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PATENT ASPECTS OF THE PHARMACEUTICAL INDUSTRY

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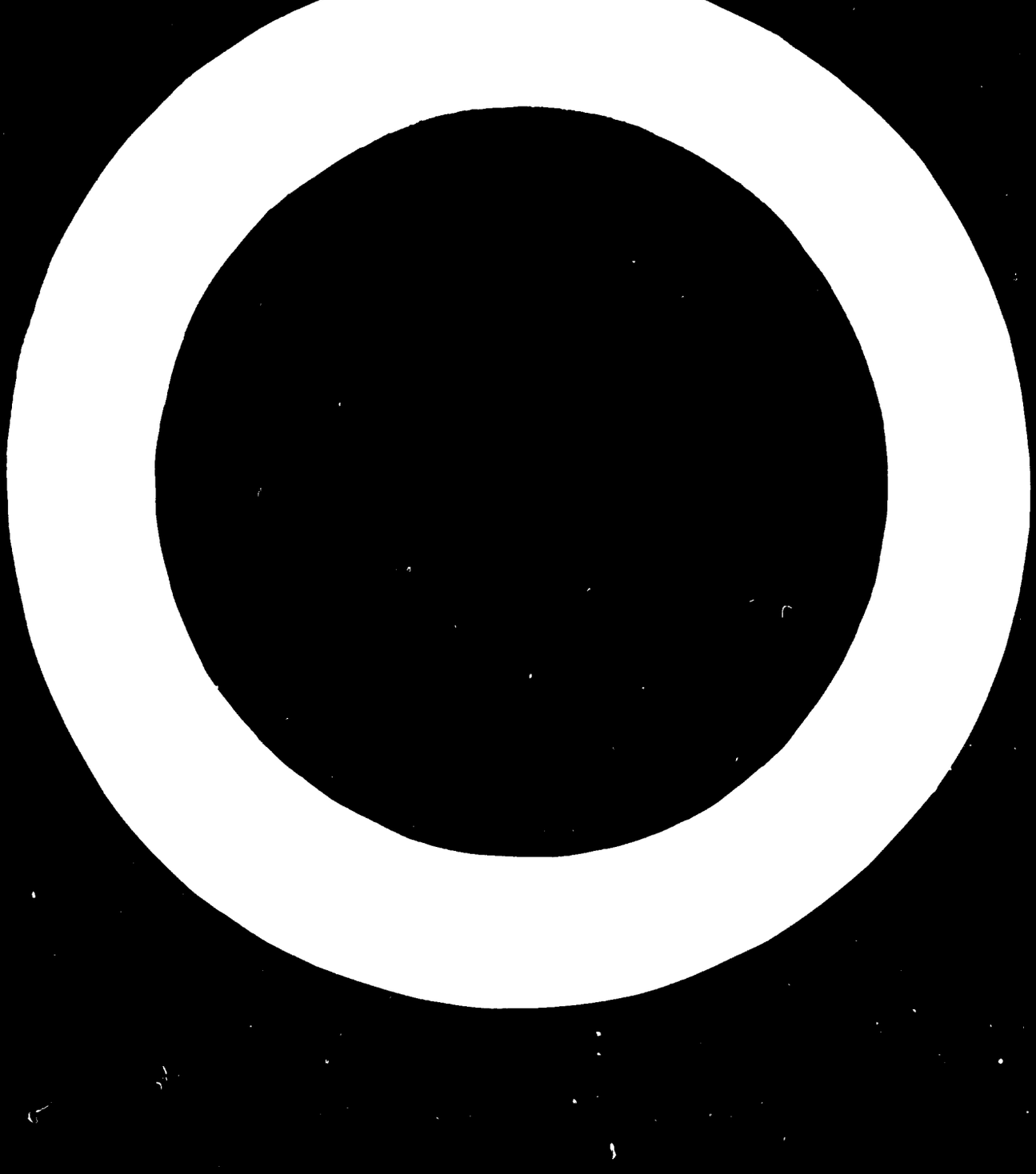

Patent Aspects of the Pharmaceutical Industry

Preface

Operative technology required for the development of the pharmaceutical industry can be classified in two broad categories. It may be of the diffused type, that is, relating to the stock of knowledge that has become public property, and is therefore freely obtainable through books and technical publications, inquiries from national and international sources, plant visits, etc. The second category of a more "secret" nature, covered or not by industrial property rights, is mostly in the hands of firms, institutes, or government agencies.

