A Guide To Licensing Biotechnology

BY KATRINA BILLS*

A discussion of the merits of licensing, structure and elements of a licence, how royalties are calculated and the issues to be considered in drafting and negotiation a licence agreement. This article based upon an essay which won the LES ANZ Prize.

1 Introduction

Biotechnology by definition is the use of biological processes to solve problems or make useful products.[1] Since the 1970's our understanding of biology has expanded significantly. We now talk about biotechnology as "a collection of technologies that capitalise on the attributes of cells, such as their manufacturing capabilities, and put biological molecules, such as DNA and proteins to work for us."[2]

In 2001 in Australia there were an estimated 190 biotechnology companies and 460 related biotechnology companies generating combined estimated revenue of $1 billion.[3] Whilst publicly listed biotechnology companies spent approximately $112 million on R&D, an average of $3.2 million private biotechnology companies spent $1 million on R&D.[4] For the same period, biotechnology represented approximately 9% of the total government expenditure on R&D.[5]

In 2001 the Federal Government allocated $20 million to the Biotechnology Innovation Fund which aims to increase the rate of commercialisation of Australian biotechnology ventures. If an organisation meets the programs eligibility criteria BIF will fund up to 50% of the costs of establishing proof of concept to a maximum individual grant of $250,000.[6] In parallel all state governments have setup assistance programs for biotechnology companies who are at proof of concept stage.

But why are the governments so keen to support this industry? The United States Department of Commerce recently completed a survey of more than 3,000 firms engaged in biotechnology-related areas, they reported that:[7]

- They employ more than 1.1 million people;
- Have total annual net sales of US$567 billion, operating income of US$100.5 billion, capital expenditures of US$29.5 billion and R&D expenditures of US$41.6 billion;
- Have 33,131 pending patent applications for biotechnology products or processes and 23,992 current portfolio biotechnology patents;
- Growth for biotechnology net sales of just over 10%;
- They are investing about twice as much in their biotechnology-related lines of business as in their businesses as a whole;
- Biotechnology related R&D expenditure represents approximately 10% of total R&D expenditure U.S.A.

In short, biotechnology business is big business and is rapidly growing; the possibility of increased employment, turnover, profit and taxes is very real. The promise of a cure looming for many diseases which plague humankind is also a powerful incentive. More than 325 million people worldwide have already been helped by more than 155 biotechnology drugs and vaccines approved in the U.S.[8] whilst more than 370 biotech drug products and vaccines are currently in clinical trials in the U.S.

However, organisations need assistance to move from unprofitable to being profitable, and that assistance is in commercialising their research. Many R&D organisations do not have the skills, finance or time to commercialise their research. Biotechnology firms also have a need for large investments of funds whilst not being able to offer a return on that investment for many years,[9] if at all.

Why? Because biotechnology companies are essentially selling unproven technology, often without an identifiable use or market.

1. BIO 2003, "Editor's and Reporter's Guide 2003-2004: Biotechnology A New Link to Hope," available: *www.bio.org/er/BiotechGuide.pdf* Accessed: 4/11/03, p1.
2. Ibid.
3. Freehills, Ernst & Young, 2001, *Australian Biotechnology Report 2001*, Paragon Printers, Australasia, Canberra, p7.
4. Ibid., p10.
5. Ibid., p11.
6. "Biotechnology Innovation Fund," available: *www.biotechnology.gov.au and www.ausindustry.gov.au*, accessed: 5/11/03.
7. Department of Commerce, Oct 2003, "A Survey of the Use of Biotechnology in U.S. Industry," available: *www.technology.gov/reports/Biotechnology/CD120a_0310.pdf*, accessed: 5/11/03, p ix-xiii.
8. BIO 2003, "Editor's and Reporter's Guide 2003-2004: Biotechnology A New Link to Hope," available *www.bio.org/er/BiotechGuide.pdf*, accessed: 4/11/03, p9.
9. Gevurtz FA, Fall 2000, "Symposium: Biotechnology and the Law: Biotechnology: Business Organisation Issues," *University of the Pacific McGeorge Law Review*, 32, p238.

Katrina Bills is a lawyer with Clarke & Kann in Brisbane, Queensland, Australia; and is the LES Australia & New Zealand Prize winner for the Queensland University of Technology 2003.

Even if there is a known use and market, it will still take many years, to receive approval for the product then produce it in sufficient quantities and quality for the end consumer and provide a return on investment. Added to this is a high-risk of unpredictable catastrophic liability[10] and particularly in the area of human health whether the use of technology is "moral."

This paper is to discuss the most common commercialisation method in the biotechnology industry, licence agreements[11] and offer some advice on the factors to be considered in drafting and negotiating a licence agreement. Firstly, it discusses the merits of licensing then the structure and elements of the agreement and finally provides an explanation on how royalties and other payments are calculated.

2 Why License?

A license is, according to Oxford Compact dictionary, "a permit from an authority to own or use something, do a particular thing, or carry on a trade." A licence agreement may also co-exist with other types of agreements such as to purchase equipment, transfer employees, provision of training or subsequent technical assistance or to supply certain products or materials.[12]

Licensing did not gain favour as a commercialisation method until the 1970s in western economies even though it was used very effectively by Japan to rebuild its industry, develop dominance in a number of fields including consumer electronics and modernise its chemical and pharmaceutical industries after World War II.[13] Today, licensing is the most common method of commercialisation in biotechnology.[14] Robert Goldscheider attributes[15] the rise in the use of licensing agreements to four factors:

1. Stronger patent protection;
2. Emergence of information technology (enabling the sharing, recording and analysing of information);
3. Internationalisation of the market place; and
4. The transient nature of many workforces (has lead to an increased focus on knowledge management).

