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The evolution of negotiations of intangible assets apart from industrial property protection in biotechnology

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ABSTRACT

Intangible assets may involve more than 2/3 of the value of enterprises and even higher, as in the case of high tech enterprises where knowledge is the main asset. Almost 70 % of the intangibles assets are not identified or they are negotiated as a whole or as a value of goodwill with the consequences that they are either overvalued or undervalued, bringing about enterprise profits or losses. This paper shows the behavior of negotiations of intangible assets, particularly in the international biopharmaceutical industry. The experience of Great Britain and France is given, since these countries have achieved the highest intangible assets identification (37 %), followed by the United States. Among the developing countries, only South Africa and China have identified a representative percentage of intangible assets. The most highly negotiated contracts are those of research and development, followed by licensing agreements and acquisitions. Manufacturing agreements prevail in south-south cooperation. In Cuba the biotechnology sector, as a model of high tech enterprises, shows great strength in novel technologies and unique patented products, which must not only be protected as intellectual property, but they must also be valued and appropriately negotiated. Therefore, a diagnostic study on the negotiation of intangible assets in the biotechnology sector is required, and therefore, a proposal of a strategy for their negotiation.

Keywords: intangible assets, goodwill, negotiation, BioCubaFarma, biopharmaceuticals, Cuban biotechnology industry

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RESUMEN

La evolución de la negociación de los activos intangibles más allá de la protección de la propiedad industrial en biotecnología. Los activos intangibles representan más de las dos terceras partes del valor de las empresas; más aún en las empresas de alta tecnología, donde el conocimiento es el activo fundamental. Cerca del 70 % de esos activos intangibles no se identifican o se negocian como un todo o como buena voluntad *(goodwill)*, lo que trae como consecuencia su sobrevaloración o subvaloración, y a su vez, la ganancia o pérdida de las empresas. En este artículo se presenta cómo se está comportando la negociación de los activos intangibles a escala internacional, específicamente en la industria biofarmacéutica. Se muestran experiencias de Gran Bretaña y Francia como los países que han logrado mayor identificación de los activos intangibles (37 %), seguidos por los Estados Unidos. Solo Sudáfrica y China (entre los países en desarrollo) tienen un porcentaje representativo de activos intangibles identificados. Los contratos de investigación y desarrollo son los que más se negocian, seguidos por los acuerdos de licencia y las adquisiciones. En la colaboración Sur-Sur predominan los acuerdos de manufactura. En Cuba, el sector biotecnológico, como ex-ponente de las empresas de alta tecnología, cuenta con una gran fortaleza en tecnologías novedosas y productos únicos con patentes, que deben ser protegidos, no solo como propiedad intelectual, sino que deben ser valorizados y debidamente negociados. Por tanto, debe hacerse un diagnóstico sobre la negociación de los activos intangibles en el sector biotecnológico, y sobre esa base, proponer una estrategia para su negociación.

Palabras clave: activos intangibles, *goodwill*, negociación, BioCubaFarma, producto biofarmacéutico, industria biofarmacéutica cubana

*I*ntroduction

Drucker in 1994 expressed that the industries that have become the center of world economy in the last 40 years are those whose business is the production and distribution of knowledge [1]; the creative industries that distribute intangible goods.

The enterprises in the industrial, commercial and services sectors are not only valued because of their facilities, machineries or buildings (the tangible assets with values kept on the books of the enterprise), but by immaterial aspects, such as the know-how, intellectual property and intellectual capital; just to give a few examples of intangible assets that lead to the true value of an enterprise. In this respect Edward Karstetter, director of Valuation Services in Grant Thornton LLP in Los Angeles, who has made more than 100 valuations of enterprises for over four billion dollars, where intangible assets have been widely negotiated, pointed out that when you define a sale price for your company, the intangible assets such as the people, knowledge and the company's position in the market may be even more important than the tangible property [2].

The aim of this paper is to show the evolution of the valuation and negotiation of intangible assets, considering their importance and potential in the biotechnology sector and in the pharmaceutical industry, particularly in Cuba. The analysis demonstrates the importance of the appropriate valuation and negotiation of these resources.

