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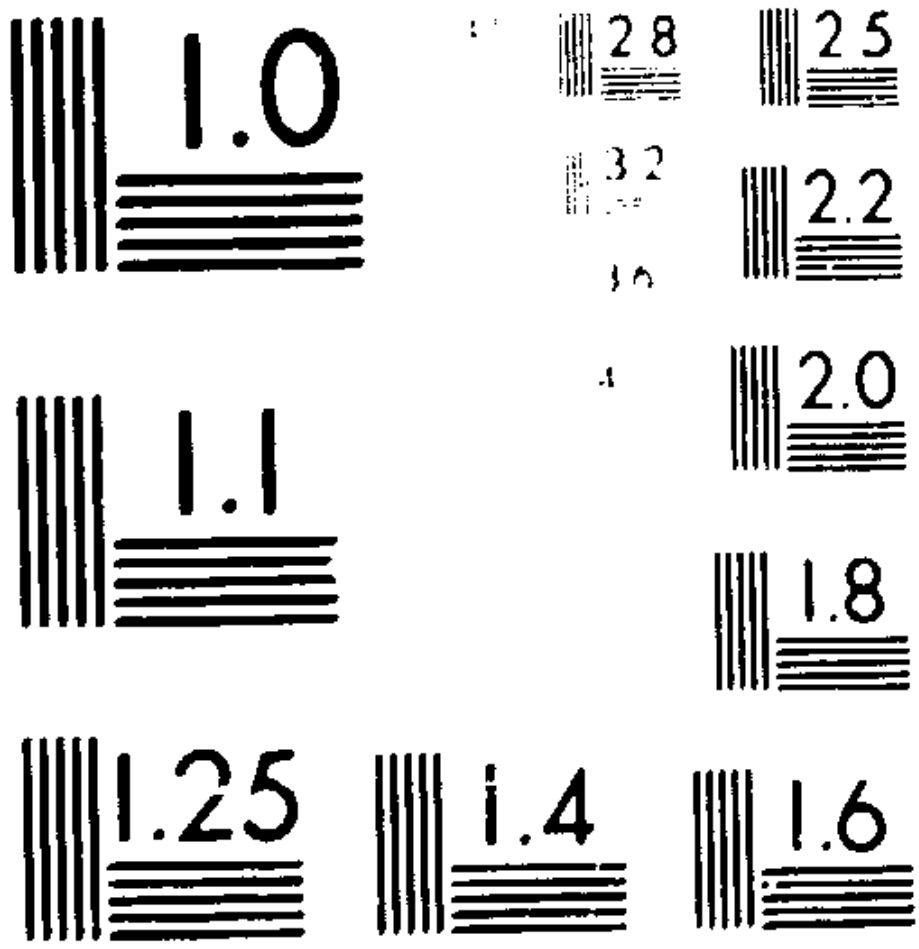
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RELEVANT ISSUES TO BE TAKEN INTO ACCOUNT WHEN NEGOTIATING TRANSFER OF TECHNOLOGY AGREEMENTS*

Prepared by
the UNIDO Secretariat

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I. INDUSTRIAL PROPERTY LEGISLATION

This section focuses on the impact of patent legislation on the pharmaceutical industry, particularly with regard to the transfer of technology (TOT) to developing countries.

An appropriate evaluation of the pros and cons of the patent system in connection with that industry, as discussed below, should be premised on two basic considerations. First, the recognition that patent protection (on pharmaceutical products or processes for their manufacture) and its scope and extent, are a matter of national sovereignity, and should therefore be viewed in the context of the pertinent national policies and legislation. Second, the discussion cannot be undertaken in abstract terms, independently of the historical, economic, social and other conditions existing in the countries concerned, particularly in developing countries, such as the concentration of production and innovation in a group of developed countries, the predominant position of transnational enterprises in world markets, and the urgent needs of developing countries to improving their health care and setting up an adequate infrastructure for the production of pharmaceuticals. As indicated in an earlier UNIDO study, the pharmaceutical industry is of vital interest to developing countries (1).

Though this is not the place to consider all such factors (2), they must constitute the general background against which the following discussion is to be examined.