Accompanying this is an increased understanding of the value of intellectual property (IP) and the importance of realising a return on their investment. Within the biotechnology industry this is often achieved by licensing their patents. Many biotechnology companies do not plan to commercialise patents themselves. Instead they are simply interested in creating IP. Other companies recognise that they do not have the skills, resources or expertise to successfully commercialise or can only do so in a specific geographic area or field of use.

Licensing patents to other organisations (licensing out) is a mechanism which creates a revenue stream which will support further R&D efforts.[16] It also allows them to retain control over the use of the patent[17] whilst contracting with someone who has the expertise to commercialise the technology,[18] ultimately providing a better return than if they attempted to do it themselves. The licensee in return obtains products or technology which would have been more expensive and less efficient to develop in-house.[19]

A licence, if the terms are reasonable and additional items such as know-how are offered can also discourage patent infringement.[20] However, a licence does have some disadvantages; ultimately what these are will depend on the agreement negotiated between the parties. Commonly, these are:

- Difficult and time consuming process of calculating license payments (royalties) which are intended to recover for costs in developing the IP[21] and provide a reasonable income stream for the licensor whilst maintaining sufficient return for the licensee;
- The licensor may be limited in how they can use their own IP[22] once the licence has been granted;
- Time and cost of ensuring the performance of the licensee;[23]
- May end up negotiating with more than one party;[24]
- Technology may not be able to be commercialised or may be superseded during the term of the agreement.[25]

Many of these disadvantages are common to all methods of commercialisation (e.g., acquisition, strategic alliance, joint ventures) however, none offer the flexibility afforded by a licence, for both the licensor and licensee. A licence agreement can encourage the use and dissemination of technology, provide income and avoid legal challenges to the patent, if drafted carefully. In addition, all

10. Ibid.
11. Medius Associations, 3 Oct 2001, "Royalty Rates: Current Issues and Trends," available: *http://pharmalicensing.com/features/disp/1002119137_3bbb1fe183dfe,* accessed: 30/09/03.
12. Razgaitis, R., *Valuation & Pricing of Technology-Based Intellectual Property*, John Wiley & Sons Inc., New Jersey, 2003.
13. Goldscheider, Robert, ed., *The LESI Guide to Licensing Best Practices*, John Wiley & Sons, New York, 2002, p4.
14. Medius Associations, 3 Oct 2001, "Royalty Rates: Current Issues and Trends," available: *http://pharmalicensing.com/features/disp/1002119137_3bbb1fe183dfe,* accessed: 30/09/03.
15. Goldscheider, Robert ed. 2002 *The LESI Guide to Licensing Best Practices*, John Wiley & Sons Inc, New York, p7.
16. Nielsen, J., "Biotechnology Patent Licensing Agreements and Anti-Competitive Conduct," *Regulating the New Frontiers: A Symposium*, Dec. 2001, p43.
17. Biotechnology Australia, *Biotechnology IP Management*, AusInfo, Canberra, 2001, p143.
18. Ibid.
19. Schreck PA & Simkin MM, "Licensing and Intellectual Property concerns Relative to Pharmaceutical and Biotechnology Collaborations," available: *www.foleylardener.com/FILES/tbl_s31Publications/FileUpload137/1412/IPCollaborations1.pdf,* accessed: 21/9/03.
20. Ibid.
21. Schreck PA & Simkin MM, "Licensing and Intellectual Property concerns Relative to Pharmaceutical and Biotechnology Collaborations," available: *www.foleylardener.com/FILES/tbl_s31Publications/FileUpload137/1412/IPCollaborations1.pdf,* accessed: 21/9/03.
22. Ibid.
23. Middleton, G., "Licensing of Intellectual Property," *ICCIR* Iss 5 Sweet & Maxwell Ltd, 2000, p156.
24. Biotechnology Australia, *Biotechnology IP Management*, AusInfo, Canberra, 2001, p143.
25. Ibid.

non-profit organisations were given royalty free licences and all licences were non-exclusive.[26]

A good example of this is the license agreement for the Cohen-Boyer patents which was held jointly by Stanford and Columbia University which expired in 1999.[27] The terms of the licence were deliberately[28] designed to be generous to encourage the uptake of licences and as a result, decrease the risk of litigation. The licence required an upfront and annual licensing fee of US$10,000.[29] If the licence was executed within five months of the first patent being issued, five times the licence and annual fees were credited back against the earned royalties which were between 1-3% depending on the use and products sold.[30] For example, earned royalties were 2% of net sales for use of the patented claimed methods for transfected cells whilst for recombinant proteins made by the transfected bacteria (produced using the claimed methods but not covered in the patent) a royalty rate of 3% of net sales applied.[31] The result was more than 350 companies were licensed, no legal challenge was made and US$225 million in royalties were collected.[32]

3 Key Components of the Licence Agreement

The reason for licensing will often affect the content of the licensing agreement and, in particular, how royalties are calculated. The most common reasons for entering a license agreement are:

- Licensor (owner of IP) believes it has the right and opportunity to enforce its ownership of IP such as an existing patent and seeks a remedy against another party, who if successful, will often become a licensee. This is known as enforcement licensing.
- Licensor has IP and other assets which it believes will be of value to the licensee. This is known as opportunity licensing.
- Licensor is exiting a particular business area or redefining its role in that area. This is known as divestiture licensing.
- Licensor seeks a business partner to provide certain resources to a joint effort in further R&D. This is known as partnering licensing.
- Licensor licenses to a new business being formed expressly for the purpose of commercializing the technology by making and selling products and services. This is known as start-up licensing.
- Licensee seeks out a licensor for the purpose of securing rights to a technology or preventing another from doing so. This is known as opportunistic licensing.

