

Environmental RTDI Programme 2000–2006

Guide to Commercialisation of Environmental R&D Outputs

*A Manual for Researchers in Receipt of Environmental
Research and Development Funding*

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Prepared for the Environmental Protection Agency

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1 Introduction

The purpose of this guide is to inform and assist environmental researchers to understand the commercialisation process, and to ensure that outputs from their laboratories are appropriately managed through the process of commercialisation. It is particularly aimed at researchers funded by the Environmental Protection Agency.

It is fully accepted that commercial outputs are only a very small proportion of the useful outputs from environmental research. The major outputs are information to guide environmental management, define environmental standards, etc. However, some outputs are of a nature that requires that private industry becomes the mechanism to ensure their widespread usage. Typically they are technologies or products that require a manufacturing step. Relevant technologies include processes for waste removal, digestion, recycling or amelioration by other means, or for detection of specific pollutants or of positive environmental indicators.

Examples of products include recyclable materials, chemicals or devices that can be used to ameliorate pollution (e.g. filters, enzymes, etc.), or equipment to measure or modify pollution or waste (e.g. bio-digesters, etc.). While there are a wide variety of possible products, in this document these outputs will be collectively known as 'inventions'.

Commercial opportunities may arise in any form of research and the researchers involved should be aware of steps to be taken to ensure that these opportunities are assessed and acted upon.

Most of the researchers to which this guide will apply are within Irish Universities and Institutes of Technology. Most of these institutions have their own policies and processes already in place. This manual is not intended as an alternative to these processes. Indeed its major purpose is to ensure that these processes are used by the researcher in environmental fields.

2 Process Outline

A simple idealised pathway for successful commercialisation is that an invention arises within a research laboratory, is further investigated to validate its technological value, is assessed by technology transfer (TT) staff to assess its patentability and commercial relevance, and is then transferred under licence to an enterprise with the competence and resources to further develop the invention to the stage where it can be placed on the market. Clearly, most inventions will fail at one of these stages of assessment. Equally, the time, expertise and resources required to complete this path vary according to the nature of the technology. The process is essentially similar whether the invention is serendipitous or the purpose of the research.

In some research, a commercial end point may be determined in advance, or an industry funder and/or collaborator may already have an agreement on the use of the technology arising from the research. In this circumstance, the industry collaborator will usually be directly involved in determining the commercial value of the technology, and in establishing a license.

In practice, a 'candidate' invention must satisfy a lot of criteria on the path from the bench to the market, and those behind the invention must be prepared to provide significant assistance to the other personnel involved in taking the invention along the proper course.

The main reason for failure is that the invention simply does not have all of the characteristics required to be commercially viable. However, many valuable inventions

have failed to reach the market because one or more of those involved in the research or commercialisation process did not play their appropriate role at the right time.

The classical pitfalls in the commercialisation process include:

- failure of researchers to recognise useful developments, or to observe intellectual property protection practice
- the inability (for resource or other reasons) of the TT staff or others to properly protect or promote the technology, or
- the inability of the recipient company to complete the commercialisation process.

These pitfalls will be described in the following description of the process.

The commercialisation process can be simply broken down into five definable stages (1 and 2 may be reversed) (Fig. 2.1):

1. Recognise the opportunity
2. Assess the commercial value
3. Assess patentability
4. Develop a commercialisation strategy
5. Implement the strategy.

