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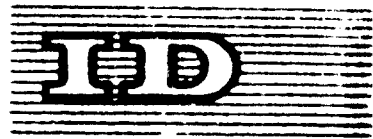
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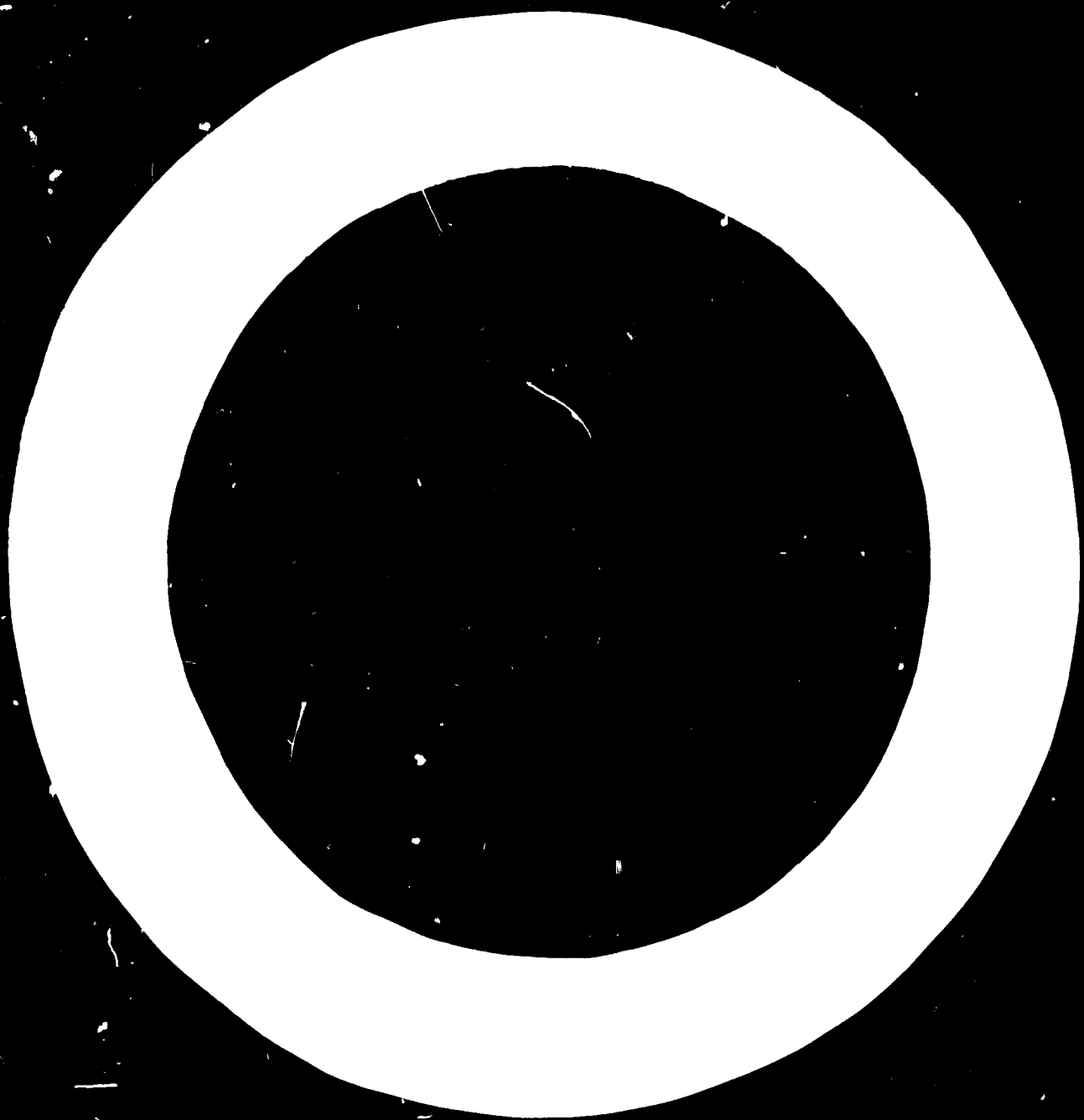
SOME ASPECTS ON THE LICENSING OF CONTRACEPTIVES
WITH SPECIAL REGARD TO THE MANUFACTURE,
MARKETING AND DISTRIBUTION IN DEVELOPING COUNTRIES ^{1/}

by

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Some Aspects on the Licensing of Contraceptives with Special Regard to the Manufacture, Marketing and Distribution in Developing Countries

1.

