Set of Guidelines Dealing with Intellectual Property Rights (IPR)

For academic start-ups

VSNU, NFU, KNAW and NWO

July, 2016

(Association of Universities in the Netherlands, The Netherlands Federation of University Medical Centres, The Royal Netherlands Academy of Arts and Science and The Netherlands Organisation for Scientific Research)

Contents

- Aim of the set of guidelines
- What is this set of guidelines about?
- Things to consider before starting a business
- Framework and conditions for the variables
- Framework and conditions for access to IPR
- Parties to the negotiations: who has a seat at the table?
- Inventory of supply and demand
- Recommended approach
- Determining the value of the IPR and setting a price
- Royalties on sub-licence income
- Exit
- Inventor's regulations
- Standard terms

Appendix: Glossary

Aim of this Set of Guidelines:

Utilising knowledge gained from research carried out at public research organisations (valorisation) is important for society, particularly in facing its challenges and economic opportunities. Intellectual Property Rights (IPR) play a relevant role in knowledge utilisation. The valorisation of knowledge by applying IPR can form the basis of a relationship with an established company or with a start-up. That means that there is a growing need for guidance on dealing with IPR for academic start-ups, especially considering the importance of stimulating the continued growth of start-ups and ensuring that there is no impediment to the upscaling of start-ups.

The aim of this Set of guidelines is to clarify for academic start-ups the principles that govern their access to the IPR of public research organisations. The approach will be to "apply or explain", ensuring predictability and transparency in terms of what start-ups can expect in this area. Although it is usually a prerequisite for success, access to IPR is rarely an adequate condition. In practice, a culture of enterprise and a clear and stable mandate within the public research organisations prove to be equally important in achieving a viable start-up.

In the interest of readability and accessibility, the focus will primarily be on the relationship between the start-up and the public research organisation. If the parties start to collaborate in a wider context, for instance with existing companies or funding bodies, then the number of variables and the level of complexity increase significantly, which is why this kind of public-private partnership falls outside the scope of these guidelines.

What is this set of guidelines about?

- *The Start-up*.
  A number of variables determine the start-up's negotiating position, to mention just a few in no particular order:
  - The market in which the company will be operating and the business plan, which needs to show how the start-up will ensure that the developed IPR will be translated into relevant products or services;
  - What role a/the employee(s) of the public research organisation will be fulfilling within the start-up, for instance providing scientific support for the company, working purely as a consultant, becoming an employee (and will this be part or full-time and in what capacity?) or will they be paid in shares or stock certificates;
  - Access to the public research organisation's people and resources, for instance contributing to courses and (helping to) raise funds for the start-up;
  - The position of the public research organisation as a shareholder (or not, or as minority or large shareholder) in relation to the other intended shareholders and the compensation mentioned above;
  - The position of the (future) management team; and
  - The team, especially Business Developers/entrepreneurs, to raise the company to the next level commercially.

- *Intellectual Property*
  This is a broad term and encompasses many categories. All knowledge, procedures, protocols and results of research within a public research organisation usually fall under this umbrella. Some of these can be formally protected through IPR, such as patents, copyright and/or database right. The rest can potentially be protected through non-disclosure.

  It is important to differentiate between these categories. Although it is relatively simple to give access to either, there are big differences. Intellectual property rights can be transferred to a start-up, but this only becomes a desirable option when the start-up has gained a more favourable risk profile; until such a time, an exclusive licence can provide the necessary flexibility. Third parties and costs often play a part as well, such as patenting bodies. Confidential information is a matter of contracts, in which agreements can be made about who can and can't use the information and under what circumstances. In both cases, the rights of third parties must be taken into account, including the scope of informed consent, open access/open source requirements and so on.

Things to consider before starting a business

The commercial exploitation of knowledge from a public research organisation is mainly carried out by businesses. In order to carry out its key task, which is knowledge utilisation, the public research organisation will look for commercial partners to implement the further development and commercialisation of this knowledge. This could be an existing company or a new one: a start-up.

Particularly when the public research organisation is actively involved, for instance because there are employees who want to work in the start-up, then good preparation, good communication, attention to detail and clear agreements are crucial. Plans will also need to be worked out both within the public research organisation and between the start-up, the public research organisation and any third parties, which is best done in a group structure that represents all the relevant expertise.