The licence agreement itself is made up of three parts: preliminary information, terms and definitions and the grant. It is important that all parts are carefully drafted to ensure that the licence agreement reflects the wishes of both parties. Each part will now be considered in turn and wherever possible examples of clauses will be provided to illustrate the discussion.

3.1 Preliminary Information

Every licence agreement will contain preliminary information that will include identifying the parties, the purpose and background to the agreement (especially if prior agreements between the licensor and licensee existed), and representations by the licensor and licensee.

The licensor will be required to state that they own the technology referred to in the licence whilst the licensee should state why they are licensing the technology and anything else which is relevant.

3.2 Terms and Definitions

It is extremely important that terms used in the licence agreement are clearly defined. These will not only be used by the Licensor and Licensee but by the court, should a problem occur. Some common terms are discussed below.

3.2.1 Parties

It is important that the parties are described fully, if the licence is granted to a parent company and its subsidiaries. It is prudent to identify each of them, not just the parent company.[34]

3.2.2 Licensed Property

This will typically include patents, the licensors know-how and confidential information.[35] It may also include trade secrets and trademarks. The property being licensed should be listed in a schedule attached to the main license agreement. This schedule should include the patent application or patent number, type of patent, patent title, countries where patent is issued or filed, filing and issued date.[36]

3.2.3 Improvements

An improvement is "any modification of a licensed product described in a licensed patent, provided such modifications, if unlicensed, would infringe one or more claims of the licensed patents."[37] Improvements may include:

- "Anything that performs the same function as the specifically licensed invention in better or more economical way;
- Any beneficial modifications of a component (or biological material) useful in the licensed invention; or

26. Ibid.
27. Goldscheider, Robert, ed. , *The LESI Guide to Licensing Best Practices*, John Wiley & Sons Inc, New York, 2002, p206.
28. Ibid.
29. Ibid.
30. Ibid.
31. Ibid.
32. Ibid.
33. Razgaitis, R., *Valuation & Pricing of Technology-Based Intellectual Property*, John Wiley & Sons Inc, New Jersey, 2003 , p7-8.
34. "Structure of a Technology Transfer Agreement (check-list)," available: *www.100ventures.com/technology_transfer/tt_contract_checklist_byunido.html*, accessed: 7/11/03, sourced from *Manual of Technology Transfer Negotiation*, General Studies Series, United Nations Industrial Development Organisation, Vienna 1996.
35. Biotechnology Australia, *Biotechnology Intellectual Property Manual*, 2002, p149.
36. "Structure of a Technology Transfer Agreement (check-list)," available: *www.100ventures.com/technology_transfer/tt_contract_checklist_byunido.html*, accessed: 7/11/03, sourced from *Manual of Technology Transfer Negotiation*, General Studies Series, United Nations Industrial Development Organisation, Vienna 1996.
37. "Chapter 6A Government, University and Biotechnology Licensing," available: *www.lexisnexis.com/practiceareas/ip/pdfs/53/CH6a.pdf*, accessed: 21/9/03.

• Anything that performs functions similar to those of the licensed invention as described in a licensed patent and infringes the claims of the licensed patent."[38]

In many cases the Licensor will require that the Licensee provide them with a right to use any improvements—this is known as a grant-back. The Licensor will also typically want the right to sub-licence its right to use any improvements to other licensee's.

3.2.4 Field of Use

This is used by a Licensor to narrow the uses of a licensed product by the licensee. It may be using technology for a particular purpose, dealing with technology for or within a particular industry. In biotechnology and pharmaceuticals the field of use is often based on a particular medical condition.[39]

3.2.5 Net Sales

Net sales is often defined as gross sales less discounts, commissions, returns, taxes and other credits. It is important to be clear on what is included in net sales, particularly if it will be used in calculating royalties payable under the license agreement.

3.2.6 Type of Licence

A licence can be exclusive, sole or non-exclusive. Exclusive means that the Licensee is the only party who may make, have made, use and sell the technology subject to any other terms and conditions of the licence.

A sole licence, however, is similar to the exclusive licence except that it may include the right for the Licensor to also carry out some or all of these activities in the same territory or field of use.[40] Whilst a non-exclusive means that the Licensor may license to other parties in addition to the Licensee. The Licensee may also be granted the right to sub-licence.

38. Ibid.
39. Ibid.
40. Middleton, G., "Licensing of Intellectual Property" *ICCIR* Iss 5 Sweet & Maxwell Ltd, 2000 , p155.

3.2.7 Licensed Territory

This is the geographical area where the Licensor will be able to make, have made, use and sell the technology. Depending on the agreement between the parties, this may be a particular state, country or worldwide. Often the Licensor may also want to restrict the licensee from selling to any entity who may sell the licensed products outside their licensed territory.[41]

3.3 Grant

This section of the licence contains the details of the agreement between the parties, such as the rights that have been granted and restrictions imposed.

