

Biotechnology Project Management vs. Non-Registered Intellectual Property

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MIRCEA NEGRUȚĂ^{1*}, NATALIA CUCU², ION NĂFTĂNILĂ³

¹Academy of Economic Studies Bucharest, Doctoral School, 11 Tache Ionescu Street, 1-st. floor, room 8102, Bucharest, 010352.

E-mail: mircea@bluecolor.ro, Tel./Fax: +4 021 668.02.72

²University Professor, University of Bucharest, Faculty of Biology, Department of Genetics

¹ 1-3 Aleea Portocalilor, Sector 5, Bucharest 060101.

E-mail: nataliacucu@yahoo.com, Tel/ fax: 0040.213118077

³University Professor, Academy of Economic Studies Bucharest, Faculty of Management

¹ 1-3 Intr. Amzei Street, 2-nd. floor, Sector 1, Bucharest, 010346.

E-mail: i_naft@yahoo.com, Tel. +4 021 201.71.02, Fax: +4 021 319.19.75

* Author to whom correspondence should be addressed; E-mail: mircea@bluecolor.ro

Abstract

The paper is trying in its first part to explore different intellectual property components in the field of project management, based on the specific literature in the field. In this effort, we found that even if there is plenty of literature dealing with the intellectual property components that are already protected, the main need for a project manager is to find out structured information regarding those intellectual property components arising in project management that are not protected. Going in further detail, the biotechnology represents a proper model for the study of the interdisciplinary aspects linked with intellectual property management. This hypothesis is based on the idea that the biotechnology is by itself a complex and interdisciplinary research field, implying numerous sub-specialties, each of them having its own innovation evaluation criteria. Therefore, we have chosen a certain research project in the biotechnology field, in order to reveal the main intellectual property issues that could arise from the interaction between its specialties.

In its second part, the paper is exploring the most important category of intellectual property components appearing in the biotechnology innovation and project management – the non protected intellectual property components. We have wondered if an average biotechnology project management team could successfully manage the common non-registered intellectual property issues, without any specialized help. The main conclusion is that a project manager or a project management team needs at least basic knowledge in the field of intellectual property.

Key words: Intellectual property (IP), project management, biotechnology, natural sciences

Introduction

Within the context of knowledge-based economy, along with the growing importance of the intangible assets, and owing, in part, to the changing criteria defining competitive advantages, there is an increasing need to address intellectual property related issues. Therefore, the intellectual property management science has evolved in the past few decades and it is becoming more and more important among the overall management science and practice.

As biotechnology projects are more and more complex, there are higher challenges the biotechnology scientist faces to embarking upon a successful and ethically responsible career in biotechnology research.

At the same time, the established and generally recognized rules and standards in the field of project management offer the basis for studying the concept of intellectual property and its application within the biotechnology research practice.

As part of both these sciences, the study of intellectual property management in the field of project management has just started and its particular application in the field of biotechnology is almost nonexistent.

This intellectual property management in the field of project management and its application in the field of biotechnology are related to intellectual property components that appear, interfere and result from the project management processes, in biotechnology projects. These aspects are much more important in scientific research projects, as the “intensity” of those intellectual property components is much greater than in a regular project.

There are only few such interdisciplinary initiatives, which provide the scientific community with specialized tools and information in helping carrying scientific projects. One of them is the Nature Biotechnology journal that has created several sections to deal with such kind of problems (for example [1]).

Therefore, studying these aspects during a biotechnology research project and comparing our results with the literature, would result in an important initial source of specialized information for project managers of such research projects in the field of natural sciences and biotechnology.

Materials and methods

The telephone survey was started from the list of approved projects published on the web-site of the National Agency for Scientific Research (<http://fonduristructurale.ancs.ro/ro/content/contracte>) – available at February 15, 2011. We have found the contact dates of 116 project managers and we have contacted them to obtain the principle accord to participate in the survey. The principle accord was obtained from a number of 92 project managers. The subjects were distributed mainly in the university cities around the country and most of them were from Bucharest. The questionnaire was composed of three simple questions: if they have in their organization a technology transfer office or an intellectual property office, if they are using *PMBOK* in carrying out their projects and if they met difficulties in their past projects regarding the intellectual property. The questionnaire was designed to avoid the potentially question/response bias in the survey by expressing clear questions and by preparing an eventually explanation of the meaning of terms or of their synonyms.

