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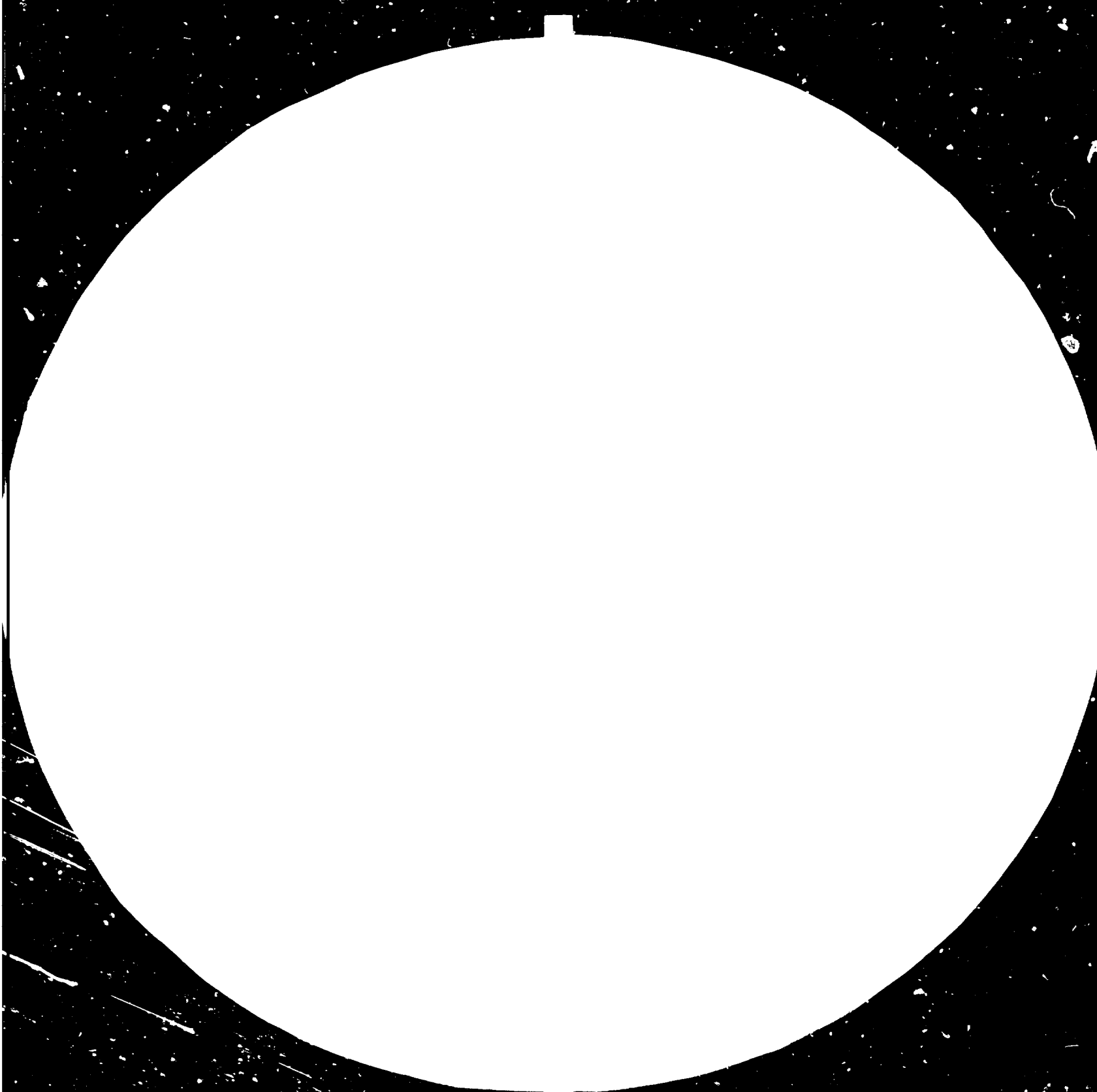

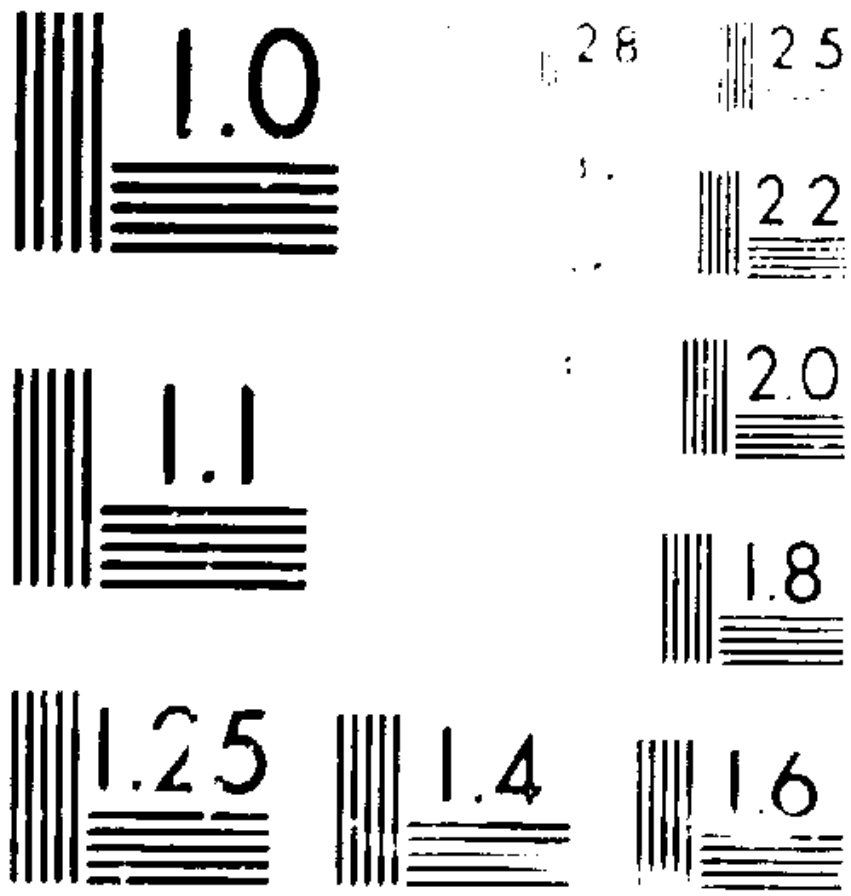
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RESTRICTIVE CLAUSES IN THE LICENSING AGREEMENTS IN THE PHARMACEUTICAL INDUSTRY *