There must be a credible team that can lead the start-up and ensure its development. A crucial factor for success has proven to be having people with relevant business and commercial experience in the relevant sector on the team. In addition to this, knowledge and skill relating to the content must be available as well as sufficient experience in turning plans into results. All this expertise must be present and focused on the same goal (so not just contracted per hour). Compensating for lack in one area by an excess in another is usually counterproductive.

This team will be working out the plans, which will include the commercial context, such as the intended products, the competition, a SWOT analysis, an estimate of the required investment and a timeline up to launch. The team will also make an estimate of future turnover, costs and profit margins, taking risks into account. The necessary infrastructure, market requirements and the quality and strength of the IPR also often form a part of this.

It is just as important that the group communicates clearly and frequently. This communication is needed to create/safeguard certain important conditions for the start-up's success:

- Clarity about the role of the inventor(s) (are they working for the start-up, for the public research organisation or a combination of the two?);
- Ensuring the availability of critical facilities/resources/people in the start-up phase of the new business;
- Clarity about the sponsor/leader's position within the public research organisation when there is a need to escalate problems/bottlenecks;
- Creating a sense of urgency when problems or bottlenecks occur because of a different dynamic in the start-up;
- Willingness on the part of the management to speak to employees who (for reasons of their own) do not endorse the interests of the start-up.

Framework and conditions for these variables

The starting point for any agreement must be that a public research organisation's contribution to a start-up should be based on non-discriminatory grounds. That means that each company that applies, start-up or not, must be treated equally. In addition to this, the public research organisation must ensure that their (public) funds are used as effectively as possible to enable them to carry out their core duties. Finally, a public research organisation must not disturb the market by offering goods or services at prices that companies selling the same goods or services cannot compete with. These arrangements must always be recorded in a contract.

In effect this means that any help, support, use of space, materials, people, resources etc. from a public research organisation must always be offset by a compensation that is in line with the current market value. This could be in cash, in kind or in shares, but it is also distinctly possible that value is created for the parties in some other way, such as by contributing to a funded project, by combining PR, offering internships for students and so on.

It is also of the utmost importance that society's confidence in the independent role that the public research organisation plays in research must not be damaged. The core values that lie at the heart of this, such as independence, transparency, lack of bias and a critical attitude, must be beyond doubt. This will be at risk if employees or other people involved become active in areas where conflicts of interest could arise. For that reason, extra care should be taken.

Framework and conditions for access to IPR

According to the 1995 Patent Law (*Rijksoctrooiwet 1995*), the public research organisation owns all property that has been developed within the employer's (in this case the public research organisation's) IPR. Within Dutch universities the rule of thumb is therefore: *ownership follows inventorship*. With regard to data sets, it is also the public research organisation who is authorised to make decisions, which is why the public research organisation must be a party to any negotiations. Ideally, someone from the Knowledge Transfer Office (KTO) would act as a representative of the public research organisation under a mandate that covers the situation.

Granting access to IPR, in whatever shape or form, must involve financial compensation for that access, as it is by its very nature a commercial transaction. Access creates a temporary commercial monopoly. This is absolute in the case of an exclusive licence or unencumbered ownership, or in the case of a non-exclusive licence there can be a group of users who each have their own field or territory. The public research organisation will offer a market player a (semi-)exclusive right to exploit the results of publicly financed research.

The market player, which could be the potential start-up, pays a fee (for example as a lump sum, as milestone payments, exit payments if and when the start-up is taken over and/or royalties) to the public research organisation. On the one hand, this is no more than reasonable because public funds were used for the underlying research. On the other hand there are also formal grounds that make it unlawful to give free access or use under conditions that do not reflect market value.

A possible model that allows the start-up and the public research organisation to share in both the success and the risk of the endeavour is by granting the rights in return for shares in the start-up. The advantage of this route is that both parties have the same interests and contribute to a long-term relationship. Another benefit is that the start-up does not have to spend money on access to the IPR in this phase and so can put the money towards development. The disadvantage is that the public research organisation soon finds that it has little or no input because, unlike the professional investors, it is not investing any further and so loses influence.

