



UNIVERSITY OF MEDICINE AND PHARMACY
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INTELLECTUAL PROPERTY POLICY WITHIN THE
UNIVERSITY OF MEDICINE AND PHARMACY
CAROL DAVILA FROM BUCHAREST

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Introduction

This document establishes the Intellectual Property (IP) policy of the University of Medicine and Pharmacy of Bucharest - UMFCO in the field of intellectual property protection and management at the UMFCO level and is addressed to all UMFCO employees, associated staff and students.

The purpose of intellectual property policy is to stimulate the creation of a favorable framework for:

- identifying, evaluating, protecting, managing and commercializing IP from UMFCO, while guaranteeing academic freedom regarding the protection and respect for the moral rights of staff and students, including in the case of interactions between students, academic/research staff and external partners interested in various collaborations;
- promoting an entrepreneurial culture at UMFCO level and stimulating students, academic/research staff to get involved in research activities, and the new knowledge acquired can be used in future educational and research activities, respectively to be capitalized on through publications, collaborations, licenses and the formation of spin-off/start-up companies;
- ensuring that the interests and needs of UMFCO and external partners are addressed in a consistent and balanced manner;
- ensuring that the results of UMFCO activities are, to the greatest extent possible, disseminated and exploited efficiently for the benefit of the socio-economic environment and society in general, both at national and international level in order to achieve UMFCO's entrepreneurial mission, defined by its capacity to generate value for society.

1. PRINCIPLES OF DOMESTIC INTELLECTUAL PROPERTY POLICY

The Code of Good Practice is based on three important sets of principles:

- **The principles of internal intellectual property policy** (hereinafter referred to as "IP") constitute the set of basic principles that public research organizations should apply to effectively manage intellectual property issues resulting from their own or collaborative research and development activities.
- **The principles of the Technology and Knowledge Transfer policy** (hereinafter referred to as "TT") complement the principles of the intellectual property policy and deal in more detail with the transfer and effective exploitation of intellectual property, whether or not it is protected by intellectual property rights.
- **Principles of collaborative and contract research** applicable to all types of research activities, carried out or funded jointly by a public research organisation and the private sector, including, in particular, collaborative research (where all parties carry out research tasks) and contract research (where the research activity is subcontracted by a private company to a public research organisation).



Thus, the University of Medicine and Pharmacy of Bucharest (UMFCD) must represent:

1. UMFCD, an environment open to collaboration with industry ¹:

- 1.1. research activities carried out within UMFCD, including industry-funded research, aim at the free exchange of ideas and the dissemination of research results in informal meetings, as well as the impact at the beneficiary level;
- 1.2. The UMFCD must impose the necessary measures, appropriate rules, to ensure that commercial pressures from industry do not hinder communication regarding the progress of research or the conclusions of its results;
- 1.3. UMFCD encourages financial interest from the economic operator that provides funding for the research activity, if it presents this interest and if it converges with that of UMFCD.

2. UMFCD, a stimulating framework for the publication and dissemination of research, development and innovation (RDI) results:

- 2.1. the freedom to publish and disseminate the results of RDI activity represents an important criterion in carrying out a research/educational project, an opportunity in transferring knowledge to industry and society;
- 2.2. the freedom (right) to publish the results of RDI activities does not also represent the obligation of the staff employed within UMFCD to publish, outside of internal norms approved at UMFCD level;
- 2.3. each employee of UMFCD, by signing the individual employment contract (IEC), accepts the Intellectual Property policy and is obliged to exercise self-discipline and critical analysis in the use, expansion and transmission of knowledge acquired within UMFCD, from a scientific point of view;
- 2.4. depending on the internal regulations of the UMFCD, it reserves the right to make the final decision on the results that can be published or on what can be published;
- 2.5. The Intellectual Property Commission (UMFCD), following the analysis of opportunities to capitalize on the results of R&D activities, may request a short delay (approximately between 30-90 calendar days) of publication, in order to analyze and review the content of the presentation of the results in the form of an article, to ensure that no information related to intellectual property or that may be the source of a potential patentable invention is disclosed;
- 2.6. involving UMFCD staff in professional activities outside the organization, with the responsibility of each employee, to ensure that such activities do not interfere with the fulfillment of tasks within the organization, but especially with the policy on service inventions and other intellectual property rights, but with the presentation of an annual

¹ We understand by industry the ecosystem formed by the national, public and private healthcare system, the industry producing devices, equipment, substances, medical consumables and the pharmaceutical industry, public and private.



report on them;

UMFCD, a code of conduct for researchers and teachers:

- 2.7. teaching staff and senior researchers encourage a conducive and open environment for research and educational activities at UMFCD, in accordance with the research and educational standards accepted at the organization level;
- 2.8. senior faculty and researchers act with respect and understanding and assume the role of advisor and mentor for newer colleagues in the organization and make reasonable efforts to promote honest academic behavior, which reflects the merits and contribution of each UMFCD employee;

3. UMFCD, a permissive framework for staff engaged in collaboration with the environment business:

- 3.1. UMFCD employees can be involved in RDI activities at the request and with the support of industry/business environment, based on research contracts financed from public funds, in which the ownership of the results belongs proportionally to the participants;
- 3.2. employees can be involved in research contracts supported by companies, with the latter retaining ownership of the research results;

UMFCD, a code of professional ethics and avoidance of conflict of interest:

- 3.3. UMFCD employees must avoid conflicts of interest, respecting the confidentiality of the activity carried out, the rights, but also the duties within UMFCD;
- 3.4. The management of UMFCD, through internal rules, is the guarantor of compliance with the framework for avoiding conflicts of interest with an emphasis on the integrity of the staff, without introducing, unjustifiably, restrictive provisions, but must create the administrative framework for consultation, so that an employee of UMFCD can consult on a certain situation possibly interpreted as a conflict of interest;
- 3.5. The organizational structures within UMFCD cannot engage in activities that may place them in a possible conflict of interest with the official obligations or activities of UMFCD.

UMFCD, a code for copyright:

- 3.6. the copyright for scientific or artistic works that are prepared through independent academic effort, without using resources or IPR belonging to UMFCD or not being part of an inventive mission on the part of UMFCD, belong to the author;
- 3.7. UMFCD employees, as well as other persons using UMFCD funds or other resources/logistics, must adhere to UMFCD's policy regarding intellectual property policy;
- 3.8. the copyright arising within UMFCD, as a result of the work of paid staff or through the use of its resources, belongs to UMFCD;



- 3.9. The copyright that results from a project/financing contract with an economic operator belongs to the UMFCFCD or the economic operator, as provided for in the financing agreement.

UMFCFCD, a code for service inventions:

- 3.10. UMFCFCD recognizes the need to encourage the practical application of research results to ensure public benefit;
- 3.11. UMFCFCD is developing an active program to identify and patent inventions with potential use and to license or sell them to companies that have the capacity to develop, produce and market them;
- 3.12. UMFCFCD employees must present all potentially patentable inventions conceived or developed while under employment contract, which are related to the field of activity in which they work, for which reason all employees, as well as other persons using UMFCFCD funds or facilities, must sign agreements adhering to the organization's intellectual property policy;
- 3.13. UMFCFCD, through its own regulations, also manages those inventions that resulted from consulting activities, without the use of UMFCFCD funds or facilities;
- 3.14. UMFCFCD aims to ensure a balance between several objectives: 1) facilitating the prompt and efficient development of industrially applicable inventions; 2) maintaining good relations with industry, for better use of research opportunities; 3) obtaining adequate income for UMFCFCD from the valorization of IPR;
- 3.15. The IP policy provides:
- 3.15.1. mandatory information to CTT-UMFCFCD regarding inventions with patent potential;
 - 3.15.2. assignment of rights for inventions made during the period of employment or use of research funds or facilities;
 - 3.15.3. exchange of rights with inventors;
 - 3.15.4. capitalizing on IPR to industry for the public benefit;
- 3.16. The UMFCFCD policy regarding the licensing and use of technologies resulting from research activity must pursue the following objectives:
- 3.16.1. establishing a mechanism for the diffusion and dissemination of research and technological development results for the benefit of society;
 - 3.16.2. establishing a mechanism for commercializing research results and establishing the terms of negotiation, in financial terms, for economic operators;
- 3.17. the terms and conditions for licensing agreements must take into account the nature of the technology, the stage of development of the invention, the effect on priority research



areas for UMFCF, the social and market impact, the payment of royalties, etc., without interfering with the principle of dissemination of research results;

3.18. the UMFCF internal regulations specify the regime of tangible assets, which may result from research activities; these may confer a commercial advantage to the research result both through use as demonstrators and through the possibility of granting commercialization rights, as well as other intangible assets;

3.19. UMFCF may allow agreements to be concluded for the commercialization of research results as long as there are no restrictions on the publication and dissemination of research results, in which case the necessary steps will be taken to protect them, when possible.

