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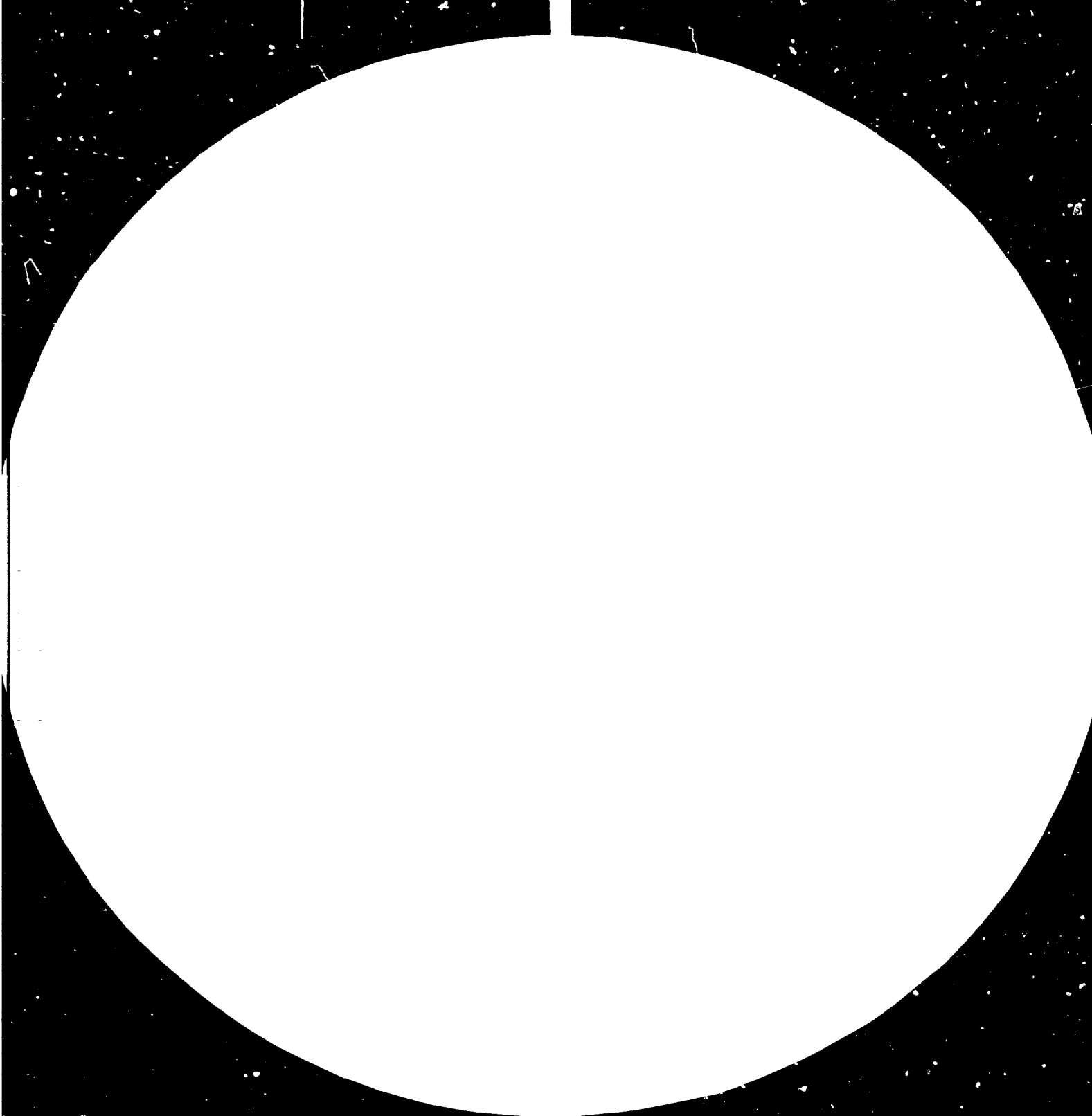

