

Transfusion Medicine Technology Transfer: Traps to Avoid

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Technology transfer is the process of commercializing technology and taking it from the laboratory to the marketplace. At some stage in the technology transfer process, a due diligence will be undertaken. A due diligence is an enquiry into the technology and, in particular, its ownership. Research organizations including hospitals, universities, and blood banks need to own the intellectual property that they seek to commercialize. They own the intellectual property created by their staff in the course of employment. But volunteers, students, and collaborators, not being members of staff, will own the intellectual property that they create. This gives rise to due diligence and ownership defects, when intellectual property may in fact be owned by someone other than the research organization that seeks to commercialize it. Joint ownership can sometimes prevent commercialization. An assignment of intellectual property

TECHNOLOGY TRANSFER is the process of taking technology from the laboratory to the marketplace. There are 2 main pathways that new transfusion medicine technology can reach the marketplace. The first is by a research organization granting a license to an industry partner that will commercialize the technology. The second is by the formation of a start up company, into which venture capital investment is injected, with the objective of taking the transfusion medicine technology to a state of market readiness.

Whatever technology transfer pathway is taken, a due diligence process on the technology will be undertaken, either by the prospective licensee or the prospective venture capital investor. A due diligence will focus on the ownership of the intellectual property in the transfusion medicine technology to be commercialized. Its purpose is to obtain a clear answer to the question, "Does the research organization own the intellectual property?"

This is an essential first step in the technology transfer process. Unless a prospective licensee or investor is satisfied that the research organization owns the intellectual property in the transfusion medicine intended to be commercialized, the license or start-up transaction will not proceed. A licensee needs to have clear, unencumbered licensed rights to the intellectual property, and an investor needs to ensure that the start up company into which an investment is proposed to be made

from a volunteer or student may sometimes be required. Such an assignment, if it inadequately deals with all relevant issues, may be void pursuant to laws throughout the world. A void deed of assignment may expose the research organization to legal liabilities. The categories of technology transfer traps to be explored are (1) ownership issues arising from the participation of students and volunteers in research, (2) ownership issues arising from collaborative research relationships, (3) ownership issues arising from the participation in research of visitors from another research organization, and (4) ownership issues arising from inventions made by employees. Each of these is considered in the context of the legal and regulatory framework in Australia, Canada, the United States of America, and the United Kingdom

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will similarly have clear, unencumbered rights to the intellectual property.

This article focuses on (1) what due diligence is, (2) common technology transfer traps arising from defects in the ownership of intellectual property, and (3) remedying those technology transfer traps and ownership defects.

Within research organizations such as a university, a hospital, or a blood service, the same technology transfer traps and due diligence defects repeatedly arise. The categories of technology transfer traps to be explored are (1) ownership issues arising from the participation of students and volunteers in research, (2) ownership issues arising from collaborative research relationships, (3) ownership issues arising from the participation in research of visitors from another research organization, and (4) ownership issues arising from inventions made by employees.

Each of these is considered in the context of the legal and regulatory framework in Australia, Canada, the United States of America, and the United Kingdom. The focus is on intellectual property, which is patentable, as most commercializable blood transfusion medical research would be. A

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patent, when granted in relation to new inventions, confers on the patent holder or its licensee the exclusive right to commercially exploit the invention encompassed in the patent.

DUE DILIGENCE

What Is Due Diligence?

A due diligence is fundamentally a fact-finding exercise. It typically involves 3 phases. The first phase is to ascertain the facts. The facts are not just whether a research organization owns intellectual property. It goes further than this. The due diligence process enquires into how the research organization has come to be the owner. It inquires into who the inventors or creators of intellectual property are; whether they are employees of the research organization, employees of a collaborator, students, volunteers, or visitors; and whether the legal relationships between these and the research organization are shown, tracing the links in the ownership chain between the inventor or creator and the owner.

The second phase is to validate the facts. This validation is usually undertaken by inspecting documents, such as deeds of assignment. These deeds show the links in the ownership chain between the inventor or creator and the owner of the intellectual property. A deed of assignment is a legal document that conveys or transfers title in intellectual property from 1 person to another.

The third phase is to assess those facts and the validation. Sometimes that assessment will expose defects in a research organization's title to the intellectual property that it believes it owns. If those defects can be remedied, they are remedied. If those defects cannot be remedied, the result may well be that a blood transfusion medical invention that merits commercialization ceases to be a candidate for a licensee or for a start-up venture capital investment.