3.3.1 Exclusive versus Non-Exclusive

An exclusive licence is the highest risk of the two types of licence. The Licensor is banking on the licensee being able to commercialise the technology successfully and provide the anticipated returns. An exclusive licence can be tied to a particular territory and/or field of use to lessen this risk.

If the Licensee wants the Licensor to continue research and development on the technology then it may request a sole licence. This allows the Licensor to continue using the technology in the same territory as them but restrict it to a field of use of research and development.

A non-exclusive licence allows a Licensor to spread the risk of a Licensee being able to successfully commercialise the technology by being able to licence to more than one Licensee in a territory and field of use.

3.3.2 Sub-licensing

If sub-licensing is allowed it is important that the Licensor's consent be required. This has the dual purpose of making the Licensor aware of the existence of a sub-license and allows them to determine whether the grant of a sub-license to that party is in its best interests. Often, sub-licences will need to be granted to enable the manufacture, distribution and marketing of the final product.[42]

Regardless of the reason, the Licensor should require that the Licensee use a standard license agreement which will bind the sub-licensee to the same terms and conditions as the Licensee. Once the sub-license has been granted, the Licensor should receive a copy of the licence and regular updates from the licensee.[43] The Licensee should also indemnify the Licensor against any actions by the sub-licensee and be required to collect any royalties payable.[44]

3.3.3 Assignment

If assignment of the licence is allowed, the Licensor's permission should be required before the licence can be assigned. The Licensor may also want to include a provision which allows it to revoke the license should the ownership of the Licensee alter. This is to protect competitors of the Licensor's obtaining access to a license through acquisition.

3.3.4 Know-How & Technical Information

In order to be able to make efficient use of the patented technology, it is often necessary that the Licensor transfer its know-how (knowledge of how to use it) to the Licensee.

Often some disclosure of know-how and/or technical information is provided prior to entering the licence agreement. A formal agreement, mirroring the requirements

41. Schreck PA & Simkin MM, "Licensing and Intellectual Property concerns Relative to Pharmaceutical and Biotechnology Collaborations," available: *www.foleylardener.com/FILES/tbl_s31Publications/FileUpload137/1412/IPCollaborations1.pdf*, accessed: 21/9/03.

42. McGinness, P., *Intellectual Property Commercialisation*, p235.
43. Ibid.
44. "Structure of a Technology Transfer Agreement (check-list)," available: *www.100ventures.com/technology_transfer/tt_contract_checklist_byunido.html*, accessed: 7/11/03, sourced from *Manual of Technology Transfer Negotiation*, General Studies Series, United Nations Industrial Development Organisation, Vienna 1996.

in the licence to keep the know-how and technical information confidential should be entered into between the Licensor and prospective Licensee before disclosure is made.

The know-how transferred should be treated as confidential unless an equitable exception applies, that is:

- The licensee can prove, with written records, is already known to a licensee or is already in their possession;[45]
- It was in the public domain prior to disclosure by the licensor;[46]
- Becomes a part of the public domain by publication or by any other means except an unauthorised act or mission by the licensee;[47]
- Is received from third parties who are under no obligation to maintain such information in confidence;[48]
- Licensee can prove, with written records, was developed by licensee independent of disclosures from licensor.[49]

Particular care is to be taken when the patent has not yet been filed. The usual practice is that the Licensor will communicate the information in their possession on commencement of the agreement.[50]

Often the right to use the know-how and technical information under a licence agreement will not incur the payment of an additional fee[51] although reimbursement of expenses may be required. The licence should specify:

(a) What information is regarded as confidential? This should include any technical information and know-how which is useful or necessary to make use of the Licensed Product as specified under the licence. If the know-how is not already documented, then it is important that either at, before, or at the time of making the licence or after the know-how is transferred that it is documented and confirmed in writing. Any technical information such as manuals, results, protocols, etc., should be specified.

(b) Purpose for which it may be used. This should be consistent with the licence grant in a particular field of use, territory and type of license provided.

(c) Person(s) to whom and circumstances when it may be disclosed. This should be consistent with the licence grant in a particular field of use, territory and type of license provided.

(d) Require that all technical information and any other written documentation relating to know-how of the Licensed Products be returned on expiration of the licence[52] and that this extends to all employees, suppliers and associated entities of the Licensee.

3.3.5 Improvements

It is likely that the Licensee may identify or discover improvements to the Licensed Products during the term of the license. As the improvements will be owned by the Licensee the Licensor will want to ensure that Licensee is required to provide them with a non-exclusive licence (with the right to sub-license) any such improvements.[53]

This allows the Licensor to offer the improvements to any other licensees for an additional fee and may improve the value of the Licensed Products to potential licensee's and may extend the term of the licence.

3.3.5.1 Restraints

A Licensor will want some control over the way in which the Licensee uses the licensed property. Usually this will be that the Licensee must obtain permission before sub-licensing the technology and that they do not use, make or sell a competing product.[54]

The Licensor will also want to ensure that the Licensee, when selling product using the licensed property, does not sell it to a company which exports or sells into a market outside the Licensee's territory. A Licensor may also restrict the Licensee production of products using the licensed property according to a minimum or maximum quantity or volume of products sold or used.

3.4 Payments

Payments made under a licence agreement can vary considerably, however the most common way payments are made are as either a lump sum or a percentage of sales (royalties) or a combination of both.