Regardless of the compensation, access can be offered in the form of a licence (‘rent’) or by transfer (‘buy’). Investors typically want as much certainty as possible, and prefer the IPR to be transferred to the start-up, whereas public research organisations are reluctant to do this. On the one hand, start-ups offer the opportunity to utilise knowledge, but on the other hand, the chance of success is usually small. Should things go wrong, then the transferred IPR would no longer be accessible to the public research organisation or other partners and would simply be used in the debt recovery process for the benefit of the creditors (usually the financiers). By agreeing on an exclusive licence with the start-up, it can usually develop without this risk.

However, when a start-up receives substantial private investment based on the IPR for the development of its own product, one can assume that these investors will do their utmost to get a return on their investment, and that they will seize every opportunity to make use of the IPR. This would mean that the public research organisation’s aims have been achieved and transfer of the IPR at such a time is a tipping point where the duty of care on the part of the public research organisation has come to an end and the market takes over that role.

Naturally, this tipping point does need to be reached before transfer can take place: ambition alone is not enough. A mechanism by which this can take place is by granting an option, through which the IPR will be transferred when investment in the start-up by third parties in a later investment round has exceeded a certain amount. But it is also possible that a certain amount of money is agreed on that the start-up then raises through crowd funding. When this transaction takes place and/or the amount has been raised, the start-up is free to use the

property and it can attract more investors for the development of its products and services. This could be in conjunction with a liquidity event.

Parties to the negotiations: who has a seat at the table?
The parties who are to come to an agreement must be clearly and unambiguously represented in the negotiations from the outset. This means the start-up will be represented by a person with a mandate from the (future) shareholders, if necessary supported by experts and often by an academic initiator. They will be joined by someone from the KTO, also with a relevant mandate from the public research organisation (or its board), to speak on behalf of the public research organisation. The KTO must be mandated to sell the IPR and to set the conditions under which the start-up is granted access to the IPR.

A common point of conflict here is when an employee of the public research organisation is part of the start-up. These initiators, who often have a substantive role, are then confronted with the consequences of their change in status. Before they devoted themselves to developing their start-up, they were an employee, but when they want to start their own company, whether or not as an employee of the company, they become a party to the negotiations. Often this is a party with interests that are in conflict with the interests of the public research organisation. Because this is often the first time that this initiator is involved in this process, this change in role and the personal responsibility that comes with it can often cause problems. This problem can be ameliorated if the person involved is aware of the potential pitfalls and is open to guidance. Guidance from the KTO as well as from experienced businesses is particularly valuable in this case. In addition to this, the roles must be kept separate and different people should be assigned specific roles in this process so that the different interests are clear in the discussions.

Inventory of supply and demand
The parties must clearly define at the start of the negotiations exactly what IPR the start-up is being given access to, for which field, in what territory and whether it will be exclusive or non-exclusive. They must also decide whether it will be a licence or a transfer of ownership of the IPR. With IPR which does not create an ownership right which can be transferred (such as confidential information) it will obviously just be the former.

Besides access to existing IPR, it may be that there will be follow-up R&D leading to additional IPR. If this is done by the start-up itself, the public research organisation will not be involved. However, if this follow-up research is done by or in collaboration with the public research organisation, this creates a different situation. The new IPR produced by this collaboration does not fall, or at least not automatically, under the licence agreement and the parties will have to come to an agreement about this beforehand. It could be that this is joint IPR, which will be exploited by the start-up. This can be arranged in a collaboration agreement in which the Joint Research is described and in which the start-up gets an (exclusive) option to gain access to the public research organisation's part of the IPR as well, for instance through a right-of-first-refusal. This would be the case for any collaboration.

Eventually, a price for the transferred IPR must be agreed upon as well as what fee must be paid by the start-up to the public research organisation under what conditions. This payment can take many different forms, for example money or shares, it can depend on achieving certain milestones and be related to commercial success (royalties). Payments early on in the development process (front loaded) are often tricky for the start-up because they do not have any turnover yet and they would prefer to put any available money into the development of the company. This is why the preference is usually for payment later in the process (back loaded). Examples are not just the milestones in the later stages of development, but also the option for start-ups to purchase the IPR for a pre-determined price or – in the case of a licence that includes royalties – a lump sum to make the licence fully paid up.

