrating these concerns into all (or most) of UNIDO's existing programs. This may require, in the first phase, internal training for UNIDO staff on the issues, and perhaps the creation of a UNIDO "industrial biotechnology service desk" to promote awareness, training, and internal advocacy.

## 5. Conclusions

Industrial biotechnology, or "white biotechnology," has become one of the key investment areas in industrialized countries and it will undoubtedly be the source of the next major wave of technologies. Not only will these have far reaching environmental, commercial, and social impacts, but they are also expected to dramatically shift how value is added in a range of industrial processes. Unless developing countries become part of this technology, they will become more and more technologically excluded.

Initiatives are urgently needed to more strongly integrate SMEs in developing countries with the world economy, beginning with technology transfer and related investments. Encouraging technology transfer alone will only show results in the very long term, hardly a good proposition for most countries. In addition to technology transfer, stronger partnerships are required to transfer know-how and to integrate the developing world's emerging private sector into the social networks that are becoming as important as "knowledge" *per se*. In the future, business will not be driven by "intellectual capital" but "social capital". Technology transfer and its requisite partnerships can be used to build social networks founded on mutual benefits and centered on common goals.

The foundation for such partnerships and networks is mutual understanding and trust, but they can only be sustained through investments in both capital and people. One of the pernicious fallacies circulating today in this era of increased public-private partnerships is that everyone sees them as a solution to almost anything. Such partnerships, however, are not a panacea, and without funding they will only exacerbate the disabling divide between the public sector and industry. Money is needed to make partnerships work. Recognizing that public investments and philanthropic funds are limited, other sources of funding—or financing—need to be leveraged, which is why the present document emphasizes partnership building activities that include investment services. To stop developing countries from being technology excluded, financing for the partnerships that will assist them must be included.

## References

- Atkinson RC, RN Beachy, G Conway, FA Cordova, MA Fox, KA Holbrook, DF Klessig, RL McCormick, PM McPherson, HR Rawlings, R Rapson, LN Vanderhoef, JD Wiley, CE Young. 2001. Public Sector Collaboration for Agricultural IP Management. *Science* 301:174-175.
- [www.sciencemag.org/cgi/content/full/301/5630/174?ijkey=bJhyNVq9ELVzc&keytype=ref&siteid=sci](http://www.sciencemag.org/cgi/content/full/301/5630/174?ijkey=bJhyNVq9ELVzc&keytype=ref&siteid=sci)
- Barton JD, Alexander, C Correa, R Mashelkar, G Samuels, S Thomas. 2002. Integrating Intellectual Property Rights and Development Policy. Report of the Commission on Intellectual Property Rights of the UK Government. DFID: London. [www.iprcommission.org](http://www.iprcommission.org)
- Blair MM and SMH Wallman. 2001. Unseen Wealth: Report of the Brookings Task Force on Intangibles. The Brookings Institution: Washington DC.
- Burrill & Company. 2003. Biotech 2003. 17<sup>th</sup> Annual Report on the Industry. Burrill & Company: San Francisco. [www.BurrillAndCo.com](http://www.BurrillAndCo.com)
- Coffman WR, JE Alexander, DJ BenDaniel, PL Carey, HG Craighead, CR Fay, PA Gould, JS Gross, JE Hunter, WH Lesser, S Loker, JN MacLeod, JJ Mingle, NR Scott & AF Krattiger. 2003. The Future of Technology Transfer at a Ma-