2. COVERAGE OF THE INTELLECTUAL PROPERTY POLICY IN UMFCF

According to the World Intellectual Property Organization ², the term intellectual property (IP) refers to "creations of the mind: inventions (patents), literary and artistic works, symbols, names, images, designs, used in commercial activities. Intellectual property is divided into two main categories:

1. Industrial property, which includes patents, trademarks and geographical indications, industrial designs and topographies for semiconductor products;
2. Copyright, which includes scientific, literary and artistic works, such as scientific works, novels, poems, plays, games, films, musical works, websites, paintings, photographs, sculptures, architectural designs, etc.

The IP policy refers to the results generated within the UMFCF, which can be:

- Patentable inventions;
- Intellectual creations (which include scientific literature and software programs);
- Databases.

The most well-known types of protection, and hence intellectual property rights (IPR), associated with these results are: patents, copyrights, database rights and confidential knowledge. IPR also covers designs, trademarks, performers' rights, geographical indications and other rights. Multiple forms of intellectual property (IP) can apply to a single creation - for example, software can sometimes be protected by both patents and copyrights.

Ways to protect IP:

- Patents and utility models: cover inventions that are new, inventive and have practical applications. It is a form of protection that is obtained on the basis of an application in

² Brochure What is Intellectual Property? World Intellectual Property Organization, page 2,
http://www.osim.ro/publicatii/editura/Brosuri/04_Ce%20este%20proprietatea%20intelectuala.pdf



accordance with the legislation in force, namely: Law no. 64/1991, Law no. 83/2014 on service inventions, Law 350/2007 on utility models;

- Confidential know-how: covers unpublished confidential information, trade secrets, processes, methods, skills, hereinafter referred to as non-patentable materials and physical materials with innovative and commercial potential. These do not require an application, but require careful management and have an unlimited maximum duration.
- Copyright: covers literary, dramatic, musical, artistic works and software; it is an automatic right that does not require an application and has a maximum duration of 70 years from the death of the author (depending on case law), according to Law no. 8/1996 on Copyright;
- Copyright and database rights: in the European Union, database protection is covered by Directive 96/9/EC . The "sui generis" right has a more limited lifespan, the term of protection being 15 years.

General knowledge and skills that the employee or student possesses and that have not been expressed in writing are not governed by this IP policy.

This policy also refers to physical materials that have been obtained by UMFCDD for use in research, education or the development of new technologies, or that have been produced in whole or in part by using university resources (InnoTher Center for Research and Development of Innovative Therapeutic Structures, Interdisciplinary Center for Research and Development in Dentistry (CICDS), Innovation and e-Health Center, Innovation and e-Health Service, Department of Medical Simulation, 3D Printing Laboratory)

The fact that the IP policy covers all forms of IPR, described above, does not automatically imply that the UMFCDD can formulate a request for full or partial takeover of all IPR.

2.1. Legal framework.

- National Education Law No. 1/2011;
- Law No. 64 of October 11, 1991 on patents, published in the Official Gazette of Romania, Part I, No. 613 of August 19, 2014;
- Law No. 8/1996 on copyright and related rights;
- Law No. 83 of June 24, 2014 on service inventions;
- Law 350/2007 on the utility model;
- Law No. 319 of July 8, 2003 on the Status of Research and Development Personnel;
- Ordinance No. 57 of 16 August 2002 on scientific research and technological development and Law No. 324 of 8 July 2003 approving Government Ordinance No. 57/2002 on scientific research and technological development;
- Government Ordinance No. 66/2000 on the organization and exercise of the profession of



industrial property advisor, republished;

- Government Decision No. 1,188/2022 on the approval of the National Research, Development and Innovation Plan 2022-2027
- Government Decision No. 1.272/2023 on the approval of the National Strategy in the field of intellectual property 2024-2028 and the Action Plan in the field of intellectual property 2024-2028, as well as for the organization and functioning of the Interdepartmental Committee for the coordination of the strategy and policies in the field of intellectual property, of 14.12.2023
- Methodological norms regarding the establishment and development of spin-offs in the field of research, development and innovation, from 16.04.2021
- Regulation implementing Law No. 350/2007 on utility models
- Research-Development-Innovation (RDI) Strategy at UMFC D - 2023-2028
- Regulation on the organization and functioning of CTT_UMFC D

3. APPLICATION OF IP POLICY

The IP Policy applies to UMFC D staff, students, associates, collaborators and other third parties, who represent potential creators of IP in their relationship with the university.

3.1. IP POLICY CONCERNING UMFC D EMPLOYEES

In order to fulfill its entrepreneurial mission and promote social responsibility, UMFC D will own, as a general rule, all IPR and materials produced, with inventive or commercial exploitation potential, that were produced in UMFC D or in UMFC D partnerships, using university resources, unless there are express exemption provisions, specified by law or by an agreement, that oblige UMFC D in this regard.

In special excepted cases, in which UMFC D does not own the rights to the research results, developed with the university's resources, UMFC D will receive, based on a specific agreement, the right to use and continue developing these results, in educational and scientific research activities.

In this context, the UMFC D Technology Transfer Center (CTT-UMFC D) may analyze and submit to the UMFC D management some additional provisions, in consultation with academic staff and students, through their organizations, regarding IPR created by:

- UMFC D staff in connection with their independent activity, during vacation or sabbatical periods;
- employees in part-time positions, or in other independent organizations;
- students working on specific projects, in collaboration with other independent organizations; and
- invited specialists and students on study visits.



3.1.1. Service inventions³

The legal framework ⁴applicable to service inventions is Law No. 83/2014 which was published in the Official Gazette No. 471/2014 and entered into force on 29 June 2014. Law No. 83/2014 applies to inventions, which can be protected by a patent or a registered utility model (art. 1, para. 2).

3.1.1.1. Definitions

- **Innovation** ⁵- the implementation of a new or substantially improved product/technology, service or process, or of a new marketing or business method, in teaching, R&D or application activities, in UMFCD internal flows or external relations.
- **The invention** ⁶is a technical solution or achievement in a field of knowledge specific to UMFCD that presents novelty and progress compared to the state known until then.
- **Innovation** ⁷is a solution to a technological problem or internal flows and processes with the aim of improving performance and technological improvement specific to UMFCD and the industry.
- **A patent** ⁸is an official title of protection for an invention (of a product, process or method), which grants its holder an exclusive right of exploitation, during its validity period.
- **Utility model** ⁹- protects a new technical invention, which goes beyond the level of simple professional skill and which is susceptible of industrial application.
- **Service inventions** ¹⁰- are inventions created by an individual inventor or a group of inventors when the individual inventor or at least one member of the group of inventors is an employee of a legal entity under public law or private law, which can be protected by a patent or registered utility model, and which meet the following conditions:
 - a) resulted from the exercise of the inventor's job duties, expressly entrusted within

³ In developing this chapter, chapter 3 of the Manual of Good Practices for the Application of Legislation on Service Inventions, UEFISCDI, June 2015, <http://uefiscdi.gov.ro/articole/4111/Manual-de-bune-practici-pentru-aplicarea-legislatiei-privind-inventiile-de-serviciu.html>, pages 4-10, which were adapted and corroborated with other legal provisions and with the vision and needs of the University, was used as a starting point.