The Result of Due Diligence Defects—Commercialisation Failure and No Community Benefit

Commercialization requires a substantial speculative investment by a licensee or investor. This is particularly so when the commercialization candidate is a blood transfusion medical invention or any other biotechnology invention. A licensee's or investor's cost of funding more research, develop-

ment, and the progression of the technology through clinical trials and the regulatory process is substantial and speculative. A licensee or investor will not make such a speculative investment, unless there are clear rights to the technology so as to justify the speculative investment. This means that the research organization clearly must own the intellectual property.

Venture capitalists and prospective licensees will invariably undertake a rigorous and penetrating due diligence on intellectual property ownership. If a research organization does not solely own all the intellectual property, there may be due diligence defects, and this can make the venture capitalist or licensee disinclined to proceed.

Unfortunately, this means that sometimes, when a commercialization candidate fails the due diligence, new intellectual property in the form of new products and new processes are not commercialised. This may result in the community never having the benefit of the new product or process that was invented.

Benefiting the community, by making new products and processes available, is the principal reason for blood transfusion medical research to be undertaken. Often those new products and processes because of due diligence defects are dismissed as candidates for the substantial and speculative investment required to bring those new products and processes available to the community. That could be detrimental to the community that is intended to be the beneficiary of blood transfusion medical research.

The Result of Due Diligence Defects—Exposure to Legal Liabilities

The due diligence process does not always identify due diligence defects, and a license to a licensee or a license or assignment to a start-up company in which an investor invests may proceed. The later discovery of a defect in title in a licensor's or assignor's ownership of intellectual property is likely to give rise to legal liabilities.

A license or assignment invariably contains warranties, or promises, that the research organization licensor or assignor owns the intellectual property that has been licensed or assigned. If there is a defect in title, when the intellectual property is in fact owned wholly by another person or partly owned by the research organization and partly by

another person, this can expose the research organization to damages. In either of these cases, the research organization that has licensed or assigned the intellectual property in fact had no title, or did not have the whole of the title, and therefore had no capacity to license or assign at all. This amounts to a breach of those warranties or promises and is the basis of the exposure to a claim for damages.

This can be a substantial exposure when a licensee, assignee, or an investor in a start-up company has made a substantial investment. The exposure can be even higher if a claim for lost profits is successful.

Being Ready for Due Diligence

A research organization therefore needs to be mindful of the need one day to submit itself and its intellectual property to due diligence and therefore needs to be mindful of the most common due diligence defects and traps that arise, the need to avoid them, and how to remedy them.

STUDENTS AND VOLUNTEERS

Joint Ownership

If a student who participates in research, solely creates an invention or a component of an invention, the research organization does not have legal title to the intellectual property in that invention to be able to license or assign it. The same is the case when a volunteer participates in research. A volunteer in this context may be a physician or another person who, not being an employee, participates in research undertaken at a research organization, such as at a hospital or blood service.

The law, broadly, is that an invention made by an employee in the course of employment is owned by the employer. But neither a student nor a volunteer is an employee. Accordingly, each personally owns any intellectual property that they may solely create.

When an invention is made jointly by a student or volunteer and a research organization's staff, the invention will be jointly owned by the student or volunteer and the research organization. Ownership in this way becomes fragmented between these co-owners, and it is this fragmentation that gives rise to due diligence defects.

In each country, the joint ownership of a patent impacts on the research organization's ability to deal with the patent. In Australia and the United

Kingdom, the patent statutes provide that although both joint owners can exploit the patent,¹ neither is able to license or to assign its interest in the patent without the consent of the other joint owner.² There is no comparable provision in the Canadian patent statute, but this is the general law position in Canada.³

So, when a patent in these countries is jointly owned, the research organization joint owner will not be able to license it to a licensee or to license it or assign it to a start-up company without the consent of the student or volunteer.

The matter cannot be addressed simply by obtaining a student's or a volunteer's consent to a license or assignment. Both a prospective licensee and a prospective venture capital investor will be disinclined to negotiate with an individual such as a student or volunteer. Each will prefer that the title to intellectual property not be fragmented between co-owners in this way and will prefer that there be assignments by each of their interest in the intellectual property to the research organization.

