REPORT

Intellectual Property Issues in Open Science, pre-competitive Research and Open Innovation

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This report deals with specificities of different ways of scientific result and data production regarding persons involved. Intensity and content of communication and collaboration as well as the number of persons involved and their specific qualifications differ. Those different ways of doing research impact differently on Intellectual Property (IP) and have economic consequences. This report focuses on various aspects of IP in the context of Open Science (OS), Pre-competitive Projects and Open Innovation (OI), in particular. These different ways of scientific result and data production show some specific common features as well as specific distinctions that will be briefly demonstrated and their impacts on IP and finally on innovation discussed.

Introduction

In a scientifically and economically competitive environment pros and cons of doing research in a standalone manner or in collaboration with other researchers, be it of the academic or industrial world, are heavily debated (Figure 1). The same holds true for open (including) versus closed (excluding) scientific processes. Which of these ways is perceived as the more efficient and which disadvantages do they have? The answer depends on the goals to be achieved and to a certain extent on personal attitudes and expectations. If timely priority (first to invent, first to file, first to publish) is rewarded highly in science, economy and IP protection, openness seems not to be the preferred way to proceed. Openness can be afforded only if it is sufficiently accepted that knowledge sharing is the more successful way to knowledge growth and that there is a tremendous potential for new insights based on already existing data. In addition, the possibility to use open data and results saves cost and time and speeds up further data generation, data analyses and finally innovation. Nowadays it is accepted that even science and research increasingly function following the principle of division of labour. Also of importance is the source of funding as public funding increasingly requests openness, access to

and re-usability of scientific results according to the FAIR Data Principle[1] and at the same time requests protection of IP to enable exploitation of results and to stimulate innovation, because of the funding bodies' responsibility to taxpayers and for providing public services and infrastructures for economic growth, jobs, health care etc. Specific opt out possibilities should solve potential contradictions between these requirements.

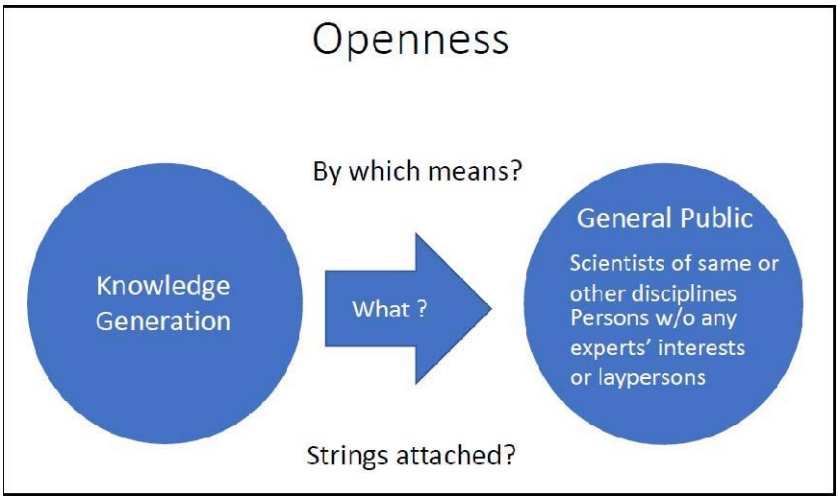

Figure 1: Openness in Science -schematic overview and entities involved

These days a hype-like increased recognition of openness in science is apparent that has even produced a specific taxonomy of OS with Open Access, Open Data, OS Evaluation, Open Reproducible Research, OS Tools etc. During the last years the concept of OI was added under the assumption that the amount and quality of innovations can be improved by making research data and results accessible and available for the development of new solutions and by involving relevant stakeholders and even citizens in general for defining the relevant questions and problems which need new – maybe unconventional and out of the box -or improved existing solutions.

Open Science

OS is of paramount importance to OI. OS is based on the concept that everybody has access to data generated by research and to scientific results presumably generated likewise through using/analyzing openly accessible data from others. It guarantees open access to – publicly funded – research results and the possibility of knowledge sharing (Figure 2). Expected benefits range from an increase in scientific knowledge to economic growth as a source of welfare in general.

