

Intellectual Property and Human Development Operationally Relevant Case Studies from Africa, Latin America and South Asia

Tuesday, December 14, 2010, 12:30 to 2:00 pm in MC 13-400

Chair: Carlos A. Primo Braga, World Bank Economic Policy and Debt Department (PRMED)

Presenters:

- ◆ Michael Gollin, PIIPA Board Chair and Founder
- ◆ Rita Khanna, Ph.D., JD, President of International Technology Transfer Management and legal counsel to Aeras Global TB Vaccine Foundation
- ◆ Caroline Okolo, Executive Director, African Artists Collaborative (AAC)
- ◆ Swarna Latha Soppadandi, LL.M, M.P.H., former IP Rights Officer for the National Biodiversity Authority of India (NBA)

Discussants:

- ◆ Gordon Myers, World Bank, International Finance Corporation (IFC) Legal
- ◆ Mark Dutz, PRMED

Abstract: Public Interest Intellectual Property Advisors (PIIPA) is a leading global network of pro bono attorneys, academics and practitioners in 49 countries providing professional services and capacity-building programs for developing countries. It has just released a book titled "Intellectual Property and Human Development", examining the social impact of IP laws relating to health, food security, education, preservation of traditional knowledge, new technologies, and contemporary challenges in promoting the arts. The presentation will summarize the main findings of the book, and illustrate concrete areas where IP has made a difference in spurring economic development including the role of: geographical indications and trademarks for premium cocoa beans in Venezuela; copyright protection in Nigeria's Nollywood movie industry anti-piracy strategy; patents and benefit sharing agreements to protect traditional knowledge in India; and patents and trademarks in attracting investors to finance a health care device in Nigeria.

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The Role of Intellectual Property in Poverty Alleviation/Reduction

HOW DO INTELLECTUAL PROPERTY RIGHTS PROMOTE ECONOMIC GROWTH AND TRADE, AND REDUCE POVERTY?

Strategic use of the IP system offers great promise in enabling developing countries participate in the global economy on a more even footing than in the past

Samuel, K., "Balanced and Accessible Intellectual Property System is a Challenge", *Business Line* (Hindu), September 26, 2007.

[Excerpt]

The ability to generate ideas, innovate and create is inherent in each one of us. These are resources that every country possesses and it is the IP system, which gives them value, allowing them to be transformed into viable, tradable assets. Through astute use of the IP system to harness their creative resources, the economic fortunes of countries no longer depend on physical factors such as natural resource endowments and geographical location. Indeed, in the era of knowledge-based economies, knowledge, information and ideas are the prime economic drivers and through use of the IP system it is possible to convert these ubiquitous intangible assets into concrete economic gain. Strategic use of the IP system, thus offers great promise in enabling developing countries to participate in the global economy on a more even footing than in the past.

Developing countries are increasingly finding that a balanced domestic IP system, which stimulates domestic innovation, allows them to obtain value from their creative resources. It will enable more opportunities for joint ventures, collaborative R&D, mergers and acquisitions, and franchising. An effective and balanced domestic IP system also serves as a powerful magnet in attracting foreign direct investment with all its implications for technology transfer and human resource training.

The availability of an effective national IP system that delivers IP titles (patents, trademarks, designs, copyright and related rights) in an efficient, timely and cost-effective manner enables a country's inventors and creators to draw value from the fruits of their labour. Awareness of the advantages to be drawn from the use of each of these tools of the IP system, however, is the key to unlocking their economic potential.

For example, trademarks play a key role in wealth creation. Trademarks are a means by which a company is able to build its reputation in the marketplace and thereby increase unit sales, cement customer loyalty, assist in responding to competitive pressure, expand and maintain market share, and differentiate its products, making them extremely valuable assets. Trademarks also help in introducing new product lines. They create opportunities for additional revenue streams by providing the foundation for franchise and licensing agreements.

The use of trademarks offers companies operating in developing countries great potential to build their commercial strength both nationally and internationally. Indeed, the exploitation of national identity and branding to attract investment and promote economic development has had noticeable success, particularly in niche and specialty marketing. In this respect, geographical indications are also a powerful tool with which to add value to prestige products from specific areas. When creatively and strategically presented to the discerning consumer, both trademarks and geographical indications can bring a considerable competitive advantage. Consider, for example, Cafe de Colombia (Colombia), Tequila (Mexico), and Mysore Silk (India).

Such tools, by securing the legal differentiation of products, thus, help increase the value of local products thereby boosting the local economy (including job creation), and improve the economic situation of small producers and SMEs and may further serve to promote local traditions, crafts and culture.

Similarly, the IP system may also be used both to preserve and draw value from a country's traditional knowledge of which there is an abundant supply in the developing world. Strategic use of the IP system to add value to traditional knowledge and/or to prevent its misappropriation presents an opportunity for indigenous and local communities to promote their own development objectives. The international IP community is currently exploring ways to ensure recognition and reward for holders and custodians of traditional knowledge used in a commercial setting.

Developing countries that recognise the opportunities afforded by effective IP protection and which are fully integrated into the international IP system are also becoming increasingly strong competitors in the information technology sector - a sector in which the potential value is harnessed through the IP system. Many are realising that this dynamic sector offers fertile ground for innovation and economic benefit - as with minimal risk and investment the potential return is substantial.

IP AND POVERTY QUOTES

We live in a knowledge-based economy. We also live in a global economy. There is no going back and pushing re-set on either of these societal trends. Intellectual property rights are integral to facilitating economic growth in a knowledge-based system. There is an increasingly undeniable link between economic growth and poverty alleviation.¹ In the current knowledge-based and global economic system, intellectual property will be an essential element in any successful effort to stimulate economic growth and achieve long-term poverty alleviation.

“On the issue of Intellectual Property Rights, **the leaders recognized that innovation plays a central role in addressing** the key global challenges of our times such as food security, **poverty eradication**, health, access to knowledge and climate change. They emphasized, in this context, the need for a balanced international intellectual property system capable of meeting those challenges on a truly global scale and reducing the technological gap.”

“ISBA: Countries, Commitment to Democratic Values, Inclusive Social Development Basis for Growing Cooperation”, *Asian News International*, April 16, 2010 (discussing the 4th Summit of the India-Brazil-South Africa Dialogue Forum).

“[A]s Africa turns to information technology for education, **to boost development and reduce poverty, it must strongly enforce intellectual property laws if it is to benefit from new innovations.**”

“Pirates Strangling Africa’s Growth”, *African Business*, December 1, 2008.

¹ See, for example: “[S]ustained economic growth is the ultimate tonic for poverty eradication....” *New Straits Times* (Malaysia), February 21, 2007.



The Role of Intellectual Property in Poverty Alleviation/Reduction

“Ministers and top officials from least developed countries (LDCs) highlighted the importance of **intellectual property (IP) as a strategic tool for alleviating poverty** and promoting wealth creation in least developed countries (LDCs) at a high-level forum organized by the World Intellectual Property Organization (WIPO) on December 12, 2007 at its Geneva headquarters. The Forum was attended by several ministers from LDCs, ambassadors and permanent representatives, and senior government officials....”