From the research organization's point of view, it is undesirable to have to seek a consent from a student or a volunteer, each of which are effectively able to veto commercialization or the terms on which commercialization takes place.

The situation is different in the United States. In that country, a joint owner does not need the consent of other joint owners to be able to grant a license to intellectual property; each joint owner is able to do so.⁴ But this raises a different trap. A licensee or prospective investor will invariably seek to ensure that the licensee or start-up company will have exclusive rights to intellectual property, being the same exclusive rights that are conferred on a patent owner.

There cannot be any such exclusive rights if only 1 joint owner participates in the transaction, leaving the other joint owner free, for example, to grant competing commercialization rights to another person. A licensee or venture capital investor will therefore similarly require that the student or volunteer assign the interest in the intellectual property to the research organization.

Deeds of Assignment from a Student or Volunteer

The result therefore is that an assignment will be necessary from a student or volunteer participant in research to the research organization. Research

organizations are accustomed to having their employees sign a deed of assignment of an invention, usually just before making a patent application. When an employee signs such a deed of assignment, it does not have the effect of transferring the ownership of the invention from the employee to the research organization. This is because the law, broadly, is that an employer owns the intellectual property created by its employees in the course of their employment. A deed of assignment signed by an employee is therefore not a document of transfer of ownership. It serves the purpose of recording the employment relationship and that the employer is the owner of the intellectual property.

But, this is not the case with students or volunteers, who are not employees. An invention made by a student or volunteer is not automatically owned by the research organization. A deed of assignment is necessary to transfer the ownership of the invention from the student or volunteer to the research organization. As a deed signed by a student or volunteer has this character of transferring ownership, the effect of the law relating to unconscionable transactions will apply. Broadly, the law relating to unconscionable transactions allows an unfair contract to be declared void.

This has important implications for an assignment from a student or volunteer to a research organization. If there is a need for such an assignment to avoid the issues of fragmentation arising from joint ownership, it is important that such an assignment be on such terms that there will be confidence that the assignment will be valid.

If it is declared void, the student or volunteer continues to own the intellectual property that was purportedly licensed or assigned. This could result in a license to a licensee or an assignment or license to a start-up company being imperfect. In turn, this could expose the research organization to a claim for damages. Having obtained an assignment from a student or volunteer, the research organization may have made warranties or promises that it had title to the intellectual property. An assignment from a student or volunteer being void, these promises are breached, resulting in the exposure to damages for the research organization.

In Australia, for example, the Trade Practices Act 1974 allows a court to declare a document that is unconscionable invalid.⁵ Unconscionability has been described in the following way:

“Relief on the ground of unconscionable conduct will be granted when unconscientious advantage is taken of an innocent party whose will is overborne so that it is not independent and voluntary, just as it will be granted when such advantage is taken of an innocent party who, though not deprived of an independent and voluntary will, is unable to make a worthwhile judgement as to what is in his best interests.”⁶

In Canada, there is a similar general law principle of unconscionability, which has been expressed in the following way:

“I take the law of the Court to be, that if two persons . . . stand in such a relation to each other that one can take an undue advantage of the other. . . a transaction resting upon such unconscionable dealing will not be allowed to stand.”⁷

This is complemented in Canada by specific legislation in some provinces.⁸ In the United States, there is similarly a general law principle of unconscionability.⁹ In the United Kingdom, the Unfair Terms in Consumer Contracts Regulations 1994, made pursuant to the European Union Directive on Unfair Terms in Consumer Contracts, makes provision in similar respect. According to the regulation an unfair term in a contract is one that “is contrary to the requirement of good faith and causes significant imbalance in the parties’ rights and obligations under the contract.”¹⁰ When there is such an unfair term, it will not be binding on the student or volunteer.¹¹ The principle of unconscionability is not dissimilar to general law principles of duress and undue influence, both of which also might invalidate a deed of assignment by a student or a volunteer.

