

How European Biological and Medical Sciences
Research Infrastructures boost Innovation
by Open Access
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Intellectual Property issues
in
Open Science, Pre-Competitive Research and
Open Innovation



Overview

- I. IP Protection and requirements

- II. Openness in Science
 - II.1 Open Science
 - II.2 Pre-competitive Research
 - II.3 Open Innovation

- III. Recommendations

Requirements Patents / Utility Modells1

Invention, i.e. Technical Teaching, versus Discovery

Novelty (6 months grace period*)

State of the art / person skilled in the art

Inventive Step / non obviousness

Susceptibility for industrial (commercial) Application

*) Utility Model

European Patent Convention:

European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial (“commercial”) application.

Patent 2

Invention

No positive definition in Patent Law e.g. EPC, Directive 98/44/EC on the legal protection of biotechnological inventions

Novelty

An invention considered to be new if **not part** of the state of the art

State of the art

The state of the art comprises everything **made available to the public** by whatever means before the date of filing of patent

Inventive step

Invention considered as involving an inventive step if, regarding the state of the art, it is **not obvious to a person skilled in the art**.

Industrial application

An invention shall be considered as susceptible of industrial application if it **can be made or used in any kind of industry**, including agriculture.

Patent 3

Right to an invention

belongs to the inventor (*physical person*) or his successor in title. If the inventor is an **employee** (service inventions), H2020: beneficiary obliged to secure transfer of ownership

Inventor to be mentioned

Inventor has the right to be mentioned as such, in any case. **Errors** in identifying inventors may lead to **invalidation** of patents.

Patent a **double-edged sword** cuts both ways:

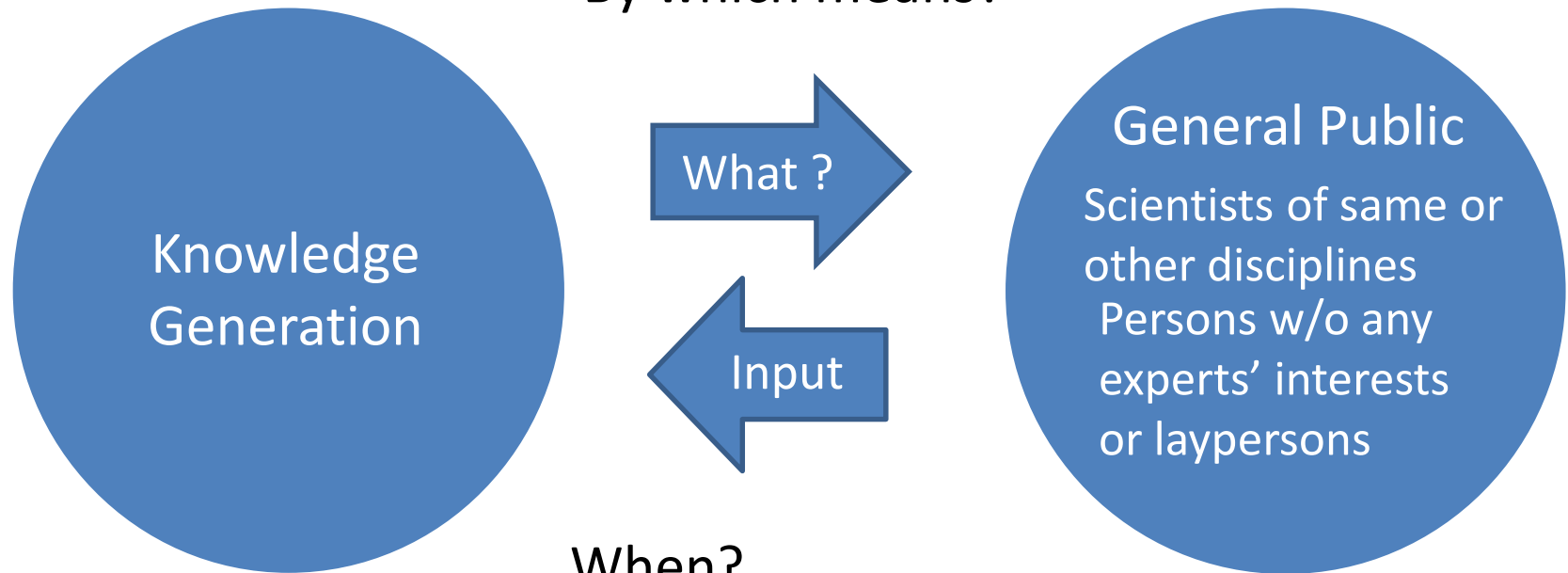
- right to prohibit someone from the use of the invention
- a contribution to the state of the art – increases the hurdle for patenting of other's **and own future inventions**