An initial payment is usually made when the licence agreement is executed. Although it may be some time before the Licensee can recoup this cost, an initial payment serves as a reminder of their obligation and will encourage them to make their best-efforts to commercialise the technology. Milestone payments may also be made—these are lump sum payable on the occurrence of specified events. Examples of these are on filing or granting of patent, commencing a particular stage of commercialisation such as pre-clinical development, obtaining government approval or product launch.[55]

The type, amount and frequency

45. "Structure of a Technology Transfer Agreement (check-list)," available: *www.100ventures.com/technology_transfer/tt_contract_checklist_byunido.html*, accessed: 7/11/03, sourced from *Manual of Technology Transfer Negotiation*, General Studies Series, United Nations Industrial Development Organisation, Vienna 1996.
46. Ibid.
47. Ibid.
48. Ibid.
49. Ibid.
50. "Structure of a Technology Transfer Agreement (check-list)," available: *www.100ventures.com/technology_transfer/tt_contract_checklist_byunido.html*, accessed: 7/11/03, sourced from *Manual of Technology Transfer Negotiation*, General Studies Series, United Nations Industrial Development Organisation, Vienna 1996.
51. Ibid.
52. Middleton, G., "Licensing of Intellectual Property," *ICCIR* Iss 5 Sweet & Maxwell Ltd, 2000 , p156.
53. "Structure of a Technology Transfer Agreement (check-list)," available: *www.100ventures.com/technology_transfer/tt_contract_checklist_byunido.html*, accessed: 7/11/03, sourced from *Manual of Technology Transfer Negotiation*, General Studies Series, United Nations Industrial Development Organisation, Vienna 1996.
54. McGinness, P., *Intellectual Property Commercialisation*, p245.

of payments, will be determined by a range of factors, including:

- Value of licensed property.
- Type of licence (i.e., exclusive or non-exclusive).
- Whether sub-licensing is allowed?
- Whether royalties are paid in advance or in arrears?
- Whether running royalties are to be paid.
- The minimum amount of royalties.
- Length of the period for which royalties are payable.

3.4.1 Royalties

Royalties are the most common method of calculating payments under a licence agreement. Royalties are a fee paid for the use of the technology which is calculated according to a base formula, and are usually paid on a periodic basis. These are often calculated with reference to the Licensees net sales for products[56] incorporating the licensed property[57] or cost savings. Why? This is simply because net sales are a concept which is understood by the general community and the Licensee generally will be more willing to disclose this information.[58]

Separate royalty calculations can be used for use of the patented technology and/or the know-how. If know-how royalties are included, they can often extend past the expiration of the licence agreement.[59] However, in biotechnology licence agreements more often than not, only patent royalties are included in the licence agreement.

There are also different types of royalties, these are:[60]

- Wedding cake—these decreases in rate with increasing sales.
- Escalating royalty—rate annually increases in-line with sales .
- Multi market royalty—different, specified royalties are used for individual products (fields of use) and/or territories.
- Royalty free—as an aid to market introduction, for goods that they might anticipate selling as a result of selling goods using the licensing technology.
- Kicker—royalty premium paid on occurrence of some milestone.

3.4.2 How do you find out the appropriate royalty?

An appropriate royalty, is one that is fair to both Licensor and Licensee. Negotiations will often start at a rate considered usual in that industry.[61] The 25% rule is often referred to amongst Licensing Executives. Whilst an industry standard rate, or range is a useful starting point it does not offer any guidance as to what should be contained in the licence agreement or how the rate should change depending on the terms and conditions agreed.

Surveys show that where technology is licensed in, the royalty rate is generally lower than if the same technology was licensed out.[62] Ob -taining quality information on the actual range of royalty rates in any given industry is difficult. A number of companies in the United States and United Kingdom provide a subscription based service where you can search within industries and technology groupings to find out what figures have been used. However, these are expensive and the value is limited.

Licensing executives are often guided by their client's instructions on what is acceptable to them; this is often based upon ad-hoc inquiries and personal knowledge of the industry. Whilst this suggests that the rate is open to negotiation, in reality both the Licensor and Licensee will calculate the value of the technology before commencing negotiation. There are numerous methods for calculating the value of technology. The five most commonly used are:

1. **Cost method.**[63] This is how much it cost the Licensor to create the technology and is often the minimum figure which will be acceptable to the Licensor. However, Licensors typically do not keep accurate records of how much the research and development cost, and as a result, this can often only be an estimate.

The cost of development thus far should not be used as the minimum figure by the Licensor, as it does not represent the cost to the buyer in developing the same technology. They may not have the same skills and resources, the cost of their resources may be higher and they may not already be working in the field of use or territory proposed.

2. **Industry Standards**.[64] As mentioned earlier, these are difficult to ascertain and rarely have an exact match to the type of technology and particular arrangements of the proposed licence. However, they are a useful starting point.

3. **25% Rule.**[65] This is a rule of thumb used by Licensing Executives as the starting point for negotiations. It has been suggested that for biotechnology the figure is lower which represents the higher risk associated with that industry.