But the principle of unconscionability goes much further and extends beyond where duress and undue influence stop. It rests on notions of fairness in a legal document. One of the main factors that a court will consider in assessing whether a document is unconscionable is the relative bargaining positions of the parties.¹²

The relative bargaining positions between a student or volunteer and the research organization is such that a student or volunteer has little or no bargaining position. A student particularly needs to be included in a research project to complete requirements for a degree and is presented with a deed of assignment. The circumstances surrounding the presentation of the deed to the student are such that the student must sign it or be excluded from the research project. A student’s likely per-

ception is that the student must sign the deed of assignment that is presented or put at risk the student's participation in the research project that is essential to the student completing the requirements for the student's degree. There is a wide gulf in the relative bargaining positions of the student and the research organization. There may well be an absence of an independent and voluntary act by a student, which leaves it open to a student to challenge the deed of assignment and to seek not to be bound by it.

A deed signed by a student or volunteer that is in the same terms as a deed signed by an employee is likely to be an unconscionable document. This is because it divests a student or volunteer of ownership of something that may be valuable, namely the intellectual property created by the student or volunteer or to which the student or volunteer may have contributed without the student or volunteer being equitably compensated.

If a court holds that a deed signed by a student or volunteer is an unconscionable document, the court can declare it invalid. This results in ownership of the intellectual property remaining with the student or volunteer, leading to the due diligence defects described and to the exposure to legal liabilities described.

Ensuring That Student and Volunteer Deeds of Assignment Are Valid

However, a deed of assignment can be prepared that reduces the risk of it being unconscionable and liable to being declared void. To reduce this risk, it is important that the terms of the deed are commercial and equitable terms and that a student or volunteer obtains independent legal advice about the terms of the deed.

To be on commercial terms, there are 4 things that a deed of assignment should make provision for: (1) financial compensation to the student or volunteer, (2) the student retaining ownership of copyright in the student's thesis, (3) the student being able to have a thesis examined without impediment, and (4) the student or volunteer being able to publish in academic journals.

Financial compensation to a student or volunteer can be achieved by the student or volunteer sharing in commercialization revenues received by the research organization from the commercialization of intellectual property in the same way that employees share in that revenue. Most research organiza-

tions have a commercialization revenue sharing policy that confers on employees who invent an expectation of receiving a share of revenue from the successful commercialization of the intellectual property that they generate. One third of commercialization revenues being distributed to inventors is a model commonly encountered.

If the student or volunteer is made a beneficiary of this commercialization revenue sharing policy, along with all other employee inventors, the student or volunteer is compensated for the assignment of the intellectual property on terms that can be regarded as commercial and equitable.

The deed should also record that the student retains ownership of copyright in a thesis. All other intellectual property made or contributed by the student should be assigned. This will not prejudice the research organization's commercial interests because it is copyright only that the student retains and the student will have obligations of confidentiality, even in relation to the contents of the thesis.

A student's ability to submit a thesis for examination, and therefore be able to complete requirements for the award of a degree without hindrance, is paramount, and this should be guaranteed in the deed of assignment. To ensure that the research organization's commercial interests are not prejudiced by the thesis prematurely entering the public domain by being disclosed to examiners, the deed should provide that before the thesis is submitted to examiners, the examiners must sign a confidentiality agreement.

Although the deed of assignment must require students and volunteers to maintain confidentiality, the deed should also allow students and volunteers to publish in a way that will not prejudice the commercial interests of the research organization. This might mean that the student or volunteer might have to accept publication being delayed until a protection strategy is put in place, such as lodging a provisional patent application. The period of the delay should be discretionary but realistic so that neither the student's or volunteer's interests, nor the research organization's commercial interests, are encumbered unfairly.

The nature of a deed of assignment is such that it is vital that the student or volunteer has the benefit of independent legal advice about the nature and provisions of the deed. The absence of that independent legal advice is a key factor that results in a deed being void. Conversely, if there is inde-

pendent legal advice, the presence of this factor will disincline a court to hold that a deed is void. The deed should ideally include a certificate by the independent legal adviser to certify that independent legal advice has been given.

This is not to suggest that on every occasion that a student participates in research that a deed of assignment on these terms and obtained in this way should be procured. To do so on every occasion would be impractical and administratively burdensome. However, when research is undertaken in which students or volunteers participate and that research has commercialization horizons or objectives or is funded by industry financial sponsorship, it is prudent to obtain such a robust assignment.

INVENTIONS BETWEEN RESEARCH COLLABORATORS

Different traps and due diligence defects may arise when there are inventions by research collaborators.