*“Importance of IP for Development in LDCs Emphasized at High Level Forum”
NewsPress (French language), December 14, 2007.*

“I see trade not only as a means of prosperity, but also as peace building. Collectively we need to devise an enlightened approach to... **transfer of technologies that help to combat poverty and such issues.**”

Lecture on globalization by Dr. Manmohan Singh, Prime Minister of India,
“Prime Minister Conferred with Degree of Doctor of Law by Cambridge University”
Hindustan Times, October 11, 2006.

LAW REVIEW ARTICLES ON INTELLECTUAL PROPERTY AND POVERTY REDUCTION

Deborah J. Cantrell, *Common Ground: The Case for Collaboration Between Anti-Poverty Advocates and Public Interest Intellectual Property Advocates*, 15 Va. J. Soc. Pol’y & L. 415, 415-445 (2008)

– This article is largely domestic in focus and is somewhat lacking in new meaningful examples. At the same time, this is one of the only articles to explicitly link public interest IP movements to poverty alleviation. The article makes a clear and convincing argument that there is space for collaboration between public interest IP advocates and anti-poverty advocates.

Mark Schultz & Alec van Gelder, *Creative Development: Helping Poor Countries by Building Creative Industries*, 97 Ky. L.J. 79, 79-148 (2008)

– This article makes the argument that creative industries are one of the best bets for economic development. “Creative clusters can be particularly powerful drivers of development in poor countries” because “they play to existing local strengths” and “suffer less from the deficiencies of poor countries.” *Id.* at 105. It would be difficult to quickly transform an undereducated, impoverished area into a competitive center of scientific or technological innovation. One pathway to successfully developing an area could be to instead first foster a creative industry. Creative industries can be powerful because they are primarily driven by private actors (engaged in both collaboration and competition). However, for a creative industry to succeed, there needs to be an institutional framework of copyright protection, licensing, and enforcement mechanisms. The authors discuss the problem of lack of copyright enforcement for musicians in Africa and suggest some ways that intellectual property laws could be better implemented and enforced to ensure that locals are able to receive the benefit of intellectual property protections.

Ronald P. Cantrell, Gene P. Hettel, Gerard F. Barry & Ruairaidh Sackville Hamilton, *The Impact of Intellectual Property on Nonprofit Research Institutions and the Developing Countries They Serve*, 6 Minn. J.L. Sci. & Tech. 253, 253-276 (2004)

– This article summarizes a symposium given by representatives of the International Rice Research Center (IRRI), a CGIAR center, on the connection between IP and poverty alleviation. The IRRI group believes that access to new technologies is central to helping people escape from poverty. They advocate for a portfolio of public intellectual property rights supplemented with case-by-case licensing from the private sector. They state that intellectual property rights accelerate, instead of impede, the movement of new technologies into the public domain. The article provides two examples of private sector donations of agricultural intellectual property – golden rice and Xa21, a gene that provides resistance to a bacterial crop disease – for further public research and development.

IP, CLIMATE CHANGE AND POVERTY ALLEVIATION

Climate change is expected to increase poverty significantly, but the degree to which it is already accountable for increased poverty is questionable. So, many climate change-related technologies are expected to help with adaptation to climatic changes, to reduce this expected increase in poverty. For example, drought resistant crops, vaccines for vector borne diseases - the incidence of which will increase with rising temperatures, etc. are all means of decreasing the human rights implications of climate change, but they would presumably have price tags, even at the competitive level, so whether they will alleviate poverty is uncertain.

Debate continues over how far climate change is caused by human activity. But one point is entirely clear: whatever its scale, humanity's impact on the climate – anthropogenic climate change, as the jargon has it – has essentially been caused by our technologies: the remarkable development and dissemination of the energy technologies that catalyzed the industrial revolution; the technological muscle that cleared much of the world's forests; the new industrial chemicals we synthesized and released into the atmosphere, unaware they would intensify the greenhouse effect. It follows that reversing the human impact on the atmosphere – climate change mitigation – also boils down to deploying the right technologies. And adapting to the inevitability of a transformed climate will also need new technologies, widely disseminated, such as crops that will still feed those living in hotter, drier, more saline conditions. So technology was the root of the problem; and technology will be at the core of the solution.

What role for intellectual property? The IP system, especially the patent system, is closely interrelated with many technologies that could help mitigate and some scenarios would cast IP as a problem – as a barrier to technology diffusion. This is a widespread assumption in the climate change policy community. IP is something you have to get around. Other scenarios would cast the IP system in a positive light, as contributing to the crafting of solutions – the many, diverse solutions we will need to address the impact of climate change.



CASE STUDY 1

ACCESS TO MEDICINE: HUMAN PAPILLOMA VIRUS VACCINE PATENTS Patent Landscape Report

Human papilloma virus (HPV) vaccines hold great promise for preventing cervical cancer, but 93 percent of mortality worldwide occurs in low- and middle-income countries, where high vaccine costs can restrict dissemination. For this reason, we understand that WHO is interested in providing HPV vaccines in developing countries such as Brazil, Indonesia, Thailand, and South Africa. In particular, WHO intends to provide HPV vaccines comprising L1 proteins from HPV 16 or HPV 18 or both. This report provides our view of the HPV patent landscape for such vaccines in the four countries of interest.

I. Search Strategy

The following patent searches were conducted in an attempt to locate relevant art:

A. Derwent World Patent Family Database

We used the search terms {"HUMAN PAPILLOMA VIRUS" or HPV} & (VACCINE IMMUNOSTIMULANT) & (L1 or "CAPSID PROTEIN" or "L1 PROTEIN"), and identified 182 patents and applications. Ten PCT applications were found to be potentially relevant and these are as follows:

- 1) WO 2009/092113 (US Government)
- 2) WO 2009/076824 (Shanghai Zerun Biotechnology Co., Ltd.)
- 3) WO 2009/059325 (Johns Hopkins University)
- 4) WO 2009/001867 (Japan Health Science Foundation)
- 5) WO 2004/056389 (GlaxoSmithKline)
- 6) WO 2003/097673 (University Cape Town)
- 7) WO 2003/077942 (GlaxoSmithKline)
- 8) WO 1996/029413 (Merck)
- 9) WO 1995/031532 (Merck)
- 10) WO 1993/002184 (University of Queensland)

B. European Patent Office Database

We searched for patents/applications filed by the six major players in the field, i.e., NIH, Georgetown University, Rochester University, Queensland University, Merck and GlaxoSmithKline, and uncovered four additional potentially relevant patents/applications as follows:

- 1) ZA9907638 (corresponding to WO 2000/035478) (University of Queensland)
- 2) ZA9606381 (corresponding to WO 1997/005164) (University of Queensland)
- 3) ZA9510832 (corresponding to WO 1996/019496) (University of Queensland)
- 4) BR9510520 (corresponding to: WO 1996/015247) (Merck)

C. Thailand Patent Office Database

As we were unable to locate a volunteer to help us in Thailand, we conducted a search of the Thai patent database, using the search terms "HPV 16," "HPV," or "human papilloma virus," and uncovered six potentially relevant patents/applications, as judged by the machine translated titles:

- 1) 0101000166. (Pfizer)
- 2) 0101003174. (GlaxoSmithKline)
- 3) 0201004728. (Saint Petrochemicals)



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- 4) 0401003173. (Merck)
- 5) 0401003770. (Merck)
- 6) 0401004490. (Merck)

D. Indonesia Patent Office Database

We initially conducted searches using search term “HPV 16,” “HPV,” or “human papilloma virus,” and found six potentially related Indonesian patents/applications.

