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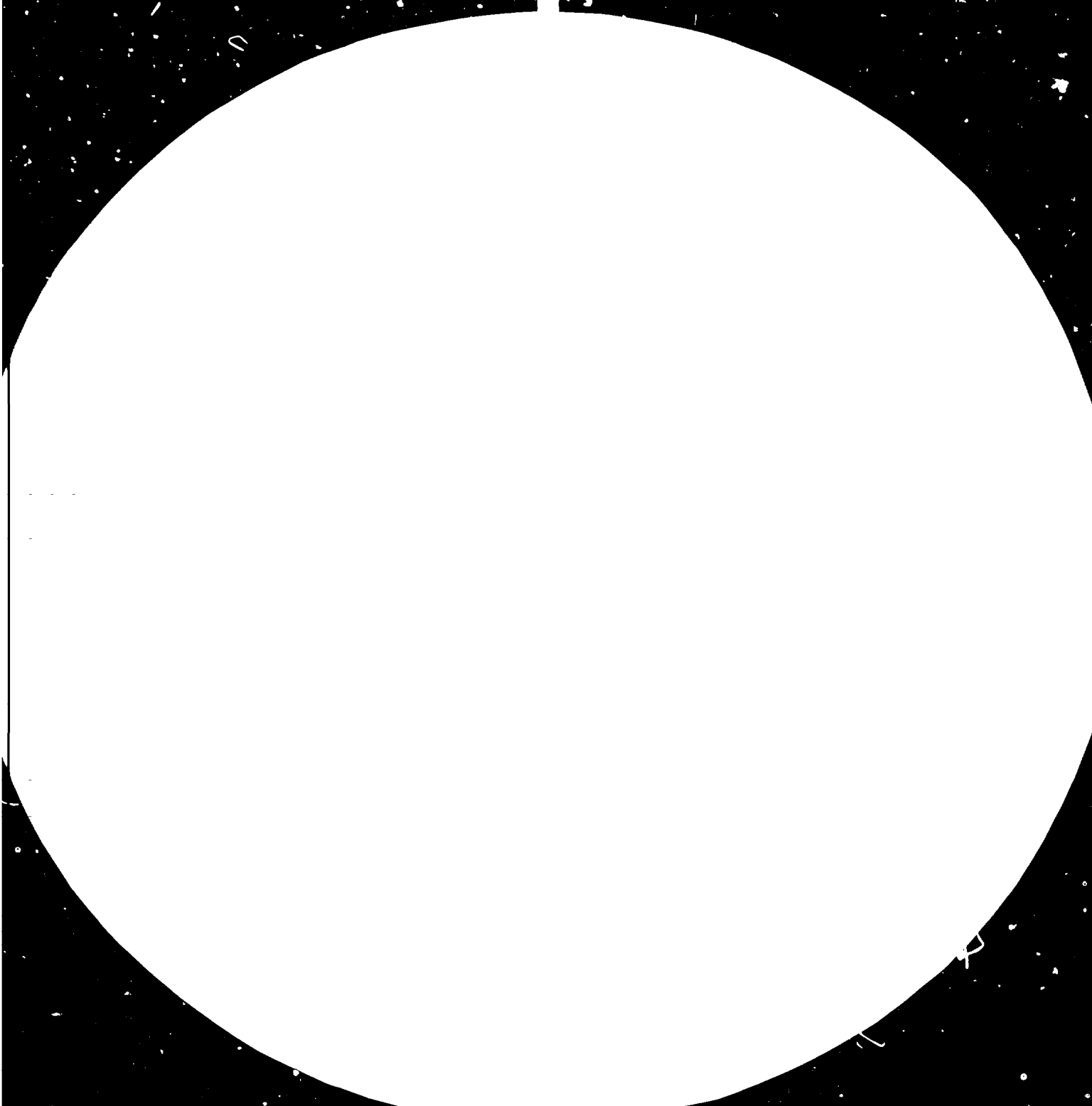

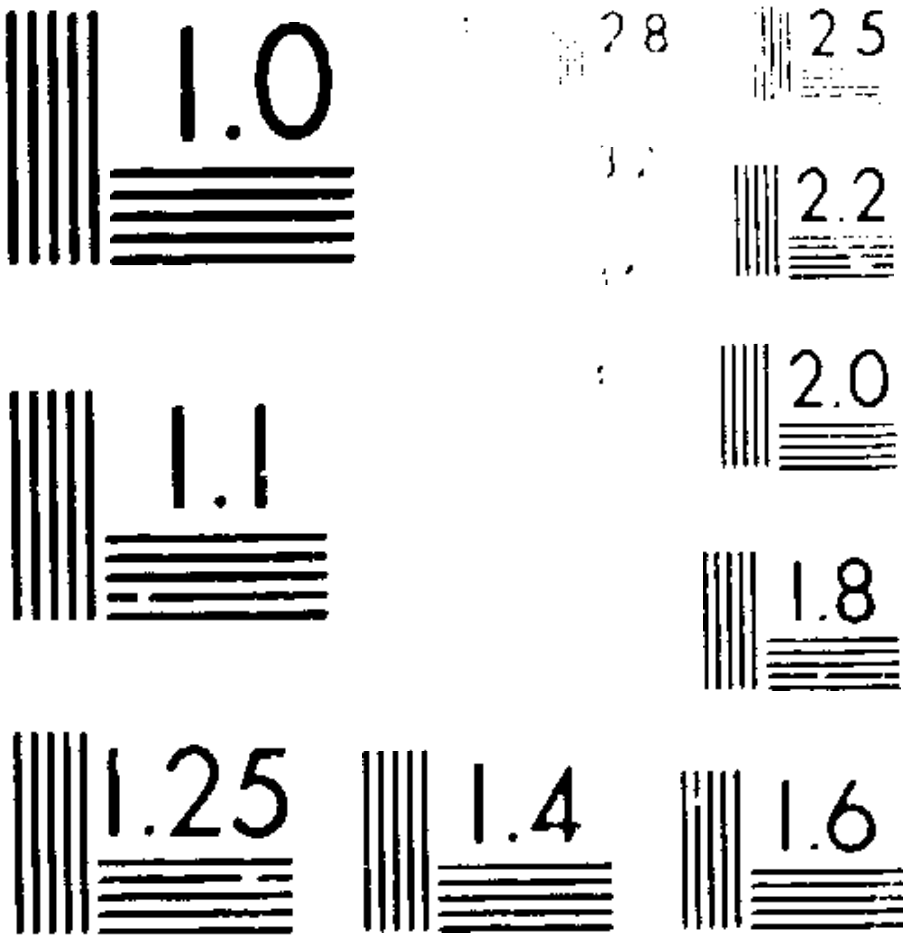
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Distr.
LIMITED

ID/WG.331/3
23 September 1980

ORIGINAL: ENGLISH

United Nations Industrial Development Organization

First Consultation Meeting on the
Pharmaceutical Industry

Lisbon, Portugal, 1-5 December 1980

Preparation of Guidelines

Background Paper*

Prepared by

the UNIDO Secretariat

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INTRODUCTION

The purpose of this document is to discuss a number of critical issues involved in the TOT through contractual means, particularly as related to the transfer of chemico-pharmaceutical technologies to developing countries. It is not intended to cover all issues involved in such transactions, but to highlight those which may have special legal, technical or economic importance, or which may give rise to controversial views from the standpoint of exporters and importers of technology.

The analysis that follows concentrates on three main sets of issues. First, a brief consideration is made on some general principles that should govern TOT in pharmaceuticals, particularly to developing countries. Second, the paper examines terms and conditions which may affect the extent of use of technology transferred, and thereby limit the potential beneficial effects of such transfer on the receiving country. Third, other relevant issues, concerning certain key problems in licensing are dealt with, taking into account the specific characteristics of the industrial sector involved.

For the presentation of discussion on the various items, the paper summarizes the different positions taken on them by developed and developing countries, either in international fora or as expressed in their national or regional laws, regulations and policies. Of course, opinions may differ within a single country or group of countries, as well as change according to evolving political and economic circumstances. Hence, opinions summarized below constitute a simplification of various positions on the items dealt with. Bearing this in mind, conceptions as described should be considered as reflecting predominant trends and currents of opinion, which may not necessarily correspond to any particular country or group of countries.

When possible, suggestions for alternative approaches on examined issues are also made. For this task previous discussions and work on TOT matters undertaken by UNIDO and other international organizations, such as UNCTAD and WIPO, are taken into account.

1. Channels for TOT

This paper concentrates on TOT that takes place through contractual means (often broadly referred to as "licensing agreements"). It is not intended to deal with other channels for technology transfer, such as the establishment of subsidiaries and the constitution of joint ventures.

Foreign investment (through the setting up of subsidiaries or branches) is not likely to be the most suitable option as a means of TOT (1), whenever the policy objective of a country is to strengthen domestic technological and productive capacity in order to reach certain national control over such a vital and strategic industry as pharmaceuticals. In particular, the effects of TOT within transnational corporations are basically confined to the precincts of the own corporation, without entailing a real access by the host country to the technology transferred (2).