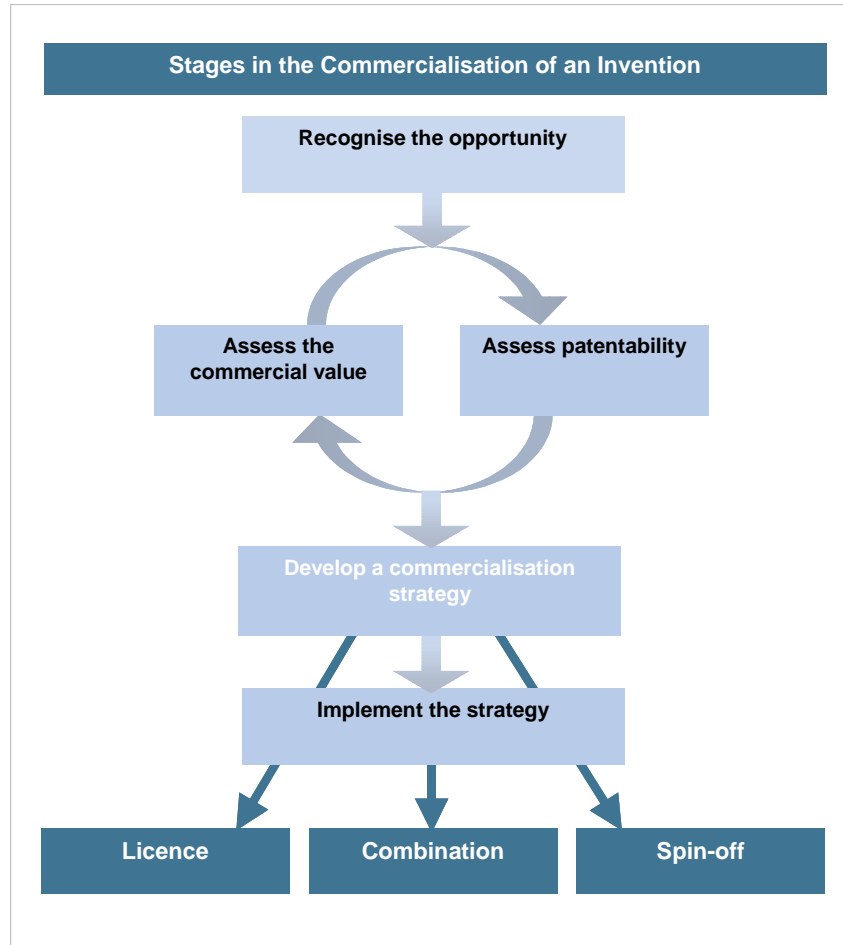


Figure 2.1. Stages in the commercialisation of an invention.

3 Recognise the Opportunity (Stage 1)

Summary

- Document research activities fully – it can be vital in proving ownership and patent status later.
- Be aware of the possibility of useful and patentable opportunities arising from research.
- Do not disclose any finding in any way until patentability has been assessed.
- Inform the TT staff within your institution – a disclosure form is usually available for this purpose.
- Be prepared to assist the TT staff in further assessment of an idea.

The commercialisation process generally starts in the laboratory with a development (planned or otherwise) that is regarded as being of potential commercial value. It is important that research staff are open to the possibility of commercialisable findings. Many valuable opportunities are lost because researchers fail to recognise the opportunity, or do not take appropriate action to ensure that they are fully assessed and protected. Louis Pasteur's observation that "*chance favours the prepared mind*" was never more apt than in the research laboratory. Researchers who are not mindful of their responsibility to seek potentially useful developments are very unlikely to do so.

Identifying useful research findings is not only of potential personal and national benefit, it is also a requirement for all institutions in receipt of State R&D funding. The range of such funding, and the agencies involved, are shown in Fig 3.1. Two Codes of Practice and a set of Guidelines¹ have been drawn up which define how institutions, and their staff, should handle this process.

For reasons which will be discussed later, proper recording of research is very important in the process of

1. Relevant Publications are:

1. *National Code of Practice for Managing Intellectual Property from Publicly Funded Research*. Forfás, January 2004.
2. *National Code of Practice for Managing Intellectual Property from Collaborative Research*. Forfás, November 2005.
3. *Funding Agency Requirements & Guidelines for Managing Research-Generated Intellectual Property*. Commercialisation Steering Group (of the Funding Agencies), February 2006.

patenting. Research notes should be kept in a Laboratory Notebook that must be:

- Bound with no loose pages
- Contain no replacement, deleted or inserted pages
- Each page must be numbered, signed, dated and witnessed
- Entries must be in ink and be consecutive.