- 1) W00200401546 (Corresponding to WO/2003/054002) (Centro de Ingenieria Genetica y Biotecnologia)
- 2) W00200501933 (Corresponding to WO/2004/056389) (GlaxoSmithKline)
- 3) W00200502537 (Corresponding to WO/2004/084831) (Merck)
- 4) W00200603565 (Corresponding to WO 2005/123125) (GlaxoSmithKline)
- 5) W00200501138 (Wyeth Holdings Corporation)
- 6) W00200703555 (GlaxoSmithKline)

Independently, our Indonesia volunteer, Tantono Subagyo, also conducted searches and identified four potentially related Indonesian patents/applications. These correspond to the first patents/applications of our list.

E. South African Patent Office Database

Our South African volunteer, Jabulani Mthombeni, conducted searches using the keywords “HPV,” or “HUMAN PAPILLOMA VIRUS,” or “HPV L1.” The relevant patents/applications uncovered in these searches overlap with the results of our searches.

F. Canadian Patent Office Database

Our Canadian volunteer, Martin Marcus, conducted searches for (i) patents covering the production in yeast of the L1 protein from HPV 16 or HPV 18, and (ii) patents covering the production of a vaccine containing both HPV 16 L1 and HPV 18 L1 in combination with aluminum adjuvant.

The relevant patents/applications uncovered in these searches overlap with the results of our searches.

II. Preliminary Analysis of the Search Results

From the search results, we then attempted to determine what patents/patent applications are currently in force in the four countries of interest. We also attempted to determine whether any claims might pose an infringement issue for the goals of the project. As we are not authorized to practice in the four countries of interest, any conclusions set forth here should be verified with a local patent attorney. We have, however, considered under general patent law considerations whether certain patents/patent applications may pose more of a problem than others in an attempt to show the current patent situation in each of the four countries of interest.

A. Pending PCT Applications

For four of the PCT applications uncovered in our searches, nos. 1) to 4) above, the time to enter national stage has not yet expired as of the date of this report. Thus, corresponding applications may eventually be filed in Brazil, Indonesia and/or South Africa. It does not appear that these corresponding Thai applications have been filed. As these four PCT applications are relatively recent, it would appear that even if filed, the applicants will not obtain broad general claims given the amount of existing prior art. Thus, general claims directed to vaccines comprising HPV16

L1 or HPV 18 L1 will most likely not be granted in those applications. Following is a brief summary of those four PCT applications:

- 1) WO 2009/092113 (priority date 11/23/2007) (US Government)
Eliciting an Immune Response in a Subject Comprises Administering an Immunogenic Composition to an Epithelial Surface of the Subject in Combination with One or More Agents or Treatments to Disrupt the Epithelial Surface
- 2) WO 2009/076824 (priority date 11/23/2007) (Shanghai Zerun Biotechnology Co., Ltd.)
Novel Codon Optimized Gene Encoding Major Capsid Protein L1, Useful for Producing Major Capsid Protein L1 of Human Papilloma Virus Used for Preventing and Treating Diseases Related to Human Papilloma Virus Infection
- 3) WO 2009/059325 (priority date 11/02/2007) (Johns Hopkins University)
Multitype HPV Peptide Compositions and Methods for Treatment or Prevention of Human Papilloma virus Infection
- 4) WO 2009/001867 (priority date 06/26/2007) (Japan Health Science Foundation)
Capsid for Producing Vaccine that Induces Neutralizing Antibody Against Human Papilloma virus (HPV) Type 16, 18, 31, 52 And 58, Has Aggregate Of Protein Comprising L2-Epitope Of HPV16 Inserted In Loop Region Of HPV16 L1 Protein

B. Status of the Related Patents/Applications in Brazil

Our Brazilian volunteer, Benny Spiewak, checked the status of all the related Brazilian patents/applications. He found that none of them have yet issued as patents and a number have been rejected and abandoned. Other than for the four PCT applications mentioned in the previous paragraph, there appears to be no impediments to the project in Brazil. The following is a summary of these Brazilian patents/applications and a description of what they attempted to cover:

- 1) BR0317544 (Corresponding to WO 2004/056389) (GlaxoSmithKline)
Abstract : A Composition Comprising Human Papilloma Virus (HPV) 16 And HPV 18 Virus-Like Particles (VLPS), Useful in Preparing a Medicament for Preventing Infection Caused by One or More Oncogenic HPV Types, Excluding Types HPV 16 and HPV 18
Status : The Brazilian phase of the PCT-related patent started on November 11, 2005. No additional info is available.
- 2) BRPI0512042 (Corresponding to WO 2004/056389) (GlaxoSmithKline)
Abstract : (see above)
Status : The Brazilian phase of the PCT-related patent started on February 6, 2008. No additional info is available.
- 3) BR0308444 (Corresponding to WO 2003/077942) (GlaxoSmithKline)
Abstract : New Vaccine Composition Comprising VLPS Containing L1 Proteins or Functional L1 Protein Derivatives from HPV 16, HPV 18, HPV 31 or HPV 45 Genotypes, Useful for Preventing or Treating HPV Infection or Cervical Cancer
Status : The Brazilian phase of the PCT-related patent started on January 1, 2005. No additional info is available.
- 4) BR9510520 (corresponding to WO 1996/015247) (Merck)

Abstract : The present invention is directed to purified recombinant proteins of papilloma viruses (PV) and methods of making, measuring, using and formulating the same.

Status : On December 30, 2003 the Brazilian PTO (INPI) denied the request for registration of such invention. INPI concluded that the invention-related application failed to meet criteria for registration.

5) BR 9507657 (corresponding to WO 1995/031532) (Merck)

Abstract : New Isolated Papilloma : Virus L1 and L2 Proteins - For Treating or Preventing Papilloma Virus Infection and for Prodn. of Antibodies, Detection and Diagnosis

Status : On December 27, 2005, the Brazilian PTO (INPI) denied the request for registration of such invention. INPI concluded that the invention-related application failed to meet criteria for registration.

6) BR 1100183 (corresponding to WO 1993/002184) (University of Queensland)

Abstract : Production of Papilloma Virus-Like Particles - Which Contain L1 And L2 Proteins, Useful as Vaccine Against Papilloma Virus Infections and in Diagnosis

Status : On October 10, 2006, the Brazilian PTO (INPI) denied the request for registration of such invention. INPI concluded that the invention was not non-patentable. This patent relates to a so-called pipeline case, arising from a mechanism adopted in Brazil and that allowed patent claims to be accepted and approved for previously unrecognized technological fields, such as pharmaceutical and food products. The applications for pipeline patents do not undergo any technical analysis by the Brazilian patent office, the National Institute of Industrial Property (INPI). INPI normally could have analyzed novelty, inventiveness and industrial application. Currently, the applicant is challenging INPI's decision. This case is still pending decision by the courts of the Federal District, i.e., Brasília.