[1] https://www.nature.com/articles/sdata201618 Findable, Accessible, Interoperable, Re-usable

OS also brings about societal benefits (accountability, citizen/user/patient involvement, increasing technology acceptance, re-usability of results and technologies) and, finally, impacts innovation. OS is about ensuring that science serves innovation and growth.

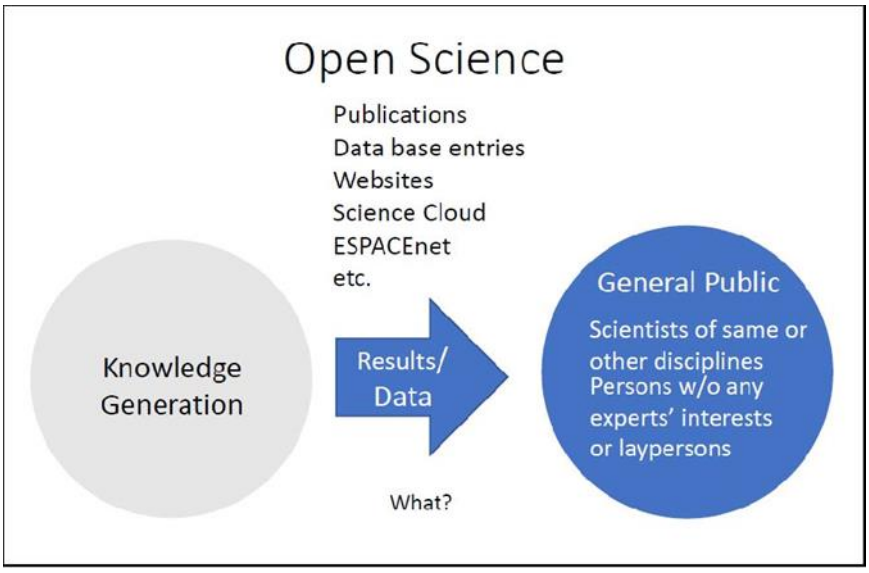

Figure 2: Open Science -schematic overview

However, OS as well as OI depend on the willingness and motivation of researchers (i.e., individuals as well as institutions) as a condition sine qua non. Why should they provide their knowledge to their – in one way or the other competing – colleagues or even to the public?
How can credit be given to scientists for their involvement in making data available for sharing? To give a satisfying answer to this question might need a change in the reward system and a general understanding that each scientist sharing his/her knowledge benefits from the knowledge shared by other scientists in the same way. Technology driven start-ups benefit from this principle and contribute to its application. In summary, knowledge seems to grow when it is shared[2].

For the user of OS the type of submitted data, its quality, completeness and interoperability with data from various other sources are critical[3]. The value of further exploitation and the willingness to invest in further exploitation depend on the soundness of data and on certain standardization.

Data producers will have to strike the balance between rapid data release, data entirety and

[2] http://viennaprinciples.org/v1/ Scientific knowledge should be a public good and as such part of the knowledge commons, in order to enable everyone in society to benefit from this knowledge.
[3] See also footnote 1

verification, and make the users aware of their respective policy.[4]

Furthermore, data producers have to address additional competing requirement such as compliance with all applicable regulations, ethical issues, privacy protection, respect of sponsor confidential information and others' IPRs. Also in this regard OS needs to respect the somehow differing expectations of stakeholder groups.

The undeniable benefit of OS is its contribution to the increase and improvement of the data and knowledge basis for further scientific progress and innovation. In addition, it speeds up the exploitation of its data by lowering access hurdles as far as possible and transferring rights to use them with the least possible (e. g. Creative Commons Licenses) or even no restrictions relating to any form of exploitation, including commercial purposes. OS is characteristically addressed to the public, be it scientists of the same discipline, be it scientists of other disciplines or persons without any experts' interests or laypersons. And the addressees are in most cases not collaborators of the project within which the respective publications and data were generated. The whole interested community is invited to further develop the innovation potential of OS data.