INTRODUCTION

The rapid population increase is one of the most important problems for the developing countries to solve in order to achieve economic progress and social welfare. A programme has been adopted by UNIDO with a view to investigating the possibilities of producing and distributing contraceptives in developing countries. With the term "contraceptives" is understood all kinds of mechanical devices and accessories as well as all chemical substances, compounds and means for the purpose of regulating human fertility. A part of the UNIDO programme is to make a survey of the legal and practical aspects on licensing contraceptives to the developing countries. A closer defined object of the present paper is to find out in which way the production, marketing and distribution of contraceptives in said countries could be achieved by means of licence and similar agreements between a licensee being or representing the Government of a developing country on one side and a licensor from an industrially more developed country being a manufacturer of contraceptives or else being specialized in the field of manufacturing and/or distributing contraceptives.

In this connection, the terms "licensor" and "licensee" are being used in the broadest possible sense to identify the supplying and the receiving party, respectively. The terms "licensor" and "licensee" are thus sometimes used in a somewhat strange context. So, for instance, the proper legal definition of the "licensor" should in some connections in this report rather be that of the "contractor". However, we have chosen the commercial licence agreement and the denominations of its partners also for the practical purposes of defining the parties and the rules applicable to the relationship between the parties.

The paper will deal with the general legal as well as commercial aspects on a licence agreement. The paper is worked out under the assumption that there is a demand for contraceptives and that the main responsibility for the informatory activities lies with a governmental family planning agency.

2.

GENERAL AND LEGAL ASPECTS ON LICENCE AGREEMENTS

In world trade during the past decades the licensing procedure has been increasingly recognized as an important field of commerce as the most efficient means to cover the market needs in industrial countries. There is a rich variety of licence agreements from simple licence granting to a related party in a foreign country the limited right to use some of the licensor's technical know-how, usually with regard to the manufacture of an already known product, up to complicated licences based on an advanced technology and/or a patented product or method. These latter licences confer

on the licensee the exclusive right to exploit the technology and use the invention of the licensor within a certain defined area. The licensee can avail himself of all the know-how, whether technical or commercial, being put at his disposal by the licensor and relating to the product or method in question including future improvements and developments thereof, patentable or not, drawings, business secrets, etc. Usually, in that type of agreement the parties are closely tied up to each other by a complexity of terms and conditions set forth in the agreement. It is beyond the scope of this paper to give a detailed description in that respect. There are, however, some aspects on certain regulations in such agreements to which particular attention is drawn.

2.1

Exclusive Licences

A licence granted on an exclusive basis means that the licensor is prevented, whether directly or indirectly, from importing the product in the licensed area or from manufacturing or selling the product in such an area as long as the agreement is in force, since any such action would violate the sole right conferred on the licensee. Accordingly, the licensor gives away to the licensee, many times for the life-time of a patent, all rights in the product or method in the licensed area. In order to ensure a reasonable income from the project, the licensor has seen to it that - apart from current royalties - the licensee is bound by the terms of the agreement to manufacture and sell minimum quantities of the licensed product. Usually, it is imposed on him an obligation to pay an annual minimum licence fee. If he fails to comply with these conditions, the licensor is entitled either to cancel the agreement on short notice, or transform the licence into a simple one. Still, however, such heavy obligations put on the licensee might not be sufficient to safeguard the interests of the licensor. After all, he has given away all rights in his technology or invention and product or method related thereto for a very long time, with regard to patents up to twenty years. When a licensee is considered having great capacity and an influential market position, it is apparent that he would be well fit for the purpose of covering a great part of the potential market. Still, the licensee might be more interested in choosing the alternative to run the project on a moderate scale just enough to comply with the minimum requirements set forth in the agreement. He could be more interested in some other project, and for that or some other reason he may have an interest in keeping the business running slowly. In order to prevent such an unfavourable development, the licensor could insist on a regulation being inserted in the agreement to the effect that within a certain period of time the licensee undertakes to achieve not only minimum quantities in his sales but also a sufficient market coverage. By this term is understood that the licensed product has to reach all the potential consumer groups envisaged in the market plans previously agreed upon between the parties.

