

## A CHECKLIST FOR LICENSE AGREEMENTS

### 1: Effective Date

### 2: Proper Identification of correct parties

In organizations where there are a number of corporate entities, whether on the side of the licensor or the licensee, you must ensure that the correct entity enters into the Agreement and that it is properly identified. ACNs and ABNs should be used in the case of Australian companies.

### 3: Recitals

### 4: Definitions

"improvements". The principal issue here is whether improvements cover all developments in the relevant field or whether they cover only those developments which require the use of intellectual property which is the source of the license.

"territory": the principal issue here is whether if more than one jurisdiction is covered by the definitions of "territory", whether separate agreements should cover those separate jurisdictions – e.g. because different intellectual property regimes apply in one jurisdiction vis-à-vis another or because different royalty rates or performance criteria apply.

"licensed subject matter": the principal issue is to properly identify the field of use in which the licensed subject matter may be used – e.g. for certain indications, certain dosage forms, human versus animal use, prescription drugs, OTC. etc.

"intellectual property"

"net sale price" – the principal issues relate to:

1: identifying the level of pricing being considered – eg ex factory, wholesale, retail

2: identifying the proper commercial deductions from the sale price – eg discounts, freight costs, etc.

3: identifying the proper government impost deductions from the sale price

4: identifying whether sales to related companies are to be covered

"know how:"

### 5: term

*The principal issue is whether the term of the license should be fixed by reference to the term of a patent/patents or without reference to the term of a patent/patents.*

**Issues arising from fixing the term of a license by reference to the term of a patent/patents:**

1: If there is more than one patent in one jurisdiction, what impact does the term of that patent expiring or the invalidity of that patent have on the balance of the term of the Agreement?

2: If there is more than one patent in more than one jurisdiction, what impact does the term of any one of those patents expiring or the invalidity of one of those patents expiring have on the term of the Agreement?

**What impact should the patenting of improvements have on the term of a license? Term extended?**

3: Issues arising from fixing of term of agreement without reference to term of patent or patents.

- If the balance of the term of a patent is five years and the license is for say eight years then Section 145, needs to be considered and in particular whether a separate know-how license

needs to be entered into in order to protect any royalty stream. Section 145 of the Patents Act provides:-

(a) "A contract relating to the lease or a license to exploit a patented invention may be terminated by either party, on giving three months' notice in writing to the other, at any time after the patent, or all of the patents, by which the invention was protected at the time the contract was made, have ceased to be in force.

(b) Subsection (1) applies despite anything to the contrary in that contract or in any other contract.

4: Right to extend term? Whose right?

## **6: Grant of License**

(a) Exclusive versus non-exclusive relative to "field of use/territory"

(b) Right to sub-license

(c) Which of the rights to make, use, exercise, vend and exploit are to be granted? To what extent? –eg entitlement to manufacture a certain number of products

(d) Reservation of rights in licensor

## **7: Consideration**

(a) upfront payments

1: not being a credit against future royalties

2: being a credit against future royalties

3: in installments upon achievement of milestones – eg upon date of signing and upon date of regulatory authority's approval

(b) Royalty payments

1: based on a fixed amount per unit manufactured

2: based on a fixed amount per unit sold

3: based on a percentage of the value of gross sales or net sales

4: based on a graduated scale of percentages dependant on the value of gross sales or net sales - et high rate for low volumes, lower rate for higher volumes

5: based on having a maximum amount per annum or maximum aggregate royalties

(c) Obligations to pay royalties should arise only so long as a patent application or patent is in force to relevant jurisdictions. A time limit on the acceptance of a patent application needs to be provided for, in order for it to be a proper base for royalty payments.

(d) Do royalties accrue on an invoice being rendered for the relevant product by the licensee or upon payment being made of that invoice?

