

The road from conception of an invention to commercialization of the technology (II): Timing, preparation, and execution

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Lunes de patentes

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BUSINESS
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Large companies most often generate value by using patents to exclude others

Major exceptions include mobile telephone and other consumer electronics industry

In contrast hereto universities, public research institutions, as well as small and medium-sized companies, generate value through technology transfer, including out-licensing

This is the perspective I will take today, and the presentation will focus on the life sciences

Licensing is not straightforward, chances are that you will be dealing with experienced licensing executives

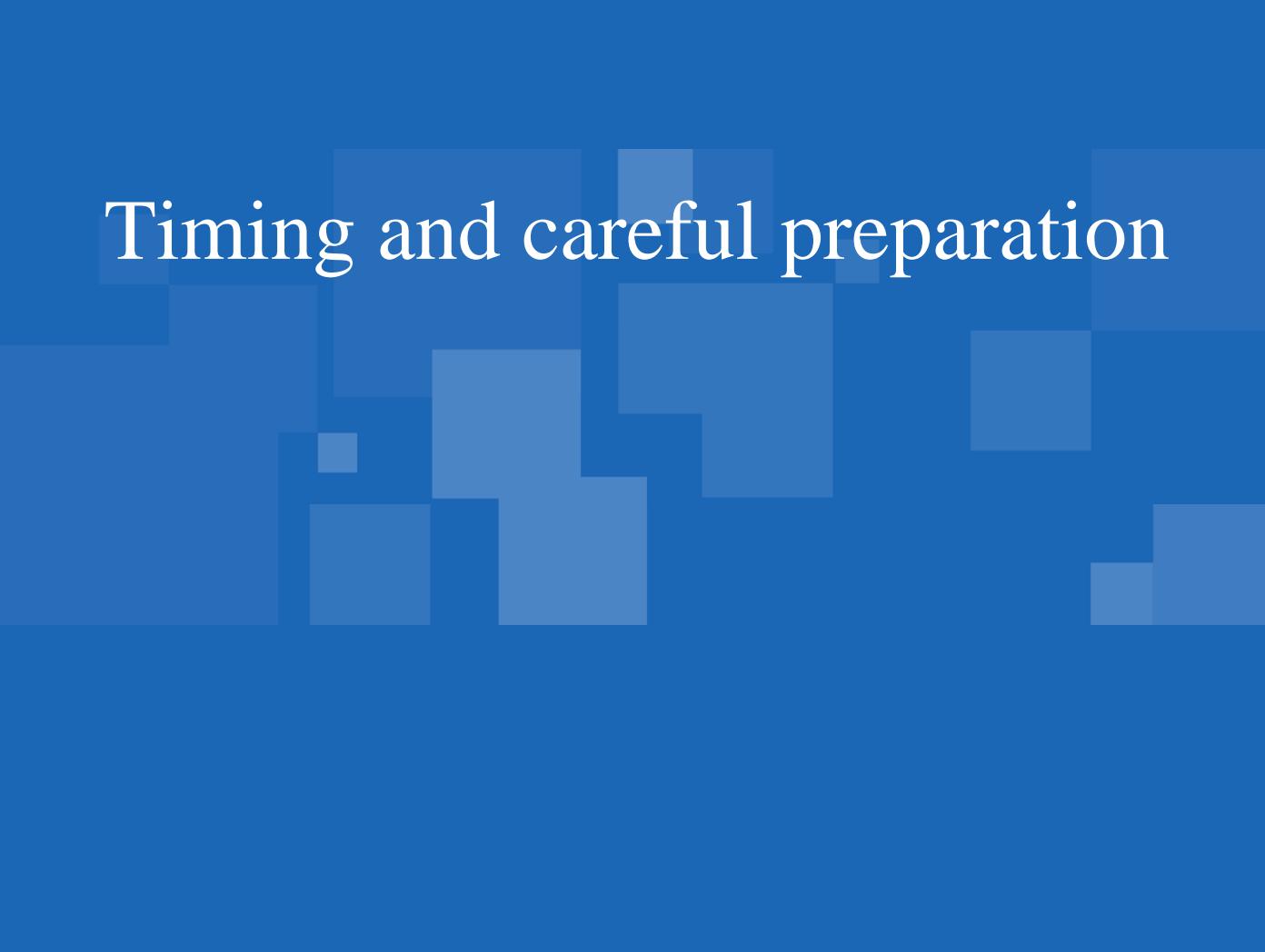
If you are not experienced in the process, seek professional advise