For the purpose of this paper we will examine some aspects of the usefulness of patents for the development of the pharmaceutical industry sector. The monopoly nature of this economic institution is generally recognized both in the literature of patents and in that of general economics. On the other hand, it is also claimed that patent laws stimulate industrial development and are conducive to a dynamic pattern in industry.

Because of the lack of importance and for practical convenience, analogous economic institutions of lesser legal and economic scope and duration are excluded from this discussion paper. Also we do not consider certificates of authorship or vouchers of invention, which involve the acquisition by the Government of ownership of the invention and the payment by the Government to the inventor of a reward dependent on the scope and importance of the invention; this system coexists in some cases with the national patent system and has not replaced it.

In the introductory section we illustrate in very broad lines what patent systems exist in practice and emphasize the operativeness of such systems. The second section discusses the economic role of patents in the pharmaceutical field with particular reference to the developing countries. The third section reviews briefly licensing actions and underlines the need of unpatented technology for the developing countries.

Patent systems as part of the economic institutions of a country

1. The development of industry in the European nations during the nineteenth and twentieth centuries testifies to the fact that the protection offered by patents can be a powerful stimulus to technical progress and economic development.

2. However, the protection of industrial property in the pharmaceutical field has often given rise to controversy. We will not enter into these disputes which usually take on a political character, but will endeavour to throw light on the role of patents in scientific and economic progress with the help of an empirical approach.

3. Since the statutory description of patentable subject matter is necessarily general in nature, the extent to which the invention claimed in a patent application must possess novelty, utility and/or inventiveness, i.e., the degree to which it must represent an improvement over the prior technology, depends in practice on the way in which the requirements set forth in the patent law are interpreted and applied by the patent office and by the national courts.

4. An examination of the registers in five countries which are major producers of pharmaceutical products - the Federal Republic of Germany, the United States, France, the United Kingdom and Switzerland - and in Italy seems to bring out the direct and positive correlation existing between the patent system adopted and the rate of introduction of new pharmaceutical products. Although it is dangerous to assess the contribution of a country to medicine on the basis of the number of basic pharmaceutical products introduced, since not all have the same therapeutic value, the bare figures will give us some indication of the level of development of each country. There are varying degrees of patent system incentives and compulsions in these various countries.

5. Under United States law, pharmaceutical patents can be issued both for new products and for new processes. Patents relating to processes, however, constitute a much weaker form of protection and play a less important role in the pharmaceutical industry than patents relating to products. Since the patent itself provides a full description of the process concerned, it is generally fairly easy for a rival company to modify the process somewhat - thus evading the patent covering it - and to embark on the production of the type of product in question without risking legal action. Product patents, on the other hand, are a relatively effective means of protection against competing producers. When a patent is issued to a company, no rival firm can sell an identical product without fear of being sued. This gives products benefiting from this form of protection a secure safeguard against the competition of products derived from the same chemical entity. Competitive research into new products is also encouraged in the United States by the absence of any legal provision on compulsory licensing.

6. In the United Kingdom, France, the Federal Republic of Germany and Switzerland, patent protection of pharmaceutical products is less complete than in the United States, for various reasons. In the United Kingdom, patent protection is available for pharmaceutical products only. In the Federal Republic of Germany, Switzerland, France before 1960, and the United Kingdom before 1949, only particular processes were protected. Italy, on the other hand, has no patent protection, either for products or for manufacturing processes. All these countries are highly industrialized, have encouraged the development of education and the establishment of new and increasingly advanced schools and laboratories, have a record of technical achievement in science generally and in the field of chemical technology, and have a potential for pharmaceutical discoveries comparable to that of the United States. A comparison of the achievements of each country in the pharmaceutical sphere gives us the following picture:

	Patent protection in the pharmaceutical field	Introduction of new pharmaceutical products from 1940 to 1959 [1]	Approximate population, for comparison
United States	Complete	65	175 million
United Kingdom, France, Federal Republic of Germany and Switzerland	Intermediate	29	150 million
Italy	None	0	50 million

7. These data show a positive correlation between the degree of protection of inventors' rights and the rate of introduction of new pharmaceuticals to the market. However, apart from the disparity of the economic institutions observed there exist many other differences between the countries compared. Nevertheless the conclusion seems justified that patent rights are an important factor in giving rise to commercialization of new pharmaceutical products.

