

# Intellectual Properties: Alternative Strategies to Value Creation in Life Sciences

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## **Introduction**

Intellectual properties (IP)<sup>2</sup> has not been an important issue when discussing development in poorer countries in the South<sup>3</sup>. One reason is that the patent system, which is one essential component of IP, was developed based on needs of the industrialized countries to stimulate and protect their innovators. Consequently, the share of patents granted to developing countries during the past 15 years has been almost negligible. However, both among academics and policy makers there is a growing awareness that IP could become important for development in the South. First, the legal infrastructure and its practice, such as ownership rights<sup>4</sup> and intellectual properties<sup>5</sup> can be of great importance when it comes to economic development. This includes the opportunity of using properties as capital for financing investment, e.g. as collateral for loans needed for innovations. Second, there is also a growing interest in IP because of the market potential of innovations based on the bio-diversity assets existing in several developing countries. Part of this potential could be developed based on what indigenous people already are aware of, which poses specific questions on rights and ownership.

In some countries in the South, such as the Andean countries, there has been a non-patenting tradition as a response to the difficulty to protect local knowledge.<sup>6</sup> This view has also been supported by international movements.<sup>7</sup> Scholars looking at the issue from an academic standpoint suggest publishing as a general strategy of protection of ideas from the South.<sup>8</sup> Also within the framework of WIPO, the international organization for intellectual property, there have been discussions on the role of IP in the South. This includes the issue of creating special conditions for the South, e.g. to promote free sharing of IP among developing countries (e.g. the PIPRA model) while at the same time protecting this IP from the competition from the North. The question has been posed if it is ethical to protect foreign innovators rights in a developing

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2 Intellectual Property (IP) is here broadly defined as intellectual resources that can be controlled and leveraged to extract value. The concept of IP expands beyond that of intellectual property rights (IPR), which focuses on patents, trademark rights, copyrights etc. IP includes all objects that can be captured and exploited along an intellectual value chain, assets such as patented inventions, proprietary know-how, contracts, license agreements, and standard agreements.

3 The South=developing countries and the North=industrialized countries

4 De Soto (2000)

5 Petrusson (2004)

6 Alänge & Scheinberg (2005)

7 E.g. GRAIN

8 E.g. Thulstrup et al. (2006)

country, i.e. that this protection increases foreign direct investment but blocks imitation, which as well could be a viable road towards development for many countries in the South. Especially, the strong conflictive dimensions of bio-innovation systems for the South have been emphasized, e.g. the very weak attention by the international biomedical research agenda to ‘illness of poverty’, the difficulties to enforce norms that protect the environment and the bio-diversity, and the discussions about IP rights concerning use of biological knowledge.<sup>9</sup>

In the industrialized world there is a new trend, which closely combines intellectual property with entrepreneurship – particularly within knowledge-based industries such as internet-/software-based and life sciences.<sup>10</sup> U.S. based universities are moving forward strongly combining entrepreneurship and intellectual property rights, e.g. universities such as MIT, Stanford and University of California at Davis. Also in Europe universities are creating platforms for combining entrepreneurship with intellectual property structures, such as the Center for Intellectual Property Studies at the Chalmers and Göteborg universities in Sweden. However, knowledge-based innovation, through start up of new firms or renewal of existing firms, is also an important strategy for development in some developing countries, e.g. there are many firms generating knowledge-based innovations, e.g. within internet/software in Bangalore, India. However, in many developing countries the structures for intellectual properties are very weak, and the understanding both within industry and university is limited. In addition, the law enforcement is practically non-existent which even more limits the interest of the industry and university to use intellectual properties for value creation.

## **Purpose**

The paper analyzes the status of intellectual property<sup>11</sup> in two Latin American countries and discusses alternative strategies for promoting and protecting knowledge on national as well as on university and company levels, with specific reference to the situation for life sciences.

In the discussion that follows below, of the conditions for IP in the South, we will primarily refer to the situation in Latin America, and more specifically to two of the poorest countries in the region in terms of economic development, Bolivia and Nicaragua. These two countries are however simultaneously immensely rich when it comes to bio-diversity. The analysis is based on 110 interviews in Bolivia and Nicaragua with representatives for different stakeholders, such as industry, government, university, financial sector, NGOs, patent offices.<sup>12</sup> With this analysis as a base, the paper presents alternative strategies for promoting and protecting knowledge in order to make it available and utilized on markets (to make business from or trade) and by society. The necessity of developing different and complementary strategies to satisfy needs from different stakeholder perspectives is emphasized, e.g. for indigenous populations, local and international business, universities and society. Finally, the paper argues for the need of taking a broader view,

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9 Arocena & Sutz (2005)

10 Petrusson (2004)

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12 Alänge & Scheinberg (2005), Arribasplata & Jiménez (2005), Scheinberg & Alänge (2006)

not only looking from the perspective of assets management, but also from the perspectives of property and capital management.

### ***IP and life sciences in two Latin American countries***

As we stated above, we will focus on the examples we collected that are linked to biodiversity. In both of these countries, Bolivia and Nicaragua, the biodiversity<sup>13</sup> is extremely rich. This biodiversity in combination with bioscience/technology is seen as a potential asset and the bioscience carries a high degree of knowledge content. However, when the knowledge has been developed it can typically be easy to copy. For example, to make bio-based pharmaceuticals is not a major problem nor extremely expensive once you have access to the recipe and an approval by the FDA, while the steps to develop this innovation in the first run could be extremely cumbersome and expensive. For example, it has been found that generic aids drugs could be produced to the cost of 2% in comparison to the sales price of the original drug (ref. India).