1. Drucker P. La sociedad postcapitalista. Bogotá, Editorial Norma; 1994.

2. Karstetter E. How intangible assets affect business value. Enterpreneur [Internet]. 2002 May 6. [cited 2013 Aug 14]. Available from: http://www.entrepreneur.com/article/51628

State of negotiations of intangible assets in the world

The tangible value of an enterprise is estimated in very low percentages, i.e. about 20 % (Figure 1); the rest lies in intangible assets that are difficult to measure or estimate as a whole under the goodwill concept, which hampers the negotiation leading to their overvaluation or undervaluation during the negotiating processes.

Goodwill is the immaterial value derived from factors such as the customers, efficiency, organization, credits, prestige, experience, and the position of the enterprise or business before third parties, a good location, quality merchandise or services, good relationships with the workers, labor stability, and the trust achieved in the financial sector because of good management. It is a highly valued asset since it enhances the possibility to obtain new clients, suppliers, credits and places the enterprise in an advantageous position in relation to competitors.

The enterprise merging and acquisition processes cover the negotiation of all of its assets, where the intangible assets prevail. In fact, the boom in merging and acquisition that took place in the 1990's was due to a boom in the negotiations of intangible assets giving rise to consulting groups such as Cambridge Partners, Ernest and Young, Appraisal Economics, Intangible Business, devoted to the valuation of these assets: brands, stocks, customer relationships, copyrights, patents, goodwill agreements, development and implementation of licensing agreements, brand and business sales, enterprise merging and acquisition, using the IFRS3 [3] and FASB 141 [4] standards as guidelines for their valuation. The former standard points out the following restrictions:

1. Only acquired intangibles are valued: those generated by the organization are not taken into account; although the companies acknowledge the new intangible assets that are being generated, it is difficult to evaluate them and they end off ignoring them.
2. Goodwill is often not identified.
3. Intangibles are undervalued: the standards applied stimulate the establishment of low values for the intangible assets.
4. The increased value of the intangible assets is not acknowledged: while prices of goods rise or fall and trends and behavior can be defined, the value of intangible assets does not increase with time, which is known as the historical cost.

Results of the studies of several companies on the identification and classification of intangible assets, published in the Intangible Business web platform are summarized in figure 1 [5]. These are derived from the analysis of the FTSE 100 (Financial Times Stock Exchange) index corresponding to the first 100 British companies in the London Stock Exchange (Figure 1A) from an audit to four large companies: Deloitte and Touch, Ernest and Young, KPMG and PWQC (Figure 1B), and from the analysis of the negotiation of intangible assets in which 118 business combinations of 154 American companies, British companies and those of the rest of the world, are included (Figure 1C).

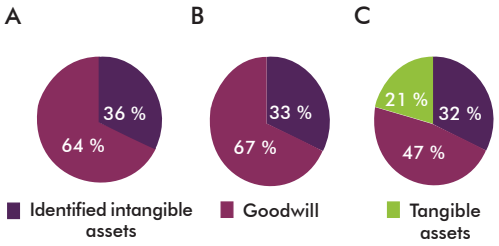

Figure 1. Distribution of the assets within the value of an enterprise: A) Analysis of the FTSE 100 (Financial Times Stock Exchange) index corresponding to the first 100 British companies in the Stock Market in London. B) Audit of Deloitte and Touch, Ernest and Young, KPMG and PWQC. C) Analysis of the negotiation of intangible assets (118 business combinations of 154 companies in the United States, Great Britain and the rest of the world). Data processed using the reference [5].

In studies A and B no tangible assets are represented since they are practically considered negligible within the value of the enterprise. Study C is the most proportionate one because it analyzes a larger and more representative sample.

The same review demonstrated that 31 % of the goodwill assets had a good description, 16 % had a limited description and 53 % showed no description [5]. When analyzed by categories linked to their position in the market, the contracts in the United States are located in first place, with a classification almost 35 %, followed by marketing in the rest of the world with 28 %, and the clients in Great Britain with 27 %. When examined according to each country it was found that Great Britain and France had the highest identification of intangible assets with 37 %, followed by China, South Africa and the United States with 36 % each. Out of the 13 countries considered in the analysis, only South Africa and China are developing countries.