8. It is unfortunately impossible to show what would have happened if a different patent system had been adopted.[2] Those in favour of patent protection have been proclaiming their faith in this institution for a long time and entertain no doubts on the subject.[3] It is possible that they are indeed right, but their convictions are based solely on faith and not on irrefutable material evidence. As regards the usefulness of patents to developing countries, the question becomes even more debatable.

1/ See Table 65, "Listing of drugs according to place of discovery" in Drug Industry Antitrust Act, Hearings before the Antitrust Subcommittee of the Committee on the Judiciary, House of Representatives, 87th Congress, 2nd Session on H.R. 6245, May 17, 18, 23 and 24, 1962, Washington, 1962, pp. 760-764.

2/ One means of obtaining the data which we lack would be to abandon the patent system in the United States for twenty years and to compare the rate of invention and industrial progress with the previous twenty years. That type of experiment would be extremely costly, in view of the effects it would have on the general well-being of the nation.

3/ The International Union for the Protection of Industrial Property, whose charter, the Paris Convention, is aimed at ensuring a minimum of protection in all States belonging to the Union, had seventy-seven member States in 1967 (several other countries were expected to join in the near future

9. It must be borne in mind that the patent system takes concrete form in a number of legal provisions concerning patentability, the consideration of patent applications, the duration of protection, procedural questions, the rights of inventors, etc., any of which may contain negative elements. Hence the efficiency or inefficiency of a given law on patents depends partly on the application of the various provisions appearing in legal texts. To the extent that the appropriate patent office, office of industrial property or ministry of a developing country does not undertake, or is not adequately equipped, to review and examine patent applications to determine novelty, utility, inventiveness and priority of invention, the rights of inventors and businessmen in that country are rendered uncertain. Such a framework tends naturally to be unsuitable for economic growth. Also, the courts of that country will carry increased responsibilities and burdens with respect to the making of such determinations. Given the premise that patent protection is useful to the promotion of technological development, uncertainty as to the protection afforded by patents may be a relevant factor to be considered in connexion with national efforts to stimulate the development and exploitation of pharmaceutical technology. It is none the less certain that the stimulating effect of competition and the introduction of new pharmaceutical products are by no means automatic. There are powerful forces which lead some enterprises or countries not to seek progress, given the high cost of competitive efforts to innovate and launch new products, the risks involved or simply the order of priorities in national development.

10. It is however clear that even with a patent statute in general a much smaller number of patent applications are filed, and patents issued, in developing than in developed countries. By way of illustration, for the year 1961, Morocco reported 372 patent applications and 395 issued patents; Ceylon, 120 patent applications and 95 issued patents. In addition in the case of developing countries, generally upwards of 90 per cent of the patents applied for and issued are in the name of foreign nationals. On the other hand, the United Kingdom reported 46,529 patent applications and 28,871 issued patents; Canada, 24,529 patent applications and 21,988 issued patents, and The Netherlands, 13,461 patent applications and 3,557 issued patents. The reasons why so few patents are applied for and issued in developing countries are the lack of inventive or entrepreneurial activity on the part of the nationals and residents of the developing

country; the unimportance of the country as a market for the patented product; other economic and legal factors militating against the establishment within the country of any enterprise producing or selling the patented product or utilizing the patented methods and processes; the absence or inadequacy of the legal protection which patents affords inventors and investors; and the relatively greater significance of unpatented, as contrasted with patented, technology.

11. It must also be mentioned that while patent systems generally allow for the patenting of products and processes, specified categories of products and processes are not eligible for patenting. Thus, in a large number of countries, pharmaceutical or medicinal products are not capable of being patented. In other countries, the exclusion from patenting extends to chemical products in general and also surgical and curative devices. The basis for such practice is that the patentee, by virtue of his patent, will be able to exact unreasonably high prices and will not furnish the public with adequate supplies of such products and devices, and that the issuance of a patent is therefore detrimental to the public interest.