Finally, it is necessary to note that arguments presented in this paper attempt to summarize different opinions expressed on the issue at stake. Therefore, it should be viewed as containing a general description of main trends and lines of thinking which may not necessarily represent the views of any particular country or group of countries on the matter.

1. The controversy on patentability in pharmaceuticals

The chemico-pharmaceutical industry has a unique relationship with the patent system. Opinions on its value and effects on this sector range from the most fervent and categoric approval and defence, to the most severe criticism, for its negative implications. Though this controversy is not

new, during the last two decades it has acquired a new dimension, basically confronting the points of view of developed countries and international industry, on the one side, and developing countries and their incipient local industry, on the other.

(a) The positive view

Research-oriented pharmaceutical enterprises are unanimous that patent protection is essential to the well-being of the industry. The most frequent economic argument given in support of this belief is that patent protection constitutes a decisive element to induce investments in research and other activities related to innovation. Without patents, there would be no incentive to carry out the development of new drugs, in view of the time and money required and the high level of risk involved.

Other benefits of patent recognition would arise out of, according to this view, an increased availability (through the publication of patents) of new knowledge in this field, the fostering of competition on the basis of innovation rather than through advertising and marketing, and the creation of adequate conditions for smaller enterprises to compete effectively within international markets (3).

Whichever the value of these arguments may be for developed economies, which concentrate almost 90 per cent of world production of pharmaceuticals and monopolizes the process of innovation, they are not automatically applicable to the developing world. With regard to the latter, specifically, advocates of the patent system argue that patent protection in a developing country is an indication of the protection of property in that country and, as such, an important element for encouraging foreign investments. Besides, patents would have the critical effect of stimulating TOT. For the owner of technology, the existence of protection for inventions would also constitute a pre-condition for the transmission of unpatented know-how.

With regard to this last argument, it has been stated that "the patent system is still the best-known legal instrument to induce the owner of technology to part with it on a contractual basis and the licensee to invest and to develop industries which depend on it" (4). The advantages offered

by patent registration would mainly consist of the disclosure of inventions in the language of the country, and the reduction of risk and uncertainty involved in transfer of unpatented know-how (5).

(b) The critical view

On the other side, many developing countries have taken the view that patents are an instrument of public policy that the State must utilize as far as it is in accordance with the general interests of the country. Conditions for granting of patents, when admitted, should reach a balance between the recognition of legal monopolies and the concrete responsibilities of the patentee.

Available evidence indicates that a great majority of patents (particularly in pharmaceuticals) registered in developing countries belong to foreign enterprises which do not effectively exploit them in the country of registration, but use them as a coverage for exports from the country of the patentee. In this context, patents would merely serve to dissuade potential competitors from importing or producing patented products, without an offsetting compensation for the country concerned (6).

The eventual existence of positive effects of patentability on the flow of capital and technology and on local inventiveness in pharmaceuticals, has been subject to specific examination and criticism.

(c) Foreign investments

As mentioned before, it has been argued that patents promote or facilitate foreign investments. However, developing countries' viewpoints seem to be that as far as patents ensure a monopolistic market position, they make it unnecessary for the patent owner to undertake direct investments in order to gain and maintain a position in a market. It would not be certainty, but uncertainty, of controlling a market that would encourage investment.

In this sense, the cases of Italy and Brazil are mentioned. In the former, the absence of patent protection gave place to an important flow of foreign investment aimed at compensating the deficiency in market control

created by non-patentability of pharmaceutical products and processes (7). In Brazil, similarly, after the total suppression of patents in that sector (1969), the flow of foreign investment to it grew at a significant rate, one of the highest in industry (see the following table).

(d) Inventive activities

As regards the fostering of inventive activity, it is noted that inventions patented by foreign enterprises in developing countries have not been developed there. Moreover, such enterprises practically do not conduct any R and D in those countries (9). In contrast, the absence of direct or indirect protection of products in pharmaceuticals is said to have allowed, in countries like Argentina and Spain, that local firms undertake activities of copying, adaptation and technological development which, in turn, permitted them to obtain an important market share and initiate the production of drugs without relying on foreign licences (10).

(e) Transfer of technology

The asserted importance and advantages of patents as a means of promotion of TOT to developing countries, has also been under serious criticism.

