

Intellectual property rights and university –born inventions

Life science Inventions at the University of Helsinki

Patentit – Teollisuus – Tekniikka 2014–2015

Project study

Sara Kangaspeska

Helsinki Innovation Services Ltd

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Tiivistelmä

Helsingin Yliopiston lääke- ja biotieteiden tutkimus (eng. life science) johtaa monien kymmenien uusien keksintöjen syntymiseen vuosittain. Helsingin Yliopiston keksintötietokantaa hyödyntäen tämä erikoistyö kartoittaa life science –alan keksintöjen tyyppejä ja alkuperää, sekä immateriaalioikeuksien merkitystä niiden kaupallistamisessa. Kerätty aineisto osoittaa, että hyvinkin erityyppisille keksinnöille voidaan hakea patenttisuojaa, joka usein on perusedellytys keksinnön kaupalliselle hyödyntämiselle. Tällaisiin keksintöihin lukeutuvat esim. diagnostiset ja terapeuttiset laitteet ja valmisteet. Verrattain suuren osan yliopistosyntyisistä keksinnöistä lohkaisevat kuitenkin sellaiset innovaatiot, kuten uudet tutkimusmenetelmät, joiden kaupallistamiseen patenttisuojaa ei välttämättä tarvitse hakea. Lääke- ja biotieteiden tutkimus on yksi Helsingin Yliopiston painopiste- ja vahvuusalueista. Tältä tutkimusalalta syntyvien uusien innovaatioiden merkitystä paitsi suomalaisen tieteen, myös koko suomalaisen talouden ja yhteiskunnan edistämiseksi on viime vuosina enenevässä määrin painotettu. Tämän työn tarkoitus onkin omalta osaltaan edistää tämän tavoitteen saavuttamista.

Abstract

Life science research at the University of Helsinki gives rise to several dozen inventions yearly, covering a wide variety of subjects and invention types. In this work, using the invention disclosure database of the university as the main source of material, these inventions as well as the role of intellectual property rights in protection and downstream commercialization of them was studied. The data demonstrates that patent applications are filed for numerous types of inventions, ranging from medical treatments and diagnostics to devices and computer methods. IP protection is often a necessity for successful commercialization of the inventions. However, some invention types such as research tools and methods, that are typical for university-born inventions, do not necessarily require patent protection for commercialization. Life science research is a focus area for the university, and generally of excellent academic quality. Additionally, increasing commercialization efforts of the inventions from life science is considered important on the national level not just in promoting Finnish science and scientists, but the economy and society as a whole. The purpose of this work is to add to this effort by providing a snapshot to the life science inventions born at the University of Helsinki.

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1 Introduction: University – derived inventions

Universities and other higher education institutions in Finland conduct research in a wide variety of academic fields and bear educational responsibility. They thereby contribute to the development of science and expansion of knowledge in the society. Whereas the inventions made by an employee at an employer's service are governed by the Act on the Right in Employee Inventions (656/1967), university-derived inventions are under a different legislation; the Act on the Right in Inventions made at Higher Education Institutions (369/2006, Appendix 1). The Act, by the Finnish Ministry of Trade and Industry, has been effective since the beginning of 2007, and its purpose is to promote the recognition, protection and exploitation of inventions made at Finnish higher education institutions. The Act defines, among other things, the ownership of the invention, and how it depends on the source of funding under which the invention has been made. Specifically, the rights to an invention under open research, i.e. without claims to IP rights or without outside funding, belong to the inventors, whereas the rights to an invention under collaborative research (or contract research), i.e. with outside funding, belong to the university. Outside funding is considered to be, for example, funding or grants from the most common Finnish research funding agencies, such as the Academy of Finland and Tekes, and also EU funding. However, regardless of the type of funding used, the ownership can also be transferred (from the university to the inventors, or vice versa) if so wished. Until 2007, the rights to all university-derived inventions resided with the inventors, and hence, the new legislation is effective since ca eight years at the moment.

Universities and other higher education institutions have been established to conduct the uppermost level of research and to offer the highest level of education available in the society. Traditionally, universities have been considered to have three missions: research, teaching and contribution to the

society. Whereas the first two form the core of the activities carried out at the universities, the importance of the third has been recently emphasized and encouraged, both nationally and internationally. Harvesting the inventions made at the universities and promoting them, for example through commercialization, aims at fulfilling, at least partly, this third mission.

1.1 Innovation services at the University of Helsinki

Every Finnish university is required to have a technology transfer unit or equivalent, responsible for transferring university-originating knowhow, methods, technologies, tools and methods to third parties such as other institutions, governments or enterprises. The very purpose of the technology transfer activities is to enable further development and exploitation of these scientific and technological assets for the benefit of society, i.e. to serve the universities' third mission. Since March 2011, the University of Helsinki (UH) has arranged its technology transfer activities through Helsinki Innovation Services Ltd, HIS (Helsingin Innovaatiopalvelut Oy). HIS is fully owned by the University of Helsinki Funds. HIS has been operational since the beginning of 2012, and thus, the data and results presented in this study cover the time period 01.01.2012-29.05.2015.

The core activities of HIS cover processing and evaluation of the invention disclosures filed by the employees of the University of Helsinki, as well as possible patent protection and downstream commercialization of the inventions (Figure 1). Moreover, HIS works closely with the Section for Research Affairs at UH that provides the researchers with funding and legal services. More detailed information on the organization and activities of HIS can be found at www.his.fi.