Consequence:

filing a patent could be too late as well as too early!

Openness in Science - schematic overview and entities involved

By which means?

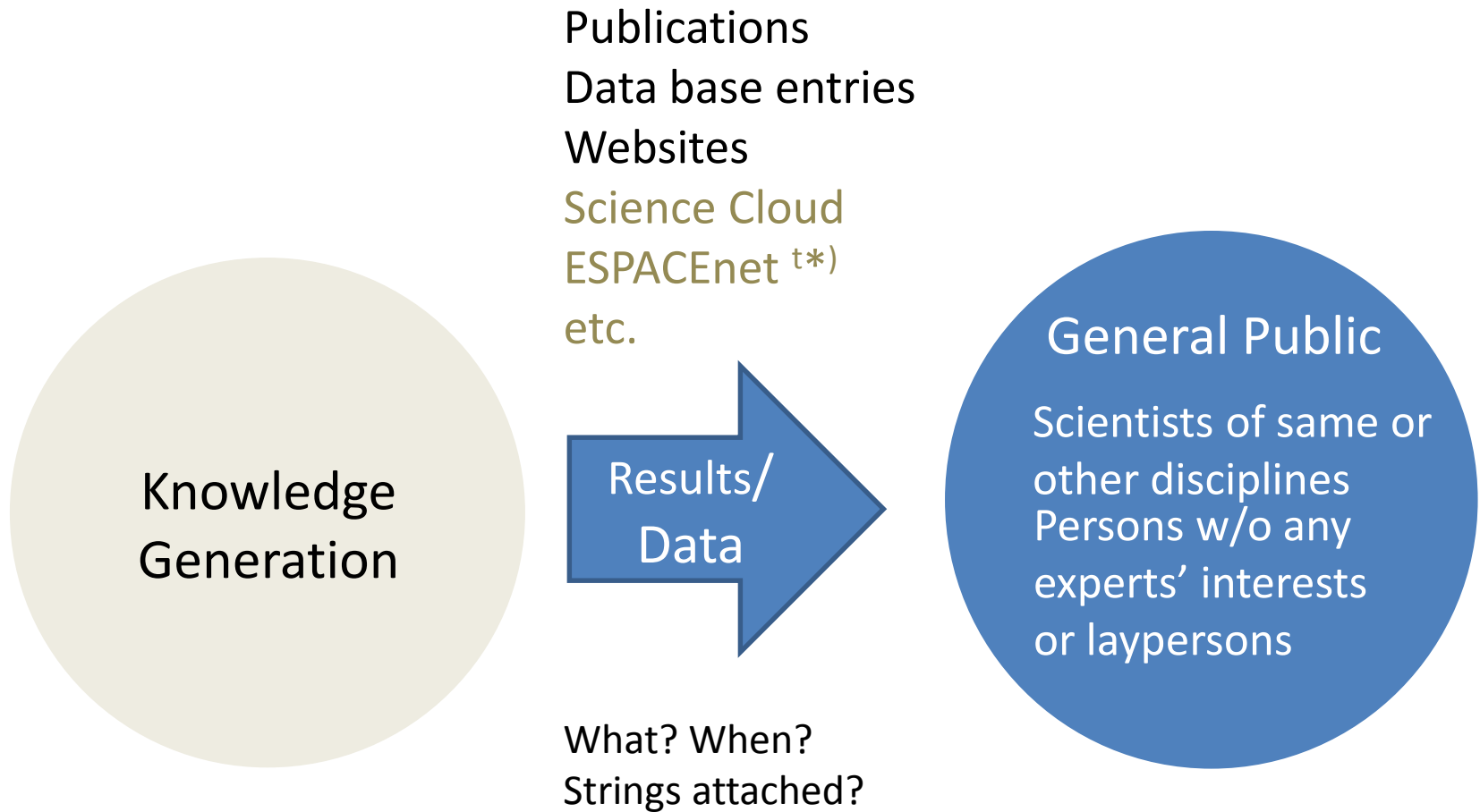


When?

