

Licensing and Technology Transfer in the Pharmaceutical Industry¹

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1. LICENSING & TECHNOLOGY TRANSFER

1.1 What is technology transfer?

Technology transfer is the process by which a developer of technology makes its technology available to a commercial partner that will exploit the technology.

There may be many reasons why a developer of the technology might consider making its technology available to another person to exploit, instead of exploiting the technology itself. Some of these are:

- Forming alliances with partners that can progress the development of the technology to take it to market.

The developer of the technology might have the resources to take the technology to a particular state of development, such as up to animal studies and toxicology studies, but does not have the resources to take the technology through its clinical and regulatory phases, and must partner with another organisation to take it through these phases, and into the market.

- Forming alliances with partners with manufacturing capability.

The developer of the technology may have taken the technology to a state of development so that it is near market ready, but does not have the clean room manufacturing capability or resources to manufacture the product, and must partner with another organisation that does have that capability.

- Forming alliances with partners with marketing and distribution capability.

The developer of the technology may have fully developed the technology, and even have obtained regulatory approvals and product registrations for the product to be sold, but it lacks the marketing and distribution channels to give it a marketing capability, and must partner with another organisation that does have that capability.

- Exploitation in a different field of application.

The developer of the technology might be capable of exploiting the technology in one field, such as diagnostic applications, but might not have the capability to exploit in another field, such as therapeutic applications.

The developer of the technology may pursue exploiting the technology itself in the field of diagnostic applications, and may grant exploitation rights to a commercial partner for the exploitation of therapeutic applications.

By transferring the technology for use in another field of application to another person, the developer of the technology creates another income stream from the exploitation that takes place in that other field.

- No commercial capability.

The developer of the technology may be a research institute or a university which does not have the capability to exploit commercially at all, and needs to partner with another organisation that does have that capability.

In each of these cases, the developer of the technology or owner has decided that it may not have the capability or resources to take its technology further, and has decided to partner with another person that can do so.

In the exploitation of pharmaceutical products, technology transfer by partnering in this way to bring a pharmaceutical product to market is a common feature of the industry.

1.2 How does technology transfer take place?

Technology transfer in this way takes place by creating legal relationships by which:

1. the owner of technology, or
2. the holder of licensed rights to exploit the technology

grants new rights of exploitation to the technology transfer partner.

These legal relationships are contractual in nature.

This means that legal agreements are entered into by which:

1. the right to exploit the technology is granted by the technology owner or rights holder, to the technology transfer partner that will exploit the technology
2. the technology owner or rights holder is compensated, usually financially, for the grant of those rights, and
3. the respective rights duties and obligations of the parties that will govern their legal relationship are set out.

1.3 What the main contractual agreements by which technology transfer takes place?

The principal mechanisms by which technology transfer takes place in the pharmaceutical industry, and the types of legal agreements used to record these mechanism are:

1. Confidentiality Agreement

A Confidentiality Agreement regulates the terms of disclose of confidential information by one person to another.

Confidentiality Agreements are further discussed in section 2.

2. Material Transfer Agreement

A Material Transfer Agreement regulates the terms upon which biological material is provided by one person to another.

A Material Transfer Agreement has similarities to a Confidentiality Agreement.

Material Transfer Agreements are discussed further in section 3.

3. Deed of Assignment

By a deed of assignment the technology owner transfers or assigns the technology owner's intellectual property.

The technology owner by the assignment ceases to own the intellectual property, and it becomes owned by the assignee.

The technology owner in this way is divested of all ownership of the intellectual property, and along with that, is divested of all future interest in the intellectual property.

The assignee of the intellectual property becomes the owner of the intellectual property.

Financial compensation is paid to the former owner.

Deeds of Assignment are further described in section 4.

4. License Agreement

By a license agreement the technology owner or rights holder grants a license, or a permission to use, the intellectual property, to the licensee.

The licensee by the terms of the license is permitted to exploit the intellectual property.

The licensee financially compensates the licensor for the use of the rights granted by the license.

Generally, the licensor is passive in this legal relationship.

The licensor does not necessarily further develop the intellectual property, nor participates in its marketing, but passively receives the financial compensation for having granted the license.

License Agreements are further described in section 5.

5. Strategic alliance or joint venture.

In a strategic alliance or joint venture the owner or rights holder of the intellectual property partners strategically with another organisation for the development and exploitation of the intellectual property.

The types of legal agreements to record such strategic alliances are:

(a) Co-Development Agreement

In a Co-Development Agreement the intellectual property is typically licensed by the licensor to the alliance partner, and as well, the two partners together jointly undertake the further development of the intellectual property.

In this way the licensor seeks to continue to add value to the development of the intellectual property, beyond just granting a license.

By continuing to add value in this way, the licensor is entitled to greater financial remuneration, than if the licensor had passively granted a license and not contributed further to the development of the intellectual property.

(b) Co-Marketing Agreement

In a Co-Marketing Agreement the intellectual property is similarly licensed by the licensor to the alliance partner, but additionally, they partner together to jointly market the pharmaceutical products developed from the intellectual property.

A licensor in this case adds value in a different way to a Co-Development Agreement. Value adding here occurs by the alliance partners together accessing their respective marketing networks and resources to jointly take a pharmaceutical product to market.

Co-Development and Co-Marketing Agreements are further described in section 6.

RESOURCES

The **World Intellectual Property Organisation** has an extensive website with a wealth of information about intellectual property and technology transfer at <http://www.wipo.int/index.html.en>

The **National Institutes of Health** has an excellent technology transfer training site which provides introductory on line web based training on aspects of technology transfer. It does focus upon NIH processes, but nevertheless provides a good introduction. The on line training can be accessed at <http://ttraining.od.nih.gov/>

The **Technology Transfer Desk Reference** was published by the United States Federal Laboratory Consortium for Technology Transfer in April 2004. It is an excellent introduction to technology transfer, from the perspective of US Federal Labs. It is available at http://www.federallabs.org/ContentObjects/Publications/T2_Desk_Reference.pdf

The **Biotechnology Industry Organisation** has a good on line primer on intellectual property, particularly patents, and aspects of technology transfer at <http://www.bio.org/ip/primer/main.asp>

2. CONFIDENTIALITY AGREEMENTS

2.1 What is a confidentiality agreement?

A confidentiality agreement is a legally binding agreement between a discloser of confidential information, and a recipient of confidential information, and deals with the terms upon which the confidential information is disclosed.

Confidentiality agreements may be called other names, such as Non Disclosure Agreements, Confidentiality Deeds, Mutual Disclosure Agreement, Secrecy Agreement, and other similar names.

2.2 What is confidential information?

Confidential information is information which is not in the public domain.

It may by way of example include a compound, a small molecule, a target, a protein, a gene sequence, a genetic structure, or any other type of invention or discovery.

Confidential information is not necessarily limited to information that relates to technology. It may also include business and financial and marketing information and strategies.

2.3 Why does confidential information need to be protected?

As confidential information is known by the discloser, and perhaps by no one else, it has a special and unique value.

The confidential information may relate to patentable subject matter and may be intended to be the subject of a patent application.

A patent can only be granted over patentable subject matter that is novel, and this means that it must be outside the public domain as at the priority date of the patent.

If confidential information was disclosed without a confidentiality agreement, the disclosure would put it into the public domain, and as a result, adversely affect its novelty, and put at risk the success of the patent application.

A confidentiality agreement is therefore critical to preserve the patentability of new intellectual property.

Some confidential information may be intended not to be included in a patent application. It may be intended that it be retained as a trade secret, and protected by secrecy, instead of by a patent. For example, a patent may

protect a compound, but manufacturing and production processes may be intentionally retained as a trade secret.