Some examples of negotiations of intangible assets are listed below [6]:

- When Proctor and Gamble purchased Gillette in 63 billion dollars in 2005, the intangible assets were valued in 55 billion dollars, of which 35 billion corresponded to goodwill, representing 63.6 % of the intangible value. Hence, there was an overestimation of the intangible goodwill assets and an underestimation of the identified intangible assets.
- Walt Disney paid 7.5 billion dollars for the Pixar digital animation studio. The intangible assets, brand and commercial names were valued in only 200 million dollars while the goodwill assets were valued in 5.6 billion dollars. This is another example of overestimation of goodwill assets and underestimation of the identified intangible assets.
- In 2006, Google purchased YouTube for 1.2 billion dollars, which reached the headlines of the brand stock exchange. Out of the entire purchase, only 200 million were attributed to the identified intangible assets and 83.4 % to goodwill. It is known that the success of YouTube is due to the expertise of the brand to attract subscribers, and therefore, the valuation made for the brand is extremely low.

These examples demonstrate that the lack of knowledge for valuing intangible assets, separating goodwill assets, as well the fact that a calculation

3. IFRS 3 — Business Combinations [Internet]. London: Deloitte Touche Tohmatsu Limited. c. 2013 [cited 2013 Aug 14]. Available from: http://www.iasplus.com/en/standards/ifrs/ifrs3

4. Financial Accounting Standard Board. Statement of Financial Accounting Standard Nº 141 (revised 2007). Business combinations [Internet]; Norwalk: Financial Accounting Standards Board ; 2010 [cited 2013 Aug 14]. Available from: http://www.fasb.org/cs/BlobServer?blobkey=id&blobwhere=1175823288072&blobheader=application%2Fpdf&blobcol=urldata&blobtable=MungoBlobs

5. Intangible Business [Internet]. London: Intangible Business Limited. c. 2003-2013 [cited 2013 Aug 14]. Available from: http://www.intangiblebusiness.com/

6. Forbes T. Shareholders None the Wiser as SFAS 141 has a minimal impact. Intangible Assets Manage. 2008 Feb [cited 2013 Aug 14]:8-12. Available from: http://www.intangiblebusiness.com/uploads/2013/02/11/358-Stakeholders_none_the_wiser_as_SFAS141_has_minimal_impact_IAM_February_2008.pdf

method has not been standardized, leads to a potential risk in its appropriate identification, and then they are overestimated or undervalued.

Figure 2 illustrates the evolution of the goodwill assets and the identification of the intangible assets [6]. Before 2002, goodwill assets covered the entire pyramid, indicating that the enterprises negotiated on the basis of that parameter, while from 2002 to 2011 there has been a progression in the identification of intangible assets that has grown in an important proportion in relation to goodwill. This is due to the growing weight of the high tech center in the economy, generating patents and technologies: negotiations of intangible assets are growing in the current globalization framework. The increase of those negotiations and the merging and acquisition of enterprises have led the consulting groups and the negotiators to try to growingly identify the intangible assets involved.

It is challenging that the identified intangible assets are predominant, with only a small portion negotiated as goodwill.

Figure 2. Evolution of the negotiation of intangible assets: Modified using the reference [6].

An overview is given below because of the importance of the process of merging and acquisition of enterprises in the negotiations of intangible assets.

According to Danzon, Epstein and Nicholson, the biotech-pharmaceutical industry has become a growingly concentrated industry in the last 15 years; in 1985 the 10 largest companies covered 20 % of all the world sales, while in 2002 the 10 largest companies covered 48 % of the sales. This concentration is mainly due to the merging process [8].

For biotech companies, the partnerships and other forms of association became more and more important as a source of capital; and for the pharmaceutical companies, they were sources of new products. According to the research carried out by professors Sean Nicholson and Patricia Danzon of Wharton University in Pennsylvania, if biotech and pharmaceutical companies join their efforts, they can increase the probabilities of achieving the approval of the regulating authorities to introduce new drugs in the market.

Therefore, the merging and acquisition of small companies by big ones is frequently found in the pharmaceutical and biotechnological industry [9].

The research appearing in the paper "Biotech-Pharma Alliances as a Signal of Asset and Firm Quality", is partly based on the analysis of 539 licensing agreements that had been signed between the years 1988 and 2000 [10]. The agreements showed that the medications produced between associated companies had a higher probability of success in getting their approval by the regulating authorities of the United States (Food and Drug Administration, FDA), than drugs developed by only one company.