In our study, it was found that the IP infrastructure in the countries studied (Bolivia and Nicaragua) was very weak: the capacity to evaluate intellectual property was very limited, e.g. there were very few lawyers trained in this area, and lack computer systems to document and organize the information; in both countries there very few patent applications (104 in Nicaragua in 2002 and 300 in Bolivia in 2001, i.e. 0,03% and 0,09 % of the amount of patent applications in the US) and of these very few nationals applied for patents, instead the large majority were foreigners (around 90%); universities offer no courses or information to students or teachers on IP and IP processes; and the IP function is poorly institutionalized by government and in addition the jurisdiction of IP seems almost negliable. As a result IP and patents were not seen as strategic by anyone (academics or managers), rather the steps towards IP was mainly a defensive move based on foreign pressure to stop copying of CDs, jeans, etc. Among our interviewees, none saw the 'other side' of the patent system, e.g. the information diffusion, as an opportunity, and no one had ever searched for information in patent data bases in order to learn and make short-cuts. In addition, a thorough understanding of alternative IP strategies, based on an analysis of potential assets and strengths and weaknesses of present IP-structures in developing countries, appeared to be totally lacking.

One case presented to us in Bolivia concerned E-plant, a particular medical plant with a great potential of becoming an important starting point for medicines that can have effects on various diseases. The healing effects of E-plant have been known by indigenous communities for hundreds of years. A research project, involving European researchers, was initiated at the University of La Paz. Starting out by using the knowledge of a local indigenous community the researchers proceeded in the laboratory and succeeded to extract the important properties that could explain the medical effect of E-plant. During the analysis process the European researchers brought all research data back to Europe. And then, without knowledge and consent of their Bolivian partners, they applied and secured patents. As a result, the Bolivian researchers were blocked from continuing their research on this Bolivian asset and they were totally hindered from

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<sup>13</sup> Biodiversity = the variety of life in all its forms, levels, and combinations. It encompasses genetic diversity, species diversity, and ecosystem diversity.

being able to create any innovations based on their work on biodiversity and the collective knowledge of indigenous communities. The consequence of this un-ethical cooperation was that the value created from this potentially valuable asset, was more or less zero for the indigenous community, the university, the local industry and the Bolivian nation. In summary, it is clear that the weak IP structure in Bolivia contributed to the unfair outcome, when Bolivian researchers were confronted with a more aggressive (and non-ethical) European research and IP culture.

There are many similar examples that can be found in the literature, where the value for developing countries and their indigenous populations has been very limited.<sup>14</sup> However, there are also some examples where agreements and contracts have been set up in order to provide something back to the country of origin. One well known pioneering example is the agreement made in 1991 between the world's then largest pharmaceutical company Merck & Co. and the National Institute of Biodiversity of Costa Rica, where Merck paid one Million U.S. dollars up front in exchange of having the right "to screen plants, microbes and insects gathered in the forests for the possible use as drugs."<sup>15</sup>

Another example concerns a gene extracted from a rice variety from Mali, which was patented by the University of California at Davis (UCD) and which has a considerable commercial potential. In this case, the chief inventor took the initiative to establish a novel mechanism to compensate the source nation. A fund was set up with USD 150.000 advance share on royalties and a certain logic set up for further channelling of royalties to this fund by the university, the co-discoverers and some royalty or tax paid by other users of the gene. It also included a review of the university commitment when the fund had reached a certain level. This fund is used to provide UCD scholarships to students from Mali, and to some other West African countries, and to the Philippines where the breeding work was done.<sup>16</sup>

A third example did not initially involve foreign organizations, but South Africa's Council for Scientific Industrial Research (CSIR) which in 1998 was granted a patent based on hoodia, a plant which the San (one of the most ancient populations on earth) had been chewing for millennia on hunting trips as an appetite suppressant and thirst quencher. This appetite suppressant was seen to have a huge economic potential as drug against obesity. The patent was filed for without San knowledge, however after some campaigning the San reached a deal with CSIR to pay them 8% of all payments it receives from its licenses, as well as 6% of all royalties once the drug is commercialized.<sup>17</sup> If the three above described cases could be considered to be fair or not, is a matter that can be discussed as there are different ways of looking at the issue.

## ***An overview of IP strategies from the perspective of developing countries***

Which are the available strategies for creating value from indigenous knowledge? A starting point can be to review both available intellectual property rights (IPR) and existing legal and non-legal forms of agreements, and then to pose the question if these are viable means for developing

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14 E.g. Posey & Dutfield (1996, pp. 66-68), Ismail & Fakir (2004)

15 Booth, W. (1991), "U.S. Drug Firm Signs Up To Farm Tropical Forests", Washington Post, September 21, 1991

16 Grenier, L. (1998, p. 21-22)

17 Martin & Vermeylen (2005, pp. 43-46)

countries to pursue. First, we will present different forms of agreements and then we will present IPRs from the perspective of TRIPS<sup>18</sup>.

