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# Practical and legal preparation for young companies seeking technology transfer

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**Abstract** This paper looks at the basic law of intellectual property as it applies to a small biotechnology company or start-up. It focuses on the systems and attention to paperwork required so that the company can maximise its intellectual property protection.

Keywords: biotechnology, contract, employees, intellectual property, start-up

#### Introduction

This paper is directed to the non-lawyer in a start-up biotechnology company and focuses on methods of maximising potential for technology transfer using basic good legal and practical housekeeping. By following a few simple rules, the value of the technology to be transferred can be increased and the ease and cost with which the transfer can be effected can be improved. Basic contract law will be discussed as well as some specific types of contract likely to be needed by a company in the initial stages together with management systems to capture intellectual property – the main basis of technology transfer. The importance of attention to these issues comes into its own in due diligence when potential backers, purchasers or partners will scrutinise the company contracts and intellectual property rights (IPRs): with all the papers to hand and in order, the task is not so daunting or costly.

This paper focuses on the law as it applies

in the UK. Although many principles will be the same, specific advice should be sought from local lawyers if dealing with foreign companies. Table 1 summarises IPRs in the UK.

# **Contract law**

A company may contract with independent researchers, technology producers, suppliers of materials, subcontractors, software suppliers, collaborators and of course technology transfer partners. The principles of establishing a paper trail and good housekeeping apply to these activities. A company may be less attractive to purchasers and partners if it has encumbered itself with liabilities. We shall look at, firstly, basic contract law and then at terms in some specific contracts that a company may encounter on a routine basis. The basic principles of contract also apply to technology transfer, collaboration and licence agreements, but looking at these types of contract specifically is beyond the

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 Table 1
 Summary of intellectual property protection available in the UK

	Can protect (seek specific advice)	Available foreign Term (years) national	Term (years)	Statutory	Registration / required?	Assignments and licences need to be in writing?	Company owns employee work?
Patent	Novel, inventive and industrially applicable inventions. Can protect cell lines and genetic material	Yes	20 (supplementary protection certificates are possible for pharmaceuticals)	Yes	Yes (use either European or national system)	Licence, no, assignment, yes. Both should be registered to be fully effective	Yes
Registered design	Registered design Novel articles such as testing kits and equipment	Yes	25	Yes	Yes	No but should be, and be registered for maximum	Yes
Design right	Not commonplace articles	EU – yes; others depends on other factors such as first	10 maximum with last 5 years licences of right available	Yes	No. Details of the design process and first marketing should be kept to assist enforcement	Yes (for exclusive licenses)	Yes (except if work commissioned by third party)
Copyright	Original software logos, Yes written material, databases, other 2D	Yes	70 plus life of the author	Yes		Yes (exclusive) licencee only	Yes
Registered trademark	denames, logans even if n use	Yes	Indefinite as long as the fees are paid	Yes, can apply Yes nationally or through		Yes	N/A
Unregistered trademark	As above	Yes	Indefinite if still used in UK		No	ON.	N/A
Confidential	Information that is confidential, not public	Yes	Indefinite or until public	No	No oN	No.	Yes, particularly if specified in employment
Plant variety Database right	Novel plant varieties Original and amended databases written and electronic	Yes EU – yes	30 maximum 15 maximum with last 5 years licence of right	Yes	Yes Y	Yes No	Yes Yes

scope of this paper. On such major agreements specific legal advice should always be sought. The legal principles of English contract law which apply to all contracts and may present a trap to the unwary are as follows.

#### **Binding agreements**

A contract does not have to be in writing to be legally binding, although some licences and assignments of IPRs need to be in writing to be effective. Otherwise as long as the parties have agreed sufficient terms to make the deal clear and there is an intention by the parties to be legally bound there is a binding contract. A written contract should always be drawn up for clarity.

Often written heads of agreement are used to indicate an intention to be bound by the terms set out in it. Generally if the intention is to be bound by the heads of agreement, it is better to continue to negotiate the full terms of the agreement since there is otherwise a danger that the heads of agreement will not include all the provisions that would be expected in a fuller formal agreement. As noted above, failing to sign an agreement that has been negotiated and agreed by the parties does not necessarily mean that the parties are not bound by the agreement. Care therefore needs to be exercised negotiating agreements to ensure that the company is not inadvertently bound, particularly by employees. If the intention is that the arrangement should not be binding, this should be expressly mentioned in the text, and the words 'subject to contract' or 'not intended to create legal relations' should be clearly marked.