Recommended approach

The process of setting up a business costs time and requires the involvement not just of an entrepreneur and an expert on the content, but also the involvement of various specialists. In order to complete this process within a reasonable amount of time, the roles and tasks need to be clear, especially if this is the first time that the people concerned are involved in such a development. Ideally, the parties openly set out their goals and planning, the critical conditions and their commercial and technical assumptions during the negotiations.

The start-up then makes its plans (desired IPR, the products to be developed, the necessary investment roadmap towards launch, including financial estimates). This can be done by making market analyses, estimates and so on. Particularly if the start-up requires access to the public research organisation's facilities, people or (future) IPR, it is important to map these requirements out as clearly as possible in this phase. This is mainly 'homework' for the team that will be setting up the business and involvement from companies, financiers and the public research organisation are important for the testing of assumptions and ambitions. This stage in the process usually proves to be the most time-consuming.

The parties carry out their negotiations based on their assumptions and objectives and agree to a term sheet. The term sheet is worked out into a complete agreement, which may be delayed until there is a liquidity event – a substantial investment, for instance. If there is a decent plan and the parties are sufficiently open with each other, this phase should take no more than a few weeks. Delays during the negotiating phase are usually caused by issues that have not been properly worked out during the planning phase or where the parties have different expectations or frameworks, for example about the value of the contribution of different people involved.

This process will partly repeat itself as, in reality, plans give direction and will frequently need to be adjusted. It is possible that within the space of 2 to 5 years, the parties will have to get together to discuss ambitions and objectives several times. It is advisable to keep this in mind in the contracts and the procedures: although goals and arrangements need to be clear, the parties must be prepared to make reasonable adjustments to them. Keeping communication lines open and mutual trust are vital in this.

The contents of the plans give an indication of the expectations for the future. Although reality always catches up with our plans, the plan does show how the team intends to overcome obstacles. The process of drawing up the plan increases the chances that the team can deal successfully with the inevitable, but as yet unknown, changes. In other words, it is not a script, but an exercise. In addition, it serves as a communication method because it makes things concrete for the people involved.

Determining the value of the IPR and setting a price

During the negotiations between the start-up and the KTO, both sides need to be sensitive to each other's interests. A good outcome will show a balance between serving the interests of the start-up, the researcher(s) and the university. The crucial ingredient for this is mutual trust.

The compensation that the start-up will then pay the institution (lump sum, royalties, milestone payments and/or exit investment), will be based on the potential future profit that the start-up can expect from the products involved. After all, the products that the start-up gets the opportunity to develop, produce and sell will in part be protected by the patent. This protection will support the start-up's competitive position in its target market.

Any costs that have already been incurred (acquisition costs) for the start-up (R&D costs) usually play a very limited part in determining the value of the IPR, unless the IPR is relatively easy to avoid. Sometimes the costs that have been made so far for establishing intellectual property rights are refunded as an upfront milestone.

The licensor has a claim to a share of the profit. For reasons of transparency and simplicity (profit can be manipulated by declaring high fixed costs), the royalties are usually expressed as a royalty percentage of the invoiced turnover. This allows the licensor to use, for example, the legal requirement to send invoices to carry out an audit of the turnover.

There are various sources that can provide an idea of what is usual in a certain market and/or give specific examples, although they are not always free of charge. American and European public research organisations have held surveys about agreements made with academic start-ups. Companies that go public in the US have to publish the important contracts through the U.S. Securities & Exchange Commission, where they can be viewed by anyone. Licenses and similar agreements about access to the most important technology normally fall in this category. Finally, various companies offer market reports about specific sectors including information about these types of agreements.

However, every case is unique, for instance in terms of what IPR is needed and what already exists in that field. The price point of the royalties may depend on the total number of licences required from third parties. Then there is also the question of whether the existing IPR will protect the products and markets to be developed; the more protection it offers, the higher the value. It will also depend on whether the technology requires a lot of investment and/or further study: the higher the costs and the greater the risks, the lower the royalties. A final factor is whether the IPR will protect the product or only a process or a part of the product.

Royalties on income from sub-licenses
Besides the royalties from the licensee's turnover described above, royalties on income from sub-licenses are also important. The licensee does not have to bring the products to market himself, but can entrust this to a sub-licensee. The price point of the royalty rate for sub-license income depends on who is carrying the risk for the development and what level of investment is needed.