⁴ Manual of good practices for the application of legislation on service inventions, UEFISCDI, June 2015, <http://uefiscdi.gov.ro/articole/4111/Manual-de-bune-practici-pentru-aplicarea-legislatiei-privind-inventiile-de-serviciu.html>, page 4.

⁵ OG 57/2002 on scientific research and technological development, Annex 1 Definitions

⁶ <https://dexonline.ro/definitie/inven%C8%9Bie>

⁷ <https://dexonline.ro/definitie/inova%C8%9Bie>

⁸ <https://dexonline.ro/definitie/brevet>

⁹ Law 350/2007 on utility models

¹⁰ Law 83/2014 on service inventions



the individual employment contract and in the job description or established by other binding acts for the inventor, which provide for an inventive mission;

b) were obtained, during the duration of the individual employment contract, as well as for a maximum period of 2 years after its termination, as the case may be, through knowledge or use of the employer's experience by using the employer's material means, as a result of the professional training and education acquired by the salaried inventor through the care and at the employer's expense or by using information resulting from the employer's activity or made available by the employer.

- **Employee/Salaried Employee** ¹¹ - any natural person who performs a remunerated activity, under an individual employment contract, for and under the authority of UMFCO.
- **Research and development activity** ¹² includes scientific research, experimental development and innovation based on scientific research and experimental development. Scientific research includes fundamental research and industrial/applied research.
- **The inventive mission** establishes the technological field in which the technical problem or problems fall, for the solution of which the employed inventor has an obligation - contractual or arising from other mandatory acts - to make a creative contribution in accordance with the job duties [L83/2014, art. 3 par. (2)]. The inventive mission refers to the general purpose or objective of the innovation or development process of an invention. It is the initial direction or vision that guides research and development efforts to achieve a certain result or benefit materialized through the invention
- **Inventive activity** refers to the concrete process of generating new ideas and developing innovative solutions that lead to the achievement of the inventive mission. It is the intellectual and technical effort made to find and implement creative and unexpected solutions to the problems or needs identified within the inventive mission. According to the legislation in force [art. 11 of Law no. 64/1991], *an invention is considered to involve an inventive activity if, for a person skilled in the art, it does not obviously result from the knowledge contained in the state of the art . The inventive activity of the invention is assessed in relation to the technical problem that it solves and to the claimed invention taken as a whole, by comparing it with the state of the art* [art. 47 para. (1) of the Implementing Regulation - GD no. 547/2008]. According to art. 47 para. (9) of the Implementing Regulation, **an invention is considered to involve inventive activity if it is, in particular, in one of the following situations :**
 - the non-obvious use of known means for another purpose and with the achievement of new, surprising effects;
 - a new use of a known device or material that overcomes technical difficulties that

¹¹ Law 83/2014 on service inventions

¹² art. 2 para. (1) of Government Ordinance no. 57/2002 on scientific research and technological development, approved with amendments and completions by Law no. 324/2003, with subsequent amendments and completions.



are impossible to overcome in a known way;

- a combination of new or known features designed in such a way that they mutually enhance their effects and a new technical result is obtained;
- a selection, within a process, of those technical parameters within a known range that produce unexpected effects on the process performance or on the properties of the product obtained;
- a selection, within a very large group of known compounds or chemical combinations, of those that present unexpected advantages;
- using the technical means of the claimed invention to solve the technical problem in a way other than that resulting from the prior art documents analyzed by the person skilled in the art

The invention is considered obvious and, therefore, does not involve an inventive step if, starting from one or more characteristics of the state of the art, the use of the general knowledge of the person skilled in the art would have allowed him, at the filing/priority date of the application, to arrive at the claimed invention [art. 47 paragraph (2) of the Implementing Regulation - GD 547/2008]. According to art. 47 paragraph (10) of the Implementing Regulation, **an invention is considered not to involve an inventive step if it is, in particular, in one of the following situations:**

- ❖ the invention represents at least one of the possible solutions, which is obvious to a person skilled in the art, to fill a gap in the state of the art;
- ❖ the invention does not differ from the prior art except by the use of equivalent well-known mechanical, electrical or chemical means;
- ❖ the invention consists only in a new use using the known properties of a known means;
- ❖ the invention consists of a replacement, in a known device, of a material with another material recently discovered and whose properties make it suitable for this use, called analogous replacement;
- ❖ the invention consists only in the use of a known technique in a similar situation, called analogous use;
- ❖ the invention consists in the juxtaposition or association of known devices or processes, each functioning or proceeding in a known manner, without resulting in an interdependence between them;
- ❖ the invention consists only in choosing a solution from a certain number of suitable possibilities;
- ❖ the invention consists in choosing certain dimensions, temperature ranges or parameters from a limited range, which could have been obtained through successive trials or by using known design methods;
- ❖ the invention is obtained only by a simple extrapolation resulting directly from the state of the art.

In order to assess the inventive step, either several documents, or parts of several documents, or different parts of the same document belonging to the state of the art, may be combined in a mosaic system and compared with the claimed invention, provided that this combination is obvious to a



person skilled in the art. The assessment of the inventive step may be carried out by means of a problem-solution approach, taking into account the closest state of the art, in accordance with the provisions of art. 47 para (4)-(6) of the Implementing Regulation - GD 547/2008].

3.1.1.2. Ownership of service inventions

Based on art. 3 and art. 5 of Law 83/2014, the right to the invention belongs to:

(1) UMFCDC, in the following situations:

- the invention is of mission resulting under the conditions stipulated in art. 3, paragraph 1, letter (a);
- the invention is related to the employer resulting from the conditions stipulated in art. 3, paragraph 1, letter (b) and UMFCDC claimed the invention within the legal term.

(2) To the employee (inventor), in the following situations:

- the invention is of mission (inventive) and there is a contractual provision whereby UMFCDC grants the inventor the right to the invention;
- the invention is related to the employer and UMFCDC did not claim the invention within the legal deadline;
- the invention made is not mission-related and is not related to UMFCDC.

3.1.1.3. The rights and obligations of the employee (inventor) and the UMFCDC (employer)

(1) The employee (inventor) has the obligation:

- to immediately notify the UMFCDC Technology Transfer Center at ctt@umfcd.ro regarding each invention through a document presenting the invention in which to describe the solution to the problem solved with sufficiently clear data to define the invention and the conditions under which the invention was created. The presentation of the invention will be made using the presentation form developed and made available by CTT-UMFCDC (Annex 1). The notification obligation also applies to former employees of UMFCDC for a maximum period of 2 years from the termination of the employment contract. In these situations, within a maximum of 4 months from the registration of the notification, CTT-UMFCDC notifies the inventor on the classification of the invention in the category of service inventions and whether UMFCDC will follow all the steps regarding claiming the right to it;
- to provide assistance and collaborate in obtaining protection and exploitation of the invention in all ways requested by UMFCDC representatives through CTT-UMFCDC;
- to inform the employer in writing about an application for a patent or registration of a utility model, in the case of an invention made that is neither of the mission nor related to the employer, (art. 8 para. 4 of Law no. 83/2014);
- not to disclose or publish the invention classified as a service invention, without the written consent of UMFCDC;
- within 2 months from the date of approval of this policy, all UMFCDC employees involved



in research and development activity, as defined in art. 3. letter a) will sign a declaration on their own responsibility regarding the assumption of the confidentiality clause in relation to possible service inventions;

- obtain the UMFCF's opinion on the method of identifying, assigning and exploiting the property right corresponding to the expected results if they intend to conclude external agreements with a third party for the performance of a research and development activity (for example, they intend to obtain funding through research projects carried out in consortium by several legal entities). Obtaining this opinion is done prior to submitting the project/funding application, even if the respective agreement is not requested during the competition phase by the financier.