Strings attached?

focus on various aspects of Open Science (“OS”), Pre-competitive Research and Open Innovation (“OI”) in the context of IP

Open Science - schematic overview



*) Enables tracking progress of emerging technologies, finding solutions to technical problems, seeing what your competitors are developing

Open Science 2

Data **generators/providers** must in the interest of users and their own interest

- strike the **balance between rapid data release, data entirety, verification, compliance** with applicable regulations and ethical issues, **privacy protection, respect of sponsor's confidential information, IP protection and others' IPRs** and make the users aware of their respective policy and
- keep in mind the FAIR Data Principle (Findable, Accessible, Interoperable, Re-usable).

The value of further exploitation and the willingness to invest in further exploitation depend on the soundness of data and on certain standardization.

OS Example: openness preferred

International Cancer Genome Consortium ICGC

principle of **rapid release of – even - of preliminary data** and publication of initial global analyses accelerate rapid translation of data to knowledge, Human Genome Project served as a model efforts for further verification and validation don't delay the initial data release. Users notified of verification level

data remain publicly accessible w/o any restrictions to maximize public benefit

no **claims to possible IP derived directly from primary data** and no IP protections sought that would prevent access or use

users (including Members) may perform **further research**. Patents on **“downstream” inventions** must not obstruct further research; fair licensing policies should be implement

OS Example: **exploitation oriented**

Horizon 2020 (AMGA)

Obligation to disseminate results to the public as soon as possible. Each beneficiary must ensure **open access** (free of charge, online access for any user) **to all peer-reviewed scientific publications plus research data needed to validate** the results presented.

BUT does **not change the obligation to protect results** (Art 27)
For actions in the **Open Research Data Pilot** the beneficiaries must *deposit digital research data in a research data repository and take measures to make it possible for third parties to openly and free-of-charge access, mine, exploit, reproduce those data (possibly by attaching an appropriate creative commons licence or by indicating that no licence is needed).*

BUT opt out at any stage *if* ... participation is **incompatible with the obligation to protect results**

Open Science 5

Where do **BMS RIs position** themselves?

- openness oriented – support/service for others
- exploitation oriented – own IP oriented; strings attached

Intended boosting Innovation → not overly tight strings!

Open Science 6

direct impact to IP issues

Public research institutions used to the principle patent before publicize. Providing easier access to those publications and connected data per se doesn't reduce the possibility for IP protection

Transferring other data (digital research data) to public w/o any conclusions as to whether it has technical problem-solving potential can but doesn't necessarily destroy IP protection as long as they, as part of the state of the art, don't make further inventions obvious. Before knowledge generators grant access to such data they better consider their further research plans and judge their chances for further inventions.

Open Science 7

Indirect impact to IP issues:

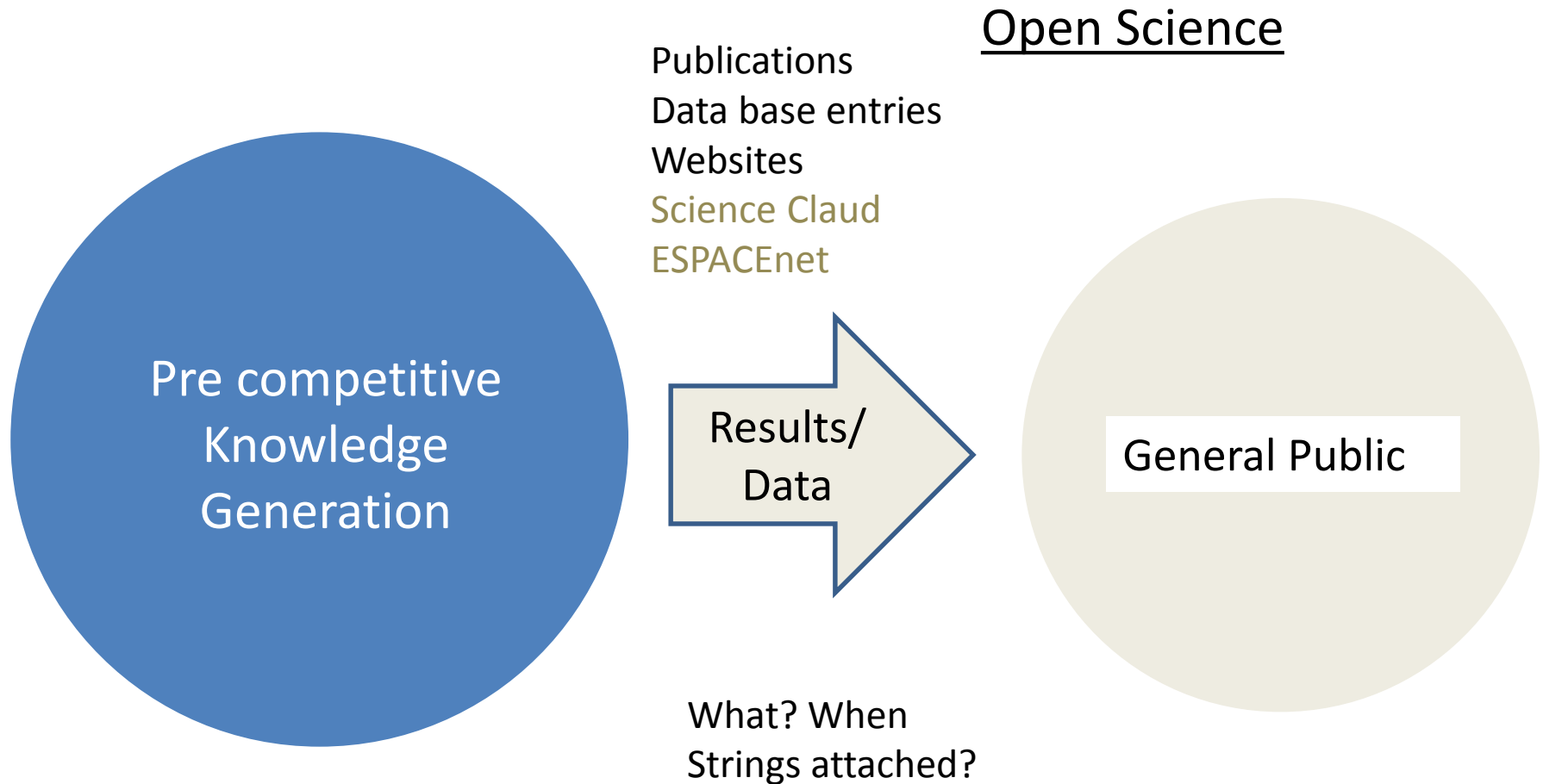
Enlarging the innovation community and reducing entry barriers for Start-ups and SMEs in generating IP accelerate the innovation process and generate a series of new challenges, such as

- increased risk of unknown parallel inventions
- increased time pressure for early filing of patents even w/o sufficient maturity
- higher risk of uncertainty regarding priority