Invention disclosure process

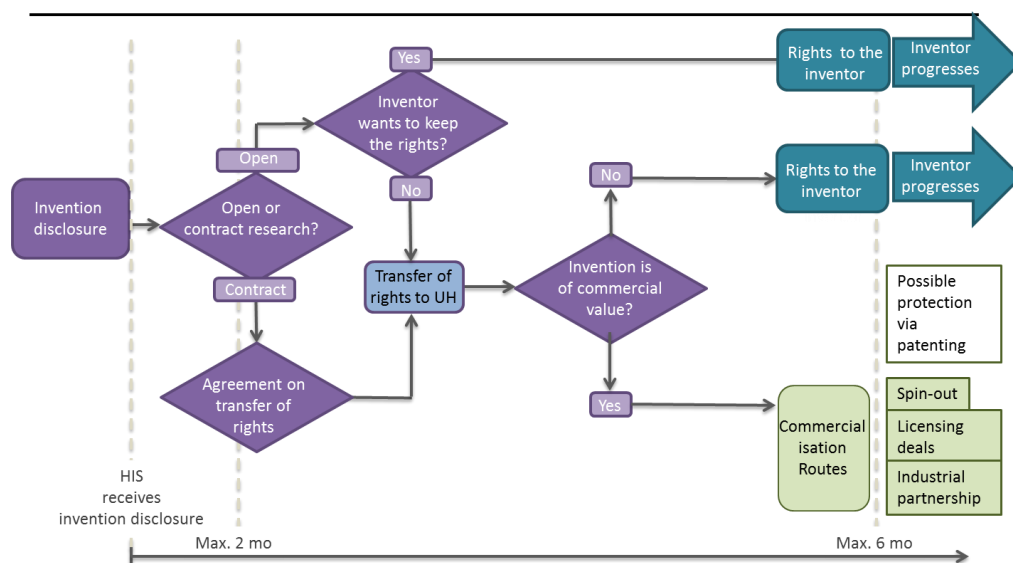


Figure 1. The invention disclosure evaluation process and downstream commercialization routes at the University of Helsinki, guided by the Act on the Right in Inventions made at Higher Education Institutions.

1.2 Life science inventions

Life science is a broad concept concerning the study and science of all living organisms such as plants, microorganisms, animals and humans. At the University of Helsinki, life science research is carried out mainly at two campuses, Meilahti and Viikki, and correspondingly, most of the life science inventions originate from these two campuses. The Meilahti campus harbors all medical research, whereas veterinary medicine, biological, environmental, pharmaceutical, as well as agricultural and forestry research is carried out at the Viikki campus. The life science research at UH is considered to be at a high international level (Tieteen tila 2014: Lääke- ja terveystieteet, published by the Academy of Finland 27.10.2014), with some key areas repeatedly being highly ranked in international evaluations. Of the Finnish universities, UH is the only one ranked in the top 100 (76th in the world in 2013, published in Academic Ranking of World Universities by Shanghai Jiao Tong University). Hence, it is nationally and internationally well-recognized that life science research at UH is at an academically high level, and is thus also one of the key focus areas of UH. Good quality basic research is also a key requirement for development of good quality, commercially viable inventions. The technology transfer of the university plays a key role in

encouraging and guiding the development of these inventions, their identification, protection through intellectual property rights and downstream commercialization.

1.2.1 Intellectual property rights in commercialization of life science inventions

Intellectual property rights (IP, IPR) are divided into copyrights and industrial rights, under which patent, utility model, trademark, and industrial design rights, among others, are classified. However, in this study, by IP rights, merely patent rights are meant. This has its grounds in the practical every day utilization of the different types of IPR for the life science inventions at UH. In practice, patent rights are predominantly applied for university-derived life science inventions, and in fact, the material used for this study contained no other type of IP rights besides patent rights.

University-derived life science inventions arise from different scientific fields, and cover a broad range of invention types. Patent protection can be sought (in the EU) for products (for example chemical entities, biologics, DNA/RNA/protein sequences), devices, methods, or uses (first and second pharmaceutical use). In contrast, diagnostic, surgical or therapeutic procedures performed on a person or an animal; cloning and commercial use of human embryos; genetic engineering of human germ cells; or genetic engineering of animals if painful without considerable medical benefit to humans or animals do not constitute patentable IP. Even though pharmaceuticals form only one type of life science inventions arising from the research carried out at UH, they do represent a special class because of the long, risky and costly development process. It is estimated that only one out of 10 000 screened potential pharmaceutical molecules makes it to the market in a process that on average takes 10-13 years from discovery to the pharmacy. Additionally, demonstration of safety and toxicity for obtaining regulatory approval is needed, which is a long and expensive process. Marketing and pricing of new pharmaceuticals is also tightly regulated, with manufacturers of generic compounds gaining more and more market space at the cost of original producers who have invested heavily in the development process. Therefore, for pharmaceuticals, in addition to the regular patent protection time of 20 years, a supplementary protection certificate of

maximally 5 years (for pharmaceuticals aimed for children 5,5 years) can be sought. Even though the actual pharmaceutical development does not take place at an academic institute such as UH, it does affect the inventions arising from this area at the institute and consequently influences the IP filed for them.

Apart from the above-mentioned tedious and expensive development process of new pharmaceuticals, there is one even more defining factor for this type of inventions that are university-derived, and that is the early stage of development. The inventions on potential new medicines that arise from university research are typically based on biology-driven academic observations, which are still a long way from the market, and do not match the needs of the pharmaceutical industry that is usually looking for new chemical entities rather than biological observations. This phenomenon is also referred to as the development gap or the valley of death. Additional experimental work to obtain proof-of-concept is often needed before a patent filing can take place, within either the university setting or elsewhere. Nevertheless, obtaining or at least filing for patent protection is often crucial (once that necessary supporting data is generated), in order to enable successful commercialization of the invention, whether it is via out-licensing, industrial collaboration or creation of a university spin-out company.

For commercialization of some life science inventions no IP rights are needed. Research tools and methods that are one of the most common types of university-born life science inventions can often be out-licensed to a commercial partner without accompanying IP. Examples include cell lines, antibodies and research methodologies. In some cases the invention is better kept as a trade secret or protected via a trademark; examples include treatment concepts and service packages. Bioinformatic methods such as algorithms and computer programs are automatically protected by copyright and can only be patent protected under certain circumstances. The algorithm or computer program needs to be part of a method or a device, (or a method is directed via a computer program, or parts of a device are directed via a computer program), the program has to be technical in nature and it has to have a technical effect. Consequently, for many cases involving algorithms and alike, it is decided that they will also be kept as trade secret upon which a university-originating spin-out company might be founded.