Such laboratory notebooks are available within most research institutions.

If a patentable or otherwise useful finding is identified, the recommended process is that the researcher should disclose the finding to the TT² office within the research organisation. These staff are entirely dependent on researchers to disclose useful developments. Only then can they apply their skills to the assessment and exploitation of commercial opportunities.

These offices are a major conduit through which technologies developed within the colleges are transferred to industry. The TT office is usually informed by means of an Invention Disclosure Form. These forms will vary according to institutional policy and examples are usually available on college websites. Some will be very simple, while others require more detailed information.

2. Most Universities have dedicated TT or industrial liaison staff; within the Institutes of Technology, this support is usually associated with the Development Office.

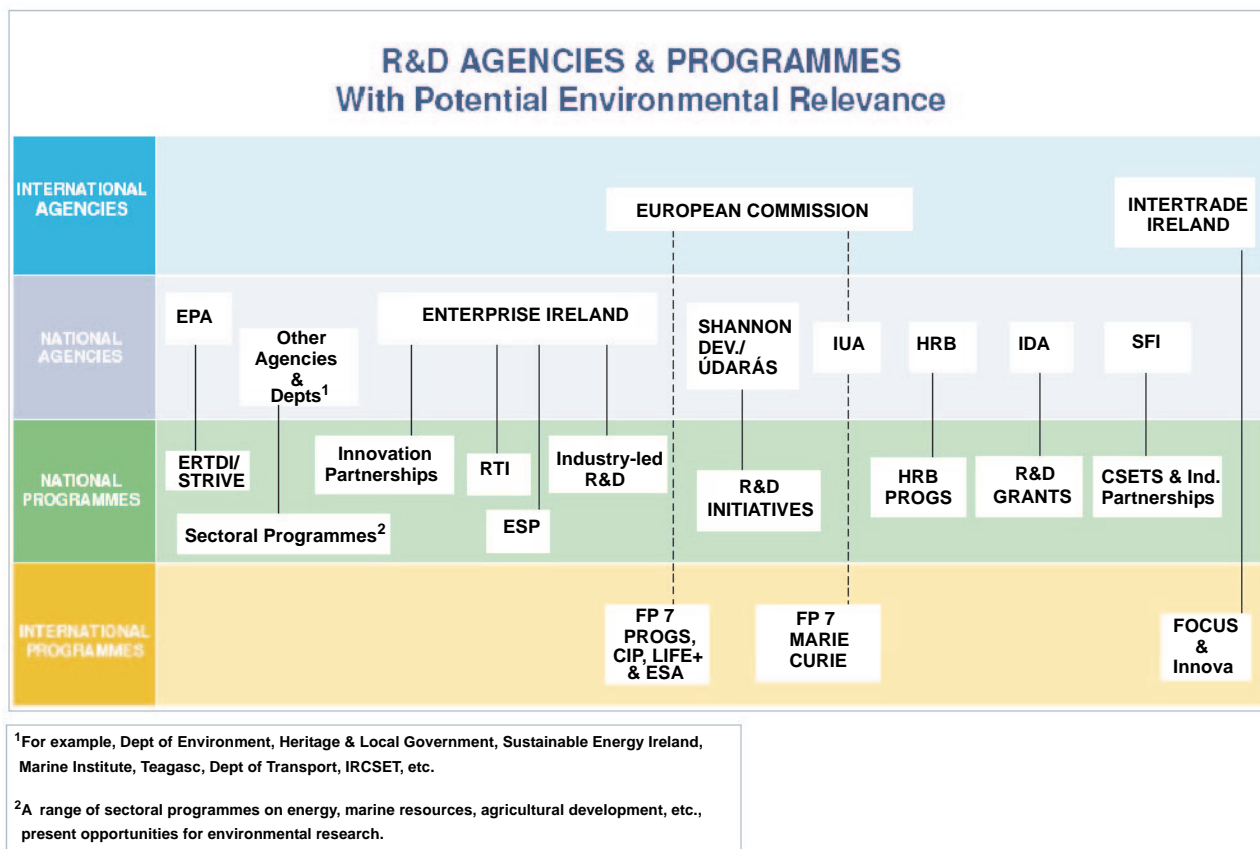


Figure 3.1. R&D agencies and programmes with potential environmental relevance.