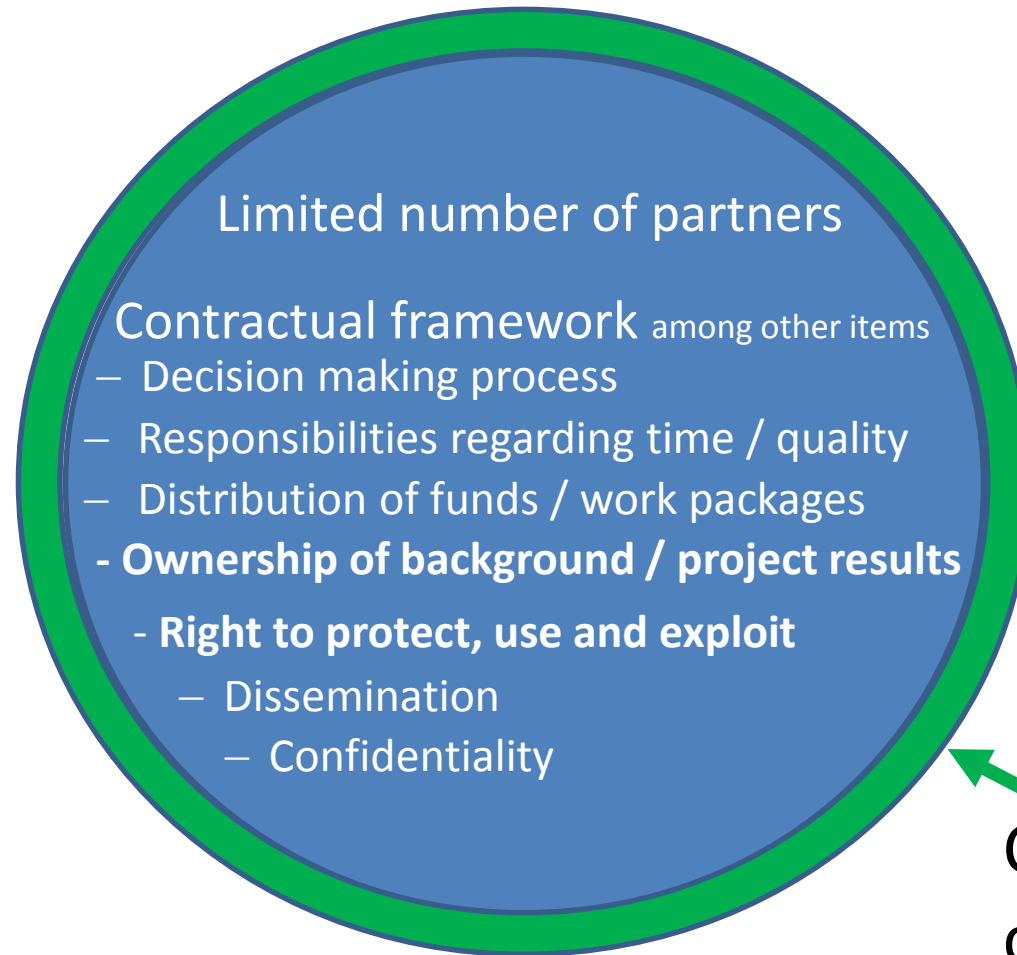
and therefore difficulties raising venture capital funding.

However, these challenges can be overcome by BMS RIs providing access to resources and services that essentially support the whole innovation chain from basic research to testing of new medicines in patients, and thus relieve the start ups and SMEs from time pressure; speeds up their research.

Pre-competitive Research and Open Science – schematic overview



Pre-competitive framework for joint knowledge generation



Comprehensive contractual shell
H2020 model

Pre-competitive 2

Partners **co-operate interactively** by providing and receiving information to or from other partners; **everyone** of them **data producer and data users at the same time**.

In contrast to OS the **information generated** in pre-competitive projects is much more **kept amongst the involved project partners** who have to comply with specifically agreed upon **confidentiality** regulations (project carried out **within a contractual shell**).

information within the project **not** regarded as publication and **contribution to the state of the art** in the sense of the Patent Law with all its consequences.