(2) The employee (inventor) has the right:

- to request assistance from CTT-UMFCF for the detailed presentation of the invention;
- to receive from UMFCF through CTT-UMFCF, within 4 months of notification of CTT-UMFCF regarding the invention, the decision regarding the classification of the invention in the category of service inventions and whether UMFCF claims the right to it;
- to be notified by the UMFCF regarding the progress of the procedures for obtaining protection, after submitting the application for protection for the service invention;
- to be informed by the UMFCF through the CTT-UMFCF of the filing of an application for a patent or for the registration of a utility model;
- to request the right to protection, in the event that UMFCF cedes the right to protection to him, not wishing to continue the procedures subsequent to the submission of the application for protection for the service invention or is not interested in protecting the service invention in certain states, other than Romania, provided that the employee grants UMFCF in this case a non-exclusive license for the patented invention;
- to receive a percentage share of the value of the income generated by UMFCF, following the application of the invention under the conditions of the creation of a service invention provided for in art. 3, para. 1, letter (b)

Once the patent/utility model is obtained, the rights of the employee who is not the patent/utility model holder are as follows:

- the right to have his/her name, surname and capacity mentioned in the act of claiming the service invention that was claimed by UMFCF, and in other acts and publications regarding the invention in question (at the express request of the employee, his/her name and surname are not published);
- the right to issue a duplicate of the invention document;



- the right to be informed by the UMFCF (the applicant for the patent/utility model application) regarding the status of the examination of the patent/utility model application and the status of the application of the invention.

(3) UMFCF (the employer) has the right:

- to be informed by the employee of the existence of the invention and to receive its detailed presentation;
- to analyze the employee's invention and decide whether to classify it in the category of service inventions and regarding the type of service invention, as well as whether to claim ownership of it, in compliance with the deadlines established by law 83/2014;
- to communicate to the employee the decision to classify the invention and the ownership right;
- to request assistance from the employee to obtain protection and exploitation of the invention;
- to file an application for a patent or for the registration of a utility model in Romania and/or in other states, claiming the right of priority in Romania;
- UMFCF, based on an internal report prepared by CTT-UMFCF, has the right to decide whether or not a patent application will be filed for a service invention;
- be the holder of the patent or registered utility model obtained for a service invention.

Once the patent/utility model is obtained, UMFCF has the following rights:

- ownership of the invention;
- the right to prohibit third parties from carrying out the following acts without its authorization:

- for products: manufacturing, marketing, offering for sale, use, import or storage for the purpose of marketing, offering for sale or use;

- for processes or methods: their use.

- the exclusive right to exploit the invention;
- the right to make the invention public.

(4) UMFCF (the employer) has the obligation:

- to provide assistance, through CTT-UMFCF, to the employee for the detailed presentation of the invention;



- to inform the employee about the filing of a patent application or registration of a utility model;
- to provide for the costs necessary to obtain a patent or to register a utility model for the claimed service invention;
- to remunerate the employee - inventor, under the terms of the law;
- to cede to the employee, at his request, the right to obtain protection, in the event that he no longer wishes to continue the procedures subsequent to the filing of the patent application, or is not interested in obtaining protection for the invention in certain states, provided that the employee grants UMFCFCD a non-exclusive license for the patented invention.
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(5).. The situation in which UMFCFCD does not claim the service invention

If UMFCFCD has determined that it will not file a patent application, then inventors may file a patent application in their own name. The non-claim of the service invention by UMFCFCD is subject to the approval of the UMFCFCD IP Committee and the approval of the Senate and an agreement between the inventor and UMFCFCD as follows:

- The inventor shall reimburse UMFCFCD for all legal expenses and fees incurred by UMFCFCD, if and when the inventor(s) receives income from the invention;
- To share with UMFCFCD 20% of the net income (the remaining income after reimbursing the expenses to the university mentioned above);
- To fulfill any obligations towards third parties who contributed to the development of the invention;
- UMFCFCD has the right to use the invention for research, education, clinical purposes and the right to grant such rights to nonprofit institutions, irrevocably in perpetuity, without property rights, non-exclusive, anywhere in the world;
- If the inventor registers patents with holders other than UMFCFCD, it should be noted that these patents were developed following research conducted within UMFCFCD.



3.1.2. Non-patented materials and physical materials¹³

3.1.2.1. Definitions

- The phrase *Unpatented Materials* developed by UMFCDC employees and students refers to unpatentable inventions (within the meaning of art. 8 of law 64/1991), scientific/academic databases or other materials useful for research or commercial purposes, for which patent applications are not filed or, if filed, the patent is not issued, as well as to materials that are developed by UMFCDC employees and students in accordance with the subject matter of an agreement between UMFCDC and a third party; or with the use of direct or indirect financial support from UMFCDC, including support or funding from any external source, public or private, assigned to or administered by UMFCDC; or with the use (other than incidental use) of space, facilities, materials or other resources made available by or through UMFCDC.
- The phrase *Physical materials* produced by UMFCDC employees and students refers to physical materials produced, with potential for commercial exploitation, which incur UMFCDC expenses/investments. Physical materials produced are characterized as any product (organic, inorganic and biological material, biobank-specific products, tissues, organoids, 3D models of these or other parts of the human body), including substances, organisms and cultures, as well as other related materials.
- In accordance with art. 8 of law 64/1991, *a patent is NOT granted for:*
 - a) inventions the commercial exploitation of which is contrary to public order or morality, including those harmful to the health and life of persons, animals or plants, and which are likely to cause serious damage to the environment, provided that this exclusion does not depend solely on the fact that exploitation is prohibited by a legal provision;
 - b) plant varieties and animal breeds, as well as essentially biological processes for obtaining plants or animals. The provision does not apply to microbiological processes and products obtained by such processes;
 - c) inventions having as their object the human body, in the various stages of its formation and development, as well as the simple discovery of one of its elements, including the sequence or partial sequence of a gene;
 - d) methods of treatment of the human or animal body, by surgery or therapy, and methods of diagnosis practiced on the human or animal body. The provision does not apply to products, in particular substances or compositions, for use in any of these methods/'
- *Authors/Co-authors* are the individuals identified by the laboratory director or principal

¹³In developing this chapter, chapter 3 of the Manual of Good Practices for the Application of Legislation on Service Inventions, UEFISCDI, June 2015, <http://uefiscdi.gov.ro/articole/4111/Manual-de-bune-practici-pentru-aplicarea-legislatiei-privind-inventiile-de-serviciu.html>, pages 4-10, which were adapted and corroborated with other legal provisions and with the vision and needs of the University, was used as a starting point.



investigator of a research program, as applicable, as having contributed to the development of the Non-Patented Materials.

3.1.2.2. Ownership rights of non-patented materials and physical materials made within the UMFC D

UMFC D owns all rights to the non-patented materials and physical materials made within the UMFC D and may make appropriate distribution in its or the public interest, including licensing or transferring non-patented materials, for research and commercial purposes. The licensing revenue regime for non-patented materials is presented in section 4.5. of this document.

3.1.3. Copyright of UMFC D employees and students

3.1.3.1. Definitions

The intellectual creation work represents the concrete result of the elaboration of a work that contributes to the transmission and enrichment of a spiritual or scientific heritage. Following a contractual relationship, UMFC D may become the protector of these rights.

Copyright over a literary, artistic or scientific work, as well as over other works of intellectual creation, is recognized and guaranteed under the terms of Law No. 8 of March 14, 1996 on copyright and related rights.

Copyright is linked to the person of the author and encompasses moral and patrimonial attributes, according to the last paragraph of art. 1, para. 1 of Law no. 8/1996.