(e) Combination products, royalty should only relate to part of net sales or gross sales value

(f) Local jurisdiction restrictions in permitted amount of royalties and remittance rights

(g) Should there be a mechanism to review the amount of the royalty for market reasons

(h) What exchange rate is to apply if Licensor is being paid in a currency other than the currency in which the products are being sold – eg exchange rate at the time of invoice, time of receipt of payment, time of remittance of payment to the Licensor, time of remittance of payment to the Licensor, time of remittance to the Licensor is due, at a fixed exchange rate irrespective of time.

(i) Should there be a mechanism to review amount of royalty payable for reasons relating to exchange rate movements outside certain range?

(j) Currency for payment?

(k) Late payments to attract interest?

(l) Who to bear bank charges, if payments direct to account?

## **8: Time for payment of Royalties**

(a) Minimum royalties payable in advance with adjustment at end of relevant period

(b) Quarterly or half yearly most usual

### **9: Licensor's Warranties**

- i) Warranty as to proper identification of patent applications/patents
- ii) Warranty as unencumbered ownership of entitlement to patents applications/patents
- iii) Warranty as to the fact that the licensor is not aware that the exploitation of the patent will at the date of this agreement infringe or in the future be likely to infringe the rights of any third party
- iv) From the licensor's perspective, no warranty as to validity of patent should be given

### **10: Licensee's Warranties**

- A) That licensee has and will continue to have during the term of the licence the personnel, expertise and resources to properly fulfil its obligations under the licence

### **11: Licensee's Performance Criteria**

- (a) Should be more onerous for exclusive licensees than for non-exclusive licensees
- (b) Minimum royalties per annum – fixed or adjustable against previous year's performance
- (c) Minimum sales per annum – fixed or adjustable against previous year's performance
- (d) Minimum royalties/sales per annum should not apply until such time as approval from the relevant regulatory authorities is obtained – eg FDA approval has been obtained
- (e) Sales to match royalties – i.e. to prevent a licensee making royalty payments without sales and so preventing third parties from obtaining rights, if non-payment of minimum royalty triggers conversion of exclusive license to non-exclusive license.
- (f) Comparable markets performance criteria – i.e. if sales of 100 units achieved in country A comparable per capita sales should be achieved in country B.
- (g) To develop improvements
- (h) If various jurisdictions comprise the licensed Territory – e.g. Australia/New Zealand – whether separate performance criteria should apply to each
- (i) Obtaining and maintaining particular market share
- (j) "Best endeavours", reasonable endeavours in best commercial judgment" etc.
- (k) Provide trigger mechanisms for converting exclusive licence to non-exclusive licence

### **12: Licensor's Obligations**

- (a) To transfer know how to the licensee in tangible form – e.g. documents
- (b) To transfer know how to the licensee at seminars
- (c) To make personnel available to licensee at no charge for certain number of days per annum and thereafter at relevant cost
- (d) To continue to conduct research and development concerning the licensed subject matter
- (e) To advise the licensee of improvements
- (f) To advise the licensee of any relevant results of its research and development which are not improvements
- (g) To advise the licensee of adverse indications
- (h) To obtain or assist in obtaining regulatory approvals
- (i) To advise of identity of other licensees

### **13: Licensee's Obligations**

- (a) To manufacture relevant produce in accordance with approved specification/registration details
- (b) To undertake research and development concerning the licensed subject matter
- (c) To advise the licensor of improvements
- (d) To advise the licensor of adverse indications
- (e) To obtain or assist in obtaining regulatory approvals
- (f) To obtain parent company guarantee

- (g) To purchase active ingredients and other products from licensor or third party nominated by licensor – section 144 Patents Act and Trade Practices Act implications
- (h) Not to challenge licensor's intellectual property rights
- (i) To use relevant licensed trade mark

#### **14: Sub-licenses**

- (a) Extent to which licensor's consent is needed to appointment of sub-licensee
- (b) Extent to which licensor's consent is needed to proposed agreement to be entered into with sub-licensee
- (c) Extent to which licensor shares licensees, sub-license income
- (d) Extent to which licensor can require that sub-licenses be in certain form