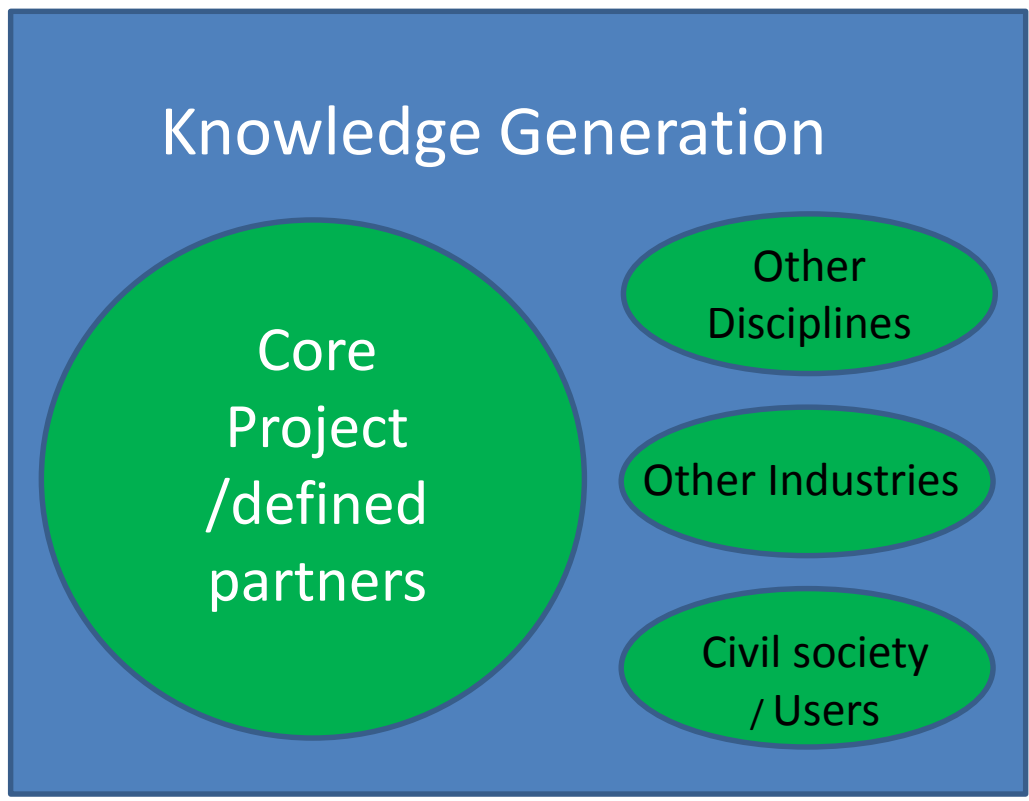
To avoid negative impacts from pre-competitive research to IP Protection an adequate contractual framework meeting standard requirements (e.g. h2020) is crucial.

Open Innovation 1

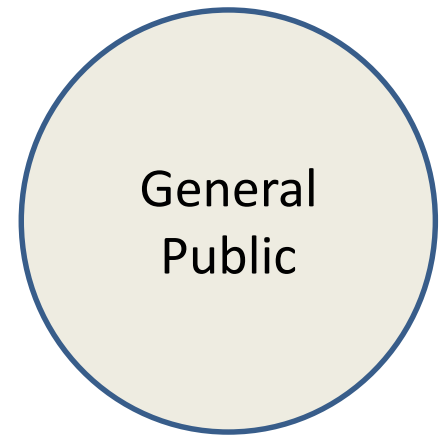
deliberately **widens the innovation processes** of companies and public research institutions and seeks – in contrast to OS - **input from outside** as a targeted and systematic **cutting-across of the boundaries** between organizations and disciplines; the inclusion of people reaches out far **beyond science, industry and the public sectors**. **Users and other citizens** not constrained by acquired limitations and mental schemas of the respective professional world are supportive in **drawing attention to needs and problems**, and provide with breakthrough thinking **possible solutions** to the innovation process. The **diversity of actors increases the potential** of generating new knowledge and even **fundamental innovation**.