However, it is to be noted that technology is mostly in the hands of individual companies. It is, therefore, desirable that these companies and the developing countries enter into long-term partnership arrangements based on mutually beneficial terms. Such an arrangement is likely to give the developing countries access to up-to-date technology, which is under constant improvement and thereby these countries have a possibility to avoid obsolescence and uneconomical production.

The constitution of joint ventures is visualized as one of the best methods for transferring technology, as far as the foreign supplier's participation ensures an efficient performance of the enterprise and an appropriate and continuous flow of technology. However, the beneficial effects to be derived for the host country on the basis of the TOT are dependent upon the real control exercised by local partners over the enterprise's activities, and upon the degree of absorption of the technology reached by local personnel. For these purposes, the terms and conditions of the licensing agreements entered into between the foreign supplier and the joint venture, constitute an essential part of the overall relationship between the parties. TOT through contractual means between independent parties provides a suitable form for increasing local technological capacities and allows a further autonomous development. This method may also represent a useful tool for technical co-operation among developing countries (3), eventually through and with the assistance of UNIDO.

The negotiation of contractual arrangements for the TOT presupposes the existence of a willingness by the potential supplier and recipient parties to conclude a contract under mutually acceptable terms and conditions, in accordance with the applicable law.

The content of such terms and conditions will vary significantly according to the type of technology transferred (processes for new products; new processes for known products; improvements on existing processes; techniques for formulation, etc.) and to the items included in the object of the agreement (licences of patents, transfer of know-how, engineering services, quality control methods, etc.). Therefore, the pertinence and relative importance of issues discussed in this report will depend upon the substance of the agreement to which they would apply.

2. Transfer of technology for formulations

The technology for formulation of final products is, in general, well-known and fairly well diffused. Agreements for the transfer of this type of technology usually involve the provision of active ingredients, the communication of medical and other scientific information needed for the registration of the products, and the licence on trade marks of the supplier. Eventually, it may comprise a patent licence, but only as a means for covering imports from the supplier. In fact, given the very limited technological contribution (regarding production techniques) that these agreements usually may provide, the contracts should be generally limited to "service agreements" or other forms of arrangements that do not imply the submission of the recipient to continuous payments or other restrictive conditions.

The transfer of techniques on formulation is likely to have a very limited impact as regards the improvement of the technological capability in the receiving country, without prejudice to its external effects as to the establishment of testing laboratories and some screening facilities. In general, such technologies do not involve any secret information, in contrast with the case of technologies for the manufacture of bulk drugs, which is more complex, and sometimes is very new and subject to the tight control of the innovators in the industry.

As stated before, the main concern of this document is to deal with questions involved in the negotiation and drafting of agreements for the production of drugs. However, as technology for formulations is sometimes transferred under "licence" agreements, many of the issues dealt with here are also pertinent for that kind of arrangement. Likewise, the paper considers some aspects that are of specific or particular relevance to such arrangements (see specially section III 1, 2 and 3).

It is important to stress that many developing countries already dispose of technology for formulation, and are in a capacity to transfer it to enterprises of other developing countries. The possibilities of establishing a useful co-operation among developing countries in this field are, therefore, very important, and should be extensively promoted in order to allow a faster development of the pharmaceutical industry in such countries.

3. Preparatory stage of negotiations

While the present document deals with contractual terms and conditions in TOT arrangements in the pharmaceutical sector it should nevertheless be borne in mind that the beneficial effects of the deal will, to a greater extent, depend upon good preparatory work done by the recipient party. It is in this phase where the basic strategic policy considerations should be clarified and the basic criteria for the choice of technology, the supplier, the modality of TOT determined. Specific consideration should be given during this phase to such issues as: specification of local needs, development policies, identification of local technological and material resources, information on alternative technological solutions, suppliers and channels of transfer, possibilities of unpackaging, possibilities of adaptation, possibilities to use the transferred technologies as a launching path for development of local technical and industrial potential. Constructive co-operation of the supplying party and the support of local governments could be instrumental to establish a sound framework, on the basis of which negotiations could start. These issues might be considered in further work undertaken for the preparation of "Guidelines for TOT in pharmaceuticals".

4. Terminology

For the purposes of this document "transfer of technology" or "licensing" agreements comprise contracts for the licence of industrial property rights, the transmission of know-how, the provision of technical assistance and related supplies (including machinery, equipment, intermediates, bulk drugs, etc.). This concept applies to transactions on technologies for the formulation of final pharmaceutical products, as well as, more properly, on technologies for the manufacturing of bulk drugs.

"Supplier" and "recipient" are used to name the persons, enterprises or other entities that provide and receive, respectively, items referred to.

"Product" is deemed to describe a form of a final pharmaceutical formulation.

"Bulk drugs" means the basic chemical entities or active ingredients in a pharmaceutical product.

"Manufacturing" means the preparation and compounding of the products from the basic raw materials and active ingredients, processing, filling packaging and control procedures until the final dosage form.

I. GENERAL PRINCIPLES FOR TOT IN PHARMACEUTICALS

The formulation of the general principles that should govern the transfer of pharmaceutical technology to developing countries, need to be based on the special characteristics of the industrial development and trade in pharmaceuticals of developed and developing countries. In this sense, it may be useful to recapitulate that (i) the latter only account for 11 per cent of world production in this sector; (ii) their expenditures in concept of imports of drugs have grown quickly over the last years; they doubled between 1972 and 1977; (iii) only seven developing countries seem to have facilities for the manufacturing of bulk drugs and 43 for formulating a range of products; (iv) transnational corporations control a very substantial portion of such countries' markets (4).

Further, available information on Latin America indicates that TOT to this region has practically consisted only of technology for the formulation of final pharmaceutical products (5). This transfer has not, therefore, created or significantly improved the capacity available in such countries to undertake more complex activities involved in the manufacturing of bulk drugs.

On the other side, transnational enterprises do not seem prepared to initiate or expand their manufacturing activities in developing countries. Thus, in India, the Hathi Committee pointed out the limited role of such enterprises in the production of bulk drugs as compared with that of public and national private enterprises (6).

This situation suggests the imperative need for developing countries to create capacity for the manufacturing of bulk drugs and the formulation of dosage forms. Transfer of technology on suitable terms may constitute a major instrument for providing a basis for such a development.

However, TOT should be viewed as a component of a broader developmental policy of pharmaceutical industry. As a result of the high concentration existing in this industry and the role of transnational corporations in it, the access to new technologies may be difficult, particularly when its possessor can exploit them through its own subsidiaries in the country concerned. As indicated by a European pharmaceutical firm, "companies now want to exploit their technologies themselves. Nowadays it is very rare to be granted a licence for an interesting product" (7).

Accordingly, the feasibility of a successful policy based on the importation of foreign technology will depend upon the degree to which the general framework applicable to the industry favours the development of a national industry. This may include, for instance, the restriction to the establishment of foreign owned subsidiaries, and the promotion of joint ventures with local participation; the exclusion of legal monopolies on the basis of which the foreign enterprises could prevent or hinder local production, and the support of potential technology recipients in the negotiation of TOT agreements.

With these considerations in mind, it is possible to define a set of principles that should govern the negotiation, conclusion and performance of TOT agreements in pharmaceuticals:

(a) TOT should contribute to the identification and solution of economic and social problems related to the production and use of pharmaceuticals in developing countries, with an aim at substantially improving, at adequate costs and quality, the provision of health care in developing countries;

(b) The parties to a TOT agreement should be responsive to the health, drug, industrial and other relevant policies of the receiving country, including import substitution, development of technical skills, promotion of local innovation, etc.;

(c) Licensing agreements should contain fair and reasonable terms and conditions, including payments, and be no less favourable for the recipient than the terms and conditions usually applied by the supplier or other reliable sources for similar technologies under similar circumstances;

(d) The agreements should, in particular,

(i) ensure the absorption of technology transferred by local personnel;

(ii) allow the use, as far as possible, of locally available materials and services;

(iii) facilitate and, in any case, do not restrict the adaptation and further development of technology received;

(iv) include adequate guarantees for the performance of the parties' obligations;

(v) provide full information on the characteristics of the technology and drugs to be manufactured, specially in respect of possible hazards and side effects;

(vi) do not contain unjustified restraints on the recipient's use of the technology.

Principles indicated in (a) and (b) above have, in general terms, been accepted by developed and developing countries as part of the basic background for international transfer of technology (8). However, strong resistance by developed countries has emerged with respect to the acceptance of the "no less favourable" clause (art. 5.3.a.i. of the draft Code of Conduct). For Group B countries, each TOT transaction constitutes a unique incomparable case, while for the Group of 77, such a clause could ensure more uniformity and fairness in TOT, particularly for the benefit of parties with lowest experience and bargaining power.