#### **15: Quality Assurance Procedures**

- (e) Manufacture only to be undertaken from premises approved by licensor
- (f) Third party manufacture only to be undertaken by party approved by licensor
- (g) Manufacture only to be undertaken in accordance with approved good manufacturing practice.
- (h) Premises from which manufacture to be undertaken to be properly accredited/licensed by any relevant statutory authorities
- (i) Source and quality of active ingredients to be from approved sources and to be of approved standards
- (j) Licensee to ensure that samples of bath kept for relevant period and access allowed to licensor
- (k) Licensee to prepare data sheets in respect of each batch and supply copies to licensor if requested
- (l) Licensee to store products in accordance with any requirements specified by licensor
- (m) Licensor to have right of access to inspect manufacturing premises and storage premises
- (n) Licensor to have right to take and analyse own samples of active ingredients and products

#### **16: Patents**

- (a) in exclusive licensee's situation, obligations on the licensee will be greater than in a non-exclusive licensee situation
- (b) Obligation on relevant party to actively prosecute patent application and keep other party advised of progress including supplying copy of all Patent Office reports, plus a default right in the other party. Expenses incurred in default situations should be credited against royalties, if the licensee undertakes the default obligation
- (c) To what extent should the licensee bear the cost of filing and/or maintenance of patents? Should this cost be credited against future royal streams?
- (d) Obligation to supply copy of Patent Office requisitions to other party
- (e) Obligation to consult in relation to Patent Office requisitions
- (f) Licensor's or licensee's right to select a patent attorney to prosecute application
- (g) The licensee should be obliged to apply appropriate markings of patent ownership and licensing in relation to the product

#### **17: Improvements**

- (a) What right should parties have to the respective improvements of the other? Royalty free to each other but any further licensing at additional royalty?
- (b) Ownership of improvements?
- (c) Who should have entitlement to patent improvements? The other party should have a right in default
- (d) Extent of obligation to consult in relation to proposed patenting programme for improvements, including extent of claims and jurisdictions

### **18: Infringement of Licensed Patent Rights**

- (a) Each party to be obliged to inform the other promptly of alleged infringement of licensed patent rights
- (b) Identify party who has primary responsibility for commencing infringement proceedings and party with default entitlement to commence infringement proceedings
- (c) A party should not be obliged to commence infringement proceedings – in the case of an exclusive licensee, this may be particularly significant where a patent's validity may be suspect
- (d) If patent proceedings are commenced, in what proportion should the parties bear the burden of legal costs/benefit of any award of damages. Assuming an exclusive licensee situation, the following circumstances may be envisaged:
  - 1: where patentee (licensor) commences proceedings without approval of licensee;
  - 2: where patentee (licensor) commences proceedings with approval of licensee, but licensee is not a party to the proceedings;
  - 3: where patentee (licensor) commences proceedings with approval of licensee and licensee is a party to the proceedings
  - 4: where patentee (licensor) defaults in commencing proceedings and exclusive licensee commences proceedings joining patentee (licensor) as plaintiff;
  - 5: where patentee (licensor) defaults in commencing proceedings and exclusive licensee commences proceedings joining patentee (licensor) as defendant
- (e) If patent infringement proceedings are commenced, what impact should this have on the licensee's obligation to pay royalties – e.g. if licensor and licensee agree to share costs of proceedings equally and exclusive licensee commences proceedings, then 50% of licensor's royalty entitlements to be paid by licensee into separate account on account of licensor's obligations to pay 50% of legal costs.
- (f) If patent infringement proceedings are commenced, the party who does not have the primary responsibility for conducting those proceedings should be obliged to offer all reasonable co-operation to properly prosecute those proceedings. To what extent should the costs of co-operation be borne by the party not having primary responsibility?
- (g) If the licensor has the sole right to initiate infringement proceedings and notwithstanding the licensee's request, refuses to do so -  
(more likely to occur in a non-exclusive licence situation) – then the licensee should have a right to terminate the licence or obtain royalty reduction.
- (h) Should the licensor's or licensee's contribution to the cost of patent infringement proceedings be limited to a certain percentage of royalties payable during the period of litigation?