Several companies offer this service

If you who want to embark on out-licensing on your own, I will try to share some of my experience and provide you with some basic advise in the following

Overview

- Timing and preparation
- How and whom to contact
- How to structure the deal
- Valuation of the technology
- Cultural differences



Timing and careful preparation

Choose your approach

It may be tempting to send out a hailstorm of e-mails to companies you think should be interested in your technology

This is not an approach we can recommend, and it is certainly not the way we operate when we work for our clients

Chances are that your e-mail will not hit the right people or receive very little attention (except “✉”)

Instead:

Plan carefully and be selective when making the first contacts

Why ?

Because exclusivity is always an important consideration

In a subsequent discussion with a potential licensee, the question about exclusivity will come up

If the potential licensee is interested in exclusivity, they will ask the question:

Have you been in contact with many other companies ?

Answer:

- a)We have sent out 500 e-mails, or
- b)We have been selective

Timing

When is the right time to out-license your technology ?

Most deals are made at the early stages, e.g. at the level of Discovery/IND prep/Pre-IND submission

From Phase 1 to Phase 3 relatively few deals are made

After approval/launch deal activity increases again (territorial ?)

In general the value of up-front payments will increase with the stage of development of the technology

Remember

As soon as you start contacting potential licensees, you actually open the negotiation about price on the basis of the current stage of development of your technology

Value of the technology will most often increase over time along with maturation of the technology

But sometimes you cannot or will not wait

From surveys we know that 61 % of the reported deals were preclinical stage (Discovery, Pre-IND/IND filed or Pre-IDE)

Source: "LES Global Life Sciences" Royalty Rates and Deal Terms Survey - 2014".

An example

Your technology is early stage but for various reasons you want to find a commercial partner

Perhaps you want to partner with a large company with experience in conducting clinical trials

Perhaps the technology has wide applications beyond the type of business

You can publish or speak at conferences to gain attention for the technology (after the patent application has published)

CRISPR/Cas system

Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR)

In 2006 researchers had made the first experimental demonstration of CRISPR/Cas mediated acquired virus resistance in prokaryotes

Reason to believe that this had wide applications in other fields

International patent application WO 2007/025097A2 (Use of one or more cas genes for modulating resistance in a cell against a target nucleic acid or a transcription product thereof) was published on 1 March 2007

The publication "CRISPR provides acquired resistance against viruses in prokaryotes (Barrangou, R. et al. 2007) was published on 23 March 2007

Science 23 March 2007: Vol. 315, Issue 5819, pp 1709-1712

How and whom to contact

Identify potential licensees

Loads of information can be found on the internet

If you cannot afford the detailed market surveys and forecasts offered by various consultancy companies

Then look for other sources. Often quite detailed information about market share etc. can be found for free

Use patent databases, patent classification codes

Search for scientific publications



Next step

When you have identified potential prospective licensees, find out as much as you can about the companies' plans

- Growth plans, field they operate in (or want to expand into)
- Decision making, e.g. centrally or in business divisions (especially important with large companies)
- Open innovation
- Partnering section in parent company
- Do they own venture companies
- Timing of fiscal year
- Cash flow, e.g. recent divestments

Prepare your case

Collect all the data and corroborating evidence you may need to present a convincing case

The more organized you are, the more likely the licensee is to think that you are in discussion with other parties as well

Perform a thorough due diligence of your case

Prepare and have a term sheet ready

Analyze the value chain

This may be straightforward if your technology is a new compound, but perhaps not so obvious if it is a device, a diagnostic technology, a new platform technology etc.

Find out where the technology can generate most value

Food industry example



Consider using an intermediary

Many in-house licensing executives will decline request made directly by the inventors

Company policy in some companies.
If they do accept to speak, they will often be skeptic and consider the inventors to be overly biased towards the benefits of the technology.