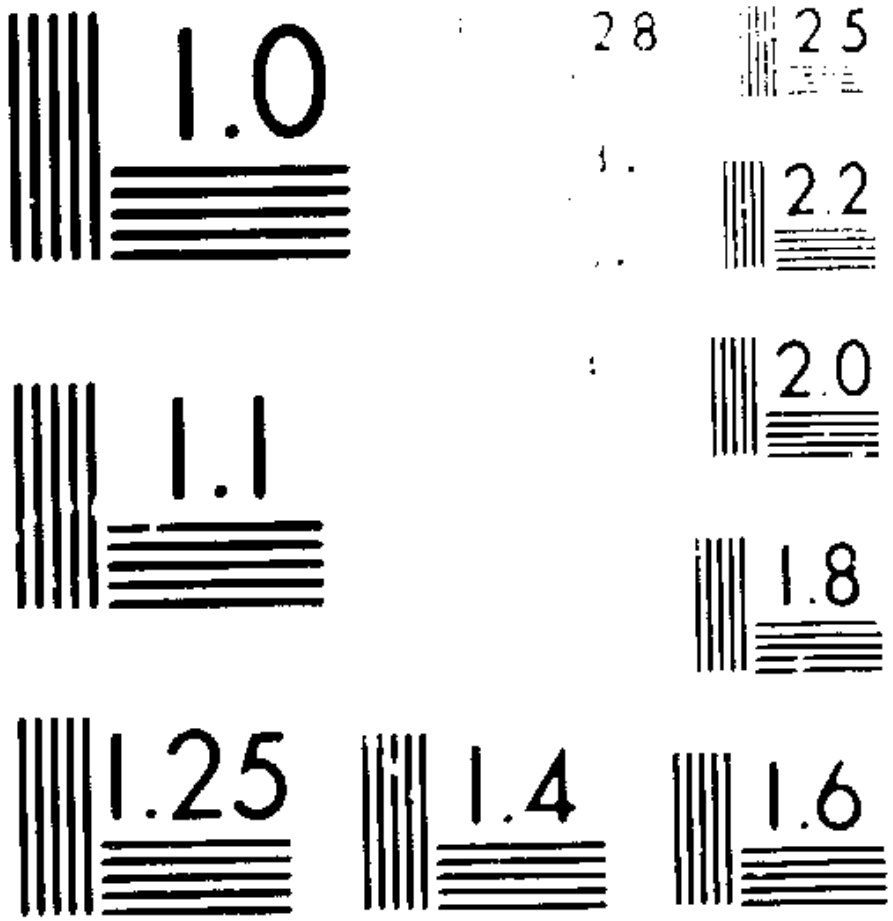
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Preparation of Guidelines

Summary and main Conclusions*

Prepared by
the UNIDO Secretariat

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Preparation of Guidelines
Summary and main Conclusions(*)

I. General principles for the transfer of technology in pharmaceuticals (p. 4 to 7)

Transfer of technology for the manufacture and formulation of drugs may constitute a major instrument for the improvement of developing countries' capacity to satisfy their urgent needs in this field. In order to attain this objective, it is indispensable that such a transfer comply with certain minimum general standards that ensure:

(a) the highest possible contribution of technology transfer to the identification and solution of economic and social problems related to the production and use of pharmaceuticals;

(b) the responsiveness of the contracting parties to the health, drug, industrial and other relevant policies of the receiving country;

(c) the acceptance of fair and reasonable terms and conditions.

II. Main conditions on the use of technology

Among the multiple aspects involved in licensing agreements, those which may affect the extent of use of the technology transferred are of outstanding importance for the parties concerned, as well as for the receiving country. For the supplier, conditions on use confine the extent to which he releases his monopoly on the technology and contributes to the emergence of a potential competitor in the relevant market. For the recipient, such conditions represent the limits to the full utilization of transferred knowledge and a potential restraint on his expansion and technological development. For the receiving country, lastly, such conditions may lead to the repetitive importation and a limited diffusion of acquired technologies.