In summary, the inventions arising from life sciences, one of the focus areas of the University of Helsinki and areas of international expertise within Finland, cover a broad field of subjects and types of inventions. For some of them, patent protection is sought in order to enable downstream commercialization. The purpose of this work is to provide an overview of the life science inventions arising from UH and the role of IPR in commercialization of them, and thereby enable better utilization of this resource for the benefit of the inventors, the university, and Finnish science and society as a whole.

2 Aims and methods

Academic research gives rise to groundbreaking scientific discoveries, but also to inventions and innovations that are potentially commercially exploitable, and the importance of these is steadily rising. As life science is a strong focus area of the University of Helsinki, there is a need for better understanding of the types of inventions arising from this field as well as their downstream commercialization. For commercialization, IPR rights play a crucial role. Therefore, the aims of the present work were many fold:

- 1) To create an overview of the life science inventions arising from academic research within the University of Helsinki
- 2) To look at the fields of science that generate life science inventions, and what types of inventions they are
- 3) To investigate the role of IPR in the downstream commercialization of these inventions

The invention disclosure database Sophia Knowledge Management System (Wellspring Worldwide Inc.) and other material provided by Helsinki Innovation Services and the University of Helsinki, have been used as the source of this work. Additionally, personal communication with the employees of HIS, the Section for Research Affairs at UH, and the researchers, has been most valuable. Due to the confidential nature of the inventions, the source material is presented in an anonymous fashion. As to the interpretation of the results, the expressed opinions are those of the writer.

3 Results and discussion

3.1 Invention disclosures

The principal tool for researchers reporting inventions to the university is filing an invention disclosure. The law governing university-derived inventions was renewed in 2006 (effective since beginning of 2007; Act on the Right in Inventions made at Higher Education Institutions (309/2006) Appendix 1), which makes notification of inventions obligatory. Since then, the amount of invention disclosures at the University of Helsinki has varied depending on the year, the average number being 55 across the years 2007-2014 (Figure 2). It has to be noted, that a competitive call for filing invention disclosures was arranged in 2009, which probably accounts for the larger number of inventions reported that year. It is also noteworthy that the statistics for 2015 only cover the first half of the year (until 29.05.2015). However, based on the numbers until then and assuming no decline in the filing activity, it seems that the number of invention disclosures might exceed those from previous years. Not included in the statistics are the unofficial requests to evaluate research ideas and preliminary inventions. There are several dozen such requests per year that are received and processed.

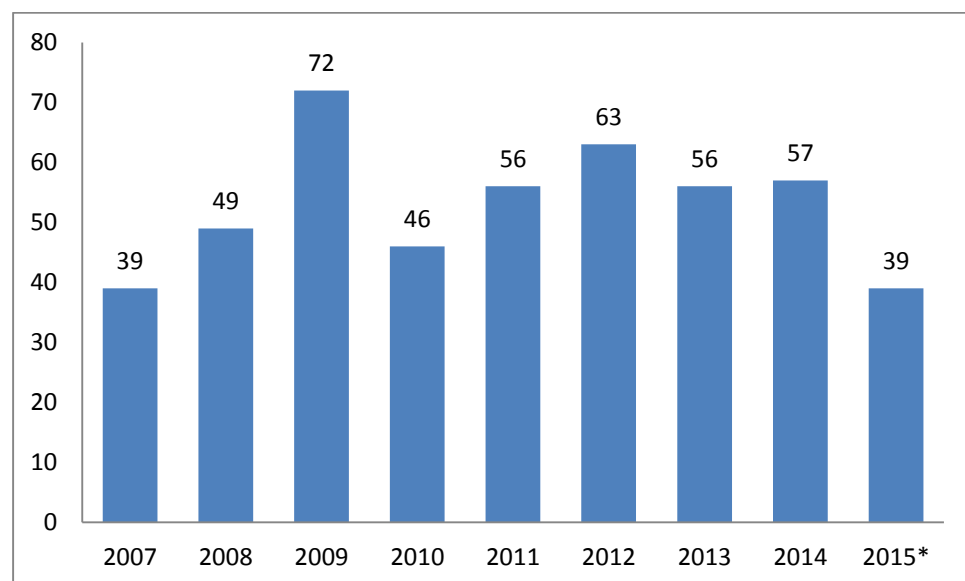


Figure 2. Total number of invention disclosures from the University of Helsinki.
* denotes invention disclosures until 29.05.2015.

Increasing awareness among the researchers on invention related matters is key in growing the number of invention disclosures. For this, a variety of means ranging from personal meetings with key researchers and principal investigators, talks at department seminars and educational events, and providing services on the internet has been used. Even though it is important to increase the number of invention disclosures, it should not be at the cost of the quality. Additionally, support and encouragement of the university leadership is essential in reinforcing the importance of inventions among the researchers. To this end, the invention guidelines of the University of Helsinki have been recently renewed, principles of commercialization of UH-originating inventions have been created and an innovation committee has been formed at UH.

3.2 Life science inventions

At the University of Helsinki life science research is mainly conducted on the Meilahti and Viikki campuses that currently have a staff of approximately 1800 and 1600 researchers, respectively. Both campuses combined, there are ca 25-35 invention disclosures reported yearly from the life sciences (Figure 3), which represents 40-61% of all invention disclosures filed at the university (Figure 4). Thus, life science represents a key area of research at UH not just in terms of academic excellence but also when it comes to research-based inventions.