Note: The inventors may play an important role at a later stage, as discussed later

**Does your laptop keep running out of power?
No longer! Use the natural power of your own laptop to recharge itself!**



The Hedgehog From Hell Industries

From <http://physics.stackexchange.com>

An intermediary will often have a network of people to contact

Even if they don't, they know how to prepare documentation to make a credible first presentation of the technology

The chance of success increases significantly if the technology has been assessed by and is offered through a professional intermediary

Finally, an intermediary will likely be able to negotiate a better deal than you can obtain on your own

How to structure the deal

Deal structure elements

- Exclusive vs. non-exclusive
- Territory
- Up-front payments
- Running royalties
- Milestone payments
- Royalty rates stepwise increased/decreased
- Fixed annual royalty payment
- Minimum royalty
- Deductible initial payments
- Royalty stacking deductions

It all depends on your case

From surveys we know that

- 80 % of all deals were exclusive
- Nearly 70 % of deals were world-wide
- Up-front payments increase with stage of development
- Nearly two thirds (64 %) had flat royalty rates
- Tiered royalty (17 %); No royalty (19 %) – common for diagnostics
- Three tiers were most common – related high potential revenue
- Less than 25 % involved co-sharing of rights

Source: "LES Global Life Sciences" Royalty Rates and Deal Terms Survey - 2014".

There is no fixed standard

But there are databases with information about:

- Average size of up-front payment, R&D funding
- Common milestones, development, sales
- Average royalty rates for different sectors/different technologies, trends in royalty rates, etc.

Be well prepared. Your prospective licensee is often represented by a licensing executive (with access to the same information)

Valuation or financial modelling

Patent Valuation Methods

No "Super Formula"

and no single generally accepted method exists

One or more of the following methods are often used:

- Cost based Methods (Historical costs)
- Market based Methods (Market conditions)
- Income based, i.e. on projected cashflows (Future value)
- Time, Discounted Cashflow (DCF), Net Present Value (NPV)
- Uncertainty, DCF taking cashflow risks into account
- Flexibility, DCF with Decision Tree Analysis (DTA)
- Changing Risk, methods based on Option Pricing Theory

Other methods: Circumvention costs, analogy methods, relief from royalty, multiperiod excess earning, incremental cashflow, internal rate of return, rNPV, peak revenue, comparables etc.

Financial modelling is not a must

From surveys we know that

- Less than than 50 % of the deals involved financial modelling
- In the US financial modelling appear to be less common than in Europe and Asia/Pacific
- The licensee is more likely to model the deal value than the licensor
- Financial modelling much more frequent in the pharma industry than in general biotech
- Large companies (USD 250 M+ revenue) appear to model more frequently than companies with revenue below USD 250 M
- Likelihood of financial modelling increases stage of development (close to 100 % for approved/launched pharma products)

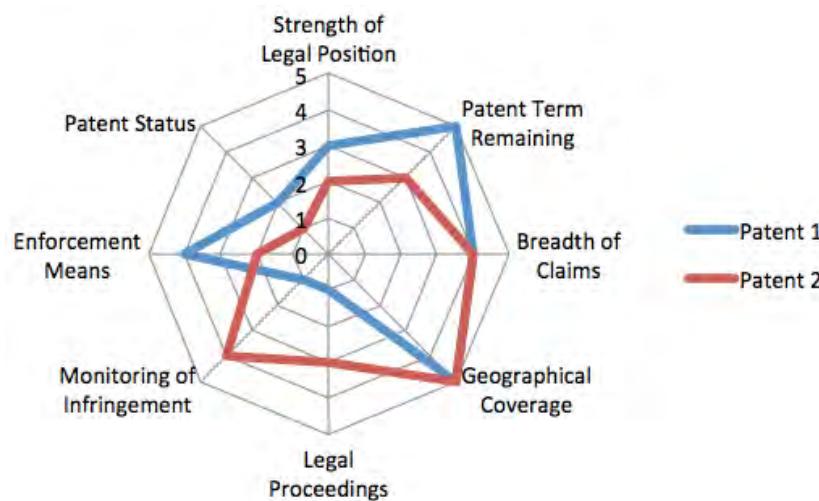
Source: "LES Global Life Sciences" Royalty Rates and Deal Terms Survey - 2014".