The authors report that out of the 691 new drugs approved by the FDA between 1963 and 1999, some 38 % were produced by partnerships. The biotech-pharmaceutical partnerships grew at an average rate of 1.4 % a year during the period of 1988-1990 and increased its growth to a rate of 5.7 % between the years 1997 and 1998. They also expressed that the biotech-pharmaceutical agreements market seems to be working well and the agreements seem to be taking place when there are mutual benefits and there is an increase in productivity of both companies because of this [10].

In the year 2000, Garnier, who was at the time Vice-president of the Belgium company GlaxoSmithKline, expressed that he believed that size is very important, since there can be no success in the final development of a drug unless there is a world infrastructure for this. He said that this can be verified every day with the biotech companies and that ImClone is proof of it. Later in 2008 ImClone was purchased by Eli Lilly who paid 6.5 billion dollars for including it in their project portfolio.

Mark Edwards, managing director of Recombinant Capital, an advisory company specialized in biotech partnerships from San Francisco, expressed that the agreements are mainly demonstrating success and that the partnerships may and should be profitable for all, but it is sometimes difficult to achieve it [10].

Sean Nicholson stated that the biotech-pharmaceutical partnerships have a role in the financial field on assigning an appropriate valuation to the small biotech enterprises. An example of this is that in 1998, the biotech companies received 6200 million dollars in pharmaceutical partnerships, which is three times more than what the received in the public and private capital markets [10].

The biotech companies tend to license their product at the final stages, when there is less risk and a higher reward. This happens when they have received enough capital to finance the expensive drug development processes.

According to Agustín Lage in his book "La Economía del Conocimiento y el Socialismo" (The Economy of Knowledge and Socialism) [11], in spite of the high development costs of a product, the strategy of Cuban biotechnology is to achieve the complete development of the product. This makes it possible to negotiate products of high added value. These negotiations only search for the commercial representation of foreign partners. Patents and technologies are also patented and developing products are negotiated for alliances with foreign partners.

These alliances offer less profit to the Cuban party than if the entire development is carried out without foreign participation, since a part of the value of the product (depending on their participation in its development) is transferred to the foreign party. This happens when the participation is absolutely necessary to obtain something required at that time to complete the drug's development, which may cover productive facilities, productive standards or regulators, or both, or just the funding needed to complete the development of the drug to be able to place it in the market at the proper time. On taking advantage of the opportunity of a partnership to complete the development of the

7. Fernández P. Valoración de marcas e intangibles. Universidad de Navarra, España; 2007.

8. Danzon P, Epstein A, Nicholson S. Mergers and acquisitions in the pharmaceutical and biotech industries. Manage Decis Econ. 2007;28(4-5):307-28.

9. Nicholson S, Danzon P, McCullough JS. Biotech-pharmaceutical alliances as a signal of asset and firm quality [Internet]. Massachusetts: National Bureau of Economic Research, Working Paper Series, Working Paper 9007; 2002 [cited 2013 Aug 14]. Available from: http://www.nber.org/papers/w9007.pdf

10. Los beneficios son mutuos en la nueva Ola de alianzas biotecnológico-farmacéuticas. [Internet]. Philadelphia: Universia Knowledge@Wharton; 2003 [cited 2013 Aug 14]. Available from: http://knowledge.wharton.upenn.edu/article/the-benefits-are-mutual-in-new-wave-of-biotechpharma-alliances/

11. Lage A. La Economía del Conocimiento y el Socialismo. La Habana: Editorial Academia; 2013.

product at the right time, this will mean arriving first at the market and receiving incomes and recovering the investments earlier.

In joint development contracts, the foreign partner supplies the risk capital for the continuation and completion of the project; pre-marketing payments are made, which include the valuation of the intangible assets created by the Cuban party. In exchange, the foreign partner receives marketing rights in certain regions, which will be effective if the project finally generates a marketable product.

This can be seen when data on transactions with intangible assets are analyzed, such as those registered in the biotech and pharmaceutical industry from 2006 to 2010, which are available at the Biopharmaceutiques web platform [12] (Figure 3).

Most transactions were recorded in the year 2008. The research and development contracts are those most highly negotiated, followed by licensing and acquisition agreements. The agreements for manufacturing are of much less importance between first world companies, and in agreements between companies of the first world and developing countries (Figure 4).

The table summarizes three out of ten business examples with intangible assets of products from the pharmaceutical industry, according to Biopharmaceutiques [12].