Where that is so it is critical that the confidential information be protected by a confidentiality agreement if it has to be disclosed.

2.4 Why are the common terms of a confidentiality agreement?

The common terms of a confidentiality agreement are:

1. Secrecy

That the recipient of the confidential information maintain its secrecy, and not disclose it to any other person without the discloser's prior written consent.

2. Use for permitted purpose

A confidentiality agreement typically identifies the permitted use or purpose to which the recipient can put the confidential information.

For example, the confidentiality agreement may state that the recipient may use the confidential information for evaluation or testing purposes.

The permitted purpose or use will be the only use to which the recipient can put the confidential information, and the confidentiality agreement will prohibit the recipient putting the confidential information to any other use or purpose.

3. Ending of obligations of confidentiality

Typically a confidentiality agreement will provide that the obligations of confidentiality come to an end in each of the following events:

- the confidential information enters the public domain
- the recipient receives the confidential information from another person entitled to disclose it, without any obligation of confidentiality
- the recipient can demonstrate it was independently developed by the recipient, by employees who did not have access to the confidential information.

4. Duration of obligations of confidentiality

In some industries it is not unusual for confidentiality agreements to state that the obligations in the agreement continue indefinitely, until one of the events set out above occurs.

This is particularly important where the confidential information is a trade secret that is intentionally sought to remain as a trade secret, and intentionally not to be made the subject of a patent application.

However, in the biotechnology sector, it is common practice for the obligations in a confidentiality agreement to automatically end after an agreed period, often five to seven years.

The justification sometimes given for this arbitrary period bringing obligations of confidentiality to an end is that the rate of change of the science is so fast, and at such a pace, that if the discloser has not sought patent protection within the agreed period, then the recipient should be relieved of the burden of having to continue to be mindful of confidentiality agreements entered into in excess of 5 years previously.

The practical result of this convention of obligations of confidentiality lasting five years only is that disclosures in the biotechnology sector, even where there is a confidentiality agreement, should be confined to patentable subject matter, and should not extend to trade secrets in respect to which no patent is ever intended.

5. One way and Two Way agreements

A confidentiality agreement may be a one way agreement or a two way agreement.

A one way agreement is where one party discloses confidential information, and the other party receives confidential information.

A two way agreement is one where each party is a discloser, and each party is a recipient in relation to the other's disclosure.

RESOURCES

Disclosing Confidential Information by V Irish,
http://www.wipo.int/sme/en/documents/disclosing_inf.htm

Understanding Confidentiality Agreements by D V Radack
<http://www.tms.org/pubs/journals/JOM/matters/matters-9405.html>

Confidentiality Agreement by Bitlaw <http://www.bitlaw.com/forms/nda.html>

3. MATERIAL TRANSFER AGREEMENTS

3.1 What is a material transfer agreement?

A material transfer agreement is an agreement that concerns the transfer of possession of biological material from one person to another.

The type of biological material with which a material transfer agreement may be concerned may include compounds, cell lines, vectors, proteins, viruses, animal models, genetic material, etc.

3.2 Why protect biological material?

The biological material with which a material transfer agreement is concerned will ordinarily encompass or embody intellectual property, and that intellectual property needs to be protected.

Just as the disclosure of confidential information can affect novelty and put at risk the patentability of intellectual property, so also the transfer of possession of biological material without the restrictions and obligations customarily dealt with in a material transfer agreement will do the same.

Additionally, the material itself needs to be protected, and who has possession also needs to be restricted, again, to protect the commercial value of the material.

3.3 Is a confidentiality agreement needed as well?

It is common for biological material to be provided, along with confidential information that relates to it.

For that reason, a material transfer agreement will customarily make provision for confidential information in the way described above, as well as make provision in relation to the biological material.

3.4 What are the common terms of a material transfer agreement?

The common terms of a material transfer agreement are:

1. Restriction on parting with possession

That the recipient will not part with possession of the material, nor any progeny or derivatives, without the prior written consent of the provider of the material.

2. Permitted purpose

That the recipient may use the biological material for the permitted purpose, and may not use it for any other purpose.

The permitted purpose would be defined in the manner agreed, such as to conduct certain specifically identified experiments, or, more broadly, to evaluate the material preparatory to exploring a commercial transaction with the provider.

Any commercial purpose of the material would usually be prohibited.

3. Ownership of new intellectual property

In the course of the recipient conducting its evaluation and experiments, the recipient will be likely to generate new intellectual property, including progeny and derivative material.

One of the difficult questions in a material transfer agreement is who should own that new intellectual property.

On the one hand, the recipient created it, and therefore the recipient should be the owner of that new intellectual property.

But on the other hand, that will fragment the ownership of intellectual property amongst both the provider and the recipient, and that fragmented shared ownership may impede, or even be an obstacle to exploitation.

The provider and the recipient might agree to the new intellectual property being jointly owned between them. Joint ownership may also impede or be an obstacle to exploitation, for the reasons set out in section 6.5.

Where the provider has the capability of generating the new intellectual property itself, this would suggest that the recipient has not necessarily added any value that would justify the recipient having any ownership, and would suggest that the provider should own the new intellectual property created by the recipient.

However, the recipient may have special skills or resources, or even equipment, unavailable to the provider, and does accordingly add value, and may as a result persuasively argue that the recipient on that occasion should own the new intellectual property.

What this demonstrates is that there is no universal way of dealing with new intellectual property created pursuant to a material transfer agreement.

On some occasions, the provider might persuasively argue that the provider should own new intellectual property created by the recipient. On another occasion, the recipient might argue that the value that it has added is such that it should own the new intellectual property. Yet on another occasion, joint ownership of the new intellectual property might be appropriate.

On each occasion, the ownership of new intellectual property is negotiated having regard to the particular occasion and what may be appropriate for that occasion.

4. Safety

Biological material may be toxic, infectious, or hazardous in some way.

A material transfer agreement typically alludes to the bio-safety issues relevant to the particular material, and requires the recipient to acknowledge that it assumes all risks associated with the material.

5. Ethical matters

The biological material might be intended to be used upon animal models.

The material transfer agreement will typically provide for any such use to be subject to all required ethical approvals.

It would also typically prohibit any use of the material upon human beings.

RESOURCES

A Quick Guide to Material Transfer Agreements at University of California, Berkeley
<http://www.spo.berkeley.edu/guide/mtaquick.html>

A Primer on Material Transfer Agreements <http://www.ovpr.uga.edu/tco/mta.html>

4. DEEDS OF ASSIGNMENT

4.1 What are the characteristics of an assignment?

An assignment has the effect of transferring the ownership of intellectual property from one person to another. This is a permanent divestment of ownership.

4.2 How common is an assignment as opposed to a license?

In the pharmaceutical sector, the assignment of intellectual property does occur, but the incidence of assignment is significantly smaller than licensing.

There are two reasons why assignment is less common than licensing:

1. Reduced financial upside

In the exploitation of intellectual property in the pharmaceutical sector, there being such a high cost of taking a product to market given the clinical and regulatory phases of development, and then the cost of servicing a global marketplace, that generally, the capital value of intellectual property at any early stage, such as at the discovery and lead candidate stage, is relatively small.

When licensing at this early stage, the prospect of financial upside can be achieved by royalties.

But when assigning for a lump sum amount of money, as is typically the case with an assignment, that lump sum of money, when arrived at after factoring into the calculation discount rates, and the probability of scientific, clinical, regulatory, and market failure, can result in a relatively small lump sum amount.

2. Inefficient financial terms

The reduced financial upside could be redressed by making an assignment for royalties, instead of for a lump sum amount.

But this carries with it other risks and unattractive features.