The types of information sought may include:

- Nature of the invention and its technical significance
- Persons contributing to the development
- Date and place of invention and documentary and material evidence
- Source of funding for the research
- Any publications³ made or planned
- External collaborators involved and any existing agreements which involve sharing of materials or information.

This information will be of value at various stages in the commercialisation process. If the patent is successful and proves valuable, others will often seek to overturn the

3. Publication in the context of a patent submission can include a conversation, letter, e-mail, poster or any other means by which an external party may have been informed of the key elements of the invention.

patent on the basis of technical or legal details. As this is likely to be many years after the invention date, it is important to detail all of the information as soon as possible.

As will be evident from the description above, the first pitfall for a potentially commercialisable new invention is that the researchers involved will not recognise the opportunity. When researchers do become aware of opportunities, they must begin the process leading to patent protection on the technology.

A further basic requirement of researchers is that potentially patentable developments are kept confidential until after the patent submission has been made. This is discussed below in [Section 3.1](#).

3.1 Patenting vs Evaluation

After a disclosure has been made to the TT office, a decision must be taken as to whether to immediately submit a patent application, or to do further assessment

before deciding if a patent application is justified. Generally this will depend on the nature of the invention.

It may be clear from knowledge of the research field that the invention is novel and worth patenting. In other circumstances, this will not be so. Further evaluation may

therefore be justified. Stages 5 and 6 may be in reverse order depending on these circumstances.

A search for patents in the area of the invention may be done to ensure that the invention is not already the subject of a patent.

4 Assess the Commercial Value (Stage 2)

Summary

- **The major purpose in this phase is to assess whether the research finding has commercial value.**
- **This will determine whether patent status will be sought, and/or whether any effort will be devoted to promoting the technology.**
- **The originating research team will usually be involved in briefing the TT officer on the research field and the potential applications.**
- **The assessment will identify users, compare with competitor technologies, assess regulatory and safety issues, etc.**
- **A significant proportion of opportunities will fail at this stage.**

Commercial relevance and value of a new invention must now be assessed to determine whether the invention is worth pursuing further. The advantage of doing a pre-assessment is that the costs of patent submission can be avoided if it is established that there is no real commercial value in the technology. This will generally be done by the TT office, with strategic assistance from the researchers involved.

The researchers will usually give the TT staff an understanding of the invention so that they can better assess the likelihood that it might be of real commercial relevance. This involves an assessment of the cost, efficacy, and regulatory, environmental and competitive nature of the technology. On average, some 75% of inventions will be abandoned following assessment of their commercial value and patent status.

The kinds of questions to be asked in this process include:

- Who is the intended end-user for the invention?
- Can they afford it, and do they need it?
- Is it better than the product or process that they are using now (if there is a competitor product)?
- Who can manufacture it? If it is difficult to manufacture, this may limit the licensing possibilities to those with the capability to make it.

- Does it require specialist marketing or service supports?
- Are there regulatory issues (safety, environmental or otherwise) which might limit its use, or increase the costs required to put it on the market?
- Can it be manufactured less expensively, or with greater regulatory or other benefits, than existing products?

Very often some of these questions cannot be answered with certainty, as they require a more in-depth knowledge of manufacturing or market realities. If the product has been patented in advance, it is possible to present the idea to industry insiders and obtain a more informed view.

Many inventions fail at this stage because they are more costly or less effective than existing technologies, or because there are attendant issues of safety, user-friendliness or manufacturability which would make them unlikely to succeed. This will usually result in a decision not to proceed with the commercialisation process.

However, if the commercial opportunity withstands this scrutiny, the next step will be to assess patentability (noting that this process sometimes precedes the commercial assessment).