### **19: Defence of Infringement Proceedings**

- (a) Each party to be obliged to inform the other promptly of any threats or commencement of infringement proceedings against them relating to the licensed subject matter
- (b) To what extent will the licensor indemnify the licensee arising from the consequences of infringement proceedings against the licensee? No indemnity to the extent that infringement arose through acts/omissions/improvements of the licensee.
- (c) Licensee's right to terminate licence upon bona fide threat of commencement of infringement proceedings or infringement proceedings being commenced against it
- (d) Licensee's right to hold payment of royalty or at least minimum royalties in abeyance upon bona fide threat of infringement proceedings or pending finalisation or settlement of infringement proceedings. Deposit royalties into separate account pending resolution of the matter.
- (e) Licensor's/licensee's right to be involved in settlement or compromise negotiations with a plaintiff or potential plaintiff even though they may not for whatever reason be a defendant in the proceedings

### **20: Most Favoured Licensee**

- (a) Good from licensee's perspective, but very dangerous from licensor's perspective
- (b) How do you compare whether one licensee is getting better terms than another if elements of license are different?

- (c) How do exchange rate variations impact on comparisons?

**21: Trademark**

- (a) Does licensed subject matter include the licensor's trademark?
- (b) If licensor's trade mark is part of licensed subject matter, is a separate royalty applicable?
- (c) Is the licensor's trademark registered or not?
- (d) If the licensor's trademark is registered, procure registration of licensee as registered user at licensee's cost
- (e) If licensor's trademark is registered, oblige licensor to register trade mark at its own
- (f) If licensee's trademark to be used, then upon expiration of patent, licensee can appropriate goodwill attaching to product, without reference to licensor – unless restriction on use of confidential information – licensor beware!
- (g) If licensor's trade mark to be used, then upon expiration of patent, licensor can effectively continue to obtain the benefit of the patent through the trade mark – although lower royalty rate may apply – licensee beware!
- (h) If licensor's trade mark is to be used, the licensee should be obliged to apply the appropriate markings of trade mark ownership and licensing in relation to the product

**22: Packaging and Advertising Material**

- (a) To what extent is the licensor's approval required to packaging and advertising material – this is more significant from the licensor's point of view, where the licensor's trade mark is being used.

**23: Time for provision of Licensee's regular written reports**

- (a) At time for payment of royalties

**24: Contents of Licensee's regular written reports**

- (a) Basis of determining royalty – eg. Net sales price and units sold
- (b) Currency of receipts
- (c) Developments in market where produce is being sold
- (d) Performance of sub-licensees including receipts from sub-licensees

**25: Maintenance and Inspection of Licensee's Records**

- (a) Licensor to have right of inspection/audit and copying of licensee's records
- (b) Licensee to be obliged to procure licensor's rights of inspection/audit and copying of sub-licensee's records
- (c) Licensee's and sub-licensee's records to be properly kept and be available for inspection-audit and copying, but not more often than agreed frequency per annum
- (d) Restricting right of inspection/audit and copying to maximum number of people, to qualified accounts, to reasonable notice of inspection/audit being given, to reasonable hours, to not interfere with licensees/sub-licensees day-to-day operations
- (e) Licensor to bear cost of inspection, unless discrepancies outside approved range discovered
- (f) Licensee to co-operate with inspection/audit
- (g) Confidentiality of inspection/audit
- (h) Period for keeping records

**26: Confidentiality**

- (a) Properly define what is "confidential information" or provide a mechanism for identifying – e.g. any documents marked "Confidential".