## Agreements

Posey & Dutfield (1996) provide an overview of legal and nonlegal agreements and comments upon their specific advantage and disadvantage for indigenous communities. They emphasize the importance of different forms of *legal agreements* (material transfer agreements, information transfer agreements and licensing agreements) as they require relatively little legal expertise to implement and they can be tailored to fit each situation. However, the requirement is that indigenous communities are able to make contracts and that they have the knowledge and resources to take legal action, if needed. Posey & Dutfield point out that the potential usefulness of contracts compared with the weakness of existing contracts calls for a need of developing guidelines for contract formulation, such as model contracts and covenants. Also *nonlegal agreements* such as letters of intent and memoranda of understanding can play a role, especially during early phases of negotiation.

## Intellectual property rights - TRIPS

Although different international agreements on intellectual properties have been in existence since the 1800s<sup>19</sup>, the TRIPS<sup>20</sup> agreement, valid from 2000, provides the first global framework for IPR, stipulating for the first time a minimum level of adequate IP protection and enforcement on an international scale. For most industrialized countries, to comply with TRIPS was not a major step while according to Levy (2000) “For developing countries, however, TRIPS requires the adoption of an entire new body of law, together with a framework to effectively enforce these new rights. This is a substantial legal and political undertaking.”<sup>21</sup> Hence, Levy expresses worries about developing countries interest in complying with TRIPS due both to the power of domestic political and economic forces and to doubts about if TRIPS are beneficial to them. Therefore, Levy argues for the need of a political will from both developed and developing countries and for a selective and strategic litigation bringing cases that are clear winners to court.

There have been some modifications of the TRIPS regulations due to needs that have developed after the introduction. One such need concerns the patent protection for pharmaceutical products in developing countries, where the need of providing medicine to the poor should not be affected by the patent system’s role in providing incentives for R&D into new medicines.<sup>22</sup>

There is a basic difference between different IPRs as regards to the openness of the information to the public. Patents, industrial designs, integrated circuit designs, geographical indications and trademarks have to be registred in order to receive protection. This registration includes a description of what is being protected and this description is public information. Copyright and

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<sup>18</sup> Trade-Related Aspects of Intellectual Property Rights (TRIPS)

<sup>19</sup> The 1883 Paris Convention for the Protection of Industrial Property (patents, industrial designs), The 1886 Berne Convention for the Protection of Literary and Artistic Works (copyright) and The 1891 Madrid Agreement concerning the International Registration of Trademarks.

<sup>20</sup> The WTO’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was negotiated in the 1986-94 Uruguay Round and introduced intellectual property rules into the multilateral trading system for the first time (WTO 2006)

<sup>21</sup> Levy (2000, p.789)

<sup>22</sup> WTO (2006, p.5)

trade secrets, on the other hand, are protected automatically and do not have to be registered, and are not seen as public information.<sup>23</sup>

## **Public information**

To be granted a *patent*, the invention must be useful (have industrial application), be novel, i.e. it should not previously be known in the public domain, and it should be non-obvious and more inventive than the mere discovery of something that already exists in nature. TRIPS stipulates that patent protection should be for at least 20 years and it must be available for both products and processes. There are possibilities for national governments to make some exemptions due to public order or morality. Plant varieties must be protectable by patents or by a special system (e.g. the breeder's rights provided by UPOV). If a patent owner abuses his rights and fails to supply to product on the market, the government may interfere and issue compulsory licences in order to make the knowledge available to others. Governments also have the right to take action in order to prevent owners of copyrights, patents or other IPRs to issue licensing agreements that restrict competition or impede technology transfer, which is abusing intellectual property rights.

*Industrial designs* must be protected at least 10 years. Owners of protected designs must be able to prevent the manufacture, sale or importation of articles bearing or embodying a design which is a copy of the protected design.

*Integrated circuits layout designs* protection ("topographies") must be available for at least 10 years.

*Geographical indications* identify a product's special characteristics, which are the result of the product's origin, e.g. champagne and feta cheese. Exceptions exist if a name is already protected as a trademark or if it has become a generic term, e.g. stilton cheese..

*Trademarks* are marketing tools to support firms' claim that their products are unique and authentic. They have also been extended to include service marks. Trademarks can also be held by an organization or association, which can let other firms use it provided they fulfil stipulated criteria, such as products being produced in a certain area or in a certain way, e.g. ecological production.

## **Private informaton**

*Copyright* protection was developed for different artistic forms of expression, such as literature, music and film. Under the heading of copyright also computer programs are protected like literary works and it nowadays also includes rental rights. For sound recordings the protection period is 50 years, while the copyright protection for computer programs is x years.

*Undisclosed information and trade secrets* can be legally recognized and protected as long as they are known only by a few persons. There is also a requirement that reasonable efforts should have been made to prevent disclosure. In the case of indigenous communities this could include restrictions on access to their area and setting up agreements with outsiders that secure confidentiality.