The main set of arguments developed against that assumption are grounded on empirical studies conducted in developing countries. Such studies have proven that the great majority of patents registered in developing countries by foreign enterprises, are not effectively exploited in such countries. For instance, in Argentina, where the pharmaceutical industry has reached a considerable development as compared with other developing countries (11), almost 80 per cent of patents registered by a sample of great foreign companies were not used at all in local production. Thirty-five per cent of such patents were related to items actually imported by the patent owners (12).

While patents granted in developing countries did not seem to have stimulated local manufacturing of drugs there, they might have served as a means to block the potential transfer of technology. In addition, the monopolistic power conferred by patents is stated to have allowed its owner to charge excessive prices for its supplies, to impose heavy restrictive practices in licences agreements, and to acquire or control local industries (13).

BRAZIL: FOREIGN INVESTMENTS (AND RE-INVESTMENTS) IN THE PHARMACEUTICAL INDUSTRY (1971-1979)

(US$.000)

1971	113.436
1972	138.276
1973	197.197
1974	233.774
1975	292.211
1976	390.625
1977	457.823
1978	574.306
1979	646.501

Source: Banco Central do Brasil

With regard to licensing agreements, the pharmaceutical sector was among the most affected by restrictive practices in Colombia, Ecuador and Mexico (14). In Venezuela, out of one hundred agreements for the transfer of technology in pharmaceuticals, 45 per cent contained tying clauses; 10 per cent price fixing; 36 per cent exports restrictions; 12.5 per cent grant-back provisions, etc. (15).

The general argument concerning patents in developing countries, according to which they disuade potential competitors from entering into the market, hinder the development of an integrated local industry, and limit the choice of alternative sources of technologies and required inputs, seems also to be pertinent with regard to pharmaceuticals.

Likewise, the informative effects of patents, in general, and particularly in developing countries is thought to be considerably limited. On the one side, patents generally do not contain all information necessary for actual use of inventions. These have become so complex and sophisticated that only a small proportion of all inventions for which a patent is granted are sufficiently disclosed (16). On the other, given the relatively lower technical capacity of enterprises in developing countries, the deficiency in disclosure deprives patent documents from any potential interest or usefulness for such enterprises. This is further aggravated by the deliberated imprecision of technical data, the multiplicity of matters and raw materials described, and the description of the process at scale of pilot plant (17).

Finally, the relative importance of patents in licensing agreements seems to be contestable and declining. In many instances, the inclusion of a patent in such agreements constitutes a mere formal requisite for obtaining drugs or other ingredients from the patent owner. That would be the case, particularly, in contracts for the TOT on formulations. In other cases, patent licences serve as an artifice to allege the compliance with working obligations established by patent laws.

The decreasing importance of patents, in general, as a component of TOT agreements is conclusively suggested by the recent experience of some Latin American countries (18).

(f) Legislative trends

The analysis of legislative trends in developed and developing countries indicates that the question of patentability of pharmaceuticals is not and, in fact, has not been historically dealt with, as an abstract issue independent from the concrete economic and technological conditions under which that industry has to operate. For instance, France and the Federal Republic of Germany only introduced product protection after their industries have reached a considerable development (1959 and 1968, respectively). The same applies with regard to Japan (1976). On the other side, Canada and Spain still maintain the exclusion of patentability for products, as well as Denmark, Holland and Austria, among the developed countries. Italy has only recently (1978) changed its legal principle on this matter, in accordance with a decision by its Constitutional Court, and in order to comply with the international commitments of the country.

Many developing countries have decided in recent years to abolish or limit patent protection in pharmaceuticals. Brazil (1969), Mexico (1975) and Ecuador (1975) abolished all kinds of patent protection in this field (19), while other countries revised their laws in order to exclude patents on products (Honduras, 1976) or otherwise limit the extent of patent rights for pharmaceuticals (India, 1970; Costa Rica, 1978; Andean Group, 1974, etc.)(20).

(g) Conclusion

To sum up, the positive view stresses the fundamental role of patents as a decisive condition for innovation, and for fostering foreign investment and the transfer of technology.

On the other side, the critical view sustains that the global impact of patents, notably when they involve any form of product protection, is not beneficial to a sound and well-balanced development of the chemico-pharmaceutical industry in developing countries. While patent protection would not promote either foreign investment or local inventiveness, the absence thereof could stimulate domestic adaptation and improvement of technology and a gradual process of local manufacturing of bulk drugs.