The survey was taken on 24-th and 25-th of February, 2011, and from those 116 project managers agreeing to participate, we could find only 78 available to answer the questions.

Regarding the first question, none of the project managers told us a clearly yes and only 3 project managers have told us that their legal office has some intellectual property competencies as they needed these competencies during past patenting processes.

Regarding the using of *PMBOK* in their projects, about a half of them asked us to explain what it is and none of them answered they use it in their projects.

The final question, if they met difficulties in their past projects regarding the intellectual property, has received a quite “colored” panel of answers, ranging from the questions regarding the intellectual property and its components, to the application of their knowledge with or without their consent and the plagiarism.

1. Project Management vs. Intellectual Property

The Project Management Institute offers the following definition of project management in the last edition of Project Management Body of Knowledge (*PMBOK*) [2]:

“Project management is the application of knowledge, skills, tools, and techniques to project activities to meet the project requirements.”

The Convention Establishing the World Intellectual Property Organization [3], gives the following main view on intellectual property:

“(viii) “intellectual property” shall include the rights relating to:

- literary, artistic and scientific works,
- performances of performing artists, phonograms, and broadcasts,
- inventions in all fields of human endeavor,
- scientific discoveries,
- industrial designs,
- trademarks, service marks, and commercial names and designations,
- protection against unfair competition, and all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields.”

Afterwards, the World Intellectual Property Organization (WIPO), explains that the “Intellectual property is usually divided into two branches, namely industrial property and copyright.” [4]

In the same paper, there are presented the main components of the industrial property [4] as follows: patents, utility models, industrial designs, intellectual property with regard to integrated circuits, trademarks, trade names, geographical indications and protection against unfair competition.

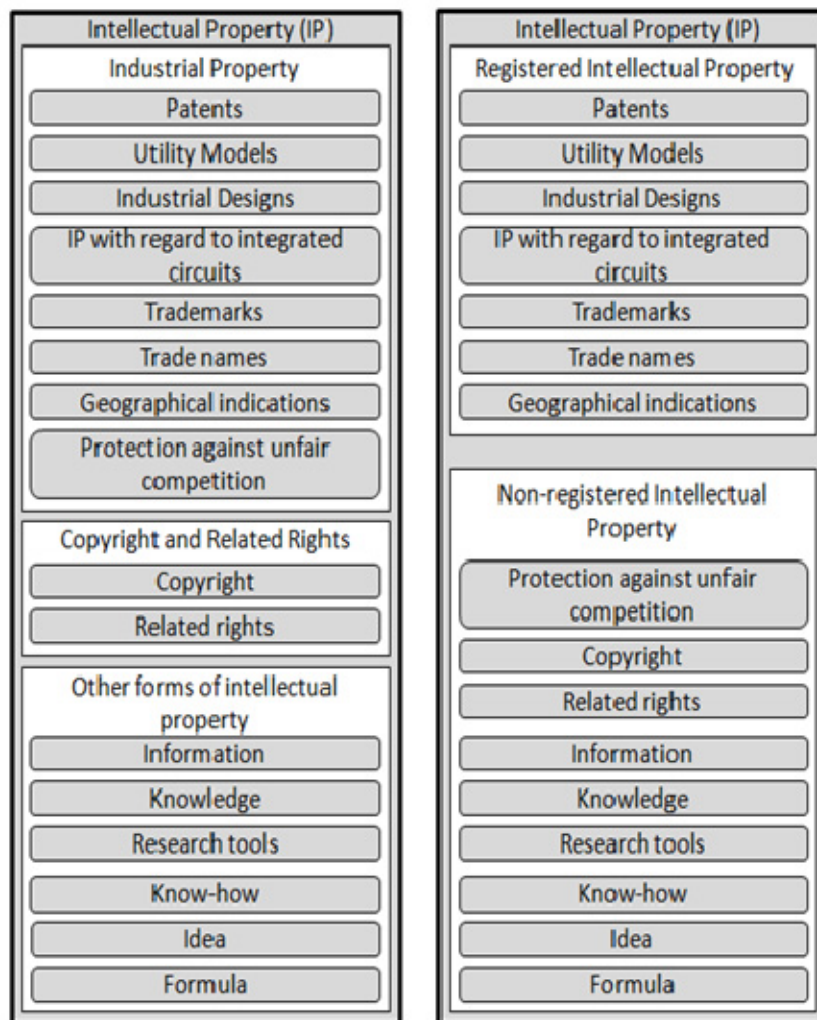
Regarding the copyright, it is generally presented as copyright and related rights [5].