If the licensee fails in any essential respect to establish

the market coverage described, and if there is no reasonable excuse for his failure, then the licensor is usually entitled to terminate the agreement or transform it into a non-exclusive licence, a so-called simple licence.

2.2 Non-exclusive Licences (Simple Licences)

For the purpose of further clarification, some words should be said about the licence agreements where the licensee operates on a non-exclusive basis.

In such cases the licensor is normally not entitled to obtain the same high rate of current royalty as is the case where the licence is exclusive. The reason is that in a non-exclusive agreement, the licensee has to operate under competition from other licensees appointed by the licensor. Furthermore, in simple licences the non-recurrent fee to be paid is considerably reduced and finally the licensee in a normal case is not bound by any minimum licence obligation. It is usual that in that respect the licensor considers it sufficient to regulate in the agreement that the licensee shall use his best efforts to manufacture and sell the product or within a certain ample period achieve some kind of minimum sales within the licenced area.

2.3 Construction of a Licence Agreement

A licence agreement has to be so constructed that in practice it will give maximum effect of the business involved, and hence maximum advantage to both of the parties concerned. The obligations of the parties have to be well balanced against each other, and a status of equilibrium with regard to the capacity and qualifications of each party should always be aimed at.

Experience shows that if a party, usually the licensor, makes use of his superiority and advanced knowledge to impose on his licensee heavy contractual obligations which the licensee is unable to fulfill, then the result will be disagreement, litigation and eventually an economic failure for both parties. It goes without saying that such a failure many times will hit the licensor very hard because he has not only made a temporary loss of an investment in a foreign market, but he has also definitely lost a part of his technical advantage and a good portion of the period of monopoly conferred on him under his patent. Moreover, if the project fails already on an initial stage, the licensee not having been able to make known or establish the trademark put at his disposal by the licensor, the initial marketing investments have also more or less gone astray, and the licensor has to start from the beginning with a new licensee.

This broad description of the relationship between the parties in a licence agreement based on purely commercial principles seems very important to keep in mind also in the present connection.

GENERAL COMMERCIAL AND PRACTICAL ASPECTS OF LICENCE AGREEMENTS

Let us first consider the practical aspects involved in

licence operation, whereby it is the task of the licensor to grant to his licensee an exclusive manufacturing right in the licensee's country or in any other place which the licensee may choose for the purpose of producing contraceptives of defined standards.

- a) The first operation of the licensor is to deliver machinery and other equipment necessary for the licensee's production.
- b) Furthermore, he has to put at the disposal of the licensee all technicality involved such as drawings, methods and other manufacturing know-how.
- c) Moreover, the licensor shall engage experienced personnel to assist the licensee in the training and education of the licensee's personnel.
- d) In many cases the licensor shall give advice to the licensee as regards suitable manufacturers or raw materials necessary for the licensee's production. By coordinating his own purchases with those of the licensee, he can obtain for the licensee favourable prices and suitable qualities.
- e) Not only the production aspects are important. In the case of consumers' goods being widely spread over the licenced area, the commercial know-how of the licensor will be of great importance to the licensee. Such commercial know-how includes marketing and other informative activity, knowledge as to market covering and the distribution of the product.
- f) Finally, it is usual in licence agreements of this type that it rests on the licensor to keep the licensee continuously informed of the technical and/or commercial development relating to the licenced product or method.