The role of patents in the pharmaceutical field

12. It would seem from above, that forces of inertia make themselves felt particularly in countries where rivals can imitate new products without restriction. If a new pharmaceutical product or a new manufacturing process can be copied rapidly by competitors and if productive capacities are not restricted by any monopolistic limitation - that is to say, if a situation of absolute free competition exists - the price of the product manufactured on the basis of the new technical knowledge will soon fall on the market to the level of production costs. The costs of research and development of the product are under such conditions no longer covered, since the imitators do not have to cover these extra expenses; as to the original producer who has had to bear these costs, they do not appear in his marginal costs. Research and development expenses incurr basically once only; they represent fixed costs and will generally not rise as production output increases. Whatever may have been the cost of the development of new knowledge, its application or utilization by imitators costs virtually nothing. Thus, if the price of the pharmaceutical products manufactured on the basis of the new technology is reduced to the level of production and overhead

costs as a result of imitation and free competition, the expenses of research and development in relation to inventions or improvements in knowledge about manufacturing techniques cannot be covered. New developed technology and know-how have indisputable economic value since they contribute to increasing the social product. But where there is no limit on their free use by competitors, they quickly lose attractiveness to the private business enterprise. Thus when it is possible for rival manufacturers to appropriate successful new products, as is the case in Italy and many developing countries, few enterprises are willing to undertake the investment in research and development necessary for the introduction of improvements and/or new products.

13. It must not be forgotten that, in creating a new product, an enterprise must not only pay the costs of research but also the substantial cost of perfecting the product. In many cases, the costs of development are much greater than the proper research costs, even if the research work done was quite sufficient to justify a patent application. Consequently, patent protection is necessary not only to encourage inventive activity but also, and perhaps even more, to encourage the pharmaceutical industry to invest in innovations. A study of trends in this industry shows that the influence of patent protection also appears in the way investments are allocated. As a result of the protection of industrial property, investments in production plant and equipment bring better returns, patented inventions are accorded their full value and their utilization is sheltered from the direct impact of competition.

14. Patent protection is aimed at combatting economic inertia. It plays a major part in four distinguishable functions: the stimulation and rewarding of invention and its utilization, the selection of inventions for adoption and for receipt of rewards, the determination of the amount and character of rewards to individual inventors and to industrial developers, and the ultimate general diffusion of the resulting benefits. Needless to say, this final function is crucial for the progress of industrialization in developing countries. To the company more than usually successful in creating and marketing a unique and novel pharmaceutical product it offers, conditioned on the fulfilment of the four functions just mentioned, the possibility of recovering its costs to an unusually large extent, without suffering losses at the hands of imitators. Patents fortify a business firm's profit incentive. With this prospect, the creative organization's investment in product and clinical research, development and

marketing activity behind the introduction of each new product can be justified economically. The possibilities of recovering these investments, however, must be substantial enough to counterbalance the ever-present risk of failure. Business self-interest is a force which effectively combats normal business inertia.

15. Patents force competitors to develop their own improvements of patented products and place them on the market, or else suffer the losses involved in the market shift which would result from any other policy. The narrowness of the scope of the pharmaceutical patents would give otherwise rival firms a chance to develop and market their own improvements without being sued for patent infringements. Thus, defending the commercial interests of the inventor may prove to be advantageous to the process of invention itself. In many countries descriptions of patents are published very widely; this enables research workers and inventors to keep abreast of technological progress and constantly gives them new subjects for study.

16. There is no doubt that rival laboratories would be able to discover manufacturing secrets as soon as the new preparations appear on the market or soon after the first utilisation of the new processes. However there exists often a long interval between the issue of a patent or the submission of the application and the initial use of the invention. Thanks to patents the new technological knowledge is available well before clinical experimentation with the product begins. Such prior disclosure is not of immediate profit to anyone under the circumstances of industrial protection, but it allows competitors to look for substitute products and processes and thus to evade the patent.