C. Status of Related Patents/Applications in South Africa

According to our South African volunteer, Jabulani Mthombeni, there are four related patents-in-force. Following is a brief summary of these patents-in-force:

1) ZA9907638 (corresponding to WO 00/35478) (University of Queensland)

Independent claim 1 : A method of treatment of an existing papilloma virus (PV) infection which includes the step of administration of PV VLPs selected from the group consisting of PV L1 VLPs and PV L1/L2 VLPs to a patient suffering from the PV infection.

2) ZA9606381 (corresponding document: WO 97/05164) (University of Queensland)

Independent claim 1 : A polyprotein construct comprising at least two amino acid sequences fused directly or indirectly together, each of said sequences being the sequence of an early ORF protein of papilloma virus (PV) or an immunogenic variant or fragment thereof, and at least one of said sequences being other than the E6 or E7 protein sequence or an immunogenic variant or fragment thereof.

3) ZA 9602245 (corresponding to WO 96/029413) (Merck)

(The claims are directed to VLPs derived from L1 of HPV 18)

Independent claim 1 : An isolated and purified DNA molecule which encodes human papilloma virus type 18 or a functional derivative thereof .

4) ZA 9510832 (corresponding to WO 96/19496) (University of Queensland)

Independent claim 1 : A variant of the human papilloma virus (HPV) E6 or E7 protein, said variant being able to elicit a humoral and/or cellular immune response against HPV in a host animal but not being cell-transforming in said host animal.

5) ZA200709210 (corresponding to WO 2004/056389) (GlaxoSmithKline)

Independent claim 1: Use of a composition comprising HPV 16 and HPV 18 VLPs in the preparation of a medicament for the prevention of infection and/or disease caused by one or more of the group of oncogenic HPV types, the group excluding types HPV 16 and HPV 18.

6) ZA200410137 (corresponding to WO 2003/097673) (University Cape Town)

Relevant claims:

Claim 18. A polypeptide ... which is a chimaeric HPV L1 virus-like particle or capsomer.

Claim 24. A vaccine including a chimseric human papilloma virus (HPV) L1 polypeptide as described in ...claim 18

Claim 25. A vaccine according to claim 24, which is for use in the prophylactic or therapeutic treatment of HPV infection.

Claim 26. A vaccine according to claim 25, which is for use in the treatment of HPV 6,16 or 18.

The status of ZA200407029 (corresponding to WO 2003/077942) (GlaxoSmithKline) is unknown. Independent claim 1 of WO 2003/077942 reads: "A vaccine composition comprising VLPs containing L1 proteins or functional L1 protein derivatives from HPV 16, HPV 18, HPV 31 and HPV 45 genotypes."

As you know, South African patents are granted without examination, so it can be assumed that they are all in force with their originally filed claims. Annual maintenance fees need to be paid to maintain these patents in force so that it will be necessary to check this before implementing any projects as some of these may not be effective in the future. For those that are effective, South African law allows for a court proceedings to be brought to revoke patents, and our understanding is that any claims that are clearly anticipated can serve as the basis for revoking the patent. Accordingly, the granting of the South African patent, of itself, is not an indication of the strength of the patent unless there is no anticipatory prior art.

D. Status of Related Patents/Applications in Indonesia

Four applications are pending at present.

1) W00200401546 (Centro de Ingenieria Genetica y Biotecnologia) (corresponding to WO/2003/054002)

Title: Peptides for the Treatment of Cancer Associated with the Human Papilloma Virus (HPV) and other Epithelial Tumors

Independent Claim 1 (in Spanish) : Péptidos con capacidad de unión al sitio de fosforilación por Caseína Kinasa II (CKII) caracterizados porque presentan las secuencias : (a) CSVRQGPVQKC (Id. Sec. No. 1) (b) CSSCQNSPALC (Id. Sec. No. 2) (c) CQIPQRTATRC (Id. Sec. No. 3) (d) CAKQRTDPGYC (Id. Sec. No. 4) (e) CWMSPRHLGTC (Id. Sec. No. 5) (f) CRNCTVIQFSC (Id. Sec. No. 6) (g) CHYIAGTVQGC (Id. Sec. No. 7) (h) CPLVSLRDHSC (Id. Sec. No. 8) (i) CKQSYLHLLC (Id. Sec. No. 9) (j) CFQPLTPLCRC (Id. Sec. No. 10) (k) CQSYHELLLQC (Id.



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Sec. No. 11) así como cualquier variante homóloga o mimética de los mismos obtenida por vía sintética o recombinante.

Status : Not yet granted.

2) W00200501933 (GlaxoSmithKline) (corresponding to WO/2004/056389)

Related Claims

Claim 1. Use of a composition comprising HPV 16 and HPV 18 VLPs in the preparation of a medicament for the prevention of infection and/or disease caused by one or more of the group of oncogenic HPV types, the group excluding types HPV 16 and HPV 18.

Claim 21. A vaccine composition comprising an HPV 16 VLP and an HPV 18 VLP which is cross protective against infection and/or disease caused by oncogenic HPV types other than type 16 and 18.

Status : Not yet granted.

3) W00200502537 (Merck) (corresponding to WO/2004/084831)

Related Claim:

Claim 1 : A nucleic acid molecule comprising a sequence of nucleotides that encodes an HPV31 L1 protein as set forth in SEQ ID NO : 4, the nucleic acid sequence being codon-optimized for high level expression in a yeast cell.

Status : Not yet granted

4) W00200603565 (GlaxoSmithKline) (corresponding to WO 2005/123125)

Related Claims

1. An immunogenic composition comprising VLPs or capsomers from HPV 16 and 18 and at least one other HPV cancer type, the other cancer type being selected from the list consisting of HPV types 31, 45 and 52, wherein the dose of the VLP or capsomer of the at least one other cancer type is reduced relative to that of HPV 16 or 18.

18. A vaccine comprising an immunogenic composition according to any preceding claim with a pharmaceutically acceptable excipient.

19. A method of preventing HPV infection and/or disease comprising administering to an individual in need thereof a composition or vaccine as defined above.

Status : Not yet granted.

E. Potentially Related Patents/Applications in Thailand

There are six potentially related patent applications in Thailand, none of which has been patent yet.

1) 9601001865 Oligonucleotides complementary to a nucleic acid of human papilloma virus
38 Claims in total

Relevant claims :

1. Synthetic oligonucleotides complementary to a nucleic acid spanning the translation start site of human papilloma virus gene E1

Equivalent to : US patent no. 6,509,149 (F.HoffMann La Roch AG.)

2) 0101000166 Anticancer compound and enantiomer separation method useful for synthesizing said compound 12 claims reduced to 8 claims after publication

Relevant claims :

1. The compound (=)-6-[Amino-(6-chloro-pyridin-3-yl)-(3-methyl-3H-imidazole-4-yl)-methyl]-4-(3-chloro-phenyl)-1-cyclopropylmethyl-1H-quinolin-2-one, or a pharmaceutically acceptable salt, solvate, prodrug, or isotopically-labelled derivative thereof.

Equivalent to : US patent no. 6,479,513 B2 (8 claims) (Pfizer)

2) 0101003174 Novel compounds 21 claims reduced to 10 claims after publication

Relevant claims :

1. A method for producing a hepatitis B antigen suitable for use in a vaccine, the method comprising purification of the antigen in the presence of a reducing agent having a free –SH group.

