

Methodology for preparing the negotiation of biotechnological products and their associated intangible assets

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REPORT

ABSTRACT

The High Tech Enterprises (HTE) are playing an increasingly significant role in the economy, generating a substantial amount of intangible assets which are a significant part of the whole enterprise portfolio. In Cuba, the Biotechnology sector group a number of HTEs with intangible assets of great value in the context of the globalize market. Therefore, it is necessary to draw theoretical and practical frameworks for the negotiation of biotechnological products and their related intangible assets, and, particularly, to develop methodological tools for their adequate negotiation process. For that purpose, a documentary analysis followed by an expert survey was conducted to identify how much attention and the relevance that intangible assets received during the negotiations in HTEs at the BioCubaFarma biopharmaceutical enterprise. There was evident the lack of a standardized evaluation tool and a negotiation methodology for intangible assets. In this work, a new methodology for the valuation and negotiation of the intangible assets is presented. It was prepared by theoretical review of the literature available and designed by including the calculation methods, parameters and indicators required for their negotiation, and their adequate values and ranges both at pre-marketing and marketing commercialization stages. This work granted the Annual Award of the National Academy of Sciences of Cuba for the year 2015.

Keywords: pre-commercial payments, upfront payments, milestones, royalties, intangible assets

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RESUMEN

Metodología para la preparación de la negociación de productos biotecnológicos con intangibles asociados.

La empresa de alta tecnología está jugando un papel cada vez más preponderante en la economía, constituyendo una fuente generadora de activos intangibles de gran valor, que tienen una marcada representatividad dentro del total de los activos de esas empresas. En Cuba las empresas del sector biotecnológico son exponentes de la empresa de alta tecnología generándose una riqueza intangible que en el contexto de la globalización en que tiene lugar se expone constantemente al intercambio con el exterior. De aquí la necesidad de profundizar en los aspectos teóricos de la negociación de los productos biotecnológicos y los intangibles que estos tienen asociados, de diseñar herramientas que faciliten una correcta negociación de los mismos. Sobre la base del análisis documental y el intercambio con expertos se realiza un diagnóstico del tratamiento que reciben los intangibles en las negociaciones que tienen lugar en BioCubaFarma, identificándose la ausencia de un método de cálculo estandarizado y de una guía para la preparación de negociaciones además de que existe falta de cultura comercial en aspectos relacionados con la negociación de intangibles siendo el objetivo general de esta investigación, el diseño de una metodología para la negociación y valorización de los intangibles, para cuyo cumplimiento se realizó una revisión bibliográfica, que aportó los fundamentos teóricos necesarios para diseñar la misma. En la metodología se establecen los pasos a seguir durante la preparación de la negociación, se recomienda el método de cálculo a utilizar y los factores y coeficientes necesarios para separar los intangibles, proponiéndose los rangos de valores en que pueden moverse los pagos tanto pre-comerciales como en la etapa de explotación comercial. Este trabajo mereció el Premio Anual de la Academia de Ciencias de Cuba para el año 2015.

Palabras clave: pagos precomerciales, pago anticipado, hitos, regalías, activos intangibles

Introduction

Since the late XX century, industrial development emerged as the key element of economical development, with knowledge as the main driving factor. In this context of the so-called Knowledge Economy, the High Tech Enterprise (HTE) plays a fundamental role, due to the considerable amount of products and services of added value. One of the most contributing areas is Biotechnology, with HTEs in this field among the leaders of economical development worldwide.

Noteworthy, the globalization, mergers and acquisitions processes and the speed of scientific and technological innovation have driven the biotechnological and biopharmaceutical companies towards

the implementation of methods for the adequate valorization of the generated knowledge and to properly protect and commercialize it. In fact, several guides are available for the negotiation of intangible assets: The entrepreneur's guide to a Biotech startup, by Peter Kolchinsky [1]; The Guide for Bioentrepreneurship, of BioSerentia [2]; and the book Valuation and Deal-making of Technology-Based Intellectual Property: Principles, Methods and Tools, by Richard Razgaitis [3], among others. All of them provide useful concepts and methods for calculating intangible-related indicators for the aim of negotiation. But the contexts and individual contribution of the relevant indicators have

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2. BioSerentia, B.A. Guía de Valoración Económica-Financiera de Proyectos Biotecnológicos. Galicia: C.E.E.I Galicia, S.A.; 2010.

3. Razgaitis R. Valuation and Deal-making of Technology-Based Intellectual Property: Principles, Methods and Tools. 2nd edition. New York: Wiley; 2009.

to be established while considering the characteristics of the given industry, and not any of those guidelines provides a methodological framework for the adequate valuation or negotiation of intangible assets.