by

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INTRODUCTION

In recent years many developing countries have introduced new laws and regulations and established institutional framework for controlling technology inflows in order to strengthen their bargaining position and improve the conditions under which technology is transferred. Apart from payments, restrictive provisions were considered to be the most critical elements in negotiations for licensing agreements. The experience accumulated within the framework of the Technological Information Exchange System (TIES) so far, provided strong evidence that such restrictive practices negatively affect the assimilation of foreign technology and its overall effects, as well as have contributed to the increased cost of acquisition.

The aim of this study is to evaluate the expereince of selected countries in controlling restrictive clauses in licensing agreements in the pharmaceutical industry and the effectiveness of respective policies and regulatory measures in that field. It has been prepared by taking into account the results of the First Consultation Meeting on the Pharmaceutical Industry held in December 1980 in Lisbon, which recommended that the UNIDO secretariat should undertake a detailed study of relevant issues to be taken into account when negotiating transfer of technology agreements in the pharmaceutical industry.[1/] The Fifth Meeting of TIES, held in 1980 in Buenos Aires also recommended that sectoral studies be conducted with particular emphasis on identifying restrictive practices in technology transactions.[2/] For this purpose, the UNIDO secretariat requested several countries who are members of the TIES system to provide information on the incidence of restrictive clauses in licensing agreements in the pharmaceutical industry, to give examples of typical clauses included in those agreements, and to appraise the effects of restricitve provisions on the development of an indigenous pharmaceutical industry as well as the effectiveness of the regulatory measures aimed at the elimination of such restrictive provisions. In addition to material collected form several countries the findings of recent UNIDO and UNCTAD studies were also taken into account.

1/ "First Consultation on the Pharmaceutical Industry", Lisbon, Portugal, 1 - 5 December 1980, UNIDO ID/259, para 3.

2. Report of the Fifth Meeting of Heads of Technology Transfer Registries, Buenos Aires, 15 - 19 September 1980, UNIDO ID/WG.325/11, para 3(a). See also UNIDO, "Proposed Guidelines for Analysis of Specific Industrial Sectors" - ID/WG.325/10, Vienna, 1980.

I. RESTRICTIVE CLAUSES IN LICENSING AGREEMENTS WITH SPECIAL REFERENCE TO THE PHARMACEUTICAL INDUSTRY IN DEVELOPING COUNTRIES

1. Definition and Types of Restrictive Clauses

Restrictive clauses in the licensing agreements belong to the broader category of restrictive business practices going back to the antitrust legislation of major industrial countries such as the USA, Japan and the European Economic Community. The overall concept is somewhat vague especially in view of the fact that despite the existence of antitrust regulations in many of them, special legal and institutional framework has been established for dealing with foreign technology transactions in a number of developing countries. In general terms, restrictive clauses in the licensing contracts might be defined as legal provisions which directly or indirectly limit the use of acquired technology in a broad sense (i.e. in production, marketing, R+D, etc.), thus enabling effective market control by the licensor.[3/] The relatively high share of such provisions in contracts covering technology transfer as compared to other business transactions results from the fact that unlike physical goods which are sold, technology transferred by a market transaction is "rented" and the licensor retains the ownership of knowledge as well as respective property rights. Thus, the incorporation of restrictive provisions in the licensing contract represents the willingness of the supplier to protect his interests by controlling the means the recipient makes use of the acquired technology.

Restrictive clauses in licensing agreements might be divided into the following groups:

a. provisions related to the duration of arrangements;
b. tie-in cluases;
c. restrictions on exports;
d. grant-back provisions;

3/ For more detailed discussion of the concept of "restrictive business practices" see "Restrictive Business Practices in Transfer of Technology", UNIDO, ID/WG. 228/1, Vienna, 1976.

e. post-expiry restrictions;

f. non-competition clauses (tie-out);

g. restrictions as to the field of use, volume and territory;

h. non-contest clauses;

i. restrictions on R+D;

j. exclusivity arrangements;

k. price fixing;

l. exclusive sales and representation arrangements;

m. cartels, patent pool and cross-licensing agreements.[4/]

Restrictive clauses most frequently used in the pharmaceutical industry are discussed in Chapter II.