17. It should be considered by the way that, for each patentable new discovery that is marketed, there are products which have been developed and will never be marketed. In the industry as a whole, it is estimated that only one out of ten patents covers a marketed product, and were it not for the nine other patents the new knowledge they represent could be kept completely secret if desired. But it is just this information that often provides the basis on which another company

builds to make a really important invention of its own. In this way patents can stimulate and promote research among independent groups.[1/]

19. Patents inevitably have an influence on the commercial career of speciality products. Actually, an innovation that has proved its value will normally give rise to near imitations or substitute devices, and will have to meet their competition, even if it is protected against literal infringements. Pharmaceutical product variations often involve combinations with other drugs and research and development undertaken in the industry can be considered to a large extent as the cost of technical product differentiation. Thus, the patents originally granted may be succeeded for an indefinite length of time by a judiciously selected series of patents of improvement. With the passage of time, new products may be developed and may to a large extent supplant the original drug, but special forms of the original product remain often on the market and continue to be used long after the initial form in which the product was presented has wellnigh disappeared. The flood of such product changes and differentiations is partly due to attempts to attain economic objectives such as producing drugs for sale at prices equivalent to or lower than those of similar products sold by rival firms, while at the same time avoiding any reduction in the price of existing specialities. The result is that, even if these ostensible new drugs are in fact only "molecular manipulations" of old products, now sold at a cheaper price under a new trade-mark, their prices are actually more flexible than generally thought.

1/ The objection that it is only those technological advances which could not in any event remain secret that are the subject of patent applications is quite valid. Without patent protection, however, the research worker's efforts would often lose some of their interest owing to the obligation of secrecy. He would become increasingly isolated from other research workers as a result of being unable to publish or discuss most of his work. In addition, the absence of industrial protection would increase the cases of duplication of research projects.

The abolition of patents would thus considerably alter the climate of scientific research in industry. There would be an atmosphere of secrecy and suspicion, the industrial world would be full of spies and the true scientist would hesitate to go into industry, where he would not be able to speak freely of what he knew nor utilize the knowledge he acquired. His research projects would thus tend to remain within a narrow framework and become much less appealing. The emphasis would be placed even more on short-term projects, long-term research not being sufficiently attractive from an economic point of view, for small and medium-sized firms, in a highly competitive climate.

19. It nevertheless remains an indisputable fact that the interest which manufacturers have in effective patent protection shows itself in the price structure of the pharmaceutical market. Thanks to the temporary monopoly situation derived from patents, trade-marks, trade names and good-will, the manufacturer is in a position to exercise a certain amount of control on the price of pharmaceutical preparations and to sell certain drugs at market prices considerably higher than production costs. The manufacturer obtains thus an important source of income which enables him to continue with his research and development work, as well as to make good losses suffered on drugs for which there is only a limited demand. If inventions were not patentable, would competition be increased? It is an interesting subject for speculation. In fact it is far from clear that the abolishing of patents would increase effective competition.

20. The considerations set out above regarding the need for industrial property rights are especially relevant to the small concern and newcomers to the pharmaceutical branch, and particularly therefore to countries which are in the process of industrialization, even if the latter often enjoy facilities for introducing themselves to the market which depend to a large extent on the type of technological process concerned and the category of pharmaceutical products manufactured. This is compatible with the principle, implicit in most existing anti-monopoly legislation, that the remedy for the monopoly power of large concerns over a given market is to confer a similar degree of monopoly power on small firms, and the recent practice of certain developing countries to award patents on the basis of priority of application rather than priority of invention [1] taking due care to safeguard the rights of prior users.

21. The large concerns producing pharmaceutical products already operating in the drug markets have the advantage of having an established position, existing

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1/ In many developing countries, the statute requires patents to be issued to the first applicant therefore. In the industrial countries and certain developing countries, the requirement is to issue the patent to the inventor - the originator of the invention - or his assignee or successor. In the latter situation the patent office, in addition to determining whether a patent application covers a patentable product or process, has the responsibility for determining whether the applicant for a patent is in fact the original inventor of the claimed invention. This is referred to as establishing priority of invention on the part of the patentee.

manufacturing facilities, active sales organizations and goodwill. In addition, they very often have sufficient financial strength to render the inventions of the small laboratories sterile, if necessary. With the patent as protection, however, the small concern or newcomer to the branch has an opportunity to overcome the advantages connected with scale and thereby challenge the established rivals. A pharmaceutical enterprise which undertakes research has, it must be admitted, more chances of succeeding if there are entry difficulties for other firms into the same field or if it can manage to raise barriers to hold back the flood of imitators. Patents constitute an important stimulus for large enterprises but for independent inventors or small firms competing with large laboratories they are vital. A fundamental invention can place a firm in a leading position and entirely alter the relative situation of each enterprise in the industry. Often, though, the only advantage that a really small firm can derive from a valuable patent lies in selling it to a larger competitor, generally for a lump sum, since it does not itself have adequate financial means to undertake the promotional expenditures necessary for the launching of the new product, even if this may prove to be of greater value.

