A Technology Transfer Model from Public to Private Sector in Biopharmaceutical Industry

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Abstract--**Describing a new model implemented by Butantan Institute – a centenary Brazilian public research institute – to develop a new molecule as a therapeutic agent with public and private funding. Different from the creation of a new technology-based enterprise, this model proposes to internalize the scale up process in the research institute in order to develop the trials, and then transfer all the technology of the process and the related knowledge to the private sector to begin the production. It seems a reasonable and feasible model for Brazilian biopharmaceutical companies, as most of them do not have research and activity-development background, nor cross-disciplinary teams or even equipment that are crucial for the development stages of innovative pharmaceutical products. In contrast, some Brazilian public institutions, such as research institutions, have some worldwide known researchers in different fields of knowledge, and also a lot of world-class equipment. The main aim of this proposal of a new technology transfer model is to enable the production of new biopharmaceutical products, thus driving innovation in the biopharmaceutical sector.**

I. INTRODUCTION

The proposal of this study is to present a model for technology transfer that enables to overcome the valley of death in new biopharmaceutical product development. Different from the creation of a new technology-based enterprise, the proposal of this model is to internalize the project, similarly to an incubation process, inside the research institute and transfer the technology to the private sector when it is ready for industrial production. This proposed model would fit between the two main existing technology transfer modes, as it is not a simple licensing, but also creation of a new enterprise is not involved. It is in accordance with the findings of Lockett in 2005, who concluded that the best choice for technology transfer would be between licensing and the creation of a spin-off [9]. The main contribution is the elimination of the stage of creating the enterprise, which is especially difficult in Brazil. In the biopharmaceutical sector, big pharmaceutical companies usually commercialize products in the market. They normally acquire spin-off companies. According to this proposed model the technology is transferred to the company, which will take the product to the market when it is ready for industrial production. Even without creating a new enterprise it is possible to transfer all the codified, and especially, all the tacit knowledge.

II. TECHNOLOGY TRANSFER

Growth models and empirical research have recognized technological advance as the driving force for economic growth and scientific knowledge has become the key input to innovation in industry and society. Universities, especially major research universities, play a key role in national and regional economic development. One important mechanism through which universities contribute to economic growth is by converting scientific inventions into innovation by filing patent applications and licensing research outputs [19]. Policy makers have devoted a significative amount of resources to promote the commercialization of new technologies and knowledge generated within universities and other public research institutions [1].

However, promising inventions frequently remain undeveloped due to lack of resources such as business expertise and know-how, keeping inventors from the assistance they need for growing [9].

Additionally, it is widely accepted in science, technology and innovation studies 'that the innovative capacity of a nation depends not only on the strength of individual "players" (firms, universities, government research laboratories) but perhaps more importantly on the links between those actors' [18]. Technological inter-firm alliances constitute a prominent complementary vehicle for the creation and exploitation of new knowledge, a process upon which economic and social development is based [18], [16], [11].

In the United States, Congress initiatives such as the Bayh-Dole Act of 1980 accelerated the rate at which new technologies from universities and federal laboratories reached firms. Bayh-Dole established a uniform patenting policy across governmental agencies, lifted some restrictions on licensing, and most importantly, enabled research institutions to own patents arising from federal research grants. Additional U.S. legislation designed to promote collaborative research, and a faster rate of university-industry technology transfer, included the 1982 Small Business Innovation Development Act, the 1984 National Cooperative Research Act, and the 1992 Small Business Technology Transfer Act. In the United Kingdom, laws were also enacted to stimulate the commercialization of university-based research, innovation in small firms, and the development of public-private research partnerships. The British government designed three key programs: University Challenge, Science Enterprise Challenge, and the Higher Education Innovation Fund. The initiatives were undertaken by national

governments to overcome innovation market failure, especially for small firms that may have insufficient financial and human capital to thrive in the marketplace [9].