This analysis cannot ignore the role played by transnational enterprises - the main advocates of patents in pharmaceuticals - and the relative position of developing countries in world production and trade of drugs. Only to mention one indicator, it is necessary to bear in mind that such enterprises control about 75 per cent to 85 per cent of developing countries' markets - with a few exceptions - in this sector (21). Patentability of drugs, in particular, is likely to reinforce this dominating position, thereby closing the routes for developing countries to build up an industrial capacity capable of adequately satisfying the urgent needs of an immense part of the Third World's population (22).

2. Some issues concerning patent licences

Before closing the consideration of this item, it seems appropriate to remark that the eventual existence and extent of patent protection on pharmaceuticals, is a major issue for consideration by the negotiating parties of a licensing agreement. In particular, for the recipient it is essential to obtain a clear identification of patent rights involved in the transaction, as well as to carefully appraise their validity and term of expiration. Clauses requiring the recipient not to challenge the validity of licensed patents should be avoided.

The extent of patent protection is singularly relevant with respect to exports to countries where patents have been granted. In its classical form, patents on products involve the patentee's right to prevent imports by third parties of the products covered by the patents. The existence of patents registered in various countries on the same substance could therefore be used by the patent owner to exclude licensee's exports to such countries. This often constitutes an "inherent" restriction in licensing agreements.

In order to avoid that patents be used as a basis for monopolizing imports, some laws in Latin America have suppressed patentee's exclusivity in this regard (Decision 85 of the Andean Group, and Mexico). Further, patents on process have been declared in Argentina not to comprise a right for preventing imports by third parties of products manufactured abroad with the protected process (23).

Notwithstanding this trend, most patent laws still recognize the import monopoly as a right of the patent owner. Group B countries have expressed during the negotiation of a Code of Conduct on Transfer of Technology, that exports could be legitimately forbidden by the supplier when destined to countries where he has obtained patent protection on the exportable product (art. 4.10). This issue is considered in more detail later in this paper (see item II.7 of ID/WG. 331/3). It is possible to point out here, however, that licensing agreements should contain a clause expressly excluding the possible use of such patents as a barrier against licensee's exports (24).

II. FISCAL AND OTHER LEGISLATION

Among the various regulatory areas that may affect the transfer of chemico-pharmaceutical technologies to developing countries, specific legislations and other measures on TOT agreements and fiscal policies are, perhaps, the most significant for the parties to such agreements.

Laws and other policies on TOT agreements establish a set of conditions and limits to the rights and obligations of such parties. Due to the imperative character of such regulations (considered in some countries "d'ordre public" or as of "national interest"), their observance is compulsory and may lead to the renegotiation or amendment of agreements as originally drafted by the parties. The enforcement of such regulations is premised on the existence of a fundamental imbalance in the bargaining position of supplier and recipient, that the State intervention would help to correct.

Fiscal legislation, on the other side, has a bearing on the net income to be obtained by the supplier for the provision of its technology and services, and henceforth, is likely to affect price fixing and other economic conditions of TOT agreements.

The following paragraphs consider, without any attempt at being exhaustive in this regard, some relevant aspects of legislations referred to.

1. Regulations on transfer of technology

A number of developing countries presently apply regulations (or guidelines) which prescribe the approval and registration of TOT agreements by local authorities, and subject them to certain substantive rules such as admissible prices, undesirable restrictive practices, guarantees to be granted by the parties, duration of agreements and other conditions (25).

In some cases, the policies referred to have been applied for a considerably long time (especially in India and Brazil), but most of them have been introduced and implemented during the last decade. At present the developing countries that apply an organic control over TOT agreements still represent a minority (not more than 20 countries) within the Third World.

From the technology suppliers' view, as far as regulations on TOT limit the contractual freedom of the parties, they are likely to hinder the flow of new and valuable technologies to developing countries. In this regard, the "critical issues" would be the recognition of an "adequate and transferable remuneration for the licensed technology and for technical assistance, the extent of permissible limitations of licences under technical and commercial aspects, and the contractual assurance of the confidentiality of know-how" (26).