Equivalent to : EP 1666487 B1 (10 claims)

Request for examination of the invention on 13/11/2008 (GlaxoSmithKline)

3) 0201004728 Peptides for treatment of the human papillomavirus (HPV)-associated cancer and other epithelial tumors 13 claims in total

Relevant claims :

1. Peptides that bind and inhibit the Casein Kinase II (CKII) phosphorylation site which present the following sequences:

No equivalent

Request for examination of the invention on 14/06/2009 (Centro de Ingenieria Genetica y Biotecnologia)

4) 04010003173 Optimizer expression of HPV 31 L1 yeast 43 claims in total

Relevant claims :

1. A nucleic acid molecule comprising a sequence of nucleic molecule comprising a sequence of nucleotides that encodes an HPV31L1 proteins as set forth in SEQ ID NO:4, the nucleic acid sequence being codon-optimized for high level expression in a yeast cell

No equivalent (Merck)

5) 04010003770 Optimized expression of HPV 45 L1 in yeast 25 claims in total

Relevant claims :

1. A nucleic acid molecule comprising a sequence of nucleic molecule comprising a sequence of nucleotides that encodes an HPV45L1 proteins as set forth in SEQ ID NO:2, the nucleic acid sequence being codon-optimized for high level expression in a yeast cell

Equivalent : PCT/US2004/031326 (WO/2005/032586) (Merck)

6) 04010004490 Optimized expression of HPV 58 L1 in yeast 29 claims in total

Relevant claims :

1. A nucleic acid molecule comprising a sequence of nucleic molecule comprising a sequence of nucleotides that encodes an HPV58L1 proteins as set forth in SEQ ID NO:2, the nucleic acid sequence being codon-optimized for high level expression in a yeast cell

Equivalent : PCT/US2004/037372 (WO/2005/047315) (Merck)

III. Conclusions

Based on the foregoing, there are no current patents claiming HPV vaccines comprising L1 proteins from HPV 16 or HPV 18 in Brazil, Thailand and Indonesia. There are at least two patents in South Africa that are relevant to the production of HPV vaccines comprising L1 proteins from HPV 16 or HPV 18. In particular, ZA 9907838 claims a method of treatment of an existing papilloma virus (PV) infection which includes the step of administration of PV VLPs selected from the group consisting of PV L1 VLPs and PV L1/L2 VLPs to a patient suffering from the PV infection. Also, ZA 9602245 claims an isolated and purified DNA molecule which encodes human papilloma virus type 18 or a functional derivative thereof.

CASE STUDY 2

COPYRIGHT PROTECTION: A NOLLYWOOD ANTI-PIRACY STRATEGY

Overview

Name:	African Artists Collaborative	Object of Protection:	Movies and Music Recordings Creative Arts
Organization Type:	NGO	Instrument of Protection:	Copyrights
Industry:	Film	Focus:	Branding, IP Management, Licensing
Country/Territory:	Nigeria (Federal Republic of)		

Background

The African Artists Collaborative (AAC) was established in the United States as a nonprofit organization to support the Intellectual Property Rights of African artistic products sold in the U.S., by creating access to US copyrights procedures and processes as well as legal representation through litigation of IP infringement of their works. AAC was established with three members of the Board of Directors of Filmmakers Association of Nigeria, USA (FAN): Tony Abulu (President & C.E.O.); Caroline Okolo (Director of Operations and IP Issues) and Samuel Adewusi (Legal Adviser).

It is pertinent to note that for the first time ever, Africans have been able to create a commercial product which has been accepted by large niche markets in the United States, the Caribbean and Europe. This is highly unprecedented! Within a five-year period (2003-2008), the African film Industry popularly referred to as Nollywood produced over 10,000 original film titles. Unfortunately, the Africans do not receive full financial benefits from the distribution of these films in the US due to massive piracy of their works. African Artists Collaborative (AAC) is poised to help reduce copyright infringement of African entertainment products in the United States.

The Copyright Problem

African artists have been at a disadvantage in comparison to their counterparts in the Americas and European nations. To date, 85% of music, film, and art, among other works, is being pirated openly in the United States and Europe, within niche market communities that boast that no legal repercussion will come out of their flagrant disregard of the United States copyright laws. Within the African communities in the US, it has become part of everyday business to patronize entities that publicly buy and sell pirated products to the public in the open market. This has caused great frustration to the IP rights owners as they travel the US to promote their work(s), frustrated that they have no access to representation or remedy to this very obvious drain on their earning capabilities. It is even worse among African musicians, who simply stand back and watch pirates buy one single copy, illegally replicate it and infinitely distribute the product, coast to coast in the US for profit, without any compensation to the artist.

In the past, FAN USA took on some obvious offenders by pleading with the store owners to work hand-in-hand with the artists to supply them with legitimate copies of their works for sale in the US. The result was discouraging, as the number of pirates increased exponentially. The majority of US



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store owners that sell these pirated products suffer no repercussion, claim that the products were not copyrighted in the US, and therefore conclude that copyright laws cannot be enforced. To date, the niche market still continues in this practice of buying and selling pirated copies causing the loss of revenue to the artists, many of whom have been sadly forced to lose all hope and go out of business in Nollywood.

If this trend is allowed to continue, the bleeding of African arts revenue will eventually lead to the death of what is heralded as a major emerging film market in Africa with the potential of creating a sustainable and significant revenue stream for numerous developing nations. The rise and demise of Nollywood could very well be playing out before our eyes, unless measures are immediately put in place to safeguard the continuity of the Nollywood industry. It is interesting to note that the African music industry (many of whom have also approached FAN and AAC for help) is suffering the same fate.

Copyright Strategy

African Artists Collaborative (AAC) was able to articulate the problem as being an excessive pirating of Nollywood movies in the United States, specifically in local niche markets and the illegal online streaming on identified websites. By identifying the problem, AAC with PIIPA's support created a Copyright Registration Initiative and Online Infringement Removal Strategy as a frontline solution to mitigate the revenue losses for African filmmakers.

The IP Solution/Strategy

Highlights of AAC's copyright registration initiative goals and strategy are:

1. **Copyright Registration Drive:** With help from PIIPA-assigned law firms, AAC is currently registering many motion picture works of Nollywood filmmakers in the United States by utilizing *pro bono* legal representation. This initiative has helped encourage the good habit of copyright registration of Nollywood motion picture works in the United States, prior to publishing or distribution.

AAC has been working with PIIPA-assigned law firms to register filmmakers who reside in Africa and also in the Diaspora, whose works are being flagrantly violated in the marketplace. The lack of proper legal representation in the US has made it a free-for-all for pirates to duplicate and openly resell the artists works without repercussions.

2. **Digital Millennium Copyright Act (DMCA):** After copyrights registration and publication of the works in the US, AAC identifies infringing websites that illegally stream the artists' films. The list is compiled and turned over to the attorney's office. The DMCA is a great tool in helping persuade Internet Service Providers (ISPs) that the streaming work is in violation of the US copyright laws and is infringing on the artists' copyrights.