It is needless to stress the crucial importance for developing countries of principles described in (d). They aim at a greater self-reliance of such countries in the manufacturing of bulk drugs. The acceptance of developed countries to such principles seems to be, at least till now, considerably qualified, as examined later in this paper in connexion with some particular clauses in licensing agreements.

Principles stated above are premised, in sum, on the critical economic and social implications that a balanced and integrated development of a pharmaceutical industry has for developing countries. TOT in this field opens possibilities of bringing about a substantial improvement in the well-being of a large part of the Third World population. Therefore, it cannot be considered solely from a profit-oriented point of view. Without prejudice to the recognition of the legitimate interests of the parties involved, it is necessary to take into account the peculiar problems involved and the consequent responsibilities of the parties and governments concerned.

II. MAIN CONDITIONS ON THE USE OF TECHNOLOGY

In order to consider the most important and controversial issues related to limitations on use of the technology, it is necessary to undertake an introductory examination on a fundamental question in TOT, concerning the legal nature of agreements for the transfer of unpatented technology.

1. "Leasing" or "sale"?

This question is to be examined in the context of transactions involving know-how, on which the supplier lacks a monopoly of use.

In accordance with developed countries' position - as expressed in the negotiation of a draft Code of Conduct on TOT - TOT agreements should contain a clause ensuring the recipient party's "respect for the ... proprietary nature of ... any trade secrets, secret know-how and all other confidential information" (art. 5.4.ii). Under this conception, TOT would constitute a mere leasing whereby the transferor retains the "property" of the technology and the transferee only obtains a right to use it for a limited period, under conditions which are assimilated to those governing patent licences. For this opinion, for instance, restrictions on the use of the transferred technology after the expiration of the agreement, are a normal consequence of the nature of the transaction.

Developing countries have sustained, on the other hand, that TOT agreements operate the "sale" of the technology which would be "acquired" by the recipient.

The thesis of the proprietary nature of know-how seems to be admitted by a majority of U.S. authors with the support of case law. This notion is based on the identification of know-how and "trade secret", and on a concept of "property" extremely more flexible and imprecise than under continental law (9). In countries with codified civil law, like France, where property rights can only be instituted by law, know-how is considered to be a mere monopoly of fact (10). The lack of a legal specific protection on know-how also stems from the application of the theory on "immaterialgüterrechte" by Italian authority (11).

In Latin America, the conception of the proprietary nature of know-how has been generally rejected as well (12). This also seems to be the position of international organizations concerned with the matter (13).

In sum, without prejudice to any national legal system that may recognize proprietary rights over know-how of a secret nature, such a notion can neither be extended to the international field, nor imposed to countries with different systems of law or where know-how is subject to different legal systems. This does not mean, however, to deny indirect forms of protection for secret know-how, for instance, under unfair competition law.

The issue under examination has meaningful implications for the negotiation and execution of TOT agreements. First, it should be clear that property over know-how cannot be created by a contractual relationship. Second, given the major differences existing in national legal systems, the determination of the law applicable to the contract will have a crucial relevance for the definition of the parties' respective rights and obligations. Third, the understanding given to this point may have important consequences with regard to field of use restrictions, confidentiality obligations, use of the technology after contract's expiry, exports to

countries where the supplier retains secret know-how, and related issues. Fourth, it should be noted that TOT agreements usually contain secret and non-secret know-how, and that a clear distinction between them is necessary for specifying the conditions applicable to each category of items transferred.

The significance of these considerations, in particular, for TOT in chemico-pharmaceutical industries is manifold. Though patents play an important role in this sector, unpatented technologies are likely to account for a substantial part of technology transfer, particularly to developing countries. As mentioned before patents do not normally contain all information necessary for the use of the protected invention. Moreover, in many developing countries patentability on pharmaceuticals has been excluded or limited (14).

2. Confidentiality obligations

(a) Specification and scope

It is common to find in TOT agreements formulations that impose on the recipient the obligation to keep confidential "all" unpatented technical information received during the lifetime of the agreement. However, technology transferred usually includes information of a different nature, from which only some specific parts may be considered as actually "secret".

The recipient party is not normally in a position to appraise which pieces of information are to be deemed confidential. He only has access to it during the execution of the agreement, and particularly when he belongs to a developing country, he has not the capacity needed for evaluating and discriminating among the different types of information transferred.

It has been suggested, for this reason, that the supplier must specifically indicate whether and which pieces of information are to be treated as confidential (15). In addition, confidentiality obligations should be expressly provided for in the agreement (16). The recipient cannot be expected to discern whether the technology transferred has or has not been previously divulged and, therefore, should not be bound, in the absence of a specific provision and indication by the supplier, to take measures that the latter has not asked for.

To the extent that the recipient's reason to enter into a TOT agreement is to obtain a technology that the supplier declares to be "secret", the agreement should contain a clear statement reflecting that disclosure thereof is the basic consideration by the supplier.

The scope of a provision on confidentiality should be limited with regard to:

(i) information which was in the possession of the recipient or was subsequently obtained by him from other sources;

(ii) disclosure by the recipient for purposes of subcontracting, procurement, etc.;

(iii) disclosure necessary for complying with requirements of national authorities concerning registration of the agreement or of the products.

A possible text for the provision, as discussed, could be the following: "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 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 purposes 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" (14).

(b) Duration

Technology suppliers generally tend to ask for confidentiality obligations of indefinite duration, at least as long as the respective knowledge has not entered the public domain. This is regarded as a necessary protection for valuable know-how, and as a condition for increasing international transfer of technology. This approach seems to prevail in most developed countries' legislations.

In many developing countries there is a trend to limit confidentiality obligations to the term of the agreement or a reasonable period thereafter. This has been the practice of the Mexican Registry on Transfer of Technology (17), as well as in Argentina (under law 20794, which was in force between 1974 and 1977) and is also required by the regulations of Brazil and Spain. In the negotiation of a Code of Conduct on TOT, the Group of 77 has, similarly, proposed that these obligations do not extend "beyond a lapse deemed to be reasonable after the transmission of each item of secret information" (art. 5.4.ii).

With regard to developing countries' views on this issue it is possible to distinguish the perspective of the recipient enterprise and that of the government. The former is normally interested - having paid for the disclosure of secret technology which may provide it a competitive advantage - in retaining the secrecy of received information as far as possible. However, the existence of excessively long restrictions is likely to prevent the subsequent sale of the technology to third parties, particularly to other developing countries. Besides technologies in pharmaceuticals are subject to rapid change, improvement and substitution, and may become obsolete in relatively short periods. The recipient can therefore resist to accept restrictions which would extend beyond the likely economic life of technology transferred.

From the developing country government's viewpoint, there may be an interest in the widest possible sharing and disseminating of technical information imported, with the goal of improving the general technological level of the country, avoiding repetitive importation of technology and promoting a more rational selection and negotiation of foreign technologies. This aim is not only related to the duration of confidentiality obligations, but also with their scope as regards the possible "sublicensing" by the recipient to third parties in the country (see point II.4 below).

The achievement of an adequate balance on these issues must take into account all interests involved. It cannot certainly rely on the recognition of undetermined obligations which restrict the use of technology sine die. It should rather admit that confidentiality is to last, for instance, 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, as provided for by Brazilian regulation, to limit such obligations to a reasonable period after each transfer of the latest information (18).

The solution given to this question, consistently with an appropriate treatment of the "sublicensing" issue and the right to use the technology after the expiration of the agreement, are essential conditions for enabling a meaningful and promising technological co-operation among developing countries in the pharmaceutical field. This co-operation will not satisfy its objectives if developing countries' recipients are condemned, under excessively broad or long confidentiality obligations, to establish such co-operation on the basis of totally obsolete products and technologies.

3. Sublicensing

In general, licensing agreements are deemed to be of a personal nature (intuitu personae) and cannot be totally or partially assigned without the express consent of the patent owner. In agreements covering know-how, sublicensing provisions are considered exceptions to the obligation of confidentiality, as far as they imply the disclosure of secret information to a third party.

The recognition in TOT agreements of the possibility for the recipient to grant "sublicences", has been viewed in some developing countries as a desirable policy for avoiding repetitive importation of technology, and enhancing the horizontal transfer and diffusion within the receiving countries of technologies already adapted to local conditions. In a broader context, sublicensing provisions may also be important with regard to the co-operation among developing countries.

The negotiation of a straight authorization for the recipient to sublicense at his discretion, is likely to give rise to certain reluctance by the supplier and, at least, to an increase in the price charged for the technology supplied. In principle, such a general clause should be negotiated only when there are actual perspectives or need for sublicensing.

A more flexible alternative would be to provide for in the agreement the participation that the supplier would have in situations where the recipient is willing to sublicense the technology to a third party. For instance, the agreement might stipulate that the recipient may grant sublicences, subject to approval of the supplier, and the sharing that would correspond to the latter on royalties or other payments to be made by the sublicensee (19).