2. Restrictive Clauses and the Distinctive Features of Technology Transfer Process in the Pharmaceutical Industry

Although the conditions prevailing in the pharmaceutical industry have been extensively used as a classic example of major problems and bottelnecks in international technology transfer, one has to be aware of the distinctive features of technology transfer in the pharmaceutical sector as against other industries. These characteristics have to be taken into account while formulating detailed policies with regard to the restrictive practices in the licensing agreements, measuring the propensity and the source of bargaining strength of the licensor, appraising the effects of the restrictive practices on the development of the pharmaceutical industry in developing countries and the effectiveness of regulatory measures aimed at eliminating such restrictions in this sector. The implications of some principal features of the pharmaceutical industry within the context of international technology transfer are briefly discussed below.

4/ For more detailed definitions of specific restrictive clauses see UNCTAD, "Control of Restrictive Practices in Transfer of Technology Transactions", TD/B/C.6/72, UN, New York, 1982 and UNIDO, "Restrictive.....", ID/WG.228/1, op. cit.

a. Pharmaceuticals and public health

Due to direct relationship of mankind, age-old concern for the attainment of health, it is widely recognized that the pharmaceuticals should be given a special status as compared to other goods. This provides a strong argument for the free availability of technology necessary for manufacturing pharmaceutical products. Even accepting the commercial conditions for transferring technology in the pharmaceutical industry it might be argued that the use of technology acquired on commercial terms should not be restricted at all, especially in the case of developing countries being the recipients of technology. On the other hand, however, the special status of pharmaceuticals contributes to the strengthening of a supplier's bargaining position vis-a-vis the recipient. Thus strong pressure in the realm of public health, may cause the licensee and/or respective regulatory agencies in developing countries to take a more flexible attitude towards restrictive provisions in the pharmaceutical industry as compared to other sectors.

b. Degree of concentration in the world pharmaceutical industry

The pharmaceutical industry has reached a substantial degree of internationalization and concentration. The world's fifty largest pharmaceutical companies account for nearly two thirds of total pharmaceutical sales (excluding centrally-planned economies), and in case of R+D activities the concentration ratio is even higher. Thus, technology being transferred to developing countries in the pharmaceutical industry comes mostly from the large transnational corporations. In the case of arms-length licensing agreements, TNC's are in a strong bargaining position when negotiating with partners in developing countries and usually insist on including restrictive provisions in the contracts on the basis of their world-wide strategy. However, the substantial part of licensing agreements in the pharmaceutical industry are intra-firm transactions, i.e. they are concluded between parent and subsidiary companies. Market shares enjoyed by foreign-controlled firms in developing countries have usually been higher than 50 per cent and in many cases have reached 80-90 per cent (e.g. in Brazil, Colombia, Mexico and Kenya).[5/] Under such circumstances the negotiating position of the respective

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5/ D. Chudnovsky, "Patents and Trademarks in Pharmaceuticals", World Development, Vol. 11, No. 3, 1983, p. 188.

government agencies is rather weak as they are usually confronted with the united attitude of the licensor and licensee.

c. R+D intensity and patent protection

The pharmaceutical industry belongs to one of the most research-intensive industries and its growth depends heavily upon the discovery of new products and processes. The high share of R+D expenditures in total manufacturing costs of pharmaceuticals and the relative ease of copying new products by competitors resulted in heavy patent protection. Patents granted are mostly owned by large pharmaceutical companies. Whilst this study does not look into the effectiveness of existing systems for the protection of industrial property, it is worthwhile noting the strong correlation between patent protection and the incidence and effects of restrictive business practices. Firstly, it should be born in mind that the majority of patents (over 80 per cent) granted by developing countries are foreign-owned and of these over 90 per cent are not used for production. In the case of such patents no "real" transfer of technology takes place and they predominantly serve to hinder local production and restrict imports of the products covered by the patents of third parties. On the other hand, when "real" technology is being acquired the patent licence constitutes a crucial element of the whole licensing package. Under such circumstances the licensor is in a much stronger position while negotiating the restrictive provisions, especially tie-in clauses and restrictions on exports.[6/]

d. The role of trademarks

With the declining role of patents in recent years, [7/] trademarks are gaining importance as a source of market power for the large transnational corporations involved in the pharmaceutical industry. Therefore,

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6/ The restrictions on exports may serve as good example. Although there is a general negative attitude towards such restrictions both in developed and developing countries, it is also accepted that the licensor may be entitled to reserve for himself those markets where he has valid patents.