It has already been indicated above what price a licensor demands to deliver this package of goods and services to the licensee. In the normal case, the licensor receives a continuous remuneration mainly in the form of current royalty fees to be paid by the licensee and being calculated on the licensee's invoiced sales of the product. Many times a particular non-recurrent fee is involved to be paid by the licensee when the agreement is signed. Furthermore, there is a guarantee for the licensor in the form of a minimum licence fee obligation imposed on the licensee and preventing him from dropping the project or working on it to an unsatisfactory extent. In some instances, where the licensor is able to put a patent at the disposal of the licensee, higher royalty rates are to be paid by the licensee.

It has already been indicated that in many cases where a patent is involved, the additional obligation is put on the licensee to cover a certain part of the market within a fixed time limit. The motivation in this case for the licensor to impose new obligations on the licensee or tighten up the conditions for the licensee is that, whenever a new patented product is concerned, the licensee can work for considerable time without being bothered by competition. Also in the case

where the licence is not exclusive for the licensee but relates to a patented product, the licensee's position seen from a marketing viewpoint is considered so strong that it is reasonable to insert regulations concerning minimum licence and possibly also an obligation for the licensee to cover a certain part of the market. Finally, in such cases where the value and importance of the licenced product is apparent and recognized by all parties, the licensee being well able to establish a solid market position, the additional regulation may appear in the agreement that, as long as it is in force, the licensee undertakes not to carry on business with any competitive product.

4. ASPECTS ON MARKETING

4.1 The Need for New Markets

Every pharmaceutical enterprise of some size and importance in international trade has to plan for the future turnover of its products. It has to explore and establish new markets. This is particularly important in a situation of increasing competition on the already established markets.

4.2 Exclusivity of Licensor in a Developing Country or Area

As long as the competitors have the same possibility as the licensor to obtain an initial position in a new market, he may hesitate to risk his money in view of the uncertainty of the project and in view of the additional efforts required to meet competition. In that situation, he can be granted some kind of security for his investment as well as a further incitement to work vigorously on the project.

In his agreement with the Governmental licensee of the developing country, he can be given some form of exclusivity limited in time. If one gives him in the agreement the sole right to manufacture and sell contraceptives in the licenced country during a period of some years, he will be able during that time to establish his trademark or trade name to identify his products. In that way, he will be able to establish his business on the new market before his competitors have had a chance to do so, and his investment may yield profit within short.

4.3 Limited Exclusivity of the Licensor in a Developing Country or Area

An alternative could also be taken into consideration, namely that the Governmental authority assumes the task to put the contraceptives at the disposal of the public within the frame of its social welfare programme. At the same time the licensor should be given the right and responsibility to cover some portion of the market. Depending on the range of such an agreement, notably the size of the market and the conditions under which the licensee is entitled to act, this could also be an attractive alternative for the licensor. The dissemination of contraceptives through the agency of the Government, will be for the licensor's part have the positive effect that the demand of the product will be increased. The parties to the demand, which cannot be satisfied through the Governmental supply, will then conquer through the

own marketing and sales. If, moreover, those sales are allowed to be made under his own firm name or trademark excluding the competitors during a certain period, it goes without saying that he will be interested in building up a strong market position as soon as possible. If he is not allowed to work under his own trademark or trade name, there is, however, the apparent risk that he is not interested in the project because in that case he established the product without any direct connection with his own business and in that way he of course also leads the way for his competitors. Also in the case that he should license a patented product to the Governmental licensee, who consequently enjoys the monopoly right under such a patent, his interests will still be limited because, seen in the future, the establishment of the own firm name or trademark is the only efficient method to build up a strong market position because his firm name and house trademark identify his entire commercial activity. It should be kept in mind that the patent right as an exclusive right is limited to the composition of the product as indicated in the patent claims. All product compositions or product groups outside the definition of the claims fall outside the patent rights and then are freely accessible to his competitors. Therefore, an exclusive market position of the kind described is of extreme importance to a licensor. Just as important for the licensee is that this exclusive right is limited in time. Should the exclusive right of the licensor be allowed to continue for a longer time than is required to justify the initial aims of the project, competition is eliminated in a future situation where such competition is necessary for the economic progress of a society. Such a development should be prevented by all means.