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<sup>23</sup> WTO (2006, pp. 3-7)

## ***Does intellectual property promote development?***

Discussions, on whether intellectual property has a positive or negative impact on development, tend to focus on the IPR regulation. A question asked is if the patent regulation has an economically positive impact or not.<sup>24</sup> Those who have a positive attitude tend to discuss IPR protection as incentives for creativity and innovative activities. They tend to discuss how the IPR regulations attract foreign investment and foreign out sourcing. A conclusion is often that the protection against piracy is a cornerstone of a globalized economy. Those who take a more skeptical stand towards IPRs are likely to question whether the patent regulation and the other IPRs only work in the interests of the industrial world. They discuss the risks of that the TRIPS provisions will result in the blocking of 1) knowledge sharing and technology transfer, 2) usage of traditional knowledge, 3) research efforts, 4) indigenous innovation, 5) diagnoses, treatments, cures, 6) and ultimately development. A focus on regulation leads this sceptical group to question whether the IPR provisions are well balanced, and further to question the criteria of protectability, the scope, the time period possible to uphold the IPR, the exemptions and the possible remedies.

However, if we limit the scope of the question and ask ourselves whether intellectual property is important in a process of utilizing, for example, bioscience, it becomes obvious that we can not really answer the question by discussing the regulation and its overall impact. We need to focus on how intellectual property concepts can be used in research and innovation. It then starts to become clear that the usage of intellectual property can both promote and block development. In a concrete situation a claim of a patentable invention in bioscience can be used to block others who would like to take further steps to innovate based on this protected invention. It can also be used to ensure openness and to promote the diffusion of the technology. The license mechanism offers a number of different ways to generate income for the patent holder and at the same time to enable access to intellectual property for others.

Below we will argue that the question of whether intellectual property will promote development or not is primarily a question of how we use the concepts of intellectual property in R&D and in business. This does not mean that we consider it to be unimportant how we handle the balance in the IPR regulations. However, we will argue the importance of going beyond an understanding of intellectual property as IPRs. In order to understand development we need to recognize and manage the institutional mechanisms that transform knowledge into assets, property and capital. Important to analyze and discuss is how intellectual property can be used to create the basis for capitalization and at the same time promote openness.

## ***An infrastructure for the creation of assets, property and capital in biotechnology***

A general conclusion as well a starting point for this section is that when it comes to intellectual property and development all countries are developing. We have for quite a while now experienced the dawn of a globalized knowledge economy. All over the world we are struggling with development processes where new knowledge is to be transformed into financial value and welfare. In more or less all business sectors we experience a structural transformation where we

struggle to find new property based value propositions and business models.<sup>25</sup> In the ICT sectors we claim software, databases, content, features, decision support systems and other knowledge based solutions as value propositions. In the biopharma sectors we for example elaborate on diagnostic tools and research tools. Many of us hesitate whether the claiming of property in early research settings will promote a sustainable development and welfare. At the same time the development very much illustrates the potential of claiming property technology when to construct 1) products and services, 2) commercial transactions and relations, 3) firms, 4) markets, and also for 5) platforms for research and knowledge sharing.<sup>26</sup> We are for example moving away from an approach to patents as a means to block others in favor for an approach where we use patents to package value propositions to others. Further, also in industrialized countries it is relatively easy to recognize that capital mechanisms are not adjusted for knowledge based business. Banks and other actors in the financial machinery are reluctant to recognize the outcome of bioscience as securities. Intellectual assets are difficult to have recognized as capital in accounting. It does not take much to end up in a bankruptcy situation. In bankruptcies and other insolvency situations values originated in biotechnology easily disappear.

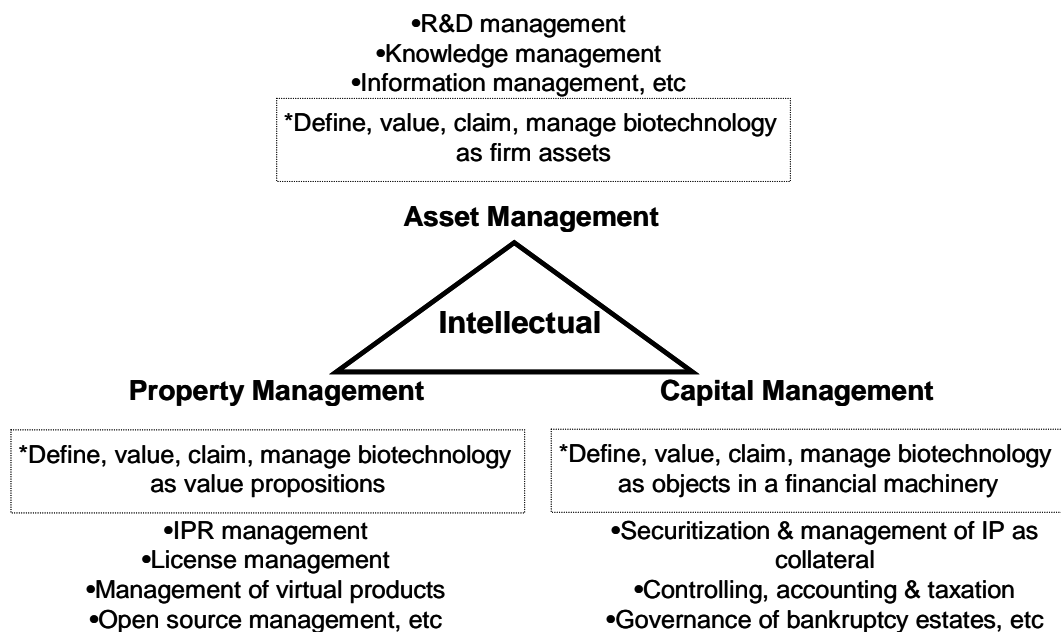
However, the fact that all countries are developing in a knowledge economy does not mean that all countries are on the same level. Of course, there are huge differences depending on industrial structure, legal tradition, etc. We can even argue that there is now a need to deal with an even more difficult gap – a “knowledge divide”. Still, all countries are explicitly or implicitly struggling with setting up a new infrastructure – “an intellectual infrastructure” – adjusted for creation of welfare from knowledge. In all countries there is a need of conceptual frameworks for when to claim 1) what is valuable for us (assets), 2) what we offer as a tradable objects (property) and 3) what should be recognized as objects in the financial machinery (capital). The discussion on the importance of intellectual property for development needs to be conducted within such a framework.