In Brazil, the context of innovation has advanced greatly after the Brazilian Innovation Law was enacted in 2004. The main contributions of this law were: to enable public research institutions to own patents; to encourage the relationship between public and private sectors, which was initially regarded with skepticism, since the relation with a for-profit institution was not in accordance with traditional norms of science; and to create, at public scientific and technology institutions, Technology Transfer Offices [TTOs], which are responsible for management of this institution's innovation policy. Although Brazil has recently faced a large advance related to topics that contribute to innovation, the country is still far from the United States and Europe specially when it comes to entrepreneurship. Brazil is getting more mature in terms of an entrepreneurial culture, as well as regarding funding for entrepreneurial activities. The most important program of the state of Sao Paulo, from the state of Sao Paulo Research Funding Agency [FAPESP], called Innovative Research in Small Enterprises [PIPE] [4] grants resources to support research activities in small enterprises in the state of Sao Paulo, leveraging the creation of University Spin-offs [USOs]. The promising results can be illustrated by a report of the State University of Campinas [UNICAMP] that presented the creation of 259 USOs in the last 30 years, with a total of 10,414 employees, which represents 40 employees, on average, per company [7].

A. Technology transfer mechanisms and USOs

Rogers, Takegami, and Yin identified five different technology transfer mechanisms from universities: (1) spin-offs; (2) licensing; (3) meetings; (4) publications; and (5) cooperative R&D agreements, out of which technology licensing and spinning out ventures were the ones with the highest commercialization value [13]. A number of researches has identified favorable conditions for universities to commercialize technology in the form of USOs as opposed to licensing. Agreements through which a university takes equity position in a company in exchange for providing the right to use university intellectual property are becoming an emerging mechanism and the focus of interest of many universities [2].

The dominant way in which technology has been traditionally transferred from the university sector to the private sector is through technology licensing [14]. This system has the advantage that the academic and the university are able to capitalize on the technology, and the academic is able to pursue his/her research without having to commit large amounts of time to commercial matters. The downsides to this approach are two-fold. First, the nature of the new technology may not be easily patented and transacted via a license agreement. Second, universities may not be able to capture the full value of their technology through a licensing arrangement and therefore may seek a more direct involvement in the commercialization of new technology through spinning-out a company. As a result, there is growing interest in the role that University Spin-off companies may play in the commercialization process. This increased interest is being observed in North America, the UK, Australia and Continental Europe [10].

Although university patenting activity has increased since the Bayh–Dole Act passed, only a limited proportion of university patents have been licensed. A closer look into the Association of University Technology Managers [AUTM] 2006 survey shows that the average licensing level across major research institutions tends to be much lower than one-third [19].

Technologies conducive to creating spin-offs are radical in nature, draw to a large degree on tacit knowledge, are in an early stage of development, serve a general purpose, are likely to produce significant customer value, involve major technical advances, and are protected by strong IP [15]. These technologies are science-based, characterized by a strong dependency on knowledge as developed by universities and public research organizations [PRO]. The search and development process is primarily based on tacit knowledge, although the outcomes of the search process can be codified in patents or publications. Spin-offs have the capacity to exploit the codified outcomes by combining it with the tacit knowledge of the inventors (as founders or as highly involved employees or consultants) required for the further development of the new technology [6].

The technology licensed to established firms is typically more incremental in nature, draws largely on codified knowledge, is in a more mature stage of development, serves a specific purpose, is likely to produce moderate rather than significant customer value, involves minor technical advances, and involves a weak IP regime [15]. This type of technology is embedded in development-based technological fields, characterized by a systemic knowledge base. The firms that exploit this technology have the capability to integrate such related technologies, a capability that cannot be taken off the shelf [6].

USOs often commercialize early-stage inventions where existing companies failed to commercialize the technology or the innovation or technology might be radical in nature, so that there are no existing companies that find interest in the new technology. USOs may provide a missing link between investments in new knowledge and economic growth, and their economic impact is likely to be more indirect than direct. This perspective emphasizes the firm's ability to convert scientific findings into innovative products and services that challenge existing technology in the market as the most important characteristic of their ability to generate long-term impact and spur economic development. To achieve the highest impact in terms of technology transfer, the innovativeness of USOs may be more important than their growth orientation. Moreover, the link between innovativeness and growth in small firms is well established in the literature [1].