With regard to IP referring to technical innovation and its protection OS per se is not a major problem, leaving copyrights aside, which do not play an important role in this context, since it means providing easy access to publications and to data mainly without any conclusions as to whether it has technical problem-solving potential, like an invention or is knowledge which potentially would make a further invention obvious. Therefore, the content of publications and data in OS contribute to the state of the art relevant in the context of IP protection. This does not only apply to the disclosure of an invention, but also to information so close to an invention that it makes the invention obvious and therefore not anymore patentable.[5] If such knowledge should be made part of OS it is to be assumed that the generator of that knowledge will have sought adequate legal protection beforehand, as normally required by regulations imposed in case of public funding.

However, this aspect is not a problem for partners in data production who might agree not to seek

[4] See in this respect the Data Release Policy of ICGC (http://icgc.org/icgc/goals-structure-policies-guidelines/e2-data-releasepolicies): "The members of the International Cancer Genomics Consortium (ICGC) are committed to the principle of rapid data release to the scientific community…. Members of the ICGC acknowledge their responsibilities to release data rapidly and to publish initial global analyses in a timely manner…. The ICGC will establish a well-articulated description of a firstlevel verification standard for each data type produced by Consortium members. … All data will be accompanied by prominent caveats to notify users of the level of verification of the data …"

[5] See Page 8 below

any protection of IP[6] related to their primary data but potentially for third parties considering further analyses of the published data.

However, by providing results and data to everybody for analyses OS already boosts the generation of IP and innovation by increasing the community involved in innovation. Own investment in the generation of that data as starting point for further analyses is not necessary; analyses on OS data are easier as compared to the situation in which data generation has to be made first by oneself. However, through these effects OS spurs competition between innovators, in particular SMEs, which leads to time pressure for proceeding with data analysis and for further development of marketable products and services. This competition and time pressure can lead to problems even with protection of IP because of the risk that others use OS data in parallel to achieve solutions for a similar problem and consequently also file patents. Therefore, patents must be applied for rapidly to secure priority. Even if the underlying invention fulfills all the legal requirements for granting of a patent, the invention might still not be sufficiently developed to secure a broad enough patent protection which can be enforced effectively. Furthermore, in the case of IP generated based on OS there is increased risk of insufficient priority because of potentially more applicants filing competing patents. This uncertainty of whether one's own priority is sufficient or not remains until the publication of the patent applications.

For SMEs and start-ups this increased risk in achieving proper IP protection could directly affect their ability to ensure proper funding, be it venture capital or revenues generated through out-licensing.

Publicly funded ESFRI Biological and Medical Research Infrastructures (BMS RIs) are expected to ease this situation by providing long-term storage and accessibility of data, be it own data or be it data conferred to them as a sort of data repository.[7] Their success and presumably further funding might depend on to which extent they can fulfil that task properly. Beyond that, BMS RIs together have the potential to build up a seamless value chain delineating the whole development process (e.g. from fundamental research to clinical development of new diagnostics and medicines), which can be accessed and used by companies.

This could significantly lower the entrance hurdle for biotech SMEs since they would be set free

[6] ICGC Intellectual Property Policy
http://icgc.org/icgc/goals-structure-policies-guidelines/e4-intellectual-property-policy
[7] ESFRI Position Paper on Horizon 2020

from the necessity to establish equipment and personnel and operate their own individual infrastructures needed to further develop their IP.[8]

This and the challenges arising from increased time pressure and competition caused by OP providing results and data to everybody for analyses OS could, at least in part, be overcome by European BMS RIs. Therefore, it is recommended to further support and develop the BMS RIs so that they can actually provide access to resources and services that essentially support the whole innovation chain from basic research to testing of new medicines in patients.