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25 Structural transformation - traces back to Marx' theory of the economy as a base and a superstructure, and how structures are based upon ideologies. Schumpeter, Hayek and others build upon this fundamental understanding. Schumpeter (1943) developed an understanding of creative destruction in structural transformation. Hayek (1945) developed an understanding of markets as selective information processes that generate spontaneous order. More recently, Nelson and Winter (1982) provided the bridge for a more operative understanding of how cognitive processes – in their words organizational routines and “genetic material” rooted in a specific historical and economic reality – are essential in shaping and constraining choices.

26 De Soto (2000)





*Figure 1: Transforming bioscience into assets, property and capital*

The challenge in this contextual framework is very much to manage the fact that intellectual assets, properties and capital are intellectual, i.e. they do not exist in themselves.<sup>27</sup> In the context of business and innovation it is obvious that intellectual properties are social constructions – constructions that are intertwined with the experienced existence of other social constructions, such as the firm, associations, financial institutions, markets etc.<sup>28</sup> Berger and Luckmann (1966:90) explain that “the origins of any institutional order lie in the typification of one’s own and others’ performances”. Focusing on patentable inventions and patents in biotechnology they can be described as typified intellectual objects (intellectual building block) created as a result of the communicative interaction of activities in four arenas. Contextually we know that patent concepts, as communicative means, have different receivers. The patent as a substantial concept means different things to the patent examiner, the judge in an infringement case, the judge in a contract-related case, the manager in a knowledge-oriented firm etc. However, this does not

<sup>27</sup> It is important to acknowledge that if we are to be able to understand the inherent complexity of intellectual property, we must question our understanding of law as well. Focusing on development we need a constructionistic approach where we recognize that neither law nor intellectual property exists in itself, and that law, as well as intellectual property, is nothing else than the beliefs which are communicated between different actors/governance structures. We need to get rid of the veil of naïve legal formalism and to foster a perspective that not only accepts that intellectual properties are social constructions, but also allows us to handle the construction process with an open mind. Legal realism, with critical analysis of intellectual property and rights as metaphysics, is an important path to increase such awareness. The Danish legal realist Alf Ross explained how law is of magical nature: Ross, Alf, *Virkelighed og Gyldighed i Retslæren - En kritik af den teoretiske retsvidenskabs grundbegreber*, Levin & Munksgaard (1934), p. 19. The Swedish legal realist Karl Olivecrona described legal phenomena as fantasy-beliefs: Olivecrona, Karl, *Lagens imperativ* (1942), p. 5.

<sup>28</sup> See further Petrusson, Ulf (2004), Lundqvist, M. A. and Petrusson Ulf, *Designing the role of the entrepreneur - using a norm constructionist approach at the interface of research, learning and innovation*, paper presented at the Triple-Helix conference, Copenhagen, Nov 6-9 2002.

necessarily result in confusion. Rather the opposite, the different communicative processes can be seen as the constructive foundation of the typified patents in the business context.

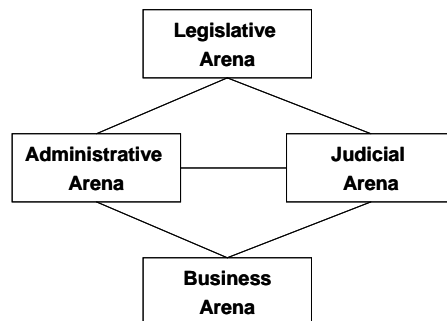


Figure 2: Creating intellectual property in four arenas

Thus, a fundamental theoretical challenge when analyzing the typification of intellectual property in a development setting is to evaluate how it interacts with the typification of other social constructs such as innovations and ventures. In this article we are especially interested in how the typification of intellectual property enables the typification of license structures for the promotion of knowledge transfer.<sup>29</sup>

### ***Analyzing transactions of intellectual property as means to promote openness***

Universities and public research organizations (PROs) all over the world are increasingly faced with the challenge of patenting in the field of bioscience. The opportunity to claim inventions “up stream”, i.e. in early research phases, generate a pressure to patent. They do increasingly also recognize the challenge to apply for patents not only to protect inventions, but also to promote openness.<sup>30</sup> For many actors this development is regarded as a response to an international pro-