This strategy of removing the infringing materials from identified websites is a critical key to the survival of the Nollywood film industry. AAC has identified at least 14 habitual offenders that we hope can be prosecuted in the near future.



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3. **Cease and Desist** letters issued to US store fronts: This strategy is to identify and possibly in the future, litigate major niche market stores and distributors in the US who are openly distributing pirated copies from their stores in the US.
4. **Copyrighted in the US Logo Initiative** was initiated in collaboration with Filmmakers Association of Nigeria, USA (FAN) and PIIPA representing attorneys. FAN USA brought major African film distributors in the US to the table, and they agreed in turn to utilize an approved logo that reads “FAN USA: US Copyright Protected” on the movie armory packaging, to clearly identify Nollywood films copyrighted in the US. This initiative has single-handedly sent a clear message to the pirates that the movies bearing the logo have been copyrighted in the US and are subject to full legal protection according to US copyright laws. The cost of the implementation of this Copyright logo campaign was born by the US-based African film distributors, even though it increased the product price. AAC has observed that the US pirates have avoided infringing on the films with the “FAN USA: US Copyright Protected” logo. There is no better advertisement or example of the power of copyright registration than the successful implementation of the logo initiative.
5. **Litigation(s)**: On behalf of its member clients, AAC hopes to link the filmmakers to a US law firm that is willing to litigate identified egregious copyright infringement cases in the near future.

Business Results

In terms of the effect that our copyright initiative has had on the cash flow intake of the affected distributors, we can readily point to three major distributors who account for 90 percent of all Nollywood distributed films in America. They are: Sanga Entertainment, Executive Image African films, and Franco films. Based on the removal of the copyrighted films from the infringing websites, revenues have jumped 20 percent so far. They release an average of 30 films a month and the effort has only been able to copyright only a fraction of their films. With added copyrighting of other titles, it is believed that sales can jump exponentially.

Success Based on IP Protection and Copyright Enforcement

The AAC/PIIPA collaborative Copyright Registration Initiative and Online Infringement Project to-date has produced great success. We have registered over 100 African films and have removed infringing materials from over 50 identified websites, especially from the sites of habitual online offenders. Most importantly, it has sent an encouraging message to the African filmmakers, who are often skeptical about the practical application of Intellectual Property Rights to their works, that the AAC/PIIPA Copyright Registration Initiative can directly impact their revenue stream.

The vision and goals discussed were developed as a culmination of events and various attempts and struggles initiated by FAN USA in support of Nollywood. As the world draws closer to becoming one giant global market, Africa is left behind in the Intellectual Property Rights race because it has not successfully linked the IP initiative to a visible revenue stream that is easily understood in plain terms by its indigenes. With the emergence of Nollywood, (which is still largely unknown in the global marketplace), an enthusiasm to understand the importance of Intellectual Property Rights issues, and its economic impact as it relates to nation building, is now dawning on the African film



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industry. This is an opportunity that AAC and its legal collaborators must seize. There is a well of opportunity for individual organizations that assist in correcting the massive piracy of the work of African artists and market share imbalance in the US market place.

As a direct result of AAC's efforts on November 4, 2010 in Brooklyn, New York, the Kings County District Attorney Charles J. Hynes announced an investigation into the counterfeiting and illegal sale of movies from the Nigerian film industry. Investigators executed search warrants at nine stores, from which they recovered more than 10,300 counterfeit DVDs; five multi-slot, high-volume disc duplicators; as well as hundreds of blank DVDs, disc cases and sleeves, and pre-printed media covers. DIs also recovered laptop computers, business records, checkbooks and bank records, from the various businesses. Those responsible could face charges including Trademark Counterfeiting and Forgery and could receive sentences of up to seven years in prison.

“The villains in this drama are the shop owners who peddle pirated DVDs, a crime that is tantamount to outright theft,” said District Attorney Hynes. “The sale of bootleg and counterfeit goods deprives the city and state of New York of millions of dollars in sales tax revenue, at a time when we all need it most, and it deprives the artists who made the movies of their well-deserved proceeds. I would like to thank Tony Abulu and the Filmmakers Association of Nigeria and the AAC for their support in this investigation.”

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Caroline Okolo, Executive Director, African Artists Collaborative

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CASE STUDY 3

Benefit Sharing Arrangements: Jeevani – A Model for the Protection of Traditional Knowledge and Poverty Alleviation in India

Overview

Name:	Kani Tribe and TBGRI	Object of Protection:	Distinctive Signs / Commercial Names, Goods with Specific Geographical Origin, Traditional Knowledge
Organization Type:	Government, Tribal Society, NGO,	Instrument of Protection:	Patents, Access & Benefit Sharing Agreements and licensing.
Industry:	Health Care, Genetic Resources	Focus:	Collective rights, IP Management and Licensing
Country/Territory:	India (Republic of)		

Background

Traditional Knowledge (TK) in India has been in practice since many centuries. The traditional systems of medicines like Ayurveda and Yoga date back approximately 7,000 years. TK is considered as manifestation of cultural heritage and accounts as a valuable attribute of the indigenous and local communities that depend on it for their health, livelihoods and general well-being. Traditional low-input agricultural systems, based on extensive and applied knowledge about natural processes and local ecosystems have successfully enabled millions of people to subsist for thousands of years in some of the most hostile environments. Traditional health care systems also offer a wide range of safe, cost effective, natural therapies, which can be used alone or in conjunction with allopathic health care. Because of these benefits, the TK systems and therapies are being largely used to meet the health care needs of the populations. It is estimated by the WHO that over 70 % of the World’s population, especially the poor, depend upon the traditional medicines, which is affordable and easily accessible.

Traditional Knowledge and Biopiracy

Due to the growing demand for the bio-products in the recent decades, commercialization of the traditional knowledge associated with the bioresources has been on pace all over the world. Biopiracy, which is widely understood as the misappropriation of the knowledge, which is in the public domain or mostly held by the individuals and groups of the indigenous and local communities, by the institutions located outside these systems and seeking exclusive monopoly control (usually patents) over these resources and knowledge without taking consent nor sharing benefits with the actual owners of such knowledge that is used to get monopoly. This has adversely affected the livelihoods of TK holding societies and also caused serious threat to the biodiversity. Moreover, traditional lifestyles of the indigenous communities have been urbanized with the migration of large chunk of indigenous and tribal people from rural areas to the urban areas. Hence, a need for the protection of TK and bioresources has been raised in the international community.

Appellation of Origin and Branding

As there were negotiations taking place under the Convention on Biological Diversity (CBD) for the international regime of benefit sharing, countries like India stood in the forefront and came up with domestic legislations for the protection of biodiversity and TK according to the mandate of Article 8(j) of the CBD. However, before India actually implemented the Biological Diversity Act in 2002 (BD Act), many scientists and civil society organizations in India came forward and took active steps for the protection of TK in India. The following case study is an example of such civil society initiatives taken in India, which later on has been heralded by the international community including the World Intellectual Property Organization (WIPO) as a model for the benefit sharing arrangements with the traditional knowledge communities for the commercialization of the TK.

Study of the “Jeevani” Benefit Sharing Arrangement

The subject of this case study is the role of intellectual property rights in the benefit-sharing arrangements concerning the “Jeevani” drug, which was developed by scientists at the Tropical Botanic Garden and Research Institute (TBGRI), based on the tribal medicinal knowledge of the Kani tribe in Kerala, South India.