The differentiation of the intangible assets by type of agreement in the biopharmaceutical industry is shown, where the terms of the negotiations reviews show the pre-marketing payments before meeting the milestones or goals.

Finally, it must be stressed that there are two aspects in the negotiation of intangible assets that also offer value, although they are hardly ever considered, these are the brand name and the intellectual capital.

After the publication of the book "Brand Name" by David Aaker in 2001, several documents have been

12. Biopharmaceutiques Internet. Puteaux Cedex: PR Editions; c2009 [cited 2013 Aug 14]. Available from: http://www.biopharmaceutiques.com/en/tables/agreements/index.html

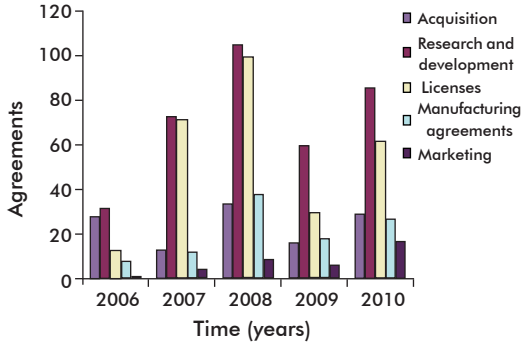

Figure 3. Behavior of the negotiation of intangible assets based on signed agreements: Data taken from the Biopharmaceutiques web platform [12].

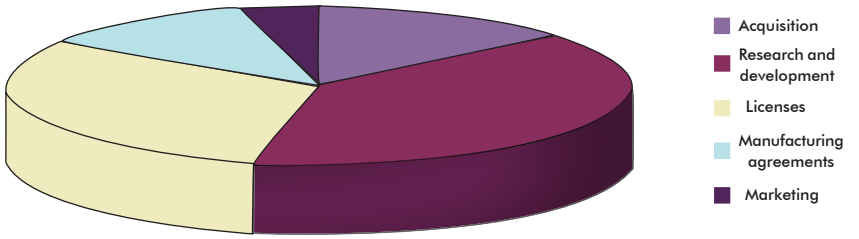

Figure 4. Participation by type of agreement in the negotiation of intangibles: Made through the data published in the Biopharmaceutiques web platform [12].

Table. Examples of the terms of negotiations of intangible assets under the contract frameworks of the biopharmaceutical enterprises *

Biotech company / Pharmaceutical company	Type of agreement (Date)	Compound/ Disease	Nature of the agreement and financial terms
Gentium (Italia) *Sigma-Tau Pharmaceuticals (Italia)*	License Manufacture Distribution and marketing (2010-01-12)	Defibrotide *occlusive arterial disease*	Gentium amended a License Agreement they had with the Italian company Sigma-Tau Pharmaceuticals. The amendment consisted of including the development and commercialization in America (North, Central and South America) of the Defibrotide intra-venous formulation. Gentium will maintain the exclusive rights on the product in Europe and the rest of the world. The two companies will share the costs of development. Sigma Tau will pay Gentium: - 7 million dollars to the when signing the license agreement - 6 million dollars when FDA approves the commercialization of the product in the United States - 2 million dollars when Gentium transfers the approved non-disclosure agreement (NDA) to Sigma-Tau - 7 % in royalties on net sales in America and a margin of 31 % of the net sales in the United States or in Euros at 50 % per unit sold in that territory
Lonza (Switzerland) *GSK (United Kingdom)*	Manufacture (2010-09-08)	Five monoclonal antibodies *Unidentified*	GSK and Lonza subscribed a new agreement under which the former will support the development of the biopharmaceutical portfolio in progress of the latter; placing the productive capacity at the disposal of GSK for the production of five monoclonal antibodies at early stages of their development. Lonza will initially produce the five lots for the clinical trials of the five components and will later give access to that capacity to GSK so that they may respond to the demand of the product.
Oxford BioTherapeutics, previously known as Oxford Genome Sciences (United Kingdom) *GSK (United Kingdom)*	Research and development Marketing and distribution (2009-05-18)	Therapeutic antibodies *Cancer*	GSK and Oxford BioTherapeutics signed a strategic partnership for research, development and marketing novel therapeutic antibodies for the treatment of primary and metastatic cancers. GSK will develop a new therapy with antibodies, in close relationship with the new developments of Oxford. At the same time, Oxford will develop an antibody for the therapy that GSK will develop. On carrying out the test of concept, GSK will take over the clinical development and later the marketing of the product. Oxford BioTherapeutics will receive 370 million dollars (272.4 million Euros) on completing the development, registration and marketing of the product.