---

55. Medius Associations, 3 Oct 2001, "Royalty Rates: Current Issues and Trends," available: *http://pharmalicensing.com/features/disp/1002119137_3bbb1fe183dfe*, accessed: 30/09/03.
56. McGavock, Haas & Patin, "Factors Affecting Royalty Rates," *les Nouvelles*, Licensing Executive Society, Jun 1992, p112.
57. Razgaitis, R., *Valuation & Pricing of Technology-Based Intellectual Property*, John Wiley & Sons Inc, New Jersey, 2003 , p44.
58. McGavock, Haas & Patin, "Factors Affecting Royalty Rates," *les Nouvelles*, Licensing Executive Society, Jun 1992, p112.
59. "Structure of a Technology Transfer Agreement (check-list)," available: *www.100ventures.com/technology_transfer/tt_contract_checklist_byunido.html*, accessed: 7/11/03 sourced from *Manual of Technology Transfer Negotiation*, General Studies Series, United Nations Industrial Development Organisation, Vienna 1996.
60. Goldscheider, Robert, ed., *The LESI Guide to Licensing Best Practices*, John Wiley & Sons Inc, New York, 2002 , p32.
61. Marshal Lee, WM, "Determining Reasonable Royalty," *les Nouvelles*, Licensing Executive Society, Sep 1992, p124.
62. McGavock, Haas & Patin, "Factors Affecting Royalty Rates," *les Nouvelles*, Licensing Executive Society, Jun 1992, p109.
63. Goldscheider, Robert, ed., *The LESI Guide to Licensing Best Practices*, John Wiley & Sons Inc, New York ,2002 , p39.
64. Goldscheider, Robert, ed., *The LESI Guide to Licensing Best Practices*, John Wiley & Sons Inc, New York (Ch 2: Technology Valuation, Dr. Richard Razgaitis), 2002 , p40.

4. **Discounted Cash Flow.**[66] This is where the projected cash flows to buyer, net of all costs and investments are used to identify the likely profit of the Licensee in using the technology. This is often combined with a calculation of the net present value of that return, the idea that a dollar paid now is worth more than a dollar paid at some time in the future.

5. **Monte Carlo Method.**[67] This is a statistical model, which will calculate the range of possible outcomes. It does not, however, consider the effect of particular decisions along the path to commercialisation.

3.4.3 What factors need to be considered in determining royalty rates?

In *Georgia-Pacific v. United States Plywood*,[68] in 1970 the courts in the United States listed 15 factors to consider in determining a reasonable royalty rate. These were subsequently modified in *Honeywell v. Minolta*, as follows:

- "Relative bargaining strengths of the parties;
- Anticipated amount of profits that the prospective Licensor reasonably thinks they would lose as a result of licensing the patent compared to the anticipated royalty income;
- Anticipated amount of net profits that the prospective Licensee reasonably believes they will realise;
- Commercial past performance of the invention in terms of public acceptance and profits;
- The market to be tapped;
- Any other economic factor that normally a prudent business would, under similar circumstances, take into consideration in negotiating the hypothetical license;
- Royalties received by the patentee in licensing the patent, providing or tending to prove an established royalty;
- Rates paid by the licensee for the use of other patents comparable to the patent;
- Licensor's established policy and marketing program to maintain their patent monopoly by not licensing others to use the invention or by granting the licenses under special conditions designed to preserve that monopoly;
- Commercial relationship between the licensor and licensee; and
- The effect of selling the patent."[69]

The courts have also accepted that an infringer should pay more than a willing Licensee.[70] However, from a strategic point of view, a Licensor and Licensee will consider a number of factors, some of which are based on those applied in *Georgia-Pacific v. United States Plywood* [71] including:[72]

- **Scope and strength of IP rights.** Generally, the stronger the IP protection available the higher the value because it is easier for the Licensor to enforce their rights. For example, the licensing of a patent will attract higher payments than the use of know-how because the patent is published and hence, the Licensor is afforded a statutory right of exclusivity of the patent for a specified period.
- **Territory and field of use granted.** The value of the territory and field of use will be determined in biotechnology, by the potential applications of the technology. If it is a technology which for example, will treat Alzheimer's, the potential for its use is world-wide. With the cost of commercialising a drug estimated at more than $200 million[73] the territory must be large enough to not only recover the costs of taking the drug to market, but also provide an acceptable level of profit to the Licensee.
- **Type of Licence.** An exclusive licence has more value than a sole or non-exclusive licence. This is because the Licensee alone has the ability to commercialise the technology and hence, 100% of the return on the technology, less any obligations under the license agreement are returned to them.
- **How innovative is the technology?** If the technology represents a great leap forward which will result in large cost savings in production of technologies or provides the first solution to a problem which is widespread, such as a cure for cancer, the value of the technology will be higher than if it has simply made a process more efficient.
- **What is the useful life of the technology?** If the technology represents the first solution, the useful life may be the same as the patent life. However, if there is a lot of research and development occurring in this area, there is a real risk that at any time, another organisation may patent a technology which supersedes the licensed technology.
- **What is the risk of commercialisation?** This is not just the potential liability if something went wrong for the consumer, but also the likelihood of being able to successfully commercialise technology at or below a particular cost. If the cost of commercialising the technology exceeds the potential returns, no matter what advances it represents, the Licensee will make a loss.
- **Is the technology aligned with the Licensee's strategy?** The closer aligned the technology is with the Licensee's strategy the more appealing it will be. Thus, a willing Licensee should pay a higher price than one which needs to be convinced of the worth of the technology.