5 Assess Patentability (Stage 3)

Summary⁴

- **This stage will assess whether the invention is patentable, i.e. is it:**
 - **Novel (there must be no prior public disclosure by any means)**
 - **Useful – it must have a defined utility**
 - **Non-obvious to one skilled in the art**
- **Prior disclosure (often by the inventors) is a major reason for failure of patents, while it may also be previously patented.**
- **Be prepared to co-operate with the TT officer and patent agent in writing the patent submission.**

Presuming that a commercial value is shown, a decision to pursue a patent will probably be made. If a patent application has already been made, then the decision will be whether to maintain the patent application or to let it lapse.

A patent is effectively the 'deeds' of the invention in that it confers ownership of the invention to the patent holder for a period. As a general rule, any invention that requires further investment in its development prior to marketing will require patent protection. Highly regulated products such as pharmaceuticals, biologics, chemicals and many devices require significant investment to (a) generate the data required to obtain market approval from regulatory authorities, and (b) develop the manufacturing process and final product formulation.

Few companies, and no investors, will be prepared to make the major investment required without protection on their return. A patent will provide this protection and is therefore very important. In some sectors, e.g. software, patents are of less concern simply because the useful life of a new software element is very short and patents are designed for long-term protection.

Assessing patentability is essentially a process of establishing whether a patent already exists, or whether the concept is already publicly known. To be patentable, an invention must be novel and also have a purpose.

4. Note that Stage 3 may precede Stage 2 if the need to submit a patent is clear.

Assessment of the patentability of a new invention is generally conducted with the support of a patent agent. A patent agent acts on behalf of an applicant in drafting a patent application, and in taking it through the various stages needed to grant the patent. He/she will usually have a technical background and also be expert in patent law and procedure. It is usual to seek a patent agent with competence in the technical area of the invention.

To assess patentability, a detailed description of the invention will be provided to the patent agent by the researchers who originated the idea. This will also include the 'claims' that are felt valid for the technology. In other words, what are the unique things that the invention can do? These claims and the underlying invention are used to conduct searches of:

- a. the patent literature to establish if there is an existing or expired patent, or an existing patent submission which is essentially equivalent, and
- b. the published literature to establish whether the idea has already been disclosed.

The outcome of these searches may mean that the claims are modified because it is found that some elements of the invention have already been patented. There may also be territorial differences. EU and US patent law differs in certain respects, so that it may be possible to patent in the EU and not in the USA, or *vice versa*.

Making and maintaining patent submissions is a significant cost issue for research organisations. The

elements of these costs are the fees for the patent agents in preparing and advancing the submission, and the fees to patent offices. The patent agent's fees will be dependent on the extent of the search required, and of the time required to address the issues that arise in the course of examination of the claim.

The patent will not be granted for up to 7 years, but the submission will nevertheless provide effective protection as no later claim for the same invention can be accepted by a patent office.

There are situations where patent protection is less important. If the unique nature of the invention can be protected by confidentiality, that is an option. Some processes may fall into this category.

If the market opportunity is likely to be short-lived (e.g. software), then a 'first-to-market' strategy combined with strong marketing and branding may be an option. These options are unusual, however, and patent protection is the desirable option in most cases.

A common pitfall in the patent process is that the researchers will publish the patentable concept before the patent application is made. A fundamental requirement for patent status is novelty. If the idea is in the public domain before submission of a patent application, a patent cannot be granted. Many patent opportunities are lost because researchers choose to publish their work before patent submission. The disclosure may also be inadvertent.

A common misconception among researchers is that 'publication' can only take place through a formal paper in a scientific journal. In reality, publication of a discovery can occur by means of a poster or abstract, an e-mail, or even a conversation with an external party. Maintaining the confidentiality of an invention until after a patent submission has been made is therefore vital.

A further misconception is that publishing and patenting are mutually incompatible. After a patent submission has been made, the invention may be published. Indeed, such a publication may be useful in promoting the invention at later stages.