But there is also a series of other elements that some authors consider as being intellectual property. A non-exhaustive enumeration of those elements could be the following:

- Information [7];
- Knowledge [7];
- Research tools [8];
- Know-how [8];
- Idea [9];
- Formula [9];
- Etc.

Besides this way of structuring the intellectual property, the need for public registration to protect the intellectual property components, will reveal interesting sights. Therefore, patents, utility models, industrial designs, intellectual property with regard to integrated circuits, trademarks, trade names and geographical indications are intellectual property components that need a public registration to come into force.

By contrary, the copyright [10], the related rights, the protection against unfair competition and all the other kinds of intellectual property components described above, are intellectual property components that do not need any official registration to exist (in certain countries there are some ways of registering the copyright as well as an idea, but generally these are intellectual property components that do not need official registration). This parallel structure is graphically illustrated in figure 1.



The left panel is presenting the main IP components structured as industrial property, copyright and related rights, and other forms of IP, while the right panel is presenting the same IP components structured as registered and non-registered IP.

Figure 1. Main branches of IP in comparison with registered and non-registered IP

In the light of project management, these different criteria of structuring the intellectual property components need specific approaches.

The intellectual property and innovation literature (at least in the research field) is also dividing those components into the following main parts: (i) intellectual property components specific to the consortium level, and (ii) intellectual property components specific to the project team level. Other works are dividing those components in external and internal [8].

One of the most elaborated guides dealing with the first category is the Guide to Intellectual Property Rules for FP7 Projects [11]. It is mainly presenting the intellectual property issues regarding the intellectual property components that appear mainly in different consortium relations. For this reason, it is mainly oriented on the consortium partners during the project preparatory phase, during the project implementation and after the project is closed. It is containing relevant information regarding the intellectual property issues occurring among the consortium partners, among them and the European Commission (as funding provider), among them and the third parties and so on. That information is highly grounded on the European Union specific rules and legislation, but most of them could also be available anywhere in the world.

On the other hand, there is no relevant literature focused on the intellectual property components specific to the project team level. There are just a few works that are not focused on the subject but have explored several scattered aspects related to them. One of the most elaborated such a work is „Intellectual Property Management in Health and Agricultural Innovation - a handbook of best practices” [8], supported by the Rockefeller Foundation. It is mainly presenting the issues of intellectual property appearing in the public funded projects and their relation with the private companies.

Therefore, a project manager could hardly find some structured information dealing with the intellectual property components specific to the project team level.

But some would wonder here if a project manager really needs intellectual property skills that are specific to the project management and are different from operational activity. Well, the first answer to such a question, and a common sense one, is obviously, yes. And this is because a project needs much more new knowledge and information than an operational activity and it is also producing much more new knowledge and information than a current activity.