One of these is that the assignor may in turn assign the intellectual property to another person. This raises the issue of who will pay the royalties, the first assignee, or the second assignee.

A common defect in assignments of this type is that they assume that the assignee will exploit the technology, and provide for only royalties on the products sold by that assignee.

But of course, the assignee may never sell any product, and may in turn assign the intellectual property to another person, receiving royalties, or a lump sum payment, or shares in a company.

An assignment for royalties, having assumed that the assignee will exploit the technology, may not anticipate these further types of remuneration that an assignee may receive, and may not make any provision for any of these types of remuneration that the assignee may earn.

3. No performance obligations

In an assignment it is unlikely that the assignor will be able to secure performance obligations from the assignee.

Performance obligations are common in a license, and are obligations that the assignee must perform or achieve, with the failure to do so resulting in the termination of the license.

For example, a license may require that the licensee take a compound to a particular stage of development, or take a compound through its clinical phases in particular timeframes, in that way ensuring that the intellectual property is developed at a reasonable pace, and is not locked away.

Another type of performance obligation that is common in a license is that the licensee achieve minimum sales, in this way ensuring that the licensor receives minimum royalties.

The failure to meet either of these performance obligations may be grounds for the termination of the license.

A deed of assignment however cannot be terminated in the same way that a license can be terminated.

An assignment is absolute, having the effect of permanently divesting the former owner.

As a change in ownership is involved, termination is ineffective to revert the intellectual property back to the original owner.

The deed of assignment might contain performance obligations, and then provide for an assignment back to the original assignor if they are not met.

This however is likely to be resisted in those countries where capital gains tax would be payable by the assignee that assigns back.

It would also incur for the original assignor expenses in each patent office in relation to registering the assignment back.

Being inconsistent with the whole notion of an assignment, performance obligations would be likely to be resisted by an assignee.

The practical implications of these three factors results in the assignment of intellectual property in the pharmaceutical sector being relatively less common than licensing.

Where a lump sum amount for an assignment can be negotiated that is acceptable, with the owner being satisfied that the assignment is permanent and irrevocable, with no future upside, and without performance obligations, assignments in the pharmaceutical sector do take place from time to time.

4.3 What are the common terms of a Deed of Assignment?

The common terms of a Deed of Assignment are:

1. Assignment

- That the assignor assigns or transfers the intellectual property to the assignee.
- That the assignor will sign any further document required to record the assignment, such as documents required in each patent office where a patent has been granted.
- That the assignor assigns the right to sue for damages in relation to any past infringement.

2. Subject matter

The assignment deed must accurately identify the subject matter of what is assigned.

This may include:

- granted patents
- PCT and provisional patent applications
- inventions, discoveries and other technical information that are not yet the subject of a patent application
- trade secrets and confidential information that are intended to remain as such.

Not all patents may be assigned. For example, an assignor may assign the patents in some countries, but retain the corresponding patents granted in other countries.

Improvements to the intellectual property, that is, new intellectual property that comes into existence after the date of the assignment, are not typically assigned.

3. Tangible things to provide

A Deed of Assignment customarily makes provision not just for the intangible property, the intellectual property with which it deals, but also for the tangible property that would be expected to accompany the intangible property.

This may include:

- the original patent grants
- the original patent applications and specifications
- laboratory notebooks
- biological materials, including cell lines, vectors, viruses, compounds etc
- the documents that demonstrate the chain of title of the intellectual property, for example, from employee to employer, from independent contractor to customer, from collaborator to joint owner, etc.

4. Warranties

It is customary for a Deed of Assignment to record warranties by the assignor to the assignee, in relation to the intellectual property that is being transferred.

These warranties are typically made in relation to such matters as:

- that the owner owns the intellectual property
- that the commercialisation of the intellectual property will not infringe the rights of a third party (although, this warranty should be prefaced by being made to the best of the owner's knowledge)
- that the intellectual property is not already licensed, nor subject to any agreement or option entered into by the owner
- that the intellectual property has not been encumbered by the owner in any way.

RESOURCES

For a short discussion on assignment versus licensing see **Negotiating and Drafting Licensing Agreements Patent, Trade Secret And Technology Licensing: Key Elements**, K F Jorda http://ipmall.info/hosted_resources/pubspapers/jorda_11_02_98.htm

Dreadful Drafting Do's and Don'ts of Warranty Clauses, J Ramsay, Les Nouvelles: Journal of the Licensing Executives Society. Vol. 38, No. 2, June 2003

5. LICENSE AGREEMENTS

5.1 What are the characteristics of a license?

An intellectual property license is a contract by which permission is given by the licensor to the licensee to exploit the licensor's intellectual property.

5.2 Is a license a contract as well?

A license is also a contract. It creates contractual rights, duties and obligations between the owner of intellectual property, and the licensee.

It is these contractual terms, and the rights, duties and obligations which they record, that regulate the relationship between the licensor and a licensee in a legally enforceable way.

5.3 How is exclusivity dealt with in a license?

Exclusivity means the right to exclude others from exploiting the intellectual property.

In the pharmaceutical sector, most intellectual property licenses are granted on an exclusive basis.

Just as a patentee relies on being the only person entitled to exploit the patent, so also a licensee seeks to be the only person entitled to exploit the patent.

This is particularly so in the pharmaceutical sector where the extent of speculative investment in the development, clinical and regulatory phases of taking a product to market relies upon exclusivity to warrant that speculative investment.

An exclusive license is one therefore where the licensee exploits the intellectual property to the exclusion of all other people, including the licensor.

This means that the licensor, by granting an exclusive license, gives up the right to exploit the intellectual property itself.

The essential characteristic of an exclusive license, and which makes the license an exclusive one, is that the owner of the intellectual property cannot:

1. license anyone else, nor
2. exploit the intellectual property itself.

In contrast, a sole license is one where:

1. the owner of the intellectual property grants the license,
2. is precluded from granting a license to any other person,
3. but retains the right to exploit the intellectual property itself.

The effect of a sole license is that there are only two people permitted to exploit the intellectual property, namely the sole licensee, and the owner.

This may occur for example, where there is a Co-Marketing Agreement (see section 5 below), but is otherwise unusual in the pharmaceutical sector.

Just as a patentee relies on being the only person entitled to exploit the patent, so also a pharmaceutical licensee seeks to be the only person entitled to exploit the patent. A sole license does not achieve this objective, but hinders it.

In contrast again, a non exclusive license is one:

1. where the owner of the intellectual property licenses one licensee,
2. is able to license other licensees as well,
3. and retains the right to exploit the intellectual property itself.

A licensor can therefore grant numerous non exclusive licenses.

In the pharmaceutical sector a non exclusive license is similarly unusual where given the extent of speculative investment a pharmaceutical licensee will seek to be the only person entitled to exploit a patent.

But this is not universally so.

Some biotechnology may lend itself to the grant of numerous non exclusive licenses by a licensor.

Some examples are:

1. a vaccine delivery system
2. a viral vector
3. a promoter
4. a cell line
5. an animal model.

A non exclusive license however will not be the appropriate type of exclusivity that a licensee of a pharmaceutical product will expect.

5.4 How are fields of application dealt with in a license?

Licenses can be limited to fields. A field describes a particular area of application of the intellectual property.

For example, each of the following may be field limitations:

- human applications
- plant applications
- veterinary applications.

Even within human applications fields can be broken down even further, for example:

- diagnostic
- therapeutic vaccines
- prophylactic vaccines.

By limiting a license to a particular field, it is possible for a licensor to

1. retain the right to exploit the intellectual property in some fields of application, and
2. to license the remaining fields of application to licensees.

For example, it is possible for a licensor to:

- grant an exclusive license in the human applications field to Licensee A
- grant a second exclusive license in the plant applications field to Licensee B, and
- grant a third exclusive license in the veterinary applications field to Licensee C.