The findings of Lockett's work, which is focused on the creation of new firms through spin-offs, as opposed to

licensing, raise issues regarding the choice between these two modes of university technology transfer. If universities are incapable of fostering sufficient commercialization and entrepreneurial skills among their academics and technology transfer officers, it may be appropriate to place more emphasis on licensing inventions [9].

Since the seminal studies conducted by Cooper in the early 1970s on the spin-off activity at Stanford University (Cooper, 1971 a, b, apud Pirnay, 2003), university-based venture creation has received increasing attention from scholars, especially in the United States. However, an in-depth review of this literature shows that most authors do not clearly define a university spin-off. Indeed, any phenomenon can be qualified as a "spin-off" as long as it simultaneously fulfils three conditions: (1) it takes place within an existing organization, generally known as the "parent organization"; (2) it involves one or several individuals, whichever their status and function may be within the "parent organization"; (3) these individuals leave the "parent organization" to create a new one. Thus, creating a "spin-off" necessarily implies an important change in the career path of an individual, namely leaving an existing organization to launch his/her own business venture. We agree that a USO refers to a spin-off firm that is created from a particular type of "parent organization", namely a university. For the purpose of clarity, we consider Pirnay's definition of University Spin-offs: "new firms created to commercially exploit some knowledge, technology or research results developed within a university" [12].

B. Biopharmaceutical development

Biopharmaceutical development is very peculiar. It generally follows a standardized process consisting of six stages: discovery, pre-clinical, the three clinical trial phases (1, 2, 3) and the approval stage. Accordingly, it usually starts with the identification of an agent with a desired biological profile. Once a potential new drug is identified, it is then subject to a range of tests, namely *in vitro* and in animals in order to characterize it in terms of safety and effectiveness in treating a disease. Then, clinical development is made to obtain approval for general medical use and to demonstrate product quality, safety and efficacy [17].

Pre-clinical trials, clinical trials and product launch require the production of sufficient quantity and quality of product. Regulatory requirements dictate that the material used for preclinical and clinical trials should be produced using the same process by which it is intended to undertake final-scale commercial manufacture. As such, an extensive early development work is critical, as well as ensuring the scalability of the process developed allowing yields to be improved. Any significative deviation from the production protocol used to generate the trial material could invalidate all clinical trial results with respect to the proposed commercialized product or entail additional testing to prove product equivalence [17].

When attempts are first made to turn a molecular discovery into a drug, new processes must be developed and relatively little is known about their properties and dynamics, and then there is considerable uncertainty in these processes. It is observed a multi-phased development path in which distinct objectives were set at the beginning of each phase. From one phase to another, development resources in terms of people, skills and equipment changed considerably. There was a repeated need for innovations in processes that were quite radical in terms of discontinuity from previous practice. These innovations were not only drivers of process economics and yields but also altered product characteristics [8].

We could say that in the biopharmaceutical industry there is not a dichotomy between product and process innovation. The idea that new ventures should use the principle of comparative advantage to specialize in drug discovery (product innovation), while established companies specialize in producing and scaling up the drug (introducing suitable process innovations), has been widely accepted as best practice. The distinction is congruent with influential theoretical perspectives that posit a sharp distinction between product and process innovation and view product development as made up of distinct and sequential stages. However, there are implications for strategy in these findings, that in biopharmaceutical activity, product and process development activities are closely interlinked. During the development of at least some biologics, product and process innovation advance in iteration. The process can constitute the product regulators' viewpoint. Industry regulations indicate that the nature of the drug required for efficacy can only be known through the specification of its process. These observations support evidence presented by Feldman and Ronzio [5] who found that U.S. biotech entrepreneurs preferred to own and control their manufacturing facilities in the longer term because they saw disadvantages in separating advances in product innovation from advances in processes. Production in biopharmaceuticals provides a source of knowledge that supports effective product–process innovation [8].

III. METHODOLOGY

The approach of the study is qualitative, through a case study and participant observation. Case studies are considered efficient methods for understanding complex phenomena [3], and for providing answers for "how" and "why" [20].