Devised through the data published in the Biopharmaceutiques web platform (http://www.biopharmaceutiques.com/en/tables/agreements/index.html) [12].

disseminated that propose methods to determine the value of the brand name, the most important commercial and institutional assets in many company sectors. However, the exact determination of its value is far from being achieved. Some authors express that it is impossible to assign values to these brand names, regardless the companies creating them, and that the values are negotiated in companies having a strong representativeness, and this includes the entire intangible value of the company [7].

In relation to intellectual capital, mainly patents, only a fraction of the technologies stated are negotiated, and most of them have a value that is lower than its registration and maintenance rate.

Almost all studies on intellectual capital are very descriptive and are far from calculating its true value. Johan and Goram Ross established an index for its measurement, which was a breakthrough in relation to assuming that intellectual capital is the difference between the market value and the book value of company stocks. However, the use of the formula has never been evidenced [7].

The intangible strength of the Cuban biotechnology industry

Modern biotechnology, which arose and was developed through the 1970's and 1980's, has been normally established as coming from industrialized countries.

The use of the recombinant DNA technology, genetic therapy, biosafety and the creation of new research institutes to develop these new technologies, were among the first goals of these developed countries. Progress in molecular biology generated important applications in the fields of health, agriculture, industry and the environment, which still today remain as a goal for emerging economies. Such is the case of Brazil, Russia, India, China and South Africa (BRICS), countries that have become active in the use of genetic engineering to develop products for human health.

The creation, development and success of the Cuban biotechnology industry has its roots in the policy established with the triumph of the Revolution when Commander in Chief Fidel Castro Ruz announce that "Cuba's future has to be necessarily one of men of science, of men of thought" [13]. The training of human resources now existing in the country was started with the literacy campaign of 1961.

The National Center for Scientific Research (Centro Nacional de Investigaciones Científicas, CNIC) was created in 1965. It was the pioneer center for what would become the Scientific Pole of Western Havana. The Biological Front was created in 1980, which had an inter-disciplinary professional structure, and worked in close connection to governmental authorities, developing the potential for the application of this emerging science. The dengue and hemorrhagic conjunctivitis epidemics of 1981 leveraged the decision to invest in biotechnology. Hence the Center for Biological Research was created in 1983; this was where the recombinant alpha interferon, the homologue of human leukocyte interferon, which was the first Cuban biotechnology product, was initially obtained. Afterwards, in 1986, the Center for Genetic Engineering and Biotechnology was inaugurated, and after that, from 1986 to 1996 an investment program for the construction of the 53 institutions now forming the Cuban group of biotechnology and pharmaceutical industries, was developed as a Higher Organization of Entrepreneurial Administration (BioCubaFarma), estimated in a billion dollars [14].

The Cuban biotechnology sector is characterized by: a) having the Cuban state as its main investor; b) the fact that biotechnology is part of the National Health System, and it prioritizes the national needs; c) having a human capital that is 100 % Cuban, which is also very highly trained; d) operating in a closed cycle strategy: from research to marketing; e) lacking the competition between centers that are integrated in the sector; it is characterized by the close collaboration between the institutions forming it; and f) the fact that the marketing companies arise from the centers themselves, which contributes to the professionalism of the managers of the commercial activity, through the knowledge they have of this sector.

This made it possible to design a portfolio of high-tech biotechnology products, more than 60 product that cover vaccines, diagnostic systems, medical equipment, generic drugs that include retroviral drugs for the treatment of the human immunodeficiency virus and others. These products of Cuban biotechnology are registered in 66 countries, exported to more than 50 countries today, and generate positive cash-flow that enables the financing of the system's own growth [8].