Notwithstanding this concern, the basic idea and aims of the adoption of legal measures and general standards, at the national and international level, for regulating the international flow of technology, seems to have reached a substantial degree of agreement within the international community, as evidenced by the advanced stage of negotiation and drafting of an International Code of Conduct on Transfer of Technology, within UNCTAD. In particular, Chapter 3 of the proposed Code - "National regulation of transfer of technology" - describes the different types of measures that States may adopt for controlling TOT.

Data available on many Latin American countries on the application of TOT regimes, reveal that these have not hindered the flow of foreign technologies to such countries.

In Argentina, the number of registered agreements rose from an annual average of 122 agreements for the period 1973-1977, to an average of 416.5 per year for 1978-1979. Payments showed a similar growing trend (27). In Brazil, authorized agreements increased steadily between 1972 and 1974, while payments grew at an average annual rate of 16.7 per cent during 1970-1976 (28). In Venezuela, the number of agreements duplicated in five years (1974-1978) (29). Information on Ecuador also indicates a sensible jump in royalty payments during 1976-1977 (30). In Colombia, finally, while the annual average of agreements examined does not seem to have decreased during 1970-1976, payments in concept of technology dropped during that period (31).

Policies on the consideration for technology transferred include, in most countries that apply TOT regimes, the determination of maximum royalty levels admissible according to the content of the agreement or the economic sector concerned. Royalty rates generally accepted for technology on the formulation and packaging of bulk drugs in selected Latin American and Asian countries, have been indicated in a previous document of UNIDO (32). In addition to these policies, some countries require that royalties be calculated on net value of sales, after deduction, inter alia, of inputs imported from the supplier party or other foreign sources

State intervention in licensing agreements has apparently ensured a considerable saving in the acquisition of technology. In Venezuela, for instance, the competent body obtained in 1978 an over-all reduction in proposed payments of 22.1 per cent which represented a saving of about US$30 million. In respect of agreements on chemicals and pharmaceuticals (72 agreements which justified 9 per cent of total proposed payments) the percentage of reduction was still higher, reaching 54 per cent of the consideration originally provided for by the parties (33).

Another important regulatory area has been the control of transfer pricing between foreign subsidiaries and their parent companies. In some countries (e.g. Brazil, Andean Group) intra-firm payments in concept of technology have been prohibited or otherwise limited.

Action by competent agencies has also permitted to eliminate from contractual documents restrictive practices, establish determined terms for and reduce the duration of agreements, contribute to some extent, to the unpackaging of TOT transactions, and control intra-firm operations of transnational corporations. The question of confidentiality obligations has been approached rather flexibly: some countries tend to establish time limits for such obligations, in order to avoid restrictions on the recipient's use of the technology after the expiration of the agreement or a reasonable period thereafter (34).

As regards restrictive practices, information collected by UNIDO on the basis of 104 licensing agreements on pharmaceuticals points out a substantial reduction in the frequency of such practices during 1973-1978 as compared to the period 1956-1973. Export restrictions, grant-back provisions and post-expiry restrictions had been reduced from two-to-three times. Tying clauses and restrictions regarding competitive products had, furthermore, disappeared from more than 80 per cent of agreements considered (35).

In countries with specific regulations on TOT, royalty remittances are conditional upon the approval and registration of agreements which originate them. Once this requisite has been fulfilled, payments authorized can be affected, in general, without requiring additional governmental consent except, eventually, the observance of formalities imposed by foreign exchange controls, where they exist. In this case, the execution of payments is subject, as other financial remittances, to the availability of foreign currency.

2. Fiscal legislation

Fiscal legislation that affects payments for technology transferred is not likely to constitute a decisive element in decisions on entering into new transactions for TOT. First, technology suppliers are generally

allowed in the receiving country (36) to deduct from taxable income the expenses incurred to perform the transfer (37). Second, there exist many mechanisms to avoid double taxation of royalties and similar rents, either by virtue of unilateral provisions of the country of the supplier (e.g. US tax credit system) or on the basis of international agreements entered into for that purpose (38). Third, and usual, though not desirable, practice by technology suppliers, has been to impose on the recipient the taxes applicable to supplier's rents (39).