This allows the licensor to maximise the benefits anticipated from the commercialisation of the intellectual property, by separately licensing different fields to different licensees.

By doing so, a licensor can choose which licensee is best suited to exploit the intellectual property in the particular field that that licensee is best placed to exploit, having regard to that licensee's particular expertise, market position, existing product range, and marketing and distribution networks.

A licensor can also retain the right to exploit in its own field of capability, for example, diagnostic applications, and to license out to another person exploitation rights in fields of exploitation where the licensor has no resources, capability, or marketing networks, such as all human applications other than diagnostic.

All these licenses, notwithstanding their field limitation, are all exclusive licenses, not non exclusive licenses, nor sole licenses.

By this is meant that in the particular field in which the license operates, the licensee only may exploit, to the exclusion of the licensor, and without the licensor having any ability to license to anyone else the right to exploit in the same field.

5.5 How is territory dealt with in a license?

In the pharmaceutical sector it is not uncommon for licensees to be granted on a worldwide basis, granting to the licensee global exploitation rights.

However, a licensor may identify a licensee as having the marketing network and capability to exploit the intellectual property in one geographical area, but no marketing network and no capability to exploit in other geographical areas.

In this case a worldwide license may be inappropriate because of the prospect that those parts of the world where the licensee has no marketing network and no capacity will not be served, with the result that no financial benefits accrue back to the owner in relation to those parts of the world.

For example, it might be appropriate to grant an exclusive license for the territory of North America to one licensee, yet grant an exclusive license of the same intellectual property to another licensee for the territory of Europe, and yet another for the territory of Asia.

An exclusive license in a territory is still an exclusive license, since the licensee only is able to exploit in that territory.

The licensor retains the right to exploit outside the territory, and this does not affect the licensee's exclusivity in relation to the territory in relation to which the license is granted.

Similarly, the licensor's right to grant licences in relation to other territories does not affect the licensee's exclusivity in relation to the territory with which the license is concerned.

In this way, an owner can maximise the benefits from exploitation of the intellectual property, by granting exclusive licenses, in territories, to particular licensees who have the capacity to exploit in the particular territories where the licenses operate.

5.6 What is the term or duration of a license?

Typically, the term of a license is expressed to be the period:

1. commencing upon the date of the license; and
2. ending upon the expiration of the last to expire patent

in this way conferring upon the license the maximum duration of the license.

The term of patents for pharmaceutical products may be extended, to compensate the holders of those patents for the lengthy clinical and regulatory process required to take a product to market.

A term of a license for a pharmaceutical license being framed in this way automatically extends the term of the license to the increased patent term.

5.7 What is licensed?

The intellectual property being licensed needs to be well defined.

This may include patents, but may also include:

- PCT and provisional patent applications
- inventions, discoveries and other technical information that are not yet the subject of a patent application
- trade secrets and confidential information that are intended to remain as such.

5.8 Are improvements licensed?

It is usual in a license to grant rights to a licensee not just in relation to the intellectual property in its state of development as at the date of the license, but as well, to license improvements to that intellectual property which the licensor might develop after the grant of the license.

It is in the interests of both the licensor and the licensee that this occurs.

The licensee wants access to improvements to the intellectual property to be better equipped to commercialise, and to bring to the market the best possible improved product.

A licensor no less wants its licensee to succeed. Its financial returns are subject to the licensee successfully commercialising, and a licensor will typically want to provide its future improvements to the licensee to maximise the licensee's ability to commercialise, and in turn to maximise the royalties and other remuneration that the licensor expects from commercialisation.

But that will not always necessarily be the case.

What if the improvement is a new application of the intellectual property? Should the licensee automatically get access to that improvement? What if the licensee, while capable of commercialising in the field anticipated by the license, is not capable of commercialising in the new field that the improvement is in? What if there is a better equipped or more capable licensee in the new field?

There needs to be a boundary, on one side of which an improvement is automatically included in a license, and made available to the licensee, and on the other side of which the improvement should not necessarily be automatically provided.

The boundary is a blurry one. Using other words such as enhancement, alteration, modification to the intellectual property may not provide much assistance. These are just more adjectives to describe the concept, or parts of the concept of an improvement, and none of these further adjectives helps to measure or quantify, or to identify where the blurry boundary might lie, on one side of which it is an improvement, and on the other side of which is not an improvement.

Sometimes the matter is sought to be addressed by capturing all other intellectual property that a licensor may develop that may in any way be useful for the exploitation of the intellectual property that is licensed. But this is usually regarded as being too broad.

It is in the interests of both a licensor and a licensee that improvements be broadly defined. But it is not in the interests of a licensor for a new application to be captured in the definition, particularly where the licensee may have no capability in that field.

So, how can the boundary of improvements be set?

Firstly, while improvements clauses that define an improvement as being an improvement do little to assist ascertaining where the blurry boundary might lie, it remains an important part of the definition, importing as it does, much judicial comment upon what an improvement is.

Secondly, there needs to be a limitation. To additionally state that the improvement must infringe the intellectual property that is licensed may not help, since by definition, it almost certainly will. To go a little further, it might state that if it is separately patentable, in other words, capable of standing on its own as a patentable invention, and meeting all the formal requirements for the grant of a new patent, then it extends beyond what would ordinarily be understood to be an improvement.

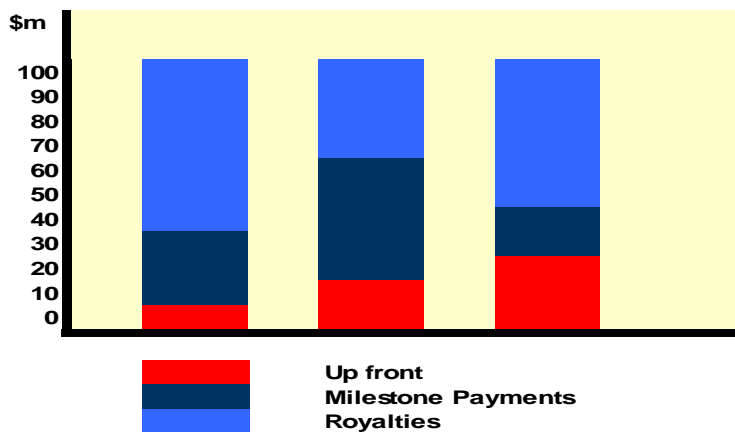
5.9 What are the financial terms of a license and its total deal value?

In the pharmaceutical sector the financial terms of a license are usually a combination of:

1. up front payments, which are paid upon the signing of the license
2. milestone payments, which are paid as particular milestones along the development, clinical and regulatory pathway are reached, and
3. royalties, once there is a product in the marketplace.

The aggregate of the present value all these payments is said to be the total deal value.

The amounts of these components may change, but theoretically, the total deal value should remain the same.



Each column represents the way that a deal may be negotiated. In all three cases the total deal value is \$100m.

In the first column, minimum up front payments are received, and maximum back end payments in the form of royalties are received.

In contrast, in the second column, the same deal value is represented by more up front payments, more milestone payments, but less royalties.

In contrast again, in the third column, the same deal value is represented by maximum front payments, the lowest milestone payments, and average royalties.

5.10 How is the total deal value determined?

Two tools are typically used in combination to determine the value of a deal:

1. A discounted cash flow analysis

This is an analysis of the net present value of intellectual property, by conducting a cash flow analysis over the life of the intellectual property.

Over the unexpired term of a patent a calculation is made of:

- Market size
- Market share
- Market price
- Market maintenance
- Cost of goods
- Probability of technical failure or success
- Probability of successfully emerging from Phase I, Phase II, and Phase III clinical studies
- A discount rate to take into account opportunity cost.