Sub-licenses are not always the result of a regular, brief negotiation, but they can also be the result of a court settlement. In this case, a much lower percentage would be reasonable for sub-licenses, as the risk and the cost for the realisation lie with the start-up, or with whoever has taken over the start-up. In addition to this, it must be taken into account that, possibly through a court case, the sublicense may have been granted in exchange for a (sub-)licence on the sub-licensee's IPR. Although it is difficult to plan for all these contingencies, it is important that the parties are aware of the various options and are prepared to include them in their negotiations.

Exit
You can make the compensation to the public research organisation dependent on the exit, in part or in full, with the compensation as a percentage of the exit value. The exit value can be determined in a number of ways, but it always reflects the expectations of the future success of the start-up: it can be linked to the sector expectations with relation to growth and revenue. It can also be determined by the company's key indicators, such as EBITDA (Earnings Before Interest, Taxes, Depreciation and Amortization), basing their calculations on current actual profit. An alternative is to take the valuation used by investors in the most recent investment round. This valuation is based on an assessment by a third party or parties, moreover it avoids discussions about methods and value between existing partners.

Inventor's regulations
At all universities and University Medical Centres, the funds received by the universities and UMCs (net = income minus expenses, usually including patent costs but possibly including other costs) are divided between the Inventor(s), privately or as a research budget to be spent freely, the research group or department in question and the institution as a whole.

Standard terms
A licence agreement must include a number of standard terms that do justice to the nature of the start-up on the one hand, and the public organisation on the other hand. These obligations and requirements on the part of the start-up are in part based on the PPP (Public-Private Principles) approved by the NFU and the VSNU in 2010:

Results of research: The university can and may publish the results of joint research without restrictions and use these findings for research and educational purposes.
Although confidentiality and exclusivity are important to businesses, public research organisations cannot always agree to this. It is for the researchers involved to decide whether to publish their results, but it goes against the interests of the public research organisation not to be allowed to publish the results of their research. This is not a carte blanche, of course, and restrictions may well apply. However, if the results cannot be protected or if protection has no practical value, the parties must come to an agreement about the possibility and desirability of confidentiality. Examples of knowledge that has possible commercial value where this is relevant are algorithms, processes and drawings. Because the interests of the parties do not naturally coincide in this case and it affects not just the public research organisation but also the researcher(s) personally, clear agreements are needed with the start-up and the researcher(s).

Follow-up research: Results of follow-up research by the public research organisation and the IPR that may be apply to it, are the property of the public research organisation. The start-up does not have automatic access to these future results/IPR; this is to ensure the academic freedom of the public research organisation. To protect the interests of the start-up, it is therefore important that clear agreements are made about possible access to future results, for instance by defining certain improvements in the licence agreement that are automatically included under the licence or that can be included in a new licence agreement on the same terms. As an alternative, an option purchase right can be agreed.

Reporting: in order to keep track of payments as well as how the results are being used, a public research organisation will expect to periodically receive reports from the start-up. The nature and content of these depends on the start-up's development phase at the time. The report could relate to technological developments, the actions and objectives relating to the launch, sales successes and any sublicenses and so on. The nature and frequency of these reports will be recorded in the licence agreement between the parties. The report may also include how many FTEs or resources have been invested in the relevant development project, depending on context.

Anti-shelving clause: access to knowledge from the public research organisation always takes place on condition that the user makes reasonable commercial effort to actively make use of this knowledge.

Support for procedures: for licensees or subsequent owners it is often of paramount importance that they have continued access to the original inventors, in the case of extending a patent or if there is a court hearing. Court hearings can cover more than just patents. It is important that

public research organisations cooperate with such requests from start-ups and offers the services of their own employees.

Appendix 1.