1. Leasing or sale? (p. 8 to 11)

Are there property rights over unpatended know-how? Do agreements for its transfer constitute mere 'leases' or do they operate the "sale" of technology transferred? The implications of the type of response given to these questions are of fundamental importance for determining the rights of the parties and, particularly, the extent to which the recipient party and its country may actually benefit from the technology transfer. Without prejudice to the acceptance of the thesis on the proprietary nature of know-how by some national laws, this

(*) Numbers included in brackets after the titles refer to the pages of the background paper on this issue.

position should neither be extended to the international field nor applied in countries which do not recognize forms of property other than those instituted by law.

2. Confidentiality obligations (p. 11 to 14)

One of the main concerns of technology suppliers relates to the scope and duration of confidentiality obligations. They fear that a negligent or faulty conduct by the recipient results in a harmful divulgation of secret information. On the other side, for the recipient, such obligations constitute a limit to the possible uses of technology.

The negotiation and drafting of confidentiality obligations involve complex and often very controversial issues. A first crucial issue is whether such obligations may be deemed implicit in any TOT agreement or whether they should be expressly provided for. A second problem arises with regard to the scope of the obligation (for instance, concerning information already possessed or obtained by the recipient from sources other than the supplier; disclosure necessary for subcontracting, etc.) Finally, the question of duration of said obligations usually poses serious difficulties, as far as the supplier tends to obtain the longest possible restriction on recipient's disclosure.

On the basis of the considerations made in the background paper, it might be suggested that a specific provision on this issue should be included in the contract as follows: The recipient shall keep confidential all technical information transferred by the supplier and specifically indicated by him as being of secret character. However, this provision shall not apply to: (i) technical information which is publicly known or is in the possession of the recipient at the time of its transfer, or which is afterwards obtained by him from sources other than the supplier; (ii) disclosure by the recipient to third parties to the extent necessary for the purpose of subcontracting, procurement or other legitimate purposes related to the manufacture or sale of the products; (iii) disclosure to governmental authorities as required for registration or approval of the agreement or products.

With regard to the duration of the obligation, the agreement should prescribe that confidentiality is to last, in principle, for the lifetime of the agreement, or for a reasonable period thereafter in cases justified by the nature, novelty, value and likely time of obsolescence of the technology transferred. Another possibility would be to limit such obligations to a reasonable period after each transfer of the latest information.

3. Sublicensing (p. 15 to 16)

While technology suppliers generally tend to circumscribe the use of transferred technology to the recipient's plants, it may be in the interest of the recipient country to promote a further use of that technology by third parties within the country. Sublicensing clauses constitute an essential condition for that purpose.

Agreements for the TOT in pharmaceuticals should provide that the recipient shall have the right to extend the benefits of the agreement to any third party upon such terms and conditions as may be agreed upon among the supplier, the recipient and any such third party, and, where appropriate, subject to governmental authorization as required by the applicable law of the receiving country.

4. Loss of secret character of know-how (p. 17 to 18)

When transferred know-how loses its secret character during the lifetime of the agreement, obligations undertaken by the recipient should, in principle, cease. This principle should be formulated in the contract by stating, for instance, that if prior to the date of expiry of the agreement, the technical information transferred by the supplier loses its secret character, independently of the recipient, the recipient shall have the right to terminate the agreement by written notice to the supplier, and to continue using that information without further payments or other obligations with respect to the supplier. The further use of patents/trademarks licensed will be the object of a new agreement to be agreed upon by the parties.

5. Use of technology after expiration of the agreement (pp.19-24)

The question of the use of technology transferred, after the expiration of the agreement is one of the most controversial issues in the field of licensing agreements.

With regard to patented technology, it would be advisable that when the license agreement ends before the expiration of licensed patents, it include a clause stipulating the extension of the license until the patent's expiration, under conditions not less favourable for the licensee than those established in the initial agreement.