A still more elastic approach conditions the recipient's right to sublicense upon appropriate negotiations with the supplier and the third party concerned. Thus, the Indian Guidelines for Industries, 1976-1977, provide that the Indian party should be free to sublicense the technical know-how, product design/engineering design under the agreement to another Indian party on terms to be mutually agreed to by all parties concerned including the foreign collaborator and subject to the approval of the government (art. 9, ii).

The sublicensing provision could, in accordance with the precedent considerations, be drafted in the following terms: "the recipient shall have the right to extend the benefits of this 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

A complex situation arises when the technology transferred loses its secret character, independently of the recipient, during the lifetime of the agreement.

In the negotiation of a Code of Conduct on TOT, the Group of 77 has put forward that no restrictions on the use of the technology can be imposed after the know-how has lost its secret character. This would include the interruption of payments that the recipient would have to make if the knowledge retained its secret character. Groups B and D have rejected this position. For the latter, the recipient should be bound to comply with all obligations emerging from the agreement, independently of the eventual divulgence of secret know-how.

While the developed countries' position may find support in certain American authority (20), Lear vs. Adkins decision seems to have clearly established in the United States that any agreement for the communication of non-secret knowledge is to be deemed invalid and that, in this hypothesis, the recipient could obtain reimbursement of payments unduly made (21). The same solution seems to be possible under French law (22).

Furthermore, the EEC Commission has stated, in its draft proposal for a block exemption regulation for patent licence agreements and ancillary know-how, that it would constitute a violation of art. 85 (1) of the Treaty of Rome the obligation on the part of the licensee to pay royalties after the know-how has entered into the public domain - without default by the licensee - without prejudice to the supplier's right to receive appropriately reduced royalties in respect of patents that remain in force or of know-how which have not entered into the public domain (23).

In sum, while the issue dealt with here has not received an explicit treatment and solution in most regulations in developing countries, the precedent examination reveals the existence of a trend in developed countries that is apparently coming closer to the position of the Group of 77, as expressed in the negotiation of a Code of Conduct.

A possible formulation of a provision on this issue could be as follows: "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 this 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/trade marks licensed herein will be the object of a new agreement to be agreed upon by the parties".

5. Use after expiration of the agreement

The restriction on the recipient to continue using the technology after the agreement's expiry is one of the most frequently found in TOT transactions. It was identified in 34.1 per cent of a sample of agreements registered in Mexico, in 63.1 per cent of contracts reviewed in Ecuador, and in 31.4 per cent of agreements considered by the Comité de Regalías of Colombia (24). In Venezuela, 10.8 per cent out of 100 TOT agreements on pharmaceuticals also contained that prohibition (25).

The restriction referred to sometimes is formulated with the corollary that all technical documentation furnished during the agreement must be returned, at its expiry, to the supplier. In some cases, the limitation further includes the production or sale of goods similar to or competitive with those covered by the agreement.

The discussion of the issue at stake obviously requires to distinguish whether the agreement involves patented or unpatented technologies. In both cases, the effects on the recipient and on the receiving country are likely to be very harmful. The recipient may, if the restriction on use is enforced, be obliged to interrupt the production of drugs or products under the agreement, which may create, in turn, at least temporarily, a shortage in the supply of the product concerned. At that moment, the bargaining position of the recipient may be so low (specially when patents are involved) that he may be faced with the loss, at the expense of the

supplier, of a market that he has tested and developed. Eventually, as a condition to renew the licence agreement, the supplier may require the sale of part of the recipient's stock, and obtain the control of the recipient enterprise. This procedure is mentioned to have been utilized by foreign suppliers to enter into the chemico-pharmaceutical industry in Colombia during the sixties (26).

(a) Patented technology

Patent licences may last for a period shorter than the patent life. Apart from the cases where this results from an agreement between the parties, policies applied in some developing countries, which establish maximum terms of duration for licensing agreements, are likely to determine that the licence agreement be ended prior to the patent's expiry. Thus, in Argentina and Brazil licences may last till the end of industrial property rights. In Mexico, the maximum duration admitted for TOT agreements - 10 years - is also the term of patent grants. However, in Colombia, Peru, Venezuela and India, maximum terms accepted for such agreements are, in general, briefer (up to five years) than the duration of patents.

Time lags between patent's and licence's expiry can give a basis for the abuse of the monopolistic power conferred by patents, to the detriment of the licensee.

In developed countries, patent laws incontestably establish the right of the licensor to prevent the licensee from using the protected invention after the licence's end. This principle is reflected in the categoric position held by Group B in the negotiation of a Code of Conduct (art. 4.14 of the draft).

The text proposed by the Group of 77 in this regard does not differentiate between patented and unpatented technology; it postulates the freedom of the recipient to continue in the use of the technology independently of its legal nature. The Code should, for this Group, condemn "restrictions on the use of the technology after the expiration of the agreement" (art. 4.14) (27).

Some developing countries have tried to overcome the difficulties posed by this type of restriction through adequate negotiation of TOT agreements. In India, according to the Guidelines for Industries mentioned before, "if the proposed item of manufacture is covered by a patent in India, it should be ensured that the payment of royalty for the duration of the agreement would also constitute compensation for the use of patent rights till the expiry of the life of the patent and that the Indian party would have the freedom to produce the item even after the expiry of the collaboration without any additional payment" (art. 9 ix, Chapter III). In Argentina, the law in force during 1974-1977 stipulated that, for the approval of a licensing agreement, the parties should agree, ab initio, on the conditions for the use of licensed patents after the expiration of the agreement.

The licensee's situation may also find some relief on the basis of provisions of patent laws concerning certain special types of compulsory licences. For instance, under Decision 85 (presently in force in Ecuador, Colombia and Peru) any interested party may obtain a licence after five years of granting of a patent (independently of the existence of effective exploitation of the patent during that period). In India, all patents in pharmaceuticals are automatically available three years from grant under similar "licences of right". In the latter country, patents in this sector are subject to a reduced time of validity (7 years).

In conclusion, when negotiating TOT agreements including patents which last beyond the normal date of expiration of the agreement, a provision should be considered stating, for example, that in such a situation, the parties will negotiate, a reasonable period before the normal expiration of the agreement, the renewal thereof under terms which will not be less favourable for the licensee than those governing the agreement that expires, taking into account all changes occurred and other relevant circumstances prevailing at the time of the renewal.

(b) Unpatented technology

The limitation to use (unpatented) technology after agreement's expiration is also apprently enforceable in most developed countries. In some of them it seems to be held that even in the absence of a specific clause in the contract, the recipient must cease using trade secrets after that date (28). This is also the position sustained by Group B in the draft Code of Conduct, according to which that limitation should be considered valid as long as the know-how retains its secret character (art. 4.14).

The limitation referred to is frequently grounded on the asserted "proprietary" nature of know-how. In accordance with this argument, the supplier authorizes, or better, "leases" the use of know-how, but retains the rights in the technology. Consequently, after the term specified in the agreement, the "leasee" could no longer exercise any rights over or use the "leased" technology (29).

The Group of 77 maintains that restricting the use of unpatented technology after contract's expiry should be per se objectionable under the Code of Conduct (30). The same has been proposed by the Latin American Group with regard to transactions of transnational corporations (31). At the national level, Argentina - under law 20794 (32) - Brazil, Mexico, Venezuela and Spain have prohibited or otherwise controlled such restrictions.

According to developing countries' approach, as mentioned before, unpatented technology is not susceptible to a property right. For some, once transferred, the technology is "acquired" by the recipient. More appropriately, it is possible to hold that the reward for know-how tends to be a function of consideration for disclosure (33) and that TOT agreements regulate, in substance, the communication or disclosure of secret information, without constituting or transferring any property rights over it.

If this last approach is followed, the supplier could not validly restrict the recipient to use the technology transferred, after the latter has complied with payments and other conditions provided for in the

agreement. In order to clarify the recipient's right in the agreement, it would be advisable to include in the contract an express clause on the matter 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".

Between the two positions described (full prohibition-full freedom), the EEC Commission has taken an intermediate approach. In Kabelmetal-Luchaire decision (1975) it held that "(the licensee's) undertaking to pay royalties after the contract expires for secret technology ... did not violate Article 85(1), since this obligation did not prevent the licensee from using the know-how after the contract has expired, even if it has to pay royalties to do so".

In the draft proposal for a group exemption regulation (1979 version) the Commission has qualified Kabelmetal-Luchaire. It proposes that restrictions on use be considered objectionable under art. 85(1), without prejudice to the supplier's right to receive a compensation for further use, but only for an "appropriate period" after the agreement's expiry. In an earlier version of the draft that period could not be of more than three years from that date.

It is pertinent to note, finally, that the recognition of a recipient's right to continue using the technology after the expiration of the agreement, does not necessarily conflict with the maintenance, for a reasonable period thereafter, of confidentiality obligations. In order to take this into account, a possible provision, as suggested above, might be complemented as follows: "However, the recipient shall refrain from disclosing any technical information which has retained its secret character for ... years after the date of expiration of the agreement".

