

Manufacturing and Supply Agreements

Issue List

I. Types of Supply Agreements

- a. Requirements Contracts
- b. Exclusive Supply Arrangements
- c. Nonexclusive Supply Arrangements
- d. Take or Pay Agreements

2. Basic Issues in Supply Agreements from Buyer

- a. Can supplier meet buyer's needs
- b. Pricing mechanism
 - i. Fixed Pricing for Initial Period
 - ii. Pricing based on "Cost Build Up" Model
 - iii. Discounts based on volume
 - iv. Goal is to reduce contract price over time and increased quantity
 - v. Payment terms
 - vi. Price changes
- c. Supply and sourcing of raw materials
 - i. Who supplies
 - 1. Customer
 - 2. Approved list of suppliers
 - ii. Quality concerns
 - iii. Storage standards
 - iv. Shelf Expiration
 - v. Maintenance of inventory
 - vi. Labelling requirements
- d. Place of Manufacture
 - i. Where (US or non-US)
 - ii. Access rights for customer
- e. Human resources
 - i. Training
 - ii. Offices to be maintained
 - iii. Are there special skills that customer will need if there is a termination so that supplier should waive employment restrictions
- f. Quality control
 - i. cGMP
 - ii. ISO 900X
 - iii. Q&A procedures
 - 1. Who monitors?
 - 2. Who supervises?
 - 3. Inspections
 - 4. Certifications
 - 5. Reports of all FDA, OSHA and other regulatory inspections
- g. Performance Metrics
 - i. Need performance metrics in an exclusive supply agreement
 - ii. Measure items such as quality, timeliness, forecasting, etc.
 - iii. Use of committee to resolve issues in performance before termination
- h. Shipping
 - i. Special procedures
 - ii. Import/export – INCO TERMS 2000
 - iii. Who pays freight, insurance and other costs
 - iv. Drop ship to customer?
 - v. Regulating quantities and delivery to reduce inventory
- i. Insurance
 - i. Product liability
 - ii. General liability
 - iii. Certificate of Insurance naming additional insureds/loss payees
- j. Acceptance Testing and Rejection
 - i. Evaluation Team
 - ii. Timing of Inspection
 - iii. Notice of Rejection
 - iv. Dispute Resolution
 - 1. Independent Laboratory
 - 2. Other?
- k. Intellectual Property
 - i. Buyer seeks to own all intellectual property rights to be able to terminate contract and/or seek alternative supplier
 - ii. Manufacturer seeks to retain ownership of IP to permit future business
 - iii. Ownership of IP vs. Licensing
 - iv. Who owns improvements to underlying technology?
 - 1. Process Technology
 - 2. Product Improvements
 - v. Confidentiality Provisions
 - vi. Representation that supplier will not introduce any third-party intellectual property into the material or manufacturing process unless it has a valid and continuing license to do so covering all aspects of the supply terms
 - vii. Infringement and Indemnity Issues
- l. Technical Data and Information
 - i. Maintained as secure
 - ii. Owned by Customer
 - iii. Customer seeks to have up to date version
 - iv. Supplier seeks to maintain rights to data to protect its competitive position
- m. Product warranties
 - i. Recalls
 - 1. Notice
 - 2. Who handles?
 - 3. Who pays?
 - 4. Notice to regulators
 - ii. Inspection
 - 1. Timing of Inspection
 - 2. Keyed in to when warranty commences
 - iii. Warranty runs from drop ship or later date?
 - 1. When can warranty be tested?

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(continued from front)

n. Problem resolution and escalation

o. Assignability

- i. Can the agreement be assigned?
- ii. Cover all forms of assignment including change of control

p. Rights of Termination and Effect of Termination

- i. Is there a right to seek alternative source of supply without terminating?
- ii. Clear definition of defaults and remedies on default

q. Competitors

- i. Can Supplier manufacture for a competitor?
- ii. Acquisition of Supplier by a competitor
- iii. Non-compete period upon termination

r. Indemnity

- i. Types
 1. Patent Infringement
 2. Product Recalls
 3. Product Warranty
 4. Breach of Contract
 5. Product Liability
 6. Personal and Property Injury
- ii. Consequential, Lost Profits, Incidental, Attorneys Fees
 1. Include or exclude?
- iii. Caps on liability
 1. E.g., annual purchases
 2. Contract amount
 3. Insurance limit
- iv. Time for making a claim
 1. Make sure that the warranty runs into the period when the product will be used

s. Hazardous Waste Disposal

t. Taxes and tariffs apportionment

u. Federal and state (and non U.S. if applicable) registrations

3. Utilize forecasting mechanism to eliminate disputes, for example:

a. Estimates by buyer for future requirements

- i. Annual, quarterly and monthly?
- ii. Binding or nonbinding
 1. E.g., nonbinding quarterly and binding monthly

b. Binding purchase order forecasts made on predicted calendar basis, no penalty on supplier for late delivery of amounts in excess of forecast

c. Is there a provision for providing a percentage variation between orders and the forecast

d. Lead time provisions

- i. How long is the lead time for orders?
- ii. Can the buyer cancel if outside the lead time?

4. Special Pricing Provisions

- a. In a development transaction, actual price for sale of product cannot always be set up front
- b. Therefore, parties sometimes use a pricing formula
- c. Attached formula contemplates a fully loaded manufacturing cost plus a profits percentage

5. Change Control Procedures for changes in arrangements

- a. New products
- b. Improved products
- c. Regulatory changes
- d. Change of raw material supplier

6. Emergency and Loss-Control Procedures

(e.g., catastrophe, loss of power and fire back up)

7. Miscellaneous

- a. Meeting competition clauses
- b. Most favored customer clauses
- c. Force Majeure