The further use of unpatented technology should be deemed as a normal right of the recipient. This might be expressly provided in a clause of the contract stating that upon the normal expiry of the agreement, the recipient will have the right to continue to manufacture the drugs and use the processes brought to his knowledge by the supplier, without any further compensation for that use. The right to use the unpatented technology after agreement's expiration should be interpreted as including the right of the recipient to pass on the technology to third parties. In any case, however, confidentiality obligations may still remain in force, as appropriate, for a reasonable and limited period.

6. Field of use restrictions (pp. 25-26)

Restrictions on the field of use of technology transferred are likely to affect the potential of technological development of recipient countries. A fair solution for the parties involved in the negotiation would be to recognize the right of the recipient to undertake uses of the technology other than those provided for in the agreement by stipulating, however, that whenever the recipient uses the technology in fields of application not specified in the agreement, the supplier will receive the same royalty as provided for the uses specified therein.

7. Export restrictions (pp. 27-30)

The recognition of freedom to export is undoubtedly one of the harsher issues in the negotiation of TOT agreements, for very important commercial interests may be affected. For developing countries which have undertaken or are willing to initiate the development of a chemico-pharmaceutical industry, the possibility to export may constitute an important condition for the viability of manufacturing at an economic scale.

A limited formulation could be as follows:

The recipient shall refrain from exporting the products covered by this agreement to the following countries: ..... as long as the technology transferred under this agreement is used there by the supplier or its exclusive licensees to manufacture said products.

III. Other relevant issues

1. Guarantees by the supplier

(a) Suitability for use (p. 31 to 32)

The suitability for use of the transferred technology should be deemed a condition inherent to all TOT agreements. A clause on this issue might stipulate: The supplier guarantees that the technology, if used in accordance with the supplier's specific instructions given pursuant to the agreement, is suitable for manufacturing the products agreed upon.

(b) Hazards and adverse effects (p.33 to 34)

Appropriate provisions should be included in order to ensure the availability of a permanent, complete and updated information about possible hazards and side effects of products covered by the agreement. A possible provision for this purpose could read as follows:

The supplier shall inform the recipient any hazards, adverse or side effects of the drugs/products which were identified after the signing of the agreement, as well as any changes in the registration status of the drugs/products in the country of the supplier and in other countries where such drugs/products are marketed or registered.

(c) Liability (p. 34-35)
The stipulation of adequate provisions on supplier's liability concerning the application of the technology transferred and the use of products manufactured with its help, must be viewed as an essential element of TOT agreements on pharmaceuticals. Such a provision must include the supplier's obligation to indemnify and hold harmless the recipient from any claims for damage or injury to persons or property or for loss of life arising out of or in connexion with the manufacture or use of the products covered by the agreement, provided that it is proven that the technology has been properly used in accordance with the supplier's precise instructions.

2. Remuneration for technology (pp.35-39)

The remuneration for the technology transferred should be

(a) discriminated, to the extent possible, according to the different items involved;

(b) limited, in general, to a royalty of up to 3% on net value of sales;

(c) calculated, when the payment of royalties has been agreed upon, on ex-factory sale's price, after deduction, inter alia, of imported drugs incorporated into the product.

Likewise, agreements should not allow the supplier to impose on the recipient the use of the former's brand names. Such a requirement may lead to an increased price of the license, to the imposition of tying clauses (directly or indirectly through quality controls) and, to a growing dependence of the recipient's productive and marketing activities.

3. Supply of drugs and intermediates (pp.40-41)

The supply of these inputs should be undertaken on the basis of the following main principles:

(a) free access to alternative sources of supply;

(b) supply at international prices, including the most favoured treatment for the recipient.

4. Grant-back provisions (p. 42 to 44)

The grant-back of inventions and improvements made by the recipient on the transferred technology, should be based on the recognition of recipient's rights over such developments, on the existence of equivalent reciprocal obligations of the supplier, and be of non-exclusive nature. Such a provision should prescribe that the recipient shall, subject to similar obligations by the supplier, inform the latter of improvements obtained by him regarding the technolgoy transferred, and shall grant the supplier a license for the use of such improvements for an appropriate compensation, taking into account the remuneration stipulated in the agreement, and for the time of validity of the agreement.