7/ See page 8 - 9.

the majority of licensing contracts in the pharmaceutical industry involve the use of trademarks.[8/] With regard to the restrictive practices, trademarks play a similar role as patents; they provide a legal framework for including restrictive provisions in licensing contracts, especially tie-in clauses, export restrictions, exclusive sales and representation arrangements, price fixing, etc.

e. The combined impact

The distinctive features of the technology transfer process in the pharmaceutical industry created unfavourable conditions for technology recipients in developing countries with regard to the elimination of restrictive clauses in licensing agreements. On the one hand, there are strong arguments against such provisions in view of the role of pharmaceuticals in the attainment of public health. But even setting aside such moral considerations and accepting trade-off approach, restrictive provisions could be approved only in exchange of vast inflows of the "real" technology. In the case of the pharmaceutical industry in developing countries, contractual arrangements are either not at all associated with "real" transfer patents not used for production and trademark licences in themselves do not constitute a transfer of technology), or the "real" transfers encompass technical assistance (manuals) and training for the formulation and packaging which are quite simple and well known. The transfer of more advanced technologies takes place only in few developing countries with facilities for manufacturing some of the bulk drugs. On the other hand licensors who are usually large transnational corporations have a keen interest in including restrictive provisions in the licensing agreements. Such propensity results from their long-term global strategy. Even though current production of pharmaceuticals in developing countries does not create any danger for their dominant position on the world markets large pharmaceutical companies usually insist on including restrictive clauses in their contracts in view of the future developments of the industry in the region, strengthening independent R+D programmes and expansion of trade in pharmaceuticals among developing countries. Such a forward looking policy aimed at protecting the dominant position in world markets may partly explain the fact that restrictive clauses are common licensing agreements concluded between parent companies and wholy or majority-owned subsidiaries in developing countries.

8/ Of the 346 licensing agreements concluded by the Andean Pact countries in the pharmaceutical industry during 1975-1980, (284), i.e. 85 per cent involved licences for the use of trademarks. See "Sectoral Study on Technology Imports in the Pharmaceutical Sector of the Andean Subregion", UNIDO/IS.320, Vienna 1982, table 11.

The size of the firms-licensors in the pharmaceutical industry, their R+D capacity, heavy patent and trademark protection, and their image on the market and worldwide experience result in the strong bargaining position of suppliers vis-a-vis recipients of technology. Thus, licensees from developing countries, if left along in the process of acquisition of foreign technology, are unable to eliminate restrictive provisions in the licensing contracts.

II. CONTROL OF RESTRICTIVE CLAUSES MOST FREQUENTLY USED IN LICENSING AGREEMENTS FOR THE PHARMACEUTICAL INDUSTRY: AN OVERVIEW

1. General Trends

In recent years many developing countries introduced new laws and regulations for technology acquisition and established institutional framework necessary for controlling technology inflows. The formulation of legal provisions with regard to restrictive clauses differ substantially between countries. In some countries rules are formulated as outright prohibitions, in others, the respective authorities have been left a considerable degree of discretion with regard to the application of additional criteria or exempting a given case from standard requirements. In any case however, the action of the respective authorities is of crucial importance for the final formulation of the contract and its individual conditions. In the process of registration and approval it is possible to take into account additional aspects and priorities with regard to some industrial branches. Recently, substantial experience has been accumulated by government agencies regulating technology imports in selected developing countries. This experience is briefly reviewed with respect to the elimination of restrictive provisions in licensing contracts in the pharmaceutical industry.

2. Trends in Protection of Industrial Property Rights in the Pharmaceutical Industry in Developing Countries

In view of the strong impact of patent protection on the incidence of the restrictive clauses, it is important to note that approximately forty developing countries have excluded pharmaceutical products from patent protection. In three countries (Brazil, Ecuador and Mexico) pharmaceutical processes have also been

excluded. Additionally, in some countries the duration of pharmaceutical patents has been shortened (e.g. Costa Rica, India) or an expeditious system of compulsory licensing introduced (e.g. Philippines). Consequently, in the majority of developing countries patent licences in the pharmaceutical industry have been eliminated from licensing packages. This in turn has weakened the legal basis for including restrictive provisions.

As for the trademarks, the attempts of several countries to switch from trademarks to generic names are worth noting. Significant effects in this field have been achieved by Cuba, Costa Rica and Sri Lanka.[9/]

3. Duration of Agreement

The duration of a licensing contract is linked on the one hand to payments and on the other to the proper absorbtion of the acquired technology. In the case of the pharmaceutical industry in developing countries where the "real" transfer of technology is limited, the approving authorities usually pay more attention to the former aspect. Legislation on technology transfer in developing countries either precisely fix a maximum duration for technology transfer contracts or prohibit "unduly" duration and the approving authorities usually insist on shortening the life of the contract. It should be noted that clauses for automatic renewal are generally not accepted. Licensors often attempt to extend the duration of agreements by including slight amendments to existing contracts when applying for renewal and therefore more strict rules are usually for extensions compared to registration procedures for new contracts.

The experience of some developing countries who began acquiring technology for manufacturing active ingredients indicates that in such cases technological considerations are gaining importance in defining the duration of contracts as the process of assimilation is complex and requires time.

9/ See D. Chudnovsky, op cit., pp. 191-192.

4. Tying

In the pharmaceutical industry tying clauses more often relate to the obligatory use of bulk drugs provided by the licensor for packaging and formulation by the licensee. As a rule, national and regional regulations prohibit such provisions with a few exemptions.

The approach of the regulatory agencies to tie-in provisions in the pharmaceutical sector has to be examined in view of the restricted availability of bulk drugs and intermediates.[10/] It constitutes one of the key factors hindering the development of the pharmaceutical industry in developing countries. Thus, in many cases the acquisition of raw materials and components on a regular basis is one of the objectives of the contract and the tie-in provisions are usually desired by the licensee itself. It is therefore felt that by including explicit requirements in the contract to the effect that the raw materials and intermediate products have to be supplied at international prices or at the lowest price already being applied to other licensees, then the restrictive impact of tie-in clauses could be reduced.