6 Develop and Implement a Commercialisation Strategy (Stages 4 & 5)

Summary

- **The options for commercialisation are: (a) licensing to an existing company, and (b) establishment of a spin-off company, or possibly some combination thereof.**
- **Spin-offs will only be feasible in about 10% of inventions.**
- **Researchers will be involved in promoting the invention to licensees, and very commonly in the development of spin-offs.**

A decision must now be made as to how to exploit the technology, and the research team is commonly involved in this process.

The options for the college therefore are:

- Licence the invention to an existing company.
- Support formation of a spin-off company to exploit the technology.
- A combination of these two – for different applications or territories.

6.1 Licence the Invention to an Existing Company

The most likely route of commercialisation is to transfer the rights to one or more commercial entities that have the expertise and facilities to put the product on the market. Colleges will, however, usually reserve the rights to use their invention for the purposes of further research.

For instance, if the invention is a single component or material, it may be sensible to transfer it to a company that markets a full range of similar components or materials to the same market. Equally, if the invention requires specialised manufacturing, it will make sense to license it to a company that has the required process capabilities.

If there are many companies with a potential interest in the technology, decisions may be required as to which of the companies to prioritise. Some universities may have a policy of support for local or national industry and therefore make first approaches to these companies.

Others may adopt an approach of obtaining the best commercial deal. The invention owner (usually the university in the Irish context) must therefore decide on the strategy to adopt before proceeding.

When this decision has been made, an information package on the invention is prepared. This is generally a one-page synopsis of the technology on offer including:

- Full description of the technology on offer
- Potential applications
- Information on the research team originating the technology
- Any scientific publications
- Patent status.

This synopsis is used to promote the invention to target companies. Target companies will be identified and approached with information on the technology. This will usually be done by TT staff by phone or e-mail.

If there is interest from a potential licensee, the research leaders will usually be involved in discussions during the process of 'selling' the invention and of agreeing a license.

A license is simply an agreement with a company under which they obtain rights to exploit the technology, and the invention owner receives one or more forms of payment. These payments may include an up-front fee at the start of an agreement, royalties based on the sales of the product or service, milestone fees based on achievement of defined technical targets, etc. R&D institutions may

also seek R&D funding (see Fig. 3.1) for further development of the research which led to the technology. The rights obtained by the company may be worldwide exclusive rights to all applications, or they may be non-exclusive, restricted to a specific territory (EU, USA, Asia, etc.) or to a specific application of the technology.

Within every university, there is a process under which the researchers will receive a proportion of income from such licensing. There is therefore a reward system for researchers.

6.2 Formation of a Spin-Off Company

Formation of a spin-off company is not suitable for all technologies. Formation of a company to make a single product, for instance, is not often advisable. Many technologies are only relevant when combined with other technologies to create a new component. In the engineering industry, for instance, new equipment will often involve 'bundling' of many inventions (materials, software and processes) into components within the final product. Nevertheless, there are inventions that are suitable as the basis of a spin-off, and Irish colleges have been actively involved in encouraging their creation.

In the creation of a spin-off company, the management team is arguably more important than the technology.

Formation of a spin-off will therefore require that some individual or team has an interest to go this route. A member of the research team that originated the invention is often involved in such a team.

If this route is chosen, there are significant supports available from Enterprise Ireland (EI) for high-potential start-ups (HPSUs)⁵ which are defined as companies that are:

- Based on technological innovation
- Likely to achieve significant growth in 3 years (sales of €1.0 m per annum and employment of 10 or more)
- Export oriented
- Ideally led by an experienced team with a mixture of technical and commercial competencies.

The EI support package can be seen as a continuum from R&D grants for research in developing the underpinning technology to feasibility and commercialisation grants for the stages in defining company business plans, grants for start-up creation, and further grants for different growth stages.

5. See: www.enterprise-ireland.com/CommonPages/High_Potential_Start_Ups.htm

7 Concluding Remarks

In practice, only a minority of inventions are licensed, and only a minority of these receive a significant level of

funding. An estimated breakdown of the fate of invention disclosures is shown in Fig. 7.1.