Cuba is not an exception, its Biotechnology sector generating a significant amount of high-value intangible assets. Those assets are exposed to the constant and dynamic exchange in the globalized market, and particular attention has to be put during its valuation and exchange as part of normal economical actions. However, a methodology for that purpose was an urgent need, due to the absence of precedent unifying frameworks. In this work, the properties of the negotiation process of intangible assets at the Cuban biopharmaceutical HTE BioCubaFarma were diagnosed. After a detailed analysis of the processes and indicators relevant for the Cuban economical relationships and the commercial activity with intangible assets in the Biotech sector, a new methodological framework was developed for the adequate valuation and negotiation of intangible assets in Cuban biopharmaceutical HTEs. This work was granted the Cuban Academy of Sciences Award in 2015.

The negotiation of intangible assets in the Biotech sector

The evolution of the Intangible assets negotiation has been pushed forward by the processes of mergers and acquisitions among enterprises. Those processes formerly involved the negotiation of intangible assets as goodwill, without its differentiation or separation from the other company assets. At present, they are identified, but most of them are still negotiated in bulk, therefore, their particularization remaining as a challenge for an adequate identification and individual negotiation, and that only a minority will be negotiated as goodwill.

Several methods have been described in the specialized literature for the valuation and negotiation of intangible assets, based on the market value, costs and the so-called 25 % rule. As reported by the companies BioSerentia [2] and Verdoto [4], the most common methods for the valuation of biotechnology projects are benchmarking, discounted cash flow (DCF) and real options methods. Particularly useful for the trademark valuation is the Interbrand method [5].

Advantageously, there are professional estimations of risks for the different projects and technologies in the Biotech and pharmaceutical industries. For instance, such estimations are considered for calculating a risk-adjusted net present value (NPV)[1, 6, 7]. Other statistical values have been taken as reference for precommercial and commercial royalty payments based on intangible assets values, also establishing the adequate value range for precommercial payments [8].

Assessing the negotiation of intangible assets at BioCubaFarma

For the aim of assessing the negotiation of intangible assets at BioCubaFarma, the negotiations in the Biotech sector were characterized. A sample of such negotiations in some of the major enterprises of BioCubaFarma was established and the expert's criteria analyzed by using the Delphi method based on the brainstorm technique. Positive and negative elements were identified; among the negative ones are: neither

all the enterprises considered the intangible assets during the negotiation process nor separated the intangible assets from the product subjected to negotiation; there were no uniform methodology at the Organization level for the valuation of intangible assets; there was an insufficient exploitation of the income potential derived from the negotiation of intangible assets; the standards of production, clinical research and research and development (R&D) projects were lower than those enforced in Europe and USA, ultimately devaluing the projects' values; and lastly, the negative effect of the USA blockade on the negotiation process for intangible assets.

Then, the working ranges were set for values of precommercial payments and royalties over the profit payments in BioCubaFarma, and they were further compared to the international values for each phase of the negotiation process. A new methodology was proposed for the negotiation and valuation of intangible assets. Its main purpose was to provide a methodological tool and the required steps for the uniform calculation of intangible assets values at every phase of the negotiation process and throughout the entire organization.

Methodology for preparing the negotiation of the intangible assets associated to biotechnological projects or products

A new methodology was established to prepare the negotiation of biotechnological products, which includes the intangible assets: early stage of development projects, trademarks, technologies and patents, from the stages of the negotiation process. The steps followed during this methodology are shown in the figure.

This methodology is theoretically exhaustive, explaining each of the steps to be followed. Moreover, the parameters to be measure for intangible assets valuation are described in detail.

In fact, to determine the price of a new product with patent strength, it should be considered the price that market is willing to pay for it rather than cost of selling it. Therefore, four typical situations of the biotechnological products are specified and it is proposed how to calculate the price in each one. For example, for new products for a disease for which there are no alternative therapies or medicines, it is proposed to take as reference the cost of the treatment that has been applied up to that time. It should be adjusted depending on the strengths and weaknesses of the new product. Pharmacoeconomics studies are conducted if the product is unique or 'first on its class' for a disease without any treatment alternative, or strategy canvas [9], must be established considering the existing treatment alternatives. Finally, the percentages of market penetration are proposed to plan the future sales for each of the typified scenarios.

A time horizon of 10 years is proposed to calculate the cash flow, considering that a patent guarantees the protection of a research result for 20 years, also considering that the results are patented in the initial stages of product development and that it takes about 10 years to completion. For the NPV calculation, a discount rate of 15 % is applied for novel products and projects in mature stages and 18% for projects in

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8. Poile S, Elvidge S. Early stage and discovery deals: Strategy, structure and payment. London: Bridgehead Pharmalicensing Group Ltd.; 2003.

9. Kim WC, Mauborgne R. Blue Ocean Strategy: How to create uncontested market space and make competition irrelevant. New York: Harvard Business Review Press; 2005.

the early stages of development. Once the traditional NPV has been calculated, the percentages of risk in the clinical development are applied to adjust the NPV at risk, as described by Olga Spasic [9]. It is proposed to combine the discounted cash flow method, by adjusting the NPV at risk, and the technology factor method, for which calculations and precisions are made to determine the factors that are applied for the separation of the value of intangible assets. In order to separate the trademark, the Interbrand method is applied [6]. Once the value of the intangible is calculated, the amounts and ranges of values of the payments to be made are proposed.