Pre-competitive Research

Although this concept is widely used, there is no compelling definition of what is meant by pre-competitive. There are either generic definitions[9] [10] or the partners in a certain precompetitive project define for the purpose of that project in concrete terms which areas should be worked on and what they regard as pre-competitive.[11] However, even in cases of precisely defined pre-competitive research one never can exclude that this research leads to results which can improve directly the competitive position of one or more of the project partners. This is an effect experienced in basic research leading – unintentionally – to directly applicable results. Furthermore, pre-competitive research could have a different meaning for start-up companies and SMEs than for large industry. E.g., newly developed procedures could even be the basis of a business model of a start-up whereas same procedure is not of commercial interest for established industries. As opposed to OS, pre-competitive projects comprise at least a limited number of participants amongst whom information and support is not one way directed but an interactive exercise oriented to the achievement of precisely defined common goals. All partners are at the same time data producers and users (Figure 3).[12]

In addition, a clear difference to OS is the fact that at least two or more partners in the project are

[8] Zatloukal, K, Hainaut, P, Human tissue biobanks as instruments for drug discovery and development: impact on personalized medicine, *Biomarkers Med.* (2010) **4**(6), 895–903

[9] http://www.ccmx.ch/projects-amp-partners/industry/how-to-participate/what-is-pre-competitive-research/ Pre-competitive research is a middle ground of focused cutting-edge research that lies between fundamental basic research conducted mainly in universities/ETH domain and proprietary research performed in corporate laboratories.

[10] Commercial Court Vienna, 04.08.2016, GZ 39-14y: not for profit research

[11] E. g. https://c-path.org/wp-content/uploads/2013/09/consensussciencemichelgoldman.pdf Michel Goldman, IMI Enhancing innovation through non-competitive collaboration: Key Deliverables of Non-Competitive Research: • Establishment of common databases • New tools for identification of drug targets • Standardization of models and assays for drug efficacy and safety • Patient reported outcomes • Classification of diseases

[12] As kind of an exemption since recent years one can see the inclusion also of representatives of other stakeholders who do not really collaborate, for instance patient advocacy groups.

competitors with clear competing economic expectations.