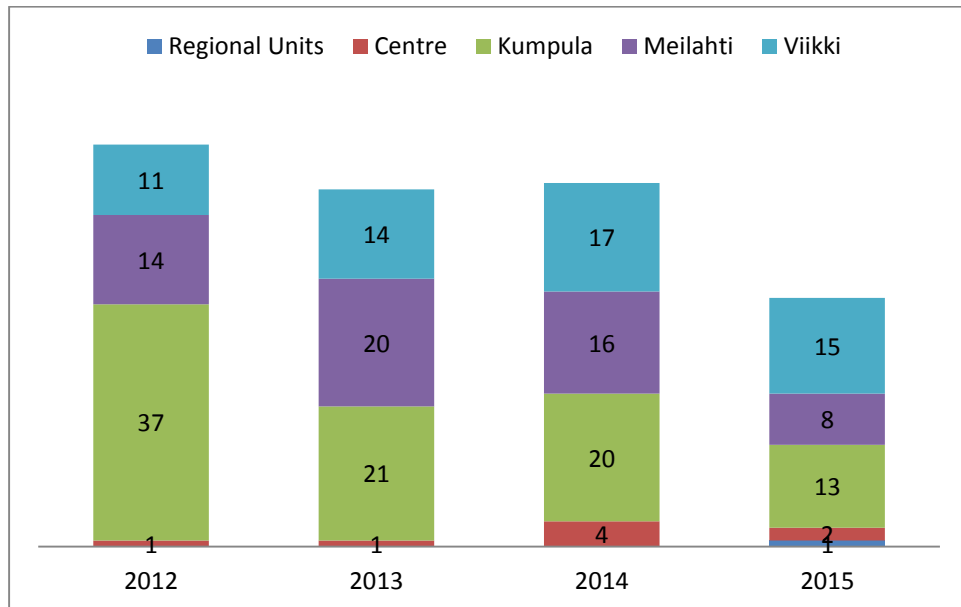


Figure 3. Invention disclosures by campus. The majority of biomedical and medical (i.e. life science) inventions arise from the Meilahti and Viikki campuses. From this point on, including the above Figure 3, all graphs are based on inventions dating from 01.01.2012-29.05.2015 unless otherwise stated.

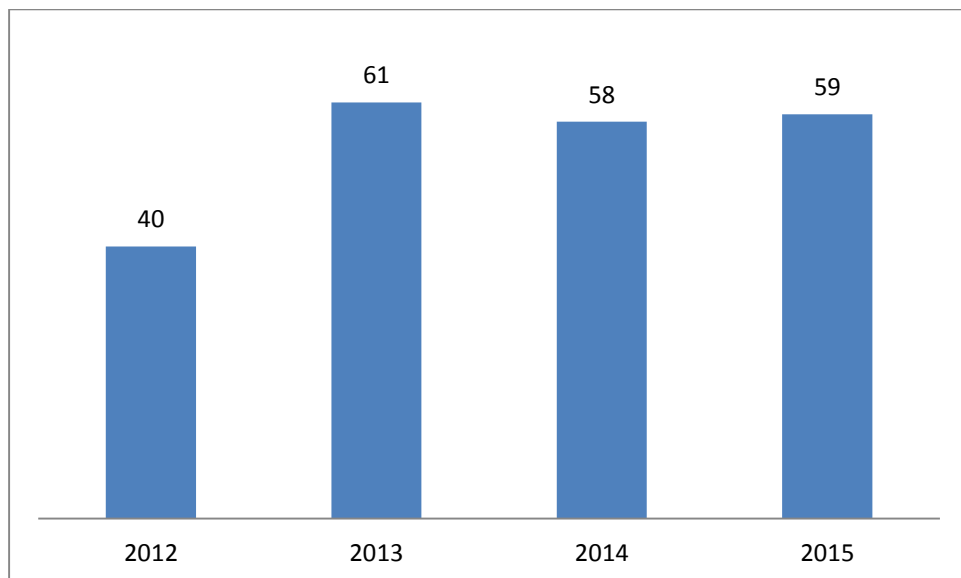


Figure 4. Percentage of life science inventions.

In order to create an overview of the life science inventions, they were classified according to the field of science as well as type of invention. Several scientific fields yielding at least ten inventions within the studied time period were identified. These include biomedicine, chemistry, neurology, oncology and pathology, accounting for 18, 24, 14, 10 and 12 inventions respectively (Figure 5). In general, life science research at the University of Helsinki comprises a large variety of subjects and is somewhat dispersed,

which is also reflected in the diversity of fields that invention disclosures are filed from. On the other hand, other factors such as tradition and urge to concentrate on academic achievements rather than commercially exploitable innovations or how applied the particular field of science is, might also affect the number of invention disclosures filed from a certain field.

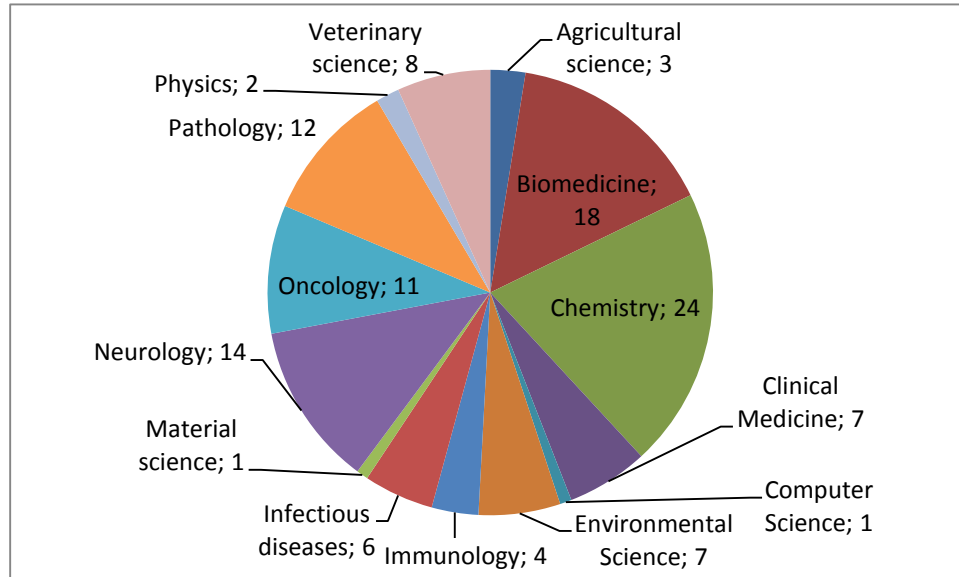


Figure 5. Life science inventions by field of science.