The result is to arrive at a figure which represents the net present value of the intellectual property.

A licensor's share of this value is then calculated, to arrive at the total deal value.

This might seem an imprecise and uncertain process.

However, the more robust the research that is undertaken in relation to each of the components of the analysis, the more reliable the data will be upon which the analysis is based, and the more defensible

the assumptions underlying the analysis, and correspondingly, the more robust the analysis, and the greater its persuasive value.

Undertaking a net present value analysis using a discounted cash flow method is therefore a highly specialised activity, undertaken by professionals producing robust and reliable analysis.

2. Benchmarking or comparables analysis

This is an analysis of comparable licensing transactions, looking at the financial terms of those licenses.

Where the intellectual property with which another license is concerned is comparable, and it is at a comparable stage of development, the financial terms of that other license, when arrived at on an arm's length basis, and responsive to market forces, are highly persuasive indicators of what the financial terms of the licensor's own license should be.

Conversely, the less comparable the intellectual property, and or the less comparable the state of development, the less persuasive that transaction will be as a comparable.

This is a common valuation method to assess the value of one's own property, whether land or intellectual property, by comparing it to other comparable property, and to be guided by the value of the comparable property to arrive at the value of one's own property.

But for this method to work, it is critical that the intellectual property being compared is truly comparable.

The less comparable it is, the less reliable the benchmarking or comparables analysis will be.

The most robust analysis is one that combines both a discounted cash flow analysis and a benchmarking or comparables analysis.

RESOURCES

Putting a Price on Biotechnology, J J Stewart, P N Allison, R S Johnson.

<http://www.biogeneticventures.com/news/feature2.pdf>

An excellent article on the use of a discounted cash flow analysis to value biotechnology

Biotechnology Valuations for the 21st Century Milken Institute

<http://www.milkeninstitute.org/publications/publications.taf?function=detail&ID=167&cat=PBriefs>

Another excellent article on the use of a discounted cash flow analysis to value biotechnology, with an accompanying template spreadsheet

<http://www.milkeninstitute.org/publications/downloads/biotech.xls>

Another excellent spreadsheet to assist in undertaking a discounted cash flow analysis is available from BioGenetic Ventures, Inc. at <http://www.biogeneticventures.com/news/Bioval60.xls>

A number of databases publish deal terms which is useful in undertaking a benchmarking or comparables analysis. The first site is **Recombinant Capital** at <http://www.recap.com/> The second site is **Knowledge Express** at <http://www.knowledgeexpress.com/> For both sites, this information is only available to subscribers.

Valuation of Biotechnology – Stage of Clinical development is most Important J Webster, T Philippon, M Hotsaliuk, les Nouvelles, Journal of the Licensing executives Society, December 2004, Vol 39, No 4, available on line to members of any of the worldwide Licensing Executives Society chapters, at <http://www.usa-canada.les.org/membersonly/default.asp>

5.11 What are milestone payments in a license?

A milestone payment is a lump sum payment that is paid by a licensee to the licensor upon certain milestone events taking place.

A milestone event demonstrates that intellectual property is progressing through its development, clinical or regulatory phase, and is getting closer to a market ready state.

As the intellectual property progresses through these milestone events, the uncertainty and speculation of market entry diminishes, and the intellectual property correspondingly becomes more valuable.

A milestone payment is in part designed to compensate the licensor for this increase in value.

It might be argued that the intellectual property always had this value, but this was uncertain as the time of the grant of the license, so that the owner of the intellectual property agrees to defer receiving the reward until the value is demonstrated.

As the increase in value is demonstrated by the achievement of the milestone events, the owner of the intellectual property is rewarded by the milestone payments made.

In relation to a license for a pharmaceutical product, the achievement of some of the following milestones might be the trigger for the making of milestone payments:

1. identification of a lead compound
2. commencement of animal studies
3. filing an Investigational New Drug application to the Food and Drug Administration of the USA, or an equivalent application to the equivalent regulatory body in another country
4. commencement of Phase I clinical trials
5. commencement of Phase II clinical trials
6. commencement of Phase III clinical trials
7. product registration.

Not all of these may trigger milestone payments.

It would be customary for there to be 2 to 4 milestone payments, with the applicable milestone being drawn from this list.

5.12 How are royalties structured in a license?

In the pharmaceutical sector there are a myriad of ways that royalty terms can be structured. The list below briefly describes some common royalty terms.

1. Royalty upon sales by a licensee

In this royalty term a licensee agrees to pay to a licensor a royalty on the revenue that the licensee receives from the sale of products that are sold.

A royalty upon sales is typically expressed as a percentage of the invoice sale price of products that are sold by the licensee.

This is the most commonly encountered type of royalty term.

2. Royalty on sub-license income received by a licensee

In this term, a royalty is paid upon sub-license income that is received by a licensee.

A licensee may grant a sub-license to a sub-licensee, for example, in different territories, or in different fields of application.

The sub-licensee will pay a royalty to the licensee, based on the products sold by the sub-licensee (as in 1 above).

The licensee in turn pays a royalty to the licensor, being a percentage of the sub-license income received by the licensee from the sub-licensee.

3. Royalty on last sub-licensee's sale

Instead of a licensee paying a royalty on sub-license income, an alternative royalty structure is for the licensee to pay to the licensor the agreed royalty rate on the invoice sale price of products that are sold, on the sales of all products, whether those sales are made by the licensee, a sub-licensee, a sub-sub-licensee, or any other licensee further down the licensing chain.

4. Royalty on sales by affiliates

In a license to a global licensee it is not unusual for the royalty model to be adopted to be a royalty upon the sale made by the affiliate companies of the multi national licensee that sells a product on the first occasion to a non affiliate, arm's length purchaser.

This is a royalty structure that is not unlike the sale by the last sub-licensee, except that these licenses are customarily expressed to be granted to the multinational licensee, and all its affiliates, which is defined by reference to the extent of control that the licensee has over the affiliate company.

5. Royalty on sales that would infringe a granted patent

Sometimes a pharmaceutical licensee is only prepared to pay a royalty in relation to products that are captured by a claim in a granted patent, and is otherwise unwilling to pay royalties.

The result is that a royalty is paid only in relation to sales in countries where a patent is granted.

Correspondingly, no royalty is paid in relation to sales made in countries where no patent has been granted.

The rationale is that in such a country, any competitor can make and sell that product, there being no patent granted in that country.

Whether this is appropriate on any given occasion depends on what global market share the granted patents represent.

For example, if patents granted in approximately 20 countries represent approximately 90% of the global market for a product, and economies of scale and geographical distance between the remaining countries being such that it is unlikely that a competitor will enter the market in the remaining 10% of the global market, it might well be appropriate for royalties to be paid on global sales, without regard to whether the sale is made in a country where no patent has been granted.

6. Royalty splitting

Royalty splitting occurs when a royalty is split into components that are referable to different parts of the intellectual property that is licensed.

For example, a royalty rate may be agreed at 5%. However, it may be agreed that it would be expressed:

- (a) as a royalty of 3% upon the sales of products in relation to that part of the intellectual property that is granted patents, and

- (b) as a separate royalty of 2% upon the sales of products in relation to that part of the intellectual property that is other than granted patents, such as trade secrets, know how, technical knowledge which complements the claims in the granted patents, and without which either products cannot be manufactured, or cannot be manufactured as efficiently.

There are at least two reasons for seeking a royalty structure that splits royalties into these separate components in this way:

- (a) by this mechanism a licensor may obtain royalties in relation to sales made in countries where no patents have been granted
- (b) in some countries, if a patent should be revoked, that is grounds for the termination of the license, yet, both the licensor and the licensee may prefer to keep the license on foot in relation to the use of know how, for the lesser royalty, until that know how enters the public domain.