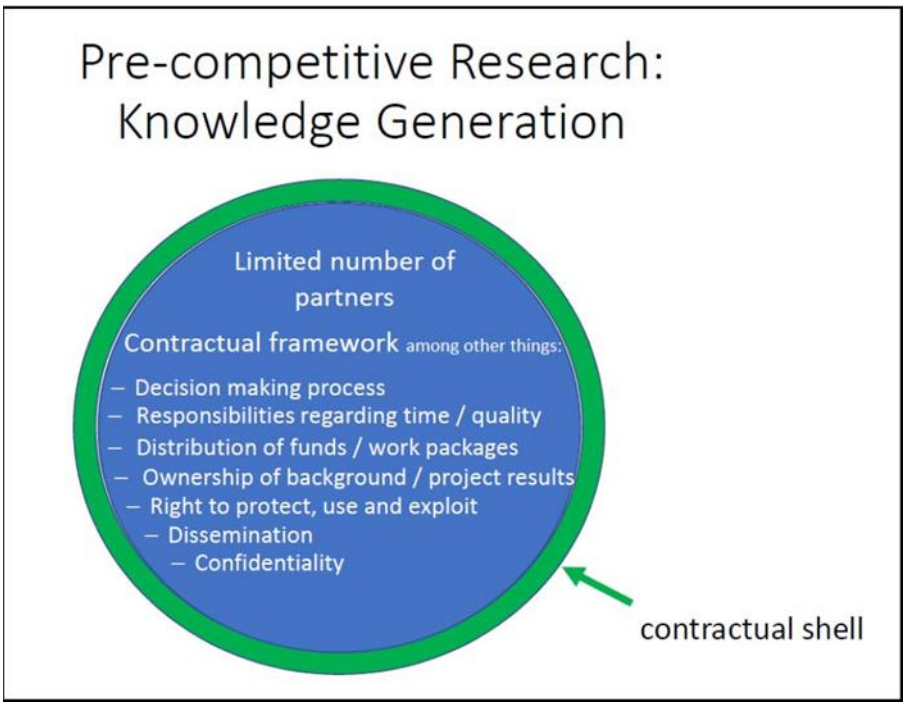

Figure 3: Pre-competitive framework for joint knowledge generation

Therefore, people and organizations involved in specific programs must balance their needs and expectations for the purpose of carrying on a specific program. The project can only deliver the expected benefits when adequate rules are in place. Therefore, a plethora of rules for collaborations exist, established by research funding bodies or by agreements between the parties involved in the form of co-operation contracts or a mixture of both. Research funding bodies require consortia of fund receivers to reach respective agreements within a certain predefined framework, on the distribution of funds and work packages, on responsibilities regarding time and quality, on the decision-making process, on the dissemination of data and results and, last but not least, on the ownership of background knowledge and project results as well as on the rights to use, exploit and protect them etc.

In contrast to OS the information generated in pre-competitive projects is primarily kept amongst the involved project partners who have to comply with specifically agreed upon confidentiality regulations (the project is carried out under a common roof) (Figure 4). In addition, the limited number of partners in a defined pre-competitive (as well as competitive) project is easy to oversee and therefore any flow of information within the project can't be regarded as publication and contribution to the state of the art in the sense of the Patent Law.

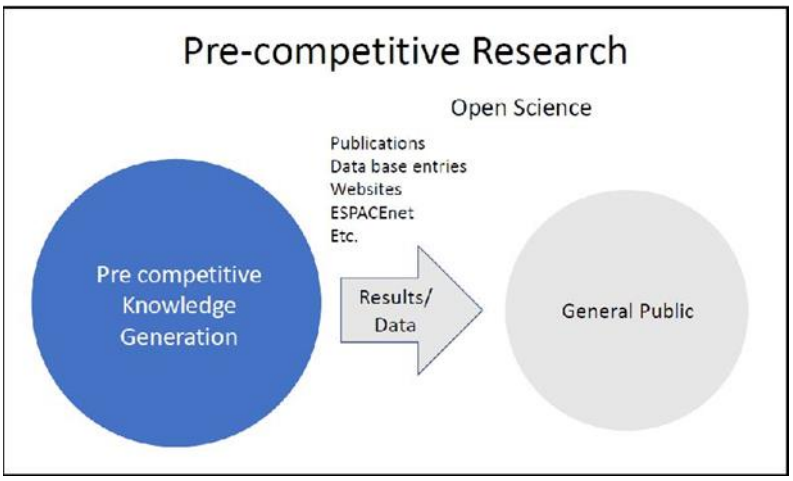

Figure 4: Pre-competitive Research and Open Science – schematic overview

Contrary to OS and because of the competing economic interest of all or certain project partners, it is essential also for pre-competitive projects to agree at the beginning on ownership (sole or joint; not to be confounded with inventorship[13]), rights to use and their extent, right to license, potential royalties or milestone payments or other forms of benefit sharing, etc. Also in projects with public partners, industrial partners emphasize their need to be granted freedom to operate to further develop the potential of the IP. Co-ownership of IP is not a prerequisite for the public partner to benefit in case of successful development since there are a variety of benefit sharing models which would address both the industry partner's need of freedom to operate and the public partner's need of financial participation (e.g., by pre-defined milestone payments).

Open Innovation (OI)

OI means not only OS and its facilitating access to scientific results and data but also a means to improve the economic potential of these results and data. To increase the innovation potential and thereby the production of new knowledge and the development of new products, services or processes, OI deliberately widens the innovation processes of companies and public research institutions.

[13] See page 9. When the Regulation of Horizon 2020 (FN 25) stipulates that results shall be owned by the participant generating them (Article 26.1 Annotated Model Grant Agreement, Version 4.0, April 21, 2017, "AMGA) the Regulation presupposes that the participant -being always a legal entity -arranged with the people involved on the participant's behalf the transfer of ownership from the inventor Article 26.3, annotation nr 2 AMGA).