Law no. 8 of 1996 stipulates in art. 1 paragraph 2 that *"The work of intellectual creation is recognized and protected, independently of being made public, by the simple fact of its creation, even in unfinished form."*, and in art. 3 paragraph 1 defines the author as *"the natural person or natural persons who created the work"* (including edited/translated).

According to art. 12 of Law 8/1996, the author of a work has the exclusive patrimonial right to decide whether, in what way and when his work will be used, including to consent to the use of the work by other authors.

3.1.3.2. The subject matter of copyright

According to art. 7 of law no. 8 of March 14, 1996, the object of copyright is *"original works of intellectual creation in the literary, artistic or scientific field, whatever the method of creation,*



the mode or form of expression and regardless of their value and destination, such as:

- a) *literary and journalistic writings, conferences, sermons, pleadings, lectures and any other written or oral works, as well as computer programs (including software tools) - which will be dealt with in this document in the next chapter;*
- b) *scientific works, written or oral, such as: communications, studies, university courses, school textbooks, scientific projects and documentation;*
- c) *musical compositions with or without lyrics;*
- d) *dramatic works, dramatic-musical works, choreographic works and pantomimes;*
- e) *cinematographic works, as well as any other audiovisual works;*
- f) *photographic works, as well as any other works expressed through a process analogous to photography;*
- g) *graphic or plastic works of art, such as: works of sculpture, painting, graphics, engraving, lithography, monumental art, scenography, tapestry, ceramics, glass and metal plastics, drawings, design, as well as works of art applied to products intended for practical use;*
- h) *architectural works, including plans, models and graphic works that form architectural projects;*
- i) *"plastic works, maps and drawings in the field of topography, geography and science in general."*

3.1.3.3.Limits to the exercise of copyright

Art. 33 paragraph 1 of Law No. 8 of March 14, 1996 stipulates that *"the following uses of a work previously made public are permitted, without the consent of the author and without payment of any remuneration, provided that they comply with good practices, do not conflict with the normal exploitation of the work and do not prejudice the author or the holders of the rights of use:*

- a) *reproduction of a work in the framework of judicial, parliamentary or administrative proceedings or for public safety purposes;*
- b) *the use of short quotations from a work, for the purpose of analysis, commentary or criticism or by way of example, to the extent that their use justifies the length of the quotation;*
- c) *the use of isolated articles or short extracts from works in publications, in radio or television broadcasts or in sound or audiovisual recordings, intended exclusively for education, as well as the reproduction for education purposes, within educational or social welfare institutions, of isolated articles or short extracts from works, to the extent justified by the purpose pursued;*



- d) *reproduction for information and research of short extracts from works, within libraries, museums, film libraries, sound libraries, archives of public cultural or scientific institutions, which operate without a profit-making purpose; the full reproduction of a copy of a work is permitted, for its replacement, in the event of destruction, serious damage or loss of the unique copy from the permanent collection of the respective library or archive;*
- e) *specific reproductions made by publicly accessible libraries, educational institutions or museums or by archives, which are not made for the purpose of obtaining a commercial or economic advantage, directly or indirectly;*
- f) *the reproduction, excluding any means that come into direct contact with the work, the distribution or communication to the public of the image of a work of architecture, plastic art, photography or applied art, permanently placed in public places, except in cases where the image of the work is the main subject of such reproduction, distribution or communication and if it is used for commercial purposes;*
- g) *the representation and performance of a work within the activities of educational institutions, exclusively for specific purposes and provided that both the representation or performance and public access are free of charge;*
- h) *the use, for advertising purposes, of images of works presented in exhibitions with public access or for sale, fairs, public auctions of works of art, as a means of promoting the event, excluding any commercial use;*
- i) *the use of short demonstrations of computer programs/software tools for educational/didactic purposes."*

3.1.3.4.Ownership of intellectual creations

Copyright, which includes the moral and patrimonial attribute over a work of intellectual creation, belongs exclusively to the author, and in accordance with art. 11 paragraph (1), moral rights cannot be subject to any waiver or alienation.

In accordance with art. 39. par. 1, the author or copyright holder may assign only his patrimonial rights to other persons by contract. The assignment of copyright patrimonial rights is regulated in *Chapter VII - Assignment of copyright patrimonial rights* of Law No. 8 of 1996.

Subject to the exceptions set forth in the subsection below, authors own the copyright *and* may retain any income derived therefrom in books, films, videotapes, works of art, musical works and materials and other copyrighted works of any nature or similar, and in any format, except for computer software which is subject to section 3.1.4. of this policy.

3.1.3.5.Exceptions

- Whenever research activity is linked to or subject to an agreement between UMFCDC and a



third party that contains obligations or restrictions regarding copyright or the use of copyrighted materials, these are dealt with in accordance with the inter-institutional agreement. In negotiating with third parties, Principal Investigators, project directors and UMFCDC should strive to protect and promote the interest of UMFCDC, both for individual copyright holders and for UMFCDC consistent with the public interest and this policy.

- UMFCDC may acquire, at any time, copyright over the materials through agreements with the author(s) or other rights holders under the terms of the agreement.

3.1.4. Copyright for computer programs (*Computer software*) of UMFCDC employees and students

For the purposes of Law 8 of 1996, computer program means *any expression of a program, application programs and operating systems, expressed in any language, whether in source code or object code, preparatory design material, as well as manuals.*

According to art. 72 par. 2 of the law *"Ideas, processes, operating methods, mathematical concepts and principles underlying any element of a computer program, including those underlying its interfaces, are not protected."*

In Romania, computer programs are considered works of intellectual creation and fall under the scope of the Copyright law. According to art. 74 of the law, *"in the absence of a contrary clause, the copyright on computer programs, created by one or more employees in the exercise of their duties or following the instructions of the employer, belong to the latter."*

In accordance with art. 75. paragraph 1, in the absence of a contrary clause, a contract for the use of a computer program shall be presumed to:

- a) the user is granted the non-exclusive right to use the computer program;
- b) the user may not transfer the right to use the computer program to another person.

3.2. PI POLICY REGARDING UMFCDC STUDENTS

Students enrolled in study programs (bachelor, master, doctoral) and students on study visits, unless otherwise agreed, are the owners of all IPR and related related rights, which they create as part of their studies/study period at UMFCDC. Section 6 describes in detail the situations of ownership of IP created at UMFCDC.

The agreements concluded between UMFCDC and students enrolled in study programs (bachelor's, master's, doctoral), respectively students on study visits, must provide for the protection of the university's right to use generated IPR, exclusively and free of charge for educational and research purposes.



In cases where IPRs are jointly generated by one or more *students and employees* of UMFCFCD and are protected by a form of co-ownership, UMFCFCD will, in all circumstances, have the right to take over the IPRs of UMFCFCD employees under that co-ownership, in accordance with the legislation in force and the concluded employment contracts.

IPRs that are created by students when they have employee status, for example in a position on a project team or as a research assistant / post-doctoral student, such IPRs are considered to be created by their own employees and are subject to Law 83/2014.

If students (usually master's and doctoral students) generate IP during their participation in study programs or research activities, they will own IPR on the results obtained, except in cases where one of the following situations applies:

- (i) The generated IP is subject to contractual terms or an agreement concluded with an organization independent of UMFCFCD, through which the IP is empowered with rights in relation to UMFCFCD or a third party; or
- (ii) The generated IP is based on previous IP elements developed by UMFCFCD employees, or by its "associates"; or
- (iii) generates IP in collaboration with UMFCFCD employees, or its "associates"; or
- (iv) students are or have the status of employees of UMFCFCD (in which case they are treated by UMFCFCD and by law as employees).

In all the circumstances listed above, students will be required to assign the IPR to UMFCFCD, and with respect to the income generated by that IP, the student will have the same rights as UMFCFCD employees.