65. Ibid., p42-44.
66. Ibid., p44-45.
67. Ibid., p45-6.
68. 318 F.Supp. 1116. 1120. 166 U.S.P.Q. 235, 238 S.D.N.Y. (1970); modified 446 F 2.2d 295, 170 U.S.P.Q. 369 (2nd Cir 1971).
69. Civil Nos. 87-8748, 88-1624 (D.N.J. Jan 28, 1992) as quoted in Cullen, JG, "Panning for Biotechnology Gold: Reach-through royalty damage awards for infringing uses of patented molecular sieves," *IDEA: The Journal of Law and Technology, PTC Research Foundation of Franklin Pierce Law Centre*, 1999, vol 39 at 553.
70. Marshal Lee, WM, "Determining Reasonable Royalty", *les Nouvelles*, Licensing Executive Society, Sep 1992, p125.
71. 318 F.Supp. 1116. 1120. 166 U.S.P.Q. 235, 238 S.D.N.Y. (1970); modified 446 F 2.2d 295, 170 U.S.P.Q. 369 (2nd Cir 1971).
72. Medius Associations, 3 Oct 2001, "Royalty Rates: Current Issues and Trends," available: *http://pharmalicensing.com/features/disp/1002119137_3bbb1fe183dfe*, accessed: 30/09/03.
73. Yamaski, M., "Determining Pharmaceutical Royalties," *les Nouvelles*, Licensing Executive Society, Sep 1996, p112.

• **What is the current stage of development?** Generally, the closer a technology is to commercialisation the higher the royalty rate.[74] In a survey completed in 2001 by Medius Associates, it was reported that the average royalty rates by stage of development were: pre-clinical 0-5%, Phase I 5-10%, Phase II 8-15%, Phase 3 10-20% and launched upwards of 20%.

• **The financial stability and history of the Licensee.** As with any transaction, the Licensor will want to ensure that the Licensee will continue to operate through the license period and that they have a track record of successfully commercialising similar technologies.

• **Does a market already exist or will it need to be created?** This is the classic technology push/pull dichotomy. Technology is either created in response to a demand (technology pull) or must create a demand in the market (technology push).[75] This holds true for biotechnology. Often the technology pull will be the need for a treatment or cure for an ailment or problem. Whilst applications which do not solve a specified problem or do so in a radical way will require the market to understand the technology and feel safe in using it before the market will it accept it. A good example of this is genetically modified foods. Whilst the idea is good, the perceived risk by consumers is high, until this is reversed, those that commercialise in this area will have to expend significant funds to convince consumers to purchase their products.

• **Does the technology incorporate any third party IP?** If so, will additional royalties be paid to the third party and what, if any, are the terms of their licence agreement. This is known as reach-through royalties. If additional royalties are to be paid, the Licensee will want to deduct these from the total royalties to be paid to the Licensor and either remit them to the third party directly or require that the Licensor do so.

3.5 Patent Provisions

Generally, the Licensor has the responsibility for prosecuting and maintaining licensed patents, however, it is not uncommon to make the Licensee responsible for prosecuting and maintaining the licensed patents in their territory, particularly if they are an exclusive licensee.[76] This may also extend to improvements to the licensed patents, if specified in the licence agreement.

If the Licensor is responsible, they will want the Licensee to notify them in writing of any potential infringement to the licensed patent that they become aware of. The Licensor will often reserve the right to decide whether to prosecute an infringer. If they decide not to prosecute,[77] the Licensee may wish to have the right to prosecute. The Licensee should also request the inclusion of a payment relief clause which comes into effect if the Licensor does not prosecute an infringer who is active in their territory.[78]

3.6 Duration & Termination

A licence agreement which is based on a patent will usually expire when the last of the licensed patents expires or if none of the licensed patents remain in effect.[79] In Australia, if the term of the licence extends past the actual expiry date of the licence, regardless of the provisions within the licence itself, either party upon giving three months notice to the other party may terminate the licence agreement. This notice will not represent a breach of contract even if contrary to terms of the contract.[80]

A licence agreement may also be terminated because of a breach by either party such as non-payment, late payment, insolvency or receivership or change of ownership.[81] On termination, it is important that it is clear what the continuing obligations of both parties are, it is suggested that at a minimum it should include:

• A requirement for prompt payment for all money due or accrued including interest for the time in arrears.

• Immediate return of all confidential information, not only the initial copies provided but any subsequent copies made.

• A clause specifying that the use of the licensed technology is no longer permitted.

• A penalty which is comparable to the lost income whilst finding a replacement Licensee and for that Licensee to be returning to the Licensor the same level of income as the previous Licensee.

• A clause reminding the Licensee that confidentiality obligation survives the termination of the licence.

3.7 Most Favoured Licensee (MFL)

The purpose of a most favoured licensee clause is to prevent a subsequent licensee from obtaining a

74. Medius Associations, 3 Oct 2001, "Royalty Rates: Current Issues and Trends," available: *http://pharmalicensing.com/features/disp/1002119137_3bbb1fe183dfe*, accessed: 30/09/03.
75. Betz, F., *Strategic Technology Management*, Mc-Graw-Hill Engineering and Technology Management Series, Mc-Graw Inc: USA, 1993, p8, 14, 113-14, 132, 135 and Twiss, B., *Managing Technological Innovation*, 4th ed, Pitman Publishing: London, 1992, p9, 89.
76. "Structure of a Technology Transfer Agreement (check-list)," available: *www.100ventures.com/technology_transfer/tt_contract_checklist_byunido.html*, accessed: 7/11/03, sourced from *Manual of Technology Transfer Negotiation*, General Studies Series, United Nations Industrial Development Organisation, Vienna 1996.
77. "Structure of a Technology Transfer Agreement (check-list)," available: *www.100ventures.com/technology_transfer/tt_contract_checklist_byunido.html*, accessed: 7/11/03, sourced from *Manual of Technology Transfer Negotiation*, General Studies Series, United Nations Industrial Development Organisation, Vienna 1996.
78. Ibid.
79. "Structure of a Technology Transfer Agreement (check-list)," available: *www.100ventures.com/technology_transfer/tt_contract_checklist_byunido.html*, accessed: 7/11/03, sourced from *Manual of Technology Transfer Negotiation*, General Studies Series, United Nations Industrial Development Organisation, Vienna 1996.
80. s145(2) Patents Act 1990 (Cth).
81. "Structure of a Technology Transfer Agreement (check-list)," available: *www.100ventures.com/technology_transfer/tt_contract_checklist_byunido.html*, accessed: 7/11/03, sourced from *Manual of Technology Transfer Negotiation*, General Studies Series, United Nations Industrial Development Organisation, Vienna 1996.