5. Restrictions on Exports

In general, national regulations on technology transfers prohibit such provisions as a matter of principle but the scope of possible exemptions differ substantially between countries. More often exemptions are granted in the case of export markets where suppliers of technology own industrial property rights and have begun manufacturing on his own or through an affiliated company, or granted exclusive licence to a third party.

In dealing with export restrictions in the licensing agreements for the pharmaceutical industry, respective regulatory agencies have to take several factors into account. Firstly, at the present stage of development the pharmaceutical industry is predominantly oriented towards local markets and

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10/"Issues that might be considered at the Consultation" - ID/WG.317/1, Vienna 1980, para 30.3.

even without restrictive provisions exports would not take place in view of the other considerations, e.f. keen competition. Secondly, restrictions on exports may vary. For instance, there may be a total ban on exports or only few countries may be excluded as export markets. Therefore, regulatory agencies therefore usually follow a balanced approach on restrictive provisions for pharmaceutical exports. It is felt however. that a total ban on exports should not be accepted as this results in the passive attitude of the local pharmaceutical firms in developing countries with regard to future export expansion, especially in intra-regional trade.

6. Grant-back Provisions

The respective provisions of licensing agreements often impose on the licensee the free transmissions to the licensor any improvements, invensions, experience,etc. related to the technology acquired. In the context of the pharmaceutical industry in developing countries it should be born in mind that the level of R+D is very low and few firms in the region conduct their own research on a substantial scale. Under these circumstances grant-back provisions in the licensing agreements are evaluated with a view to their reciprocal character. It is believed that reciprocity in that respect might be advantageous to the recipient.

7. Post-expiry Restrictions

The concept of the "rental" of technology is being reflected by the obligations imposed on the licensee not to make use and/or keep secret the technology acquired after normal expiration of an agreement. Recent trends in the regulation of technology transfer in developing countries indicate that the "rental" concept is not accepted, i.e. it is acknowledged that the licensee should freely use the acquired technology once the agreement has been terminated. Such conditions are accepted only if the agreement terminates as a result of the licensee's fault or if the restrictions are connected to industrial property rights valid after expiration of an agreement.

As for the technology transfer in the pharmaceutical industry, the elimination of such restrictions have to be viewed within the context of the future establishment of the indigenous pharmaceutical sector in this region. Therefore, actions aimed at eliminating such provisions are fully justified even though at present the negative effect of such clauses might be negligible. The most important problem is to eliminate indetermined post-expiry restrictions. For example, the recently negotiated technical service agreement between a Malaysian firm and a UK pharmaceutical company originally contained the provision that during the period of the agreement and thereafter the licensee shall not disclose any of the technical information given by the licensor. The contract was finally approved with the additional amendment of the words "only five years thereafter".

8. Non-competition Clauses (Tie-out)

In the case of such provisions the freedom of the licensee is restricted regarding the manufacture and/or selling of competing products and the acquisition of competing technologies. Usaully national legislation prohibits such clauses, with a few exemptions under exceptional circumstances, e.g. when the restriction is made in order to protect the confidentiality of know-how or where an exclusive licence has been granted. Similarly, the negative effects of non-competition clauses in licensing agreements for the pharmaceutical industry have to be viewed in the long-term perspective. As the number of pharmaceutical firms in developing countries is very limited, future acquisition of alternative and possibly more efficient technologies and manufacturing processes for competing products should not be excluded. It is considered therefore that non-competing clauses should be avoided. However, as the experience of some regulatory agencies shows, when such clauses have to be accepted it is important to formulate precisely the respective provisions in the contract. The term "competing product or technology" in the pharmaceutical industry is very vague and can easily be extended to products loosly related to the original technology. Thus, in the case of Portugal, non-competing clauses are approved by the Foreign Investment Institute only when they cover pharmaceutical products with an identical formulation to the licensed ones.

III. APPRAISAL OF THE REGULATORY MEASURES AND THEIR EFFECTS WITH REGARD TO THE RESTRICTIVE PRACTICES IN THE PHARMACEUTICAL INDUSTRY

1. General Observations

While evaluating the scope and effectiveness of government regulations with regard to the elimination of restrictive practices in the pharmaceutical industry, it has to be born in mind that the practical experience of developing countries in that field is relatively short in most cases relating only to the last 5-10 years. On the other hand the pharmaceutical industry serves as a classic example of the dominant position of technology suppliers (mostly large TNC's) who are extensively using restrictive clauses in licensing agreements as a means of protecting their monopolistic position in the world market.

The experience of selected developing countries clearly indicates that the introduction of respective legislations is merely the first step in the long-term strategy aimed at eliminating restrictive clauses in licensing contracts. The persistent efforts of the regulatory agencies involved in the process of registration and approval play a decisive role in the final outcome of the regulatory measures. In this context the relative flexibility of the institutions approving the contracts should be mentioned again with respect to the distinct features of the technology transfer process in the pharmaceutical industry. On the one hand there are strong arguments for outright prohibition of restrictive provisions in the licensing agreements with a limited scope for manoeuvres of the regulatory agency for granting possible exemptions. Considering the strong bargaining position of the large pharmaceutical companies supplying technology and the pressures resulting from the acute shortage of pharmaceuticals, the discretion of the regulatory agency may not bring satisfactory results regarding the elimination of restrictive provisions. This may happen, in the first instance, in technology transactions among related companies (intra-firm contracts). Arguments however for the relative flexibility of the regulatory agencies in dealing with restrictive practices should also be mentioned. First, depending on the situation in a given industry, and taking into account specific technologies, the effects of various restrictive provisions may differ substantially - in extreme cases some provisions usually considered as"restrictive" can be beneficial to the recipient of technology (e.g. tied purchases of bulk drugs upon world market