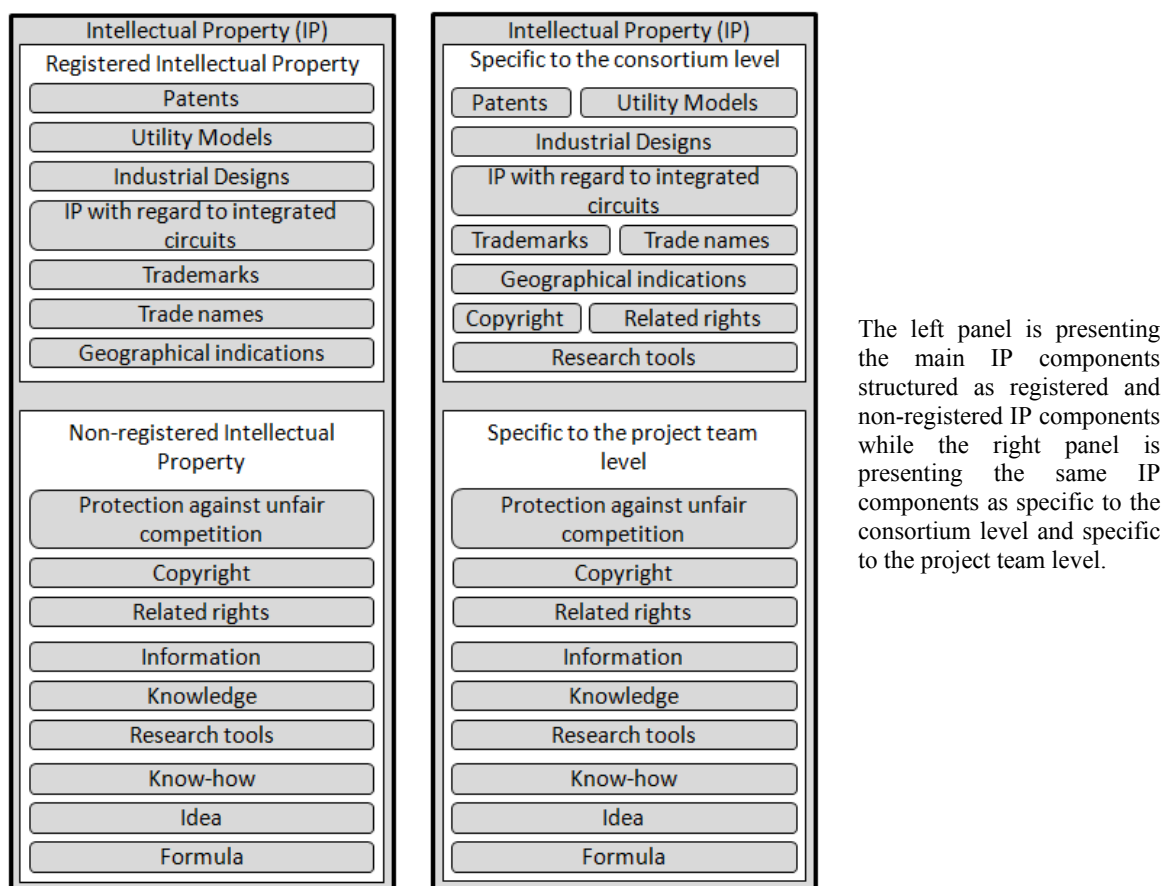
A more elaborated approach regarding this issue is provided by Jiang, in his paper: „Key Elements of a Successful Project Manager” [12]. He is considering the project management as well as science (“hard skills”) and as art (“soft skills”). The “hard skills” are related with the specific methods and instruments to conduct a project and they are easily found in different project management works or guides (one of the most known is PMBOK [2]). The “soft skills” are considered highly responsible for the success or the failure of the projects and a non-exhaustive list of them is provided as follows [12]: communication, organization effectiveness, leadership, problem solving, team building, flexibility and creativity, and so on.

In this context, to this non-exhaustive list, we can add: knowledge management, intellectual property management, standards, rules, and so on.

As a conclusion, a project manager, among the other “soft skills”, needs intellectual property skills to carry out successfully the projects to their end.

But, as we presented before, these intellectual property components are those that are protected (as patents, trademarks, and so on) and those that are not protected (as copyright, trade secrets, and so on).

On the other side, these intellectual property components are those specific to the consortium level and those specific to the project team level. Even if it is not a clear correspondence between these two categories (the protected intellectual property corresponds to the components specific to the consortium level and the non protected intellectual property corresponds to the components specific to the project team level), the literature is referring mainly at the protected intellectual property components when it is addressing the consortium level and it is referring mainly at the non protected intellectual property components when it is addressing the project team level. One of the examples is the World Intellectual Property Organization in its WIPO Magazine [6]. Therefore, a sample of a graphic presentation regarding this fragile correspondence that could be observed in the literature may be drafted as the Figure 2.