22. The ability to put out large sums in carrying the innovation to the stage of commercial exploitation is in fact one of the undeniable advantages of the large firm, as is the ability to enjoy large scale economies of production. Sometimes these advantages result in oligopolistic or even monopolistic situations in a whole product line, and sometimes they could not be enjoyed without first creating monopolistic conditions. It is very true in some pharmaceutical product lines that monopolistic conditions promote growth, in the sense that size promotes growth, and that size and monopoly are related. But we must not exaggerate and make this argument into a general rule for the whole pharmaceutical industry and for all levels of operation.

23. It may be desirable to protect a new industry in the pharmaceutical field in the early stages of its development, provided that the protection is removed within a reasonably short period of years. This was actually the origin of the British patent system (Statute of Monopolies of 1624). A new invention in those days covered also new industries introduced to the country from other countries, however old and well established the techniques of the industry might have been in other places. The statute implicitly recognized what is called today the "infant industries" argument.

24. In principle, developing countries should rather favour monopolistic situation than combat them because of their shortage of native entrepreneurship and the great risks of investment in such countries. In general, governments of developing countries show their willingness to grant protection to new industries. Whether this is achieved in the form of tariffs, of licences, of subsidies, or of patents or a combination of different policies is rather secondary and must be examined in each case separately. The economic history of Japan, as well as the history of the pharmaceutical industry itself, shows that the successful entrepreneurs tend not only to dominate the industries in which they started, but also to spread their interests out from one branch of industry to another. With the development of the developing economies there will also be an increase in the supply of managers and the risks of investment will decline as industrialization progresses. The much feared domination of the economic scene will then become difficult, and monopolistic situations will become harder to create and to maintain. In other words, the monopoly argument for developing countries which is often closely related to the granting of exclusive rights is an argument of temporary significance only, and is subject to the same limitation that a prolongation of the monopolistic situation may reduce the economy's vitality.

25. While it is of importance to protect the new against the newer, it is equally essential to protect the new against the old. Patent protection serves the first intent, whereas constant review of patent legislation to prevent its abuse serves the second aim.[1] Therefore the developing countries need also some general anti-monopoly legislation to prevent the established growing manufacturing concerns, indigenous as foreign, from using their power, for instance, to set too high prices in relation to social marginal cost pricing or to deny newcomers access to the market. In fact industrial corporations are more likely to make new discoveries

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1/ Border-line practices include accumulation of patents by assignment, non-use of patents, grant-back of subsequent improvements to licensor or their use to extend the term of the patent monopoly, price-fixing of the patented article, limits on the field of use, tying clauses, restrictions on patentee, package licensing, cross licensing or interchange (which has different significance according as the patents interchanged are complementary or competing), and blackmail of competitors by unwarranted infringement actions or - in reverse - defense against warranted infringement actions by unwarranted allegations of antitrust violation (Cf. J.M. Clark, Competition as a Dynamic Process, The Brookings Institution, Washington, D.C., 1963, p. 206).

and produce new inventions and utilize them if they are under pressure and it is also generally agreed that a good proportion of dynamic innovational contributions are achieved by new entrants into a given market. The enactment and enforcement of such legislation calls however for very thoughtful judgement, since monopolistic situations are both needed for growth in certain industrial fields as they can impede fast industrialization under certain circumstances. It is clear, that the relationship between patents, trademarks, and monopolistic situations, and economic development does not lend itself to simple conclusions. Whatever temporary advantages and dynamic efficiencies large dominating firms may bring to the developing countries in their earlier stages of economic growth, it is sound practice to watch them carefully and to seek to restrict their powers if necessary. Protective measures change their role in the course of development always.