When categorized according to the type, the life science inventions can be separated into 13 different classes, medical treatment (33), diagnostics (19), and physical device (17) accounting for the largest ones (Figure 6). The groups research method and research tool, which together account for 20 inventions, also comprise a relatively large proportion of all the inventions.

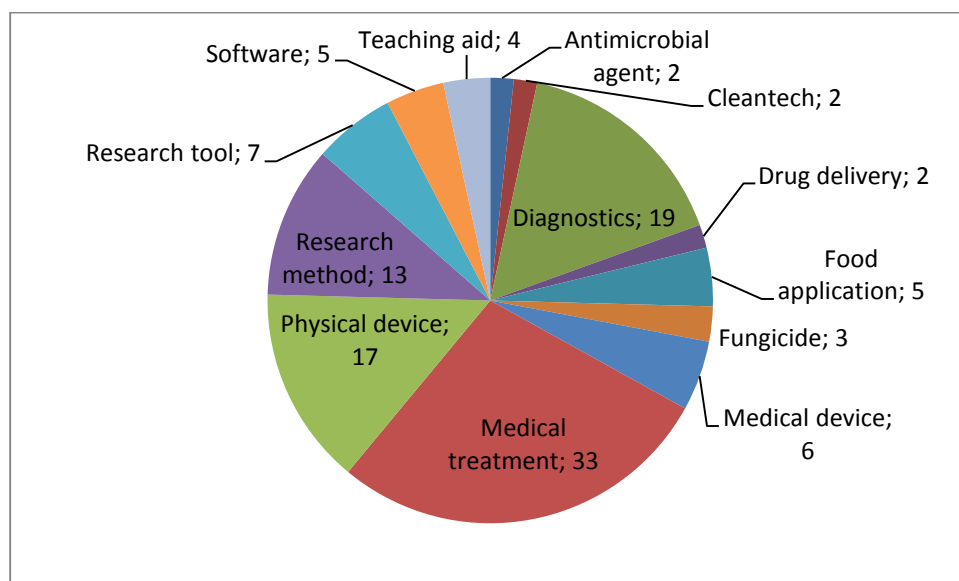


Figure 6. Life science inventions by type of invention.

Even though inventions often combine aspects of several different fields of science, and can only seldom be categorized under one defined class, it is worth cataloguing them. Classification enables identification of the active areas of research and consequently helps to concentrate resources into promoting their IPR protection and commercialization.

As the source of funding under which the invention was made dictates the ownership of the rights (please see above, Introduction), the type of research funding was investigated. Briefly, if the invention was generated under open research, the rights to it belong to the inventor, and if under contract research, the rights are with the university. The owner of the rights has the primary right to protect the invention (for example through an IP filing) and to promote it (for example through commercialization, licensing or creation of a company). As per notification of the inventors, ca 2/3 of the life science inventions have been made under contract research, and the rest under open research (Figure 7). A fraction of cases remain unsolved, which reflects the often complicated funding situations, or reluctance of the researchers to reveal these. The distribution resembles that of all invention disclosures at the University of Helsinki across all fields of science (data not shown).

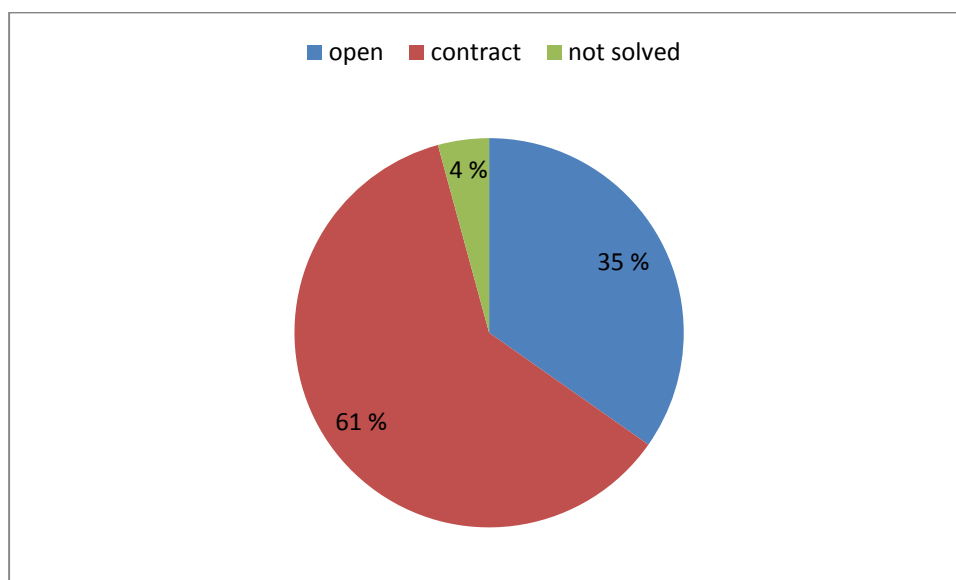


Figure 7. Percentage of life science inventions under open or contract research.