The left panel is presenting the main IP components structured as registered and non-registered IP components while the right panel is presenting the same IP components as specific to the consortium level and specific to the project team level.

Figure 2. Registered and non registered intellectual property vs. intellectual property specific to the consortium level and specific to the project team level

For the case of intellectual property components that are already registered, their use in a project is quite similar with their use in the operational activities of an organization. In this case, in order to protect the intellectual property rights, the project management team needs to ensure the following:

- not to use unauthorized intellectual property registered components that belong to third parties, and;
- to be sure that no one from outside would use intellectual property components belonging to the project team or to the project's organization.

In this context, as there is plenty of literature coping with the intellectual property components that are already protected, the main need for a project manager is to find structured information regarding those intellectual property components that are not protected and often arise in project management.

2. Project Management vs. Non-Registered Intellectual Property

First of all, we need to point out here that the intellectual property literature is talking about a technology transfer office [8] or another kind of specialized intellectual property office (or at least a legal office specialized in intellectual property rights) that the researches

have at their disposal in their organization and that they could consult in coping with intellectual property issues they meet during their projects.

Based on a telephone survey of 78 research project managers (many of them in the public research field), we found that less than 5 % have such a resource at their disposal. Therefore, the vast majority of the research project managers have to manage their projects with no such specialized help (unless they have included into the budget such a specialized service) and almost all of those we were questioned have told us that they need at least basic knowledge regarding the intellectual property issues for project management. This conclusion corresponds with those of another authors: [13], that states: “University faculty and scientists anywhere need a working knowledge of what intellectual property is and what can be done with it so that they are able to make decisions about their laboratories’ IP issues”.

Based on these findings we have wondered if an average project management team could successfully manage the common non-registered intellectual property issues (those that are mostly appearing at the project team level), without any specialized help.

Therefore we choose to explore these issues during a biotechnology public funded project, called “Elaboration and implementation of a new diagnosis algorithm in malign pathology of the mammary gland and genital tract, based on the correlation between the clinical and para-clinical factors and the epigenetic markers” (Contract 62086/2008). The project was funded by the National Research and Development Programme II, through the National Authority for Scientific Research in Romania. The project had a coordinator and four partners. Among them, we have decided to study these issues at the level of the project team of the Bucharest University. It was the third partner, with a team of 9 people. The period we have studied this project team was from November 2008 to November 2010.

Our first goal was to reveal the main issues regarding the non-registered intellectual property components in a project, during its implementation.

Taking into account the fact that there are so many approaches regarding the project management, we chose to rely, during our analyzing process, on the *PMBOK* [2].

First, we defined the project team, based on the *PMBOK*, as follows:

- project manager;
- project management team;
- other project team members (“who carry out the work but who are not necessarily involved with management of the project”);
- the sponsor (we have considered the project parent organization).

For the project we chose to study, the team was composed of:

- a project manager;
- a project manager assistant;
- a financial management responsible;
- a law specialist;
- 5 molecular genetics specialists;

Therefore, the project we have studied has a project manager, a project management team having three members, other six project team members and the sponsor of the project (the project parent organization).

The diagram presenting this structure and the project hierarchy is presented in figure 3.