- (b) Obligation on licensee only to use confidential information for purposes of fulfilling its obligations under the licence
- (c) Obligation on licensee not to disclose confidential information to third parties
- (d) Parties permitted access to confidential information?
- (e) Obligation on licensee to procure confidentiality undertaking from third party who may be permitted to confidential information
- (f) Obligation on licensee to indemnify licensor from breach of confidentiality obligation
- (g) Obligation on parties to return confidential information to source upon termination or expiration of licence
- (h) Mutuality of confidentiality obligations?
- (i) Exceptions to recipient's obligation to keep confidential :
  - .. Demonstrated to be previously known to recipient
  - .. Rightfully obtained from third party
  - .. Publicly known without default of recipient
  - .. Independently developed
  - .. Necessary to disclose to obtain regulatory approvals
- (j) Restriction on post-termination/expiration use of confidential information
- (k) Terms and conditions of license confidential

**27: Licensee not to use Licensor's name without permission**

**28: Government approvals to licence agreement**

**29: Product Liability**

- (a) Licensee to indemnify licensor in relation to defects in product arising from improper manufacture
- (b) Licensor to indemnify licensee in relation to defects in product arising from faults in licensor's specification to the product
- (c) Licensee to effect product liability insurance noting interest of licensor, with approved insurer and for approved amount and vice versa regarding licensor's indemnity

**30: Indemnification**

- (a) Relating to breach of express warranties
- (b) By licensee relating to advertising and promotion of product
- (c) By licensor relating to licensee being alleged to infringe third parties intellectual property rights

**31: Limitation of Liability**

- (a) Relating to breach of express warranties
- (b) By licensee relating to advertising and promotion of product
- (c) By licensor relating to licensee being alleged to infringe third parties intellectual property rights

**32: Limitation of Liability**

- (a) Repair costs?
- (b) Replacement costs?
- (c) Replacement of products?
- (d) Recall costs?
- (e) Lost Profits?
- (f) Consequential losses?

- (g) To value of royalties?

**33: Termination**

- (a) Mutual rights or unilateral?
- (b) Termination upon breach
- (c) Termination without breach
- (d) Termination following opportunity to rectify breach
- (e) Termination right on change of ownership or management
- (f) Termination right on change of ownership or management only where detriment can be demonstrated
- (g) Termination to be without prejudice to rights accrued up to that time

**34: Consequences of Termination**

- (a) Licensee to have right to dispose of inventory of licensed products and complete orders. Royalties to continue
- (b) Licensor to have right to acquire inventory of licensed products held by licensee at certain price
- (c) Licensee to return all licensor's property to licensor and vice versa
- (d) Licensee to cease exercising rights under licence and in particular cease using trade mark, or other indicia crating association with licensor or benefiting from licensor's rights
- (e) Parties rights to be paid outstanding monies? Any right of set off?
- (f) Licensee to procure novation of such sub-licences as nominated by licensor in favour of licensor.
- (g) Maintenance of confidentiality post termination?

**35: Assignment**

- (a) With or without consent to non-related parties
- (b) With or without consent to related parties. Consent only valid as long as party remains related party
- (c) Absolute discretion as to consent
- (d) Consent not to be unreasonably refused.
- (e) Qualities of assignee to be pre-determined – e.g. technical expertise, financial viability
- (f) Change in shareholding being deemed to be an assignment?

**36: Right of Refusal**

- (a) If licensor wants to assign
- (b) Period of right during licence or some post termination/expiration right?
- (c) Limited to number of occasions?
- (d) Applying to equipment and not just rights

**37: Withholding Tax**

- (a) Impact on royalty payments?

**38: Severability**

- (a) If clause or part thereof severed, should either party have right to terminate?

**39: Force Majeure**

- (a) Obligation to forthwith notify force majeure
- (b) Right of termination if period of force majeure exceeds certain time



(c) Obligation to remove force majeure as soon as possible

**40: Notices**

**41: Proper Law**

**42: Method of Dispute Resolution**

- (a) Courts – identify which courts, if any, have exclusive jurisdiction
- (b) Arbitration
- (c) Mediation
- (d) Conciliation
- (e) Identify which, if any, of (b)-(d) have to occur first before litigation commenced
- (f) Cost of alternative dispute resolution – eg. 50% each, loser to pay or as determined by adjudicator
- (g) Which matters cannot be subject of alternative dispute resolution – eg. Arbitration not to deal with validity of patent

**43: Entire Understanding**

**44: Waiver**

**45: Further Assurances**

**46: Language of Agreement to take precedence**

**47: Method of Amendment**

**48: Headings**