7. Royalty stacking

Royalty stacking occurs when a number of separate royalty obligations, in relation to the same product, but pursuant to separate licenses to separate licensors, are stacked or layered, each upon the other.

A product may rely upon a number of separate technologies to be combined, each being critical to the product, and without which there would not be a product for sale.

For example, in the case of a pharmaceutical product, a compound may be licensed in from Licensor A, and a delivery system for the compound may be licensed in from Licensor B. Both licenses are required to enable the product to be produced and sold.

The benchmark royalty rate for the compound from Licensor A may be 5%.

The benchmark royalty rate for the delivery system may be 3%.

However, the economics of the product may be such that a combined royalty of 8% cannot be sustained, and that the maximum royalty that can be sustained and be paid upon that product is 7%, with any greater royalty rate putting at risk the economic viability of exploiting the product at all.

This is where a royalty stacking structure can be used.

The licensee may wish to stack, or layer the royalty to Licensor A, and the royalty to Licensor B, so that the aggregate of them reduces the total royalty obligations for a particular product, and reduces correspondingly the possibility that the sum of all royalty obligations may put the economic viability of the product at risk.

The result of royalty stacking in this way may be, by way of example:

1. the licensor may commence with a royalty rate of 5%
2. in a second license the licensee pay have to pay to the second licensor a royalty of 3%
3. the licensor may as a result have its royalty reduced from 5% to a lower amount, such as by one half of the second royalty, reducing its royalty to:

$$5\% - (3\% \times 0.5) = 3.5\%.$$

Sometimes, a royalty stacking mechanism will refer to a minimum royalty rate, so that despite all royalty stacking calculations, particularly where there may be more than one other parcel of intellectual property to be licensed in, there would always be a minimum rate.

Another occasion where royalty stacking may be used is where a freedom to operate obstacles are anticipated.

That is, where it is anticipated that the exploitation of the licensor's patent may infringe another person's patent, so that a second royalty may have to be paid to the second patent holder.

Again, this may affect the economic viability of exploitation, or, it may indicate that the licensor's patent has a reduced value.

In either case, it may be a justification for the burden of the second royalty to be shared by both the licensor and the licensee, using the royalty stacking mechanism.

8. Reach through royalties

Reach through royalties are royalties that are paid:

1. not on the sales of products that are derived from a licensor's intellectual property,
2. but instead, on products which are enabled or produced with the licensor's intellectual property.

The critical aspect of reach through royalties is that a royalty is paid in relation to the sale of a product that is unrelated to the intellectual property that is licensed.

An example is where a licensor has a research tool such as a transgenic mouse that validates a drug target, and results in the development of a drug for that validated target.

As the research tool when licensed was expected to play a critical role in the validation of the drug, it is possible at the time of that license to negotiate a royalty for the intellectual property in that mouse model, based on the sales of the product that was developed as a result of that validated drug target.

9. Minimum Annual Royalties

A minimum annual royalty operates as an alternative to performance obligation (See 5.14).

It is a royalty provision intended to provide incentive to a licensee to reach market entry, and to achieve minimum sales, and operates to penalise a licensee that fails to do so, without the penalty extending as far as the termination of the license.

It operates to effectively require the licensee to pay a minimum agreed amount as a royalty to the licensor.

If actual royalties based on sales are less than the minimum amount, the balance is payable, or termination occurs if it is not paid. If actual royalties exceed this amount, no further amount is payable.

Looked upon in that way, a minimum annual royalty is an annual fee, or annual price, that the licensee pays, to continue to be licensed, without termination being invoked, regardless of the amount of royalties that are paid, or even if no royalties are actually paid.

RESOURCES

Royalty Terms in Licenses, by P Mendes, Tech Monitor, Sept-Oct 2003,
http://www.techmonitor.net/techmon/03sep_oct/tm/pdf/03sep_oct_sf4.pdf

A number of databases publish deal terms and these are useful to see the royalty structures agreed upon in other licensing transactions. The first site is **Recombinant Capital** at <http://www.recap.com/> The second site is

Knowledge Express at <http://www.knowledgeexpress.com/> For both sites, this information is only available to subscribers.

5.13 What accounts, inspection and audit provisions are in a license?

License agreements typically make provision for:

1. a licensee to be required to maintain proper accounts and records in relation to all transactions affecting the exploitation of the intellectual property
2. the licensor being permitted to inspect those accounts and records
3. the licensor to bare the cost and expense of that inspection, unless the inspection demonstrates there has been an under payment of the amount required to be paid, exceeding say 5%, in which case the costs of the inspection is paid by the licensee.

The accounts and inspection clause typically makes provision for the mechanics to arrange and undertake inspections, and the obligations of the licensee in relation to the inspection.

5.14 What are performance obligations in a license?

There are two types of performance obligations that are relevant in an exclusive license:

1. commercialisation milestones that are intended to be achieved by the licensee up to the time of market entry, and
2. sales targets that are expected to be reached after market entry.

Commercialisation milestones are milestones which indicate that the licensee is travelling the commercialisation pathway to market at a reasonable rate.

Typically, these milestones will have dates by which they need to be achieved, and there is usually some flexibility that permits dates to be extended.

However, once that flexibility has been exhausted, if a milestone is not achieved by the licensee, this will be grounds for the licensor to terminate the license, and to license another license, which is able to meet the performance obligations.

Examples of performance obligations may be

1. the commencement of animal studies, or toxicology studies, or some other pre-clinical study
2. the commencement of Phase I, II, or III clinical studies
3. product registration.

Where the intellectual property is in an advanced state of development, for example, having completed Phase I studies, it would not be unusual to have such commercialisation milestones in the license, and dates for their achievement, with the right of termination arising if they are not achieved.

Conversely, the more infant the state of development of the intellectual property, and correspondingly the greater the risk, and greater the uncertainty of its development future, the harder it is to negotiate these commercialisation milestone and the right of termination.

Sales targets on the other hand are performance obligations that commence after the product has entered the market.

Examples of performance obligations that are sales targets are:

1. selling a minimum of X units of products in North America during the first year after product registration
2. selling a minimum of Y units of products in Europe during the first year after product registration
3. selling a minimum of Z units of products in Asia and the Pacific during the first year after product registration
4. selling a minimum of 2xX units of products in North America during the second year after product registration
5. selling a minimum of 2xY units of products in Europe during the second year after product registration
6. selling a minimum of 2xZ units of products in Asia and the Pacific during the second year after product registration
7. etc.

Customarily, if these minimum sales are not achieved, exclusivity in a territory might be lost, or the license might be terminated.

An alternative to sales targets, or indeed, both types of performance obligations, is to negotiate a minimum annual royalty (see 5.12).

5.15 How is patenting dealt with in a license?

Where patents have not yet been granted, a license customarily makes provision for the application, management and cost of patents.

A licensor will typically require that the licensee pay all costs in relation to patents.

A licensee is typically also required to pay patent maintenance expenses.

5.16 What warranties are in a license?

Typically, a licensee will require warranties from the licensor in relation to the intellectual property. These usually include:

1. that the owner owns the intellectual property
2. that the commercialisation of the intellectual property will not infringe the rights of a third party (although, this warranty should be prefaced by being made to the best of the owner's knowledge)
3. that the intellectual property is not already licensed, nor subject to any agreement or option entered into by the owner
4. that the intellectual property has not been encumbered by the owner in any way.

There may be additional warranties sought as well. Usually, a licensor will seek to take a minimalist approach to warranties.