Open Innovation and Open Science - schematic overview

Open Science

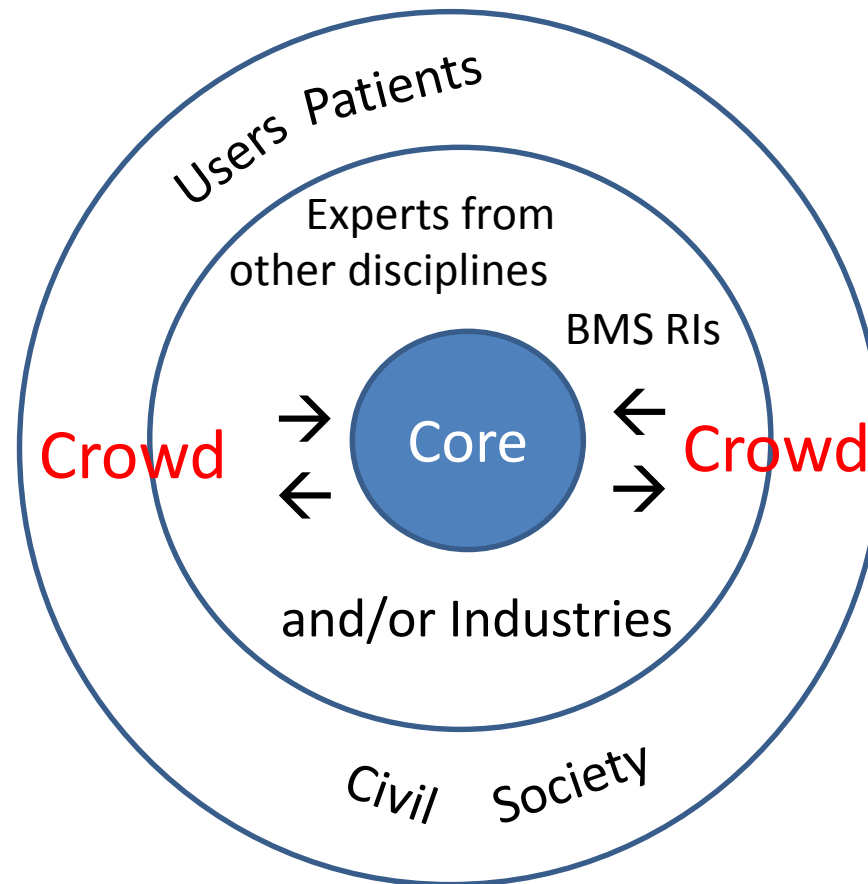


Publications
Data Base Entries
Websites
Science Cloud
ESPACEnet



↑ other's infrastructures ?

Open Innovation – knowledge generation



→ Communications on Input, Results etc.

Open Innovation 2

OI deliberately open for interactions with outside and has nothing like a **comprehensive contractual shell** as pre-competitive projects. In view of the variety of actors and their differing roles and tasks, the **mutual expectations** and a clear **sophisticated process of participation** have to be defined and agreed upon specifically, in the interest of both, core and crowd

The **core** project itself will presumably fulfill the **requirements like pre-competitive** projects.

In addition to that, for the **involvement of people of 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, presumably case by case.

Open Innovation 3

Referring to IP, these **rules on the involvement of the crowd** and the collaboration within the OI project should cover the following:

- Confidentiality: Also, people from the **crowd** who are expected to actively participate in the innovation process and to provide useful input **must receive** like other participants **sufficient information** on open questions, progress of the project and on results, **possibly even on inventions** made by other participants. Leaving aside competition issues, from a **mere IP point of view** confidentiality must **cover inventions** made as well as foreseen future inventions **and information** which **could increase the state of the art** in a way that **novelty and inventive step** of future inventions might be destroyed and therefore, not anymore patentable.

Two direction confidentiality.

Open Innovation 4

- notification on inventions made in the crowd: Namely, also participants in the **crowd** can contribute with **own inventions**.
- transfer of ownership of results from crowd to core: The partners in the center of the OI project have a justified interest in obtaining **ownership also to inventions made by participants in the crowd**.
- system of compensation for inventive input by participants in the crowd as the **counterpart to the obligation to transfer ownership of an invention**, that must be motivating and fair.
- rights to access, use, exploit and protect any input from crowd

BMS RIs core or crowd? If **BMS RIs** are to support innovation projects they act **in support of core** as participants in the **crowd** and must **follow the specific rules of the crowd**.

Recommendations

The as early as possible **drafting of such rules** (“contractual shell”) for OI projects can be **supported by establishing a collection of building blocks for collaboration contracts** (beyond just PTC) to minimize need of re-inventing the wheel and the risk to lose time in each case. One might also consider “**general terms and conditions of trade**”. Templates should also address issues of international OI concerning **different jurisdictions**.

Challenges arising from time pressure and competition caused by OS providing results and data to everybody for analyses could be eased with the help of BMS RIs . Therefore, it is recommended to **further support and develop the BMS RIs** in order that they can actually provide primarily to start ups and SMEs access to resources and services along the innovation chain from basic research to testing of new medicines in patients.

Thank you for your attention!

zacherl@imgus.at