Me too, and novel products are developed, which include:

- The preventive vaccine against *Neisseria meningitidis* type b, with patents granted in several countries, is the only one with a demonstrated efficacy against the main causes of child death due to meningitis;
- PPG, a unique product with three patents granted: one, as a product producing cholesterol reduction; another one, for the procedure; and the third patent that combines the product with the procedure. The patent has been granted in more than 12 countries through the European Patent Office (EPO).
- The vaccine against *Haemophilus influenzae* type b, the only commercial vaccine obtained by chemical synthesis.
- Heberprot-P®, a unique product with a patent, with a demonstrated high effectiveness in the treatment of diabetic foot ulcers. A high percentage of patients using it have not needed amputation. Its clinical use has been of over 140 000 patients treated in Cuba and other countries. The product received the Gold Medal of the World Organization of Industrial Property in the year 2010, and the main researcher of the group received the Award to the Best Young Inventor.

Furthermore, there is a project portfolio with the potential of novel biopharmaceutical products having high added values. In the last five years, the requests for patents and those granted have grown.

The productive facilities of the enterprises belonging to BioCubaFarma have been inspected by prestigious regulatory authorities from different countries:

- World Health Organization (since 2001),
- Brazil: Anvisa (September 2008),
- Biotik: access to regulations of the European Medicines Agency (EMA; May 4-5, 2008),

13. Castro Ruz F. Discurso pronunciado por el comandante Fidel Castro Ruz, primer ministro del gobierno revolucionario, en el acto celebrado por la Sociedad Espeleológica de Cuba, en la Academia de Ciencias, el 15 de enero de 1960. Versiones taquigráficas. La Habana: Consejo de Estado; 1960 [cited 2013 Jan 5]. Available from: www.cuba.cu/gobierno/discursos/1960/esp/f150160e.html

14. López E, Silva R, Acevedo B, Buxadó JA, Aguilera A, Herrera L. Biotechnology in Cuba: 20 years of scientific social and economic progress. J Commer Biotechnol. 2006;13(1):1-11.

- Ukraine regulating authority (July 15-24, 2008),
- ICON Mexico, S.A. of C.V. to access the Good Clinical Practices of EMA (September 17-18, 2008),
- Good Manufacturing Practices in Critical Water Systems, by the Barcelona Systems Validation Society, Spain (October 13-17, 2008),
- Dr. Erik D'Hondt; Qualified person from Bioven, to access regulations of EMA (April 8, 2009),
- South African regulatory authority (May 2009),
- CESIF-Praxis S.A. to access regulations of EMA (September 2009).

Having the endorsement of these institutions is a demonstration of the quality of the Cuban biotech products and promotes their introduction into the market.

Just considering the enterprises that form part of BioCubaFarma, the country has a treasure in intellectual property, in intangible assets that must be protected, valuated and well negotiated, since we live in a globalized world where companies are merged every day and acquire the assets of others. Licensing agreements are signed, giving the rights to exploit someone else's knowledge, while also the system of intellectual property ensures the participation of foreign capital in research and development. This system is the most visible form of privatization of knowledge. Hence, the importance of having a negotiating system for these assets in the most representative sectors of intellectual property in the country.

Economic impact

Identifying the importance of the negotiation of intangible assets in sectors with a potential in intellectual property leads to the proposal of the design of a strategy enabling the maximum benefits in the negotiations. Here the intangible assets are not always negotiated, and large sums of money are lost because of this.
An example of this is the Center for Genetic Engineering and Biotechnology, one of the enterprises of BioCubaFarma, which through the negotiation of intangible assets (projects and pre-marketing payments) has earned millions of dollars in the last 6 years. Through the negotiation of Heberprot-P®, a unique product with a strong patent position that has made it possible to fix a price on the basis of the value of intellectual property and not on the basis of its production cost, the center has received incomes rising to over hundreds of million dollars in the last 6 years. The intangible assets are a substantial part of the economical benefits that a biotech enterprise can receive, even before a product is placed in the market.

Conclusions

The tangible assets only represent 21% of the assets of the companies. The difference corresponds to the intangible assets, which are not highly differentiated and are negotiated as goodwill. Ignoring the valuation of the intangible assets, as well as the lack of a standardized method for their calculation, leads to a potential risk in their identification and they are then over or under estimated, with the consequent returns or losses to the enterprises.

The strength of intellectual property of the biopharmaceutical industry inserted in a globalized world, where the trend is the merging and acquisition of enterprises, makes it necessary to consider the need of an appropriate diagnostic of intangible assets in negotiations taking place in the group of Cuban biotech and pharmaceutical industries (BioCubaFarma), and to work in the design of a strategy for the negotiation of their intangible assets, which will have a multiplying effect on current returns.

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