OI seeks as a targeted and systematic cutting-across of the boundaries between organizations, sectors and disciplines– in contrast to OS -input from outside; the inclusion of people reaches out far beyond science, industry and the public sectors (Figure 5). The users and other citizens who aren't constrained by the assumed limitations and mental schemas of the respective professional world are playing an increasingly important role drawing attention to needs and problems, and provide with breakthrough thinking possible solutions to the innovation process or support the development of such solutions.[14] The diversity of actors increases the potential of generating new knowledge and even fundamental innovation.[15]

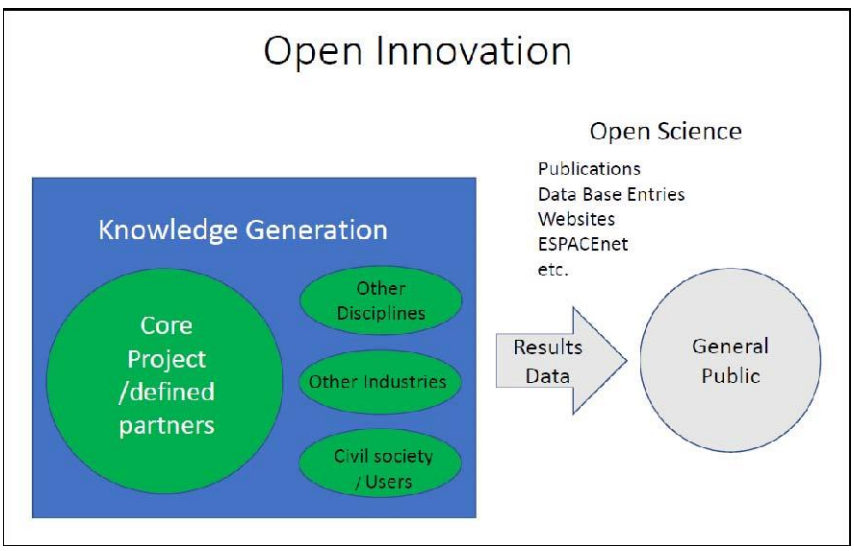

Figure 5: Open Innovation and Open Science -schematic overview

OS is an instrument to communicate results and data generated by one partner to an undefined public. In this respect, it is per se a one-way communication from data producers to potential data users without requirement of any aspect of collaboration. In a pre-competitive project the number of partners in the project is limited and the partners' activities, rights and obligations within the project are well-defined by a comprehensive collaboration contract and – in case of a publicly funded project – through the requirements of the respective funding program. According to these rules the partners can be controlled according to an agreed governance structure. The partners co-operate following a strict project plan by supporting each other and by providing and receiving information to or from other partners; all of them are data producers and data users at the same time.

[14] Poetz, M.K., Franke, N., and Schreier, M. (2014). Sometimes the Best Ideas Come from Outside Your Industry. Harvard Business Review, November 21, 2014 online. https://hbr.org/2014/11/sometimes-the-best-ideas-come-from-outside-yourindustry

[15] http://openinnovation.gv.at/wp-content/uploads/2015/08/OI_Barrierefrei_Englisch.pdf ; „Open Innovation Strategy for Austria" one of the first EU Member States' OI strategies

OI differs from both OS and pre-competitive projects and their ways of knowledge production. Most probably one can regard an OI project as concentric circles and assume that it consists of a nucleus -be it a pre-competitive or a single partner project -that initiated the OI project -based on input from across the boundaries or not -and invites scientists or specialists experienced in fields other than project-specific fields and sectors across the boundaries either to become full project partners or to serve as sort of consultants or just as a sounding board. The outer circle then consists of other people / citizens in their quality as users, opinion leaders or citizens concerned in a broad sense. They bring in their needs, expectations, fears and opinions regarding the goals of the project, its processes and expected outcomes, i.e. innovations. Normally, the interactions and contributions of persons in these several concentric circles -the "crowd"[16] -are different in subject, scientific or experts' quality, intensity and involvement (Figure 6).