It is possible to provide that certain provisions of the heads of agreement are enforceable, while the overall thrust of the document is not. The sort of provisions to consider as an exception to the non-binding nature of the document would be those as to confidentiality; precluding discussion with third parties directed towards a similar transaction until the deadline for completion of the formal detailed agreement has expired (known as a 'lock-out' or exclusivity

period); payment of costs; the exclusion or imposition of the duty to negotiate in good faith; and governing law/jurisdiction. In certain European jurisdictions a duty to negotiate in good faith can arise, and may be more likely to do so if heads of agreement are signed. In such circumstances unilateral withdrawal could render a party liable for breach of duty.

Parties sometimes try to include terms in a contract to negotiate a renewal or other contract in good faith or similar vague terms, often called legally an agreement to agree. This is not legally binding and parties must treat it as nothing more than an expression of faith.

#### Competition law

There are both EU and UK competition rules that apply to contracts. Generally these might apply if the deal contains restrictions on competition by one or other of the parties and/or any exclusive arrangements. Breach of these regulations can involve substantial fines, so legal advice should be sought. Generally speaking price-fixing in any form is outlawed. However certain clauses, which might otherwise be regarded as restricting competition, have been sanctioned by 'block exemptions' by the EU on policy grounds or on the grounds that they do not have significant effect in the market-place.

#### Limitation or exclusion of liability

Parties may want to limit or exclude their liability, eg under an indemnity, but there are legal limits as to how far liability can be limited or excluded and in particular in relation to product liability. You will need to take detailed legal advice on the enforceability of any limitation or exclusion of liability. In the UK the Unfair Contract Terms Act 1977 applies to consumer contracts and contracts entered into on standard written terms, imposing a 'reasonable' standard in the case of the exclusion of statutory implied warranties and limitations or exclusions of liability generally.

### Choice of law/choice of jurisdiction

There are increasingly complicated international rules over where disputes under a contract can be heard and which law applies, complicated even further in relation to intellectual property. It is better to agree specifically which law should apply to the contract and where disputes will be litigated, otherwise you may find yourself litigating in an inconvenient jurisdiction or under a system of law that has no relation to either party.

# Ownership of intellectual property

Ownership of IPRs is determined by law, but varies from country to country and from IPR to IPR. In key contracts it is better to spell out precisely who will own the technology and intellectual property arising out of the project, as well as the right to license such intellectual property. One of the most common arrangements is to provide that rights in and to inventions and all other IPRs resulting from developments made in the course of the project will belong to the inventing party, ie the party whose employees carried out the work that gave rise to the IPRs.

An option to be avoided in general is coownership of intellectual property rights arising. The law of co-ownership varies from country to country and may also differ even within the jurisdiction as among different types of IPRs. In the UK and elsewhere in Europe, in the absence of express agreement to the contrary, co-ownership in general only allows the co-owners to exploit for themselves the jointly held rights and does not permit them for example to license (or even arguably to subcontract) third parties, or to assign the rights, without the consent of the other party.

If, for political or commercial reasons, coownership is selected as an option, it is very important to deal expressly in the agreement with variations to the general rules and legal presumptions that will otherwise be imposed. A further issue that must be addressed is whether the co-owners should be 'joint tenants' or 'tenants in common', ie in the event of the death of an individual co-owner or liquidation of a coowning company, what is to happen to the share in the jointly held right. If the parties are joint tenants, then the share will devolve automatically to the other party. If they are tenants in common, then the share of the deceased or liquidated co-owner will not pass to the other, but to the estate or the liquidator of the former co-owner. If the contract is silent, the parties will be assumed to be tenants in common, which can, in practice, seriously hamper the exploitation of the rights in question, because assignment or licensing to third parties cannot take place without the consent of the estate or liquidator.

# **Specific contracts**

# Confidentiality agreements

Keeping information confidential in discussions with third parties may be essential to protect the intellectual property of the company. This might be because the intellectual property is the confidential information itself or there are prospects of applying for a patent in the future. In order to apply for a patent it is essential that the idea has not been disclosed publicly before the date of the application, as otherwise the patent is invalid. Sometimes companies refuse to sign a confidentiality agreement as it may limit their ability to conduct research in an area similar to that of the proposed transferor of the confidential information. If this is the case then the transferor should, if possible, file a patent application before disclosure.