The methodology designed facilitates the negotiation of intangible assets, since it establishes the steps to be followed during the preparation of the negotiation, recommends the method of calculation and the ranges of values in which the pre-commercial payments can move. It also includes recommendations on the percentages of royalties and the multiplier factor to be used to separate the different intangibles from the same project.

This last element is of great importance and utility, since the separation of the intangible assets marks an important pattern of its negotiation. It is not the same to negotiate a goodwill as a whole than to be able to valueate each intangible asset differentially. Besides, the percentages of initial market penetration are specified and the methodology recommends on what basis the prices of biopharmaceuticals should be calculated in different situations typical for these products. It should be noted that the explanations given constitute theoretical contributions of this work. Its novelty relies on the design of the methodology itself. Indeed, there was not any integrative approach as the one proposed inhere in the previously consulted literature, able to consider all the elements mentioned, also including both, the valuation and separation of the intangible assets, and their negotiation.

The designed tool will facilitate the companies of BioCubaFarma to valueate and negotiate in a homogeneous and systematic way the intangible assets associated with the products and novel projects they generate. Taking into account that it is a tool that is generalizable and widely applicable in the biotechnology sector, its applicability can be assessed in other Cuban companies generating intangible assets, adapting it to the characteristics of the sector or branch in which the business model is developed.

Relevance of the study

The research that is presented is one of the results of the research project on the negotiation of biotechnological products with associated intangibles.

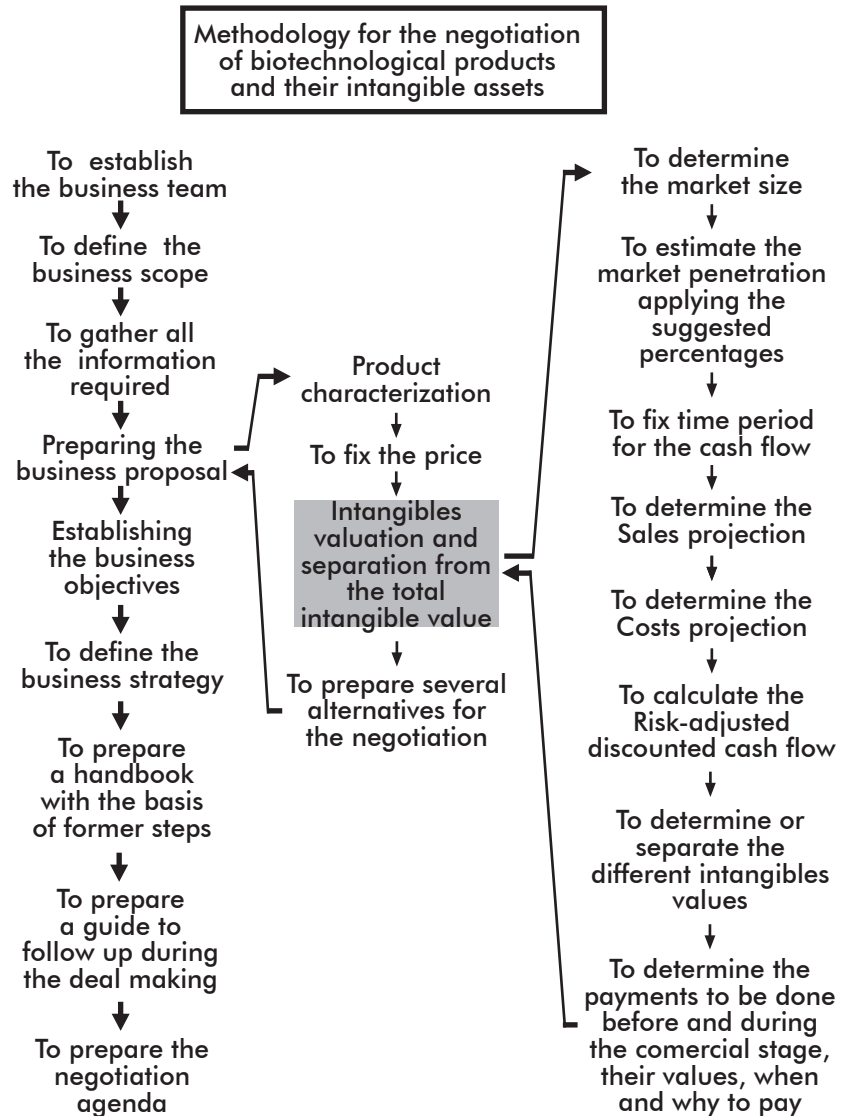


Figure. Methodology proposed for the negotiation of biotechnological products and the valuation and negotiation of their intangible assets.

It has been the result of a pyramidal research process. So far, it is the first ever tool developed for the valuation and negotiation of intangible assets in the biotechnological industry in Cuba. Additionally, it provided a graduate thesis and a PhD thesis on Humanities, this last also awarded by the Cuban National Academy of Sciences in 2015 as the Best PhD Thesis in Economics.