prices). Second, some restrictive provisions may vary in degree, e.g. there is a substantial difference between a total ban on exports and restrictions on exports to selected countries only. Third, a contract without restrictive provisions is not necessarily a "good" one as the licensor may achieve similar effects through other forms of control e.g. capital participation, which often happens in the pharmaceutical industry. The experience of the Foreign Investment Institute of Portugal shows that the acquisition of technology from abroad is often a matter of survival for the local companies. Under such circumstances a realistic approach is advisable, with an attempt to eliminate the most abusive provisions.

At the moment it is difficult to resolve which of the two approaches outlined above is more effective with regard to the elimination of restrictive business practices. It seems that a combination of the two approaches may also be a possibility.[11/]

One of the most important factors in the process of eliminating restrictive practices is the close co-operation and mutual understanding between the regulatory agency and the recipient company in the process of registration and approval of the contract. The possible conflicts of interest most often result from the fact that the local companies acquiring foreign technology in the pharmaceutical industry usually tend to neglect those restrictive provisions which may bring negative effects in the long-run but without significant implications for the immediate future. [12/] On the other hand the long-term contractual implications of technology transfer have in the first instance to be taken into account by the approving authority. The possible way of resolving such conflicts is to support routine regulatory actions with specialized training for the prospective licensees on the various aspects of technology transfer.

11/ In India, for example, unacceptable restrictions have been precisely defined but exemptions and conditions for granting them by the approving authority are also spelled out.

12/ This occurs most often with regard to the restrictions on exports or on R+D. Recipient firms in developing countries usually do not see chances for export or own R+D in the first period after acquisition of technology and therefore tend to consider negative implications of such provisions as negligible.

In the case of licensing agreements concluded between related parties, i.e. between parent and subsidiary companies, the position of the respective regulatory agencies with regard to elimination of restrictive provisions is extremely difficult. It might be noted that under such circumstances the approving authorities usually take a more strict attitude and insist on eliminating some restrictive provisions which could eventually be approved in agreements conlcuded between unrelated parties. This coincides with the policies on technology payments which in several developing countries are not authorized if they occur between related companies. (The assumption is that technology acquired from the parent should be remunerated only in the form of increased profits resulting from the implementation of more effective processes and products).

2. Recent Experience of Selected Countries

The data collected from several countries may indicate the scope and possible effects of the regulatory measures taken with regard to the elimination of restrictive clauses in the licensing agreements.

A. Andean Group

As a result of Decision 24 and respective Decisions 84 and 85 of the Cartagena Agreement, the Andean Group countries follow a strict attitude towards restrictive clauses in technology transfer contracts. The restrictive provisions most oft appearing in the licensing agreements in the pharmaceutical industry are banned and the scope of possible exemptions is very limited. It has to be pointed out in this respect that under Decision 85, patents cannot be granted for pharmaceutical products. As a result patent licences which were very common in previous periods have been excluded from the licensing agreements.

The actions taken by the respective national authorities in recent years resulted in the shortening of the duration of contracts. In Colombia, for example, the maximum duration permitted is 5 years with an average duration of 3 years.

The restrictive provisions banned under Decision 24 have been eliminated from licensing agreements.[13/] It was also found that the incidence of restrictive provisions in draft contracts submitted for registration was substantially lower than in the past. However, some restrictive clauses still appear, e.g. agreements construed or disputes settled according to foreign law, exclusivity provisions, post-expiry restrictions, etc. As a result of the intervention of the national authorities the bargaining position of the local firms'-licensees has been substantially strengthened.

The Colombian experience indicated that firms usually comply with the requirements of the registration authority and that as a result of government intervention a more effective co-operation among partners at the stage of implementation of the contract has been assured.

B. Argentina

Since 1981 Argentina has experienced a process of de-regulation of technology transfer processes. Unlike the previous regulations of 1971 and 1977, the new law introduced in 1981 substantially liberalized the procedure of the acquisition of technology. With regard to the restrictive clauses it has to be pointed out that the subject of evaluation and approval were only contracts between economically affiliated companies, whereas arms-length technology transactions are recorded for information purpose only. Secondly, the new law on the transfer of technology of 12 March 1981 contains no provisions on restrictive clauses.

The analysis of 296 contracts registered or recorded during 1982 revealed the upward trend with regard to the duration of agreements which are not evaluated by the Instituto Nacional de Tecnologia Industrial (arms-length transactions). On the other hand the duration of agreements evaluated and registered did not exceed the averages prevailing in the previous years.[14/]

13/ See "Sectoral Study ..... ", UNIDO/IS.320,op.cit., pp. 43-44.

14/ See TIES Newsletter, No. 20, March 1983, pp. 3-4.