26. To summarize this section we may say that the pharmaceutical industry is an industry in which the patent system represents both a constant threat and a constant opportunity for each firm. By rewarding the innovating concern with a strict right to exclude others from exploitation of the invention, the patent system encourages laboratories to take risks and forces competitors to innovate in their turn or perish; at the same time, thanks to the protection which it gives, it also ensures the appearance of newcomers in the market to some extent and guarantees a certain degree of economic mobility in the branch.

Licensing actions and unpatented technology

27. The holder of a patent can grant a license for the use of the invention revealed or claimed in his patent to a third person in return for financial compensation (royalties) or some other arrangement to be settled by agreement with the purchaser of the license. The issue of a simple non-exclusive license in respect of a particular patent consists of the signature of an agreement under the terms of which the inventor undertakes not to take any legal action against the licensee in respect of the exploitation of the invention. Subject to the public policy of the country issuing the patent, the patentee (licensor) may prescribe limitations or restrictions on the way the licensee exploits the licensed patent or include other conditions in the patent license agreement.

28. The sharing of a patent, that is to say, the granting of a license, is a means whereby the patent-holder can increase the potential profits from his invention.

In granting a license, the patent-owner grants a rival firm the right to manufacture, exploit and/or sell the products in question. The patent-holder can also limit the area in which the licensee is authorized to market the product, he can limit the amount of a product authorized to be manufactured under the license, and if there is no cross-licensing agreement he can fix the price at which the licensee can sell the product.

29. The granting of licenses has played a particularly important role in the production of antibiotics and, more recently, of tranquillizers. The granting of a license to a rival firm for the production and sale of a product subject to a particular patent enables the patent-holder to broaden the scope, but not the control, of his monopoly rents. It may happen that the enterprise taking out the license has better relations than the patent-holder with the medical corps or with pharmacists, or the licensee may have a larger sales capacity which permits greater concentration of marketing efforts. It is also not infrequent for a patent-holder to grant a rival firm a license for the production or sale of a product because of its usefulness for public health or because the patent-holder himself could not cover the whole potential market alone without extending his plant installations. The wide granting of licenses may, inter alia, have the result of reducing market prices to as low a level as is compatible with profits which still permit all producers to compete. This effect is well illustrated by the example of isoniazide, an anti-tuberculous drug of high therapeutic value, in respect of which a Swiss company granted many licenses.

30. Whenever, in the efforts of companies to imitate and improve on each other's products, a product or production process thus developed is more efficient than the original product or process, the companies concerned are in a situation favouring cross-licensing. This is particularly the case when the manufacture of a final pharmaceutical product requires the use of a number of intermediate products some of which can be produced by chemical synthesis or by culture or fermentation. A striking example is the broad-spectrum antibiotic tetracycline, discovered separately by several pharmaceutical laboratories at the same time.

31. The danger of negotiations aimed at establishing cross-licensing agreements is that groups of enterprises will succeed in avoiding competition among themselves by means of either explicit agreements (cartels) or of implicit agreements (concerted practices). However, although cross-licensing agreements or

non-exclusive license agreements concluded between laboratories apply to a limited number of producers, they may lead to an expansion of markets, an improvement in production techniques and an increase in technological efficiency. The community of interests in regard to production often gives rise to a common price policy. Cross-licensing agreements may, however, lead to vigorous competition, particularly in regard to prices, on the part of the laboratories excluded, encourage faster development of new products for the purpose of maintaining profit margins and put pressure on the research organizations of enterprises.

32. This type of agreement has made possible a satisfactory settlement of patent controversies between various groups of laboratories regarding a number of products, including dihydrostreptomycin and the original form of tetracycline, and has provided a means of speeding up the marketing of several anti-arthritic agents of the prednisone family. Frequent cross-licensing is nevertheless economically dangerous, since it may result in understandings of a monopolistic nature and lead some enterprises to adopt the policy of leaving another laboratory to incur the expenses of research and apply for a license. If the enterprises were to refuse to grant licences for all their patents and vigorously and constantly oppose legislation which authorized or would authorize compulsory licensing, that would prevent this practice from spreading in industry.