5.17 What competition law issues are there in licensing?

Competition laws throughout the world regulate the conduct of business relationships, and are aimed at promoting competitiveness and making unlawful anti competitive practices that may for example have the effect of lessening competition.

Intellectual property licenses are subject to competition laws, as are other business relationships.

In the United States, competition laws are called antitrust laws.

In the United States, certain anti competitive conduct is prohibited per se, and other conducted is subject to what in the United States are called rules of reason, that analyse conduct and consider its anti competitive effect.

In Europe a technology transfer block exemption of the European Union identifies certain provisions in a license which are considered to have an impact on competition, and identifies provisions that would be regarded as being anti-competitive.

The types of provisions in a license which may require a consideration of competition law include:

- price restrictions or price minimums
- market division
- export restrictions
- product quantity limitations
- compulsory assignment of improvements from a licensee to a licensor.

An exclusive license is not anti-competitive per se.

In fact, licensing has a pro competitive effect, doing as it does, broadening the use of intellectual property, and creating new products that compete with existing products.

However, it is necessary to be mindful of competition laws in licensing, and to consider whether the terms of a license may bring competition laws into operation.

RESOURCES

In the United States the Department of Justice and the Federal Trade Commission have issued joint **Antitrust Guidelines for the Licensing of Intellectual Property** which are available at <http://www.usdoj.gov/atr/public/guidelines/ipguide.htm>

In Europe the European Union has issued the **Technology Transfer Block Exemption** which regulates licenses and their effect on competition, and is available at http://europa.eu.int/eur-lex/pi/en/oj/dat/2004/l_123/l_12320040427en00110017.pdf

5.18 What other provisions may a license contain?

A license will contain numerous other provisions that both a licensee and a licensor will need to protect their respective interests.

Amongst these will be clauses dealing with:

1. reporting obligations,
2. confidential information, and imposing obligations of confidentiality and non use
3. the ability of the parties to publish in academic journals in a way that is sympathetic with a patenting strategy
4. the defence of the intellectual property if patents are opposed or infringement is asserted
5. the prosecution of infringers
6. product liability insurance
7. release, indemnities, and limitations upon liability

8. dispute resolution
9. termination for breach

A license will also contain many standard provisions that may deal for example with the following:

1. special terms which are defined
2. special rules of interpretation of the contract
3. the service of notices
4. waivers that must be in writing to be valid
5. the governing law of the contract
6. the severance from the agreement of void or invalid terms.

RESOURCES

The following are all excellent resources on licensing.

les Nouvelles, The Journal of the Licensing Executives Society is an excellent resource on all aspects of licensing. The journal is published quarterly, and is free to members of any of the worldwide Licensing Executives Society chapters. The journal is also available on line, and searchable, free to members of any of the worldwide Licensing Executives Society chapters, at <http://www.usa-canada.les.org/membersonly/default.asp>

Pharmalicensing is a website with numerous on line articles on the licensing of pharmaceutical technologies at <http://pharmalicensing.com/>

Licensing Technology: Drafting and Negotiating Licensing Agreements, N Byrne, Anthony Rowe Ltd, 1994

The LESI Guide to Licensing Best Practices: Strategic Issues and Contemporary Realities, Robert Goldscheider, Ed, Wiley, 2002

Drafting Patent License Agreements B G Brunsvold, D P O'Reilley. Washington, DC: Bureau of National Affairs, 5th ed., 2004.

6. STRATEGIC ALLIANCES: CO-DEVELOPMENT AND CO-MARKETING AGREEMENTS

6.1 What is a strategic alliance?

A strategic alliance is a relationship where two parties contribute their different but complementary resources and capabilities to achieve a common objective.

For example:

1. two companies have different but complementary research capabilities, so that together they can further develop intellectual property, which is something that neither could do without the other
2. one company may have a research capability, but no capability to guide a product through its regulatory and clinical pathway, with the second company having the expertise to guide a product through that pathway

3. one company may have promotion and marketing capability, but no manufacturing capability.

In each of these examples, the companies consider forming a strategic alliance to combine their different but complementary resources and capabilities to bring a product to market.

There are many types of strategic alliances. The relative resource and capability contributions that the alliance partners make can be diverse, and differs from one strategic alliance to another, having regard to the specific contributions that those specific parties may make to that specific strategic alliance.

Broadly, strategic alliances in the pharmaceutical sector will fall into one of two categories:

1. a Co-Development Agreement, and
2. a Co-Marketing Agreement.

6.2 What is the difference between a license and a strategic alliance?

A license is fundamentally a passive relationship.

It is passive in the sense that the licensor, having granted the license, is not required to do anything else, but passively stands by to collect the royalties and other payments required to be made by the licensee.

On the other hand, a strategic alliance is a very active relationship, with resources and capabilities being contributed by the alliance partners.

A strategic alliance will almost invariably also involve a license.

That is, the granting of a license by one alliance partner to the other is likely to be one of the contributions that one alliance partner makes to the alliance.

All the comments made in section 3 therefore apply equally in the case of a strategic alliance.

6.3 What are the motivations for a strategic alliance?

1. Maximising financial returns

If an owner of technology only granted a license, all it would receive would be up front payments, milestone payments, and royalties, having regard to the state of development of the intellectual property at the time of the license.

A strategic alliance is a more sophisticated relationship.

It may be a co-development alliance, where the alliance partners contribute to the joint further development of the intellectual property. By contributing to the further development of the intellectual property, the licensor becomes entitled to a larger share of milestone payments and royalties than otherwise would have been the case.

Similarly, it may be a co-marketing alliance, where the licensor, having the capability to contribute to marketing, does so to be able to secure a greater financial return than if this contribution had not been made.

Or, a licensor may have manufacturing capability, and seeks to contribute to the alliance by manufacturing products, in that way again securing a greater financial return than if this contribution had not been made.

In each case, a licensor seeks to contribute more than just the grant of a license, and by doing so seeks to capture a greater share of the available financial returns.

Where for example a company grants a license of an unvalidated drug target, where there are not yet any therapeutic products associated with that target, the value of the intellectual property at the time of granting that license is relatively small. It is unknown whether those targets will result in proteins or other pathways in relation to which a drug can be developed, and so it is unknown whether a drug ever will be developed. If the license is at a very early stage, it is also impossible to predict the potency, toxicity, safety, solubility, absorption and metabolic stability of any product. A license granted in these early phases will therefore attract only the minimum financial payments. However, a license granted in these early phases as a part of a strategic alliance where the licensor can further contribute to the further development of the intellectual property will entitle the licensor to greater financial returns, and in that way to share in the upside from the exploitation of its intellectual property.

2. Prohibitive cost of taking a drug to market requires partnering

The cost of taking a single drug to market is variously estimated at between USD\$450 million and USD \$800 million.

It is beyond the capability of most companies to incur those amounts of money on just a single drug candidate, let alone if it tries to balance its risk by having a portfolio of drugs all of which will cost that amount to take to market.

The timeframe of going to market, being measured in years, as the clinical and regulatory timeframes themselves can take six to eight years, also means that this cost is one that is prohibitive. Most companies simply cannot have that amount invested for that long without a return.

Partnering with strategic alliance partners will help defray this cost, which the alliance partners can share.

3. Development of skills

Partnering with a strategic alliance partner can also be a very effective way of companies developing its skills.

A company may for example have little more than a target or an enabling technology, and accordingly few or little skills or capacity in target validation, lead generation, lead optimisation, managing animal studies or toxicology studies.

Partnering with a strategic alliance partner where the company can contribute in these respects means that it acquires new skills, and those skills might for example be put to use in other projects, other than the alliance project, to establish a more successful company.

6.4 Which types of companies are alliance partners?

Most strategic alliances will be between:

1. a biotechnology company and another biotechnology company, or
2. a biotechnology company and a pharmaceutical company.