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29 Bruno Latour is one of the important contributors to an understanding of the innovation and innovation projects as cognitive construction processes. Latour explains how research results, techniques, innovations, projects etc. are not autonomous objects and are not part of an existing ontology. Research and innovation projects, even in natural science, are social construction processes. They are cognitive processes that sometimes give themselves a context and some times do not. According to Latour we can have the word “context” replaced by the more friendly word “network” (Latour 1996: 135). Latour claims that technological projects are “deployed in a variable-ontology world”. This world is a result of the inter-definition of partakers and other actors (Latour 1996: 173). The project becomes a contextual and network-based translation and negotiation process. If we want systems, structures, institutions etc. to exist we must have normative closure. This is because they do not exist in themselves and thus cannot be described. Cognitive complexity has to be conceptualized and described as objects, persons, relations, autonomous disciplines, roles, etc. Spender (1996: 57) states: “Closure mechanisms are those aspects of the firm’s or industry’s internal processes which generate its autonomy and self-regulation facility, define its boundaries and interactions with others and help attenuate consideration of its endless externalities”

30 In European Union there is an increasing discussion going in relation to intellectual property rights can be used in the promotion of open innovation. “To the question “Why should PROs protect intellectual property” appropriate answers are “To encourage the economic applications of their discoveries for the benefit of the public” and “To make the research function more attractive and better supported”. To the question “How should this property be protected”, it is appropriate that the PRO takes steps itself, provided that these steps reflect good understanding of where

patent development – and a response to limit the impact of the ”patent thicket”, i.e. a situation where cross-licensing and a science-based R&D, where new knowledge builds on earlier developed and patented knowledge, risk resulting in a slow down of innovation processes.<sup>31</sup> Many of the initiatives that so far have been launched can also be characterized as experimental and are in relatively early phases in their development.

Just by elaborating on the intellectual property mechanism as a building block in a bioscience setting we can distinguish between a number of different approaches to openness, for example:

- open for evaluation without restrictions,
- open for research without restrictions,
- open for development without restrictions,
- open for research and/or development under payment (with or without fair and reasonable terms),
- open for development under payment and with grant back obligation (with or without fair and reasonable terms or not),
- open for commercialization under payment (with or without grant back),
- open for development & open distribution/commercialization – ”an open source model”,
- open for development, open distribution and open grant back ”another open source model”, and
- open without IP claims – ”traditional open science model”.

An example of open source development was recently published, which focuses on the process of making the antiviral drug Tamiflu (used to bloc the entry of bird flu virus into human cells), a production that presently is restricted due to a shortage of one key ingredient coming from a rare plant, the Chinese spice star anise. Two research groups have simultaneously published new synthetic ways of making the drug, one Japanese and one U.S. research group.<sup>32</sup> While the Japanese research group has patented their approach, the research group at Harvard University led by Nobel Prize winner Elias Corey (1990 for chemical synthesis) decided to put their process in the public domain. The Harvard research group has developed a new way of making the drug from two cheap, plentiful petrochemicals, acrylate and butdiene to replace the use of the rare plant. Asked why they did not file for an international patent Corey replied:

“I think that in situations like this where the issue is a humanitarian issue, involving possible loss of many human lives, the most important thing is to do anything one can to minimize those dangers and to increase the supply of the drug which should result in lowering the costs. So to me, it's just common sense that in a matter of public health one should do everything one can to make sure lives are saved.”<sup>33</sup>

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and how the benefits can accrue.” Responsible Partnering. Joining forces in a world of open innovation. A guide to better practices for collaborative research and knowledge transfer between science and industry, p.3. January 2005.

31 See e.g. Shapiro, C. (2006), “Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting”, in Jaffe, A. et al. eds., (2001), *Innovation Policy and the Economy*, Vol.1, MIT Press, Cambridge, MA

32 Both published online April 25, 2006, by the Journal of the American Chemical Society.

33 Prigent, G. (2006), “Big hope for the production of Tamiflu – a bird flu drug on large scale”, <http://scitizen.com>, 1 Jun, 2006

However, he also commented

“I hope the work will stimulate others to work on different ways of synthesizing Tamiflu.”...”Although our route is very efficient, it’s conceivable that when you put new developments together, you’ll have an even better and cheaper process.”<sup>34</sup>

Hence, Corey’s process invention put into the public domain can be seen as an open source development, or an open science model to the chemical synthesis process, which simultaneously, if successful, will provide tremendous human benefits but also a lowering of the demand for a rare plant (today around 90% goes to the production of Tamiflu), which of course can affect the producers of this plant. This logic of the innovation process that something is destroyed when something new is constructed, however, brought into the domain of indigenous knowledge of plants with medical effects and a subsequent research on and synthesizing of the effective components poses questions on the appropriation of value. Is it only the researcher/modern corporation that is to benefit or is there also at least a moral obligation of providing something back to the communities which originally developed the knowledge of the medical effects? Hence, in the perspective of openness, can the South find ways to thrive or do weaknesses on asset management and property management prevent the participation in a global open research society?