Patent Value Indicators

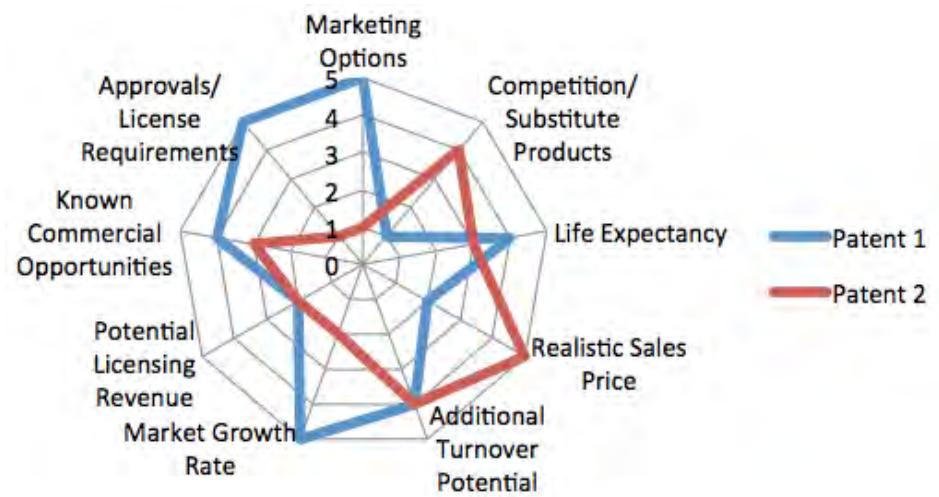
- Legal Status (e.g. pending or granted; unitary or national)
- Number of Opponents; Opposition/Litigation proof
- Geographical coverage (how many and which countries)
- Scope of Protection (product claims, IPC classes)
- Organisation behind (willingness and capability to prosecute and defend)