The level of taxation of royalties in Latin America ranges from 18 per cent (Argentina) to 47.2 per cent (Colombia), without prejudice to the application, in certain countries, of progressive rates. The level of taxation may also depend upon the nature and usefulness of technology transferred. In Chile, for instance, the applicable tax of 40 per cent can be increased up to 80 per cent with regard to technologies which are qualified as "improductive" or "unnecessary" for the economic development of the country.

Finally, in order to promote international co-operation, countries which possess and can export technologies in the pharmaceutical field should adopt measures for encouraging and give incentive to their enterprises and institutions, so as to promote TOT to developing countries on fair and reasonable terms (40).

Notes

(1) UNIDO, The growth of the pharmaceutical industry in developing countries: problems and prospects, ID/204, p. 1.

(2) See UNIDO, op. cit: UNCTAD, Principales cuestiones que plantea la transferencia de tecnología a los países en desarrollo. Estudio monográfico de la industria faramacéutica, TD/BC.6/4, 1975; UN Commission on Transnational Corporations, Transnational Corporations and the Pharmaceutical Industry, New York, 1979; OECD, Impact of multinational enterprises on national scientific and technical capacities. Pharmaceutical Industry, Paris, 2-12-77.

(3) See OECD, op. cit., p. 62, 249 and 250.

(4) E.M. Jucker and B.A. Yorke (Sandoz Ltd., Switzerland), The role of patents in licence agreements, with special emphasis on recent legislative changes in developing countries, paper presented at the Seminar on Licences, Geneva, Feb. 1975, WIPO, AT/LS/5, p. 2.

(5) See Herbert Stumpf, "Interests and conflicts of interest in technology transfer. The role of patents", IIC, vol. 9, No. 4/1978, p. 30.

(6) See C. Vaitsos, Patents revisited. Their function in developing countries, Lima, 1971. With regard to imports, a recent empirical analysis has proven that a strong patent system positively affects imports per capita and thus negatively influences the development of pharmaceutical industries in Latin American countries. See Axel Seel and Monika Mundkowski, "Patent protection and economic development. Some results of an empirical analysis in the pharmaceutical industry in Latin America", IIC, vol. 10, No. 5/1979, p. 71.

(7) See Junta del Acuerdo de Cartagena, Resumen de los estudios realizados por la Junta del Acuerdo de Cartagena sobre política tecnológica, J/AJ/31, Rev. 3, Lima, 5 April 1973, p. 70.

(8) See E. White, "La industria farmacéutica internacional, la legislación comparada sobre patentes y el caso argentino", Revista del Derecho Industrial, Año 1, No. 2, 1979, Buenos Aires, p. 358.

(9) See UNCTAD, op. cit., para. 30.

(10) See D. Chudnovsky, "The challenge by domestic enterprises to the transnational corporations domination: a case study of the Argentine pharmaceutical industry", World Development, vol. 7, 1979, p. 45; and Carlos Gasóliba, El sistema de patentes y sus efectos en la industria farmacéutica en España, Ed. Ariel, Barcelona, 1978.

(11) See UNIDO, Issues that might be considered at the First Consultation, ID/WG.317/1, 21 March 1980, table I.

(12) See Jorge Katz, Oligopolio, firmas nacionales y empresas multinacionales. La industria farmacéutica argentina, Siglo XXI, Buenos Aires, 1974, p. 89.

(13) See Vaitsos, op. cit., p. 28.

(14) See SELA, Restrictive business practices in the importation of technology in Latin America, Sp/Di No. 7, 10 Oct.1978, table 5.

(15) See SIEX, Industria farmacéutica en Venezuela, Caracas, 1975, p. 12.

(16) See Beier, "Future problems of patent law", IIC, vol. 2, 1972, p. 424.

(17) A. Mayo, A. Makuc and C. Correa, "Aspectos de la transferencia de technología al sector farmacéutico", SAFYBI, vol. 16, No. 45, 1976, p. 1004.

(18) In Brazil, for instance, while during 1957-1961 "industrial property justified 44.6 per cent of total payments in concept of TOT, this percentage dropped to 4.5 per cent during 1972-1974. See A. Figueira Barbosa, Propriedade e cuase-propriedade no comércio de tecnología, CNPQ, Rio de Janeiro. Similarly, no agreement in force in Colombia in 1977 registered by the Comité de Regalías contained patent licences. See Recuento de las labores del Comité de Regalías 1967-1977, Bogotá, p. 15.