### ***The relative strength of North and South***

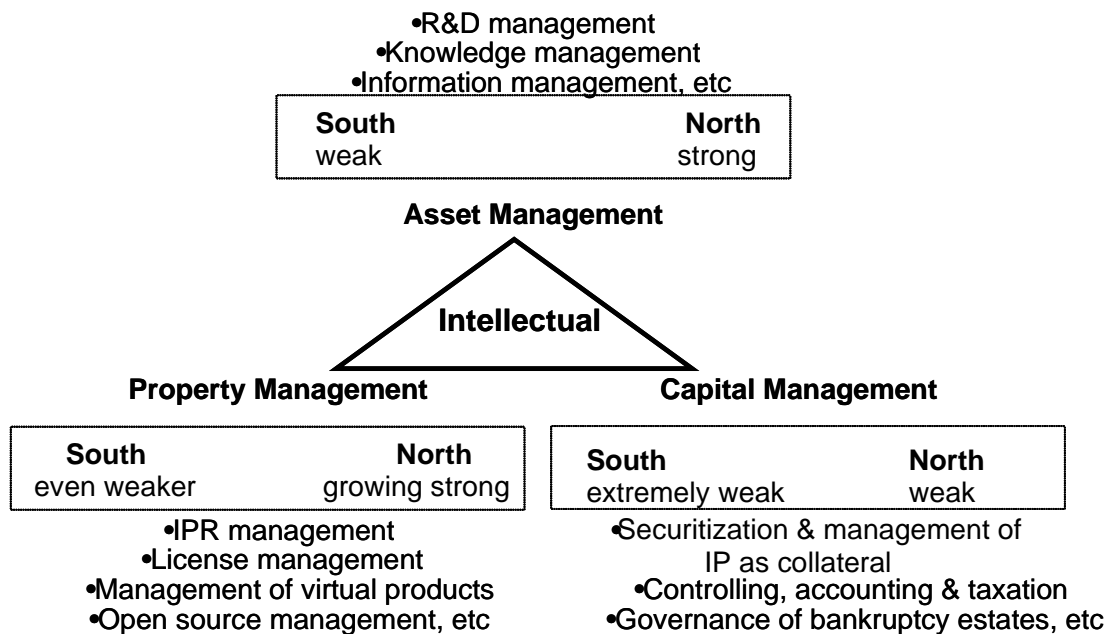
In order to understand relative strength of North and South in a knowledge economy - in terms of asset management, property management and capital management - we will now use the triple management model presented earlier to analyze the situation (see Figure 3).

The North is considerably stronger than the South in *asset management* in terms of management of information, knowledge and in conducting research and development. This especially concerns knowledge based on modern science. However, indigenous communities in the South are the guardians both of biodiversity and the knowledge of this diversity.

When it comes to *property management* the North is continuously growing stronger and is even more superior than the South, as the management of IPR and licences both in industry and governmental structures are poorly developed in most developing countries. In addition, these structures have been developed based on the needs of industrialized countries, i.e. of the North and its legal structures.

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<sup>34</sup> Thayer, A. (2006), “New Routes to Tamiflu Emerge: Research groups in the U.S. and Japan develop routes that avoid shikimic acid”, Chemical & Engineering News, May 1, 2006, p5



*Figure 3: The relative strength of South and North in management of intellectual assets, property and capital*

It is well known that weaknesses in the legal system around ownership and the use of land and physical assets as collateral has provided entrepreneurs in many countries in the South with severe problems in securing needed capital for investment.<sup>35</sup> However, when it comes to *Capital Management* the industrialized world is also weak and in search for new ways of using IP as collateral and a viable instrument for company development. Starting from an extremely weak position, the South is still far behind the North, as there are few if any who are aware of the need of developing new structures and instruments in order to use IP as capital for investments in development.

### **Strategy Alternatives for the South**

There is an array of strategies available for creating value from biodiversity and indigenous knowledge. Examples of these strategies include: IPR-based mechanisms, different forms of contracts, cooperations and practical use of knowledge. A starting point is to make sure that there will be no limitations to future use of the knowledge for traditional products and for local development.

One strategy alternative is to make sure that the knowledge enters into the public domain, for example by publishing books or articles describing the knowledge and how it can be used, e.g. for traditional medicine. This is done in order to block others from patenting what is known and used in a traditional society. A characteristic of such knowledge is that it is not written down but kept and diffused in an oral tradition. There are cases where foreign companies have succeeded to

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<sup>35</sup> De Soto (2000)

patent plant varieties which have been in the “public but oral domain” for centuries<sup>36</sup> but not have been “easily” found by the authorities granting patents, and hence, defensive publishing has a role to play to block such patenting at an early stage.

Many authors have been highly critical to the IPR system’s potential to contribute to value creation to the benefit of the South in general and indigenous communities specifically.

“IPR laws are generally inappropriate and inadequate for defending the rights and resources of local communities. IPR protection is purely economic, whereas the interests of indigenous peoples are only partly economic and linked to self-determination. Furthermore, cultural incompatibilities exist in that traditional knowledge is generally shared and, even when it is not, the holders of restricted knowledge probably still do not have the right to commercialize it for personal gain.

Various indigenous communities and ethnic groups that have occupied similar environments may possess the same, or similar, technical knowledge regarding a specific resource and its use. Therefore, payments to one community could engender conflict...