Information can be kept confidential by the use of a simple confidentiality agreement which should be signed by the third party before the information is disclosed. This agreement is often referred to as a non-disclosure agreement or 'NDA'. The essential characteristics of all confidentiality agreements are that the information to be kept confidential should be defined in as much detail as possible; the use to be made of the information should be agreed; and any background/foreground

information should be defined. The agreement may include a term that no notes are to be made during the disclosure of the information and all papers provided should not be copied and must be returned at the end of the project. Disclosure may be limited to a small number of people - the fewer the better. However, a third party may want to share the information with technical staff, and patent agents and lawyers may well need to evaluate the technology protection. Named individuals may be required to sign individual confidentiality agreements - any information handed over in written form should be marked as 'confidential' - simple but effective. There is usually a provision that the restriction will not apply if the information is public knowledge or if the company receives the information from a third party who is freely in a position to divulge the information. The agreement usually lasts for as long as the information is confidential, although some parties may ask for the agreement to be time limited. If it is time limited it is less effective and this would not be appropriate if the company seeks to rely on confidential information protection as the only method of protection. The agreement need not be formal and is often in the form of a letter.

Even without the signed written agreement, a duty of confidentiality may be implied by the circumstances and can then be enforced in court. Having something in writing is preferable because it removes the necessity to prove a duty of confidentiality. The defining of the background information, which is known information and therefore not confidential, can remove later argument over what was publicly known at the time given the fast-moving nature of biotechnology.

#### **Assignments**

Intellectual property produced by freelance subcontractors (ie non-employees generally) belong to that contractor by law, and not to the company or principal. It is essential therefore that if any intellectual property is to be produced that the contract with the

subcontractor includes a term that any intellectual property created will be assigned to the company. This can include a logo or other design input, or some bespoke software as well as core technology. At an early stage of creation of the technology, this may seem irrelevant, but may turn out to be a major asset of the company in later years. It is useful, therefore, to be able to show that the design/software belongs to the company. (Software companies may not to be prepared to assign the copyright. At the very least the company should obtain a nonexclusive licence to the software which is transferable.) Conversely of course a company may be asked to assign IPRs if carrying out work for other companies or as part of a collaboration agreement. IPRs must clearly be defined to avoid inadvertently giving away assets of the company.

It is wise to check whether non-employee subcontractors or consultants have inconsistent obligations as a result of contracts previously entered into with other bodies which, in return for sponsoring research in the same or a related area, require the assignment or licence to them of IPRs arising from that research. For example, in the case of research students or professors, the terms and conditions of any funding or sponsorship agreements (whether from government or commercial sources) as well as any contract with the university concerned need to be carefully scrutinised to check whether such funding bodies already have rights in the field of technology to be developed by the company.

Full legal title to rights not yet in existence cannot in general be assigned in advance of those rights coming into existence, although in the UK copyright is an exception to this. For this reason it is advisable to include some mechanism, such as a covenant for further assurance or express declaration of trust, to provide the paying party with a mechanism for calling on the other party to perfect the paying party's rights.

# Supply contracts

A supply contract can relate for example to essential materials for the conduct of

research. In all cases a simple contract, which again can be in the form of a letter, should be entered into. This contract should define the scope of work to be carried out, the standard of any work to be carried out, the delivery method/time, the payments to be made and payment method, the responsibilities and liabilities of the parties and the usual choice of law and dispute mechanism clauses.

### Material transfer agreements

These agreements specify the terms under which owners of chemical or biological materials are prepared to transfer small quantities to other companies for research or other evaluation. Many companies have standard forms for such transfer and there may be little room for negotiation. If so, the transferee must scrutinise the terms to ensure that they can make full use of the material for their needs and likewise the transferor needs to ensure that any rights in the material are protected. If no terms are specified, it should be clear from correspondence or some document what use the transferee can make of the materials and who owns any IPRs. This will be particularly important for reproducible material and the transferor may well try to limit the use to be made of the material and may seek a claim in any IPRs (so-called 'reach-through' patent claims) arising out of use of the material.

Beware also of licences offered to use screening techniques or screening agents on the basis of high royalty rates being required if and when a commercial product results from the use of that technique. A particular pitfall is the attempt to impose such licence terms by printing them in small type on the back of invoices or acceptance forms for the supply of a screening agent. The rationale for using such licences is that, assuming the contract is valid, it will be irrelevant that the reach-through patent claim is invalid, since the action for failure to pay royalties on future sales of products would be based on breach of contract and not patent infringement.

This area is complex and if there is any

doubt about use of the material, legal advice should be sought. On a practical level the contract may well discuss how the material is to be delivered, how it will be kept at the transferee's premises, how long it may be kept, how it will be returned or destroyed, the liability of the parties, payment terms and the usual clauses on choice of law and dispute mechanisms.

## Shareholder and company documents

If you are at the company formation stage, the principals in a company (or partners in a partnership) should ensure that everybody is comfortable with their share ownership in relation to their comparative contributions. A solicitor should be employed to draw up a simple shareholders agreement, and can also advise on initial ownership, any tax considerations and ownership of any existing IPR in the company or partnership.