Students may own ownership of independently obtained new and original knowledge exclusively subject to the following conditions:

- There must be written approval from UMFCFCD that the students are the sole Authors/Inventors;
- There must be confirmation from UMFCFCD that UMFCFCD resources have not constituted a significant part in the development of new and original knowledge;
- There are no funding agreements that require the assignment of IPR.

At the request of the students, UMFCFCD may, through CTT-UMFCFCD, take over the IPR and contribute to the commercial exploitation of the results obtained in their activity. In connection with such a voluntary transfer of IPR, for their commercial exploitation and the distribution of the royalties obtained, the entire process is governed by a separate agreement, concluded between the students and UMFCFCD, with the support of CTT-UMFCFCD.

3.3. PI POLICY REGARDING ASSOCIATED UMFCFCD STAFF



Individuals who are affiliated with UMFCDD activities, but who are neither employees nor students, but are considered in *the category of associated staff* (e.g.: laureates (DHC, scientific awards, etc.), principal investigators in research (for whom UMFCDD offers internships), professors / visiting researchers), may be required to assign IPRs they create during their activity to UMFCDD. In this regard, UMFCDD may have obligations towards the organizations that fund the respective research activities, which it will not be able to honor without such an assignment of rights.

Associates are considered employees of UMFCDD for the purposes of IPR and fall under the scope of Law No. 83 of 24 June 2014 on service inventions. For visiting professors, who remain employees of another organization while carrying out their research activity at UMFCDD - e.g., see the case of projects to attract specialists from abroad), special arrangements will be required regarding the ownership and use of IP that they may generate during their internship at UMFCDD. Such arrangements will be negotiated on a case-by-case basis, generally with the employer of the "associated" person. Any person who falls into such a category should contact CTT-UMFCDD for legal advice and solutions, before the actual start of the internship at UMFCDD.

3.4. NOTIFICATION REQUIREMENT

UMFCDD employees must notify through CTT-UMFCDD all results obtained and all physical materials produced with inventive or commercial exploitation potential.

The notification requirement does not apply to traditional academic content (scientific monographs), works of art and materials for exclusively didactic use.

3.5. THE IP PROTECTION AND MANAGEMENT STRUCTURE AT UMFCDD CONSISTS OF:

3.5.1. UMFCDD Intellectual Property Committee . The UMFCDD IP Commission validates the classification of patents, validates the calculation of the NPV (Negotiation Starting Value) and approves the type of exploitation.

3.5.2. Technology Transfer Center (CTT-UMFCDD) CTT-UMFCDD is responsible for promoting, developing and improving the quality of IP protection tools and Technology and Knowledge Transfer activities within the university. CTT-UMFCDD activities in this area include:

- Assessing the commercial potential of IPR resulting from research and development activities;
- Support and consultancy provided for the protection and commercialization of IPR;
- Support and consultancy provided for the preparation of strategies and business plans, justifying the creation of Spin-Off/Out and Start-up companies in UMFCDD; and
- Identifying and managing IPR resulting from research activities, also providing



UNIVERSITY OF MEDICINE AND PHARMACY
" CAROL DAVILA" from BUCHAREST
Technology Transfer Center



37 Dionisie Lupu Street, Sector 2, Bucharest, 020021 Romania, www.umfcd.ro, email: rectorat@umfcd.ro

advice/continuing professional training services, for the development of entrepreneurial skills of the research community and students of UMFC D .

CTT UMFC D has the role of contributing to the achievement by UMFC D of its strategic objectives included in its mission, on the innovation and entrepreneurial component, with an emphasis on knowledge transfer and commercialization of innovative technologies. This structure, with its components, provides professional services and is concerned with the implementation and improvement of the university's IP policy.

This structure also provides assistance to UMFC D staff in the commercialization of innovative ideas and research results that UMFC D holds in accordance with national legislation or through an agreement by which UMFC D has received a specific authorization to manage certain IPRs. In a professional manner, this structure evaluates the commercialization opportunities for all innovative ideas (results of projects and other work carried out in UMFC D) and inventions that have been notified, in advance, to this structure.

If this structure does not identify a commercialization opportunity, for the initiation of a dedicated IPR exploitation project or for the continuation of a CDI project, based on the notification received from UMFC D employees, they will have the right to commercialize the technologies/research results, duly protected by IPR, on their own account, in accordance with the procedures in the *IP exploitation Guide* in force at that time, and in accordance with the specific terms agreed upon between the parties. These terms will be included in an agreement that will protect, among other things, the investments that have already been made in the development of that technology/research result, until the date of conclusion of that agreement.

If the notified inventions or other research results are to be further developed by UMFC D through "proof-of-concept" mechanisms or by other means, the further development will be governed by the contract concluded between UMFC D (with the support of CTT-UMFC D), a UMFC D commercialization company (e.g. UMFC D Innovation SA) and, if applicable, the external party(ies) involved.

In its activities, CTT-UMFC D is supported by representatives designated by faculties/departments, who have the mission to identify research results and IPRs achieved/in progress at the level of departments/faculties, to analyze them from the perspective of the need for their protection in relation to their commercialization potential. Also within CTT-UMFC D, Marketing and Commercialization activities will be carried out to identify potential clients for taking over research results and their preparations for commercialization.

The final results of the CTT-UMFC D analyses, carried out in collaboration with representatives of the departments/faculties, are transmitted to the UMFC D Intellectual Property Commission for validation and then submitted to the UMFC D Board of Directors, which decides on the commercialization and conclusion of agreements/contracts with interested companies. CTT-UMFC D carries out all commercialization efforts after the approval of the UMFC D Board of Directors.



4. ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS (IPR)

In order to fulfill its entrepreneurial mission, UMFCDC is committed to encouraging the valorization/commercialization or valorization of IP. If UMFCDC believes that there is commercialization potential, it will request, as appropriate, IP protection through patenting or other legal means, with financial support from its own funds, respectively, it will identify and negotiate potential commercial technology transfer partnerships through the UMFCDC CTT. In this regard, the UMFCDC CTT will ensure adequate IPR protection and all legal arrangements for licensing and/or the formation of start-up/spin-off companies. After the successful commercialization of IP owned by UMFCDC and the generation of a revenue stream, an *Inventors' Reward Scheme will be applied*, which provides that the persons involved in the creation of the commercialized IP will be eligible to be awarded a negotiable but significant share of the net revenues generated.

CTT-UMFCDC will provide professional advice on various commercialization and knowledge transfer options to meet the objectives of the UMFCDC intellectual property policy, including:

- Licensing the use of IPR to a third party;
- Assignment of IPR to a third party;
- Capitalizing on the commercial potential of IPR through a Spin-Off or Start-Up company;
- Capitalizing on the commercial potential of the IPR with a third party through Technology Transfer and/or any other legal arrangement that may be considered appropriate, based on the IPR held by UMFCDC.

The analysis of the commercialization potential of a patent application / IPR will be carried out at the CTT-UMFCDC level by the innovation manager . The result of this analysis containing the CTT-UMFCDC proposals will be submitted to the IP Commission of the UMFCDC and subject to approval by the CA and the Senate of the UMFCDC, after which the CTT UMFCDC will proceed to the operationalization of the capitalization decision. The CTT-UMFCDC will ensure, accordingly, that all documents regarding the commercialization of IPR explicitly stipulate the retention of the right of use and free access to the commercialized IPR, for the purpose of continuing the research and educational activities of the UMFCDC.

In the case of commercialization of IPRs in co-ownership with a third party organization, the terms regarding their protection will be regulated by drawing up and signing a specific collaboration agreement for research activities in partnership, research activities that may involve the transfer of technology and knowledge from UMFCDC to the partner, the partnership agreement being accompanied by the technology transfer contract.

4.1. Definitions

- **Licensing** - the process of granting the right to use intellectual property assets to a third party.