The result of a collaboration may be that an invention is jointly owned by the 2 research organizations. If the employees of two research collaborators have contributed to an invention, the result is likely to be joint ownership of the invention between the two research collaborators.

When there is joint ownership in this way, the joint owners jointly enjoy the exclusive rights conferred by a patent. It is inconsistent with this if 1 joint owner was to be permitted to assign its interest in the patent or to grant a license over the patent without the consent of the other joint owner. This would have the effect of diluting the joint interest held by the joint owners.

In Australia, Canada, and the United Kingdom, the result of a research collaboration leading to a joint patent is therefore that 1 joint owner is unable to assign its interest, or to grant a license, without the consent of the other joint owner.¹³ This may prevent the commercialization of the technology that is sought to be commercialized. One joint owner may decline to grant its consent or may effectively veto the terms on which commercialization is sought.

When the research collaborators are both research organizations, such as 2 universities, joint ownership in this way usually leads to the 2 research organizations proceeding to commercialize

together or, more likely, one granting a license to the other to do so on behalf of both.

However, when the 2 joint owners are not research organizations but instead are a research organization and a private sector company that same cooperation cannot necessarily be expected. A private sector joint owner, unless it is the proposed licensee, has its own interests to protect and is unlikely to consent to an assignment or license, doing as that does equipping a competitor.

When there is joint ownership of a patent between a research organization and a private sector company, all the benefits of ownership are held by the private sector joint owner, and the research organization is unable to enjoy any of the benefits of ownership at all. This is the result of the research organization's inability to license or assign without consent, the unlikelihood of the joint owner being inclined to grant consent, the research organization lacking the capacity to itself exploit by entering the marketplace, and the private sector joint owner being the only one of the joint owners with the capacity to exploit.

The situation is not necessarily much better if the research organization joint owner proposes to grant a license to the private sector joint owner. Necessarily, because of the research organization's inability to license or assign without consent, the unlikelihood of the joint owner being inclined to grant consent, the research organization lacking the capacity to itself exploit by entering the marketplace, and the private sector joint owner being the only one of the joint owners with the capacity to exploit, the research organization's bargaining position is adversely affected. Negotiations conducted on such an unequal footing, with such inequality of bargaining power, operate to result in the terms of any final negotiation being likely to be less than the commercial terms that might otherwise have been expected. The research organization in this case has little to bargain with, and this often results in royalty rates and other financial terms being less than those that commercial benchmarks might have suggested are appropriate.

The situation is different in the United States where 2 joint owners are each able to grant a license without the consent of the other.¹⁴ But, here there are other challenges. A licensee or venture capital investor will be disinclined to invest when less than the whole of the rights available are

granted, which is the case when 1 joint owner remains at liberty to grant a license to a competitor to the licensee or start-up company in which the investment is proposed to be made. The licensee or investor will not unexpectedly wish to secure the whole of the available rights to be in the same exclusive position in which a sole patent holder would be.

Joint ownership between research collaborators therefore presents problematic technology transfer traps and due diligence defects and, ideally, should be avoided.

In the culture of scientific collegiality among researchers, this is easier said than done. Scientific collegiality means the exchange of information between scientists, and this leads to suggestions from colleagues and inventive contributions being made to research. Often, this arises when a transfer of biological materials occurs between research organizations without there being an appropriate material transfer agreement in place that regulates the ownership of intellectual property arising from research undertaken by the recipient of the biological material. More often, it can arise by scientists employed by different research organizations simply collaborating with no appropriate legal agreement in place regulating their respective positions.

Collaborative relationships can be managed to avoid joint ownership when not doing so impedes commercialization. This will be the case when research has a commercialization horizon or objective or when it is funded by industry financial sponsorship. In these cases, ideally, the collaborative research relationship should be documented with an appropriate agreement, which should address ownership, including, if appropriate, providing for joint ownership, but containing a license for commercialization purposes to one of the joint owners.