While once pharmaceutical companies relied almost wholly upon their own internal research and development resources to develop new drugs, in the last two decades in particular this has changed dramatically, and increasingly, pharmaceutical companies rely upon strategic alliances with biotechnology companies to broaden their pipeline of new drug candidates.

6.5 What are the intellectual property aspects of Co-Development Agreements?

In a Co-Development Agreement the alliance partners will often collaboratively undertake research.

The collaboration may occur in different cities, or indeed in different countries, this not being at all unusual in pharmaceutical strategic alliances.

The collaboration may occur with the staff of the alliance partners in separate laboratories, or with the staff of the alliance partners working side by side in the same laboratories.

Developing new intellectual property that builds upon the licensed intellectual property is the aim of the collaboration.

The parties will have to address how that new intellectual property will be owned.

They may agree that they will jointly own all the new intellectual property.

Or, they may agree that each will own the intellectual property that each separately develops, and any joint ownership is restricted to any intellectual property that may be jointly owned.

But more complex ownership regimes may need to be considered.

For example, the alliance may be restricted to one field of application only. In that case, the alliance partner whose platform intellectual property is the subject of the collaborative research, and which licensed it to the alliance partner, may need to secure sole ownership of the new intellectual property, so that it is unencumbered for use in other applications, and licensed to the alliance partner in the same field as the existing intellectual property.

Also by way of example, one alliance partner may be advancing significant monies for the collaborative research, for the development for example of new assays, and may require that it solely owns the intellectual property in all those assays, although it may be happy to take only a very restricted license of for example, of the intellectual property in the peptides with which that assay was developed.

There may be a myriad of ways in which not just the collaboration may work, but as well, the ownership of intellectual property arising from the collaboration.

The law relating to the joint ownership of intellectual property is very relevant here.

In most countries, where a patent is jointly owned, neither owner may license its interest in the jointly owned patent without the consent of the other (Japan: Article 73(3) The Patent Law, UK: Section 36(3) Patents Act 1977, Australia: Section 16(2) Patents Act 1990), Canada: *Forget v. Specialty Tools of Canada Inc* (1995) 62 CPR (3d) 537). However, a joint owner can exploit without consent, and without having to account for any profits it makes from that exploitation.

In the United States however, one joint owner may grant a license of its interest in a patent, without the consent of the other joint owner, and without having to account to the other joint owner for any royalties or other payments received pursuant to that license (*Schnack v. Applied Arts Corporation* 278 N.W. 117 Mich 434).

Neither situation is necessarily ideal, nor necessarily in the interests of the alliance partners.

The alliance partners need to consider how they may want to regulate their joint ownership relationship.

They may choose for example that all jointly owned intellectual property will be neither licensed nor exploited by either alliance partner unless they do so jointly, and that way negating the laws of the United States as well as the laws of other countries which provide otherwise.

Or, they may agree that the collaboration contributions will occur in different fields, so that all intellectual property in each field respectively is owned by each alliance partner respectively, solely, and not jointly.

There are a myriad of ways that the ownership and rights of new intellectual property arising from the collaboration may be treated, to be responsive to the needs of the alliance partners for the specific alliance.

6.6 What are the financial aspects of strategic alliances?

A strategic alliance will invariably involve a license of intellectual property, with the payment of up front monies, milestone payments, and royalties, and so all the comments in section 5 will be applicable.

In a strategic alliance it might be expected that in all other respects the alliance partners will contribute their resources and capability to the strategic alliance at their own expense.

However, quite imaginative financial deal terms can be struck.

For example, an alliance partner such as a pharmaceutical company or a large biotechnology company might:

1. make payments for further research undertaken by the licensor
2. make limited recourse loans
3. purchase equity in the licensor, or
4. make convertible loans (loans that can be converted to shares)

to a smaller biotechnology company.

By doing so, the larger alliance partner provides the financial resources that equips the smaller alliance partner to contribute, at its expense now, the resources and capacity to the alliance.

Purchasing equity, and advancing monies as a convertible note, which has a high prospect of being converted into shares, leads to one alliance partner becoming a part owner of the other alliance partner, and results in a very intimate relationship between them.

A limited recourse loan is a loan with terms that allow the loan to be forgiven in certain events, such as the identification of lead compounds, entry into clinical trials, etc, and is only repayable to the extent that these events do not occur.

A limited recourse loan might also be upon other favourable terms, such as being interest free.

6.7 What are the manufacturing aspects of strategic alliances?

Manufacturing rights are part of the rights that are licensed to a licensee, with the licensor becoming a passive intellectual property owner collecting royalties.

Strategic alliances can be framed however, where manufacturing rights are retained by the licensor.

The terms of the strategic alliance might be that worldwide manufacturing is retained by the licensor, which supplies the product to the licensee, and the licensee is granted worldwide marketing and sales rights.

A strategic alliance framed in this way secures to the licensor not just royalties on sales of products, but additionally, profits on the manufacture and supply of products to the licensee.

6.8 What are the Co-marketing aspects of strategic alliances?

Marketing and selling rights are similarly part of the rights that are licensed to a licensee, with the licensor becoming a passive intellectual property owner collecting royalties.

But again, strategic alliances can be framed with some marketing and sale rights being retained by the licensor.

The terms of the strategic alliance might be that the licensee is licensed all manufacturing rights, has marketing and sale rights, but additionally supplies products to the licensor which the licensor markets and sells.

A strategic alliance framed in this way secures to the licensor not just royalties on sales of products by the licensee, but additionally, profits on the sale of products which the licensee supplies to the licensor.

These co marketing and sale rights might operate in the same territory, making the strategic partners competitors in that territory. Or, they may operate in different territories.

6.9 What are the cross licensing aspects of strategic alliances?

In a strategic alliance the alliance partners may deal with more than one parcel of intellectual property, or more than one product.

The major focus of the strategic alliance may be a particular parcel of intellectual property owned by the licensor, and it is that parcel of intellectual property in relation to which the parties will undertake co-development to bring a product to market. There may then be co-marketing rights that the alliance partners will share.

But an additional aspect of the strategic alliance may be that the pharmaceutical company appoints its alliance partner its co-marketer or distributor for an already developed and registered product.

In this way the alliance broadens to cover not just the intellectual property to be the subject of further research and development, but additionally, an already existing product, by the cross license. This as a result increases the revenues of the licensor alliance partner.

RESOURCES

Biotechnology Alliances, Co-Development and Co-Marketing Agreement, by B Limpert and S Kim
<http://www.gowlings.com/resources/PublicationPDFs/BiotechnologyCoDev.pdf>

Licensing and Intellectual Property Concerns Relative to Pharmaceutical and Biotechnology Collaborations, by P A Schhreck and M M Simkin,
http://www.foley.com/files/tbl_s31Publications/FileUpload137/1412/IPcollaborations1.pdf

The Many facets of Co-Development by JV Brunt, Signals Magazine
<http://www.signalsmag.com/signalsmag.nsf/657b06742b5748e888256570005cba01/89d7d5e3cfea9e2888256a50000afe23?OpenDocument>

Early Stage Biotechnology Collaborations by J Wilkinson, B Vandermeulen, P Drouault-Gardrat U Paulsson, http://pharmalicensing.com/features/disp/1054806563_3edf1223618ab

The Position of Co-marketing and Co-promotion Between EU Regulatory and Competition Rules, by C Piria, Regulatory Affairs Journal, 2002, V ol. 13(8), 653
<http://www.franzosi.com/english/article/legals15.htm>

Pharma-Biotech Alliances: A Case Study, by M Cha,
http://leda.law.harvard.edu/leda/data/625/Cha_redacted.html