“Jeevani” is a restorative, immune-enhancing, anti-stress and anti-fatigue agent, based on the herbal medicinal plant Arogyapaacha, used by the Kani tribes in their traditional medicine. Within the Kani tribe the customary rights to transfer and practice certain traditional medicinal knowledge are held by tribal healers, known as Plathis.

The knowledge was divulged by three Kani tribal members to the Indian scientists who isolated 12 active compounds from Arogyapaacha, developed the drug “Jeevani”, and filed two patent applications on the drug. The technology was then licensed to the Arya Vaidya Pharmacy, Ltd., an Indian pharmaceutical manufacturer pursuing the commercialization of Ayurvedic herbal formulations.

Partnership

A Trust Fund was established to share the benefits arising from the commercialization of the TK-based drug “Jeevani”. The operations of the Fund with the involvement of all relevant stakeholders, as well as the sustainable harvesting of the arogyapaacha plant, have posed certain problems which offer lessons on the role of intellectual property rights in benefit-sharing over medicinal plant genetic resources and traditional medicinal knowledge. This arrangement was expected to improve the livelihood of the Kani tribes with the money accrued through this benefit sharing arrangement.

The benefit sharing arrangement between the TBGRI and the Kani tribes for the “Jeevani” has played significant role in shaping the Indian laws, especially the BD Act to ensure benefit sharing arrangements with the applicants seeking access to bioresources and with those seeking to commercialize and seeking IPR protection for the traditional knowledge that is acquired or accessed from India. To implement the BD Act, India has established the National Biodiversity Authority (NBA) which is responsible to make arrangements for benefit sharing with the traditional knowledge communities.

Success Based on IP Protection and Benefit Sharing Agreements: Criteria for Benefit Sharing under the BD Act

While the NBA gives Indian nationals/researchers permission to access biological resources, it will also lay down some conditions as to how any benefits that arise should be shared with local communities. The Act provides that benefit sharing may include monetary payment, technology transfer or joint ownership of IP rights, but this is not an exhaustive list. The Act, subject to Section 21 and Rule 20 of the Biodiversity Rules, insists upon including appropriate benefit sharing provisions in the access agreement on mutually agreed terms related to access and transfer of biological resources or knowledge occurring in or obtained from India for commercial use, bio-survey, bio-utilization or any other monetary purposes. The suggested benefit sharing measures includes 'monetary benefits' such as, royalty, joint ventures, technology transfer, product development, and 'non – monetary benefits' such as, education and awareness raising activities, institutional capacity building, venture capital fund, etc. The time frame and quantum of benefits to be shared is decided on case-to-case based on mutually agreed terms between the applicant, Authority, local bodies, and other relevant stakeholders, including local and indigenous communities. One of the suggested mechanisms for benefit sharing includes direct payment to persons or group of individuals through district administration, if the biological material or knowledge was accessed from specific individuals or organizations. In cases where such individuals or organizations could not be identified, the monetary benefits may be paid to the National Biodiversity Fund. 5% of the benefits may be earmarked for the Authority or State Biodiversity Board which will be utilized for the benefiting the traditional knowledge communities of by various means such as providing education, creating awareness among the indigenous communities about different ways, including IPRs, to protect their knowledge and also how to economically benefit from their knowledge. Till now, NBA as entered into more than 200 agreements that secured an average of 5% of royalty to be shared with the traditional knowledge communities.

Business Results

This system has allowed for ensuring that the communities have given informed consent to the companies for using the traditional knowledge and also for the sharing of benefits accrued by such commercialization and IPR protection. Furthermore, as it is said earlier, IP arrangement between the Kani Tribe and the TBGRI is still seen as a model by the policy makers around the world for enacting international laws for protection and conservation of traditional knowledge resources and at the same providing benefits for the indigenous communities. The reports of the NBA also show that after the implementation of the BD Act in India, there have been many benefit sharing arrangements made with the IP applicants and the indigenous communities have considerably benefited from these arrangements both economically and also socially.

Source

Swarna Latha Soppadandi, PIIPA IP Corps Volunteer

* LL.M 2010 American University Washington College of Law, Washington, D.

CASE STUDY 4
HEALTH CARE: USING IP TO ATTRACT INVESTORS

Overview

Name:	EAT-SET Industries	Object of Protection:	Distinctive Signs / Commercial Names, Inventions
Organization Type:	Entrepreneur	Instrument of Protection:	Patents, Trademarks
Industry:	Health Care Equipment and Services	Focus:	Commercialization, Financing, Partnerships, Research and Development
Country/Territory:	Nigeria (Federal Republic of)	Global Issues:	Public Health

Background

The Emergency Autotransfusion Set (EAT-SET) is a device invented in 1989 by Dr. Otu Oviemo Ovadje, a Medical Doctor in the Nigerian Army, to resolve the problems arising from ruptured ectopic pregnancy. This pregnancy-related complexity, which is common in developing countries, often leads to internal hemorrhage, causing death of many patients. The absence of a well organized blood transfusion service is a factor in the increased morbidity and mortality in this group of women. The fatality can be reduced by procuring blood from laboratories, but many people in low-income countries cannot afford it. The EAT-SET reduces the hazards from internal hemorrhage through a medical technique known as autotransfusion.

Research and Development

Dr. Ovadje’s research took place at a military hospital in Lagos. Understanding the need for an economical solution to the health risks from internal hemorrhage, he focused his research on finding an efficient way to reuse the patient’s own blood instead of depending on donors’ blood. His device, the EAT-SET, is designed to do exactly that. The autotransfusion process facilitates the recovery of blood from the body cavity during operations and then re-infuses it back into the patient’s body after a filtration process.

Its primary application is for patients with internal hemorrhage due to ruptured ectopic gestation, road accidents and so on. This re-infusion process is medically safe if the blood is processed within the first 24 hours after the occurrence of the hemorrhage. Since it is the patient’s own blood that is being re-infused, it not only is instantly available, but also prevents transmission of diseases, and avoids immunological complications of homologous transfusion. The device underwent initial clinical trials in Geneva under the guidance of the World Health Organization (WHO) in 1996, and since then has been tested in three Nigerian hospitals.

Partnerships and Financing

Dr. Ovadge started the EAT-SET project in 1989 with a meager sum of eighteen thousands Naira (approximately 120 US dollars). The Nigerian government supported the program by providing research facilities at the Military Hospital Ikoyi Lagos. The project also obtained support from the United Nations Development Program (UNDP) from the very beginning. The UNDP provided financial resources for research, development and testing of the project while the WHO participated as the executing agency.

EAT-SET Industries was established in April 2001 to facilitate the commercialization of the medical device. The company has already attracted several investors, both public and private, and the investments made so far have grown to almost 100 thousand US dollars. It is reported that investors are also willing to put in an additional amount of about one million US dollars in the company. Currently, EAT-SET industries is focusing on designing other appropriate medical tools for developing countries, which generally have limited capabilities for acquiring expensive, sophisticated technologies.