Glossary

Academic Start-up	Start-up based on knowledge gained from scientific research carried out at Dutch universities, UMCs and institutes of NWO and the KNAW.
Access	Access to knowledge and IPR in order to commercially exploit this knowledge and IPR for financial compensation. The compensation may consist of a lump sum, royalties, milestones, shares or a combination thereof.
Anti-shelving clause	The user of the knowledge and IPR is obligated to continue to develop this knowledge and IPR as appropriate and to make every effort to utilise it commercially or to make it available to others, for instance by developing products or services and making these available to society. This type of clause aims to prevent research from being 'shelved'.
Assignee	The person to whom the Intellectual Property Right is transferred; in American patent right this is often the 'owner'.
(Dis)investment	The point in time when third parties invest in the start-up, and earlier shareholders cash in their shares (disinvestment). The level of their compensation - in other words, the price of a share - reflects the value that investors have assigned to the start-up. This can be in cash or as a discount and can give a start-up a 'fresh start'.
Exclusive licence	A licence which only grants one user certain rights, who does not need to share these rights with any others (this could be the owner himself). It is crucial to clearly set out in the licence agreement what rights of use are retained by the public research organisation, both in terms of the research exception and other sorts of use: a public research organisation should ensure that an exclusive licence does not block future research.
Exit	The point in time that shareholders sell their shares in the start-up.
Field	A commercial sector within which the knowledge can be utilised.
Inventor	A private individual/private individuals who have invented something. These persons have contributed to (a part of) the so-called inventive step. This is recorded in the text of the patent claims, in which the contribution made by each inventor can be indicated.
Inventor's regulations	The internal regulation within universities and UMCs relating

	to inventions. This compensation is mostly calculated as a percentage of the net proceeds (proceeds minus patent costs) and is divided among the inventor(s), the research team and the organisation as a whole.
IPR	Intellectual Property Rights, such as patent rights, copyright and database rights. Intellectual property rights are rights of prohibition, which means that the holder of the right (the owner) has the exclusive right to make use of these rights and to give others permission to do the same, for instance by granting them a licence.
Joint Research	Collaborating on (scientific) research. This may occur between two different parties, such as a commercial or industrial party and an academic institution, but also between several of these parties (a consortium), potentially making use of a government grant (public-private partnership).
KTO	Knowledge Transfer Office, also frequently referred to as Technology Transfer Office.
Licence	The right to make use of Intellectual Property Rights or any other contractual arrangement for the use of other people's property or rights, possibly under certain conditions such as a fee.
Liquidity Event	A point at which the start-up receives liquid assets, such as an exit or when new shares are issued.
Lump sum	A one-off payment, which can be made in cash and/or shares. Mostly relevant for access to knowledge of modest value, with a minimal administrative burden.
Milestone payments	One-off payment when a particular goal has been realised or when an event occurs that causes an increase in value; in cash for preference, but can be in options/shares. Milestone payments are often used in sectors where a long lead time until launch is usual and where there is a significant risk that it will never launch. In order to retain a claim to income as an owner, an amount is agreed on for the attainment of a predetermined goal during the development period. This is often used in the biotech and life science sector.
Non-exclusive licence	A licence that allows various users/licensees the right to utilise and exploit the IPR/knowledge commercially. Often used in certain sectors such as ICT/software.
Patent	A patent is the exclusive right to prohibit others from commercially using a protected invention within a certain area. The rights are national.
Patent application	An application submitted to a patent office or the European Patent Office in order to obtain a patent.
Patent family	A group of patents/patent applications that relate to each

	other, as in a family, because the same invention is described but the applications have been submitted in different areas.
Patent owner	The owner of a patent, or the patent applicant.
Patent transfer	Transfer of patent ownership.
Public Research Organisation (PRO)	A legal entity governed by public law which primarily carries out publically financed research, possibly also providing education.
Right-of-first-refusal	The right to be the first party to be offered something (and either to accept it or reject it).
Royalties	A percentage of the sale price of goods or services sold individually to (end)users. Cash, percentage of the profit (based on invoiced amounts). Traditional, administratively the most challenging, but no cash-out until there is profit. The advantage is that the licensee does not have to pay cash up front and an advantage for the licensor/owner is that they profit from the success of the product or service.
Sole License	A licence through which the Public Research Organisation remains free to do whatever it wishes with the licenced knowledge.
Start-up	A recently set up (within the last 5 years) legal entity or partnership.
Term sheet	Arrangements about the most important and relevant terms of a deal, that will need to be worked out in more detail in a definitive agreement between two parties.
Territory	Geographical area about which arrangements are made.
Upfront	A sum of money that needs to be paid upon signing the agreement. This can be used as compensation for historical (patent) costs but can also serve to establish the value of the agreement itself.