- **License** - the authorization that the owner of intellectual property rights grants to a third party to use them.
- **Licensor** - the owner of the property right or, as the case may be, his agent.
- **Licensee** - the natural or legal person who purchases the license.
- **Royalties**¹⁴ - payments of any kind received as a consideration for the use of, or the right to use, any copyright of literary, artistic or scientific work, including cinematographic films and computer programs, any patent, trade mark, design or model, plan, secret formula or process, or for information concerning industrial, commercial or scientific experience; payments for the use of, or the right to use, industrial, commercial or scientific equipment. In addition, royalties include any amount paid in cash or in kind for the right to record or transmit in any form shows, broadcasts, sporting events or other similar activities;
- **The term for first commercialization of the product** is the time required for the buyer/licensor to make the first sales on the market of the product that was the subject of the licensing.
- **spin-off** - economic operator with legal personality, established in the form of commercial companies (Law 31/1991), whose activity is oriented towards the valorization of the results of research and development activities obtained by the research organization's staff. *The spin-off enterprise is established on the basis of a result obtained in UMFCD. The project director is the UMFCD employee, who participated in obtaining the results on which the new project proposed by the spin-off is based.* This enterprise will finance projects that provide a researcher (or a group of researchers) with the opportunity to leave UMFCD, where he developed a research project and obtained a result, in order to continue the researched solution within his own company until its completion, in order to produce and commercialize the results on the market. The researcher is not obliged to leave UMFCD. *UMFCD may participate as an associate in a spin-off through direct financial contribution or by equating intellectual property elements as a capital contribution.*
- **services provided by the research organization** - all services provided for a fee to the spin-off by the research organization or by persons designated by it, which arise from the knowledge, technologies or results of the research and development activity belonging to the research organization.
- **start-up** - economic operator with legal personality, established in the form of commercial companies (Law 31/1991), whose activity is oriented towards innovation through R&D projects carried out individually or in partnership with UMFCD, for the purpose of innovating processes and products in industry sectors¹⁵ that present growth potential and is based on the transfer of research and development results obtained in UMFCD or on patented ideas, in order to create new

¹⁴Fiscal Code, art 257.

https://static.anaf.ro/static/10/Anaf71legislatie/Cod_fiscal_norme_09022017.htm#A257

¹⁵ We understand by industry the ecosystem formed by the national, public and private healthcare system, the industry producing devices, equipment, substances, medical consumables and the pharmaceutical industry, public and private.



or significantly improved products and services to launch on the market.

4.2. Analysis of the innovation manager within CTT UMFCD regarding determining the opportunity to capitalize on IP for commercialization.

This analysis will conduct a formal process of verifying the pre-existing legal, financial, and operational situation before commencing the actual commercialization or transfer of UMFCD IPR, in order to reduce the risk of non-compliance with the terms and conditions of a third party (e.g., a R&D funding organization, a partner in the project that generated the IP, etc.) and identify other potential obligations to those third parties. There are two types of IP that are subject to analysis:

- **The IP** (idea with potential for invention, patented or not) **is of interest for commercialization**. CTT UMFCD will pursue the steps to obtain the patent and/or commercialize the IPR through the most appropriate method established during the analysis process: IPR licensing (generally a patentable or patented invention to a company or licensing to a CTT UMFCD strat-up). The following are the steps to be taken for commercialization of IPR on CTT UMFCD's IP.
- **The IP** (idea with potential for invention, patented invention or not) **is not of interest to be exploited through commercialization** by CTT UMFCD. In this case, the inventors of CTT UMFCD may request the assignment of IP, after receiving information from CTT UMFCD, after completing all the analysis stages of the exploitation process.

At the same time, to start this process, inventors must complete a form Annex 2, which requires them to explicitly specify the following:

- Who are the researchers from CTT UMFCD and the external collaborators who contributed to the invention;
- What were the sources of funding for the research projects that led to the invention;
- What were the materials, obtained from sources independent of CTT UMFCD, that were used to generate that invention;
- What computer programs, obtained from sources independent of CTT UMFCD, were used to generate the respective invention;
- What other contractual arrangements were involved to generate that invention.

Based on this information, CTT-UMFCD will then verify the financing conditions and any other agreements related to the IP and propose solutions to resolve any issues that may arise from that analysis.

The analysis-diagnostic document will contain at least:

- comparative analysis of the type of IP exploitation (licensing, spin-off, start-up, others),
- recommendation on how to capitalize
- the proposal for distribution of income generated from the commercialization of IPR.

The document will be endorsed by the UMFCD IP Committee and submitted to the approval of the UMFCD Board of Directors and Senate, after which the UMFCD CTT will proceed to operationalize the capitalization decision.



4.3. The licensing process is

In the case of a licensing decision, the Licensing Terms (licensing contract) proposed by CTT UMFCFCD will be validated by the IP Commission of UMFCFCD and submitted to the approval of the CA and the Senate of UMFCFCD. CTT UMFCFCD operates according to a series of fundamental principles: predictability, fairness, transparency towards patent authors regarding the status of the licensing process and professional communication in relations with third parties.

Licensing involves a contract with rights and obligations by which the parties are legally bound - including respect for the intellectual property of the licensor, in this case UMFCFCD.

4.3.1. Financial conditions regarding licensing

The standard licensing method agreed by UMFCFCD is to request the licensee to pay a lump sum upon signing the licensing agreement and pay an annual royalty expressed as a percentage of sales for a minimum of **5 years**, starting with the first year of marketing the product. The term of first marketing of the product cannot exceed **2 years from the date of signing the licensing agreement**. In case of exceeding this term, the licensing agreement is renegotiated.

The minimum lump sum accepted by the UMFCFCD must cover the amount of emergency patenting expenses and the costs of maintaining protection for a period of at least 5 years from the grant of the patent.

The amount of annual royalties represents on average **5% of the sales generated by the application of the license that is the subject of the licensing and cannot be less than 2%**. This amount will be established depending on the stage of industrialization of the patented technology, the existence of a quantifiable market for the product to be created as a result of the use of the licensed technology, the existence of several companies willing to acquire the license for the existing patent, etc.

4.3.2. Licensing exceptions

4.3.2.1. If the patent is in the patentability examination stage (patent pending) and the buyer/licensee provides (at his own expense) a detailed business plan covering a period of at least 5 years, respectively an investment to bring the patent to a commercial stage within 2 years from the date of signing the license agreement, or presents a solid financial investment proposal for the experimental development phase of the product/technology in UMFCFCD, the amount of annual royalties may be set at a minimum threshold of 1%.

4.3.2.2. For service inventions for which UMFCFCD has decided not to file a patent application, the exploitation conditions will be negotiated on a case-by-case basis.

4.3.2.3. The assignment of intellectual property, which CTT UMFCFCD has decided not to commercialize to inventors is a process by which inventors in CTT UMFCFCD request the assignment of IPR over an IP, which is not subject to a commercialization decision according to 4.3.2.2. In this case, CTT-UMFCFCD will formally notify the inventor(s) by e-mail of the decision



to abandon commercialization and, upon receipt of this message, the inventor(s) may request that that IP be assigned to him/her, also in writing, in response to the e-mail received. This email correspondence will be subject to a legality and opportunity analysis at the CTT UMFCO level, meaning that any co-owner or financier of those IPRs will also be notified/consulted on the CTT UMFCO decision, in the sense of formulating an option to attempt to commercialize them, by assigning those IPRs, and in case of refusal they may be offered to the inventor(s). Before being assigned those IPRs, inventors will be asked to present their reasons for wanting to be assigned the IP in question and may be asked to demonstrate their reasonable ability to commercialize those IPRs.

Two legal instruments will be defined that regulate the transfer of IP to the inventor:

- The assignment agreement and
- Agreement to distribute a share of the revenues generated through marketing to CTT UMFCO.

Inventors who take ownership of those IPRs are no longer eligible to receive a share of the revenue stream that CTT UMFCO may accrue from commercialization.

