Trade and international investment are an obvious form of international business. An important key to sound economic management is a move towards free trade through the liberalization of trade barriers. Whilst multilateral liberalization (World Trade Organization) is to be preferred, bilateral liberalization (a free trade agreement) is a step in the correct direction of the Asia-Pacific biotechnology sector.

International diversification is a strategy through which Asia-Pacific biotechnology firms expand the sales of goods or services across the borders of global regions and countries into different geographic locations or markets. Because of its potential advantages, international diversification should be related positively to Australian biotech business's returns. International expansion is accomplished by exporting products, licensing arrangements, strategic alliances, and acquisitions and establishing new, wholly owned subsidiaries.

In the commercial exploitation of opportunities in biotechnology, the process of deal making will involve a consideration of the relevant documentation that an enterprise will utilize to bring the opportunity to fruition.

Biotechnology businesses are no different to any other type of business. There are common determinants in any business enterprise no matter if the product is washers or biotechnology.

The starting point for any business venture is the legal structure of the enterprise. This is to be determined after careful consideration factors, such as the nature of the enterprise, its market arena (national or international), its projected growth, its projected funding requirements, taxation issues, liability issues and the compliance costs and regulatory requirements of the entity chosen. These are decisions that must be made in conjunction with legal and financial advisors. Choosing the wrong enterprise structure can create serious impediments for the enterprise to achieve its goals and result in other detrimental consequences.

The most common enterprise structures are sole traders, partnerships, private companies and public companies. It is beyond the scope of this paper to consider these structures in detail or to opine as to what is the most appropriate business structure, suffice to say that it can be safely assumed that businesses operating in an international arena are generally corporations.

Biotechnology enterprises may often find that the project to be undertaken will require a project partner (either to develop or further develop a project) that brings benefits such as expertise, funding, and reputation or information technology or intellectual property. The enterprise structure between the prospective partners is also a matter to be determined after careful consideration of various factors in conjunction with financial and legal advisors.

The most common structures for such enterprise ventures between partners are partnerships, unincorporated joint ventures and corporate joint ventures.

Moreover, it is beyond the scope of this paper to consider these structures in detail or to opine as to the most appropriate joint enterprise structure, suffice to say that corporate joint ventures are usually utilized for major projects.

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Assuming that a biotechnology enterprise has, through good business practices such as networking, painstaking research, serendipity or other method identified a business opportunity to pursue a project that will realize profits, the enterprise will then be faced with the process of courtship, negotiation and contractual relations (CNC).

The project may require funding, project partners, suppliers, and distributors, manufacturers and other project needs. All steps in the project will require CNC and a familiarity with the pre-contractual and contractual documentation common to commercial dealings. Needless to say, legal advice must be obtained at all times to ensure that what is intended is feasible and documented properly to avoid subsequent litigation, project difficulties and financial loss.

The courtship process usually involves an initial face-to-face meeting with a general discussion of the commercial needs and expectations of the parties and the establishment of personal relationships and trust. Such meetings are not, of course, always possible, as the other party may be located interstate or overseas. Video conferencing rather than email, letter or telephone conferencing is a better option in such circumstances.

Initial meetings may or may not entail the provision by the biotechnology enterprise of confidential information. The enterprise's position may be protected by a patent or other intellectual property protection. This is not always the case and the project may involve the exploitation of a good idea not yet exploited by anyone else and confidentiality may be of vital importance lest the project details be leaked and exploited by another enterprise. The enterprise should always come prepared with project information packages with alternative confidential and non-confidential information.

Prior to divulging any confidential information, the other party should always be asked to first execute a properly drawn confidentiality agreement. This is a document that contractually binds the other party not to disclose the confidential information to any other party without the disclosing party's prior consent. The agreement should provide that the enterprise may claim damages against the disclosing party if the information is disclosed in breach of its terms. This is an extremely important document in commercial transactions, especially in the biotechnology industry where cutting edge ideas are the usual basis for commercial exploitation.

Be prepared for the other party refusing to sign a confidentiality agreement. The non-confidential information package may not contain sufficient information to persuade the other party to be involved in the project and the enterprise may be faced with a difficult commercial decision of whether to hand over the confidential information package without the protection of a confidentiality agreement. In such circumstances, careful consideration should be given as to the consequences of taking the risk of disclosing confidential information and relying on the other party to act responsibly and honestly.

The confidentiality agreement is document utilized in contract negotiation rather than contract formation. In between the negotiations and the final contract documents, there are other documents that are commonly utilized to facilitate final agreement.

If the parties decide that it is in their mutual self-interest to proceed, they will enter into the second phase of CNC, namely, contractual negotiations. Needless to say, the enterprise should have a clear understanding of its goals, needs and a position to adopt during negotiations. It should also put itself in the other party's shoes and have a strategic plan to deal with the usual arm wrestle in relation to each party's position.