(19) In Mexico, process for pharmaceuticals can obtain an "inventor certificate" which does not confer exclusivity of exploitation.

(20) See E. White, op. cit., p. 330, and Jucker and Yorke, op. cit., who analyse certain cases of what they call "patent erosion" in developing countries, in particular connection with pharmaceuticals.

(21) See studies quoted in note 2, above, and WHO background document A 33, 25 Feb. 1980.

(22) It is pertinent to recall here the resolution of the Fifth Conference of Heads of States of Non-Aligned Countries, Colombo, 1976, which recommended "that in the context of the revision of the industrial property system, consideration be given to excluding pharmaceutical products from the grant of patent rights or alternatively the curtailment of the duration of patents for pharmaceuticals".

(23) See the decision by the Argentine Supreme Court in American Cyanamid vs. UNIFA, 21-12-70, La Ley, T. 141, p. 320.

(24) See WIPO, Licensing Guide for Developing Countries, Geneva, 1977, para. 184.

(25) For the analysis of TOT policies applied in Latin America, see C. Correa, Regímenes de control de la transferencia de tecnología en América Latina, Intal-Banco Central del Ecuador, Buenos Aires, 1979.

(26) IFPMA, paper submitted to the UNIDO Preparatory Meeting for the First Consultation on the Pharmaceutical Industry, Cancun, 24-27 April 1980, p. 6.

(27) See El Cronista Comercial, 23-11-78 and 30-5-80, Buenos Aires.

(28) See Fung, S. and Cassiolato, J. The international transfer of technology to Brazil through technology agreements. Characteristics of the government control system and the commercial transactions, MIT, 1976.

(29) See SIEX, Memoria, 1978, Caracas.

(30) See BIEL, March 1979, p. 5.

(31) See Recuento de las labores, op. cit., p. 19; UNCTAD TD/B/C.6/55, 1980.

(32) ID/WG.317/1, op. cit., table V.

(33) SIEX, op. cit., table 13.

(34) See item II.2 of ID/WG.331/3.

(35) See ID/WG.317/1, op. cit., table VI.

(36) On taxation of royalties and fees in Latin America, see R. Balbi, La tributación sobre la renta de las empresas transnacionales, Intal, Buenos Aires, 1978.

(37) For instance, in Argentina, the law presumes that 60 per cent of supplier's income is expenses. Hence, though the tax amounts to 45 per cent, the real taxation is only 18 per cent.

(38) Brazil, for instance, has subscribed agreements for avoiding double taxation with the Federal Republic of Germany, Austria, Belgium, Denmark, Finland, France, Spain, Japan, Portugal, Sweden and Norway. Argentina, with the Federal Republic of Germany and Sweden.

(39) This practice is forbidden by Colombian Decree 1234/72.

(40) Some developed countries have implemented measures to promoting TOT, including insurance schemes, tax exemptions, etc., but they usually do not discriminate according to the degree of development of the technology receiving country or the industrial branch involved. See UNCTAD, Principales cuestiones que plantea la transmisión de tecnología a los países en desarrollo, TD/B/AC.11/10.Rev 1, paras. 178-184.

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RELEVANT ISSUEDS TO BE TAKEN INTO ACCOUNT WHEN NEGOTIATING TRANSFER OF TECHNOLOGY AGREEMENTS *

Addendum

Prepared by
the UNIDO Secretariat

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b 1. (i) Health sector structure and health-care delivery system

It is now widely recognized that health development is not only the concern of the health sector but is closely interlinked with all aspects of social and economic development[1]. The health service of a country should be developed in accordance with existing disease patterns and the possibilities for acting on them. The operation of a country's medical and health services requires three main components[2]

- qualified personnel (doctors, pharmacists, auxiliaries)
- adequate infrastructure (hospitals, dispensaries, warehouses)
- medical supplies including pharmaceuticals of adequate quality and in sufficient quantity suitable to meet the needs of different levels of health services.

These facilities should be reoriented to the needs of health care. Structure of health and drug policies have been dealt with in detail in Global Study of the Pharmaceutical Industry[3].