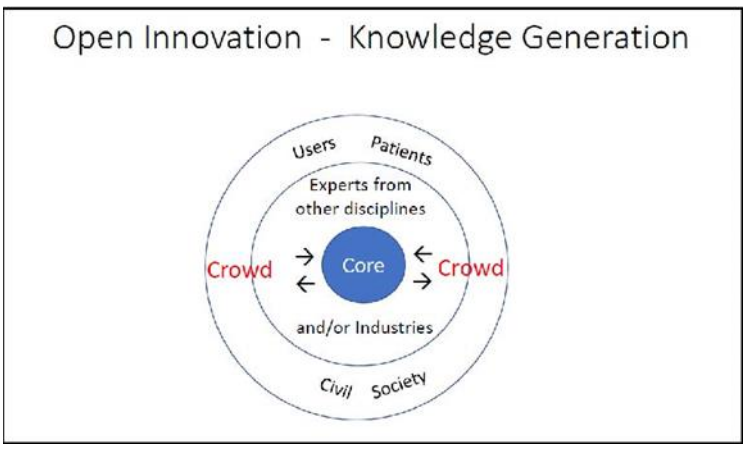

Figure 6: Open Innovation – knowledge generation

In view of the variety of actors and their differing roles and tasks, a clear process of participation and the mutual expectations have to be defined and agreed upon. However, this defined participation process will also have to give an answer whether and how all the different actors should be rewarded for their various contributions, when it comes to IP.[17] A specific aspect in this context is whether a contribution fulfils the requirements of a patentable invention.

Based on the European Patent Convention (EPC) there are several requirements for patenting as the most common way to IP-protection. European patents will be granted only for an invention describing how to technically solve a technical problem suitable for industrial (economic) application. Besides others, discoveries, scientific theories, mathematical methods and computers

[16] ibidem
[17] ibidem

are not regarded as inventions in that sense.[18] The concept of invention differs from innovation. The latter is the transfer of a novel idea, which could be but not necessarily has to be an invention, into practice. An innovation could be but is not necessarily such a transfer of an invention.

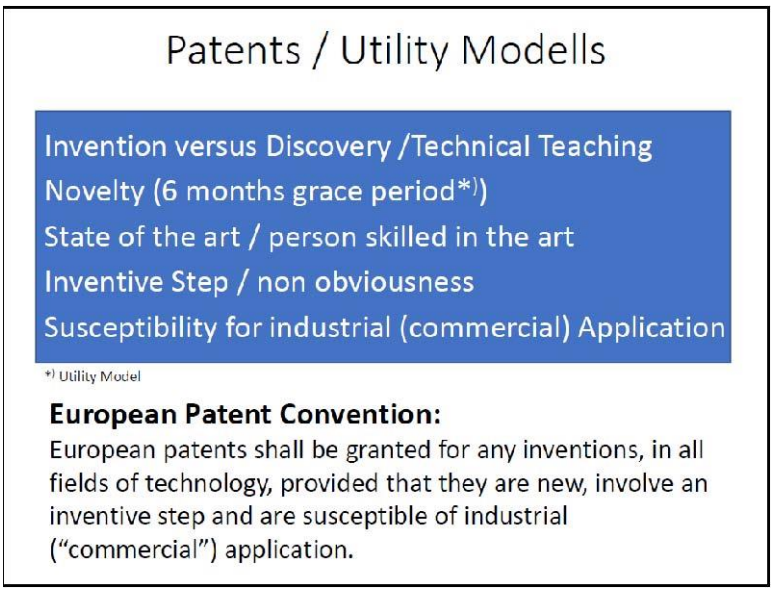

Figure 7: Overview Patent Requirements

Patents can be granted for an invention if it is new, involves an inventive step and is susceptible of industrial (economic) application (Figure 7).[19] An invention is not new if it forms part of the state of the art which comprises everything made available to the public by whatever possible means before the filing of the patent application inclusive of prior patent applications.[20] Whether or not an invention involves an inventive step depends also on the relevant state of the art as the yardstick. Regarding that state of the art, the invention must not be obvious to a (fictitious) person skilled in the art.[21] Therefore, a publication, even if not containing the respective invention itself, can make an invention not patentable if it discloses information based on which the invention becomes obvious in the described sense.