During 1981 - 1982, INTI evaluated and registered 20 licensing contracts in the pharmaceutical industry which were concluded between economically afiliated companies. The average duration of those contracts was approximately 5 years as compared to 5.5 years for all of the contracts in the pharmaceutical industry. Despite the lack of specific provisions in the new legislation, INTI took into account the restrictive practices in the process of evaluation. It was found that none of the 20 contracts registered contained restrictive clauses typically occuring in the pharmaceutical industry. On the other hand, restrictive practices were often found in contracts between non-related parties, such as tie-in clauses and export restrictions.

C. Philippines

Since October 1978 to June 1981 the Philippine Technology Transfer Board arbitrated on 30 technology transfer agreements in the pharmaceutical industry, of which 23 were concluded with companies controlled by foreign capital and 7 were purely technical collaboration agreements.

The existing guidelines require a maximum period of duration of the contract of five years. Under exceptional circumstances the duration exceeding five years is accepted when for instance the longer time period is justified for the absorption of technology and/or penetration and development of the market. This happened in the case of two contracts in the pharmaceutical industry.

The data contained in Table 1 indicates that the incidence of restrictive provisions in the contracts submitted for approval during 1978-1981 decreased substantially as compared to previous years in case of export restrictions and tie-in clauses, whereas in the case of post-expiry, non-competing clauses and applications of foreign laws showed a reverse trend. However, according to the rules and regulations of TTB, such restrictions are in principle not allowed and all contracts with restrictive provisions had to be renegotiated.[15/] In the process of renegotiation of contracts, the TTB has payed much attention to the

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15/ L.R. Buatista, "Philippine Experience in Technology Transfer Regulation", UNIDO, ID/WG.349/3, Vienna, 1981, pp. 16-18.

Table 1

The incidence of selected restrictive clauses in technology transfer contracts in the Philippine pharmaceutical industry, 1972 and 1978-1981

Type of restriction	1972		1978-1981	
	No. of contracts	% of the total number	No. of contracts (as submitted)	% of the total number
Export restrictions	27	46.6	4	13.3
Tie-in purchase of raw-materials	41	70.7	1	3.3
Grant-back provisions	2	3.4	3	10.0
Post-expiry restrictions	-	-	10	33.3
Prohibition of manufacture of competitive products	-	-	5	16.7
Agreements/construed disputes settled according to foreign laws	1	1.7	13	43.3
Total number of agreements	58	x	30	x

Source: Restriction on exports in foreign collaboration agreements in the Republic of the Philippines, TD/B/388,UN,New York, 1972,5.11 and L.R.Bautista,"Philippine experience in technology transfer regulation", UNIDO, ID/WG.349/3, Vienna, 1981, Table 10,pp.32-33.

elimination of those provisions which may hinder local export activity (total ban on exports and restrictions to export through the licensor's agents/ distributors are absolutely prohibited). It is hoped that such actions of TTB shall contribute to the broadening of export potential of the Philippine industry. On the other hand the negative effects of tie-in provisions had been diminished to a large extent by the request of TTB to include an explicit statement in the contract that sourcing from suppliers other than the licensor is allowed, provided the quality specifications and standards of technology suppliers are met.

D. Poland

The experience of Poland with regard to restrictive clauses might be of interest to those developing countries which began to manufacture bulk drugs and intermediates.[16/] The pharmaceutical industry in Poland has reached a relatively high level of development and the foreign technology is being acquired mostly for the production of active ingredients. The analysis of the six sample contracts revealed that the duration of licensing agreements is relatively long (ten years in four out of six contracts). However, in the case of more advanced technologies such long periods might be necessary for effective absorption and are often required by the recipient.

Although existing guidelines clearly stipulate that restrictive provisions in the contracts be eliminated to the maximum, negotiation practices show that this is a very difficult task in view of the strong bargaining position of the technology suppliers in the pharmaceutical industry. Although substantial progress has been made with regard to eliminating non-reciprocal grant-back provisions and territorial restrictions on the use of technology, the results are not satisfactory in the case of sub-licensing rights and export restrictions (see Table 2). The Polish experience may suggest that at the higher level of development of the pharmaceutical sector in some developing countries, suppliers of technology may strengthen their efforts in order to protect their monopolistic position on the world markets for pharmaceutical products and technologies through restrictive provisions in the licensing contracts.

16/ See "Restrictive Contract Clauses in East-West Trade", Economic Commission for Europe, SC.TECH/SEM.8/R.10/Rev.1, Geneva, 1982.

Table 2

Restrictive provisions in the sample of six licensing agreements in the Polish pharmaceutical industry

Contract	Duration	Sublicensing rights	Grant-back provisions	Territorial restrictions on the use of technology	Export restrictions
A	1967-73	prohibited	no such provisions	restricted	total ban
B	1968-69	prohibited	no such provisions	restricted	total ban
C	1971-81	prohibited	no such provisions	restricted	total ban
D	1975-85	prohibited	reciprocal	not restricted	some countries excluded
E	1976-86	prohibited	reciprocal	not restricted	only to other socialist countries
F	1978-88	prohibited	reciprocal	not restricted	some countries excluded

Source: Foreign Trade Data Centre

E. Portugal

In the case of Portugal one may rely on comprehensive data covering a longer period of time. The legislation that settled the regime of authorization of technology transfer contracts was published in 1973 and in 1977 the registration competence was transferred from the Bank of Portugal to the Foreign Investment Institute. The effects of the actions taken by the F.I.I. are quite significant. The final versions of contracts approved in 1980-1981 in the pharmaceutical industry showed a usual duration of 5 eyars or less (78 per cent of the total number of contracts). The duration proposed in the drafts submitted for evaluation was generally higher and the action of the F.I.I. has led in the first instance to the elimination of undetermined durations and of terms longer than 15 years. As can be seen from data presented in Table 3, the regulatory actions taken by the Foreign Investment Institute have led to a significant decrease of the incidence of restrictive clauses in the final versions of contracts, namely those concerning exports and grant-back provisions. It has to be pointed out that all finally approved tie-in clauses contained additional provisions stating that the raw materials and intermediate products should be supplied at international prices or at the lowest price already applied to other licensees.