### **Employee contracts**

All employees should have a written employment contract, including directors. On a practical level a contract avoids disputes over, for example, salary, holidays, job description, notice period and grievance procedures. Certain terms such as these are in the UK required by law to be set out in a written statement of terms. A written contract is an opportunity to remind the employee of his or her duty of confidence to the company, and defines the information that the company regards as confidential. With key personnel, restrictive covenants, that is obligations limiting the ability of the employee to work for competitors or in a particular locality, may also be used. The enforceability of the restrictive covenant will vary depending on the seniority and the value of the personnel to the company. Generally, restrictive covenants are only enforceable to the extent that they protect the legitimate interests of the company. They cannot be punitive or unnecessarily fetter employees from earning their living. Needless to say if employees move around, it is difficult practically to protect the knowledge of the company and the best

way to avoid this issue is to look after one's employees. If an employee does leave, having an exit interview is advisable as it serves to remind the employee of his or her obligations of confidentiality and to hand back all company papers.

In most countries if an employee invents something in the course of his or her employment, the rights to that invention will automatically belong to the employer, but it may be necessary in certain jurisdictions to obtain a specific assignment from the inventor. The contract may contain any employee incentives in relation to inventions, and can also specify the duty of the employee to make good laboratory records and to abide by other company policy rules.

# Capture and maintenance of intellectual property

Maximising the intellectual property created and owned by a technology company is one of the essential tasks for company management. It requires creating the right atmosphere in the company and adherence by the employees to company policy and good practices. Here, in brief, are some methodologies that may assist in practice:

- A standard company policy either on intranet or paper/book form which sets out the rules on for disclosure of confidential information including a pro forma letter/NDA which all the employees/managers of the company have to obtain prior to disclosure to a third party.
- A company filing policy so that all confidentiality agreements signed throughout the company are kept in one place. This also applies to any other contracts entered into by the companies such as software contracts and particularly any undertakings given by the company. If the company has grown significantly it may be appropriate to put details of contracts/undertakings entered into by the company on an intranet facility, so that management can see at a

- glance which contracts are still extant. This does, however, involve administration to ensure that the intranet is up to date, and meanwhile a simple manual file of all original contracts with any variations should be kept centrally. Copies can also be kept by individuals. Company policy should also specify authority to enter into contracts.
- A regular review of intellectual property held by the company with its patent agents/lawyers. This review will focus on which intellectual property should be renewed or even applied for having regard to a cost/benefit analysis. Costs include continued professional fees, official fees and management time. Benefit will look at the expected use to be made of the IPR such as exploitation directly or by licensing or assignment. Discussions will also centre on any patent searches made in the area of activity of the company to ensure that the company will not infringe third party IPRs.
- The company should maintain records internally of all intellectual property applied for, their status and likely further action required. Often a patent agent can supply these details and the company should ensure that the patent agent is in a position (usually assisted by technology) to provide up-to-date details of the status of any IPR applied for within a few days, if not by return.
- Keep records of any amendments to databases. These can often turn out to be valuable assets of the company, for example, the databases of genetic information such as DNA or protein sequences which are now being generated. The 15 year period of protection afforded by the database right can be increased by keeping records of additions and amendments since these can be used to demonstrate a new period of protection which starts as a result of making substantial changes.
- Develop a culture of confidentiality within the company. This can include marking all documents regarded as confidential as 'confidential', keeping an area of the laboratory that is sensitive

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fenced off from general personnel or restricting access in some other way that is physically feasible. Senior managers should discourage careless talk particularly outside the premises. Valuable biological or chemical material should be kept under lock and key. A company policy is useful so that employees are clear as to what they can and cannot do. If the company has to argue in court that information is confidential, demonstrating that the company took care to keep information confidential within the company is powerful evidence.

- Perhaps most essential of all is that good laboratory notebooks should be kept. This should be a cornerstone of company policy. At trial, laboratory notebooks may well have to be used in court to support any dispute over patent entitlement or validity. Entries should be continuous, dated and signed.
- If the company operates a website, care should be taken over the information that

- is put on the website, as often too much information can easily be given away. A company policy is useful specifying that information can only be put on the company website with authorisation of a senior manager. Similar care should be taken by scientists exchanging information over the Internet. Company policy can also remind employees of their duty of confidence and to take care when corresponding with external colleagues.
- Protect any copyright in the company by marking documents as copyright belonging to the company, the name of the individual author and the year of the document.

#### Conclusion

Having followed these simple steps and avoided common pitfalls, the young company should be in a position to enter into significant technology transfer contracts or find funding unfazed by the scrutiny of due diligence.

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