Patents and Trademarks

With the help of UNDP, Dr. Ovadge acquired patent protection for his invention at the African Intellectual Property Organization, OAPI (patent no. 40893). Currently the EAT-SET device is protected by patents in nine African countries. The inventor also acquired trademark protection for EAT-SET in nine countries. Dr. Ovadge believes that the patents and trademarks held by EAT-SET Industries have played a key role in enhancing the confidence of the investors. He, however, believes that securing IP protection is not very easy for African inventors: “Most inventors in Africa lack the necessary funds to be able to pursue patents and trademarks. It is very expensive to process patent applications... Definitely there are... periods of loneliness and frustration which the inventor most necessarily go through. But I think these are some of the ladders you must climb to be able to push your creativity through”.

Commercialization

Until early 2006, an Indian company produced three thousand units of the EAT-SET device, to be sold at a retail price of 30 US dollars each. The product is being commercialized jointly by EAT-SET Industries and First Medical and Sterile Products.

Business Results

The EAT-SET device has increasingly been receiving attention from all over the world. Lives of many patients are being saved by the use of the EAT-SET device. Prof. Denis R. Morel, Chief Medical Director of Geneva University Hospital said that he was “surprised by the efficacy of the device”, identifying the EAT-SET development project as one “which could potentially save a great amount of human lives”.

The establishment of EAT-SET industries and the subsequent growth of its business and financing demonstrate the success of Dr. Ovadge. The World Intellectual Property Organization (WIPO) and the Organization of Africa Unity (OAU) have recognized the invention of Dr. Ovadge.

In 1995 he was declared the best African Scientist and was awarded the 1995 WIPO/OAU gold medal for scientific work designed to save women who usually die from abnormal pregnancy. He has also won a number of other awards including the Sasakawa Health Prize (2000) from the WHO, the World Bank Institute Award (2000), and J.P. Morgan Chase Health Award (2002).

The Key Success Factor: Focus on IP for Securing Investment

The EAT-SET case is an example of how strong IP protection can play an important role in attracting financing. Strong IP protection provided an incentive to investors in the development and commercialization of the EAT-SET device. Dr. Ovadje's success in making the EAT-SET project a reality will help many developing countries to save patients suffering from internal hemorrhage.

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CASE STUDY 5

BRANDING MATTERS: THE SUCCESS OF CHUAO COCOA BEAN

Overview

Name:	Empresa Campesina de Chuao	Object of Protection:	Distinctive Signs / Commercial Names, Goods with Specific Geographical Origin, Traditional Knowledge
Organization Type:	Co-operative	Instrument of Protection:	Geographical Indications and Appellations of Origin, Trademarks
Industry:	Food Products	Focus:	Branding, Partnerships
Country/Territory:	Venezuela (Bolivarian Republic of)		

Background

The climate, geography and human resources in the sea-locked part of the Aragua valley in the north of Venezuela combine to produce first class criollo cocoa. Among all the varieties of cocoa, criollo is often referred to as the most noble and is used as the basis for some of the finest chocolates in the world. In the plantation of Chuao, one of the first villages founded in Venezuela in the middle of the sixteenth century, unique soil conditions and a microclimate including high equatorial humidity and heavy rains (that wash rich and fertile silt down the mountainsides into the 140-hectare plantation) create perfect cocoa growing conditions.

This enables a skilled, geographically-isolated population, whose life has centered on cocoa production for more than 300 years, to coax a high-quality bean from the criollo. Although said to give the most subtle, sweet and complex beans, criollo trees are very difficult to farm and are particularly susceptible to disease. Expert caring and specific geographic conditions are essential for coaxing the high-quality beans from these trees which are the least productive of all cocoa varieties.

Traditional Knowledge

The Chuao plantation, situated within the boundaries of one of Latin America’s oldest national parks (the Parque Nacional Henri Pittier Rancho Grande), is owned by the local community and managed by the community’s own cooperative, the Empresa Campesina de Chuao (Campesina). The cooperative comprises around 100 farmers who tend the trees and harvest, dry, and ferment the delicate beans, carefully manufacturing cocoa paste and cocoa nuggets entirely by hand – with no artificial additives or flavorings. Ingeniously improvised dams and irrigation systems made of banana leaves ensure that the cocoa trees receive sufficient water.

To the local indigenous people, Chuao cocoa is not just an agricultural product; it represents much more. It is their life, their identity, their pride. For them, the cocoa nuts that they have planted, bred and selected for centuries are inseparable from their lives, their culture, their land, and their language. This holistic concept is a large part of what makes Chuao cocoa so special.

Appellation of Origin and Branding

In order to protect this considerable national asset, an application (No. 00-14373) for recognition of Chuao as an appellation of origin (AO) was filed in Venezuela on August 10, 2000 by Campesina. The Declaration of Recognition was granted and published in the Official Journal of Industrial Property of Venezuela in November 2000. The grant protects the name Chuao and restricts its use to beans and cocoa products from that specifically defined geographical area, recognizing the influence of climatic and human factors on the quality of those products.

Criollo cocoa comprises just a fraction of the total cocoa production in Venezuela (only 3 out of every 16,000 tons of cocoa is criollo cocoa), and among the criollo, Chuao holds a very small share. Yet, the quality, reputation and characteristics of Chuao cocoa have made it a premium product and the region a hallmark, underscoring that the incomparable quality of this cocoa is essentially attributable to its geographical origin. The protection of the Chuao AO has proved to be a very effective tool for marketing and branding of the Chuao cocoa; the name itself denotes the unique character of the product, serves as a guarantee of quality and enhances consumer recognition.

Partnership

The recognized quality and protection of Chuao cocoa allowed the Campesina cooperative to work out an agreement in 2000 with a chocolate company – Amedei s.r.l. of Italy – for supplying cocoa. Under the deal, Amedei receives the entire production of Chuao cocoa from Campesina. Campesina has benefitted from increased earnings from its product and from the chocolate company also having taken over the debts of the cooperative.

Trademark

Following the agreement with Campesina, Amedei sought further protection for the name “Chuao” by registering it as a trademark through the Madrid system. The Italian company now is famous for its Chuao brand dark chocolates. Valrhona, a French chocolate company that used to produce Chuao brand chocolates stopped using the name after Amedei made the registration. Prior to the registration of the AO, “Chuao” was often used by some chocolate producers even though the cacao was not from Campesina. The AO protection has also reduced the instances of such uses of the Chuao name.

Business Results

Recognition of the market potential of the special characteristics of Chuao cocoa and their protection through intellectual property rights (IPRs) have enabled the area’s farmers to increase their income substantially. Soon after the recognition of the Chuao cocoa as an AO, the Campesina cooperative had enough market power to negotiate with its customers and settle a price rate for Chuao much higher than what it used to obtain previously. The protection has led to an influx of foreign direct investment to the plantation, contributing to further wealth creation.

Success Based on IP Protection and Branding

Chuao criollo cocoa is an example of how IP rights can be used by agricultural communities to generate wealth. The AO led to the creation of a trusted brand which helped chocolate producers

and consumers differentiate Chuoa from other cocoa varieties. This differentiation based on higher quality and IP protected by IPRs enables traditional products to compete with mass-produced counterparts and thus ensures the sustainability of local rural communities and the preservation of traditional knowledge.

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