Legal status and market value indicators using IPscore® 2.2

Legal Status

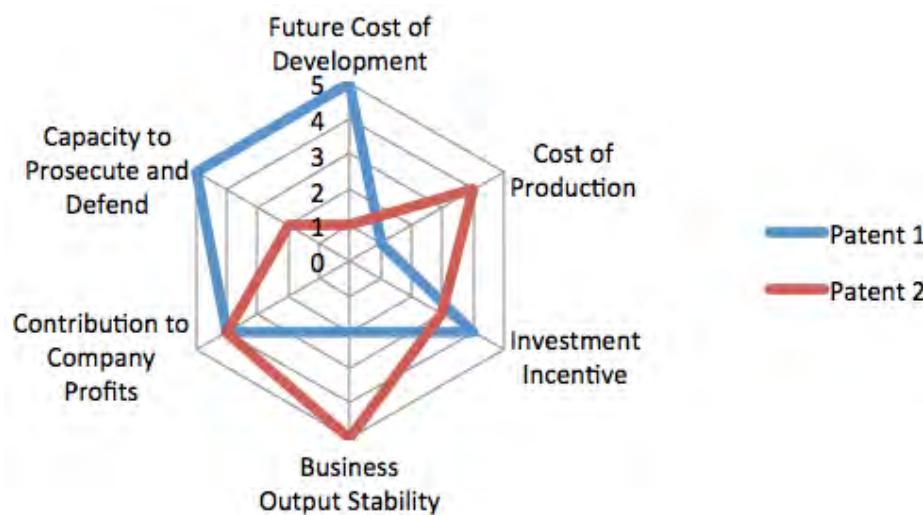


Market Conditions

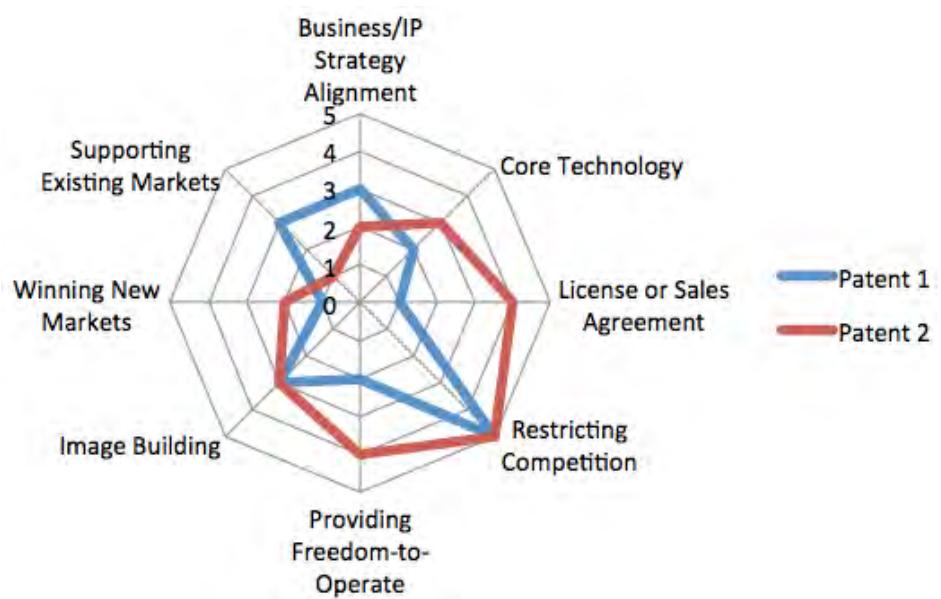


Financial and strategic value indicators using IPscore® 2.2

Financial profile



Strategic profile



You have contacted a number of
companies

You have prepared well and
you believe they should
be interested in your technology

But they say: NO THANKS

**Don't despair, several factors may be in play, but
it is quite likely that you have run into the Not-Invented-Here
(NIH-syndrome)**

**Many large companies like IBM, Eli Lilly and Proctor & Gamble
have experienced with open innovation**

**Proctor & Gamble developed the connect and develop
innovation model (C&D) and the term “Proudly-Found-
Elsewhere” (PFE) was born.**

**Unfortunately, many companies have still not replaced NIH
with PFE**

So what can you do ?

The best thing you can do is to try to find an “ally” inside the company that you are in discussion with

There are several ways of achieving this, but one that I have often used successfully is to find an “ambassador”

An example

New technology (at the time) known as “Positive selection”

Selection without anti-biotic markers (e.g. kanamycin resistance) for genetically transformed plant cells

Contact had been established with major players in the field

I knew the technology was in fierce competition with other technologies developed in-house



The “ambassador”

We offered to give a scientific presentation to the staff scientists at their research location

One of our inventors gave a presentation and during the subsequent discussion, we tried to spot a person who was active in the discussion, and appeared to have a favourable view on our technology

We had found an “ambassador”

For all subsequent exchange of technical information the ambassador became the contact person

... and eventually the deal went through

Not all fairy tales have a happy ending

On one occasion, I negotiated a deal on behalf of a client

It was late in the year and the business development division (with whom we negotiated) was very eager to close the deal

We had agreed on up-front and other payments, and the business division had the money in their budget

Unfortunately, the company had a centralized corporate legal function in a different country

Despite massive pressure from the business division the legal counsel could not find time to review and sign off on the agreement before the end of the year – the deal fell

Cultural differences

Cultural differences are diminishing



- but they should not be ignored

The language problem may be the least of your problems



Patience may be needed

License deal with a Japanese company
about 1.200 km south of Tokyo

Subject:
Anhydrofructose technology
1,5-anhydro-D-fructose (AF)



From J. Agric. Food Chem., 2005, 53 (24), pp 9491–9497



From Google Maps/Google Earth

It took nearly thirty (30) months
from the first contact till the
license agreement was signed

The road to commercialization is a long and bumpy road with plenty of pitfalls

If you are not experienced in the process, seek professional advise

Several companies offer this service, and often they will create more value than the professional fee they charge

Thank you for your attention



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