INVENTIONS BY VISITING SCHOLARS FROM OTHER ORGANIZATIONS

Staff members from research organizations often accept positions as visiting scholars at other research organizations. When these visiting scholarships are confined to teaching only, no intellectual property due diligence issues are likely to arise. However, when a visiting scholar is concerned with research, similar issues of joint ownership and the same joint ownership traps may

arise. For example, a visiting scholar may, during the visit to another research organization, wish to continue research on an existing project. If the visiting scholar will be paid by the research organization that the visiting scholar is visiting, that research organization, as the visiting scholar's employer, will be the owner of the intellectual property generated by that visiting scholar. If, for example, a patent arises that is based in part on inventions made by the visiting scholar before the visiting scholarship commenced, which are owned accordingly by the research organization from which the visiting scholar has taken leave and in part during the visiting scholarship, the result will be that the patent will be jointly owned by the 2 research organization employers.

Similarly, a visiting scholar may, during the visit to another research organization, be asked to participate in research already being undertaken at the research organization that is being visited. If the visiting scholar continues to be paid remuneration by the employer from which leave has been taken, that research organization, as the visiting scholar's employer, will be the owner of the intellectual property generated by that visiting scholar. Similarly, the result will be that a patent will be jointly owned by the 2 research organization employers.

This is, in fact, just another example of what is considered a collaboration between research organizations, although it is seldom recognized as being such a collaboration. All the comments mentioned previously in relation to such collaborations apply equally in the case of visiting scholars. Ideally, when visiting scholars will be involved in research, there should be a legal agreement between the 2 respective research organization that regulates their respective positions about the ownership of intellectual property.

INVENTIONS BY EMPLOYEES

Broadly, the law is that an employer owns the intellectual property created by its employees in the course of their employment. But among the countries under consideration, this conclusion is arrived at along different paths.

In Australia, there is no statutory provision that an employer owns the intellectual property created by its employees. Ordinarily, this is addressed expressly in the terms of the employment contract, and prudently, it should be. If it is not, a term will

have to be implied into the employment contract that intellectual property created in the course of employment is owned by the employer, and the courts have had little difficulty in implying such a term.^{15,16} The situation is the same in Canada, which similarly has no statutory provision, but whose general law provides to a similar effect.^{17,18} The situation is the same as well in the United States.

In the United Kingdom, there is statutory provision that intellectual property made by an employee is owned by the employer when it arises in the course of the employee's duties.¹⁹ However, it is not uncommon for universities in the United Kingdom to forgo rights to intellectual property created by its employees and to allow their employees to retain ownership of the intellectual property that they generate even when made in the course of employment.

In each country, an individual inventor has the right to apply for a patent, unless the principles mentioned operate to vest this right in the employer. It is problematic, however, to decide what is within and outside the course of employment for the purpose of implying a term into the employment contract that the employer owns the employee's inventions. The courts will have regard to the specific employment duties, whether the employee was responding to directions from the employer, whether the employee's duties prompted the innovation or provided access to the wherewithal to make it, and whether other factors existed. But these are all factors to be weighed and, accordingly, do sometimes give rise to conflicting and at times irreconcilable conclusions, and it is that which is unsatisfactory and has the potential to lead to due diligence defects.

It is not unusual, therefore, for a research organization to make warranties, or promises, that intellectual property was created by its employees in the course of their employment. In cases in which it is afterwards found that intellectual property was created by an employee outside the course of

the employee's employment, these warranties or promises may be breached, giving rise to an exposure in damages. It is prudent, therefore, to always have an express term in an employment contract that describes the scope of an employer's entitlement to the intellectual property created by its employees.

MANAGING INTELLECTUAL PROPERTY OWNERSHIP

A research organization cannot always presume that it is the owner of intellectual property created at the research organization. It might have been created by students, volunteers, collaborators, visiting scholars, or even employees outside the course of their employment.

The most common technology transfer trap that research organizations find themselves falling into is presuming ownership of the whole of the intellectual property that is sought to be commercialized. It is only after a due diligence is undertaken by a prospective licensee or venture capital investor that these types of due diligence defects are discovered.

Often, these defects can be and are remedied. But, even then, this is sometimes at the risk of devaluing intellectual property and lengthy negotiations to effect the remedial steps required, bringing with it sometimes lost commercialization opportunities. Increasingly, research organizations are becoming more conscious of the need to implement policies to avoid these technology transfer traps and to educate their staff about these traps.

Some research organizations are even becoming proactive. They are undertaking their own due diligence on their own intellectual property, identifying for themselves the technology transfer traps, lurking and remedying them as part of the commercialization assessment process and before a licensee or venture capital investor instead discovers them, becomes disinclined, and rejects the commercialization opportunity.

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