4.4 Obligations of Licensor

The licensor should not only be responsible for the manufacture of the contraceptives but also have the exclusive right and the duty to market and distribute the products in the licensed area or the part of the area licensed to him, however, under Governmental supervision, as foreseen in the agreement. In an agreement of this kind the licensor should also bear the undertaking to cover within a certain fixed time a defined part of the potential market. If he fails to fulfill this obligation, he will run the risk that the agreement is either cancelled by the Governmental licensee or transformed into a non-exclusive agreement.

4.5 Qualifications of Licensor

Important conditions in this connection seen from the viewpoint of the Governmental licensee are the following:

The licensor should be an enterprise of international importance in the field of contraceptives. Ideally, he should be able to offer a wide range of quality means and preparations for contraceptive purposes. Furthermore, he should have efficient productive units, and, preferably, a wide experience of foreign marketing and distribution of contraceptives.

4.6

Division of Markets

In large countries with a division of the population in several separated areas it may be advisable for marketing purposes to divide the whole area into geographically separate units and make a licence arrangement with a licensor for each such area. Such a division might well be practical for both the licensor and the Governmental licensee. Nothing prevents the Governmental licensee to choose different licensors for these areas, as long as they are of the size and competence to give an essential market contribution to the licensor.

5.

JOINT VENTURES OF LICENSORS

It should be discussed in this connection whether a usual form of commercial cooperation in the form of a joint venture would be acceptable or suitable. Seen from the size of the project such a joint venture, being a cooperation between important enterprises, would be suitable per se. Such a joint venture could enter into an agreement with a Government agency of a developing country and would involve a coordination of vast resources both in the manufacture and the marketing fields.

Technical difficulties might, however, arise, as experience shows. Nevertheless, it is a fact that there is a steadily increasing cooperation in the world market between leading pharmaceutical companies. In view hereof it is realistic to assume that also in projects for developing countries as regards contraceptives, some enterprises would be able to establish a joint venture for the purpose.

Would it be desirable and in that case possible for UNIDO to act as intermediary in this connection in order to initiate a joint venture of important enterprises in the contraceptive field?

6.

SUB-LICENSING AND SUB-CONTRACTING

When the time limit of the licensor has expired, and the original agreement with him has ceased to exist, the contraceptive project could be carried on by the Government of the developing country. Such a party would then be in a position to appear as licensors to competent manufacturers, foreign or domestic, within the area or areas involved. While in this instance the marketing and distribution of contraceptives shall principally be in the hands of the Government and its bodies, it may be favourable to appoint one or more licence manufacturers. According to an agreement with such a manufacturer, he shall deliver a certain quantity of contraceptive goods of approved standards and at a price to be agreed on to the Governmental licensor for further distribution. Such an agreement will have to include the usual conditions relating to minimum quantities to be manufactured, control of manufacture, calculations, book-keeping etc. However, in view of the fact that it is still an important motive for the Government licensor to achieve the widest possible distribution and market coverage of contraceptives, he may decide to give to the licensee-manufacturer the additional right to sell in

the area all the surplus contraceptives made by him exceeding the quantities to be delivered to the Governmental licensor. The licensee should have such a right to sell freely in the area provided that he gives to the licensor the undertaking to achieve certain minimum sales and market coverage within a certain time limit to be agreed upon. If he fails to do so, his right to sell contraceptives will cease. This seems to be the best possible way to achieve the purpose of broadest market coverage. It is important that the licensee-manufacturer is allowed to act freely in his sales activity apart from the undertaking to achieve minimum sales and a defined market coverage. So, for instance, his licensor should not put on him any restriction as regards prices because if the project fails, the licensee will certainly claim, rightly or wrongly, that such a failure is due to the intervention of his Governmental licensor.