The institution selected for the case study is a public research institute in Brazil, Butantan Institute, which presents the model of technology transfer that will be described, where access to documents and interviews were possible, as well as due to the possibility of participant observation by one author. The information was acquired mainly through personal in-depth interviews with the coordinator of the project used for proposing the model, Dr. Ana Marisa Chudzinski-Tavassi.

Participant observation carried out by the author as coordinator of Butantan Institute Technology Transfer Office, over a period of three and a half years, contributed to provide

an in-depth understanding of the project carried out, the organizational structure and management systems, and mainly of technology transfer processes.

IV. RESULTS AND DISCUSSION

The model proposed for technology transfer is described in this section. First of all, a brief introduction is made about the institution used in this case study. Then, we will describe how this project has begun at this institution and, later, this model will be discussed according to some aspects and it will be justified why this model is different from the ones that have been studying in-depth on the literature and why it is an interesting one.

A. Butantan Institute

Butantan Institute [BI] is an institute of science and technology located in the state of Sao Paulo, directly owned by the State Department of Health of Sao Paulo. It has a support foundation, which is a private and nonprofit association, the Butantan Foundation, that helps speeding up administrative processes. BI was founded in 1901 and carries out research, development and production of immunobiological products. It is a leading manufacturer of immunobiological products in Latin America and is responsible for providing more than half of hyperimmune sera and vaccines demanded by the Brazilian Ministry of Health. Besides the production of sera and vaccines, research activities and the concern to disseminate science have always been present in its everyday life, giving it an international recognition. BI is a leading biomedical research center and highlights the permanent search for updating and integrating its resources and, thereby, the innovation.

B. The project

We will use the case of a project carried out at BI from which we could propose this model. This project arose as part of the Program Research, Innovation and Diffusion Centers [CEPID], of the state of Sao Paulo Research Funding Agency [FAPESP]. CEPID Program is a FAPESP initiative to develop fundamental and applied investigation, and actively contribute to innovation. The groups that are awarded with this program are required to have structure and staff that ensure: that the projects will be adequately managed; that they will concentrate efforts to establish partnerships with private companies so that innovation occur; that the groups will be assessed periodically and the transfer of funds will be conditioned upon the approval of annual reports. In 2000 BI was awarded with its first CEPID program called Applied Toxinology Center [CAT] and the projects were developed over 2000 and 2011.

This project has begun focused on studies of the saliva of a tick, looking for anticoagulant activities. For a better comprehension, it was necessary to study the salivary gland gene. More than two thousand genes were analyzed and one was selected. This selected clone has generated a protein, obtained in the recombinant way using one bacteria, according to genetic engineering techniques. This protein of interest, called Amblyomin-X, has presented anticoagulant activity, but surprisingly, also selective toxic activity for tumor cells. Since these first concept proofs evidencing these activities, some Brazilian pharmaceutical companies have been contacted. One has gotten very interested in this project and has begun to collaborate in this CEPID program. Therefore, since the beginning it was a public-private funding project in which the private company invested 10% per year of the amount invested by FAPESP.

As the results were very promising, a patent application was filed in 2004 and the private company was one of the applicants (public and private applicants). Since then the private company was responsible for all the patent family costs, which was filed in 23 countries. In 2005, a license agreement was entered into between Butantan Institute and the private company. It was a standard license agreement, which did not consider the knowledge necessary for all these following development stages (scaling up process, establishment of mechanisms of action, pre-clinical trials, etc.), so later it was necessary to renegotiate a technology transfer agreement.

The private company, together with FAPESP, was responsible for annual investments in the project, which were applied to the following development stages: more concept proofs, establishment of mechanisms of action, establishment of protocols for laboratory scale production, etc.

It was observed that the protein presented selectivity for tumor cells, and more interesting, animals presenting tumor cells induced obtained, after treatment with this protein, presented reduction or regression of the tumor mass. Then, the molecular target for the cell death was defined.

After that the execution of the pre-clinical trials for pharmacological safety began. It was necessary to establish a methodology to produce protein in enough concentration for the treatment of all animal groups. This stage was accomplished with public and private funding.