- Corning Land Grant University: Report of the Cornell University Land Grant Panel on Technology Transfer. *IP Strategy Today* No. 6-2003. Pp. 1-44. [www.bioDevelopments.org](http://www.bioDevelopments.org)
- De Gregorio E and B Lemaitre. 2002. The mosquito genome: The post-genomic era opens. *Nature* 419:496-497.
- de Soto H. 2000. *The Mystery of Capital: Why Capitalism Triumphs in the West and Fails Everywhere Else*. Bantam Press. London.
- Ernst & Young. 2003. *Beyond Borders: The Global Biotechnology Report 2003*. [www.ey.com](http://www.ey.com)
- Friedman MA, H den Besten, A Attaran. 2003. Out-licensing: a practical approach for improvement of access to medicines in poor countries. *Lancet* 2003; 361: 341-44
- Graff G and D Zilberman. 2001. Towards an Intellectual Property Clearinghouse for Agricultural Biotechnology. *IP Strategy Today* No. 3-2001, pp 1-13. [www.bioDevelopments.org](http://www.bioDevelopments.org)
- Hardin G. 1968. Tragedy of the Commons. *Science* 162:1243-1248.
- Heller M and R Eisenberg. 1998. Can Patents Deter Innovation? The Anticommons in Biomedical Research. *Science*, 1 May.
- Holt RA *et al* 2002. The genome sequence of the malaria mosquito *Anopheles gambiae*. *Science* 298:129-149.
- Keusch GT & RA Nugent. 2004. Intellectual Property and Licensing: Impacts on Global Public Goods for Health (Perspectives from a Public Sector Biomedical Research Agency). Forthcoming in *IP Strategy Today*. [www.bioDevelopments.org](http://www.bioDevelopments.org)
- Klein JI. 1997. An address to the American Intellectual Property Law Association on the subject of cross-licensing and anti-trust law. Reprinted at [www.usdoj.gov/atr/public/speeches/1123.htm](http://www.usdoj.gov/atr/public/speeches/1123.htm)
- Krattiger AF and WH Lesser. 1995. The 'Facilitator': Proposing a New Mechanism to Strengthen the Equitable and Sustainable Use of Biodiversity. *Environmental Conservation* 22: 211-215.
- Krattiger AF. 2002. Public-Private Partnerships for Efficient Proprietary Biotechnology Management and Transfer, and Increased Private Sector Investments. A Briefings Paper with Six Proposals Commissioned by UNIDO. *IP Strategy Today* No. 4-2002. [www.bioDevelopments.org](http://www.bioDevelopments.org)
- Krattiger AF. 2004a. Technology transfer to developing countries and technology diffusion: The role of capacity, regulations (biosafety, IPRs and trade), and funding. In *Handbook of Plant Biotechnology* (eds. Paul Christou and Harry Klee). John Wiley & Sons, London. In press.
- Krattiger AF. 2004b. The Importance of Material Transfer Agreements: What Policy Makers and Senior Managers Should Know. *Plant Physiology* (Editor's Choice Article). In preparation.
- Krattiger AF. and RH Potter. 2002. The Status of Plant Variety Protection Issues in the Asia-Pacific Region. *APSA Technical Report*. APSA: Bangkok.
- Kryder RD, S Kowalski and AF Krattiger. 2000. The intellectual and technical property components of pro-Vitamin A rice (*GoldenRice™*): A Preliminary Freedom-to-Operate Review. *ISAAA Briefs* 20. pp. 74.
- Lesser W. 2002. The Effects of Intellectual Property Rights on Foreign Direct Investment and Imports into Developing Countries in the Post-TRIPS Era. To be published in October in *IP Strategy Today* No. 5-2002. [www.bioDevelopments.org](http://www.bioDevelopments.org).
- Mahoney RT (Ed.). 2004. Glossary. In *Handbook for Management of IP in Health R&D MIHR—Centre for the Management of Intellectual Property in Health Research and Development*: Oxford and *IP Strategy Today* ([www.bioDevelopments.org](http://www.bioDevelopments.org)). Forthcoming.
- McCarthy JT. 1996. McCarthy's Desk Encyclopedia of Intellectual Property. Second Edition. The Bureau of National Affairs, Inc.: Washington DC. [usinfo.state.gov/products/pubs/intelprp/glossary.htm](http://usinfo.state.gov/products/pubs/intelprp/glossary.htm)
- Merges RP. 1999. *Institutions for Intellectual Property Transactions: The Case for Patent Pools* [www.law.berkeley.edu/institutes/bclt/pubs/merges](http://www.law.berkeley.edu/institutes/bclt/pubs/merges)
- Monbiot G. 2003. *The Age of Consent: A Manifest for a New World Order*. Flamingo: London.
- Nalebuff BJ and I Ayres. 2003. *Why Not? How to Use Everyday Ingenuity to Solve Problems Big and Small*. Harvard Business School Press: Boston MA.
- Nottenburg C, PG Pardey and BD Wright. 2001. Accessing Other People's Technology: Do Non-Profit Agencies Need It? How To Obtain It. EPTD Discussion Paper No 79. IFPRI: Washington DC.
- Sachs J. 2000. A new map of the world. *The Economist* (June 24).
- Uehling MD. 2002. Rice sequence has global potential. *Bio-IT World*, [www.bio-itworld.com/news/050702\\_report263.html](http://www.bio-itworld.com/news/050702_report263.html)
- UNIDO 2002. Industrial Development Report 2002/2003: Competing through Innovation and Learning. UNIDO: Vienna. [www.unido.org/userfiles/hartmany/12IDR\\_full\\_report.pdf](http://www.unido.org/userfiles/hartmany/12IDR_full_report.pdf)
- UNIDO. 2003. Developing Industry: *Productivity enhancement for social advance*. UNIDO's corporate strategy. UNIDO: Vienna. [www.unido.org/file-storage/download/?file\\_id=13135](http://www.unido.org/file-storage/download/?file_id=13135)
- WHO. 1988. WHO's Special Programme of Research, Development and Research Training in Human Reproduction. WHO: Geneva.