In general the concept of open and contract research and how it defines the ownership of rights to the invention is sometimes considered strange, difficult

and arbitrary. On the one hand, one arm of the system (contract research) follows the central European and American practice where the rights are with the employer, and on the other hand, the other arm of the system (open research) follows the Swedish practice, where the rights are with the inventor. Settling the ownership issues requires a significant amount of resources and time, which could instead be used for the actual evaluation, patent protection and commercialization activities of the inventions. Additionally, it is often difficult for researchers to specify under which funding an invention was made. The practices also vary from university to university and research institute to research institute. For some universities, having used just one source of contract funding for the invention classifies the invention as been born under contract research, whereas for others, several sources of contract funding are required. Further complication arises in case of inventions where the inventors have dual employments, one at the university, and another at an employer such as a hospital. Dual employments are common especially within the life sciences, where a researcher is often also a practicing clinician and can be employed simultaneously by the University of Helsinki as well as the Helsinki University Central Hospital (HUCH). Whereas universities are bound by the Act on the Right in Inventions made at Higher Education Institutions, hospitals are under the Act on the Right in Employee Inventions. Employers that comply with the Employee Invention Act, usually automatically own the rights to the inventions made by their employees, whereas for university employees the ownership first has to be defined based on the source of funding. Finally, as the law also gives the possibility to transfer the rights from the inventors to the university and vice versa, one might ask whether it is actually meaningful to define the ownership based on the funding source.

3.3 Life science inventions and IP rights

As stated above, ownership of the rights is crucial for the IP protection of the invention, i.e. the university can only file IP for the inventions to which it has the rights. As a result of the evaluation process, the university gives its opinion on the possible IP protection and commercialization potential of the inventions, and if positive, the university initiates the transfer of rights from the inventors to the university (please see above, Figure 1). As to the life

science inventions, the university has obtained rights to ca 1/3 (32%) of the inventions in order to enable the downstream IP filing and/or commercialization activities (Figure 8). Included in the chart are also inventions for which the evaluation process was still ongoing at the time of writing, i.e. the transfer of rights was not yet decided. These make up the bulk of the cases under the class "not decided".

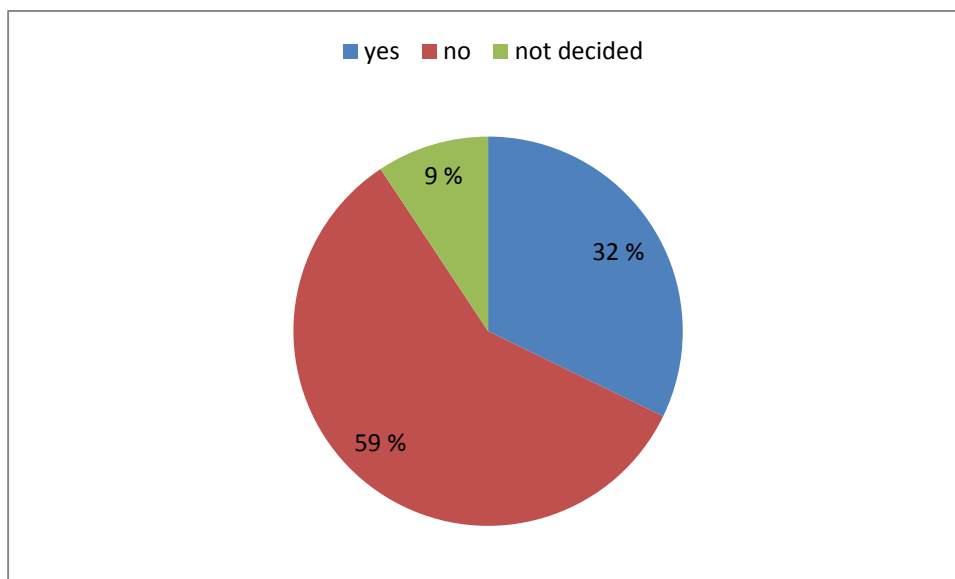


Figure 8. Transfer of rights of life science inventions from the inventors to the university.

From all the inventions that the university has obtained rights to, it has proceeded with a patent application in 1 (2012), 8 (2013), 14 (2014) and 4 cases (2015 until 29.05.2015, Figure 9). Of these, roughly half have been based on life science inventions, i.e. they have arisen from the Meilahti and Viikki campuses (Figure 10). At the time of writing, there were four more life science –based patent applications being prepared.

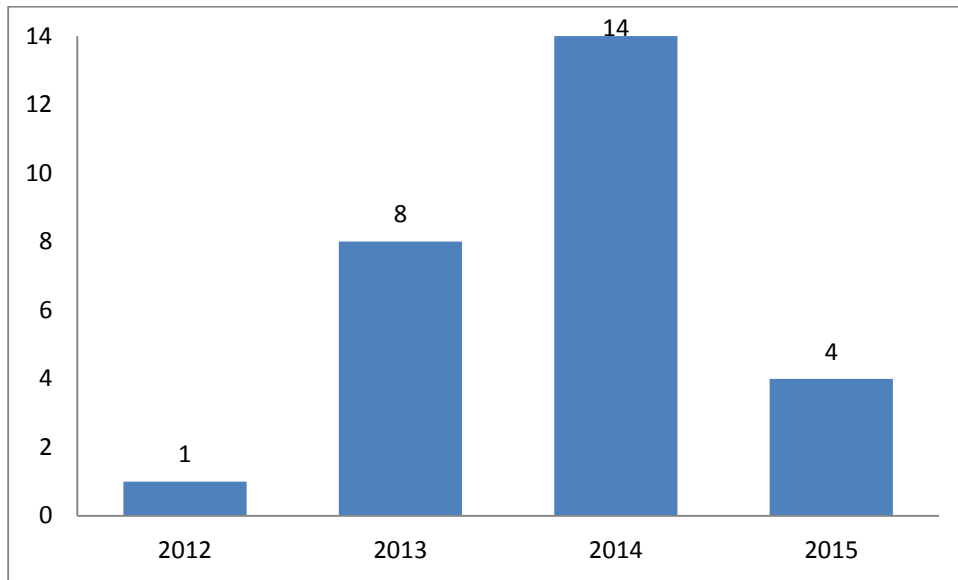


Figure 9. Patent applications across all fields of science with the University of Helsinki as applicant.