Taking into account that Brazil did not have an available laboratory with infrastructure for some research and development stages that require traceability and reproducibility (Good Laboratory Practices – GLP), a laboratory was built in Butantan Institute meeting all these specifications. It was called “Development and Innovation Platform”. This platform followed international requirements and can also be used for other projects. For the construction of this platform a project was written and applied for funding from the federal funding agency of the Ministry of Science, Technology and Innovation [FINEP].

This project was incubated at this platform for: the development of the best clone; the establishment of the protocol for producing up to 10 liters in bioreactor; the study of the best vector of expression; the establishment of the protocol for the purification of the protein; the establishment of stability analysis studies considering the scaling up process that will be implemented by the industry.

Pre-clinical trials of cytotoxicity, acute toxicity and repeated-dose toxicity in rodents, and the determination of

the molecular target that induce the selectivity death in tumor cells were also conducted at this platform.

For the development of the scaling up process up to 50 liters with the aim of having the protocol for transferring it to the private company for the beginning of the industrial production, a development project was written and received a grant from the Brazilian Development Bank [BNDES]. It was a project belonging to three institutions: Butantan Institute, the private company (that was also responsible for funding 10% of the amount invested by BNDES) and Institute for Technological Research [IPT], a public research institution linked directly to the Secretariat for Economic Development, Science, Technology and Innovation of the State of Sao Paulo, that is one of the largest and most important research institute of the state of Sao Paulo. IPT is responsible for scaling the process up to 50 liters. We expect to begin clinical trials when this BNDES project is completed.

It is important to emphasize that licensing technologies developed at BI for external institutions is an activity in line with the purpose of the institute. BI main business is vaccines and sera production. However, based on researches carried out at BI with animal secretions and toxins, the results are a large number of molecules with a wide variety of activities, including pharmacological applications. BI focus is not on internal production of all these molecules. BI does not have structure for such. Moreover, it is more interesting for BI to prioritize internal vaccines and sera production and then license these other technologies developed internally for pharmaceutical industries, so that these companies will carry out the manufacturing process and take these products to the market.

As the project has been presented, now the factors considered most important to enable the existence of this model proposed will be discussed.

C. Funding and the relationship with external institutions

In order to present this model the presence of the private company was crucial since the beginning of the project. Its commitment and funding were very important to the progress of the project. The patent was filed together with the private company, which covered all its costs. This fact enabled to file the patent in 23 different countries, which would be very difficult to achieve only with public resources.

As discussed above, this project was born in a CEPID program, which probably is the most important funding program of the state of Sao Paulo for applied research. The program takes ten years, and financial resources are high, compared with other research funding programs. Then funding from FINEP and from BNDES was achieved. Thus, it is possible to say that this project was funded by the three most important innovation programs in Brazil.

The cooperation with IPT was very relevant as adding IPT's expertise on scaling up processes was fundamental to the progress of the project.

D. Infrastructure

The Development and Innovation Platform previously mentioned was essential in building the translation bridge between basic research and development. It has been structured with facilities and laboratories that contemplate the main areas involved in the discovery and production of new drugs, including research, development and scalability. Equipped with certified laboratories and state-of-the-art equipment, this platform was essential for performing pre-clinical trials and in the scaling up process. The three laboratories (protein purification, cellular biology and microbiology and fermentation) are biosafety certified and are currently implementing Good Laboratory Practices [GLP]. This platform has six main facilities: (1) computational chemistry; (2) heterologous expression and protein purification; (3) protein chemistry and hemostasis laboratory: chemical and biochemical analysis; (4) mass spectrometry multiuser laboratory; (5) cellular biology facility: proofs of concept, identification and validation of targets; (6) animal model: proofs of concept and pre-clinical trials.

E. Human resources

First, it is important to emphasize that this project was born as a research project with applied aim. The coordinator of this project, Dr. Ana Marisa Chudzinski-Tavassi, was essential for its success. Having an entrepreneurial profile, she led the relationship with the private company and strived for public funding. She has formed an up-to-date and committed cross-disciplinary team to dedicate themselves to this project comprised of: engineers (chemical and process), biologists, biomolecular biologist, pharmacists, chemists, veterinarian, biostatistician, and some of them are technicians and post-doc students.