33. Concern is sometimes expressed that patented inventions will not be worked within developing countries and that such countries will be unable to obtain adequate supplies of patented products or products involving patented processes. In order to cope with this problem and also to avoid in some instances unreasonably high prices by virtue of a patent monopoly, the patent statutes of most countries (including some developed countries) contain provisions providing for compulsory licensing or revocation of patents in many cases, especially on pharmaceutical and medical products and devices that are not being worked within the country, and/or are being worked on a basis inadequate to supply the requirements of that country. Some countries make provisions for compulsory licensing and have no provisions for revocation; a few possess only a revocation procedure; many have both types of provisions. The time periods before the expiration of which applicants may not apply for compulsory licenses, or patents may not be revoked, differ from country to country.

34. The question remains, however, whether the granting of protection, subject to an obligation on the patentee to license without limitation, guarantees those thus protected sufficient income from royalties on licences to permit the future commercial development of valuable new technological knowledge. The principle of compulsory licensing is completely justified in cases of non-use of patents considered to be of public interest, when, for example, the Government wishes to facilitate the use of new improvements or of secondary patents dependent on a basic patent or to limit the abusive use of a patent, or when spheres of general interest such as public health or national defence are concerned.

35. Generally speaking, statutory procedures for the compulsory licensing or revocation of unused or inadequately used patents are rarely resorted to in practice. It is also impossible to evaluate the extent to which the mere existence of such provisions, and the potential threat of invoking them, stimulates the working of the patents in a country. An alternative statutory procedure for promoting the utilization of unexploited patents exists in a few developing countries, where, the law provides for a compulsory license to the Government, or for its expropriation by the State, so that it may be available to all.

36. Lastly, attention must be drawn to the fact that many licensing agreements merely authorize the use of a specific patented procedure, and carry with them no instructions, documentation or technical assistance. These have to be obtained separately from some other enterprise or consultant firm.

37. Modern industrial development is dependent, in fact, not only on patented, but also on unpatented technology, which is often referred to as know-how or technical information. This technical know-how may take the form of trade secrets, specific formulae, experimental and clinical data, which may involve inventive developments as novel and as important as those which qualify for patent protection, but which their possessor has decided to keep secret instead of disclosing in a patent application. In the usual case, however, it takes the form of diffused know-how such as specifications, manuals, blueprints, plant design, plant construction, plant operation, product design or records involved in scientific research and development. Also included in the concept of know-how is the technical expertise possessed by the scientists, chemical engineers and other persons engaged in fabrication, scientific research and development.

38. Even in industrialized countries, the know-how is frequently more important than the technology disclosed in patents. In the case of developing countries, such unpatented technological and technical information assumes an even more important role. Therefore the manufacture of pharmaceuticals in developing countries is, as a rule, not only dependent upon access to patented inventions, but even more, is confronted with the introduction and adaptation to local conditions of pharmaceutical technology that is already established in the industrial countries. Therapeutic methods and conditions of drug administration may differ from those in developed countries. Malnutrition, local nutritional habits, or genetic disorders may lead to adverse physiological reactions not observed during the clinical trial period in the country where the pharmaceutical patent in question had been issued first. Thus the unpatented know-how will in most cases be much more important than the patents to the licensee and to the technological development of the developing countries.

39. Therefore, to the extent that patents may play only a negligible part, in the technology transfer to a developing country, they have no, or a very limited effect, on the establishment or development of a pharmaceutical industry in that country. In those cases where foreign-owned patents have some importance for a pharmaceutical industry in a developing country, they have usually to be licensed in the same agreement with unpatented know-how.

Conclusions

40. The patent system is a public policy, adopted to promote the interests the public has in invention and its utilization, in establishing primarily private business enterprises and is useful for state owned companies. In the pharmaceutical field there exist different patent legislation systems to encourage indigenous inventors and investors to develop new technology, adapting imported technology and stimulating industrialization by protecting indigenous and foreign inventions. The many defects of the established systems in operation do not extinguish its dynamic role for industrial development, for which any radically different system would have to find a substitute of a less automatic sort. Patent legislation is a very complex subject matter, and therefore to appreciate its influence on industrial development it is necessary to take account of the level of economic and social development achieved in a country, that is to say, the attitude prevailing with regard to competition, research and development, industrialization in general, the inflow of foreign capital and establishment of foreign enterprises, and other essential factors. Patent protection can stimulate as well as hamper industrial development.

4. 2. 74