license on more favourable terms than them. Whilst a simple concept, drafting a clause which works is not as easy as it sounds.

The main problem is how to compare licence agreements. What if the licence is for different territories, fields of use or is calculated using different payment options? Should it only be a comparison of financial obligations or all the terms and conditions of the licence agreement? In drafting a MFL clause you should consider whether it:

- Extends to all other licenses for the licensed property or only future;[82]
- Applies to other licenses that have the same/substantially the same scope;[83]
- Applies to express licence or extends to implied;[84]
- Applies only to royalties or other consideration terms?[85]

It is also important to consider to what extent the licensor has an obligation to disclose terms of alternative licence. A simple compromise may be to give the Licensee first right of refusal for any subsequent licences the licensor may propose to give.[86] It is also important to consider what, if any, rights the Licensee is entitled to if the Licensor breaches its obligations for example, non-disclosure of a more favourable licence agreement.

3.8 Warranty and Indemnification

Licensor may not agree to warrant the validity of the licensed patents and may not assume an obligation to defend or indemnify the licensee against a third party suing the licensee for patent infringement.[87] However, a Licensee will require some level of warranty by the Licensor before they enter into the licence agreements, at a minimum[88] the Licensee will want the Licensor to warrant that:

- They own or have the right to use the licensed patents;
- They have disclosed all the relevant know-how and/or technical information;
- There is no current or threatened action regarding the Licensed Property;

The Licensee will also want the Licensor to indemnify them with respect to these.

3.9 Other Provisions

The standard notices with respect to severability, entire agreement, force majeure, notices, taxation, insolvency, dispute resolution and applicable laws should not be overlooked. It is also important to consider how defaults by either party under the agreement will be treated.

If royalties are to be paid and definition of what records will need to be produced and kept by the Licensee with respect to royalty payments will also be required. As will a provision which will enable the Licensor to audit the Licensee to ensure that they are adhering to the terms of the licence.

4 Conclusion

It has been suggested that when negotiating a licence agreement particular attention should be paid to:

- Amount of and structure of compensation to licensor, in particular if payments are linked to achievement of milestones then due-diligence provisions must be included to ensure that the Licensee makes best-efforts to commercialise the technology at the expected rate;[89]
- Termination provisions;[90]
- Confidentiality[91]—not only with respect to the Licensed Property but also that the Licensor treats any information provided by its Licensee as confidential;
- Control of patent prosecution & litigation which should remain with licensee to avoid its patent rights being jeopardized/biased towards licensor's field.[92]

However, I believe that the most important consideration is the strategic objectives of the Licensor and Licensee and that all decisions to be made in negotiating the licence agreement will be based on these objectives. It is also imperative that you understand the general principles of intellectual property protection and understand, at least generally, what the licensed technology is and it's potential.[93]

In the biotechnology industry, where the primary IP is patents, licence agreements can offer organisations a real alternative to commercialising the technology themselves. Whilst there are advantages and disadvantages to consider in deciding whether a licence is appropriate, in the end it will depend on the strategic objectives of the organisation.

If the organisation is solely focussed on research and development, they are more likely to licence out their technology. However, if they are an organisation, such as a large pharmaceutical company whose research and development area is part of the same or an affiliated organisation, they are less likely to licence out the technology.

Licence agreements, if they are negotiated to meet the strategic objectives of both the Licensor and Licensee, can provide a win-win outcome for both parties.

EDITOR'S NOTE: The full text of the original essay upon which this article is based, including a bibliography of materials and a collection of suggested clauses to implement the recommendations in this article, can be found at <www.clarkekann.com.au> or obtained from the author at <katrina@taltingan.com.au>.

82. McGinness, P., *Intellectual Property Commercialisation*, p238-9.
83. Ibid.
84. Ibid.
85. Ibid.
86. Ibid., O'Reilly, DP & Morin MA, "Troubles for Most-Favored Licensees," *les Nouvelles*, Licensing Executive Society, Mar 1998, p31.
87. "Structure of a Technology Transfer Agreement (check-list)," available: *www.100ventures.com/technology_transfer/tt_contract_checklist_byunido.html*, accessed: 7/11/03, sourced from *Manual of Technology Transfer Negotiation*, General Studies Series, United Nations Industrial Development Organisation, Vienna 1996.
88. Ibid.
89. Goldscheider, Robert, ed., *The LESI Guide to Licensing Best Practices*, John Wiley & Sons Inc, New York, 2002 , p211-212.
90. Ibid.
91. Ibid.
92. Ibid.
93. Ibid.