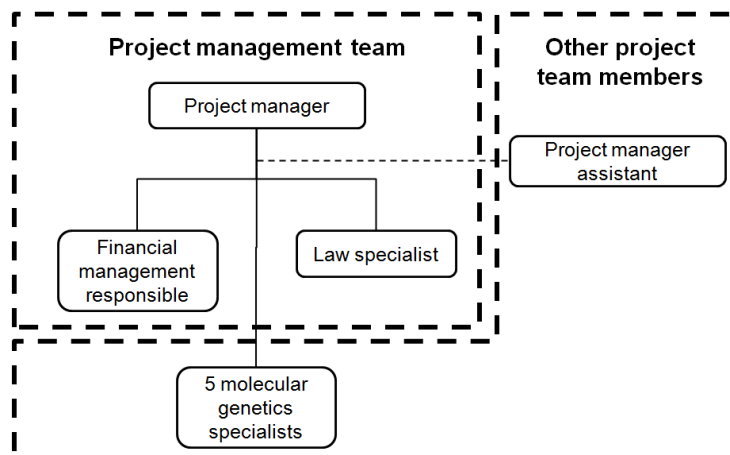


Figure 3. The structure of the studied team project

At this point, we have to add that the project was not managed based on the PMBOK principles and we choose this work only to have a standard to compare. Moreover, we need to point out that we have added in the 78 telephone survey that we mentioned before, a question regarding the standard project management document these project managers use in their project management activities. We found then that none of the project managers that answered our questions have told us they use the *PMBOK* as a reference. In fact, many of them have told us that they are managing projects in their own style, based on the main funding authority criteria. This conclusion is also corresponding to the one expressed by Duffy [14], who states that many of the project managers think that “obtaining funding is the hard part” and “managing grants will simply come naturally – as if these skills are either instinctual or so mundane that anyone will learn them. What a recipe for disaster!”.

Second, we have tried to define the situations we have met during the project, to explore the literature hoping we could find reasonable solutions and to apply those findings to the project we have studied. Regarding the intellectual property, we could not find a dedicated work dealing with the intellectual property issues at the project team level, and we had to pick up the information from various and different works. The paper is trying to present the most valuable such kind of problems and proposed solutions (the ones we found during the project and those we found studying the literature), in order to help project managers and project management teams in their efforts.

Therefore, one of the first problems we faced was related to the individual intellectual property rights for each member of the project team.

We had to decide who owns all the intellectual property rights for the project. Normally, the project organization (or sometimes the sponsor), but this is quite difficult to enforce, especially for the case of non-registered intellectual property.

The project we have studied was setting on the following biotechnology sub-domains:

- health biotechnology and medical services (clinical and para-clinical diagnosis in selection of the relevant cancer cases);
- health biotechnology linked with animal and human models of cancer;
- fundamental biology (searching of new molecular targets, explaining aberrant gene expression associated with cancer, based on the new gene concept: genetic and epi-genetic information levels);
- analytical bio-chemistry applied in biotechnology as a latest methodology envisaging the detection of the new molecular targets.

In the project we have approached, those rights derived from the biological, either fundamental or analytical were belonging to the Bucharest University.

Studying the literature, we found that a common practice used by the project organizations is to sign individual agreements with all the project team members, providing that all the intellectual property rights related to the project belong to the project's organization [15]. Additionally, or in the same agreement, someone could also find confidentially or nondisclosure clauses. In this way, the project manager and the project's organization are intending to clearly define the owner of the rights arising in a project and to "protect confidential information from disclosure to third parties". [8]

The Bucharest University chooses to rely on the individual working contracts for each member of the project.

The second problem we faced was related to the way we could enforce these things. As we found in the literature, in those cases, it is advisable "to set up a system to classify as "confidential" information which will be disclosed later and at various intervals over a period of time, in order to benefit from the protection granted by the confidentiality agreement" [16]. But this is not always an easy work to do. Therefore, one of the most used and simply methods is to keep an accurate record of any data and information as well as of any discussions regarding the project. [17]. Some other authors indicate to "keep a diary or other written record of the date when your idea was conceived and the steps taken and work that took place". [15]

Going into further detail and using the *Project Management Body of Knowledge* (4-th edition) [2] as a reference, we found at least 70 documents that could be used and issued into a project (many of them were presented into non exclusive lists, and therefore, the total number of documents used in a project could be significantly larger) and at least 115 instruments and techniques that are commonly used in project's processes. Now, we have to take into account the fact that those instruments and techniques could also create ideas, documents or know how. Moreover, depending on the project complexity and field, they could be added with other specific project instruments and techniques. Therefore, the combination of documents, instruments and techniques used by any project manager or project management team for each project, is unique and the way they are used to protect the non registered intellectual property are case by case situations. On the other side, any public funded projects (and not only), have specific compulsory documents requested by the funding authority. They are important resources of describing the work and the ideas arising in a project during its implementation. Moreover, those documents need specific annexes, that could also be excellent resources to express ideas, information and data to certify who own them and when they were arisen.