To guarantee the success of the technology transfer, there is a close relationship between professionals from the research institution and the company for discussion of results and planning the following stages, as trials, formulation and regulatory affairs. There are also some professionals that are working in this project at the research institute, like fellows and post-doc students, who are being trained and will be hired by the private company when the technology is transferred. The convergence of professionals from both sectors to common goals, discussing results, challenges, presenting solutions for them and planning the following stages, in an appropriate infrastructure, certainly reduce the distance between research and production and boosts the development process. This relationship raises the confidence between parties, contributes for risk reduction and certainly reduces the cost of development, which is crucial for enabling radical innovations in the pharmaceutical sector.

F. Summarizing the proposed model

We will use the figure below which contains the stages of development in the pharmaceutical industry to conclude the explanation of the proposed model:

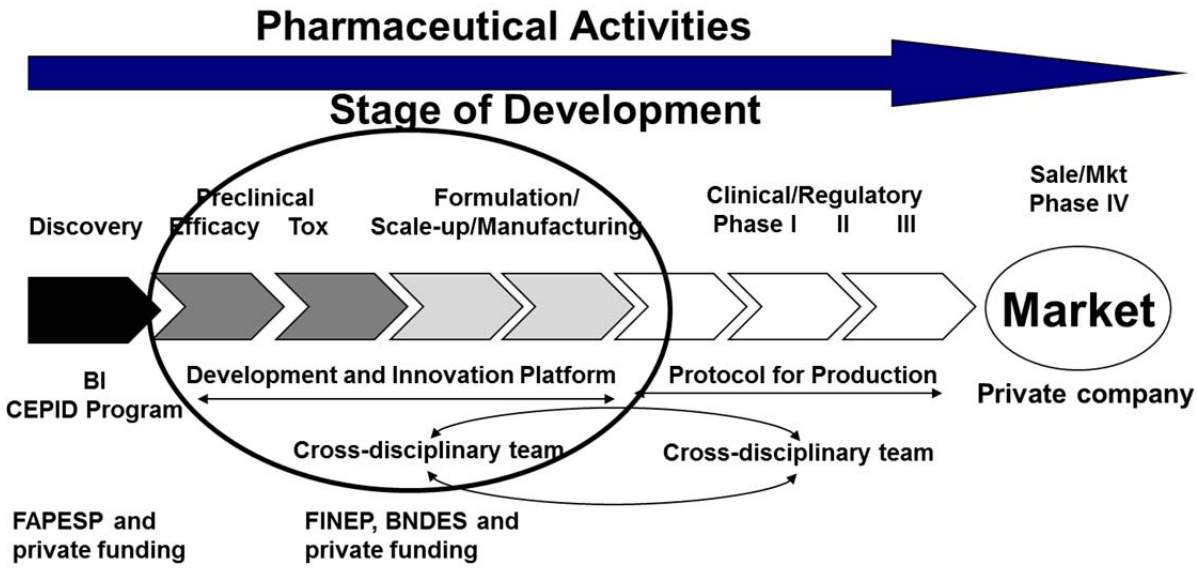

Figure 1: Stages of development in the proposed model

It is very common that the discovery of molecules with potential pharmaceutical activities happens in the university and research institutes. Usually these institutions obtain funding from research funding agencies to conduct the projects in the laboratorial scale until the stage of concept proofs. When the amount of money increases abruptly for doing the pre-clinical trials and to increase the scale of production, but you still have a lot of uncertainties and the risk is high, and there isn't any expectation to take it to the market, it is very difficult to obtain funding. Probably it will not be possible to find a private funding. Usually the projects end up at the bench at that stage.

In the proposed model, the project began at the research institution as part of a program with applied aim. Since the concept proofs there was a collaboration with the private company, which had a commitment to invest money in the project in order to take it to the market.

To carry out the pre-clinical trials and for scaling up the process of production there was an application for a public funding together with the private company, on which the private company had the commitment to invest a percentage of the money invested by the public funding.