It is beyond the scope of this paper to deal with the negotiation process itself, suffice to say that it is recommended that a legal advisor be consulted or employed to deal with negotiations as pre-contract representations may, in some circumstances, lead to future litigation based upon common law misrepresentation or upon statutory remedies such as misleading and/or deceptive conduct and unconscionability under statutes such as the Commonwealth Trade Practices Act.

Once the parties have agreed to enter into a contract in principle, they may wish to document the important points pending the drafting of a comprehensive contract by their legal advisors. Such a document is usually called a Heads of Agreement or a Memorandum of Understanding. These are the usual documents relevant to the negotiation phase.

The principles of contract formation vary from jurisdiction to jurisdiction. This is a consideration when contracting with overseas companies.

In Australia, to be enforceable, a contract must, amongst other things, contain all of the essential terms (that is, they must be complete) and they must not be unclear (that is, incapable of any precise definite meaning).  

2 Axelsen v O'Brien (1949) 8 CLR 219.
What is an essential term depends upon the intention of the parties. At minimum, there must be certainty as to the identity of the parties, the subject matter of the agreement, the principal undertakings and the price. It is not always possible at an early stage of negotiations to identify all of the terms the enterprise will come to consider to be essential, especially when dealing with complex subject matters or joint enterprises. It is often as negotiations progress that views crystallize.

Many Heads of Agreements and Memoranda of Understanding are legally unenforceable. They often do not contain all of the essential terms (especially in the quite complex transactions that biotechnology will usually spawn). They are really a stage in the negotiation process rather than a final agreement.

It is not uncommon during the negotiation phase (and occasionally in final contracts), especially with complex deals or when dealing with complex subject matters, for the parties to agree on some things and put others to one side, that is, “to agree to agree at a later date.” This can be very useful in working though a deal and these items are often included in Heads of Agreement or Memoranda of Understanding. Australian courts have held that an agreement may be incomplete (and therefore unenforceable) if the parties omit an essential term or because they agree to agree to an essential term at a later time (deferred terms). It is possible to agree to agree at a later time if there is a clear formula to regulate the alteration or the parties provide a dispute resolution mechanism to resolve the “agree to agree” subject matter (such as arbitration).

It is not always necessary to resort to documentation in the nature of Heads of Agreement or Memoranda of Understanding, and the negotiations can lead directly to final contract documents. This is more likely to be the case when dealing, for example, with finance providers where there is little room to negotiate on standard loan documents. However, it is suggested that such interim documents are a very useful tool to assist the enterprise to develop its thinking in relation to the proposed transaction and draw out the other party’s thinking process and they should be employed wherever possible. Many a good deal has been made better through the evolution of negotiations.

The final phase of CNC is entering into a contract. This process must be facilitated through legal advisors who (in biotechnology transactions, it is suggested) are experienced in commercial contracts, information technology, intellectual property and, ideally, au fait with the biotechnology sector.

The enterprise must ensure that the legal advisors fully understand not only the commercial outcomes sought by the enterprise and the brief generally, but also the biotechnological asset and its potential applications and commercial exploitation possibilities. This is vital for the legal advisors to properly draw documents and a lack of communication or understanding (or an erroneous assumption of understanding) may result in drastic consequences down the track.

All contracts (and documents generally) should be carefully read and fully understood before signing. If there are clauses that are not understood, an explanation should be sought. If there are issues and outcomes that appear to be either not dealt with or not in accordance with the enterprise’s instructions they should be raised and dealt with. All too often documents are signed on the mistaken assumption they accurately reflect the enterprise’s understanding and of the transaction. This is more likely to happen when the documentation is voluminous and drawn in legalese. It should be remembered that the devil is often in the detail.

The enterprise must balance the commercial need to move quickly to exploit an asset (or risk missing the boat) with the need to avoid the ills than come from unseemly haste. The need for covering all bases is exacerbated in the biotechnology sector due to its inherent cutting edge subject matter. Whilst courts will apply accepted legal principles to new situations and technologies, such situations often lead to increased uncertainty as to outcomes of legal disputes due to a lack of precedent and the sometimes difficult task of making the legal shoe fit.

Remember that courts will generally enforce contracts and will not (in the absence of conduct by the other party such as misrepresentation or unconscionability) allow an enterprise to breach a contract without being liable for damages or being subject to other consequences just because it turns out to be a bad deal. The rule is to get it right or risk wearing the consequences, which may include failure to realize the asset’s potential or even financial loss.

Well-drawn documentation is a vital tool for enterprises in the biotechnology sector. The success of the enterprise in its exploitation of an asset, either on its own, or in partnership with other venture partners or in the favorable outcome of litigation if things go awry, is founded upon well drawn and well thought out documentation at every step of the CNC process.

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3 Bridge Wholesale Acceptance Corp (Australia) Ltd v Burnard (1992) 27 NSWLR 415.
4 Thorby v Goldberg (1964) 112 CLR 597.

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