This is a way a project manager or a project management team will make aware the team members of the fact that she/he knows and have noted all the ideas and information arose during the project. Therefore, as the project we choose to study was a public funded one, the team decided to rely only on the working documents the funding authority have requested them.

At this point, we have to add that, even the ideas could not be protected as such, we have found that there is a method (which is not yet available in all the countries), to officially ensure a certain date for it. This means that for important ideas, a project manager or a project's organization could fill a written description of the idea in order to secretly submit it to be kept at the national patent office. This will ensure a certain date and will establish a certain owner for an idea.

Moreover, some projects could imply visitors, or project team members having access to some prototypes, demonstrations, working flows or other processes. Assisting viewing and

understanding the way those processes are working could be valuable know-how and a project manager could be interested to keep it secret. Therefore, in such cases, one of the most used common practices is to require those persons to sign an invention assignment agreement on their arrival or on the moment they will start having access to the process [8].

The third problem we faced was related to the way a project team could write and publish intermediary or final project results. For a public funded project, the main such kind of publications could be:

- paper articles;
- reports to funding authority;
- patents filling or invention disclosure;
- internal documents.

A private funded project could add licensing or invention marketing documents.

Paper articles are covered by the copyright. But, the copyright does not cover the ideas expressed in those articles [15]. It is covering only the way of their expression. Therefore, once an article is published, if there are no other means to protect the ideas expressed there, anyone could apply those ideas without any cost.

On the other hand, the copyright owner could be the funding authority or the project organization and not the authors. Moreover, even the ideas (procedures, products, processes, etc.) expressed in an article, could belong to the funding authority or to the project's organization.

And, quite often, the funding authority or the project's organization, intends to publish a "success" but to keep secret the real way it was acquired. Moreover, the funding authority or the project's organization could be more interested in acknowledging the possible use and the best applications of those ideas, instead of the scientific information behind them [18].

In these cases, project managers and project management teams should be quite careful what they are publishing and be sure that the final form of the paper has been approved by the rights holder. In those moments the project management team and all the experts in the project team have an important role in keeping the real valuable know-how "in house". In other cases, some articles could be published only after the funding authority or the project's organization has previously protected the valuable ideas expressed there. In those cases, the project manager or the project management team have to take into account the gap between an article is submitted and the moment it is published [8].

The way someone could protect such ideas is different from country to country, ranging from the patent filling, to patent disclosure or to ensure a certain date for them. For the project we have studied, the project team of the Bucharest University was scientifically responsible for publishing an article for the entire consortium. This decision was taken because it has the major scientific contribution and knowledge to integrate all the information and studies provided by all the consortium members. The team is also intending to publish the article only after the valuable information contained in it has established the owner and the certain date. It will be done by submitting at the patent office of an "ideas envelope" that is going to be kept in secret and to certify the owner and the certain date.

On the other side, the team decided to focus mainly on the results and to describe in general the scientific methods they have developed and used to obtain them, in order to keep secret the know-how behind those results.

Not the last, the project team will offer the final form of the article to the partners, in order to approve or modify it.

As regarding the reports to the funding authority, this is also a case of the right owner. Therefore, if all the rights belong to the funding authority, those reports should cover all the ideas the project has produced (excepting those ideas or know-how that the team members

brought into the project from previous activities or projects). In the case were not all the rights belong to the funding authority, depending of those rights, the project manager and the project management team could take them into account only after they have the approval of the rights owner ad declaring their source.

In the project we have studied, the reports to the funding authority were made by the project coordinator based on the individual reports of each partner. Therefore, each partner and each project manager could report only the information regarding to their team.

Regarding the patents, depending on the project agreements, some project team members could be allowed to become patent authors. Sometimes, it would be advisable to submit a patent application at the time the paper article or the report to the funding authority is made [8]. This is a method of protecting the scientific information included in those documents while waiting the acceptance of the scientific paper or the approval of the report. Therefore, using a registered intellectual property component, someone could protect information contained in non-registered intellectual property components.