The right to use the technology, after that date, should be interpreted as including the possibility to pass on the technology to third parties, under the sole condition, in case that confidentiality obligations were still in force, that the third party concerned keep the secrecy of information for the remaining duration of such obligations.

6. Field of use restrictions

Under field of use restrictions the recipient is prevented from applying the technology transferred to uses other than those specifically provided for in the agreement. Thus, the recipient can be forbidden to give a drug a therapeutical use different to that mentioned in the contract, or to apply it to veterinary when it had been licensed for human health.

In accordance with developed countries' legislations, field of use restrictions in patent licences are, in principle, valid and enforceable. The patentee is recognized the right to place restrictions on the method, place or time of use of the protected invention by the licensee (34).

On the basis of the alleged "proprietary" nature of know-how, it has also been considered in such countries that restrictions under discussion apply to agreements on know-how as well (35). Consistently, Group B has rejected in toto the draft proposal by the Group of 77 concerning a possible regulation of field of use restrictions, as proposed in the negotiation of the Code of Conduct (art. 4.15).

The EEC Commission has taken a different view. In the already cited draft regulation, it suggests the unlawfulness of "a restriction on the licensee against using secret manufacturing processes or other secret know-how communicated by the licensor except for specified purposes; without prejudice to any right of the licensor to require payments at an appropriate higher rate for any use by the licensee not covered by the agreement and not protected by patents of the licensor" (art. 3.11).

Field of use restrictions are prohibited or otherwise condemned in most developing countries that apply specific TOT régimes, and in Spain, under general formulations which comprise patented and unpatented technologies and which refer to the "structure" or "features" of production (36).

For the negotiation of licensing agreements involving patent rights, the parties should take into account the provisions existing in patent laws applicable to the contract. Most developing countries' laws on the subject have been framed on the basis of legislative patterns prevailing in developed countries' legislations, under which, as stated above, field of use restrictions are legitimate. Even in these cases, however, the parties may exclude such practices for the benefit of the recipient position, or they may be legally excluded by TOT régimes in force.

Wherever patent protection is not granted to pharmaceuticals, or the agreement does not involve such rights, the principle should be that the recipient be recognized the right to use the technology in fields other than those specified in the contract, provided that the supplier should be entitled to an adequate remuneration for such use on terms not less favourable for the recipient than those originally provided for. This principle could be translated in a provision as follows: "if 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".

In cases where the supplier has granted certain guarantees related to the specified uses, their extension to new applications should be the object of a particular negotiation, in accordance with the terms of the agreement and the nature and properties of the technology and uses concerned.

7. Export restrictions

Limitations on exports have been one of the most frequent practices in TOT to developing countries. Their impact on the transfer of technologies in pharmaceuticals to such countries has two outstanding features. First, they are likely to prevent the achievement of economies of scale in the

manufacturing of drugs, thereby potentially hindering the development of adequate and efficient productive capacities. Second, they may adversely affect efforts by developing countries to expand their exports of manufactured goods and of regional or subregional economic integration.

International trade in pharmaceuticals is very significant nowadays. The world exports amounted, in 1973, to about US$ 4,700 million. Imports by developing countries were, in that year, about US$ 1,900 million. Even though developed market economy countries are, as a group, net exporters of pharmaceutical products, only 10 of them had a positive trade balance in this sector. As regards developing countries, if Hong Kong, Singapore and Bahamas are excluded, only four developing countries had pharmaceutical exports valued at over US$ 10 million (Mexico, Yugoslavia, Argentina and India) (37).

It is evident from the preceding figures both the importance of international trade in pharmaceuticals, and the insignificant share of developing countries in it. The elimination of exports restrictions in TOT agreements will not automatically lead to the effective realization of exports. However, it will give the recipient the opportunity to do so whenever possible.

The control of export restrictions has been one of the main concerns of countries which established specific régimes on TOT. With different degrees of rigidity or flexibility, such restrictions have been regulated in Argentina, Brazil, India, Mexico, the Andean Group countries, Japan, Spain, Portugal, etc. (38). In general, applicable regulations or guidelines give competent authorities enough flexibility to grant exemptions with regard, for instance, to countries where the supplier has granted exclusive licences covering the same products.

The Group B position, as expressed in the negotiation of a Code of Conduct on TOT, is that such practices could, in principle, be condemned when they are "unreasonable restrictions which prevent or substantially hinder export by means of territorial or quantitative limitations or prior

approval for export or export prices of products or increased rates of payments for exportable products resulting from the technology supplied, unless justified, for instance, to prevent export of such products to countries where they are protected by the supplying party's industrial property rights or where the relevant know-how has retained its confidential character, or where the supplying party has granted a licence to use the relevant technology" (art. 4.10) (39).

Some aspects of exports restrictions emerging from patent rights have been dealt with previously in connexion with item b, part 1. It is possible to add here that the Group of 77's view, in connexion with the text reproduced above, seems to be that a justification of such restrictions cannot be based on the mere existence of patent rights, but, if at all, in the actual possibility of using such rights (through infringement procedures) to prevent imports to the country concerned. The validity of contractual clauses aimed at supplementing patent rights in this respect has also been contested in some developed countries (40).

Likewise, in the context of EEC, the Commission has taken the view that export restrictions between member countries constitute a violation of the Treaty of Rome, even if the licensor owns a possible patent covering the products in the country to which exports are prevented. In AOIP-Beyrard (1976) the Commission held that an exemption could be granted in an appropriate case for a prohibition on exports applicable to the first sale only and of limited duration, the object of which is the mutual protection of the parties or of other licensees (41).

When the licensor has obtained the same patent in many countries, it would be for the benefit of the recipient to expressly exclude in the agreement the use of such patents as a possible barrier against recipient's exports. WIPO's Licensing Guide suggests, in this sense, that neither the licensor nor any person entitled by him will, on the basis of patents registered in third countries, claim infringement by the licensee or prevent exports made by him to such countries (42).

Another unusually controversial issue is the possible justification for export restrictions to be recognized in cases of countries "where relevant know-how has retained its secret character" (art. 4.10 quoted) as asked for by Group B. This position, implicitly grounded on the proprietary nature of know-how as discussed before, has been rejected by Groups 77 and D. The progress of such a position is likely to encounter important obstacles from a legal point of view, particularly in legal systems which do not recognize a specific protection for know-how.

It is generally accepted that the possessor of know-how has not exclusive rights on his use, and that therefore he cannot exclude third parties from using it. A fortiori he cannot prevent imports of a product manufactured with a similar know-how, in any case, without prejudice to any action for misappropriation or other unfair conduct conferred by the applicable law. Morever, to admit that the existence of secret know-how in a country is a valid reason to impose export restrictions to that country, would implicitly create a protection larger and longer than that granted by patents. In sum, and leaving apart the enormous factual difficulty to prove whether certain know-how has retained or not its secret character in each country, the position referred to seems to go far beyond the logical implications of any possible conception on the legal nature of know-how.

The negotiation of clauses relating to exports must be faced with a pragmatic approach, taking into account the actual and potential possibilities (plant capacity, marketing networks, etc.) of the recipient party. In some cases, freedom to export to its own regional market may be the basic concern of the recipient. In any case, to the extent that a complete freedom to export is not sought for by the recipient party or country, or it is not reachable, a limited restriction, like the following might be stipulated: "the recipient shall refrain from exporting the products covered by the 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

The following paragraphs are intended to point out other relevant issues in TOT agreements, which usually give rise to controversial or conflicting views, either with respect to the inclusion or not of certain clauses, or regarding their extent and possible implications.

1. Guarantees by the supplier

The nature and extent of guarantees to be granted by the supplier depend upon the characteristics of the technological "package" to be furnished, the type of technology involved, its degree of novelty or maturity and other conditions related to the technology and the form of the transfer. Since it is not possible to deal with all these complex matters here, this section is only intended to briefly examine and stress the importance of guarantees on suitability for use of the technology, on the characteristics of products and conditions concerning supplier's liability.

(a) Suitability for use

In the negotiation of a Code of Conduct on TOT all regional Groups have agreed that TOT agreements should contain "the technology supplier's guarantee that the technology, if used in accordance with the supplier's specific instructions given pursuant to the agreement, is suitable for manufacturing of goods or production of services as agreed upon by the parties and stipulated in the agreement" (art. 5.4.v).

Notwithstanding the agreement reached on the wording of the provision just mentioned, it is not yet cleared up whether such a guarantee should be considered an implicit condition in TOT agreements, or only apply when expressly provided for in the contract. The first alternative has been suggested by the Group of 77 (and Group D). It is also incorporated into the Argentine law on TOT (law 21617, art. 8 a). The necessity of an explicit provision has been held, on the other side, by Group B.