... the unequal power relations between (indigenous communities) and the corporate world would make it very difficult for communities to defend their IPR. Preventing companies from infringing their IPR ... presents serious difficulties because of the potentially high cost of litigation. (Posey & Dutfield 1996, p. 77)

Some authors have talked about a need of reforming or even about weakening of the international property protection as a means for developing countries to catch up. This is the same approach as the U.S. took when it was a young country striving to catch up and refusing to respect international intellectual property rights as it was seen as necessary for the nation’s social and economic development.<sup>37</sup>

However, according to Posey & Dutfield (1996), “IPR laws have usually been inimical to the interests of indigenous communities, but there are ways in which these laws can serve the interests of these communities.” (p.63). Using indigenous people’s knowledge of biodiversity as a starting point, there are a number of strategy alternatives available in order to create value. It is not possible to secure a product patent on naturally occurring organisms or genes that have not been isolated, which put limitations on what indigenous knowledge that is possible to protect by patents. But a process patent could be an alternative based on local knowledge of how to prepare substances based on natural resources. However, it is expensive and takes time to patent and a patent when granted has to be renewed annually. For some indigenous groups this process, to gain and uphold a patent, might in itself be too costly and demand too much. The most serious problem occurs when the patent holder needs to defend the patent from infringements. Then there is a competence and resource need, first to monitor possible infringements and second to take possible cases to court, which may be well beyond the abilities of patent holders in the South. Hence, the issue of obtaining a patent has to be combined with strategies on how to protect and create value based on the patent applied for.

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<sup>36</sup> One of the most flagrant was when the U.S. patent office granted a U.S. firm patent on quinoa, a grain that has been known and used in the Andes for centuries – however, this patent was challenged and in this case the U.S. patent office had to revise its decision.

<sup>37</sup> Martin & Vermeylen (2005, p.46)

Given today's competence and resource situation in developing countries one way to create value for indigenous communities is to make an agreement (contract) with an international organization with knowledge and resources. These international organizations could be universities or commercial firms, as in the examples provided earlier, which could be partners in the research process leading to a patent, the filing for a patent and in the subsequent commercialization and protection of the patent. Some universities and MNCs have tremendous resources and capabilities to create strategies around patents, which could be of great benefit to patent holders from a developing country. However, the extreme difference in competence and resources also makes the negotiation process concerning the conditions of the agreement very uneven, and as there are no rules for what is a fair agreement, as this is very much up to the stronger party's discretion. Sometimes this can lead to a more favorable agreement, sometimes to a less favorable for the weaker party from the South. In the example presented earlier of a patented gene extracted from a rice variety from Mali, the foreign researcher's own idea of what was a fair agreement mattered, in the same way as the example where a professor decided not to patent but to put his ideas in the public domain in order to stimulate further development in an open source fashion. However, in the future we could see a need for local advisory services, e.g. NGO's or university based technology transfer units, which can have a role both in creating business strategies and in negotiating agreements.<sup>38</sup> Local patent offices could as well develop this competence, but today their expertise is more typically limited to the area of filing for patents.<sup>39</sup>

Patents or non-patenting publishing in the public domain are not the only strategy alternatives available. There is a possibility of using other IPRs. Trademarks can help indigenous people marketing their knowledge and trademarks can also support claims for "unfair competition". Geographical indications could be an important way of protecting products provided it is possible to make an area based claim of specificity. To protect knowledge as trade secrets is definitely a viable road provided that steps are taken to delimit the access for everyone to the area. There is also an opportunity to develop cooperation approaches with different degree of openness and limitation in terms of who gets invited to share the knowledge, regardless of how it is legally protected. Here, different forms of open source approaches could play a role, including those which provide special focus on knowledge exchange open only for the South.

Looking at the relative strength of the South in an interconnected world where biodiversity provides potential for value creation, there is definitely a need of building capabilities in the South. In order to being able to influence that a substantial part of this value goes to the South local competence is needed, not the least in property management and capital management. Hence, this is a process that has to take place on several different levels simultaneously; in universities, industry, government agencies such as the national patent office, but also in government/parliament as legislators creating the foundations for ownership and capital management – including the use of intellectual capital as collateral. This process cannot take

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<sup>38</sup> From the perspective of being able to commercializing knowledge such unit could both support entrepreneurship towards new company formation as well as supporting innovation processes in existing firms.

<sup>39</sup> Private patent offices in the U.S. has developed this kind of business competence and to an increasing extent we see the same development in European patent offices which today not only hire patent lawyers but also professionals in strategy and business development..

place in isolation – there is a need of global cooperation on different levels<sup>40</sup> – international agencies and associations, cooperation with universities and MNCs in selected areas and a sharing of experiences across different countries in the South.

## **Conclusions**

We can conclude from above, that there is not one answer to the question on how to create value from indigenous knowledge, and there is not one strategy that fits all possible applications. Instead, there is a need of developing competence in analyzing and selecting among different strategic alternatives, including the use of IPRs. This competence development includes intellectual assets management and intellectual property management, which today both are weak in countries in the South. However, for value creation based on biodiversity and bioscience, there is like in other knowledge-based areas, also a need of developing capabilities in the area of intellectual capital management, which can be seen as a very big step, but a necessary step in order to take part in value creation in an interconnected world, where economic development to an increasing extent is dependent on knowledge based industry.

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<sup>40</sup> Not the least it is of importance to form alliances that possibly could influence the future development of global agreements including needed modifications of and/or additions to the TRIPS agreement to better fit the needs of developing countries, e.g. concerning issues such as respecting community ownership of intellectual property.



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