The developing countries have been consuming over the years pharmaceutical products obtained through imports or local production by units in the national sector or foreign subsidiaries. Health sector structure and health-care delivery system established through international co-operation are existing in these countries. What is now contemplated through technology transfer is the local production of some essential bulk drugs, which were being imported by these countries so far. Such a technology transfer does not call for any special health-care structure and health-care delivery system radically different from what has been in existence so far. The functioning of foreign subsidiaries shows that the necessary parameters concerning health-care structure were available. In view of this, health-care structure and health-care delivery system need not be preconditions to the transfer of technology. In case any adjustments in this system are warranted, the developing countries can take parallel action on these.

1/ Sixth report on the World Health Situation, WHO, 1980

2/ Pharmaceuticals for developing countries, National Academy of Sciences, 1979

3/ Global Study of the pharmaceutical industry, UNIDO

b 1. (ii) Local technical skills and supporting technical infrastructure

Technical skills

Pharmaceutical manufacture, quality control, formulation, packaging and storage constitute skill intensive operations. The sophisticated technology involved in synthetic chemical production and antibiotic fermentation call for the supply of trained manpower. In view of this an appraisal of manpower and occupational skills available at national and regional levels should be given due consideration when planning personnel requirements.

The holders of technology often insist that the required technical personnel should be available locally when negotiating a technology transfer agreement. Although the availability of local technical skills is essential, this need not be a precondition for the following reasons: first the technology transfer relating to bulk drug production concerns the relatively more "advanced" developing countries which have invariably an adequate base for manpower training. UNIDO country studies showed that universities and technical institutes have been established in several developing countries in Africa, Asia and Latin America. These institutes impart basic training in the fields of science, engineering and technology. In fact there has been a serious brain drain of skilled manpower from some of these countries, due to lack of opportunities. Second the technology transfer arrangement should include a provision for technical training at the establishment of the licensor. This will enable the locally trained personnel to acquire the necessary skills peculiar to the pharmaceutical industry.

Infrastructure

The availability of requisite infrastructure is vital to any industry and this also applies to the pharmaceutical industry. Hence an assessment should be made of the requirements of the energy, transport, water, communications and housing for the project. The pharmaceutical industry has some special requirements such as uninterrupted power supply especially when sterile techniques are involved; refrigerated transport and storage. Water used in this industry has to conform to certain standards of purity. Here again the developing countries wishing to acquire technology for the production of bulk drugs already have some industrial base and necessary infrastructure. In view of this, supporting technical infrastructure need not be a precondition to technology transfer. Where necessary, suitable adjustments can be made in the existing infrastructure to meet the requirements of the pharmaceutical industry.

b 1. (iii) Economies of scale

The concept of minimum economical size is also applicable to the pharmaceutical industry, especially to the production of bulk drugs. Production capacities have tended to increase rapidly to take advantage of economies of scale. Increased capacities involve proportionately lower investment outlays because of the increased output, resulting in lower production costs.

The holders of technology argue that the available process technology and equipment are often standardized at specific capacities and if these are adapted to lower production scales, costs of such adaptation may be disproportionately high resulting in higher production costs and prices. In view of this, they are reluctant to transfer technology, when according to their assessment, the minimum economic size is not applicable.

The concept of minimum economical size is no doubt sound and hardly debatable. However, in certain engineering goods industries and pharmaceutical industry involving multi-product manufacture, a much greater degree of flexibility is possible as production capacity can be distributed between a number of products during different periods. In such cases it is a question of choosing a proper combination to achieve optimum results. In fact the concept of multi purpose plant has emerged in the developed countries. Such multi purpose plants for bulk synthetic drug production are successfully functioning in some developed countries in Europe, as otherwise they could not have entered into this industry. In view of this, the economy of scale will not be a stumbling block in the way of technology transfer negotiations, given the will on the part of the holders of technology to co-operate.

Further there are also instances in some developing countries wherein viable manufacturing units have been established in the case of chloramphenicol, sulphamethoxazole, diiodohydroxy quinoline, isoniazid and oxyphenbutazone in the capacity range of 2-3 tons. This suggests that lack of large scale production cannot be the reason for not transferring technology.

Besides the economy of scale cannot be considered in isolation and the factors such as strategic value of the industry, the anticipated savings in foreign exchange etc. have to be taken into account. The pharmaceutical industry should, therefore, be considered from the standpoint of the country's health requirements, rather than merely as a commercial proposition.