One of the principal reasons for the recipient to conclude a licensing agreement, is his willingness to acquire or improve his capacity in a technological field that is outside his knowledge and control. While the supplier

is supposed to master the technology he offers to transfer, the recipient generally lacks thorough knowledge and skills to evaluate the technical merits of the technology to be transmitted. Moreover, secret know-how involved in the agreement is only brought to the recipient's knowledge during the execution of the contract. At its inception the recipient does not know, in fact, what he will pay for. These considerations apply, in particular, to the situation of recipients in developing countries, whose technical capacity is usually far lower than that of the supplier.

On these grounds, it has been suggested that the supplier should, in principle, be responsible for the suitability of the technology even in the absence of specific provisions therefor. That would be the case when his technology is not reasonably suited to the general uses for which it was developed (43) and transferred, or to the particular purposes of the recipient as specified in the agreement.

The suitability of technology in pharmaceuticals should be considered when referred to new products, not only with regard to the application of the technology, but also in respect of the therapeutical effects attributed to the drugs or products concerned by the supplier. The latter should guarantee, in effect, that the drugs or products to be obtained with the help of the technology, serve the purposes that the recipient had in view when subscribing to the TOT agreement, as specified therein.

(b) Hazards and adverse effects

The supplier should inform, during the negotiation of the agreement and in due time, to the recipient, the exact properties and possible hazards of the drugs/products involved, as well as the registration status thereof in the supplier's and other countries, including any reason known to the supplier on account of which the drugs/products would not comply with the standards or requirements existing in the recipient country, already known to him or specifically drawn to his attention by the recipient (44).

The importance of obtaining a full picture of the drugs/products involved in the agreement, as suggested above, is illustrated by the experience of certain developing countries, where great drug transnational corporations have undertaken promotional activities which grossly exaggerated the value of their

products, or glossed over or totally ignored their hazards. By using these methods, such corporations could establish a double standard of advertising: full disclosure in developed countries and less than complete disclosure in developing countries (45). Moreover, many products that had been prohibited in the USA and other developed countries have continued to be sold by such enterprises in the latter countries, such as in Brazil and other Latin American countries (46).

The supplier's duty to inform, completely and correctly, about the properties and effects of products involved in a licensing agreement, should not be confined to the negotiating phase, but be envisaged on a continuous basis for the lifetime of the agreement. New research, stringent controls or prolonged application of a drug may reveal effects which were unknown at the time of signing of the agreement. More restrictive requirements in certain countries may also imply the prohibition of certain drugs or therapeutical uses. It will be a basic ethical and legal duty of the supplier to bring all these events, without delay, to the knowledge of the recipient. A possible provision for this purpose could read as follows: "the supplier shall inform the recipient of any hazards, adverse or side effects of the drugs/products which were identified after the signing of the agreement, as well as of 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

The terms and extent of the liability of the supplier regarding the application of the technology transferred and the use of products manufactured with its help, is one issue that generally entails difficult negotiations. In pharmaceuticals important consequences may arise when the use of drugs/products covered by a TOT agreement may be deemed to cause injury to persons treated with them. As mentioned before, a recipient (as well as the pertinent agencies in charge of drug approval and registration) in a developing country usually has not the capacity and skill for fully appraising possible risks involved in licences drugs/products which are unknown in the country concerned. Moreover, the conclusion of licensing agreements is often looked at by potential recipients as a means of avoiding risks involved in the introduction of new products in the market, by relying on more experienced and skilled foreign suppliers. In particular, in agreements for TOT on formulations, the supplier also provides,

normally, scientific and clinical information necessary for the registration and sale of the products of the agreement.

In some developing countries (Argentina, Brazil), existing regulations contain provisions aimed at ensuring the liability of the supplier in cases of damage or injury to persons or property resulting from the use of the technology or related products. In the negotiation of a Code of Conduct on TOT the Group of 77 has proposed, with Group D's support, a text on the supplier's liability (art. 5.4.xv) which has not yet been agreed upon.

WIPO's Licensing Guide has, on its side, suggested a formulation that may provide a basis for negotiation of a specific clause on the matter, on the basis of which the following text might be suggested: "the supplier agrees to indemnify and hold harmless the recipient and its directors, officers and employees from any and all claims for damage or injury to persons or property or for loss of life arising out of or in connection with the manufacture or the use of the Product manufactured using the Technical Information furnished under this agreement, provided that it is proven that the technology has properly been used in accordance with supplier's precise instructions".

An appropriate stipulation on supplier's liability should be viewed as an essential element in any agreement for the transfer of pharmaceutical technology. The total amount of the responsibility should not be arbitrarily limited; whenever a contractual maximum level is negotiated it should take into account the over-all compensation obtained by the supplier and the profit made on the licensing operation.

2. Remuneration for technology

The amount of payments made by developing countries in concept of TOT in pharmaceuticals seems to vary significantly according to the degree of development and structure of property of the industry, and to the existence or not of governmental policies on the matter.

In Brazil, none of 60 firms (which accounted for 75% of total industry's sales) considered in a study of FINEP (47) paid royalties during 1971-1975,

and only one maintained a technical assistance agreement with a foreign supplier. The whole industry paid, during 1975, only about one hundred thousand dollars in concept of royalties for technologies in pharmaceuticals (48). The very reduced dimension of technology payments in pharmaceuticals in Brazil can be explained, one, by the fact that local industries were technically able to produce formulations without foreign licences; two, by the important control that foreign enterprises maintain on the Brazilian market, and the legal prohibition imposed on subsidiaries from paying royalties to their parent companies for the use of patents and trademarks registered in Brazil; and three, by the policy apparently applied by governmental authorities in the sense of severely limiting the authorization of new contracts and emerging payments for technologies on formulations. The situation just described for Brazil contrasts with that observed in other developing countries. In Peru, for instance, the pharmaceutical industry was - according to payments made - the most important acquirer of foreign technology in 1971 and 1972, the second in 1973 and the fourth in 1974 (49). In Argentina, in 1972, the pharmaceutical industry was the economic sector which accounted for the highest number of TOT agreements, and it had the second position (after the car industry) measured by payments. The application of TOT régimes and other fiscal limitations on payments from subsidiaries to their foreign parent companies, seem to have significantly reduced the relative importance of licensing in pharmaceuticals after 1972. In 1976 only 2 new agreements were approved, which accounted for 0.07 per cent of total payments of the country authorized during that year. In 1977, 3 new agreements were approved, over 120 agreements registered by the Argentine competent agency that year (50).

As mentioned before, most agreements for the transfer of technology in pharmaceuticals to developing countries are likely to consist of technologies on formulations. This has not prevented technology suppliers to charge very high royalty rates, incommensurate with the real value and novelty of technology supplied, without prejudice to prices charged, in addition, for drugs sold under the general coverage of the licensing agreement (see point III. 3. below). Thus, in Peru (51) and Guatemala (52) royalty rates of up to 20 per cent have been identified. In Venezuela, the average ratio royalties/net sales in the

pharmaceutical sector was, in 1973, considerably higher (7 per cent) than that verified for other industrial branches (e.g. petrochemicals, 1 to 2 per cent) (53).

Many developing countries have implemented measures to avoid excessive or unjustified payments in concept of TOT. In addition to policies related to the determination of maximum royalty rates (54), some countries - Argentina, during 1974-1977, Brazil, Dominican Republic - have prescribed that calculation of royalties is to be made on net value of sales, deducting the value of imports made from the supplier or a source designated by it. In India, and apparently Venezuela, such a deduction should include all imported inputs, even from sources independent or not designated by the supplier.

Agreements for the transfer of technology on formulations, basically provide a channel for the supply of drugs necessary for the preparation of the products. Technology involved is normally very simple, as already indicated in this paper. Therefore, payments should generally be circumscribed to the market value of drugs supplied. Eventually, a lump sum for the transfer of technical and scientific information might be considered in the light of the importance and nature of the information to be transferred, services and training necessary for its effective transmission to the recipient.

Agreements for the elaboration and sale of formulations should not contain restrictions that impair the commercial and technological freedom of the recipient. Among such restrictions, in this type of arrangement it is of particular importance the imposition to use a determined brand name is indicated by the supplier. This practice may have significant short-term and long-term implications.

On the one side, the recipient will be normally obliged, in addition to a compensation for the brand name's use, to comply with quality controls and advertising standards prescribed by the supplier. This, in turn, may lead to tying clauses concerning the provision of basic drugs.

On the other side, in the long term, the recipient is likely to become increasingly dependent upon the supplier, as far as the maintenance of the licensed product is subject to the continuation or renewal of the licensing agreement. In order to avoid this weak and vulnerable position of the recipient, some Latin American countries and India have attempted at limiting or discouraging the licensing of foreign trademarks (55).

Payment conditions in agreements for the manufacture of bulk drugs may vary significantly. They may provide for a lump sum, royalties or a combination thereof. In any case, a breakdown of the contract price according to the different items involved in the agreement should be established, taking into account that the majority of payments are to be done after production starts. Whenever the modality of royalties is selected, they should be calculated on net ex-factory value of sales and not extend beyond a period of 5 years.