Upon award of such IPRs, the inventor(s) will be solely responsible for commercializing the associated IP and for meeting the deadlines for filing patent applications and associated costs. In this situation, it should be noted that such IPRs are awarded in a personal capacity and that activities related to such IPRs are subject to the CTT UMFCO conflict of interest policy and require completion of the annual declaration of interests.

4.4 . Establishment of Spin-Off or Start-Up companies

It is a form of IPR valorization and UMFCO encourages academic/research staff and students, where applicable, to consider commercializing IPR by forming a company specifically created for this purpose, taking into account the two legal forms **Spin-off** (*where UMFCO is associated in the company to be established according to the Methodological Norms regarding the establishment and development of spin-offs in the field of research, development and innovation, of 16.04.2021, part of Order 28/07.05.2021*) and **Innovative Start-up** (*where UMFCO is not associated but the start-up's activity is oriented towards innovation through R&D projects carried out individually or in partnership with UMFCO, for the purpose of innovating processes and products in industry sectors¹⁶ that have growth potential and is based on the transfer of research and development results obtained in UMFCO or on patented ideas, in order to create new or significantly improved products and services to launch on the market*).

Through this form of exploitation of IPR, UMFCO provides a researcher (or a group of researchers) with the opportunity to leave UMFCO, where they developed a research project and

¹⁶ We understand by industry the ecosystem formed by the national, public and private healthcare system, the industry producing devices, equipment, substances, medical consumables and the pharmaceutical industry, public and private.



obtained a result, in order to continue the researched solution within their own company until its completion, in order to produce and commercialize the results on the market.

CTT-UMFCD provides free consultancy for the establishment and administrative management of these companies by promoters - researchers within UMFCD and they must make a request to CTT-UMFCD which must include:

- complete list of IPR belonging to UMFCD that is proposed to be used by the respective newly established company, which can be :
 - a patent
 - patent application
 - doctoral thesis (of the project director – the initiator of the spin-off/start-up)
 - The rights to use the research results in the project for the case of research, carried out in the public institution where the spin-off initiator comes from and financed through a public program (the spin-off initiator was the project director)
- innovative business proposal, based on advanced technologies, or a document regarding an innovative business strategy, developed by the promoters;
- Business plan
- Documents proving that the newly established company has a space in which to carry out its activity - it can be a rental contract or a lease with UMFCD;
- Certificate from the institution – the project director is an employee of a public research organization
- list of founding members of the newly established company and how they will be involved/employed;
- Proposal for Association Agreement/Technology Transfer Agreement/IPR License Agreement with UMFCD, as applicable;

4.5. Utilization of non-patented materials.

UMFCD owns all rights to the unpatented materials and physical materials made under UMFCD and may make appropriate distribution in its or the public interest, including licensing or transferring unpatented materials, for research and commercial purposes.

Physical materials produced within UMFCD are characterized as any product (organic, inorganic and biological material, biobank-specific products, tissues, organoids, 3D models thereof or of other parts of the human body), including substances, organisms and cultures, as well as other related materials, with potential for commercial exploitation. They are the university's expense/investment and are the property of UMFCD, as long as this does not infringe, either now



or in the future, the rights of third parties, being created or produced with university resources or, by other means, being acquired or related to the activities carried out in UMFCD.

Academic staff from UMFCD may transfer physical materials held or available to the university to third parties, under the following conditions:

- Before transfer/shipment, a special agreement ("Material Transfer Agreement - MTA" will be concluded);
- part of the material must remain in the UMFCD, i.e. the resource must not be exhausted, normally;
- The transferee must not transmit the material to other interested parties without the prior written consent of the UMFCD Intellectual Property Committee;

Non-patented or physical materials developed within the UMFCD will be provided for research purposes only and not for commercial use. In this regard, the transfer recipients will make a declaration on their own responsibility that the material will be used only in compliance with the ethical principles in scientific research activities in force at the UMFCD.

5. DISTRIBUTION OF REVENUES FROM THE MARKETING OF IPR

5.1. Inventors' Reward Scheme

In order to streamline the IPR valorization activity, the Technology Transfer Development Fund is being established.

The distribution of income obtained through licensing is as follows:

5.1.1. In the case of patented or patent pending service inventions

5.1.1.1. *The lump sum obtained upon conclusion of the licensing agreement belongs entirely to CTT-UMFCD and is intended to support patenting costs.*

5.1.1.2. *The annual royalties resulting from the commercialization/licensing of service inventions made by UMFCD employees are distributed as follows:*

- *50% for the research team that made the invention. By way of example but not limitation, the research team may use the funds for internal research projects, awarding inventors under the terms of the law, co-financing projects of the research team that made the invention, etc. The research team will inform CTT-UMFCD in writing on how it intends to use these funds;*
- *10% for the Inventor's Department;*
- *40% for the Technology Transfer Development Fund - managed by CTT-UMFCD and at the disposal of the Vice-Rector responsible for Scientific Research.*

If there are multiple inventors of a single invention, the shares will be allocated according to the number of inventors, in accordance with their written agreement or, if there is no agreement, then equal shares. The research team and department share will be divided equally if the inventors are from different research teams/departments, regardless of the number of inventors from each research team/department, unless otherwise agreed by the inventors.

5.1.2. In the case of service inventions provided for in art. 3 paragraph 1 letter b) of Law 83/2014



, claimed by UMFCF, the amounts are divided as follows:

5.1.2.1.30% for former employee inventors;

5.1.2.2.30% for the research team that made the invention. By way of example but not limitation, the research team may use the funds for internal research projects, awarding inventors under the terms of the law, co-financing projects of the research team that made the invention, etc. The research team will inform CTT-UMFCF in writing on how it intends to use these funds;

5.1.2.3.10% for the Inventor's Department;

5.1.2.4.30% for the Technology Transfer Development Fund - managed by CTT-UMFCF and at the disposal of the Vice-Rector responsible for Scientific Research.

If there are multiple inventors of a single invention, the shares will be allocated according to the number of inventors, in accordance with their written agreement or, if there is no agreement, then equal shares. The research team and department share will be divided equally if the inventors are from different research teams/departments, regardless of the number of inventors from each research team/department, unless otherwise agreed by the inventors.

5.1.3. In the case of non-patented materials or physical materials

The amounts obtained from the commercialization of non-patented materials or physical materials are distributed as follows:

5.1.3.1. 50% for the research team that created the materials. By way of example but not limitation, the research team may use the funds for internal research projects, awarding inventors under the law, co-financing projects of the research team that created the invention, etc. The research team will inform CTT-UMFCF in writing on how it intends to use these funds;

5.1.3.2. 10% for the inventor's Department;

5.1.3.3. 40% for the Technology Transfer Development Fund - managed by CTT-UMFCF and at the disposal of the Vice-Rector responsible for Scientific Research.

If there are multiple inventors of a single invention, the shares will be allocated according to the number of inventors, in accordance with their written agreement or, if there is no agreement, then equal shares. The research team and department share will be divided equally if the inventors are from different research teams/departments, regardless of the number of inventors from each research team/department, unless otherwise agreed by the inventors.

6. CONFLICT RESOLUTION

6.1.CTT-UMFCF is responsible for the implementation of intellectual property policy in UMFCF.

6.2.UMFCF is committed to resolving conflicts internally and amicably. Members of the academic/research community and students of UMFCF may appeal decisions of the CTT-UMFCF, regarding the application of the intellectual property policy, to the UMFCF



Intellectual Property Commission, and its decisions may, in turn, be further appealed to the UMFC D Rector.

7. REVIEW OF INTELLECTUAL PROPERTY POLICY

The UMFC D Intellectual Property Policy will be reviewed by the CTT-UMFC D at least once every five years, and more often if necessary, to determine its effectiveness and to identify and implement necessary changes, if necessary.

Changes to the intellectual property policy must be approved by the UMFC D Board of Directors. All changes to the intellectual property policy will be posted on the UMFC D website and such changes will become applicable and effective from the date of publication.



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