## List of Abbreviations and Acronyms

AATF	African Agricultural Technology Foundation
AIDS	Acquired Immune Deficiency Syndrome
ARV	Antiretroviral drug
ASCAP	American Society of Composers, Authors and Publishers
B2B	Business-to-Business
BINAS	Biosafety Information Network and Advisory Service
BSPB	British Society of Plant Breeder's
CBD	Convention on Biological Diversity
CD	Compact Disc
CGIAR	Consultative Group on International Agricultural Research
CVI	Children's Vaccine Initiative
DND	Drugs for Neglected Diseases
DVD	Digital Versatile Disc
EPO	European Patent Organization
ESTs	Expressed Sequence Tags
EU	European Union
FAO	Food and Agriculture Organization of the UN
FDA	Food and Drug Administration (of the USA)
FTO	Freedom to Operate
GATBD	Global Alliance of TB Drug Development
GATT	General Agreement of Trade
GM	Genetically modified (or transgenic)
GMOs	Genetically Modified Organisms
GMP	Good Manufacturing Practices
HIV	Human Immunodeficiency Virus
IC	Intellectual Capital (intangible assets)
IFC	International Finance Corporation
IGOs	Inter-Governmental Organizations
IMF	International Monetary Fund
IP	Intellectual Property
IPOs	Initial Public Offerings
IPRs	Intellectual Property Rights
ISAAA	International Service for the Acquisition of Agri-Biotech Applications
ISO	International Standard Organization
LDCs	Least Developed Countries
M&As	Mergers and Acquisitions
MPEG2	Motion Picture Experts Group 2
NGO	Non-governmental organization
NIH	National Institutes of Health of the USA
OECD	Organization for Economic Cooperation and Development
PCT	Patent Cooperation Treaty
PIPRA	Public Sector Intellectual Property Resource for Agriculture
PSO	Product Specific Organization
SME	Small and Medium Size Enterprise
STR	Special Programme of Training and Research (WHO)
TB	Tuberculosis
TP	Tangible property
TRIPS	Trade Related Aspects of Intellectual Property Rights
UK	United Kingdom
UN	United Nations
UNCED	United National Conference on Environment and Development
UNDP	United Nations Development Program
UNEP	United Nations Environment Programme
UNIDO	United Nations Industrial Development Organization
UPOV	Union for the Protection of New Varieties of Plants, known through its French acronym <i>Union Internationale Pour la Protection des Obentions Végétales</i>
US	United States
USA	United States of America
USPTO	United States Patent and Trademark Office
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

## ***IP Strategy Today***

**An eJournal Sharing Creative and Innovative Ideas  
in Intellectual Property Strategies and Management  
related to Global Development and Biotechnology in Agriculture, the Environment and Health**

ISSN  
1534-6447

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