The model proposes to internalize the pre-clinical trials and the scaling up of the process in the research institution. These stages were conducted at the research institution and for scaling up the process there was a collaboration with another research institution with expertise in processes. In Brazil it is very rare to have a place to realize pre-clinical trials. Even more in research institutions and universities. Usually pharmaceutical industries have to outsource this stage with Contract Research Organizations – CROs. It was just achieved in Butantan Institute due to the Development and Innovation Platform, which have infrastructure and human resources for that. The existence of this platform was essential for allowing the internalization of the pre-clinical and scaling up process stages to the research institution. And this platform was constructed and equipped with the money of another public funding.

To guarantee the success of the transference of the technology from the research institution to the private company, a close relationship and common goals between multidisciplinary teams from both sectors, discussing results, challenges, presenting solutions for them and planning, were essential.

The main proposal of this model is to internalize some stages of the development of new pharmaceutical product, similarly to an incubation process, inside the research institute and transfer the technology to the private sector when it is ready for industrial production. If you have the expectation to take it to the market through the commitment of a private company since the discovery, this internalization with a close relationship between teams helps to diminish the risk, lower the costs of development and allows the project to move forward in the stages of development. But to this internalization succeed it is necessary to have in the research institute an appropriate infrastructure and a multidisciplinary and committed team. Funding is also essential for allowing the progress of the project. To perform the pre-clinical trials and scaling up the process, when there is a lot of uncertainties and a high risk, it is very important to have a public funding. But the commitment of the private company, since these stages, investing money, was very important for enabling the progress of the project.

V. CONCLUSION

The model for technology transfer that has already been proposed seems to be a reasonable, viable and very

interesting one for biopharmaceutical companies, especially in Brazil, as most of them lacks local expertise in R&D activities, cross-disciplinary teams and even equipment that is critical for the development of innovative biopharmaceutical products. In contrast, Brazilian public institutions, as research institutions, have well-trained researchers in different fields of knowledge, and also modern instruments and facilities. Additionally, in Brazil it still is very difficult to create an enterprise based on a technology developed in a university or research institute.

The model proposed is not a common licensing, but it also does not involve the creation of a new organization, which is a requirement for being considered a spin-off company [12]. According to Pirnay's definition of University Spin-offs: "new firms created to exploit commercially some knowledge, technology or research results developed within a university" [12], we could say that the model proposed fits between the two main existing modes of technology transfer, and it is in accordance with Lockett's findings in 2005, who concluded that the best choice for technology transfer would be between licensing and the creation of a spin-off [9]. The main contribution of this proposed model is the elimination of the stage of creating an enterprise, which is achieved by the internalization of the technology, similarly to an incubation process, into the research institute, and transferring it to the private sector when it is ready for industrial production.

This model is even more important to the biopharmaceutical sector, in which product and process development activities are closely interlinked and thus, product and process innovation advance in interaction. Production in biopharmaceuticals provides a source of knowledge that supports effective product–process innovation, so it would be more interesting to own and control the manufacturing facilities in the long term [8].

According to this model proposed it is possible to transfer a technology radical in nature, which draws largely on tacit knowledge, which is in a more mature stage of development, which is likely to produce significant customer value, involves major technical advances, and is protected by a strong IP without creating a spin-off. It is opposed to Shane's findings in 2002 [15]. The main differences relies on the stage of development and on the possibility of transferring tacit knowledge. As the development stage has been internalized at the research institute, the technology can be transferred to the private sector when it is in a more mature stage of development. The transfer of tacit knowledge is achieved by the formation of a cross-disciplinary team dedicated to the project and its close relationship with the company's team. The possibility of migrating these professionals from the research institute to the company also contributes to the success of transferring tacit knowledge.

The main contribution of this study is to present a new technology transfer model that enables to overcome the valley of death in new biopharmaceutical products development, as in the initial stages of drug development specific requirements and expertise are required that are not available on most Brazilian pharmaceutical companies, but are available on some research institutes. Thus, it is a model to accelerate innovation in Brazilian biopharmaceutical sector.

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