Whenever the stipulation of royalties is agreed upon by the parties and approved, if required, by the competent authority of the receiving country, the following guidelines should apply:

(a) The agreement should discriminate, to the maximum extent possible, prices to be charged for each item included in the agreement (56). No minimum royalties, independent of production or sales, should be admitted (57).

(b) Range of royalties (over-all rate):

(i) based on essential drugs in WHO list - 0 to 1 per cent;

(ii) based on speciality drugs, according to the level of the technology transferred - 1 to 2 per cent;

(iii) in exceptional cases - up to 3 per cent.

(c) In any case, royalties should be calculated on net ex-factory sales price after deduction of allowances, rebates, discounts, sales or turnover taxes and the price of drugs imported and incorporated in products sold.

Like in other transfer of technology transactions, these agreements may be associated to joint-venture arrangements with the foreign supplier. In this case, the rate of royalty to be paid to the foreign partner should be inversely proportional to the percentage of its equity in the capital.

3. Supply of drugs and intermediates

The special characteristics of TOT agreements in pharmaceuticals have generally allowed the supplier to impose tying clauses regarding the supply of drugs or intermediates. They can also give a framework for transfer pricing policies within transnational corporations.

In fact, incomes obtained by suppliers from sales of drugs and other inputs related to TOT agreements, largely exceed those accounted for royalties and similar concepts. For instance, in Argentina, in 1972, imports declared as originating from technology suppliers were 7.4 times higher than royalty payments effected to them (58). In Venezuela, in 1973, the ratio was of 3:5 (59).

The main guidelines that should govern the negotiation and drafting of clauses related to the supply of drugs and intermediates necessary for the recipient's production, can be resumed in the following principles:

(a) Free access to alternative sources of supply

Tying clauses are condemned under antitrust laws of developed countries, as well as in TOT régimes in force in developing countries. In the draft Code of Conduct there is also an agreement, in principle, as regards the exclusion of such practices, subject, however, to three possible justifications, where the clause is required (i) to maintain the quality of the product, where the supplier's trade name or other identifying item is used by the recipient; (ii) to fulfil a specific performance obligation which has been guaranteed, provided that adequate specification of the ingredients is not feasible or would involve the disclosure of additional technology not covered by the agreement (art. 4.9). In any case, these exceptions should be qualified by the prices of supplies to be made, which should correspond to international competitive prices of products of similar quality and provided under similar conditions.

In order to make effective the possibility of recipient's choice of alternative sources of supply, a clause in the agreement might state that "the supplier shall furnish the recipient with the drugs/intermediates, as listed in ..., necessary for the manufacture of the products/bulk drugs, as required by the recipient. Notwithstanding the foregoing, the recipient shall be free to buy drugs from whatever sources he prefers; provided that if the supplier is willing and able to offer the recipient the drugs/intermediates at the same price as the recipient is able to secure from alternative reliable sources or at a lower price, then the licensee shall buy the drugs/products from the supplier at such a price".

(b) International prices and most-favoured clause

The agreement should also provide that, in any case, drugs or intermediates should be supplied at an international competitive price, no less favourable than the price usually charged by the supplier to other recipients for equivalent drugs/intermediates (60).

4. Grant-back provisions

The obligation imposed on the recipient to grant back to the supplier any improvements achieved by the recipient, is one of the most frequent restrictive practices in TOT agreements.

The imposition of these clauses in their stricter forms have been common in different sectors in Latin America. In Venezuela, for instance, 12.5 per cent out of one hundred TOT agreements for pharmaceuticals stipulated that the recipient had to assign improvements made by him to the supplier and grant him licences for its irrevocable use, exempt from royalties, with the right to sublicense. In Ecuador, 55 per cent of agreements on pharmaceuticals and cosmetics contained such restrictions (61).

According to the type of technology and rights involved, grant-back provisions may be divided into three main categories:

(i) provisions by which the recipient is obliged to inform the supplier of all the knowledge and experience that the recipient has acquired in connection with the goods and services covered by the contract;

(ii) provisions that oblige the recipient to assign the rights (patent rights or rights arising from application thereof) related to any improvement, invention or application of inventions which the recipient has made;

(iii) provisions that oblige the recipient to grant to the supplier a licence on any patentable improvement developed by the former.

As mentioned before, technological innovation is one of the most concentrated factors in pharmaceuticals. Besides, TNCs tend to tightly monopolize new technologies. "Owing to the increased difficulty in discovering new ideas for new drugs, those firms which have developed technology internally appear

increasingly reluctant to share their findings with other companies" (62). Grant-back provisions may contribute to preserve such a monopoly, to the detriment of technology importing countries and the setting up of an indigenous industry. Moreover, they may seriously affect the possibility of technological co-operation among developing countries.

TOT régimes applied in developing countries generally prohibit or otherwise control these provisions in broad terms. For instance, Decision 24 (Andean Group) refers to provisions "requiring the purchaser of the technology to transfer to the supplier any inventions or improvements obtained through its use" (art. 20 f) (63). In Brazil, all rights to improvements or advances incorporated by the recipient in the product or process covered by the agreement, are deemed to belong to the recipient (law 5772, art. 29.3; Normative Act 015/75, INPI, art. 2.5.1).

In developed countries, grant-back provisions may also be subject to prohibition, in cases where they are exclusive and/or non-reciprocal (64). In the USA the Justice Department has expressed that "an exclusive grant-back tends to perpetuate a monopoly of the licensor and may discourage innovation by the licensee. Of course the licensor has a legitimate interest in assuring that it has access to improvements on its patent, but this interest, we believe, can normally be satisfied by a non-exclusive grant-back, at least in the case of a non-blocking patent" (65).

In accordance with the EEC Commission, such practices can be admitted only if they "are not exclusive and if the licensor has entered into similar undertakings" (Notice on Patent Licensing Agreements, art. I, D) (66).

The obligation to assign back improvements reached by the recipient has been held illegal in the Federal Republic of Germany (67). Similarly, the EEC Commission draft proposal for a block exemption regulation suggests that it would be a violation of article 85 (1) of the Treaty of Rome "the obligation on the part of the licensee to assign to the licensor rights in or rights to patents for improvements or new applications of the licensed patents" (art. 3.12).

The extent to which grant-back provisions may be admitted has constituted one of the most controversial issues in the negotiation of a Code of Conduct on TOT. While for Groups B and D only exclusive and non-reciprocal grant backs should be objectionable, for the Group of 77 both types of restrictions should be equally condemned (art. 4.1).

In order to avoid adverse effects of grant-back restrictions, provisions on this issue should be based on three main criteria:

(i) the recipient should remain, in all cases, the owner of improvements made on received technology. Consequently, assignment of rights in or to such improvements should be clearly excluded;

(ii) the supplier should bear obligations which, in substance, be equally balanced with the recipient's obligations (68). In particular, this should include a proper balance with regard to compensation and the duration of the agreement;

(iii) grant backs should be non-exclusive, so as to allow the wider diffusion of improvements and adaptations within the receiving country or their export to other countries.

Taking into account the precedent discussion, a possible formulation for such a clause could read as follows: "the recipient shall, subject to similar obligations by the supplier, inform the latter of improvements obtained by him regarding the technology transferred, and shall grant the supplier a licence 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".

Notes

(1) See UNCTAD, Handbook on the acquisition of technology by developing countries, New York, 1978, para. 194.

(2) A revealing research conducted by the Development Centre Studies of OECD, regarding the behaviour of subsidiaries of transnational corporations in 12 countries of different degrees of development, has showed, inter alia, that: (i) the host country does not benefit from mobility of the subsidiary's technically skilled personnel, since its rotation is very low; (ii) subsidiaries do not undertake practically any R + D; (iii) the relationship of subsidiaries with the local technical and scientific system is very weak. See OECD, Transfer of technology by multinational enterprises, Paris, 1977, part one.

(3) See UNIDO, Report of the second meeting of the Expert Group on the Pharmaceutical Industry, Vienna, 28 February-3 March 1978; International Center for Public Enterprises in Developing Countries, Report of the International Seminar on Joint Ventures and Public Enterprises in Developing Countries, Ju-6, dic. 1979, p. 52.

(4) See on these issues UN Commission on Transnational Corporations, Transnational Corporations and the pharmaceutical industry, New York, 1979; UNIDO, The growth of the pharmaceutical industry in developing countries: problems and prospects, ID/204.

(5) See Superintendencia de Inversiones Extranjeras (SIEX), Industria farmacéutica en Venezuela, Caracas, 1975, p. 21; D. Chudnovsky, Dependencia Tecnológica y estructura industrial. El caso argentino, FLACSO, Buenos Aires, 1976, p. 215.

(6) See Hathi Committee, Report of the Committee on Drugs and Pharmaceutical Industry, New Delhi, 1975, p. 61.