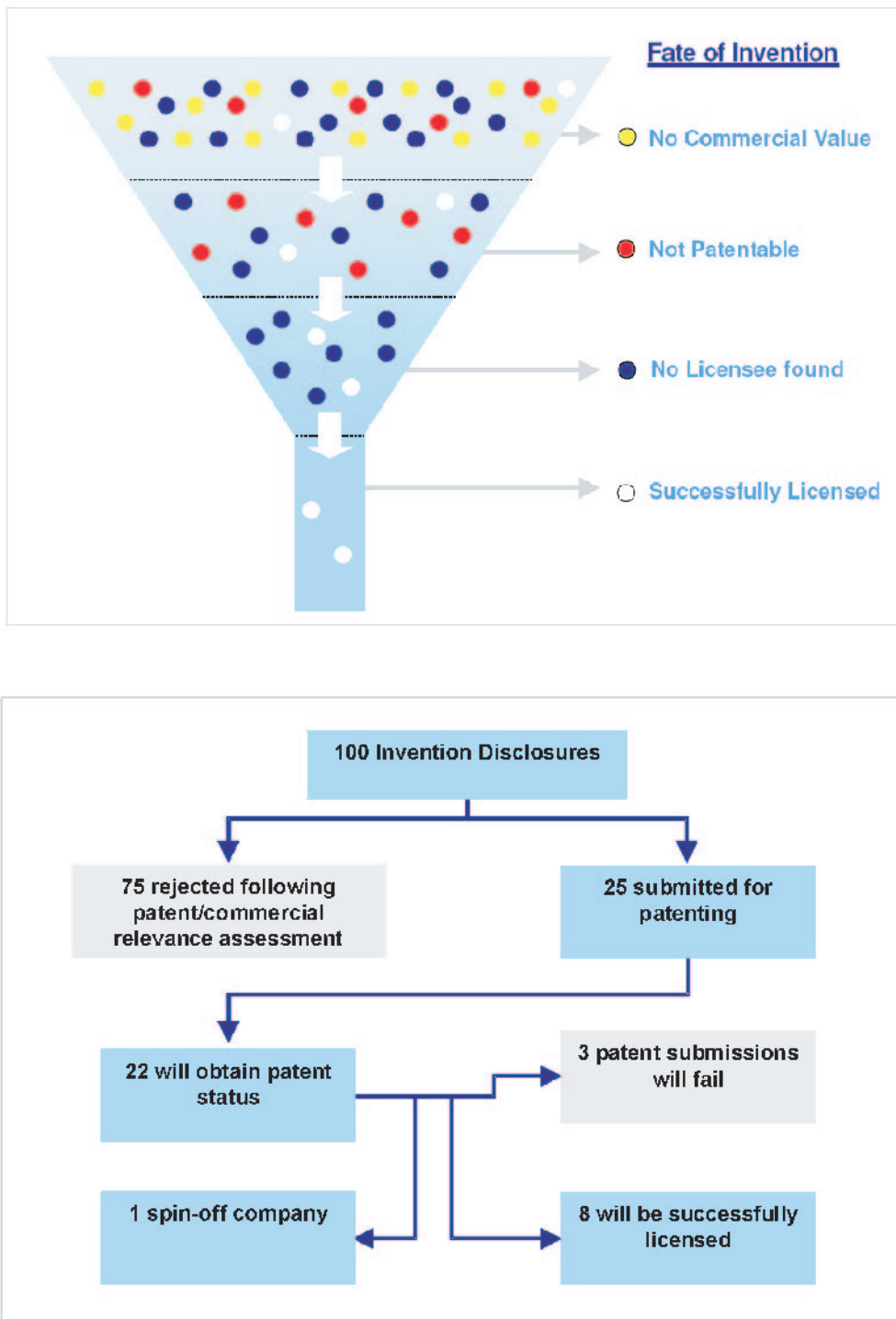


Figure 7.1. What happens to inventions.