An interesting aspect regarding the information contained in patent documents is the fact that they are revealing only the scientific or the technical parts of an invention [8]. The information regarding the potential applications of the invention could merely be found in paper articles or in reports. Therefore, someone wishing to publish such articles should carefully choose this kind of information to disclose.

In the project we have studied, the project team was intended to apply for a patent based on an algorithm of estimating the cell methylom stability, in diverse ambient conditions, associated with specific health conditions (associated with the aging, with the cancer, with the reproduction defects and rare diseases). The information and the know-how implied by the patent are coming not only from the present project, but also from other projects, carried out in different structures and partnerships. Therefore, the algorithm that representing the object for the patent, is based on diverse intellectual property rights, owned by different people, obtained in different moments and with the help of different other resources.

We found that, in this case, the traceability of the intellectual property rights that contribute to the algorithm, is not respected because different results that were used for obtaining the final form have uncertain sources, some of them being free of use (those provided from the public projects), and the others having no contractual rules established between different right owners. Therefore, these are some reasons the team could not apply for a patent to protect the algorithm they developed.

Regarding the internal documents, apart from the “official” ones, there are individual notes, drawings and other papers that are difficult to control. Therefore, even if the “official” internal documents of a project are parts in a well organized and protected information flow, to keep all the information confidential “rely on a culture of trust, not a culture of secrecy” [8]. This is more a problem of team building, of people quality, of people motivation and perspectives than a problem of secured databases, information control, agreements and any other kind of restriction.

In the project we have studied, the team took the decision to keep all this kind of technical and scientific documents only for the project manager and those 5 molecular genetics specialists.

The fourth problem we faced was related to trade secrets. Sometimes, trade secrets are complementary forms of protecting an invention, instead of filling a patent application or any other kind of registered intellectual property components. The information or the knowledge that someone intends to protect as trade secret should be kept secret, and must also to confer an “advantage over competitors who do not know or use it” [10]. Therefore, the main difference in protecting the knowledge or information as a trade secret in comparison with a

patent or other kind of registered intellectual property components, is related to the fact that the protection of a trade secret does not require a detailed public description as it is required in patent documents or other kind of registered intellectual property components documentation. In such a situation, for a project management team, the main issue is to ensure the fact that the sensible information or knowledge is kept secret after the project is finalized and any team member would work in other different positions.

In those cases, the project manager could propose an addition to the confidentiality agreement, stating the secret or the secrets the team, or the individual members of the team, got in touch with, and clearly explain the rights those people have regarding this information or knowledge.

This is especially interesting because a trade secret has no time limitation as the patents or any other kind of registered intellectual property components.

In the project we have studied, the team decided to keep secret some valuable information regarding the project and to fill a written description of them in order to secretly submit it to be kept at the national patent office. This will ensure a certain date and will establish certain owners for this information.

Conclusions

The paper was intended to find out how an average project management team could successfully manage the common non-registered intellectual property issues, without any specialized help. This is much more important as the actual biotechnology includes more than genetic information along with the epi-genetic information in order to explain the multiple functions of a gene.

In its first part, the paper, tries to review the main literature regarding the subject and to clarify some important aspects regarding the non-registered intellectual property used in a biotechnology project.

In its second part, the paper is considering a biotechnology project in order to reveal the main issues regarding the non-registered intellectual property components that the team has met during the project's implementation. In the same time, the paper is presenting the chosen solutions that the team has considered for the presented biotechnology project, along with the arguments they are based of and with the alternatives found in the specialized literature.

Therefore, one of the conclusions we draw out is that a project management team has an important role in managing non-registered intellectual property issues in a biotechnology project.

The second conclusion we found could be expressed in the following sentence: more and more the project manager, the project management team and the entire project team, need "an awareness of basic IP management best practices" in order to "understand and identify potential IP issues" [8].

Moreover, as the project management intellectual property field is still at the beginning, much more its application in the field of biotechnology is requesting at least a basic sample approach of its specific elements that subsequently will provide valuable project management instrument to be applied by different biotechnology project management teams in certain situations.

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