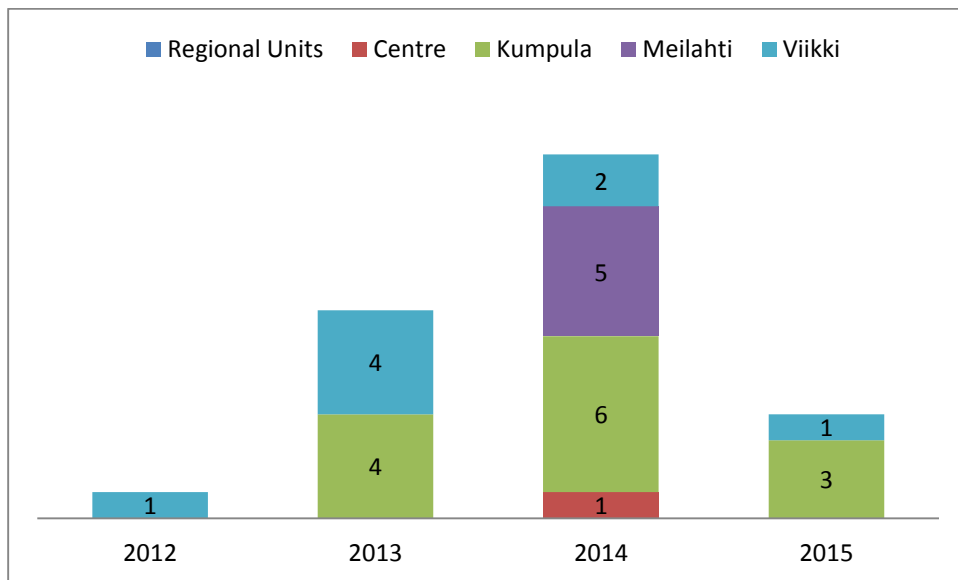


Figure 10. Patent applications by campus with the University of Helsinki as applicant. The majority of Life science inventions arise from the Meilahti and Viikki campuses.

All in all, from 81 life science invention disclosures filed at UH during 01.01.2012-29.05.2015, the university took rights to 38 of them, and from these, patent application has been filed (or filing is about to take place at the writing moment) for 17 (Figure 11).

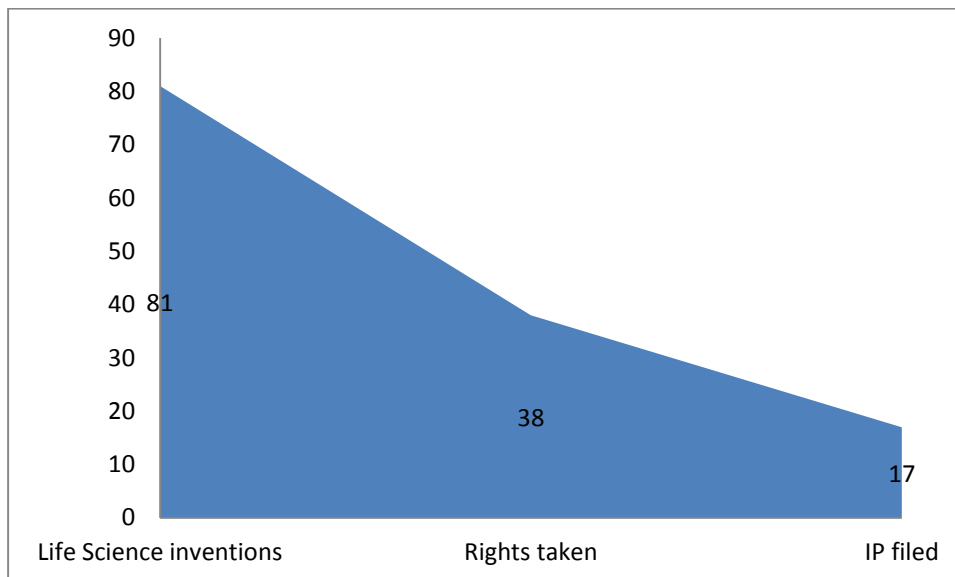


Figure 11. Number of life science invention disclosures that were received (81), the rights taken to the university of Helsinki (38), and IP was filed for (17) during 01.01.2012-29.05.2015.

In order to gain an understanding of the role of IP rights in downstream commercialization of life science inventions, the type of inventions that the university has filed IP for was analysed. Examples of such inventions are listed in Table 1. Several subfields of life science including clinical as well as biomedicine, chemistry and oncology are embodied. Additionally, the subfields cover different invention types such as innovations on medical treatments, diagnostics as well as research tools and methods (Table 1). This illustrates the diversity of commercial opportunities arising within the life sciences at the university. It is also noteworthy that a majority of the inventions, for which patent applications were filed, originated from contract research (data not shown).

Table 1. Examples of life science inventions where patent applications have been filed by UH., by field of science and type of invention.

Field of science	Invention type
Biomedicine	Medical device
Immunology	Medical treatment
Oncology	Diagnostics
Clinical medicine	Medical treatment
Infectious diseases	Medical treatment

Chemistry	Antimicrobial agent
Chemistry	Research tool
Chemistry	Research method
Biomedicine	Research tool
Oncology	Medical treatment

In order to enhance the promotion (through IP protection and commercialization) of life science inventions, those inventions that were not patent protected were analysed, i.e. the 59% of all life science inventions that the university had either not obtained the rights for or that IP was not filed for (please see above, Figure 8). These represent all subfields of life science as well as all types of inventions (Figure 12).