CONCLUSIONS AND RECOMMENDATIONS

While evaluating negative implications of the restrictive provisions in technology transfer contracts in the pharmaceutical industry in developing countries a clear distinction should be made between short-term and long-term effects. The immediate implications such as a heavy balance of payment burden, are predominantly related to the increased cost of imported technology, largely brought about by overpricing of tied purchases of bulk drugs and intermediates, as well as poor export earnings caused partially by the respective restrictions on sales abroad. Such negative effects are well documented in a number of empirical studies conducted in several developing countries.

Table 3

Restrictive clauses in the licensing agrements in the Portugese pharmaceutical industry (% of the total number of licensing contracts)

Type of restriction	Untill 1973 (84 contracts)	1973-1978 (20 contracts)	1980-1981 (71 contracts)		
			As submitted	As approved	Reduction index
A.Tie-in clauses	79.7	55.0	57.7	47.9	17.1
B.Non-competing clauses	47.3	20.0	45.1	39.4	12.5
C.Restrictions on exports	81.1	90.0	67.6	23.9	64.6
D.Grant-back provisions	35.1	65.0	18.3	7.0	61.5
E.Post-expiry conditions	44.6	50.0	84.5	63.4	25.0

Source: Foreign Investment Institute

Even more important, though less visible, are the long-term effects of the restrictive provisions on the development of the pharmaceutical industry in developing countries. Through restrictive practices the suppliers of technology tend to perpetuate the traditionally assymetric patterns of development of the world pharmaceutical industry, in which the developing countries are totally dependent on the supplies of active ingredients and pharmaceutical technologies from developed countries, whereas the local industry is being subordinated and tightly controlled by a handful of transnational pharmaceutical companies.

Therefore the actions taken by the respective regulatory agencies aimed at eliminating restrictive provisions in technology contracts have to be seen in close perspective with the national and collective efforts for the establishment of an indigenous pharmaceutical industry in developing countries. In recent years a substantial experience has been accumulated with respect to the regulation of restrictive provisions in technology transactions. The results achieved so far clearly indicated that eliminating restrictive provisions is one of the most difficult tasks amongst the regulatory procedures, especially if placed within the context of the pharmaceutical industry. However, as has been shown in the case of those developing countries which already have well established legal and institutional frameworks for controlling technology transfer, persistent efforts may bring positive results in the long run. In fact, in some countries the positive effects of such actions taken by their respective regulatory agencies are already visible, as the incidence of restrictive provisions in licensing agreements declined substantially in recent years.

The positive effects of the regulatory measures with regard to the elimination of restrictive clauses depend on the experience accumulated over a longer period of time, the qualifications and competence of government staff and the close collaboration of the respective agencies with local firms - recipients of technology.

Bearing in mind that the future growth of the pharmaceutical industry in developing countries will still depend on the acquisition of technology from developed countries, it is recommended that UNIDO's technical assistance programmes in that sector should be further extended so as to cover the various aspects of

restrictive business practices, with special emphasis on the long-term effects of such provisions.

Since the elimination of restrictive clauses in the licensing agreements requires a thorough knowledge and experience it is recommended that specialized workshops and seminars be organized with the participation of the representatives of national registries and the local business community. Such training programmes should contribute towards strengthening the negotiating capabilities of local enterpreneurs thereby making the actions of regulatory agencies aimed at elimination of restrictive provisions more effective.

In view of the above, the importance of co-operation and exchange of experience among regulatory agencies within UNIDO's Technological Information Exchange System (TIES) should be mentioned. It is therefore recommended that the activities of the TIES system be expanded, taking into account the distinctive features of technology transfer in the pharmaceutical industry. In the first instance, the investigation of restrictive provisions should be extended to other developing countries in order to establish a sound data basis for evaluating prevailing trends in the pharmaceutical sector. In-depth studies have to be undertaken by the member countries with the assistance of the UNIDO secretariat on the real effects of the various restrictive clauses on the establishment of the pharmaceutical industry in developing countries as well as the possible implications of the actions taken by the regulatory agencies and aimed at the elimination of such provisions (impact on the scope of technology transfer, cost of acquired technology, counter-strategies of technology suppliers, etc.). In view that a substantial part of technology transfer in the pharmaceutical industry occurs between parent and affiliated companies, the characteristic features of intra-firm transfers should also be studied in detail.

The exchange of information on specific contractual provisions in the pharmaceutical industry among national registries should be extended beyond the standard formats of the TIES system. On the other hand, the discussions and exchange of practical experiences at the regional and international level may eventually lead to the elaboration of common rules and policies towards restrictive practices, taking into account the distinctive features of the technology transfer process in the pharmaceutical sector in developing countries.