In practice, many varying alternatives can arise regarding the cooperation on a licence basis between a Governmental licensor and its local licensee or licensees. However, it does not seem necessary to make a further survey of such alternatives in this review because the principles to be followed are very much the same as indicated and elaborated in the preceding part of the paper.

7.

CONCLUSION

Having considered the aspects above, the question arises as to what kind of agreement would be the most favourable one for a developing country to achieve efficient manufacture, distribution and marketing of contraceptives.

The alternatives and their variations are multiple but the finally selected one must suit the special circumstances existing in the developing country in question. Some alternatives will be mentioned below for further discussion.

7.1

Alternative A. Exclusive rights for the Licensor.

The licensor or a joint venture of licensors obtain the complete and exclusive rights to establish a production of contraceptives in a developing country and acquire the exclusive rights as well to market and distribute the products in the said area provided, however, that such exclusive rights cease to exist after a certain period of time.

An important condition for such exclusive rights shall be that the licensor or licensors within a certain, reasonable time limit acquire and cover a certain defined part of the potential market for contraceptives. Failure in that respect would result in loss of the exclusive right.

A final and crucial condition would be that the licensor sells contraceptives made by him at a non-profit price level during the time he is enjoying monopoly position under the agreement. After all, his principal aim is to achieve a good market position within a certain restricted period.

It is clear that the licensor or licensors need all practical assistance from the Governmental bodies and officials in carrying through the project. It is also evident that the Government should exercise control to ensure that the licensor fulfills his contractual engagements.

However, a mixture of actions both from the side of the licensor and from the licensee in a homogenous project may result in unnecessary double work and misunderstandings as to what is to be done with a view to covering the market with contraceptives. No need to say that such fallacies might easily result in the people losing confidence in the new product if they cannot get it on the occasion and at the place they were promised to have it. This is, indeed, a most serious aspect.

Seen from a legal, contractual viewpoint it is, according to this kind of overall licence agreement, purely the task and obligation of the licensor to continuously cover the market with contraceptives of high standards at the lowest price within a certain time fixed in the agreement. If the Governmental licensee and its bodies and officials are engaged in the marketing and distribution of the contraceptives, and the project fails in some essential respect, e.g. a sufficient part of the market is not covered, so that the Governmental licensee is formally entitled to cancel the agreement, then the licensor may claim, rightly or wrongly, that the failure is due to the intervention and actions of the licensee and his people. A dispute may arise, and the object of the project to solve a most important social problem would be jeopardized.

Thus, it may be argued that if this alternative is chosen, it should be the sole task and responsibility of the licensor to cover the market and fulfill the obligations of the agreement. However, it appears very essential that, besides of all other undertakings of the agreement, it shall rest on the licensor to educate and train the Government personnel to ensure that, when the exclusive period of the agreement has ended, the Government should have the resources to carry on alone the former activity of the licensor and maintain, deepen or even increase the market coverage of contraceptives in the country.

7.2

Alternative B. Joint efforts of the Licensor and the Licensee

If joint efforts of the licensor and the licensee will be used, to distribute and market contraceptives, then it is necessary that the agreement regulates in detail all practical aspects of such cooperation. However, even if a detailed division of the various tasks of the parties is made, experience shows from similar arrangements in commercial licence agreements that clashes of interest and disputes are almost inevitable.

7.3

Alternative C. Production by Licensor. Distribution and Marketing by Licensee.

Another alternative would be that only the production of contraceptives is the exclusive task of the licensor, and that the responsibility of marketing and distributing the products would rest on the Governmental licensee and its bodies.

If they need know-how regarding testing, marketing, advertising and distribution from the licensor, they have to get it from him under a separate agreement. Where a sole right of some length for the contraceptive products of the licensor is concerned, and where he has a contractual possibility to build up a market without being disturbed by competitors, he might very well offer his services to the Governmental licensee free of charge.

In view of the fact that it is most important that the production and the distribution of contraceptives are closely coordinated to ensure a continuous flow into the market, both parties must pay special attention to the coordination problem in this alternative.





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