An invention is considered as susceptible of industrial application if it can be made or used commercially in any kind of industry.[22]

An invention can only be made by a natural person; a legal entity can never be an inventor. When the invention is developed jointly by several people, they are co-inventors. The right to a patent

[18] Article 52 EPC
[19] ibidem
[20] Articles 54 and 55 EPC
[21] Article 56 EPC
[22] Article 57 EPC

belongs to the inventor or his/her successor in that right. The proprietary rights connected to the invention follow from the inventorship.[23] Even in the event of assigning his/her proprietary rights (ownership) to another natural person or a legal entity the inventorship remains with the inventor; his/her right to be mentioned as inventor survives during the further lifetime of a patent and beyond.[24]

Even in case of service inventions, which are inventions made by an employee within his/her contractual obligations using resources provided by the employer, the employee is and remains the inventor. However, as a peculiarity, the employee must inform the employer about the invention made and the employer can subsequently claim ownership of that invention.

Coming back to the mentioned need for well-defined and agreed upon rules regulating the internal life of an OI project one should distinguish between the core project in the center of the concentric circles (see above) and the OI project as an entirety. Presumably the project in the center will have to fulfil the requirements mentioned for pre-competitive projects, in particular if it is funded publicly. In addition to that, for the involvement of people in the crowd, specific rules, not yet generally established, must be agreed upon by all the participants to ensure the orderly course of the OI project. These rules could be drafted in analogy to the consortium agreement required by Article 24 section 3 (except lit b) of the Regulation for Horizon 2020[25], by respecting the peculiarities of an OI project (distributions of funding, dissemination, use and access rights, ownership etc., background and results). Most probably, actors in the crowd will be treated differently to the partners in the core project in these respects.

In general, in the context of OI and IP a tense relationship is discussed; OI processes are seen as an antipode to IP. What are the potential risks of OI to the protection and exploitation of IP generated in the OI project? There are four issues, novelty, inventive step, ownership / freedom to operate and rewarding the participants in the crowd.

Widely opening the innovation process could endanger the novelty of inventions. Also, people from the crowd who are expected to actively participate in the innovation process and to provide useful input to the knowledge producing process must receive sufficient information on the progress of the

[23] Article 60 EPC ; https://www.preubohlig.de/de/Patent-Guide/Employees-Inventions/Inventorship.html
[24] Article 62 EPC
[25] Regulation (EU) No 1290/2013 of the European Parliament and the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 -the Framework Program for Research and Innovation (2014-2020)", http://www.fch.europa.eu/sites/default/files/h2020-rules-participation_en.pdf

project and on results, like the other participants. In addition, the more people who have access to such information the more difficult it is to avoid any disclosure to the outside world. Furthermore, also participants in the outer circle can contribute through own inventions and get information on inventions made by other participants. In order, not to endanger the patentability of those inventions as well of future inventions all participants must be obliged to strict confidentiality regarding inventions as well as information which could make a future invention not patentable by causing the lack of an inventive step.

The partners in the center of the OI project have a justified interest in obtaining ownership also to inventions made by participants from the crowd. Therefore, they expect rightfully those inventors to transfer ownership to their invention. The counterpart of such an obligation to transfer ownership to an invention is a model of compensation for inventive input by participants in the crowd that must be motivating and fair.

In summary, an OI process needs clear specific regulations regarding its running, the distribution of tasks, the mutual obligations of all the participants and on how IP related issues will be dealt with, and risks to IP protection minimized. Those terms must be implemented on a contractual basis. Drafting of contracts between the innovation partners is therefore of major importance.[26]

In supporting this drafting of contracts establishing a collection of building blocks or templates of collaboration contracts might be considered to minimize the need of the participants of OI projects to re-invent the wheel in a sometimes highly spontaneous process and lose time in each case. Such collections or templates should also address specific issues of OI projects with participants from different jurisdictions to foster international OI.

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[26] see footnote 14