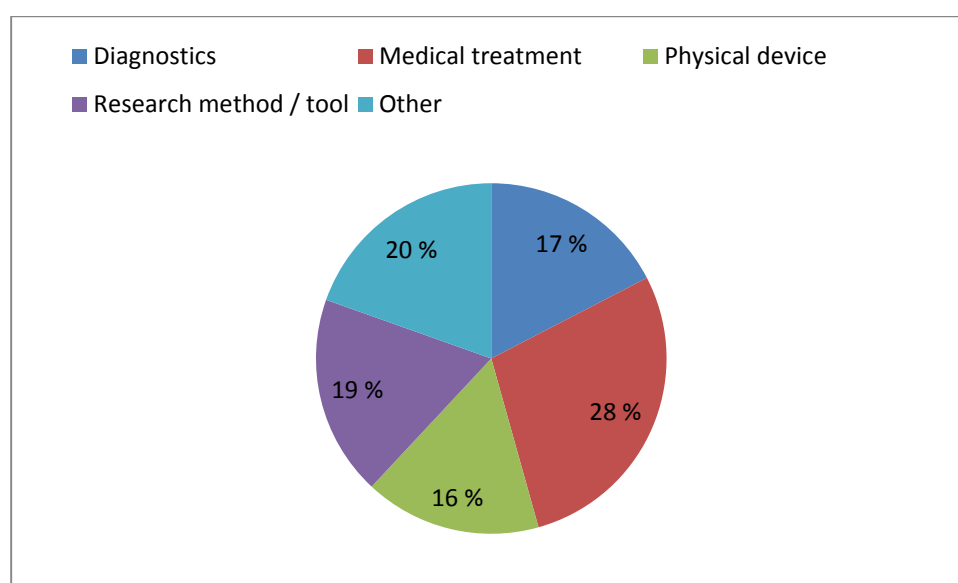


Figure 12. Percentage of life science inventions by type of invention that the University did not obtain the rights for. Invention types with <5 cases were included under the category "other".

Almost one-third (28%) of these inventions are medical treatments, and ca one-fifth (20%) are classified as diagnostics. Both of these classes harbor some inventions that utilize biomarkers, i.e. typically DNA/RNA sequences, proteins, and/or measuring levels of these that are then correlated with a specific diagnosis and/or treatment of disease. Biomarkers form a specific class of life science inventions due to the patent legislation associated with them. Whereas in Europe biomarkers can be patent protected, the legislation in the US is challenging. In June 2013, the US Supreme Court ruled that *"Patents on naturally-occurring DNA sequences (often referred to as "gene*

patents") are not patent-eligible subject matter". In addition to these "gene patents", of which many are biomarker-related patents, various other nature-related patent claims are affected: *"Examples of subject matter that falls within the scope of the Guidance include: "chemicals derived from natural sources (e.g., antibiotics, fats, oils, petroleum derivatives, resins, toxins, etc.); foods (e.g., fruits, grains, meats, vegetables); metals and metallic compounds that exist in nature; minerals; natural materials (e.g., rocks, sands, soils); nucleic acids; organisms (e.g., bacteria, plants, multicellular animals); proteins and peptides; and other substances found in or derived from nature."* (Campbell, 2014; Hirschfeld, 2014). To enhance the likelihood that biomarker-related claims are accepted, an enabling technical step is required that makes the claimed subject matter markedly different from what occurs in nature. The technical step can be, for example, an engineered antibody that is used in detection of the (DNA) biomarker. However, in practice, at least for the moment, successfully claiming biomarkers in the US seems to be somewhat unpredictable with the decisions also varying depending on the patent examiner.

How crucial is it to obtain IP protection for the life science inventions in order to commercialize them? Examining the inventions for which IP has been filed (Table 1 and data not shown) reveals that they cover nearly all subfields of life sciences as well as all invention types. There are certain invention types that do not require IP protection in order to enable commercialization, such as research tools and methods. They make up ca one-fifth of the non-protectable life science inventions (Figure 12). For essentially any other type of invention, IP protection is needed in order to secure the interest of a licensee or upon which to build a company. The success in downstream commercialization is a sum of multiple things, including negotiation skills and how well the offered IP fits in the portfolio of the potential licensee. In a fraction of cases, the invention is kept as a trade secret.

Finally, there is a subclass of inventions, ranging across all research fields at the university, where the university has obtained the rights but IPR has not (yet) been filed (data not shown). For these cases, 39% (46/118) are from the life sciences. In addition, there were four inventions whereby IPR filing had not been decided at the time of writing. As is typical for university-derived inventions, these are usually characterized by being early stage discoveries

Results and discussion

where further development or proof-of-concept data is still needed before IPR can be filed.

4 Conclusions: Intellectual property rights and university – derived life science Innovations

Life science research carried out at the University of Helsinki (UH) is diverse and internationally highly ranked. The purpose of this work was to map the types of life science inventions arising from the university, and to review how intellectual property rights (patents) are used to protect them and to promote their downstream commercialization. Since 2012, the technology transfer functions, and thereby evaluation and commercialization of UH-derived inventions, has been organized at Helsinki Innovation Services (HIS), whose in-house database of UH inventions was used as source for this work. At UH, patent protection is sought for various types of inventions, and it is often a necessity for out-licensing or spin-out formation. On the other hand, there is a significant amount of inventions typical for research institutions, namely research tools and methods, which do not necessarily require patent protection for commercialization. Promotion of these inventions is an avenue requiring further consideration. It is a challenge for a university to maintain a patent portfolio and successfully utilize it for commercialization. Firstly, there is no one primary subject or technical area around which the patent portfolio is built; instead, patentable inventions arise from a variety of fields. This in turn creates a challenge for any university's technology transfer, both in terms of resources and expertise. Secondly, the inventions are typically at a very early stage and are often academic observations in nature. Thirdly, the law governing the ownership of university-derived inventions is complicated, and can unfortunately also be misused by some. However, despite these challenges, inventions and their commercialization is seen as a task with growing importance not just for the university in fulfilling its third mission – to contribute to the development of the whole society -, but also for the researchers, the inventors, and their careers. With top-notch science, committed inventors and professional technology transfer functions, life

Conclusions: Intellectual property rights and university – derived life science
Innovations
science inventions from the University of Helsinki can be successfully
commercialized based on a strong IPR position.

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6 Appendices