(7) OECD, Impact of multinational enterprises on national scientific and technical capacities. Pharmaceutical Industry, Paris, 2 December 1977, p. 235.

(8) See art. 3(vi) and 5.2 of the draft on an International Code of Conduct on Transfer of Technology (hereinafter referred to as "Code of Conduct"). The UN Conference convened by the General Assembly to adopt a Code of Conduct, has held three sessions. Texts mentioned in this paper correspond to the draft as at the close of the last session, as reproduced in UNCTAD, TD/CODE TOT/25, 2 June 1980. It should be noted that, notwithstanding the substantial progress reached by the Conference, agreement has not been attained on a number of issues by all the regional Groups participating in the negotiations (Group of 77: developing countries; Group B: developed countries of market economy; Group D: socialist countries and Mongolia; and China).

(9) See F. Dessemontet, Le savoir-faire industriel. Définition et protection du know-how en droit américain, Imprimeries Réunies S.A., Lausanne, 1974, p. 274.

(10) See F. Magnin, Know-how et propriété industrielle, Librairies Techniques, 1974, p. 246.

(11) See T. Ascarelli, Teoria de la concorrenza e dei beni immateriali, Giuffré Ed., Milano, 1957, p. 448.

(12) See M. Laquis, "Revisión del Convenio de París en el marco latinamericano. La propiedad industrial y el abuso del derecho. Problemas de la transferencia de tecnología (know-how) a los países en desarrollo. La declaración de México", Revista del Derecho Comercial y de las Obligaciones, Vol. 9 No. 52, 1976, p. 447.

(13) A WIPO's study indicates that "so far as the unpatented know-how element is concerned, no proprietary rights exist in respect of which a 'licence' in its true sense could be granted", WIPO, Legal aspects of licence agreements in the field of patents, trademarks and know-how, Geneva, PJ/92, 1972, para. 7; see also P. Mathély, Summary Report, AIPPI/1972/I, p. 34.

(14) See item b, part 1, para. I.1.e.

(15) See, for instance, the draft proposal by the Latin American Group of New York on a Code of Conduct on Transnational Corporations, SELA, SP/GRULA/DF No. 1/Rev. 1, 13 March 1979, art. III, B, 4, first para. h.

(16) The implicit character of this obligation is held in Anglo-American law. The Argentine law on TOT of 1977 has followed this conception.

(17) See J. Alvarez Soberanis, La regulación de las invenciones y marcas y de la transferencia de tecnología, Ed. Porrúa, 1979, México, p. 376.

(18) See Normative Act 015, 1975, Instituto Nacional de Propriedade Industrial, art. 4.5.2.d.vi.

(19) For instance, the model contract of the Agence National de Valorisation de la Recherche (ANVAR) for patent licences abroad (JPB/D2/mg/130869), stipulates that the licensee may, subject to ANVAR's approval, grant sublicences, and that 50% of royalties paid by the sublicensee corresponds to ANVAR.

(20) See R. Milgrim, "Sears to Lear to Painton: of Whales and other matters", 46 New York University Law Review, 17 March 1971, p. 31, and Warner Lambert Pharmaceutical Co. Inc. v. John J. Reynolds Co. Inc. (1959).

(21) See Dessemontet, op. cit., p. 159.

(22) See Magnin, op. cit. p. 322.

(23) For the text of this draft, see Official Journal of the European Communities, No. C-58, 3 March 1979.

(24) See SELA, Restrictive business practices in the importation of technology in Latin America, Sp/Di No. 7, 10 October 1978, p. 40.

(25) SIEX, op. cit., p. 11.

(26) See C. Vaitsos, Patents revisited. Their function in developing countries, Lima, 1971, p. 28.

(27) In a compromise text presented by the Group of 77 at the sixth session of the preparatory work of the Code, that Group offered a considerably more flexible solution. It stated that "in the case the licensed industrial property rights remain valid after the expiration of the arrangement, the acquiring party shall have the right to continue using the industrial property rights under no less favourable conditions than those prevailing at the time when the agreement expired". This text was deleted in later negotiations. See TD/CODE TOT/1 Add. 1, Annex I, chapter V, art. 5 (v).

(28) See A. Wise and A. Seyler, "Secrets, know-how under siege", Les nouvelles, March 1978, p. 1.

(29) Ibidem.

(30) The original Group of 77 draft contained a reference to the "normal" expiration of the agreement, qualification that disappeared during subsequent negotiations. See UNCTAD, TD/B/C.6/1, Annex III, p. 7.

(31) See SELA SP/GRULA/DF No. 1/Rev. 1, op. cit.

(32) See art. 7.

(33) See Milgrim, op. cit. p. 30.

(34) See UNCTAD, Control of restrictive practices in transfer of technology transactions, TD/AC.1/17, 16 June 1978, p. 93.

(35) See B.I. Cawthra, Patent Licensing in Europe, Butterworths, London, 1978, p. 145.

(36) See UNCTAD, TD/AC.1/17, op. cit. p. 89.

(37) See UNIDO, ID/204, op. cit., Annex I, table 7; UN Commission on Transnational Corporations, op. cit., p. 21.

(38) See UNCTAD, TD/AC.1/17, op. cit., p. 73

(39) For a comparison of this text with Group of 77 and Group D proposals, see TD/CODE TOT/25, op. cit., art. 4.10.

(40) See UNCTAD, TD/AC.1/17, pp. 79 and 75. With regard to the Japanese Guidelines for International Licensing Agreements (1969), which admits the restriction of exports to countries where the technology is patented, it has been pointed out that this rule authorizes the licensor to preclude exports even to countries where patents are granted without screening, by simply registering a patent there. Ibidem., p. 75.

(41) Ibidem, p. 81. See also the 1979 version of the draft proposal for a block exemption regulation of the EEC Commission, art. 1.1.4 and 1.2.

(42) WIPO, Licensing Guide for Developing Countries, para. 184.

(43) See W. Vukowich, "Implied warranties in patent, know-how and technical assistance agreements", California Law Review, Vol. 56, 1968, p. 197.

(44) See art. 5.3.c.i of the draft Code of Conduct.

(45) See M. Silverman, The drugging of Americas, University of California Press, p. xi.

(46) See "La industria de los medicamentos de Brasil se defiende", Ciencia Nueva, Buenos Aires, No. 33, 1977.

(47) FINEP, Tecnología e competicao na indústria farmacéutica brasileira, November 1978, p. 112.

(48) Idem, p. 113.

(49) ITINTEC, Efectos del proceso de importación de tecnología en el Perú (1971-1974), Lima, 1975, table 18.

(50) See INTI, Aspectos económicos de la importación de tecnología en la Argentina en 1972, Buenos Aires, 1974, table 2; Cuadernos de IDEA, III, No. 13, April 1978, tables 6 and 9.

(51) ITINTEC, op. cit., table 10.

(52) Secretaría General del Consejo Nacional de Planificación Económica, Unidad de Ciencia y Tecnología, Análisis tecnológico del sub-sector farmacéutico en Guatemala (mimeo), table 34.

(53) SIEX, op. cit., p. 16.

(54) See UNIDO, ID/WG.317/1, op. cit., table V.

(55) See C. Correa, "Main issues in the regulation of licence arrangements on foreign trademarks: the Latin American experience", World Development, vol. 7, No. 7, July 1979, p. 705; and Indian Guidelines, cit. Chapter III, art. 9.vi.

(56) See the proposal by the Group of 77 and Group D concerning the "unpackaging" of TOT transactions, art. 5.4.xii.a, draft Code of Conduct.

(57) See Indian Guidelines for Industries, 1976-1977, Chapter III, p.iii; Normative Act 015, various provisions, etc.

(58) See D. Chudnovsky, "Dependencia Tecnológica ...", op. cit., p. 197.

(59) See SIEX, op. cit., p. 16.

(60) See UNIDO, Guidelines for the acquisition of foreign technology in developing countries, ID/98, 1973, p. 29.

(61) See SELA, Sp/Di No. 7, op. cit., p. 18.

(62) See OECD, Impact of multinational ..., op. cit., p. 224.

(63) A similarly broad provision is contained in Ministry of Industry Order of 5 December 1973, section 3.2, of Spain.

(64) See UNCTAD, TD/AC.1/17, op. cit., p. 22.

(65) Department of Justice, Antitrust Guide for International Operations, 26 January 1977, p. 43.

(66) See also Commission's decision in Raymod Nagoya and Davidson Rubber Co., O.J.E.C., L 143, 23 June 1972.

(67) See UNCTAD, TD/AC.1/17, op. cit., p. 23.

(68) See Japanese Guidelines for International Licensing Agreements (1969). In the Federal Republic of Germany, the Federal Cartel Office has interpreted that "the requirement of reciprocity is not satisfied, if the licensor undertakes grant-back obligations without practical meaning, e.g. if he does not exploit the patent himself or stops research and therefore gathers no additional experience", UNCTAD, idem, p. 23.